

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

# DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

# PARANIX ENVIRONNEMENT

Product type 18

# 1,R-trans phenothrin (CAS No.26046-85-5) Pyriproxyfen (CAS No.95737-68-1)

as included in the Union list of approved active substances

Case Number in R4BP: BC-RQ019662-18  
  
Evaluating Competent Authority: France

Date: 29 September 2017

Updated (post AMM): January 2021

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**Note to the reader**

This consolidated PAR for the product authorisation of PARANIX ENVIRONNEMENT is based on the PAR of the first authorisation and each section contains the initial assessment and the subsequent successive assessments (administrative changes), in which post-authorisation data assessment have been included (highlighted in grey).

The section 2 includes the summary of product characteristics proposed for decision on the basis of the post authorisation data assessment.

# History of the dossier

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /)** |
| NA-APP | *FR* | *BC-RQ019662-18* | 27.10.2017 | Initial assessment |
| NA-ADC | *FR* | BC-PG035330-53 | 15.01.2018 | Administrative changes |
| NA-ADC | *FR* | BC-FC037313-65 | 16.03.2018 | Administrative changes |
| NA-TRS | *FR* | BC-ML058093-33 | 29.05.2020 | Transfer of asset owner |
| n.a | *FR* | n.a | tbd | Post-authorisation data (received on 13/11/2020) : resistance and stability |

# CONCLUSION

The biocidal product PARANIX ENVIRONNEMENT based on 1 R-trans phenothrin (0.28 %) and pyriproxyfen (0.015 %) is an aerosol ready-for-use insecticide. It is intended to be used against lice and nits (eggs) for direct surface treatment. PARANIX ENVIRONNEMENT is applied by spray application by general public

**Conclusion on physico-chemical properties and analytical methods**

The appearance of the biocidal product PARANIX ENVIRONNEMENT is an homogeneous limpid liquid colourless with a characteristic odour. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (aluminum can).

The product is not explosive and has no oxidizing properties

The provided methods for the determination of the active substances in the product are validated.

For 1R-trans phenothrin, analytical methods were provided at EU level for the determination of the sum of isomers residue in soil, water (drinking) and air with respectively LOQ = 0.01mg/kg, 0.1µg/L and

0.001 mg/m3.

1R-trans phenothrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required

For pyriproxyfen, analytical methods were provided at EU level for the determination of the active substance residues in soil, water (surface and tap) and air with respectively LOQ = 0.01mg/kg, 0.01µg/L, 0.1µg/L and 1.0 µg/m3.

Pyriproxifen is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.

The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of 1R-trans phenothrin and pyriproxyfen residues in food/feed of plant and animal origin is not required.

* **Post authorisation 2020 :**

The post authorisation data confirm the current shelf life of 2 years at ambient temperature when stored in commercial packaging.

**Conclusion on efficacy**

Regarding the use against lice (*Pediculus humanus capitis)* the efficacy data presented in the dossier are sufficient to demonstrate the efficacy of the product PARANIX ENVIRONNEMENT against larvae and adults of human head lice (*Pediculus humanus capitis*) for a curative treatment.

Regarding the use against nits (eggs) of *Pediculus humanus capitis*, the efficacy data presented are not sufficient to demonstrate the efficacy of the product PARANIX ENVIRONNEMENT. Indeed, the mortality of eggs was achieved within 12 days instead of the contact time of 10 minutes claimed by the applicant. Furthermore, the rate of non-hatched eggs of 58 % obtained in the test is considered as a low rate of efficacy and not sufficient to contribute to the prevention of re-infestation.

* **Post authorisation 2020 :**

In order to answer to the post authorization requirement of implementing a monitoring of the resistance of the head lice *P. humanus capitis* to the active substance 1R-trans phenothrin, two ways have been proposed by the applicant: a literature search and customer service feedback.

Based on the results from a literature search and analysis of the feedbacks to Omega Pharma France customer service, no new 1R-trans phenothrin resistant populations of lice, nor lack of efficacy of the product, have been reported.

The applicant should continue the monitoring of scientific literature related to the resistance of the *Pediculus humanus* to the active substance 1R-trans phenothrin and provide the outcome of the assessment at the renewal of the authorisation.

**Conclusion on human health**

Regarding the primary exposure, the risk is acceptable if the risk mitigation mesures here below are applied:

⁻ leave the room just after treatment;

⁻ no entry in the room is allowed during 2 hours before the aerosol falls on the surface.

For the secondary exposure scenarios, the risk is acceptable in Tier 1 (substance by substance) and Tier 2 (additivity) of the mixture approach.

For the combined exposure scenarios, the risk is acceptable in tier 1 for adults and children older than 2 years old. For children younger than 2 years old the risk is acceptable if the mattress is not treated.

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

The product is intended for indoor spraying surface uses against lice and nits by non-professional on objects that could have been in contact with lice (bedding, comb, armchair, helmet...). No specific residue data were submitted in the context of this dossier.

According to this intended uses,no direct or indirect contamination of food is expected. To avoid any contamination, the following precautionary statement is proposed:

“ Avoid any direct or indirect contact with food and feed.”

**Conclusion on ecotoxicology and environment**

Following the application of the product PARANIX ENVIRONNEMENT, the risk for non-target species of aquatic (surface water and sediment) and terrestrial compartments are unacceptable.

Concentrations in groundwater related to the use of product Paranix Environnement are also higher than the benchmark value set by Directive 98/83/EC in the conditions of use proposed by the applicant.

The following instruction of use and risk mitigation measure can limit the environmental exposure:

* Do not apply to washable surfaces or washable textiles.
* During application, protect the adjacent surfaces with a non-washable plastic sheet.

It is considered that these measures will reduce risk for non target organisms of aquatic and terrestrial compartment and for groundwater.

# ASSESSMENT REPORT

## Summary of the product assessment

## Administrative information

* + - 1. **Identifier of the product**

|  |  |
| --- | --- |
| **Identifier** | **Country (if relevant)** |
| PARANIX ENVIRONNEMENT  PARANIX ANTI POUX SPECIAL ENVIRONNEMENT  PARANIX EXTRA FORT ENVIRONNEMENT  PARANIX EXTRA FORT SPECIAL ENVIRONNEMENT  PARANIX EXTRA FORT ANTI POUX SPECIAL ENVIRONNEMENT  DUO LP PRO ANTI-POUX SPECIAL ENVIRONNEMENT  DUO LP PRO SPECIAL ENVIRONNEMENT ANTI-POUX  DUO LP PRO SPECIAL ENVIRONNEMENT  DUO LP PRO ANTI-POUX ENVIRONNEMENT  DUO LP PRO ENVIRONNEMENT ANTI-POUX  DUO LP PRO ENVIRONNEMENT | France |

* + - 1. **Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | OMEGA PHARMA INTERNATIONAL N.V. |
| **Address** | VENECOWEG 26  9810 NAZARETH  BELGIUM |

* + - 1. **Manufacturers of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | LABORATOIRE ARDEPHARM |
| **Address of manufacturer** | LES ILES FERAYS  07300 TOURNON-SUR-RHONE  FRANCE |
| **Location of manufacturing sites** | LES ILES FERAYS  07300 TOURNON-SUR-RHONE  FRANCE |

* + - 1. **Manufacturer of the active substances**

|  |  |
| --- | --- |
| **Active substance** | 1,R-trans phenothrin (CAS No.26046-85-5) |
| **Name of manufacturer** | Sumitomo Chemical (UK) Plc |
| **Address of manufacturer** | Hyte house W 7NL  London  United Kingdom |
| **Location of manufacturing sites** | Aza-sabishirotai 033-0022  Aomori Japan |

|  |  |
| --- | --- |
| **Active substance** | Pyriproxyfen (CAS No.95737-68-1) |
| **Name of manufacturer** | Sumitomo Chemical (UK) Plc |
| **Address of manufacturer** | Hyte house W 7NL  London  United Kingdom |
| **Location of manufacturing sites** | Aza-sabishirotai 033-0022  Aomori Japan |

## Product composition and formulation

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

Yes No



## Identity of the active substances

|  |  |  |
| --- | --- | --- |
|  | **Main constituent(s)** | |
| **ISO name** | | Not assigned |
| **IUPAC or EC name** | | 1,R-trans phenothrin |
| **EC number** | | 247-431-2 |
| **CAS number** | | 26046-85-5 |
| **Index number in Annex VI of CLP** | | / |
| **Minimum purity / content** | | 89% w/w |
| **Structural formula** | |  |
|  | |  |
| **ISO name** | | Not assigned |
| **IUPAC or EC name** | | pyriproxyfen |
| **EC number** | | 429-800-1 |
| **CAS number** | | 95737-68-1 |
| **Index number in Annex VI of CLP** | | 613-303-00-3 |
| **Minimum purity / content** | | 97% w/w |
| **Structural formula** | |  |

* + - 1. **Candidate(s) for substitution**

The active substances 1,R-trans phenothrin and pyriproxyfen contained in the biocidal product PARANIX ENVIRONNEMENT are not candidates for substitution in accordance with Article 10 of Regulation (EC) No.528/2012.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS**  **number** | **EC number** | **Content (% w/w)** |
| 1,R-trans phenothrin  (Pure) | 3-phenoxybenzyl (1R,3R)-2,2-dimethyl- 3-(2-methylprop-1- enyl)cyclopropanecarb oxylate | Active substance | 26046-85-5 | 247-431-2 | 0.28 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS**  **number** | **EC number** | **Content (% w/w)** |
| Pyriproxyfen (pure) | 4-phenoxyphenyl (RS)-2-(2-  pyridyloxy)propyl ether | Active substance | 95737-68-1 | 429-800-1 | 0.0146 |
|  | Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | Solvent  Substance of concern | 93685-81-5 | 297-629-8 | 99,667 |

The detailed composition is presented in the confidential annex (separated document)

## Information on technical equivalence

Not concerned.

## Information on the substance(s) of concern

The product PARANIX ENVIRONNEMENT contains one substance of concern.

|  |  |
| --- | --- |
| IUPAC name or other accepted chemical name | Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated |
| EC number | 297-629-8 |
| CAS number | 93685-81-5 |
| Concentration (g/kg or g/l) | 745.5 |
| Classification and Labelling according to Regulation (EC) No 1272/2008: | Flam. liq 3 H226 Asp Tox. 1 H304 H413  EUH066 |
| Relevant toxicological/ecotoxicologic  al information |  |
| Other grounds for concern1 |  |

## Type of formulation

AE - Aerosol dispenser

Please include PBT, vPvB, POP and ED properties, if relevant.

## Hazard and precautionary statements

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

**Table 2.1.3-1: Proposed classification of the biocidal product PARANIX ENVIRONNEMENT**

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Flam. Aerosol 1  Asp. Tox 1  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H222 Extremely flammable aerosol.  H229 Pressurised container: May burst if heated. H304 May be fatal if swallowed and enters airways. H400 Very toxic to aquatic life.  H410 Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H222 Extremely flammable aerosol.  H229 Pressurised container: May burst if heated. H410 Very toxic to aquatic life with long lasting effects. |
| Additional hazard  statement | EUH066 Repeated exposure may cause skin dryness or  cracking. |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.  P102 Keep out of reach of children.  P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use.  P273 – Avoid release to the environment P391 – Collect spillage  P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50ºC/ 122oF.  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

* + 1. **Authorised use(s)**
       1. **Use description**

**Table 2.1.4-1. Use 1 –Spray Application by general public**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact**  **description of the authorised use** |  |
| **Target organism (including development stage)** | Human head lice  *Pediculus humanus capitis*  Larvae and adults |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying  Curative treatment on porous and non porous surfaces infested by lice. |
| **Application rate(s) and frequency** | 26.7 g/m²  Contact time 10 minutes  The product has not residual efficacy  Application can be renewed upon reappearance of the lice |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Can in aluminium with internal epoxyphenolic varnish of 270, 335 and 520 mL |

### Use-specific instructions for use

* + - * 1. ***Use-specific risk mitigation measures***
        2. ***Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment***
      1. **Where specific to the use, the instructions for safe disposal of the product and its packaging**
         1. ***4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***
    1. **General directions for use**
       1. **Instructions for use**
* Always read the label or leaflet before use and respect follow all the instructions provided
* The users should inform if the treatment is ineffective and report straightforward to the registration holder
* Shake well before use
* Spray directly onto objects likely to have been in contact with lice by holding the aerosol at 30/40 cm of the objects to be treated
* Proceed with short pressures without prolonged spraying
* Spray 27 g / m², Contact time of 10 minutes and then suck the dead lice
* In case of re-infestation, renew the application
* Integrate other control measures against lice (high temperature washing, wet combing, use of anti-lice products applied on the hair (medical device)…).
  + - 1. **Risk mitigation measures**
* During application indoor open the windows.
* After application open the windows and leave the room and wait 2 hours before re- entry .
* Do not apply on mattress of children younger than 2 years old.
* Avoid any direct and indirect contact with food and feed.
* Do not apply to washable surfaces or textiles.
* During application protect the adjacent surface with a non-washable plastic sheet.
* Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
  + - 1. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

Ingestion: Wash out mouth with water. Do not drink or induce vomiting. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.

Eye contact: Immediately flush with plenty of water, occasionally lifting the upper

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and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.

Keep the container or label available.

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* + - 1. **Instructions for safe disposal of the product and its packaging**

Completely empty the container. Keep the label on the container.

Dispose of this material and its container at hazardous or special waste collection point in accordance with local/national regulations.

The disposal of this packaging in the environment will be banned.

Do not empty into drains and streams.

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* + - 1. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 2 years

Do not store at the temperature higher than 40°C

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## Other information

## 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)** |
| Multi-shot aerosol can | 270 mL (=150 mL of aerosol) | Metal: aluminium Internal  epoxyphenolic varnish | Diffuser with valve  Cap in  polypropylene | General public | Yes |
| 335mL = | Metal: | Diffuser with | General | Yes |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 225or 250 | aluminium | valve | | public |  |
| mL of | Internal | Cap | in |  |
| aerosol) | epoxyphenolic | polypropylene | |  |
|  | varnish |  | |  |
|  | Metal: | Diffuser | with | General public |  |
| 520 mL= | aluminium | valve | |  |
| 300 mL of | Internal | Cap | in | Yes |
| aerosol) | epoxyphenolic | polypropylene | |  |
|  | varnish |  | |  |

## Documentation

* + - 1. **Data submitted in relation to product application**

**Physico-chemical properties studies and analytical data**

Physico-chemical properties studies and analytical methods on the biocidal product PARANIX ENVIRONNEMENT were provided by Laboratoire Omega Pharma France and summarized in Annex 3.1.

## Efficacy data

Following laboratory studies have been taken into account for the assessment of the efficacy of the product PARANIX ENVIRONNEMENT:

* Screening test with the product PARANIX ENVIRONNEMENT (1,R-trans phenothrin 0.28% w/w and pyriproxyfen 0.015% w/w) on *Pediculus humanus capitis*;
* Laboratory test with the product PARANIX ENVIRONNEMENT (1,R-trans phenothrin 0.28% w/w and pyriproxyfen 0.015% w/w) on *Pediculus humanus capitis*;
* Laboratory test with the product PARANIX ENVIRONNEMENT (1,R-trans phenothrin 0.28% w/w and pyriproxyfen 0.015% w/w) on nits of *Pediculus humanus capitis* and *Pediculus humanus humanus*.
* Physico-chemical tests and chemical analyses before and after a storage procedure for 36 months at 20°C on the aerosol PARANIX ENVIRONNEMENT NOUVELLE FORMULE

**Toxicology data**

No specific data were submitted in the context of this dossier.

**Environnemental data**

No specific data were submitted in the context of this dossier.

**Residues data**

No specific residue data were submitted in the context of this dossier. The product PARANIX ENVIRONNEMENT is intended to be applied indoor by non-professional users on objects that could have been in contact with lice (bedding, comb, armchair, helmet...). PARANIX ENVIRONNEMENT will not get in contact with food, feed and drink. Residue in food, feed and drink are not expected.

## Access to documentation

Laboratoire Omega Pharma France has access to data on the active substances 1R-trans phenothrin and pyriproxyfen with a Letter of Access of Sumitomo, applicant of the two active substances.

Data on the manufacturer and the manufacturing location is reported in the confidential part.

## Assessment of the biocidal product

* + 1. **Intended use(s) as applied for by the applicant Table 2.2.1-1. Intended use 1 – Spraying**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | The product Paranix Environnement is an aerosol ready-for-use insecticide for direct surface treatment against lice and nits. It is applied by spray application on objects that could have been in contact with lice (bedding, comb, armchair, helmet…). |
| Target organism (including development stage) | Pediculicidae (sucking lice: pediculid lice) Eggs  Larvae Adults |
| Field of use | Indoor |
| Application method(s) | Spraying |
| Application rate(s) and frequency | 26.7 g product/m²  Reapply upon reappearance of the lice. |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

## Physical, chemical and technical properties

The biocidal product is not the same as the representative product assessed for the inclusion of the active substances in annex 1 of the biocidal product Directive 98/8/EC. The composition of the product is confidential (see confidential annex).

The product contains two active substances:

* 0.315% of technical active substance (sum of all phenothrin isomers) at min purity 89% and 0.28% of pure 1R-trans phenothrin.
* 0.0150% of technical pyriproxyfen at min purity 97% and 0.0146% of pure pyriproxyfen.

The product does not contain PT6 preservative and is not diluted for use:

* Formulation type: Aerosol (AE)
* Hydrocarbon and H304 co-formulant content: 99.67%

The product PARANIX ENVIRONNEMENT is packaged in aerosol in aluminium can with internal epoxyphenolic varnish of 270mL (with 150mL of aerosol), 335mL (with 225-250mL of aerosol) and 520mL (with 300mL of aerosol).

## Table 2-Physical, chemical and technical properties

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Visual method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Homogeneous limpid liquid  Same observation after accelerated storage stability study | Acceptable | Demangel B. 2016  Study report No 15-912035-015 |
| Colour at 20 °C and 101.3 kPa | Visual method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Colourless  Same observation after accelerated storage stability study | Acceptable | Demangel B. 2016  Study report No 15-912035-015 |
| Odour at 20 °C and 101.3 kPa | Visual method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Characteristic odour  Same observation after accelerated storage stability study | Acceptable | Demangel B. 2016  Study report No 15-912035-015 |
| Acidity / alkalinity | Statement | PARANIX ENVIRONNEMENT | As the product Paranix Environnement is a non-aqueous ready-to-use product, it is not intended to be applied as aqueous solutions, therefore the determination of pH of neat product or 1% aqueous solution is not justified. | Acceptable | IUCLID |
| Relative density / bulk density | Method EC.A3  Pycnometer method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | D420 = 0.748 at 21.6°C | Acceptable  After the pulverisation the propellant gas is gone. It is acceptable to test the liquid formulation without the propellant gas. | Demangel B. 2016  Study report No 15-912035-013 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  8 weeks at 40°C in aluminium aerosol can  Analytical method HPLC-UV (15-912035-017 and 15-912035-018)  Internal method  Internal method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE and aluminium aerosol of 270mL (with 150mL of product), smallest size  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | - Active substance content:   |  |  |  | | --- | --- | --- | | % | T0 | T8w | | 1R-transphenothrin | 0.297 | 0.300 | | Pyriproxyfen | 0.0150 | 0.0149 |   - Satisfactory operation of the aerosol and spray volume:  Multi-shot aerosol:  Weight of aerosol before and after 5s pulverisation and calculation of the volume with the density has been made.  Mean volume after 5s spray   |  |  | | --- | --- | | T0 | T8w | | 5.92mL | 6.70mL |   Nozzles of the aerosol were checked and no blocking were observed  - Spray diameter and pattern:  Multi-shot aerosol:  Diameter when spraying at 30 cm during 5s has been measured.   |  |  | | --- | --- | | T0 | T8w | | 16cm | 19cm |   The shape was circular in each case | Acceptable  The liquid formulation without the propellant gas has been used for the determination of the active substances contents. After the pulverisation the propellant gas is gone. It is acceptable to test the liquid formulation without the propellant gas.  The aerosol with the smallest size (270mL) has been used for the packaging material compatibility and technical properties.  The test has been performed at 40°C instead of 54°C for security reason as the aerosol is classified H229. A risk mitigation measure: store at maximum 40°C should be specified. Moreover with the classification H229 there are two precautionary statements:  P410+P412 : Protect from sunlight. Do no expose to temperatures exceeding 50 oC/122oF. | Demangel B. 2016  Study report No 15-912035-015 |
| Storage stability test – **long term storage at ambient temperature** | 36months at 20°C in aluminium aerosol can  Technical monograph no.17  Analytical method HPLC-UV (15-912035-017 and 15-912035-018)  Internal method  Internal method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE and aluminium aerosol of 270mL (with 150mL of product), smallest size  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | The study is on-going.  Beginning: 21 October 2015  End: November 2018  Active substances contents, Satisfactory operation of the aerosol and spray volume and pattern will be determined after 6, 12, 24 and 36 months.  Intermediate results after 6 months and 12 months have been provided:  Content of the two actives substances have been measured.   |  |  |  |  | | --- | --- | --- | --- | | % (w/w) | T0 | T6m | T12m | | 1R-transphenothrin | 0.297 | 0.314 | 0.316 | | Pyriproxyfen | 0.015 | 0.0155 | 0.0144 |   Variation < 10% after 6 months and 12 months for the active substance content.  Appearance of the packaging and weight variation is the same after 6 and 12 months: no sign of degradation or leak, weight variation 0%  Spray volume and spray diameter for the product:  Spray volume (5s):   |  |  |  |  | | --- | --- | --- | --- | | mL | T0 | T6m | T12m | | 270mL | 5.945 | 7.467 | 7.075 |   Spray diameter   |  |  |  |  | | --- | --- | --- | --- | | cm | T0 | T6m | T12m | | 270mL | 16 | 16 | 20 |   The shape was circular in each case  The nozzles were checked and no blocking was observed in each case | Acceptable  Intermediate results after 6 months and 12 months have been provided.  The product is stable after 12 months.  After the pulverisation the propellant gas is gone. It is acceptable to test the liquid formulation without the propellant gas. | Demangel B. 2016  Study report No 15-912035-016 |
|  | 36 months at 20°C in aluminium aerosol can  Technical monograph no.17  Analytical method HPLC-UV (15-912035-017 and 15-912035-018)  Internal method  Internal method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE and aluminium aerosol of 270mL (with 150mL of product), smallest size  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Final study of shelf life study.  The product was stored in aluminium can at 20 +/6 2°C :   |  |  |  |  | | --- | --- | --- | --- | | % (w/w) | T0 | T24m | T36m | | 1R-transphenothrin | 0.297 | 0.298 | 0.287 | | Pyriproxyfen | 0.015 | 0.0148 | 0.0149 |   Variation < 10% after 24 months and 36 months for the active substance content.  Appearance of the packaging and weight variation is the same after 24 and 36 months: no sign of degradation or leak, weight variation 0%  Spray volume and spray diameter for the product:  Spray volume (5s):   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T24m | T36m | | mL | 5.94 | 5.87 | 5.81 |   Spray diameter   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T24m | T36m | | cm | 16 | 18 | 19 |   The shape was circular in each case  The nozzles were checked and no blocking was observed in each case | Acceptable  The product is stable after 36 months.  As no minor change dossier was submitted by industry since product assessment report of the biocidal product, the shelf life of the product is kept at 24 month, as provided in the initial SPC. | Demangel B. 2019  Study report No 15-912035-016 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  7 days at 0°C in aluminium aerosol can  Internal method  Internal method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE and aluminium aerosol: commercial packaging  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | - Stability:   |  |  | | --- | --- | | T0 | T7d | | Homogeneous colourless limpid liquid | | | No sign of corrosion or degradation in the aluminium aerosol can | |   - Satisfactory operation of the aerosol and spray volume:  Multi-shot aerosol:  Weight of full aerosol, weight aerosol after 5s spray and calculation of the volume with the density has been made.   |  |  | | --- | --- | | T0 | T7d | | 5.86mL | 5.53mL |   Nozzles of the aerosol were checked and no blocking were observed  - Spray diameter and pattern:  Multi-shot aerosol:  Diameter when spraying at 30 cm during 5s has been measured.   |  |  | | --- | --- | | T0 | T7d | | 20cm | 19cm |   The shape was circular in each case | The propellant gas is not solubilized in the liquid moreover it is azote which congelation point is -270°C. Therefore only the aspect of the liquid stored in transparent tube has been observed after 7 days at 0°C.  The complete aerosol has been used for the packaging material compatibility and technical properties.  Acceptable | Demangel B. 2016  Study report No 15-912035-014 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | PARANIX ENVIRONNEMENT | Not required as the commercial packaging of the product Paranix Environnement is opaque (white aluminium multi-shot aerosol). | Acceptable | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  | PARANIX ENVIRONNEMENT | The test item PARANIX ENVIRONNEMENT was considered to be stable after 8 weeks at 40 ± 2°C (please refer to section 3.4.1.1) and after 7 days at 0 ± 2°C (please refer to section 3.4.1.3).  The individual commercial packaging (aerosol) is sealed. With this closure system, the packaging is leak-tight (see section 12.3). | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3  8 weeks at 40°C in aluminium aerosol can | PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | No sign of corrosion and degradation after accelerated storage stability study  Weight difference:   |  |  | | --- | --- | | T0 | T8w | | 172.7g | 172.7g |   -0% of difference | Acceptable | Demangel B. 2016  Study report No 15-912035-015 |
| Wettability |  |  | No data provided. | Not relevant for an AE |  |
| Suspensibility, spontaneity and dispersion stability |  |  | No data provided. | Not relevant for an AE |  |
| Wet sieve analysis and dry sieve test |  |  | No data provided. | Not relevant for an AE |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | No data provided. | Not relevant for an AE |  |
| Disintegration time |  |  | No data provided. | Not relevant for an AE |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | No data provided. | Not relevant for an AE |  |
| Persistent foaming |  |  | No data provided. |  |  |
| Flowability/Pourability/Dustability |  |  | No data provided. |  |  |
| Burning rate — smoke generators |  |  | No data provided. |  |  |
| Burning completeness — smoke generators |  |  | No data provided. |  |  |
| Composition of smoke — smoke generators |  |  | No data provided. |  |  |
| Spraying pattern — aerosols | Internal method | PARANIX ENVIRONNEMENT aluminium aerosol of 270mL (with 150mL of product), smallest size  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Spray diameter and pattern:  Multi-shot aerosol:  Diameter when spraying at 30 cm during 5s has been measured.   |  |  | | --- | --- | | T0 | T8w | | 16cm | 19cm |   The shape was circular in each case | Acceptable | Demangel B. 2016  Study report No 15-912035-015 |
| Physical compatibility | Statement | PARANIX ENVIRONNEMENT | The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Paranix Environnement with other biocidal products, chemicals or active substances is required. | Acceptable | IUCLID |
| Chemical compatibility | Statement | PARANIX ENVIRONNEMENT | The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Paranix Environnement with other biocidal products, chemicals or active substances is required. | Acceptable | IUCLID |
| Degree of dissolution and dilution stability |  |  | No data provided. | Not relevant for an AE |  |
| Surface tension | Method EC.A5  Ring method | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Pure test item  21.4 mN/m at 20.4°C  The liquid formulation is surface active. | Test has been performed on the product Paranix Environnement without the propellant gas. After the pulverisation the propellant gas is gone. It is acceptable to test the liquid formulation without the propellant gas.  Acceptable  The liquid formulation is surface active. | Demangel B. 2016  Study report No 15-912035-013 |
| Viscosity | Method OECD 114  Viscometer with rotational spindles | Liquid formulation without the propellant gas  PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-transphenothrin and 0.015% pyriproxyfen | Dynamic viscosity:  1.44 mPa.s at 20°C  1.09 mPa.s at 40°C  Calculated kinematic viscosity:  (V(kin.) = V(dyn.) / d)  The calculated kinematic viscosity of the test item Paranix Environnement was 1.93 mm²/s at 20°C and 1.46 mm²/s at 40°C.  As the product Paranix Environment has a kinematic viscosity ≤ 20.5 mm²/s at 40°C and contains more than 10% w/w of a formulant classified H304, it is classified Asp. Tox. 1, H304 in accordance with the CLP. | Test has been performed on the product Paranix Environnement without the propellant gas. After the pulverisation the propellant gas is gone. It is acceptable to test the liquid formulation without the propellant gas.  Acceptable  Newtonian liquid  Classification H304 of the liquid formulation | Demangel B. 2016  Study report No 15-912035-013 |
| Net content of formulation | Quality control data:  Net content of product | PARANIX ENVIRONNEMENT  Aerosol of 270mL (with 150mL of product) | |  |  | | --- | --- | | Weight (g) | Net content | | 05/07/2016 – 15h05 | 119.71 | | 05/07/2016 – 15h35 | 119.94 | | 05/07/2016 – 16h05 | 119.54 | | 05/07/2016 – 16h35 | 119.50 | | 06/07/2016 – 5h45 | 119.3 | | 06/07/2016 – 6h15 | 119.6 | | 06/07/2016 – 6h45 | 119.4 | | 06/07/2016 – 7h15 | 120.8 | | 06/07/2016 – 7h45 | 122.03 | | 06/07/2016 – 8h15 | 122.32 | | 06/07/2016 – 8h45 | 122.85\* | | 06/07/2016 – 9h15 | 122.90\* | | 06/07/2016 – 9h45 | 121.32 |   \*seems to have an error  Mean: 120.3 g  The acceptable quality control ranges are: 113-124 g | Acceptable  Range have been provided, with QC data (7 measures) and mean of the 13 measures  Acceptable  Only data have been provided for aerosol with the smallest size | AEROFARM,  2016  Study report Edition du 07/07/2016 – Lot CC581 |
| Internal pressure | Quality control data:  Internal pressures at 20°C and 50°C, measured with specific manometer | PARANIX ENVIRONNEMENT  Aerosol of 270mL (with 150mL of product) | Measure at 20°C   |  |  |  |  | | --- | --- | --- | --- | | bars | 1 | 2 | 3 | | 05/07/15 – 15h00 | 9.00 | 9.10 | 9.20 | | 05/07/15 – 15h15 | 9.00 | 9.40 | 9.60 | | 05/07/15 – 15h30 | 9.00 | 9.00 | 9.00 | | 05/07/15 – 15h45 | 9.40 | 9.40 | 9.60 | | 05/07/15 – 16h00 | 9.20 | 9.10 | 9.40 | | 05/07/15 – 16h15 | 9.40 | 9.40 | 9.60 | | 05/07/15 – 16h30 | 9.40 | 9.10 | 9.20 | | 05/07/15 – 16h45 | 9.10 | 9.20 | 9.20 | | 06/07/15 – 7h00 | 9.80 | 9.80 | 9.60 | | 06/07/15 – 7h15 | 10.2 | 10 | 10 | | 06/07/15 – 7h30 | 9.80 | 9.80 | 9.20 | | 06/07/15 – 7h45 | 10 | 10 | 10.20 | | 06/07/15 – 8h00 | 10 | 10 | 10 | | 06/07/15 – 8h15 | 10.2 | 10 | 10 | | 06/07/15 – 8h30 | 10 | 10.40 | 10.20 | | 06/07/15 – 8h45 | 10 | 10.20 | 10.20 | | 06/07/15 – 9h00 | 10.00 | 9.80 | 10.00 | | 06/07/15 – 9h15 | 10.00 | 10.20 | 9.80 | | 06/07/15 – 9h30 | 10.00 | 10.00 | 10.00 | | 06/07/15 – 9h45 | 10.20 | 10.00 | 10.00 | | 06/07/15 – 10h00 | 10.00 | 10.20 | 10.20 | | 06/07/15 – 10h15 | 10.00 | 10.00 | 10.00 |   Mean: 9.73 bars at 20°C  The acceptable quality control ranges are: 9-10.5 bars | Acceptable  Range have been provided, with QC data (22 measures in triplicate) and mean of the 22\*3 measures  Acceptable  Only data have been provided for aerosol with the smallest size | AEROFARM,  2016  Study report Edition du 07/07/2016 – Lot CC581 |
| Discharge rate | Quality control data  measured on the aerosol can equipped with the valve and actuator at 20°C:  The can containing the product is weighed (P1 in grams), then emptied by continuous spraying. The spraying time (t in seconds) is determined and the can is weighed again (P2 in grams). The discharge rate (d in grams/second) is calculated with the following equation: d = (P1 – P2) / t | PARANIX ENVIRONNEMENT  Aerosol of 270mL (with 150mL of product) | |  |  |  |  | | --- | --- | --- | --- | |  | Net weight (g) | Emptying time (s) | Discharge rate (g/s) | | 05/07/15 – 15h25 | 114.34 | 167 | 0.68 | | 06/07/15 – 7h10 | 121.12 | 172 | 0.70 |   Mean: 0.69 g/s | Acceptable quality control range values should have been provided for the discharge rate.  Only data have been provided for the aerosol with the smallest size | AEROFARM,  2016  Study report Edition du 07/07/2016 – Lot CC581 |
| Clogging of the dispenser valves | Quality control data | PARANIX ENVIRONNEMENT  Aerosol of 270mL (with 150mL of product) | Satisfactory operation of the valve is determined during the quality control of the aerosol packaging containing Acardust | Acceptable  Only data have been provided for the aerosol with the smallest size | AEROFARM,  2016  Study report Edition du 07/07/2016 – Lot CC581 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The formulation PARANIX ENVIRONNEMENT is an Aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is an homogeneous limpid liquid colourless with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability study data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium can packaging material (commercial packaging material).  The long term storage stability study (36 months) is on-going. Intermediate results after 6 and 12 months have been provided and are acceptable.  Final results at 24 months were provided as post authorisation data and deemed acceptable.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AE formulation. Quality control data have been provided for net content of formulation, internal pressure and discharge rate for the product PARANIX ENVIRONNEMENT. Mean net content is 120.3 g, mean internal pressure is 9.73 bars at 20 °C and the mean discharge rate is 0.69 g/s for the aerosol with the smallest size (270 mL, with 150 mL of product).  The liquid formulation is classified H304.  Risk mitigation measure: Do not store at the temperature higher than 40 °C |

## Physical hazards and respective characteristics Table 2-1Physical hazards and respective characteristics

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test**  **substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| Explosive | DSC | Liquid formulation without the propellant gas PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-  transphenothrin and 0.015%  pyriproxyfen | According to the evaluation of 1R-trans phenothrin and pyriproxyfen under Biocidal Products Regulation, these active substances (0.295% w/w total) have no explosive properties.  The Differential Scanning Calorimetry (DSC) graphs do not show any exothermic decomposition up to 600°C, what demonstrates that the product Paranix Environnement is unlikely to be explosive and the test on explosive properties according to UN Test series 1 to 3 described in Part I of the UN-MTC should not be performed. | Moreover the propellant gas is has no explosive properties therefore the product is not considered as explosive.  Acceptable | Demangel B. 2016  Study report No 15-  912035-013  Detrimont H. Ambrosi D., (2016),  ASC report No.15/80  IUCLID |
| Flammable gases |  |  | No data provided. | Not relevant as the product is an AE |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Flammable aerosols | Statement | PARANIX ENVIRONNEMENT | Test is not required as the product Paranix Environnement is already classified as extremely flammable aerosol (Flam. Aerosol 1, H222 and Flam. Aerosol 1, H229). | Not acceptable, the test should be provided.  As no data have been provided on the flammability of the aerosol. The product PARANIX ENVIRONNEMENT is classified Flam Aerosol 1 H222 by default The aerosol is also classified  Flam. Aerosol 1, H229 | IUCLID |
| Oxidising gases |  |  | No data provided. | Not relevant for an AE |  |
| Gases under pressure |  |  | No data provided. | The product is classified H229 |  |
| Flammable  liquids |  |  | No data provided. | Not relevant as the product is  an AE |  |
| Flammable solids |  |  | No data provided. | Not relevant as the product is an AE |  |
| Self-reactive substances and mixtures | DSC | Liquid formulation without the propellant gas PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Essai 150922  0.28% 1R-  transphenothrin and 0.015%  pyriproxyfen | Considering the high proportion of not- self-reactive ingredients (in total 99.685% w/w), the product Paranix Environnement is not expected to present a significant hazard for self-reactivity.  According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances should be considered for classification in this hazard class unless their exothermic decomposition energy is less than 300 J/g. As no exothermic reaction was observed in the temperature range used from 25°C to 600°C (DSC graphs), testing according to UN Test series A to H described in Part II of the UN-MTC is considered as  unnecessary. | Moreover the propellant gas is not self-reactive therefore the product is not considered as self-reactive mixture.  Acceptable | Demangel B. 2016  Study report No 15-  912035-013  Detrimont H. Ambrosi D., (2016),  ASC report No.15/80  IUCLID |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pyrophoric liquids | Statement | PARANIX ENVIRONNEMENT | Not required as experience in manufacture and handling shows that the product Paranix Environnement does not ignite spontaneously on coming into  contact with air at normal temperature. | Acceptable | IUCLID |
| Pyrophoric solids |  |  | No data provided | Not relevant as the product is an AE |  |
| Self-heating substances and  mixtures |  |  | No data provided |  |  |
| Substances and mixtures  which in  contact with  water emit flammable  gases | Statement | PARANIX ENVIRONNEMENT | Not required as the product Paranix Environnement contains no ingredient classified as Water-react. 1 or Water- react. 2 according to Regulation (EC) No. 1272/2008 and as the chemical structures of the ingredients do not contain metals or  metalloids. | Acceptable | IUCLID |
| Oxidising liquids | Statement | PARANIX ENVIRONNEMENT | Considering the high proportion of not- oxidising ingredients (in total 99.965% w/w), the product Paranix Environnement is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. | Acceptable | Detrimont H. Ambrosi D., (2016),  ASC report No.15/80  IUCLID |
| Oxidising solids |  |  | No data provided. | Not relevant as the product is an AE |  |
| Organic  peroxides |  |  | No data provided. | Not relevant |  |
| Corrosive to metals | Statement | PARANIX ENVIRONNEMENT | Not required as experience shows that the product Paranix Environnement is not corrosive to metals*.*  Moreover no co-formulants or propellant gas is classified corrosive to metal | Acceptable | IUCLID |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Auto-ignition temperatures of products (liquids and gases) | Statement | PARANIX ENVIRONNEMENT | As no ingredient is not-auto-flammable, the product Paranix Environnement is not expected to present a significant hazard for auto-flammability, and testing is considered as unnecessary. | Acceptable | Detrimont H. Ambrosi D., (2016),  ASC report No.15/80  IUCLID |
| Relative self- ignition temperature for  solids |  |  | No data provided. | Not relevant as the product is an AE |  |
| Dust explosion hazard |  |  | No data provided. | Not relevant as the product is an AE |  |

|  |  |
| --- | --- |
|  | **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not explosive and has no oxidizing properties. No test has been provided but the product is classified as extremely flammable aerosol by the applicant.  Implication concerning labelling: Flam. Aerosol 1, H222; H229 | |

* + 1. **Methods for detection and identification**

**2.2.4.1 Formulation analysis**

Report: Ricau H. 2016, Validation of the analytical method for the determination of 1R-trans phenothrin in PARANIX ENVIRONNEMENT NOUVELLE FORMULE

Report no 15-912035-017

Test facilities: DEFITRACES Z.A. des Andrés 150, rue Pré-Magne 69126 BRINDAS, France

Principle of the method:

The method is based on the CIPAC method 356/TC/(M)/2 which allows to determine 1R-trans phenothrin in technical material.

The liquid formulation without the propellant gas is dissolved in hexane and 1R-trans phenothrin is analysed by HPLC-UV by external standard calibration.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4 except for the linearity.

Validation data:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed and chromatograms have been provided:   * Solvent blank (hexane) * Formulation blank * Pyriproxyfen reference item * Formulation blank + Pyriproxyfen reference item * Phenothrin reference item * 1R-trans phenothrin reference item * Test item   No interference was found: no peak appears in the solvent blank and in the formulation blank. Retention times of pyriproxyfen and 1R-trans phenothrin are different.  Moreover there are different retention times for the 1R-cis, 1S-  cis, 1R-tans and 1S-trans phenothrin. | | | |
| Linearity | No data have been provided for linearity: no calibration curve, equation and R2 | | | |
| Compound | Linearity % | | |
|  |  | | |
| Precision | Repeatability was evaluated by analyzing twice five test item solutions. | | | |
| Compound | | Mean | Repeatability (RSD) |
| 1R-trans phenothrin | | 0.314% | RSD = 1.15% |

Accuracy

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n |
| 114.44 mg/L (=0.285%) | 97%, 96.6% | 96.8% | - | 2 |
| 117.18 mg/L (=0.293%) | 100.2%,  100.0% | 100.1% | - | 2 |

As the provided analytical method for the determination of the active substance 1R-trans phenothrin is a CIPAC method, limited validation data are required. Therefore based on the provided data, the analytical method is considered fully validated for the determination of the active substance 1R-trans phenothrin in the liquid formulation without the propellant gas.

Accuracy was determined by analysis of 2 reconstituted samples and by comparison with a reference item. The accuracy results are expressed as the recovery rate.

Report: Ricau H. 2016, Validation of the analytical method for the determination of pyriproxyfen in PARANIX ENVIRONNEMENT NOUVELLE FORMULE

Report no 15-912035-018

Test facilities: DEFITRACES Z.A. des Andrés 150, rue Pré-Magne 69126 BRINDAS, France

Principle of the method:

The liquid formulation without the propellant gas is dissolved in hexane and pyriproxyfen is analysed by HPLC-UV by external standard calibration.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4. Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed and chromatograms have been provided:   * Solvent blank (hexane) * Formulation blank * 1R-trans phenothrin reference item * Phenothrin reference item * Formulation blank + 1R-trans phenothrin reference item * Pyriproxyfen reference item * Test item   No interference was found: no peak appears in the solvent blank and in the formulation blank. Retention times of pyriproxyfen and 1R-trans phenothrin are different.  Moreover there are different retention times for the 1R-cis, 1S- cis, 1R-tans and 1S-trans phenothrin. | |
| Linearity | Linearity was studied by carrying out five concentrations between 50% and 150% of the reference item. Twice determinations have been made at each concentration.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Pyriproxyfen | 50% to 100% = (2.83mg/L to 9.28mg/L) Y = 2.66x105 X – 9.30x104 R2 = 0.9984  n=5 | | |
| Precision | Repeatability was evaluated by analyzing twice five test item solutions. | | | |
| Compound | | Mean | Repeatability (RSD) |
| Pyriproxyfen | | 0.0149% | RSD = 1.05% |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted | | | |
|  | samples and by comparison with a reference item. The | | | |
|  | accuracy results are expressed as the recovery rate. | | | |
|  | Fortification Recovery Mean RSD n | | | |
|  | level rate recovery rate (%) | | | |
|  | 5.97mg/L 99.9%, 99.7% - 2 | | | |
|  | (=0.0149%) 99.5% | | | |
|  | 5.88mg/L 91.1%, 91.1% - 2 | | | |
|  | (=0.0146%) 91.2% | | | |

The provided analytical method is fully validated for the determination of the active substance pyriproxyfen in the liquid formulation without the propellant gas.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
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|  |  |  |  |  |
|  |  |  |  |  |

Analytical methods for 1R-trans phenothrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report 1R-trans phenothrin Product-type 18 (insecticides) (Mars 2013) and additional document (May 2016). The applicant Laboratoires Omega Pharma France have a Letter of Access from Sumitomo for these data.

Moreover based on the intended uses of the product and on the nature of the active substance, on its physico-chemical properties and on its relations structure/function, no contamination of the environment is foreseen (indoors use only). Analytical methods for 1R- trans phenothrin residues in soil, air, water (including drinking water) and sediment are unnecessary.

As the active substance 1R-trans phenothrin is not classified Toxic or Very Toxic, an analytical method for the determination of 1R-trans phenothrin residues in human body fluids and tissues is unnecessary

Analytical methods for pyriproxyfen in soil, air, water (drinking water) and sediment are available in Assessment Report pyriproxifen Product-type 18 (insecticides, acaricides and products to control other arthropods), September 2012. The applicant Laboratoires Omega Pharma France have a Letter of Access from Sumitomo for these data.

As the active substance pyriproxyfen is not classified Toxic or Very Toxic, anNo analytical method for the determination of pyriproxyfen residues in human body fluids and tissues is unnecessary

|  |  |
| --- | --- |
|  | **Conclusion on the methods for detection and identification of the product** |
| The provided methods for the determination of the active substances in the product are validated.  For 1R-trans phenothrin, analytical methods were provided at EU level for the determination of the sum of isomers residue in soil, water (drinking) and air with respectively LOQ = 0.01mg/kg, 0.1µg/L and 0.001 mg/m3.  1R-trans phenothrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  For pyriproxyfen, analytical methods were provided at EU level for the determination of the active substance residues in soil, water (surface and tap) and air with respectively LOQ = 0.01mg/kg, 0.01µg/L, 0.1µg/L and 1.0 µg/m3.  Pyriproxifen is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of 1R-trans phenothrin and pyriproxyfen  residues in food/feed of plant and animal origin is not required. | |

## Efficacy against target organisms

* + - 1. **Function and field of use**

Main Group 03: Pest Control

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

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

The product PARANIX ENVIRONNEMENT (0.28 % w/w 1R-trans phenothrin, 0.146 % w/w pyriproxyfen) is a ready-for-use insecticide aerosol for direct surface treatment against human head lice *Pediculus humanus capitis*. The product is applied by spray application on objects that could have been in contact with head lice (bedding, comb, armchair, helmet…). The application rate is 26.7 g product /m² corresponding to 31 seconds of spraying per m².

The product Paranix Environnement is intended to be used for the curative treatment against head lice *Pediculus humanus capitis* (adults, larvae and nits) by non-professional (general public) indoor buildings. No residual efficacy is claimed.

The product is used for the purpose of the protection of human health.

## Effects on target organisms, including unacceptable suffering

As described in the Assessment Report, 1R-trans phenothrin acts on harmful organisms by contact and ingestion. Target insects are knocked down and killed upon contact with the active ingredient.

The pyriproxyfen acts by contact. It interrupts the development of the target: egg hatching, metamorphosis of larvae into pupae, and pupae into adult.

## Mode of action, including time delay

The active substance 1,R-trans phenothrin is a pyrethroid insecticide and acaricide. It acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. The prolonged opening of sodium channels produces a protracted sodium influx, which leads to repetitive firing of sensory nerve endings, which may progress to hyper-excitation of the entire nervous system. At high pyrethroid concentrations, conduction block can occur and the insects and mites will die (1R-trans phenothrin PT18 Assessment Report, March 2013).

The active substance pyriproxyfen is an insect growth regulator and acts as a juvenile hormone mimic, interrupting the insect morphogenesis. It prevents (depending upon the time of application) egg hatching, metamorphosis of larvae into pupae, and pupae into adult (pyriproxyfen PT18 Assessment Report, 2012/09/21).

In the IRAC (Insecticide Resistance Action Committee) mode of action,

* 1,R-trans phenothrin belongs to Group 3 (sodium channel modulators), sub-group 3A (pyrethroids and pyrethrins)
* pyriproxyfen belongs to Group 7 (juvenile hormone mimics), sub-group 7C (pyriproxyfen).

According to the tests conducted with the product PARANIX ENVIRONNEMENT, mortality of the head lice is achieved according to the development stage targeted between a time delay of 10 minutes for larvae and adults to 12 days for eggs.

## Efficacy data

The applicant submitted following studies: Table 2-2: Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Funct ion** | **Field of use**  **envisaged** | **Test substanc**  **e** | **Test organism(s)** | **Test method** | **Test system / concentrations applied /**  **exposure time** | **Test results: effects** | **Refere nce** |
| PT18 | Acaricide Direct spraying Indoor application | Paranix Environne ment (1,R- trans phenothrin 0.28% w/w and pyriproxyfe n 0.015%  w/w) | Human head lice (*Pediculus humanus capitis*)  ± 20 human head lice per replicate, mixed gender adult and 3rd  stage nymphal | Laboratory test The principle of the method is to treat a filter paper and then expose the lice. Treated filter discs were left to stand for 10 minutes before use.  Mortality of the lice is  evaluated after, 1, 2 and 4 hours of  exposure. | Temperature: 30°C+/-2°C Relative humidity: 50%+/- 15%  Dose: ready-for-use aerosol, sprayed at several doses   * 67.2 g product/m² * 33.6 g product/m² * 16.8 g product/m² Surfaces: Whatman No 1 filter paper   Size: disc of 90 mm diameter (64 cm²)  Replicates: 1 per dose and treatment (product / control). | After 2 hours of exposure, mortality of the lice was complete on the filters treated with the 2 highest application rates (33.6 and  67.2 g product/m²  Mortality on the filter treated at the lowest rate (16.8 g product/m²) was 95.5%.  On the control, mortality after 2 hours of exposure was 5%. | Brunton E., 2015  (a)  RI = 2 |
| PT18 | Acaricide Direct spraying Indoor application | Paranix Environne ment (1,R- trans phenothrin 0.28% w/w  and pyriproxyfe | Human head lice (*Pediculus humanus capitis*)  ± 20 human lice per replicate, | The principle of the method is to place the lice on representative surfaces that  are then  sprayed with | Temperature: 30°C+/-2°C Relative humidity: 50%+/- 15%  Dose: ready-for-use aerosol, sprayed at a dose corresponding to 29.3 g product/m².  Surfaces: non-porous vinyl | The lice were killed after 10 minutes of exposure on the foam fabric, and immediately on vinyl fabric and mattress ticking.  They were knocked-down, with no recuperation at further examination. | Brunton E., 2015  (b)  RI = 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | n 0.015%  w/w) | mixed gender adult and 3rd  stage nymphal | the test  product. Mortality of the lice is  evaluated every 10 minutes until  1 hour, then every 30  minutes until 4 hours, and  finally after overnight exposure. | "fabric" (as on a seat cover), porous polyester mix mattress ticking and porous foam "fabric" (as in a helmet).  Size: disc of 55 mm diameter (23.8 cm²)  Replicates: 3 per surface and treatment (product / control). | Mortality was complete.  On the control surfaces, mortality was null until 4 hours of exposure. After an overnight exposure, the mean mortality varied between 12 % and 26 %.  Dose tested is slightly higher (29.3 g/m²) than claimed (26.7 g/m²). According to the applicant, for aerosol, it is difficult to measure exactly the duration of spraying and to have a continuous flow to  meet the application rate. |  |
| PT18 | Acaricide Direct spraying Indoor application | Paranix Environne ment (1,R- trans phenothrin 0.28% w/w and pyriproxyfe n 0.015%  w/w) | Human head lice (*Pediculus humanus capitis*) Human body lice (*Pediculus humanus humanus*) Eggs  ± 50 eggs per replicate | The principle of the method is to place the lice on a  representative surface:   * already treated with the test product (*P. humanus capitis*), or * treated   afterwards with the test product (P*. humanus humanus*).  The eggs are then let to | For *Pediculus humanus capitis*, temperature: 34.3°C+/-0.05°C and relative humidity: 55%+/-10%  For *Pediculus humanus humanus*, temperature: 30.2°C+/-0.05°C and relative humidity: 54%+/-10%  Dose: product pipetted and spread at the rate of 2.7 mg/cm² or 27 g/m² (claimed application rate)  Surfaces: porous foam "fabric" (as in a helmet).  Size: sample of 1\*2 cm, i.e. 2 cm²  Replicates: 3 per treatment | *Pediculus humanus capitis* Non hatched eggs: 58 % was achieved after 12 days incubation  Dead eggs : 7 %  The dead eggs was not taken into account in the mortality rate of 58 % as we didn’t know if the mortality of eggs is due to the product or to another factor.  Hatched eggs 34 %  Non treated sample | Toubate B., 2016  RI = 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | incubate, and hatching is evaluated after  12 to 15 days incubation. | (product / control) and species | (control):  Hatched eggs 71 % Dead eggs 3 %  Non hatched eggs 26 %  The results against *Pediculus humanus humanus* was not taken into account as this species  was not claimed. |  |

Additional data were also submitted with other products different from PARANIX ENVIRONNEMENT based only on the active substance pyriproxyfen. They were considered as supportive data to demonstrate the effect of pyriproxyfen on larvae and nits (eggs).

* + - * + For larvae and adult stages

Lice are paurometabolous insects, then metamorphosis to the adult state from the juvenile state is gradual and without any sudden. In this form of development, immature stages ([nymphs](http://bugguide.net/node/view/112388)) resemble small adults. They live in the same habitat as adults, typically taking the same food. Therefore the study performed on mixed gender adult and 3rd stage nymphal has been accepted to demonstrate efficacy on both adults and larvae stage.

No section is dedicated to lice in TNsG for PT18/19 but according to appendix 1, the use claimed is assimilated to a contact direct spray treatment. These involve application directly into insects, and are normally only possible when the insects are visible and available to be sprayed.

The study Brunton E., 2015 (b) has been conducted on laboratory, but FR CA considered the methodology, appropriate to simulate the use of the product: representative surfaces (non- porous and porous) surfaces are treated following conditions of use (i.e curative treatment with direct spray application on the surfaces infested by lice without remanence) and mortality has been assessed after 10 minutes contact time. It shall be noted that head lice survive with difficulties on surfaces outside scalp during several hours, which is a constraint to be take into account for testing.

According to the tests submitted on adults and larvae of human head lice *Pediculus humanus capitis*, efficacy was demonstrated against larvae and adults of human head lice *Pediculus humanus capitis* on porous and non-porous surfaces within 10 minutes, therefore the efficacy of curative treatment of the product PARANIX ENVIRONNEMENT against larvae and adults of *Pediculus humanus capitis* is demonstrated.

* + - * + For egg developmental stage

The efficacy of PARANIX ENVIRONNEMENT against nits (eggs) of head lice *Pediculus humanus capitis* was not demonstrated as the contact time of 10 minutes claimed is not consistent with the result observed, since mortality was achieved within 12 days. Furthermore, the rate of non-hatched eggs of 58 % obtained in the test is considered as a low rate of efficacy and not sufficient to contribute to the prevention of re-infestation.

|  |  |
| --- | --- |
|  | **Conclusion on the efficacy of the product** |
| In conclusion, according to efficacy data, the product PARANIX ENVIRONNEMENT is effective against larvae and adults of human head lice *Pediculus humanus capitis* for curative treatment.  Regarding the use against nits (eggs), French competent authorities (FR CA) consider that the elements presented in the dossier are not sufficient to demonstrate the efficacy of the product PARANIX ENVIRONNEMENT against nits (eggs) of *Pediculus humanus capitis*. | |

## Occurrence of resistance and resistance management

1,R-trans phenothrin is a class 1 pyrethroid (1,R-trans phenothrin PT18 AR, 2013/03). It is classified by IRAC in mode of action group 3A insecticide (sodium channel modulators, pyrethroids and pyrethrins). Any insect or mite population may contain individuals naturally resistant to 1,R-trans phenothrin and other group 3A insecticides. If these insecticides are used repeatedly, the resistant individuals may eventually dominate the pest insect or mite population. These resistant insects and mites may not be controlled by 1,R-trans phenothrin or by other group 3A insecticides.

Several literature references mention that resistance to 1,R-trans phenothrin had developed for head lice. Resistant head lice were recovered in the UK and in France at the beginning of the 1990s (Chosidow *et al*., 19942; Burgess *et al*.,19953). Resistance appears to be widespread in various countries, but varies in intensity and is not yet uniform (Durand *et al*., 2012)4. It seems probable that pyrethroid resistance in *P. humanus capitis* is due to a combination of nerve insensitivity (knockdown resistance or 'kdr') and monooxygenase resistance mechanisms (Hemingway *et al*., 19995; Durand *et al*., 20124).

There are indications that there is a possibility of development of resistance against pyriproxyfen. No literature reference has been found mentioning resistance of the lice eggs to pyriproxyfen up to now.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

⁻ Integrate other control measures against lice (high temperature washing, wet combing, use of anti-lice products applied on the hair (medical device)…).

⁻ The users should inform if the treatment is ineffective and report straightforward to the registration holder.

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

* Implement a monitoring of scientific literature related to the resistance of the head lice *P. humanus capitis* to the active substance 1R-trans phenothrin and provide an assessment of this monitoring every 2 years.
* The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
* **Post authorisation 2020 :**

In order to answer to the post authorisation requirement of implementing a monitoring of scientific literature related to the resistance of the head lice *P. humanus capitis* to the active substance 1R-trans phenothrin, two ways have been implemented by the applicant:

* Submission of scientific literature search and analysis on the resistance of the head lice *P. humanus capitis* to the active substance 1R-trans phenothrin;
* Analysing the Omega Pharma France customer service feedback regarding Paranix Environnement.
* **Literature research:**

The research has been carried out from the most commonly used databases: PubMed, Science Direct and Google Scholar. The chosen period for the research was between 2013 and 2020 as the studies on resistance mentioned in the Product Assessment Report were dated until 2012. The keywords used are:

* Resistance
* AND pediculus humanus OR lice
* AND 1R-trans phenothrin OR phenothrin OR CAS Number 26046-85-5

From the literature references research, two studies could be highlighted: (please refer to the annex for the summary of the bibliographic search)

[Masayo Komoda](https://pubmed.ncbi.nlm.nih.gov/?term=Komoda+M&cauthor_id=32383287) et al, 2020[[1]](#footnote-1): The results suggest that the combined use of 1R-trans phenothrin and ivermectin is safe and effective for the treatment of pyrethroid-resistant head lice in Japan. However, there is no specific data on new lice populations resistant to 1R-trans phenothrin.

[Kelsey Larkin](javascript:;) et al, 2020[[2]](#footnote-2): This study shows the presence of a mutation, which could lead to pyrethroid resistance in *Pediculus humanus capitis*, in Honduras. However, this study does not present any specific data on 1R-trans phenothrin. Its highlights the necessity of proactive resistance management programs, designed to detect pyrethroid mutations before they become established within populations of head lice.

Nevertheless, the literature search confirms that in the last 7 years, there has been no study published reporting the development of new lice populations resistant to 1R-trans phenothrin.

* **Customer service feedback:**

There have been 11 feedbacks regarding Paranix Environnement to the customer service since the  
authorisation of this product. Please refer to the table in Annex .

None of them concerns a lack of efficacy and/or resistance.

In conclusion, based on literature research for the period 2013-2020, and analysis of the feedbacks to Omega Pharma France customer service, no lack of efficacy of the product have been reported up to now.

The applicant should continue the monitoring of scientific literature related to the resistance of the *Pediculus humanus* to the active substance 1R-trans phenothrin and provide an assessment of this monitoring at the renewal of the authorisation.

## Known limitations

None

1. Chosidow O, Chastang C, Brue C, Bouvet E, Izri M, Monteny N, Bastuji-Garin S, Rousset JJ, Revuz J. , Controlled study of malathion and d-phenothrin lotions for *Pediculus humanus* var *capitis*-infested schoolchildren.
2. [Burgess IF,](https://www.ncbi.nlm.nih.gov/pubmed/?term=Burgess%20IF%5BAuthor%5D&amp;cauthor=true&amp;cauthor_uid=7549714) [Brown CM,](https://www.ncbi.nlm.nih.gov/pubmed/?term=Brown%20CM%5BAuthor%5D&amp;cauthor=true&amp;cauthor_uid=7549714) [Peock S,](https://www.ncbi.nlm.nih.gov/pubmed/?term=Peock%20S%5BAuthor%5D&amp;cauthor=true&amp;cauthor_uid=7549714) [Kaufman J.](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kaufman%20J%5BAuthor%5D&amp;cauthor=true&amp;cauthor_uid=7549714) , Head lice resistant to pyrethroid insecticides in Britain
3. Durand R, Bouvresse S, Berdjane Z, Izri A, Chosidow O., Insecticide Resistance in Head Lice: Clinical, Parasitological and Genetic Aspects
4. Hemingway J, Miller J, Mumcuogly KY., Pyrethroid resistance mechanisms in the head louse *Pediculus humanus capitis*

## Evaluation of the label claims

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product PARANIX ENVIRONNEMENT against larvae and adults of human head lice (*Pediculus humanus capitis*) for a curative treatment.

Regarding the use against nits (eggs) of *Pediculus humanus capitis*, the efficacy data presented are not sufficient to demonstrate efficacy the product. Then the contribution of the product to avoid re-infestation is not supported in the frame of this dossier.

The application rate validated is the following:

⁻ 26 g of product/m² within 10 minutes for a curative treatment indoor against larvae and adults of human head lice *Pediculus humanus capitis*.

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

The product PARANIX ENVIRONNEMENT is not intended to be used with other biocidal products.

## Risk assessment for human health

* + - 1. **Assessment of effects on Human Health**

No toxicological study has been submitted for the product PARANIX ENVIRONNEMENT. The classification of the product has been set according to the calculation rules presented in the CLP regulation.

Given the content of active substances and co-formulants, a classification **Asp Tox 1 – H304**

is required. The specific labelling mention **EUH 066** should also be added.

### Skin corrosion and irritation

Not submitted

### Eye irritation

Not submitted

### Respiratory tract irritation

Not submitted

### Skin sensitization

Not submitted

### Respiratory sensitization (ADS)

Not submitted

### Acute toxicity

Not submitted

### Information on dermal absorption

No dermal absoprtion study has been prodvided for the product PRANIX ENVIRONNEMENT.

The contents of active s.a is lower than 5 %, therefore the default dermal absorption value of 75 % from the EFSA guidance on dermal absorption6 may be used.

However, the oral absorption values of both active substances are lower than 75 %: 40% for pyriproxifen and 60 % for 1R-trans Phenothrin. As stated in the EFSA guidance mentionned above, these oral absorption values may be used as a surrogate dermal absorption values for in-use dilutions.

Morover, in the CAR of 1R-trans Phenothrin, a dermal absorption value of 4.5 % has been set for a solution containing 1% a.s in ethanol. It was deemed appropriate for higher concentration (5.25 %) products and lower concentration products (0.04 %).

1. Guidance on dermal absorption, EFSA journal 2012; 10(4):2665

Considering that PARANIX ENVIRONNEMENT is a solvent based formulation similar to the representative product assessed in the CAR, this value has been considered relevant for 1R- trans Phenothrin in the product PARANIX ENVIRONNEMENT.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | | **Pyriproxifen** | **1R-trans Phenothrin** |
| Value(s)\* | | **40 %** | **4.5 %** |
| Justification for the selected value(s) | | Oral absorption value < 75% | Value from the CAR of the a.s |

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

Due to the proposed classifcation including in the submitted MSDS and its impact on the classification of the product, the solvent Heptane 2,2,4,6,6 pentamethyl (CAS 93685-81-5) has been identified as a substance of concern.

This substance leads to a classification **Asp Tox 1 – H304** and **EUH 066** of the product. Therefore, the BAND A evaluation scheme is applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

### Available toxicological data relating to a mixture

No data sumitted.

### Other

No data sumitted.

## Exposure assessment

The product PARANIX ENVIRONNEMENT is a ready-for-use insecticide aerosol for direct surface treatment against lice. The product is applied by spray application on objects that could have been in contact with lice (bedding, comb, armchair, helmet…). The application rate is 26.7 g aerosol/m².

It is used by non-professionals, indoors.

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

According to the intended uses of the product PARANIX ENVIRONNEMENT (surface spraying by non-professionals), primary exposure is intended *via* inhalation, dermal and oral (non respirable) routes. Secondary exposure is intended for bystanders/residents (adult and children) *via* inhalation route following exposure of volatilised residues, dermal route following contact with the surfaces, and/or oral route following hand-to-mouth behaviour.

## Table 2.2.6.2.1-1 Summary of main paths of human exposure

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: relevant paths of human exposure** | | | | | | | |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industria l use** | **Profession al use** | **Non- professiona l use** | **Industrial use** | **Profession al use** | **Gener al public** | **Via food** |
| Inhalation | na | na | Yes | na | na | Yes | no |
| Dermal | na | na | Yes | na | na | Yes | no |
| Oral | na | na | Yes | na | na | Yes | no |

Non-professionals are expected to be exposed to 1R-trans phenothrin and pyriproxyfen for which physico-chemical and toxicological data are summarized in the following table (source: 1,R-trans phenothrin Assessment Report, March 2013; pyriproxyfen Assessment Report, September 2012):

## Table 2.2.6.2.1-2. Physico-chemical and toxicological data on active substances

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Active Substance** | **Concentr ation**  **(% w/w)** | **Molecul ar weight**  **(g/mol)** | **Vapor Pressur e**  **(Pa)** | **Lo g Po**  **w** | **Inhalatio n absorpti**  **on** | **Dermal absorpti on** | **Oral absorpti on** |
| **Pyroproxifen** | 0.015 | 321.37 | < 1.33\*10-5 | 4.8  6 | 100 % | 40 % | 40 % |
| **1R-trans**  **Phenothrin** | 0.315 | 350.46 | 2.37\*10-5 | 6.8 | 100 % | 4.5 % | 60 % |

### List of scenarios

**Table 2.2.6.2.2-1 Summary of exposure scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: scenarios** | | | |
| **Scenari o number** | **Scenario** | **Primary or secondary exposure Description of scenario** | **Exposed group** |
| 1. | Spraying application | **Primary exposure, inhalation and dermal** The product is sprayed onto surfaces that could have been in contact with lice (bedding, comb, armchair, helmet...) | Non- professionals |
| 2. | Inhalation of volatiles residues | **Secondary exposure, inhalation**  The product is sprayed onto surfaces and adults and children are exposed to volatilised residues. | General public |
| 3. | Adults and children > 6 years old  exposure by  contact with treated surfaces | **Secondary exposure, dermal**  The product is sprayed onto surfaces and adults and children are in contact with the freshly treated surfaces. | General public (adult and children > 6 years old) |
| 4. | Child (2-6 years old), toddler and infants playing on treated surfaces | **Secondary exposure, dermal and oral**  The product is sprayed onto surfaces and toddler and infant are in contact with the dried residues on the surfaces. They are exposed dermally and orally following hand-to-mouth behaviour. | General public (Child 2-6  years old,  toddler and infant) |
| 5 | Adults, children (> 6 years old and between 2-  6 years old,) toddler and infants sleeping on a treated mattress | **Secondary exposure, dermal**  The product can be applied on beds, so general public can be dermally exposed when sleeping on a treated mattress. | General public (Adult, children, toddler and infant) |

* + - * 1. ***Industrial exposure***

The product PARANIX ENVIRONNEMENT is intended to be used by non-professionals only. Therefore, industrial users are not expected to be exposed to the product and no exposure assessment is deemed necessary.

### Professional exposure

The product PARANIX ENVIRONNEMENT is intended to be used by non-professionals only. Therefore, professionals are not expected to be exposed to the product and no exposure assessment is deemed necessary.

### Non-professional exposure

*Scenario 1: primary exposure - spraying by non-professionals*

## Table 2.2.6.2.5-1 description of scenario 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [1]** | | | | |
| The product PARANIX ENVIRONNEMENT is a ready-for-use insecticide aerosol for direct surface treatment against lice. The product is applied by spray application on objects that could have been in contact with lice (bedding, comb, armchair, helmet…). The application rate is 26.7 g aerosol/m².  During the spray application, exposure occurs *via* dermal and inhalation routes.  The Pest Control Fact sheet (surface application with aerosol can), updated with the New default values for the spray model (2010) has been used in ConsExpo web to estimate exposure during application of the product.  For dermal exposure, the indicative dermal exposure values (75th percentile) from the “Consumer spraying and dusting model 1” (Aerosol Can; TNsG 2008) have been used leading to a total dermal exposure of 269 mg/min (Hand/forearm: 156 mg/min + Legs/feet/face: 113 mg/min).  According to the applicant’s data, the maximal content of the aerosol can is 335 mL. Considering a relative density of 0.748 and a mass generation of 0.69 g/s, a spray duration of 363 s (6.05 min) for the use of one aerosol can. The default value proposed by ConsExpo web is 10 min, but it has been considered that the use of the realistic spray duration was more appropriate.  The maximal treated surface for one aerosol device can be calculated as follow: Content (335 mL) x density (0.748 g/ml) / efficacy dose (26.7 g p.b./m²) = 9.38 m²  In the Consexpo Factsheet, the user then stays in the room after application leading to a total exposure duration of 240 min. This approach will be used as a tier 1. As a tier 2 it will be considered that the user leaves the room just after treatment and re-entry is not allowed during 2 hours. Total spray duration is 363 seconds or 6.05 minutes, as between the different spot to be treated the applicator can have to do other tasks like to turn pillows, mattress over to treat each side the exposure duration is considered as the double of the spraying time. So, in tier 2, a duration of 726 seconds or 12.10 minutes is considered. | | | | |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Weight fraction Pyriproxifen | 0.015 | % | Applicant’s data |
| Weight fraction 1R trans Phenothrin | 0.315 | % | Applicant’s data |
| Frequency | 97 | per year | Default value from ConsExpo |

1. It has to be noted that the result taken into account at the end of the calculation is the Internal dose on day of exposure; therefore the frequency of exposure has no real impact.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Spray duration | 363 | s | Applicant’s data |
| Exposure duration | 240 | min | Default value from ConsExpo |
| Room volume | 58 | m3 | Default value from ConsExpo |
| Room height | 2.5 | m | Default value from ConsExpo |
| Ventilation rate | 0.5 | per hour | Default value from ConsExpo |
| Inhalation rate | 1.25 | m3/h | HEEG opinion no 17 |
| Mass generation rate | 0.69 | g/s | Applicant’s data |
| Airborne fraction | 0.2 | - | Default value from ConsExpo |
| Density non volatile | 0.748 | g/cm3 | Applicant’s data |
| Inhalation cut off diameter | 10 | µm | Default value from ConsExpo |
| Dermal absorption value Pyriproxifen | 40 | % | - |
| Dermal absorption value 1R trans Phenothrin | 4.5 | % | - |
| Oral absorption value Pyriproxifen | 40 | % | - |
| Oral absorption value 1R trans Phenothrin | 60 | % | - |
| Inhalation absorption value Pyriproxifen | 100 | % | - |
| Inhalation absorption value 1R trans Phenothrin | 100 | % | - |
| Body weight (adult) | 60 | kg | HEEG opinion no 17 |
| **Tier 2** | Exposure duration | 12.1 | min | Assumption linked to a label |

*Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.*

### Conclusion on non-professional exposure

**Table 2.2.6.2.5-2 : calculations for Scenario [1] primary exposure – Spraying by non- professionals**

Considering a non-professional application, only Tier 1 without PPE is taken into account.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from non-professional uses** | | | | | |
| **Exposure scenario** | **Active substance** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral (non respirable) uptake**  **(mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tier 1** | | | | | |
| Scenario [1] | 1R trans  Phenothrin | 5.90 x 10-2 | 3.84 x 10-3 | 1.80 x 10-4 | 6.30 x 10-2 |
| Pyriproxifen | 2.80 x 10-3 | 1.63 x 10-3 | 5.80 x 10-6 | 4.43 x 10-3 |
| **Tier 2** | | | | | |
| Scenario [1] | 1R trans  Phenothrin | 7.70 x 10-3 | 3.84 x 10-3 | 9.3 x 10-5 | 1.16 x 10-2 |
| Pyriproxifen | 3.70 x 10-4 | 1.63 x 10-3 | 2.60 x 10-6 | 2.00 x 10-3 |

### Exposure of the general public

*Scenario [2] inhalation exposure of general public to volatile residues (adults and children)*

## Table 2.2.6.2.6-1 Description of scenario

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [2]** | | | | |
| The product PARANIX ENVIRONNEMENT is applied by spray application on bedding, comb, armchair, helmet…. A secondary exposure *via* inhalation of evaporated 1R-trans phenothrin and pyriproxyfen is regarded as negligible as the active substances have low vapour pressures (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C respectively).  However, in order to ensure a high level of protection of adults and children, an inhalation exposure is assessed according to the HEEG Opinion No.138. This document proposes scenario calculations to determine worst-case long-term inhalation exposure to volatilised active substances on 24-hours.  The inhalation exposure (iE) of an infant, toddler, child 2-6 years old, child > 6 years old and adult over a total of 24 hours can be calculated as follows:  iE = (SVC \* IR) / BW  with:   * SVC = saturated vapour concentration (mg/m3) * IR = 24h-inhalation rate (m3/24h-occupancy) * BW = body weight (kg)   The saturated vapour concentration (SVC) of the active substance has to be calculated using the following equation:  SVC = [(vapour pressure \* molecular weight) / (Gas constant \* Temperature)] | | | | |
|  | Parameters1 | Value | Unit | Reference |
| Tier 1 | Gas constant | 8.31 | J mol-1 K-1 |  |
| Temperature | 293 | K |  |

1. HEEG Opinion No.13 - Assessment of Inhalation Exposure of Volatilised Biocide Active Substance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Vapour - 1R-trans phenothrin | 2.37 x 10-5 | Pa |  |
| Molecular weight - 1R-trans phenothrin | 350.46 | g/mol |  |
| SVC - 1R-trans phenothrin | 3.41 x 10-3 | mg/m3 |  |
| Vapour - pyriproxyfen | 1.33 x 10-5 | Pa |  |
| Molecular weight - pyriproxyfen | 321.37 | g/mol |  |
| SVC - pyriproxyfen | 1.76 x 10-3 | mg/m3 |  |
| Inhalation rate - Infant | 5.4 | m3/24h | HEEG opinion no 17 |
| Inhalation rate - Toddler | 8 | m3/24h | HEEG opinion no 17 |
| Inhalation rate – Child 2-6 years old | 10.1 | m3/24h | HEEG opinion no 17 |
| Inhalation rate – Child > 6 years old | 12 | m3/24h | HEEG opinion no 17 |
| Inhalation rate - Adult | 16 | m3/24h | HEEG opinion no 17 |
| Body weight - Infant | 8 | Kg | HEEG opinion no 17 |
| Body weight - Toddler | 10 | Kg | HEEG opinion no 17 |
| Body weight – Child 2- 6 years old | 15.6 | Kg | HEEG opinion no 17 |
| Body weight – Child > 6 years old | 31.8 | Kg | HEEG opinion no 17 |
| Body weight - Adult | 60 | Kg | HEEG opinion no 17 |

1. *Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.*
2. *Only include the parameters changed with respect to the previous Tier.*

## Table 2.2.6.2.6-2 : Calculations for Scenario [2] inhalation exposure of general public to volatile residues (adults and children)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from non-professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **1R-trans phenothrin** | | | | | |
| Adult | Tier 1 no PPE | 9.10 x 10-4 | - | - | 9.10 x 10-4 |
| Child > 6 years old | 1.71 x 10-3 |  |  | 1.71 x 10-3 |
| Child 2-6 years old | 2.21 x 10-3 | - | - | 2.21 x 10-3 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Toddler |  | 2.73 x 10-3 | - | - | 2.73 x 10-3 |
| Infant | 2.30 x 10-3 | - | - | 2.30 x 10-3 |
| **Pyriproxyfen** | | | | | |
| Adult | Tier 1 no PPE | 4.68 x 10-4 | - | - | 4.68 x 10-4 |
| Child > 6 years old | 8.81 x 10-4 |  |  | 8.81 x 10-4 |
| Child 2-6 years old | 1.14 x 10-3 | - | - | 1.14 x 10-3 |
| Toddler | 1.40 x 10-3 | - | - | 1.40 x 10-3 |
| Infant | 1.18 x 10-3 | - | - | 1.18 x 10-3 |

*Scenario [3] hand contact with treated surfaces*

## Table 2.2.6.2.6-3 Description of scenario 3

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [3]** | | | | |
| The product PARANIX ENVIRONNEMENT is sprayed onto surfaces and adults and children are in contact with the treated surfaces. An exposure *via* dermal route is therefore expected.  Considering absorption values of 4.5% and 40%, for 1R transphenothrin and pyriproxyfen, respectively, the dermal exposure can be calculated as follows:  **Contamination of hand surface (mg a.s)** = *Application rate (mg/cm2) x dislodgeable fraction from the treated surface (%) x Hand surface exposed (cm2) x a.s fraction in the product (%)*  **Dermal exposure (mg/kg bw/d)**= Contamination of hand surface (mg a.s) x dermal absorption value (%) / body weight (kg) | | | | |
|  | Parameters1 | Value | Unit | Reference |
| Tier 1 | Application rate | 2.7 | mg/cm2 | The applicant claimed an application rate of 26.7 g pb/m2 |
| Percentage dislogeable from the treated surface | 9 | % | TNsG 2008 for a dried fluids on carpet |
| Hand surface- adult | 410 | cm2 | HEEG opinion no 17 (only palms of both hands) |
| Hand surface- child | 214 | cm2 | HEEG opinion no 17 (only palms of both hands) |
| Body weight – Child > 6 years old | 23.9 | Kg | HEEG opinion no 17 |
| Body weight - Adult | 60 | Kg | HEEG opinion no 17 |

1. *Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.*
2. *Only include the parameters changed with respect to the previous Tier.*

## Table 2.2.6.2.6-4 Calculations for Scenario [3] hand contact with treated surfaces

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from non-professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **1R-trans phenothrin** | | | | | |
| Adult | Tier 1 no PPE | - | 2.35 x 10-4 | - | 2.35 x 10-4 |
| Child | - | 3.08 x 10-4 | - | 3.08 x 10-4 |
| **Pyriproxyfen** | | | | | |
| Adult | Tier 1 no PPE | - | 9.95x 10-5 | - | 9.95 x 10-5 |
| Child | - | 1.30 x 10-4 | - | 1.30 x 10-4 |

*Scenario [4] Child, toddler and infant playing on treated surface*

## Table 2.2.6.2.6-5 Description of scenario

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Description of Scenario [4]** | | | | | | | |
| The product PARANIX ENVIRONNEMENT is sprayed onto surfaces and toddler and infant are in contact with the freshly treated surfaces, dermally and orally following hand-to-mouth behaviour.  Exposure assessment is based on rubbing off model from CONSEXPO pest control fact sheet modified with transfer coefficient from HEAdhoc.  For 1R transphenothrin, absorption values of 4.5 % (dermal absoprtion) and 60 % (oral absorption) has been used.  For pyriproxifen, absorption values of 40 % (dermal absoprtion) and 40 % (oral absorption) has been used. | | | | | | | |
|  | Parameters1 | | Value | Unit | Reference | | |
| Tier 1 | Application rate | | 2.7 | mg/cm2 | The applicant claimed an application rate of 26.7 g pb/m2 | | |
| Child 2-6 years old Transfer coefficient (TC) | | 3317 | cm2/h | HEAdhoc recommendation no 12 | | |
| Toddler Transfer coefficient (TC) | | 2255 | cm2/h | HEAdhoc recommendation no 12 | | |
| Infant Transfer coefficient (TC) | | 2000 | cm2/h | HEAdhoc recommendation no 12 | | |
| Exposure duration | | 1 | h | ConsExpo Fact sheet | Pest | Control |
| Dislogeable fraction the treated surface | from | 9 | % | TNsG 2008 for a dried fluids on carpet | | |
| Dermal absorption value - 1R transphenothrin | | 4.5 | % | - | | |
| Dermal absorption value - pyriproxifen | | 40 | % | - | | |
| Hand to mouth transfer | | 10 | % | ConsExpo Fact sheet | Pest | Control |
| Child 2-6 years old Body weight | | 15.6 | kg | HEEG opinion 17 | | |
| Toddler Body weight | | 10 | kg | HEEG opinion 17 | | |
| Infant Body weight | | 8 | kg | HEEG opinion 17 | | |

1. *Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.*
2. *Only include the parameters changed*

## Table 2.2.6.2.6-6: Calculations for Scenario [4] toddler and infant playing on treated surface

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from non-professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **1R-trans phenothrin** | | | | | |
| Child 2-6 years old | Tier 1 no PPE | - | 7.32 x 10-3 | 0.00 | 7.32 x 10-3 |
| Toddler | Tier 1 no PPE | - | 6.99 x 10-3 | 1.04 x 10-2 | 1.73 x 10-2 |
| Infant | Tier 1 no PPE | - | 7.75 x 10-3 | 1.15 x 10-2 | 1.92 x 10-2 |
| **Pyriproxyfen** | | | | | |
| Child 2-6 years old | Tier 1 no PPE | - | 3.1 x 10-3 |  | 3.1 x 10-3 |
| Toddler | Tier 1 no PPE | - | 2.96 x 10-3 | 3.29 x 10-4 | 3.29 x 10-3 |
| Infant | Tier 1 no PPE | - | 3.28 x 10-3 | 3.65 x 10-4 | 3.65 x 10-3 |

**Scenario [5] adult, child, toddler and infant sleeping on a treated mattress Table 2.2.6.2.6-7 : Description of scenarios**

|  |
| --- |
| **Description of Scenario [5]** |
| Adult, child, toddler and infant could be exposed during sleeping in a treated bed. In order to determine the exposure, it is considered that they sleep without cloth and all the surface body can be exposed. The surface body used were determined according to the HEEG opinion 17.  The body will not be in direct contact with bed, as there is sheet. In this context, a protection factor of 50 % is considered.  From this surface a fraction of active substance is dislodgeable:For dried surface, the value of 30 % proposed in TNsG for dried surface will be used. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Parameters1 | Value | Unit | Reference |
| Tier 1 | Application rate | 2.7 | mg/cm2 | The applicant claimed an application rate of 26.7 g pb/m2 |
| Active substance  concentration - 1R transphenothrin | 0.315 | %w/w |  |
| Active substance concentration - pyriproxifen | 0.015 | %w/w |  |
| Sheet protection factor | 50 | % | HEADhoc recommendation 8 |
| Dislogeable fraction from the treated surface | 30 | % | TNsG 2008 for a dried fluids on carpet |
|  |  |  |  |
| Dermal absorption value - 1R transphenothrin | 4.5 | % |  |
| Dermal absorption value - pyriproxifen | 40 | % |  |
| Skin surface in contact with bed adult – child > 6 years old – child 2-6 years old – toddler - infant | 16600 – 9200  – 6800 - 4800  - 4100 | cm² | HEEG opinion 17 |
| Body weight adult – child > 6 years old – child 2-6 years old – toddler - infant | 60 - 23.9 –  15.6 – 10 - 8 | kg | HEEG opinion 17 |

**Table 2.2.6.2.6-8 Calculations for Scenario [5] adult, child, toddler and infant who sleep on a treated mattress**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from non-professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **1R-trans phenothrin** | | | | | |
| Adult | Tier 1 no PPE | - | 1.57 x 10-2 | - | 1.57 x 10-2 |
| Child > 6 years old | Tier 1 no PPE | - | 2.19 x 10-2 | - | 2.19 x 10-2 |
| Child 2-6 years old | Tier 1 no PPE | - | 2.47 x 10-2 | - | 2.47 x 10-2 |
| Toddler | Tier 1 no PPE |  | 2.73 x 10-2 | - | 2.73 x 10-2 |
| Infant | Tier 1 no PPE | - | 2.91 x 10-2 | - | 2.91 x 10-2 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Pyriproxyfen** | | | | | |
| Adult | Tier 1 no PPE | - | 6.65 x 10-3 | - | 6.65 x 10-3 |
| Child > 6 years old | Tier 1 no PPE | - | 9.25 x 10-3 | - | 9.25 x 10-3 |
| Child 2-6 years old | Tier 1 no PPE | - | 1.05 x 10-2 | - | 1.05 x 10-2 |
| Toddler | Tier 1 no PPE | - | 1.15 x 10-2 | - | 1.15 x 10-2 |
| Infant | Tier 1 no PPE | - | 1.23 x 10-2 | - | 1.23 x 10-2 |

*Combined scenarios*

Table 2.2.6.2.6-9: **combined systemic exposure from non-professional uses**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral (non respirable) uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **1R trans phenothrin** | | | | |
| Adults Scenarios [1,2,3,5]1 | 8.61 x 10-3 | 1.98 x 10-2 | 9.30 x 10-5 | 2.85 x 10-2 |
| Child > 6 years old Scenarios [2,3 5] | 1.29 x 10-3 | 2.22 x 10-2 | 0 | 2.34 x 10-2 |
| Child 2-6  years old Scenarios [2,4 5] | 2.21 x 10-3 | 3.21 x 10-2 | 0 | 3.43 x 10-2 |
| Toddler Scenarios [2,4,5] | 2.73 x 10-3 | 3.42 x 10-2 | 1.04 x 10-2 | 4.73 x 10-2 |
| Infant Scenarios [2,4,5] | 2.30 x 10-3 | 3.68 x 10-2 | 1.15 x 10-2 | 5.06 x 10-2 |
| **Pyriproxifen** | | | | |
| Adults Scenarios [1,2,3,5]1 | 8.38 x 10-4 | 8.38 x 10-3 | 2.60 x 10-6 | 9.22 x 10-3 |
| Child > 6 years old Scenarios [2,3 5] | 6.62 x 10-4 | 9.38 x 10-3 | 0 | 1.00 x 10-2 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral (non respirable) uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Child 2-6  years old Scenarios [2,4 5] | 1.14 x 10-3 | 1.36 x 10-2 | 0 | 1.47 x 10-2 |
| Toddler Scenarios [2,4,5] | 1.40 x 10-3 | 1.45 x 10-2 | 3.29 x 10-4 | 1.62 x 10-2 |
| Infant Scenarios [2,4,5] | 1.18 x 10-3 | 1.56 x 10-2 | 3.65 x 10-4 | 1.71 x 10-2 |

1 Please include the Tier where relevant

### Monitoring data

No user survey study and no data related to the exposure of the biocidal product are available.

### Dietary exposure

The product PARANIX ENVIRONNEMENT is intended for indoor spraying surface uses against lice and nits by non-professional on objects that could have been in contact with lice (bedding, comb, armchair, helmet...). No specific residue data were submitted in the context of this dossier.

As regards the intended use of the product PARANIX ENVIRONNEMENT, no direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statement is proposed:

“ Avoid any direct or indirect contact with food and feed.”

## Table 2.2.6.2.8-1: Residue definitions

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table of other (non-biocidal) uses** | | | |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1.  pyriproxyfen | Plant Protection Products use | Use against greenhouse and cotton whitefly on tomato (greenhouse), eggplant (greenhouse) and cotton | MRLs published in Regulation (EU) No 2016/1902  Residue definition for MRLs and risk assessment: pyriproxyfen (fat soluble) |
| Veterinary use | Antiparasitic use for cats and dogs. | No MRL. |
| 2. 1R-trans- phenotrin | None | None | None |

*1 e.g. plant protection products, veterinary use, food or feed additives*

*2 e.g. MRLs. Use footnotes for references.*

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

Since exposure during formulation of the product is not beyond the scope of the BPR, this point is not further addressed here.

### Aggregated exposure

***Summary of exposure assessment***

**For 1R-Trans phenothrin**

**Table 2.2.6.2.10-1: Scenarios and values to be used in risk assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment** | | | |
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| 1. spray application | Non-professionals | Tier 1/ No PPE | 6.30 x 10-2 |
| Tier 2/ No PPE but RMM | 1.16 x 10-2 |
| 2. exposure to volatile residues | Adult | Tier 1/ No PPE | 9.10 x 10-4 |
| Child > 6 years old | Tier 1/ No PPE | 1.71 x 10-3 |
| Child > 6 years old | Tier 1/ No PPE | 2.21 x 10-3 |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment** | | | | | | | | |
| **Scenario number** | | | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | | | **Estimated uptake (mg/kg bw/d)** | **total** |
|  | | | Toddler | Tier 1/ No PPE | | | 2.73 x 10-3 | |
| Infant | Tier 1/ No PPE | | | 2.30 x 10-3 | |
| 3. hand contact with treated surface | | | Adult | Tier 1/ No PPE | | | 2.35 x 10-4 | |
| Child > 6 years old | Tier 1/ No PPE | | | 3.08 x 10-4 | |
| 4. Child 2-6 years old, toddler and infant playing on treated surface | | | Child 2-6 years old | Tier 1/ No PPE | | | 7.32 x 10-3 | |
| Toddler | Tier 1/ No PPE | | | 1.73 x 10-2 | |
| Infant | Tier 1/ No PPE | | | 1.92 x 10-2 | |
| 5. sleeping treated mattress | | on | Adult | Tier 1/ No PPE | | | 1.57 x 10-2 | |
| Child > 6 years old | Tier 1/ No PPE | | | 2.19 x 10-2 | |
| Child 2-6 years old | Tier 1/ No PPE | | | 2.47 x 10-2 | |
| Toddler | Tier 1/ No PPE | | | 2.73 x 10-2 | |
| Infant | Tier 1/ No PPE | | | 2.91 x 10-2 | |
| **Combined exposure** | | | | | | | | |
| [1,2,3,5] primary and secondary exposure | | | Adult | Scenario 1 tier Tier 1 No PPE | 2 | others | 2.85 x 10-2 | |
| [2,3,5]  exposure | secondary | | Child > 6 years old | Tier 1/ No PPE | | | 2.34 x 10-2 | |
| [2,4,5]  exposure | secondary | | Child 2-6 years old | Tier 1/ No PPE | | | 3.43 x 10-2 | |
| [2,4,5]  exposure | secondary | | Toddler | Tier 1/ No PPE | | | 4.73 x 10-2 | |
| [2,4,5]  exposure | secondary | | Infant | Tier 1/ No PPE | | | 5.06 x 10-2 | |

**For Pyriproxyfen**

**Table 2.2.6.2.10-2: Scenarios and values to be used in risk assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment** | | | | |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non- professionals, bystanders)** | | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| 1. spray application | | Non-professionals | Tier 1/ No PPE | 4.43 x 10-3 |
| 1. spray application | | Non-professionals | Tier 2/ No PPE but RMM | 2.00 x 10-3 |
| 2. exposure to | | Adult | Tier 1/ No PPE | 4.68 x 10-4 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment** | | | | |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non- professionals, bystanders)** | | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| volatile residues | | Child > 6 years old | Tier 1/ No PPE | 6.62 x 10-4 |
| Child 2-6 years old | Tier 1/ No PPE | 1.14 x 10-3 |
| Toddler | Tier 1/ No PPE | 1.40 x 10-3 |
| Infant | Tier 1/ No PPE | 1.18 x 10-3 |
| 3. hand contact with treated surface | | Adult | Tier 1/ No PPE | 9.96 x 10-5 |
| Child > 6 years old | Tier 1/ No PPE | 1.30 x 10-4 |
| 4. Child 2-6 years old, toddler and infant playing on treated surface | | Child 2-6 yeras old | Tier 1/ No PPE | 3.10 x 10-3 |
| Toddler | Tier 1/ No PPE | 3.29 x 10-3 |
| Infant | Tier 1/ No PPE | 3.65 x 10-3 |
| 5. general public sleeping on treated mattress | | Adult | Tier 1/ No PPE | 6.65 x 10-3 |
| Child > 6 years old | Tier 1/ No PPE | 9.25 x 10-2 |
| Child 2-6 years old | Tier 1/ No PPE | 1.05 x 10-2 |
| Toddler | Tier 1/ No PPE | 1.15 x 10-2 |
| Infant | Tier 1/ No PPE | 1.23 x 10-2 |
| **Combined exposure** | | | | |
| [1,2,3,5] primary and secondary exposure | | Adult | Scenario 1 tier 2 others Tier 1 No PPE | 9.22 x 10-3 |
| [2,3,5] secondary exposure | | Child > 6 years old | Tier 1/ No PPE | 1.03 x 10-2 |
| [2,4,5] secondary exposure | | Child 2-6 years old | Tier 1/ No PPE | 1.47 x 10-2 |
| [2,4,5] secondary exposure | | Toddler | Tier 1/ No PPE | 1.62 x 10-2 |
| [2,4,5] secondary exposure | | Infant | Tier 1/ No PPE | 1.71 x 10-2 |

* + - 1. **Risk characterisation for human health**

**Table 2.2.6.3-1 Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value (mg/kg bw/d)** |
| **1R trans phenothrin** | | | | | |
| AELshort-term | Developmental rabbit study | 30 mg/kg bw/d | 100 | 60 | 0.18 |
| AELmedium- | 1-year dog study | 8 mg/kg bw/d | 100 | 60 | 0.05 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value (mg/kg bw/d)** |
| **1R trans phenothrin** | | | | | |
| term |  |  |  |  |  |
| AELlong-term |
| ARfD | Developmental rabbit study | 30 mg/kg bw/d | 100 | - | 0.3 |
| ADI | 1-year dog study | 8 mg/kg bw/d | 100 | - | 0.08 |
| **Pyriproxyfen** | | | | | |
| AELshort-term | 28-day rat study | 3 mg/kg bw/d | 100 | 40 | 0.12 |
| AELmedium- term | 1-year dog study | 1 mg/kg bw/d | 100 | 40 | 0.04 |
| AELlong-term |
| ARfD | Not allocated | | | | |
| ADI |

1 Please explain background and reason for assessment factor.

### Risk for industrial users

The product Paranix Environnement is intended to be used by non-professionals only. Therefore the risk characterisation assessment for industrial is not relevant.

### Risk for professional users

The product Paranix Environnement is intended to be used by non-professionals only. Therefore the risk characterisation assessment for professional users is not relevant.

### Risk for non-professional users

The product contains 2 different active substances; therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, Part B of 20159

The first step (Tier 1) of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL.

In a Tier 2, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).

**If HI ≤ 1** the risk related to use of the mixture will be considered acceptable;

**If HI > 1** the risk related to use of the mixture will be considered unacceptable and a refinement is needed.

## Systemic effects

9 Guidance on the Biocidal product Regulation, Volume III Human Health – Part B risk assessment, 2015.

**Table 2.2.6.3.3-1 :** *Tier 1 (acceptability of each a.s)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/ Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake mg/kg**  **bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable (yes/no)** |
| **Pyriproxifen** | | | | | |
| 1. | Tier 1/ No PPE | 0.04 | 4.43 x 10-3 | 11.1 | Yes |
| Tier 2/ No PPE but RMM | 0.04 | 2.00x 10-3 | 5.00 | Yes |
| **1R trans phenothrin** | | | | | |
| 1. | Tier 1/ No PPE | 0.05 | 6.3 x 10-2 | 126.0 | **No** |
| Tier 2/ No PPE but RMM | 0.05 | 1.16 x 10-2 | 23.28 | Yes |

**Table 2.2.6.3.3-**2 *Tier 2 (additivity)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Pyriproxifen** | **1R trans phenothrin** | **HI**  **(∑ HQ a.s)** | **Risk** |
| **HQ (Exposure/AEL)** | |
| **Scenario [1] (non-professional)** | | | |
| 0.05 | 0.23 | **0.28** | **Acceptable** |

## Local effects

No need to consider local effects separately.

## Conclusion

 The risk is not acceptable in tier 1 for non-professionals during the application of the product considering the active substance 1R trans phenothrin. PARANIX ENVIRONNEMENT is intended for non professional uses only, therefore no refinement of exposure considering PPE is possible

 In Tier 2 considering that the user leaves the room just after treatment and will not reenter during two hours, the risk is acceptable .

### Risk for the general public – secondary exposure

**Systemic effects**

*Tier 1 (acceptability of each a.s)*

## Table 2.2.6.3.4-1 :Tier 1 (acceptability of each a.s)

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | **bw/d** |  |  |
| **Pyriproxifen** | | | | | |
| 2 (Adult) | Tier 1/ No PPE | 0.04 | 4.68 x 10-4 | 1.17 | Yes |
| 2 (Child > 6 years old) | Tier 1/ No PPE | 0.04 | 8.81 x 10-4 | 2.20 | Yes |
| 2 (Child 2-6  years old) | Tier 1/ No PPE | 0.04 | 1.14 x 10-3 | 2.84 | Yes |
| 2 (Toddler) | Tier 1/ No PPE | 0.04 | 1.40 x 10-3 | 3.51 | Yes |
| 2 (Infant) | Tier 1/ No PPE | 0.04 | 1.18 x 10-3 | 2.96 | Yes |
| 3 (Adult) | Tier 1/ No PPE | 0.04 | 9.96 x 10-5 | 0.25 | Yes |
| 3 (Child > 6 years old) | Tier 1/ No PPE | 0.04 | 1.30 x 10-4 | 0.33 | Yes |
| 4 (Child 2-6 years old) | Tier 1/ No PPE | 0.04 | 3.10 x 10-3 | 7.75 | Yes |
| 4 (Toddler) | Tier 1/ No PPE | 0.04 | 3.29 x 10-3 | 8.2 | Yes |
| 4 (Infant) | Tier 1/ No PPE | 0.04 | 3.65 x 10-3 | 9.1 | Yes |
| 5 (Adult) | Tier 1/ No PPE | 0.04 | 6.65 x 10-3 | 16.6 | Yes |
| 5 (Child > 6 years old) | Tier 1/ No PPE | 0.04 | 9.25 x 10-2 | 23.1 | Yes |
| 5 (Child 2-6 years old) | Tier 1/ No PPE | 0.04 | 1.05 x 10-2 | 26.2 | Yes |
| 5 (Toddler) | Tier 1/ No PPE | 0.04 | 1.15 x 10-2 | 28.8 | Yes |
| 5 (Infant) | Tier 1/ No PPE | 0.04 | 1.23 x 10-2 | 30.8 | Yes |
| **1R trans phenothrin** | | | | | |
| 2 (Adult) | Tier 1/ No PPE | 0.05 | 9.10 x 10-4 | 1.82 | Yes |
| 2 (Child > 6 years old) | Tier 1/ No PPE | 0.05 | 1.71 x 10-3 | 3.43 | Yes |
| 2 (Child 2-6  years old) | Tier 1/ No PPE | 0.05 | 2.21 x 10-3 | 4.42 | Yes |
| 2 (Toddler) | Tier 1/ No PPE | 0.05 | 2.73 x 10-3 | 5.46 | Yes |
| 2 (Infant) | Tier 1/ No PPE | 0.05 | 2.30 x 10-3 | 4.61 | Yes |
| 3 (Adult) | Tier 1/ No PPE | 0.05 | 2.35 x 10-4 | 0.47 | Yes |
| 3 (Child > 6 years old) | Tier 1/ No PPE | 0.05 | 3.08 x 10-4 | 0.62 | Yes |
| 4 (Child 2-6  years old) | Tier 1/ No PPE | 0.05 | 7.32 x 10-3 | 14.7 | Yes |
| 4 (Toddler) | Tier 1/ No PPE | 0.05 | 1.73 x 10-2 | 34.7 | Yes |
| 4 (Infant) | Tier 1/ No PPE | 0.05 | 1.92 x 10-2 | 38.5 | Yes |
| 5 (Adult) | Tier 1/ No PPE | 0.05 | 1.57 x 10-2 | 31.4 | Yes |
| 5 (Child > 6 years old) | Tier 1/ No PPE | 0.05 | 2.19 x 10-2 | 43.7 | Yes |
| 5 (Child 2-6 years old) | Tier 1/ No PPE | 0.05 | 2.47 x 10-2 | 49.5 | Yes |
| 5 (Toddler) | Tier 1/ No PPE | 0.05 | 2.73 x 10-2 | 54.5 | Yes |
| 5 (Infant) | Tier 1/ No PPE | 0.05 | 2.91 x 10-2 | 58.2 | Yes |

 No unacceptable is identified for secondary exposure of each active substance.

**Table 2.2.6.3.4-2 :*Tier 2 (additivity)***

|  |  |  |  |
| --- | --- | --- | --- |
| **Pyriproxifen** | **1R trans phenothrin** | **HI**  **(∑ HQ a.s)** | **Risk** |
| **HQ (Exposure/AEL)** | |
| **Scenario [2] (Adult)** | | | |
| 0.01 | 0.02 | **0.03** | **Acceptable** |
| **Scenario [2] (Child > 6 years old)** | | | |
| 0.02 | 0.03 | **0.05** | **Acceptable** |
| **Scenario [2] (Child 2-6 years old)** | | | |
| 0.03 | 0.04 | **0.07** | **Acceptable** |
| **Scenario [2] (Toddler)** | | | |
| 0.04 | 0.05 | **0.09** | **Acceptable** |
| **Scenario [2] (Infant)** | | | |
| 0.03 | 0.05 | **0.08** | **Acceptable** |
| **Scenario [3] (Adult)** | | | |
| 0.002 | 0.005 | **0.007** | **Acceptable** |
| **Scenario [3] (Child > 6 years old)** | | | |
| 0.003 | 0.006 | **0.009** | **Acceptable** |
| **Scenario [4] (Child 2-6 years old)** | | | |
| 0.08 | 0.15 | **0.22** | **Acceptable** |
| **Scenario [4] (Toddler)** | | | |
| 0.08 | 0.35 | **0.43** | **Acceptable** |
| **Scenario [4] (Infant)** | | | |
| 0.09 | 0.38 | **0.48** | **Acceptable** |
| **Scenario [5] (Adult)** | | | |
| 0.17 | 0.31 | **0.48** | **Acceptable** |
| **Scenario [5] (Child > 6 years old)** | | | |
| 0.23 | 0.44 | **0.67** | **Acceptable** |
| **Scenario [5] (Child 2-6 years old)** | | | |
| 0.26 | 0.49 | **0.76** | **Acceptable** |
| **Scenario [5] (Toddler)** | | | |
| 0.29 | 0.55 | **0.83** | **Acceptable** |
| **Scenario [5] (Infant)** | | | |
| 0.31 | 0.58 | **0.89** | **Acceptable** |

The risk is acceptable for secondary exposure scenarios

## Combined scenarios

**Table 2.2.6.3.4-3 :** *Tier 1 (acceptability of each a.s)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake mg/kg**  **bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable (yes/no)** |
| **Pyriproxifen** | | | | | |
| Adults Scenarios  [1,2,3,5]1 | Scenario 1 tier  2 others Tier 1 No PPE | 0.04 | 9.23 x 10-3 | 23.0 | Yes |
| Child > 6 years old Scenarios  [2,3 5] | Tier 1/ No PPE | 0.04 | 1.00 x 10-2 | 25.1 | Yes |
| Child 2-6 years old Scenarios  [2,4,5] | Tier 1/ No PPE | 0.04 | 1.47 x 10-2 | 36.8 | Yes |
| Toddler  Scenarios [2,4,5] | Tier 1/ No PPE | 0.04 | 1.62 x 10-2 | 40.6 | Yes |
| Infant  Scenarios [2,4,5] | Tier 1/ No PPE | 0.04 | 1.71 x 10-2 | 42.9 | Yes |
| **1R trans phenothrin** | | | | | |
| Adults Scenarios  [1,2,3,5]1 | Scenario 1 tier  2 others Tier 1 No PPE | 0.05 | 2.85 x 10-2 | 57.0 | Yes |
| Child > 6 years old Scenarios  [2,3 5] | Tier 1/ No PPE | 0.05 | 2.34 x 10-2 | 46.9 | Yes |
| Child 2-6 years old Scenarios  [2,4,5] | Tier 1/ No PPE | 0.04 | 3.43 x 10-2 | 68.6 | Yes |
| Toddler  Scenarios [2,4,5] | Tier 1/ No PPE | 0.05 | 4.73 x 10-2 | 94.7 | Yes |
| Infant  Scenarios [2,4,5] | Tier 1/ No PPE | 0.05 | 5.06 x 10-2 | 101.3 | **No** |

 For Infant combined exposure [2,4,5], the risk is not acceptable considering 1R trans phenothrin. For other population risk for combined exposure is acceptable.

 For pyriproxifen, the risk is acceptable in tier 1 for all populations.

**Table 2.2.6.3.4-4 :*Tier 2 (additivity)***

|  |  |  |  |
| --- | --- | --- | --- |
| **Pyriproxifen** | **1R trans phenothrin** | **HI**  **(∑ HQ a.s)** | **Risk** |
| **HQ (Exposure/AEL)** | |
| **Scenario [1 tier 2, 2,3,5] (Adult)** | | | |
| 0.23 | 0.57 | **0.80** | **Acceptable** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario [2,3,5] (Child > 6 years old)** | | | |
| 0.25 | 0.47 | **0.72** | **Acceptable** |
| **Scenario [2,4,5] (Child 2- 6 years old)** | | | |
| 0.37 | 0.69 | **1.05** | **Unacceptable** |
| **Scenario [2,4,5] (Toddler)** | | | |
| 0.41 | 0.95 | **1.35** | **Unacceptable** |

## As unacceptable risk cannot be excluced in Tier 2 (additivity) for children between 2 and 6 years, and toddlers, the mixture risk assessement needs to be refined by the Tier 3 approach

*Tier 3B (specific for organs in common)*

A Tier 3B approach is considered since the 2 active substances have common target organs

* The AEL medium – long term of R-trans phenothrin (0.05 mg/kg/d) is based on liver effects observed at 26.8 mg/kg/d in a 52 weeks study on dogs.
* The AEL medium – long term of pyriproyfen is based on no effect observed at 10 mg/kg/d in a 52 weeks study on dogs.

However, the pyriproxyfen has effects on liver at 81 mg/kg/d in a 78 weeks study in mice (NOAEL 16 mg/kg/d). In this context an AEL for liver organ can be fixed at 0.064 mg/kg/d.

Using this refined AEL:

%AEL for toddler exposed to pyriproxifen is 25.4% instead of 40.6%;

%AEL for child 2-6 years old exposed to pyriproxifen is 23.0% instead of 36.8%.

## Table 2.2.6.3.4-5 :Tier 3B (specific for organs in common)

|  |  |  |  |
| --- | --- | --- | --- |
| **Pyriproxifen** | **1R trans phenothrin** | **HI**  **(∑ HQ a.s)** | **Risk** |
| **HQ (Exposure/AEL)** | |
| **Scenario [2,4,5] (Child 2-6 years old)** | | | |
| 0.23 | 0.69 | **0.92** | **Acceptable** |
| **Scenario [2,4,5] (Toddler)** | | | |
| 0.25 | 0.95 | **1.20** | **Unacceptable** |

Unacceptable risks are observed for liver for toddler exposeds. Therefore it is unnecessary to assess the risk for the others organs. The risk is considered unacceptable.

As the main exposure of toddlers comes from sleeping in a bed, a restriction “do not apply on mattress of children younger than 2 years old” is proposed.

With this restriction, IH in Tier 2 is 0.52 for toddler and 0.55 for infant.

## Local effects

No need to consider local effects separately.

### Risk for consumers via residues in food

Based on the intended use and the proposed risk mitigation measure, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

**Conclusion**

Regarding the primary exposure, the risk is acceptable if the risk mitigation mesures here below are applied:

⁻ leave the room just after treatment;

⁻ no entry in the room is allowed during 2 hours before the aerosol falls on the surface.

For the secondary exposure scenarios, the risk is acceptable in Tier 1 (substance by substance) and Tier 2 (additivity) of the mixture approach.

For the combined exposure scenarios, the risk is acceptable in tier 1 for adults and children older than 2 years old. For children younger than 2 years old, the risk is acceptable if the mattress is not treated.

Regarding consumer health protection, there are no objections against the intended uses.

## Risk assessment for animal health

No need to consider risk assessment for animal health due to the intended uses claimes by applicant.

## Risk assessment for the environment

Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes.**

Paranix Environnement is a biocidal product containing 0.3% w/w sumithrin (sum of all isomers) (*i.e.* 0.28% w/w 1R-trans phenothrin) and 0.015% w/w pyriproxyfen as active substances. The product is a ready-for-use insecticide aerosol applied by spray application at the dose of 26.7 g product/m² on objects that could have been in contact with lice (bedding, comb, armchair, helmet…). It is used by non-professionals, indoors.

**Infobox 1 - FR CA position:**

The risk assessment of the product PARANIX ENVIRONNEMENT is based on the

|  |  |  |  |
| --- | --- | --- | --- |
| information provided in the Assessment Report of 1,R-trans phenothrin PT18 (March 2013), on the Assessment Report of Pyriproxyfen PT18 (September 2012) and on a summary fact sheet of a PBT Working Group concerning the co-formulant named ‘hydrocarbons, C4, 1,3- butadiene-free, polymd., triisobutylene fraction, hydrogenated’ which is identified as a substance of concern.  The co-formulant ‘hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated’ is classified as Aquatic chronic 4, H413 and it is present at a high concentration (>99%) in the product PARANIX ENVIRONNEMENT. This co-formulant is not a POP or PBT substance, and it is not readily biodegradable. Nevertheless, it does not meet the B and T criteria as a borderline case, but the substance meets the screening P/vP criteria.  The applicant did not consider this co-formulant as a substance of concern. However and according to the appendix 1 of the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, the calculation of the relative toxic units of compounds shows that the toxicity of product is principally linked (more than 98%) to the toxicity of the hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated. | | | |
| **Summary of relative toxic units** | | | |
|  | 1,R-trans phenothrin | Pyriproxyfen | Hydrocarbons, C4, 1,3- butadiene-free |
| Content in the product [w/w %] | 0.315 | 0.015 | 99.67 |
| Aquatic compartment | | | |
| Fish | 1.04 | 0 | 98.95 |
| Invertebrates | 0.32 | 0 | 99.68 |
| Algae and cyanobacteria | 0.95 | 0 | 99.05 |
| Therefore, the co-formulant ‘hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated’ is considered as substance of concern based on its content in the product in comparison to the content in 1,R-trans phenothrin and pyriproxyfen and based on the aquatic ecotoxicity data from the summary fact sheet of a PBT Working Group available on the ECHA website. It is therefore taken into account in the mixture toxicity assessment of the product PARANIX ENVIRONNEMENT.  There are no indications for synergistic effects for the active substance and the coformulants in the literature.  Conclusion: the environmental risk assessment of the product Paranix Environnement is based on the active substances 1,R-trans phenothrin and pyriproxyfen, and also on the hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated. | | | |

## Effects assessment on the environment

**Infobox 2 - FR CA position:**

**PNEC derivation- Active substance**

PNEC values were proposed in the Assessment Report of 1,R-trans phenothrin PT18.

|  |  |
| --- | --- |
| **Summary table on PNEC for Pyriproxyfen** | |
| **Environmental compartment** | **PNEC value** |
| PNEC STP | 1.01E-01 mg.L-1 |
| Surface water | 3.00E-06 mg.L-1 |
| Freshwater sediment (EPM) | -1  1.40E-03 mg.kgwwt |
| Soil (EPM) | -1  1.10E-03 mg.kgwwt |
| Predator organisms (small | -1  6.7 mg.kgfood |
| Predator organisms (birds) | -1  19 mg.kgfood |

|  |  |
| --- | --- |
| **Summary table on PNEC for the SoC**  **(hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction,** | |
| **Environmental compartment** | **PNEC value** |
| Surface water | 1.28E-04 mg.L-1 |
| Freshwater sediment (EPM) | -1  8.45E-03 mg.kgwwt |
| Soil (EPM) | -1  8.83E-03 mg.kgwwt |

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| --- | --- | --- | --- |
|  | **Summary table on PNEC for 1R-trans phenothrin** | |  |
|  | **Environmental compartment** | **PNEC value** |
|  | PNEC STP | 10 mg.L-1 |
|  | Surface water | 4.70E-05 mg.L-1 |
|  | Freshwater sediment (EPM) | 0.129 mg.kgwwt-1 |
|  | Soil (EPM) | 0.0104 mg.kgwwt-1 \* |
|  | Predator organisms (small | -1  10 mg.kgfood |
|  | Predator organisms (birds) | -1  1.87 mg.kgfood |
| \* The additional factor of 10 needed for PNEC defined using the EPM method and LogKow is > 5 is included in this value  PNEC values were proposed in the Assessment Report of Pyriproxyfen PT18.  Endpoint values were proposed in summary fact sheet of SoC (hydrocarbons, C4, 1,3- butadiene-free, polymd., triisobutylene fraction, hydrogenated).  No ecotoxicological data are available to set a PNEC value for the Hydrocarbons, C4, 1,3- butadiene-free, polymd., triisobutylene fraction, hydrogenated for the STP compartment  and for secondary poisoning. | | | |

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### 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

Aquatic Acute 1

Aquatic Chronic 1

Value/conclusion

**Classification of the Product Paranix Environment**

**Infobox 3 - FR CA position:**

|  |  |
| --- | --- |
|  | |
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|  |  |

|  |  |
| --- | --- |
| **Classification of the Active Substance 1R-trans phenothrin** | |
| Value/conclusion | Very toxic to aquatic life  Very toxic to aquatic life with long-lasting effects |
| Justification for the value/conclusion | Very acutely toxic to fish, Daphnia and algae, with LC50/EC50‘s ≤ 1 mg/L in all cases. The lowest chronic ecotoxicity endpoint: invertebrates 72h NOEC 0.47 µg.L-1. |
| Classification of the product according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR:   * Aquatic Acute 1; H400; M = 100 * Aquatic Chronic 1, H410, M = 10 |

|  |  |
| --- | --- |
| **Classification of the Active Substance Pyriproxyfen** | |
| Value/conclusion | Very toxic to aquatic life  Very toxic to aquatic life with long-lasting effects |
| Justification for the value/conclusion | Very acutely toxic to fish, Daphnia and algae, with LC50/EC50‘s ≤  0.4 mg/L in all cases. The lowest chronic ecotoxicity endpoint: invertebrates 72h NOEC 1.5E-2 µg.L-1. |
| Classification of the product according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR:   * Aquatic Acute 1; H400; M = 1 * Aquatic Chronic 1, H410, M = 1000 |

There is no ecotoxicological data available for the product Paranix Environnement. The classification of the product is therefore based on data on the active substances and co- formulants.

Several aquatic ecotoxicological data are available on the 2 active substances (see Assessment Reports of 1R-trans phenothrin PT18, March 2013 and pyriproxyfen PT18, 21/09/2012). These data used for the environmental classification of the substances and the product are presented in the following table:

## Table 2.2.8.1.1-1: summary of aquatic ecotoxicological data on active substances

|  |  |
| --- | --- |
| **1R-trans phenothrin**  **CAS No.26046-85-5** | **Pyriproxyfen**  **CAS No. 95737-68-1** |
| Fish | |
| *Oncorhynchus mykiss*  LC50 96 h  0.0027mg a.s./L | *Lepomis macrochirus*  LC50 96 h  > 0.27 mg a.s./L   * *93 mg/L (PYPAC)*   *0.27 mg/L (4’-OH-pyriproxyfen)*  *5.1 mg/L (DPH pyr)* |
| *Oncorhynchus mykiss*  NOEC (ELS)  0.0011 mg a.s./L | *Oncorhynchus mykiss*  NOEC 95 d  0.0043 mg a.s./L |
| Aquatic invertebrates | |
| *Daphnia magna*  EC50 48 h  0.0043 mg a.s./L | *Daphnia magna*  EC50 48 h  0.40 mg a.s./L   * *95 mg/L (PYPAC)*   *1.8 mg/L (4’-OH-pyriproxyfen)*   * *9.8 mg/L (DPH pyr)* |
| *Daphnia magna*  NOEC 21 d  0.00047 mg a.s./L | *Daphnia magna*  NOEC 21 d  15 ng a.s./L |
| Sediment dwelling organisms | |
| - | *Chironomus riparius*  NOEC 28 d  2.2 µg a.s./L |
| Algae | |
| EbC50 *72* h  > 0.011 mg a.s./L | *Selenastrum capricornutum*  ErC50 72 h  0.15 mg a.s./L *Pseudokirchneriella subcapitata ErC50 72 h*  *30 mg/L (PYPAC)*   * *2.5 mg/L (4’-OH-pyriproxyfen)* * *9.5 mg/L (DPH pyr)* |
| NOErC *72* h  0.0036 mg a.s./L | *Selenastrum capricornutum*  NOErC *72* h  0.05 mg a.s./L *Pseudokirchneriella subcapitata NOErC 72 h*  *22 mg/L (PYPAC)*  *0.5 mg/L (4’-OH-pyriproxyfen)*  *2.0 mg/L (DPH pyr)* |
| Micro-organisms | |
| Activated sludge EC50 3 h   * 100 mg a.s./L | Activated sludge EC50 3 h   * 100 mg a.s./L |

The product Paranix Environnement is classified according to Regulation (EC) No.1272/2008 (CLP) based on data presented in Table 2.2.8.1.1-1 with the worst-case classification:

Signal Word: Danger

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

The classification of the product is presented in Section 12, Classification & labelling, of the IUCLID file.

According to the SDS (see Section 13 'Summary and evaluation of the substance dataset' and 'Summary and evaluation of the mixture dataset' in the IUCLID file), one component of the product Paranix Environnement other than the active substances is classified for the environment according to Regulation (EC) 1272/2008 (CLP) and has the following classification (see Confidential document "A3.6\_Confidential\_composition\_Paranix Environnement\_20160111" in Section 13 of the IUCLID file):

- "Component 3":

Aquatic Chronic 4, H413 with a content of 99.670% w/w in the product

This co-formulant is not expected to have significant impact on the ecotoxicological classification of the product as it is classified Aquatic Chronic 4, H413 and the product is already classified H400/H410 due to the presence of 1R-trans phenothrin, which is classified H400 with a factor M of 100 and H410 with a factor M of 100 and pyriproxyfen which is classified H400 with a factor M of 1 and H410 with a factor M of 1000.

Therefore, it is not suspected that the composition of the product Paranix Environnement would influence the ecotoxicological properties of the active substances in a way that may considerably alter the conclusions of the risk characterisation.

Taking into account all these considerations (*i.e*. worst case classification of the product based on active substances data and composition of the product not influencing the ecotoxicological properties of the active substances), the classification of the product Paranix Environnement is based on the active substances data, according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and no further aquatic ecotoxicity data on the product Paranix Environnement are deemed necessary.

### Further Ecotoxicological studies

**Infobox 4 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies. |
| Justification | The product Paranix Environnement is used indoors by non- professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …). According to the label, the treated objects can’t be cleaned with wet methods. It is thus not expected that the environment will be contaminated directly or indirectly. Therefore the risk of exposure of non-target organisms is very limited when using the product according to label recommendations.  Moreover, several aquatic and terrestrial ecotoxicity data are available on the active substances and are presented in Table 2.2.8.1.1-1 (see Section 2.2.8.1.1) and Table 2.2.8.1.2-1 below.  In addition, it is not suspected that the composition of the product Paranix Environnement would influence the ecotoxicological properties of the active substances in a way that may considerably alter the conclusions of the risk characterisation.  Thus no additional aquatic and terrestrial ecotoxicological study with the product Paranix Environnement was conducted to address this point. |

The terrestrial ecotoxicological data on the active substances are presented in the following table:

## Table 2.2.8.1.2-1: summary of terrestrial ecotoxicological data on active substances

|  |  |
| --- | --- |
| **1R-trans phenothrin**  CAS No.26046-85-5 | **Pyriproxyfen**  CAS No. 95737-68-1 |
| **Earthworm** |  |
| Acute:  Not tested as this compound is for indoor use only | Acute: *Eisenia fetida* LC50 14 d   * 1 000 mg a.s./kg |
| Reproduction: Not required | Reproduction: No data available |
| **Plant** |  |
| - | Barnyardgrass (*Echinochloa crus-galli*), oats *(Avena sativa*), velvetleaf (*Abutilon theophrasti*), radish (*Raphanus sativus*)  EC50 19 d   * 8000 g a.s./ha |

|  |  |  |
| --- | --- | --- |
| **1R-trans phenothrin**  CAS No.26046-85-5 | **Pyriproxyfen**  CAS No. 95737-68-1 | |
| **Soil micro-organisms** | | |
| Not tested as this compound is for indoor use only | Nitrate transformation rate and respiration | |
| rate: | |
| NOEC 28 d in loamy sand soil   * 1.5 mg a.s./kg d.w. | |
| **Mammals** | | |
| Rat  LD50 oral   * 5 000 mg a.s./kg b.w. | Rat  LD50 oral   * 5 000 mg a.s./kg b.w. | |
| Dog  NOAEL (52 weeks)  8.2 mg a.s./kg b.w./d. (eq. to 300 mg/kg food) | Reproduction: | |
| No data |  |
| **Birds** | | |
| - | *Colinus virginianus / Anas platyrhynchos*  LD50   * 1906 mg a.s./kg b.w. | |
| *Colinus virginianus*  LC50 5 d  1.87 mg a.s./kg food eq. to 5620 ppm | *Colinus virginianus / Anas platyrhynchos*  LC50   * 4956 mg a.s./kg diet | |
| Reproduction:  Not tested as this compound is for indoor use only | *Colinus virginianus / Anas platyrhynchos*  NOEC   * 572 mg a.s./kg diet | |
| **Bees** | | |
| *Apis mellifera*  LD50 contact  0.005 µg a.s./bee | *Apis mellifera*  LD50 oral and contact   * 100 µg a.s./bee | |
| **Other beneficial arthropods** | | |
| Not tested as this compound is for indoor use only. | *Aphidius rhopalosiphi*  LR50  213 g a.s./ha *Typhlodromus pyri* LR50  20 g a.s./ha | |

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

**Infobox 5 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |

|  |  |
| --- | --- |
| Justification | The product is applied indoor by spray application by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …). According to the label, the treated objects can’t be cleaned with wet methods.  The product is only used indoors and is not intended to be applied in the environment. It is thus not expected that the environment will be contaminated directly or indirectly. Therefore the risk of exposure of non- target organisms is very limited when using the product according to label recommendations. Moreover, several ecotoxicity data are available on the active substances and are presented in the sections above. In addition, it is not suspected that the composition of the product Paranix Environnement would influence the ecotoxicological properties of the active substances in a way that may considerably alter the conclusions of the risk characterisation.  Thus no additional terrestrial ecotoxicological study with this product Paranix Environnement was conducted to address this point. |

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

**Infobox 6 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product Paranix Environnement is an aerosol ready- for-use insecticide. It is not in the form of bait or granules.  Therefore no additional study is deemed necessary to address this point. |

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

**Infobox 7 - FR CA position:**

No data is available.

No data is on the product Paranix Environnement available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |

|  |  |
| --- | --- |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product Paranix Environnement is an aerosol ready-for- use insecticide. It is not in the form of bait or granules.  Therefore no additional study is deemed necessary to address this point. |

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

**Infobox 8 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated |
| Justification | The product Paranix Environnement is an aerosol ready-for-use insecticide. The product is applied indoor by spray application by non- professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …).  The product is for indoor uses only and is therefore not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type is treated with the product Paranix Environnement and it can be concluded that no secondary ecological effect is expected when using the product according to label recommendations. |

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

**Infobox 9- FR CA position:**

No data is available.

The foreseeable routes of entry in the environment are determined on the basis of the uses envisaged and the behaviour of the product is extrapolated from the information on the active substances.

Paranix Environnement is a biocidal product containing 0.3% w/w sumithrin (sum of all isomers) (*i.e.* 0.28% w/w 1R-trans phenothrin) and 0.015% w/w pyriproxyfen as active substances. The product is used indoors by spray applications by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …). According to the label, the treated objects can’t be cleaned with wet methods.

Based on the intended uses of the product no direct or indirect contamination of the STP, the surface water (including sediment) and the soil (including groundwater) is foreseen and the

expected concentrations of 1R-trans phenothrin and pyriproxyfen in these compartments from the uses of the product are expected to be negligible.

Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to

3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.

Therefore the risk of contamination of air can be considered as negligible and this foreseeable route of entry in the environment is not of concern.

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

**Infobox 10 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies on fate and behaviour in the environment |
| Justification | As explained in Section 2.2.8.1.7 above, the soil including groundwater and the surface water including sediment are not expected to be contaminated by the product Paranix Environnement because the product is for an indoor use only and is intended to be applied on objects which are not subject to washing once treated as stated in the label. Since the product is an aerosol, the air compartment can be expected to be contaminated. However, based on the indoor application, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, 1R- trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to 3.63 hours and 0.307 day, for 1R-trans phenothrin and pyriproxyfen respectively, indicate a rapid degradation. Therefore the risk of contamination of air can be considered as negligible and this foreseeable route of entry is not of concern.  According to the SDS (see Section 13 of the co-formulants datasets) one of the components other than active substances is considered as substance of concern in the product Paranix Environnement considering the definition set in Regulation (EU) No 528/2012. But this co-formulant is not expected to have significant impact on the ecotoxicological classification of the product as it is classified Aquatic Chronic 4, H413 and the product is already classified H400/H410 due to the presence of 1R-trans phenothrin, which is classified H400  with a factor M of 100 and H410 with a factor M of 100 and pyriproxyfen which is classified H400 with a factor M of 1 and H410 |

with a factor M of 1000. Moreover it is a volatile gas with a vapour pressure of 100 Pa at 20°C, it can be assumed that following application the co-formulant is evaporated and only the active substances remain.

It is therefore not suspected that the composition of the product will influence the fate and behaviour of the active substances in the environment in a way that may considerably alter the conclusions of the risk characterisation

Moreover, several environmental data are available on 1R-trans phenothrin and pyriproxyfen (see Assessment Reports, 1R-trans phenothrin PT18, March 2013 and pyriproxyfen PT18, 21/09/2012). These data are summarised in the table 2.2.8.1.8-1 below.

Therefore, it can be concluded that there is no need to conduct additional environmental studies with the product Paranix Environnement.

## Table 2.2.8.1.8-1: Fate and behaviour data on active substances

|  |  |  |
| --- | --- | --- |
| **Active substance** | **1R-trans phenothrin** | **Pyriproxyfen** |
| Molecular Mass (g/mol) | 350.46 | 321.37 |
| Log Pow | 6.8 (pH 7) | 4.86 (25°C, pH 7) |
| Boiling point (°C) | * 301 | 318 |
| Melting point (°C) | - 41.4 | 48.0 - 50.0 |
| Vapour pressure (Pa) | 2.37\*10-5 Pa at 20°C  4.17\*10-5 Pa at 25°C | <1.33 \* 10-5 Pa at 22.81°C |
| Water Solubility (mg/L) | 2.0\*10-3 (21°C) | 0.101 (20°C, pH 7) |
| Henry's Law Constant (Pa.m3/mol) | 4.2 (20°C) | < 4.23 \* 10-2 at 20-23°C |
| Koc (L/kg) | 125 892.5 | 21 175 |
| DT50 air | 3.63 hours | DT50 of 0.26 d  (derived by the Atkinson method of calculation)  DT50 of 0.307 d  (derived by the TGD method of calculation (0.5\*106 OH/cm3;  24-h day time)) |
| DT50 water/ sediment | **In whole system**:  19.15 d at 12°C | **In water:**  2.8 d at 12°C  **In sediment:**  64.5 d at 12°C  **In whole system:**  12.3 d at 12°C |
| DT50 soil | 27.2 days at 12°C | 14.8 days at 12°C |

### Leaching behaviour (ADS)

**Infobox 11 - FR CA position:**

No data is available.

The product Paranix Environnement is used indoors by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …).

The product Paranix Environnement is not intended to be used for the treatment of surfaces exposed to weathering as the product is for indoor use only. Thus no leaching is expected when using the product according to label instructions.

Based on this assessment a leaching study is not required for the product Paranix Environnement.

### Testing for distribution and dissipation in soil (ADS)

**Infobox 12- FR CA position**: No data is available.

As explained in sections above, the soil (including groundwater) is not expected to be

contaminated by the product Paranix Environnement because the product is for an indoor use only and is intended to be applied on objects which are not subject to washing once treated as stated in the label.Data on distribution and dissipation in soil are however presented below.

Environmental data, including distribution and degradation data, are available on 1R-trans phenothrin, pyriproxyfen and their relevant metabolites. These data are issued from the Assessment Reports of the active substances (see 1R-trans phenothrin PT18, March 2013 and pyriproxyfen PT18, 21/09/2012) and are summarised in the Table 2.2.8.1.8-1 above.

A fugacity model is used to estimate distribution in soil, water and air of the 2 active substances. The model is Level III fugacity model (in EPISuite v4.11). The data on active substances used for the simulation are presented in the Table 2.2.8.1.8-1.

The results for the soil compartment are presented below:

|  |  |  |
| --- | --- | --- |
| **Active substance** | **1R-trans phenothrin** | **Pyriproxyfen** |
| Soil | 53.5% | 51.3% |

There is no need to conduct additional studies on distribution and dissipation in soil with the product Paranix Environnement.

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

**Infobox 13 - FR CA position:**

No data is available.

As explained in sections above, water (including sediment) is not expected to be contaminated by the product Paranix Environnement because the product is for an indoor use only and is intended to be applied on objects which are not subject to washing once treated as stated in the label. Data on distribution and dissipation in water are however presented below.

Environmental data, including distribution and degradation data, are available on 1R-trans phenothrin, pyriproxyfen and their relevant metabolites. These data are issued from the Assessment Reports of the active substances (see 1R-trans phenothrin PT18, March 2013 and pyriproxyfen PT18, 21/09/2012) and are summarised in the Table 2.2.8.1.8-1 above.

A fugacity model is used to estimate distribution in soil, water and air of the 2 active substances. The model is Level III fugacity model (in EPISuite v4.11). The data on active substances used for the simulation are presented in the Table 2.2.8.1.8-1.

The results for the water and sediment compartments are presented below:

|  |  |  |
| --- | --- | --- |
| **Active substance** | **1R-trans phenothrin** | **Pyriproxyfen** |
| Water | 8.08% | 5.32% |
| Sediment | 38.4% | 43.3% |

There is no need to conduct additional studies on distribution and dissipation in water with the product Paranix Environnement.

### Testing for distribution and dissipation in air (ADS)

**Infobox 14 - FR CA position:**

No data is available.

Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to

3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.

A fugacity model is used to estimate distribution in soil, water and air of the 2 active substances. The model is Level III fugacity model (in EPISuite v4.11). The data on active substances used for the simulation are presented in the Table 2.2.8.1.8-1 above.

The results for the air compartment are presented below:

|  |  |  |
| --- | --- | --- |
| **Active substance** | **1R-trans**  **phenothrin** | **Pyriproxyfen** |
| Air | 0.0158% | 0.0616% |

There is no need to conduct additional studies on distribution and dissipation in air with the product Paranix Environnement.

### 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)

**Infobox 15 - FR CA position:**

No data is available.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product Paranix Environnement is used indoors by spray application by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …).  The product is not intended to be sprayed in or near surface water. Therefore no overspray is foreseen and the contamination of the surface water, including sediment is considered as negligible.  Therefore, based on this assessment an overspray study is not required for the product Paranix Environnement. |

### 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)

**Infobox 16 - FR CA position:**

Not relevant.

No data on the product Paranix Environnement is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Data on overspray behaviour to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product Paranix Environnement is used indoors by spray application by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …).  The product is not intended to be sprayed into the environment and it has no potential for large scale formation of dust. Therefore there is no risk of exposure of honeybees and non-target arthropods as the product is only intended to be applied indoors.  Based on this assessment, no additional study with the product was conducted to address this point. |

## Exposure assessment

Paranix Environnement is a biocidal product containing 0.3% w/w sumithrin (sum of all isomers) (*i.e.* 0.28% w/w 1R-trans phenothrin) and 0.015% w/w pyriproxyfen as active substances.

The product Paranix Environnement is used indoors by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …) According to the label, the treated objects can’t be cleaned with wet methods. . The product is applied by spray application at the dose of 26.7 g product/m².

Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to

3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.

As the product is for indoor use only and directed onto objects that can’t be cleaned by wet methods once treated according to the label, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected.

Therefore, no exposure assessment is deemed necessary for the product Paranix Environnement.

|  |  |  |  |
| --- | --- | --- | --- |
| **Infobox 7 - FR CA position: General information** | | | |
|  | Assessed PT | PT 18 |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Assessed scenarios | PARANIX ENVIRONNEMENT - ready-for-use insecticide aerosol applied by spray by non-professionals for the curative treatment of objects that could have been in contact with lice and nits. According to the SPC and information during exchanges with the applicant, these include bedding, mattress, combs, armchairs, carpets, helmets, head supports, child car seats, … – These  objects cannot be cleaned by wet methods. |  |
| ESD(s) used | Emission scenario document for insecticides, acaricides and products to control arthropods for household and professional use (ESD for PT18, OECD, 17/07/2008) |
| Approach | Average consumption |
| Distribution in the  environment | Calculated based on ECHA Guidance on the BPR Vol IV  Part B ; April 2015 |
| Groundwater simulation | A higher tier model (FOCUS model) wasn’t performed |
| Confidential Annexes | No |
| Life cycle steps assessed | * Application step   During the indoor application on surfaces, the product PARANIX ENVIRONNEMENT reaches directly the targeted surfaces (bedding, mattress, combs, armchairs, carpets, helmets, head supports, child car seats, …) and also the adjacent floor by spray drift, the applicator clothes and the indoor air. A scenario for a barrier treatment is applied.   * Cleaning step   Cleaning events result only in emission to wastewater in considering that the floor and clothes of the applicator are washable. As proposed by the applicant, treated surfaces are not washed. Nevertheless adjacent floor can be wet cleaned. |
| Remarks |  |
|  | | | |

### Fate and distribution in exposed environmental compartments

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
|  | Fresh- water | Freshwater sediment | Sea- water | Seawater sediment | ST P | Air | Soil | Ground- water | Other |
| Indoor use | No | No | No | No | No | No | No | No | No |

Infobox 8 - FR CA position:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure**  **pathway** | | | | | | |
|  | Freshwat er | Freshwate r sediment | STP | Air | Soil | Groundwater |
| PARANIX | yes | yes | yes | no | yes | yes |

**Active substance: 1,R-trans phenothrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters used in the environmental exposure assessments according to the CAR (March, 2013)** | | | | | |
| Input | Value | | | Unit | |
| **1,R-trans phenothrin** |  | | |  |  |
| CAS number | 26046-85-5 | | | - | |
| Molecular weight |  | 350.46 | |  | g.mol-1 |
| Vapour pressure (at 20°C) |  | 2.37E-05 | |  | Pa |
| Water solubility (at 21°C) |  | 2.00E-03 |  |  | mg.L-1 |
| Partition coefficient (log POW) (pH 7) |  | 6.8 | |  | Log 10 |
| Biodegradability |  | Not Ready biodegradable | |  |  |
| Degradation in water/sediment (DT50) (at 12°C) |  | 19.15  143.6 (PBacid) | | days | |
| Degradation in soil (DT50) (at 12°C) |  | 27.2 | |  | days |
| Adsorption / desorption Koc |  | 125 892.5 | |  | L.kg-1 |
| Henry’s Law Constant (at 20°C) | 4.2 | | |  | Pa.m-  3.mol-1 |
| Photo-oxidative degradation in air (DT50) |  | 3.6 | |  | h |
| BCF fish |  | 1 878 | |  | L.kg-1 |
| BMF fish |  | 10 | |  | - |
| BCF earthworms |  | 75 716 | |  | L.kg-1 |
| **Metabolites** | | | | | |
| **Pbacid** | | | | | |
| Molecular weight |  | 214.22 | |  | g.mol-1 |
| Max. % occurrence water |  | 18.6 | |  | % |
| Max. % occurrence soil |  | - | |  | % |
| Koc |  | - | |  | L.kg-1 |
| **HO-trans-PHN** | | | | | |
| Molecular weight |  | 366.46 | |  | g.mol-1 |
| Max. % occurrence water |  | 21.1 | |  | % |
| Max. % occurrence soil |  | - | |  | % |
| Koc |  | - | |  | L.kg-1 |
| **Pbalc** | | | | | |
| Molecular weight |  | 200.24 | |  | g.mol-1 |
| Max. % occurrence water |  | 20 | |  | % |
| Max. % occurrence soil |  | 12.9 | |  | % |
| Koc |  | - | |  | L.kg-1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters used in the environmental exposure assessments according to the CAR (September, 2012)** | | | | | |
| Input | Value | | | Unit | |
| CAS number | 95737-68-1 | | | - | |
| Molecular weight |  | 321.37 | |  | g.mol-1 |
| Vapour pressure (at 23°C) |  | 1.33E-05 | |  | Pa |
| Water solubility (at 20°C) |  | 1.01E-01 |  |  | mg.L-1 |
| Partition coefficient (log POW) (pH 7) |  | 4.86 | |  | Log 10 |
| Biodegradability |  | Not Ready biodegradable | |  | - |
| Degradation in water/sediment (DT50) (at 12°C) | 12.5 | | | days | |
| Degradation in soil (DT50) (at 12°C) |  | 14.8 | |  | days |
| Adsorption / desorption Koc |  | 21175 | |  | L.kg-1 |
| Henry’s Law Constant (at 20°C) | 4.23E-02 | | |  | Pa.m-  3.mol-1 |
| Photo-oxidative degradation in air (DT50) |  | - | |  | h |
| BCF fish |  | 1 495 | |  | L.kg-1 |
| BMF fish |  | 1 | |  | - |
| BCF earthworms |  | 870 | |  | L.kg-1 |
| **Metabolites** | | | | | |
| **4’-OH-Pyr** | | | | | |
| Molecular weight |  | 337.4 | |  | g.mol-1 |
| Max. % occurrence water |  | 15 | |  | % |
| Max. % occurrence soil |  | 6.3 | |  | % |
| Degradation in soil (DT50) (at 12°C) |  | 65.4 | |  | days |
| Koc |  | 2.6E03 | |  | L.kg-1 |
| **PYPAC** | | | | | |
| Molecular weight |  | 167.2 | |  | g.mol-1 |
| Max. % occurrence water |  | 24 | |  | % |
| Max. % occurrence soil |  | 8.6 | |  | % |
| Degradation in soil (DT50) (at 12°C) |  | 12.9 | |  | days |
| Koc |  | 2.1E01 | |  | L.kg-1 |
| **DPH-Pyr** | | | | | |
| Molecular weight |  | 245.3 | |  | g.mol-1 |
| Max. % occurrence water |  | 12 | |  | % |
| Max. % occurrence soil |  | - | |  | % |
| Degradation in soil (DT50) (at 12°C) |  | - | |  | days |
| Koc |  | 9.62E03 | |  | L.kg-1 |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Calculated fate and distribution of 1,R-trans phenothrin in the STP (EUSES**  **model 2.1)** | |  |
| Compartment | Percentage [%] |  |
|  |  |
| Air | 0.271 |  |
| Water | 12.9 |  |
| Sludge | 86.8 |  |
| Degraded in STP | 0 |  |
| **Active substance: Pyriproxyfen** | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters used in the environmental exposure assessments according to the ECB-Summary fact sheet (March, 2008) and EPI suite model.** | | | | | |
| Input | Value | | | Unit | |
| CAS number | 93685-81-5 | | | - | |
| Molecular weight |  | 170.33 | |  | g.mol-1 |
| Vapour pressure (at 20°C) |  | 100 | |  | Pa |
| Water solubility (at 21°C) |  | 5.30E-02 |  |  | mg.L-1 |
| Partition coefficient (log POW) (pH 7) |  | 5.94 | |  | Log 10 |
| Biodegradability |  | Not Ready biodegradable | |  |  |
| Degradation in water/sediment (DT50) (at 12°C) | - | | | days | |
| Degradation in soil (DT50) (at 12°C) |  | 1.00E+06 | |  | days |
| Adsorption / desorption Koc |  | 3000 | |  | L.kg-1 |
| Henry’s Law Constant (at 20°C) | 3.21E+05 | | |  | Pa.m-  3.mol-1 |
| Photo-oxidative degradation in air (DT50) |  | - | |  | h |
| BCF fish |  | - | |  | L.kg-1 |
| BCF earthworms |  | - | |  | L.kg-1 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | |  |
| **Calculated fate and distribution of Pyriproxyfen in the STP (EUSES model 2.1)** | |
|  | |
| Compartment | Percentage [%] |  |
|  |  |
| Air | 0.0516 |  |
| Water | 31.5 |  |
| Sludge | 68.4 |  |
| Degraded in STP | 0 |  |
| **Substance of concern: hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated** | | | |
|  |  | |  |
| **Calculated fate and distribution in the STP (EUSES model 2.1)** | |
|  | |
| Compartment | Percentage [%] |  |
|  |  |
| Air | 76.2 |  |
| Water | 4.28 |  |
| Sludge | 19.5 |  |
| Degraded in STP | 0 |  |

### Emission estimation

As explained above, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected.

Regarding the air compartment, based on the indoor application of the product and based on the physical chemical properties of the active substances, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Infobox 9 - FR CA position:  To cover the use of the product on non-wet washable objects and furnishings (bedding, mattress, combs, armchairs, carpets, helmets, head supports, child car seats...) to treat lice and nits infestations, the barrier scenario has been applied as proposed by UK (and adopted in WG-I-2017 for a substance with identical intended uses). The treatment is intended to take place on objects and furnishings which are not expected to be subject to regular wet cleaning. So an area of 5.9 m2 of floor where spray drift can be deposited and subsequently wet cleaned in a domestic home (barrier) and a default cleaning efficiency of 20 % for a surface application (taken from the ESD) have been adopted.  In absence of information on the reapplication of the product, except the label indication ‘In case of re-infestation, renew the application’, a best case of 1-2 applications per year has been applied (Fsimultaneity of 0.204%). As the product is intended for non-professional applications, only houses have been taken into account. | | | | | | |
|  | **Input parameters for calculating the local emission** | | | | |  |
| **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** |
| **Ready-for-use product used by non-professionals for the curative treatment of non-wet washable objects and furnishings against lice and nits infestations** | | | | |
| **INPUTS** | | | | |
| Fraction of active substance (1-R trans phenothrin) in the  product (tech) | FAI | 0.315 | [%  w/w] | 1-R transphenothrin (sum of all isomers) |
| Fraction of active substance (Pyriproxyfen) in the  product (tech) | FAI | 0.015 | [%  w/w] | Pyriproxyfen (sum of all isomers) |
| Fraction of substance of concern in the product | FAI | 99.67 | [%  w/w] | hydrocarbons, C4, 1,3- butadiene-free, polymd.,  triisobutylene fraction,  hydrogenated (sum of all isomers) |
| Surface or air space treatment | Surface treatment (area) | | | - |
| Application scope | Targeted spot application | | | - |
| Quantity of product applied | Q prod | 26.7 | [g.m- 2] | - |
| Area treated per house | AREA  treated | 20 | [m2] | Default value for barrier treatment – Technical Agreements for Biocides  (2016) |
| Area wet cleaned per house | AREA wet cleaned | 5.9 | [m2] | WG I 2017, reflect the area wet cleaned in a domestic  home (barrier) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Number applications per house | per | of day | N appl | | 1 | | [d-1] | Intended to be used once to two times per year | | | |  |
| Fraction emitted to air during application  step | | | F air | | 0.02 | | [-] | Default value - ESDP PT18 | | | |
| Fraction emitted to applicator during application step | | | F  applicator | | 0.004 | | [-] | Table 3.3-1 - ESDP PT18  (self-pressurised aerosol  dispenser for surface treatment) | | | |
| Fraction emitted to floor during  application step | | | F floor | | 0.126 | | [-] | Table 3.3-3 - ESDP PT18  (self-pressurised aerosol dispenser for surface  treatment) | | | |
| Fraction emitted to treated area during  application step | | | F treated | | 0.85 | | [-] | (1 – (0.02 + 0.004 + 0.126)) | | | |
| Fraction emitted to  wastewater during cleaning | | | F ww | | 1 | | [-] | - | | | |
| Cleaning efficiency of  the applicator’s clothes | | | FCE appl | | 1 | | [-] | ESDP PT18 | | | |
| Cleaning efficiency of the floor | | | FCE floor | | 0.2 | | [-] | Table 3.3-8 - ESDP PT18  (RTU Aerosols – surface) | | | |
| Number of private houses connected to a STP | | | N HOUSE | | 4 000 | | [-] | Default value  Agreements (2016) | | –  for | Technical Biocides |
| Simultaneity factor | | | F  simultanei ty | | 0.204 | | [%] | Paranix Environnement may be applied by spraying on surfaces once to two times  per year. | | | |
|  | | | | | | | | | | | | | |
|  | **OUTPUTS FOR THE ACTIVE SUBSTANCE: 1-R TRANS PHENOTHRIN** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| ***Emission during the application*** | | | | | | | | | | | | |
| Emission to the applicator | | | E applicator | | | 6.73E-06 | | | [kg.d-1] | | | |
| E 𝐚𝐩𝐩𝐥𝐢𝐜𝐚𝐭𝐨𝐫 = 𝐍 𝐚𝐩𝐩𝐥 × 𝐅 𝐚𝐩𝐩𝐥𝐢𝐜𝐚𝐭𝐨𝐫 × 𝐐 𝐩𝐫𝐨𝐝 × 𝐅𝐀𝐈 × 𝐀𝐑𝐄𝐀 𝐭𝐫𝐞𝐚𝐭𝐞𝐝 | | | | | | | | | | | | |
| Emission to the floor | | | E floor | | | 6.25E-05 | | | [kg.d-1] | | | |
| E floor = N appl × F floor × Q prod × FAI × AREA wet cleaned | | | | | | | | | | | | |
| Emission to treated surface | | | E treated | | | 4.22E-04 | | | [kg.d-1] | | | |
| E treated = N appl × F treated × Q prod × FAI × AREA wet cleaned | | | | | | | | | | | | |
| ***Emission during the cleaning step for one house*** | | | | | | | | | | | | |
| ***Emission from treated area/floor to*** | | | E  ww | treated/floor, |  | 9.69E-05 | | | [kg.d-1] | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | ***wastewater for one house*** | | | | |  | |  |  |
| E 𝑡𝑟𝑒𝑎𝑡𝑒𝑑/𝑓𝑙𝑜𝑜𝑟 , ww = (E floor + E treated) × F ww × F CE floor | | | | | | | | |
| ***Emission from***  ***applicator to***  ***wastewater for one house*** | | | | | E  ww | applicator, | 6.73E-06 | [kg.d-1] |
| E applicator, w𝒘 = 𝑬 𝒂𝒑𝒑𝒍𝒊𝒄𝒂𝒕𝒐𝒓 × 𝑭 𝒘𝒘 × 𝑭 𝑪𝑬 𝒂𝒑𝒑𝒍 | | | | | | | | |
| ***Total emission to the wastewater*** | | | | | E total,ww | | 1.04E-04 | [kg.d-1] |
| E total, ww = E treated/floor, ww + E applicator, ww | | | | | | | | |
| ***Total Emission to the wastewater for one STP*** | | | | | | | | |
| ***Total emission to the STP*** | | | | | E local water | | 8.46E-04 | [kg.d-1] |
| E local water = E total, 𝒘𝒘 × 𝑵 𝑯𝑶𝑼𝑺𝑬 × 𝑭 𝒔𝒊𝒎𝒖𝒍𝒕𝒂𝒏𝒆𝒊𝒕𝒚 | | | | | | | | |
|  | | | | | | | | | |
|  | **OUTPUTS FOR THE ACTIVE SUBSTANCE: PYRIPROXYFEN** | | | | | | | | |
|  | | | | | | | | |
| ***Emission during the application*** | | | | | | | | |
|  | Emission applicator |  | to | the | E applicator | | 3.20E-07 | [kg.d-1] |
| E applicator = N appl × F applicator × Q prod × FAI × AREA treated | | | | | | | | |
| Emission to the floor | | | | | E floor | | 2.98E-06 | [kg.d-1] |
| 𝑬 𝒇𝒍𝒐𝒐𝒓 = 𝑵 𝒂𝒑𝒑𝒍 × 𝑭 𝒇𝒍𝒐𝒐𝒓 × 𝑸 𝒑𝒓𝒐𝒅 × 𝑭𝑨𝑰 × 𝑨𝑹𝑬𝑨 𝒘𝒆𝒕 𝒄𝒍𝒆𝒂𝒏𝒆𝒅 | | | | | | | | |
|  | Emission surface | to |  | treated | E treated | | 2.01E-05 | [kg.d-1] |
| E 𝒕𝒓𝒆𝒂𝒕𝒆𝒅 = 𝑵 𝒂𝒑𝒑𝒍 × 𝑭 𝒕𝒓𝒆𝒂𝒕𝒆𝒅 × 𝑸 𝒑𝒓𝒐𝒅 × 𝑭𝑨𝑰 × 𝑨𝑹𝑬𝑨 𝒘𝒆𝒕 𝒄𝒍𝒆𝒂𝒏𝒆𝒅 | | | | | | | | |
| ***Emission during the cleaning step for one house*** | | | | | | | | |
| ***Emission from treated area/floor to wastewater for one***  ***house*** | | | | | E  ww | treated/floor, | 4.61E-06 | [kg.d-1] |
|  | E treated , ww = (E floor + E treated) × 𝑭 𝒘𝒘 × 𝑭 𝑪𝑬 𝒇𝒍𝒐𝒐𝒓  floor | | | | | | | | |
| ***Emission from***  ***applicator to***  ***wastewater for one house*** | | | | | E  ww | applicator, | 3.20E-07 | [kg.d-1] |
| 𝑬 𝒂𝒑𝒑𝒍𝒊𝒄𝒂𝒕𝒐𝒓, 𝒘𝒘 = 𝑬 𝒂𝒑𝒑𝒍𝒊𝒄𝒂𝒕𝒐𝒓 × 𝑭 𝒘𝒘 × 𝑭 𝑪𝑬 𝒂𝒑𝒑𝒍 | | | | | | | | |
| ***Total emission to the wastewater*** | | | | | E total,ww | | 4.93E-06 | [kg.d-1] |
| E total, ww = E treated/floor, ww + E applicator, ww | | | | | | | | |
| ***Total Emission to the wastewater for one STP*** | | | | | | | | |
| ***Total emission to the STP*** | | | | | E local water | | 4.03E-05 | [kg.d-1] |
|  | E local water = E total, ww × N HOUSE × F simultaneity | | | | | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  | **OUTPUTS FOR THE SUBSTANCE OF CONCERN: HYDROCARBONS,C4, 1,3-**  **BUTADIENE-FREE, POLYMD., TRISOBUTYLENE FRACTION, HYDROGENATED** | | | | | | | |
|  | | | | | | | |
| ***Emission during the application*** | | | | | | | |
| Emission applicator |  | to | the | E applicator | | 2.13E-03 | [kg.d-1] |
| E applicator = N appl × F applicator × Q prod × FAI × AREA treated | | | | | | | |
| Emission to the floor | | | | E floor | | 1.98E-02 | [kg.d-1] |
| E floor = N appl × F floor × Q prod × FAI × AREA wet cleaned | | | | | | | |
| Emission surface | to |  | treated | E treated | | 1.33E-01 | [kg.d-1] |
| E treated = N appl × F treated × Q prod × FAI × AREA wet cleaned | | | | | | | |
| Emission during the cleaning step for one house | | | | | | | |
| **Emission from treated area/floor to wastewater for one**  **house** | | | | E  ww | treated/floor, | 3.06E-02 | [kg.d-1] |
| E treated/floor, ww = (E floor + E treated) × F ww × F CE floor | | | | | | | |
| **Emission from**  **applicator to wastewater for one**  **house** | | | | E  ww | applicator, | 2.13E-03 | [kg.d-1] |
| E applicator, ww = E applicator × F ww × F CE appl | | | | | | | |
| **Total emission to the wastewater** | | | | E total,ww | | 3.28E-02 | [kg.d-1] |
| E total, ww = E treated/floor, ww + E applicator, ww | | | | | | | |
| Total Emission to the wastewater for one STP | | | | | | | |
| **Total emission to the**  **STP** | | | | E local water | | 2.68E-01 | [kg.d-1] |
| E local water = E total, ww × N HOUSE × F simultaneity | | | | | | | |
| O: outputs values | | | | | | | | |

### Calculated PEC values

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected. Regarding the air compartment, based on the indoor application of the product and based on the physical chemical properties of the active substances, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale.

PEC values for all compartments are therefore expected to be negligible.

Infobox 10 - FR CA position:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| The results are summarised in the following table. | | | | | | | |
|  | **Summary table on calculated PEC values** | | | | | |  |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg.L-1l] | [mg.L-1] | [mg.kgw -  wt  1] | [mg.kgw -  wt  1] | [μg.L-1] |
| Active substance:  1-R trans  phenothrin | 5.46E-05 | 4.59E-06 | 1.26E-02 | 9.56E-04 | 1.33E-04 |
| Active substance: Pyriproxyfen | 6.35E-06 | 6.15E-07 | 2.84E-04 | 2.75E-05 | 1.63E-05 |
| Substance of concern: Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | 5.72E-03 | 5.70E-04 | 3.76E-02 | 3.03E-01 | 4.08 |

### Primary and secondary poisoning

*Primary poisoning*

Primary poisoning, i.e. the direct consumption of the product by birds or mammals is not considered as relevant for the product Paranix Environnement. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product Paranix Environnement.

*Secondary poisoning*

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no risk of secondary poisoning *via* ingestion of potentially contaminated food (e.g. earthworm or fish) by birds or mammals is expected.

**Infobox 11 - FR CA position:**

As the active substance 1-R trans phenothrin has a log Kow > 3 (log Kow = 6.8) and a BCF

* 100 (mean BCF in fish = 1 878 L.kg-1, BMF = 10 and BCF in earthworm = 75 716 L.kg-1), secondary poisoning may occur via the aquatic food chain and via the terrestrial food chain. The concentration of 1-R transphenothrin in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated.

In the same way, the second active substance pyriproxyfen has a log Kow > 3 (log Kow = 4.86) and a BCF > 100 (mean BCF in fish = 1 495 l.kg-1, BMF = 1 and BCF in earthworm = 870 L.kg-1), secondary poisoning may occur via the aquatic food chain and via the terrestrial food chain. The concentration of pyriproxyfen in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition** | | |
|  | **PEC** | **PEC** |
| [mg.kg wet fish-1] | [mg.kg wet earthworm-1] |
| Active substance: 1-R trans phenothrin | 4.31E-02 | 4.53E-03 |
| Active substance: Pyriproxyfen | 4.60E-04 | 6.66E-06 |

## Risk characterisation

The results for the two active substances are summarised in the following table.

No ecotoxicological data are available to set a PNEC value for predator organims for the Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated, thus there is no secondary poisoning assessment.

### Atmosphere

Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to 3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.

Therefore, the risk for the atmosphere compartment is considered as negligible when using the product Paranix Environnement according to the label recommendations.

Infobox 12 - FR CA position:

The vapour pressure of active substances 2.37\*10-5 Pa (at 20°C, for 1R-trans phenothrin) and 1.33\*10-5 Pa (at 23°C, for pyriproxyfen) indicates that they will not readily volatilise into the atmosphere at ambient temperature and pressure. It is not expected that substances will fulfil the screening criteria for the potential for long-range environmental transport. Furthermore, there is no monitoring data available or other evidence indicating potential for long-range environmental transport.

Due to the intended use of the Paranix Environnement which is limited to indoor application and on basis of the available substance information the environmental risk to the atmosphere of Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated for the atmosphere can be assumed as low.

Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded

that the use of the product Paranix Environnement will not pose a significant risk to the atmospheric compartment.

### Sewage treatment plant (STP)

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no contamination of the STP is expected.

Therefore, the risk for the STP is considered as negligible when using the product Paranix Environnement according to the label recommendations.

**Infobox 13 - FR CA position:**

\*No ecotoxicological data are available to set a PNECSTP value for the Hydrocarbons, C4,

1,3-butadiene-free,

compartment.

polymd.,

triisobutylene fraction, hydrogenated for the STP

Conclusion: The risk characterisation ratios are below 1 for the application by spraying on unwashed furnishings. Therefore, the risk for the STP is acceptable when using the

products Paranix Environnement.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | **Conclusion** |
|  | **PEC/PNECSTP** |
| Active substance: 1-R trans phenothrin | 5.46E-06 | Acceptable |
| Active substance: Pyriproxyfen | 6.28E-05 | Acceptable |
| Substance of concern: Hydrocarbons, C4, 1,3-butadiene- free, polymd., triisobutylene fraction, hydrogenated | - | No data\* |

### Aquatic compartment

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no contamination of the aquatic compartment, either directly or indirectly, is expected.

Therefore, the risk for the aquatic compartment is considered as negligible when using the product Paranix Environnement according to the label recommendations.

**Infobox 14 - FR CA position:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Summary table on calculated PEC/PNEC values** | | | | | | **Conclusion** |
|  | | **PEC/PNECwater** | | **PEC/PNECsed** | |
| Active substance: 1-R trans phenothrin | | 9.77E-02 | | 9.74E-01\* | | Acceptable |
| Active substance: Pyriproxyfen | | 2.05E-01 | | 2.03E-01 | | Acceptable |
| Substance of concern: Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | | **4.46E+00** | | **4.46E+01\*** | | **Unacceptable** |
| \* An additional factor of 10 has been considered as PNECsed was defined using the EPM method and LogKow is >5  **Aquatic compartment: Risk assessment for the major metabolites of 1-R transphenothrin**  According to the Assessment Report 1,R-trans phenothrin PT18 (March 2013), three metabolites were identified as major environmental metabolites, PBalc, PBacid and HO- *trans*-PHN. In using the same approach that developed in the AR (PEC values for metabolites are estimated from PEC values for d-phenothrin taking into account the molecular weights, and the maximum observed levels), PEC/PNEC values for the sum of PBalc and PBacid and HO-trans-PHN are calculated and shown below. PNECs for 1-R transphenothrin are considered as covering the toxicity of metabolites and are used to determine the ratios. | | | | | | | |
|  | **Summary table on calculated PEC/PNEC values for Total metabolites** | | | | | **Conclusion** | |
|  | **PEC/PNECwater** | | **PEC/PNECsed** | |
| Total metabolites of 1-R trans phenothrin | 4.31E-02 | | 4.30E-01 | | Acceptable | |
| **Aquatic compartment: Risk assessment for the major metabolites of pyriproxyfen**  According to the Competent Authority Report of Pyriproxyfen PT18 Doc II-C (May 2012), three metabolites were identified as major environmental metabolites in aquatic compartment, 4’OH-Pyr, PYPAC and DPH-Pyr. In surface water, for each metabolite, a PNEC aquatic-continuous are considered relevant for emissions via the STP and leaching from land to surface water. So, the PNEC aquatic-continuous for DPH-PYR, 4’-OH-pyriproxyfen and PYPAC are 5.1 µg/L, 0.27 µg/L and 26 µg/L, respectively. In sediment, only the 4’-OH- pyriproxyfen are considered relevant for the risk assessment. The PNEC sediment-continuous for 4’OH-Pyr is 15 µg/kg ww. For both compartments, PEC values for metabolites are estimated from PEC values for Pyriproxyfen taking into account the molecular weights and the maximum observed levels of the metabolites. PEC/PNEC values for the metabolites are calculated and shown below. | | | | | | | |
|  | **Summary table on calculated PEC/PNEC values for Total metabolites** | | | | | **Conclusion** | |
|  | **PEC/PNECwater** | | **PEC/PNECsed** | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 4’OH-Pyr :metabolite of Pyriproxyfen | 3.59E-04 | 2.98E-03 | Acceptable |
| PYPAC :metabolite of Pyriproxyfen | 2.95E-06 | - |  |
| DPH-Pyr :metabolite of  Pyriproxyfen | 1.10E-05 | - |  |
| Conclusion: The risk characterisation ratios are above 1 for the surface water and/or the sediment compartments for the substance of concern. Therefore, the risk for the aquatic compartment is unacceptable when using the product Paranix Environnement. | | | | |

### Terrestrial compartment

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no contamination of the terrestrial compartment, either directly or indirectly, is expected.

Therefore, the risk for the terrestrial compartment is considered as negligible when using the product Paranix Environnement according to the label recommendations.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | **Conclusion** |
|  | **PEC/PNECSoil** |
| Active substance: 1-R trans phenothrin | 9.19E-02 | Acceptable |
| Active substance: Pyriproxyfen | 2.50E-02 | Acceptable |
| Substance of concern: Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | **3.43E+02\*** | **Unacceptable** |

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| --- | --- | --- | --- |
| **Infobox 15 - FR CA position:**  \* An additional factor of 10 has been considered as PNECsoil was defined using the EPM method and LogKow is >5  **Terrestrial compartment: Risk assessment for the major metabolites of 1,R-trans phenothrin**  According to the information available in the Assessment Report 1,R-trans phenothrin PT18 (March 2013), PBalc, PBacid and HO-*trans*-PHN can be considered as relevant metabolites in soil as formed in water. It is considered that the PNEC soil value derived for d-trans- Phenothrin provides a sufficient level of protection. In using the same approach that developed in the AR (PEC values for metabolite are estimated from PEC values for d- phenothrin taking into account the molecular weights and the maximum observed levels of the metabolite in water), PEC/PNEC values for the sum of PBalc and PBacid and HO-*trans*- PHN are calculated and shown below. PNEC soil for 1-R transphenothrin is considered as covering the toxicity of metabolites and is used to determine the ratio. | | | |
|  | **Summary table on calculated PEC/PNEC values for total** | **Conclusion** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **metabolites** | |  |  |
|  | **PEC/PNECSoil** |  |
| Total metabolites of 1-R trans phenothrin | 4.12E-02 | Acceptable |
| **Terrestrial compartment: Risk assessment for the major metabolites of pyriproxyfen**  According to the Competent Authority Report of Pyriproxyfen PT18 Doc II-C (May 2012),” In laboratory incubated soil, the maximum level of the main degradation products 4’-OH- pyriproxyfen, DPH-Pyr and PYPAC in any of the investigated soils was <10% AR Therefore, these metabolites need not be assessed.” Consequently, no terrestrial risk assessment for pyriproxyfen metabolites has been achieved.  Conclusion: The risk characterisation ratio is above 1 for the substance of concern in the soil compartment. Therefore, the risk for the soil compartment is unacceptable when using the product Paranix Environnement. | | | | |

### Groundwater

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no contamination of the groundwater is expected.

Therefore, the foreseeable concentration of the active substances and their relevant metabolites are considered as negligible and are not expected to exceed the maximum permissible concentration of 0.1 µg/L laid down by Directive 98/83/EC.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC groundwater (µg/L) Comparison with the limit value of 0.1 µg/L.** | | |
|  | | **Conclusion** |
| Active substance: 1-R trans phenothrin | 1.33E-04 (<0.1) | Acceptable |
| Active substance: Pyriproxyfen | 1.63E-05 (<0.1) | Acceptable |
| Substance of concern: Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | **4.08 (>0.1)** | **Unacceptable** |

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| **Infobox 16 - FR CA position:** | | |
|  | **Summary table on calculated PEC groundwater (µg/L) for relevant 1,R- trans phenothrin and pyriproxyfen metabolites**  **Comparison with the limit value of 0.1 µg/L.** | **Conclusion** |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Total 1,R-trans phenothrin | 5.95E-05 (<0.1) | Acceptable |
| 4’OH-Pyr :metabolite of Pyriproxyfen\* | 3.33E-05 (<0.1) | Acceptable |
| PYPAC :metabolite of Pyriproxyfen\* | 3.94E-04 (<0.1) | Acceptable |
| \* only relevant metabolite for groundwater assessment according to the CAR for pyriproxyfen  Conclusion: The concentration for the substance of concern in the groundwater compartment is higher than 0.1 µg/L. Therefore, the risk for this compartment is unacceptable when using the product PARANIX ENVIRONNEMENT. | | | |

### Primary and secondary poisoning

*Primary poisoning*

Primary poisoning, *i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product Paranix Environnement. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product Paranix Environnement.

**Infobox 17 - FR CA position:**

Not relevant.

*Secondary poisoning*

As the product is for indoor use only and is intended to be applied onto objects that are not subject to washing once treated as stated in the label, no risk of secondary poisoning *via* ingestion of potentially contaminated food (*e.g.* earthworm or fish) by birds or mammals is expected.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Infobox 18 - FR CA position:** | | | | | | |
|  | **Summary table on secondary poisoning** | | | | | |
| **Scenario** | **PECoral predator** | | | **PEC/PNECbirds** | **PEC/PNECmammal** |
| Active substance: 1-R trans phenothrin | 4.31E-02 mg.kg-1 wet fish | | | 2.31E-02 | 4.31 E-03 |
| 4.53E-03  earthworm | mg.kg-1 | wet | 2.42E-03 | 4.53E-04 |
| Active substance: Pyriproxyfen | 4.60E-04 mg.kg-1 wet fish | | | 2.42E-05 | 6.86E-05 |
| 6.66E-06  earthworm | mg.kg-1 | wet | 3.51E-07 | 9.94E-07 |
| Conclusion: The RCRs are below 1 for the birds and for mammals in the aquatic and the terrestrial food chains. Therefore, the risk of secondary poisoning is acceptable when using  the products Paranix Environnement according to the label recommendations. | | | | | | |

No ecotoxicological data are available to set a PNECoral value for the Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated for the risk assessment of secondary poisoning.

### Mixture toxicity

**Infobox 19 - FR CA position:**

See infobox 1 at the beginning of the part 2.2.8 Risk assessment for the environment for screening step for the determination of the relevant substances of concern. Mixture toxicity assessment is presented in infobox 30.

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments.

Paranix Environnement is a biocidal product containing 0.3% w/w sumithrin (sum of all isomers) (*i.e.* 0.28% w/w 1R-trans phenothrin) and 0.015% w/w pyriproxyfen as active substances.

The product Paranix Environnement is used indoors by spray application by non- professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …) According to the label, the treated objects can’t be cleaned with wet methods.

Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to 3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.

As the product is for indoor use only and directed onto objects that can’t be cleaned by wet methods once treated as stated in the label, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected.

Therefore, a significant exposure of environment is unlikely and a mixture toxicity assessment is not necessary for the product Paranix Environnement.

Screening Step 2: Identification of relevant substances

Screening Step 3: Screen on synergistic interactions

**Infobox 20 - FR CA position:**

The result of mixture toxicity assessment of the product containing active substances (1,R-

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| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
| **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECsoil** | **PECGW** |
| 6.83E-05 | **4.76** | **4.57E+01** | **3.44E+02** | **4.08** |

### Aggregated exposure (combined for relevant emission sources)

trans phenothrin and pyriproxifen) and the substance of concern ‘hydrocarbons, C4, 1,3-

butadiene-free, polymd., triisobutylene fraction, hydrogenated’ is summarised in the following table.

Conclusion: The sum of RCRs is above 1 for the aquatic compartment (water and sediment), the soil and the groundwater compartment. Therefore, the risk assessment for

the environment is unacceptable when using the product Paranix Environnement.

To have acceptable risk, the use of the product should lead to no emission to environment. Instruction of use and mitigation measure could limit the releases to wastewater after the application of the product such as :

* Do not apply to washable surfaces or washable textiles.
* During application protect the adjacent surface with a non-washable plastic sheet.

**Infobox 21 - FR CA position**:

Aggregated exposure is not relevant for the product Paranix Environnement, indeed only one use is claimed.

An assessment of aggregated exposure is judged not relevant for the product Paranix Environnement based on the decision scheme developed by UBA (see Figure 1). Indeed, as emissions into the environment are negligible because the product is for indoor use only, there is no need for estimation of aggregated exposure.



\* a) aggregate only compartments and consider only PTs where overlap in time and space exists

b) if production or formulation is within Europe, add a qualitative description of the respective environmental exposure e.g. in CAR

***Aggregated No aggregated*** *exposure estimation exposure estimation required for a.s./b.p.\* required for a.s./b.p.*

§ Part 1 has to be checked for all PTs affected

Different a.s. form the same

relevant metabolite

Different use/service life/waste

scenarios

**no**

**yes**

**or**

a.s. is relevant metabolite

of other a.s., and vice versa

**or**

**Overlap in time and**

**space?**

Wide dispersive use

**or**

Multiple b.p. for same purpose

**or**

Same a.s./b.p. in different PTs

**or**

Main constituent of a.s. is part of other a.s.

Other a.s. affected

Uses of a.s./b.p. within >1 PTs

Different user categories

Part 2

Uses of a.s./b.p. within 1 PT

Part 3

Part 1§

**yes**

**no/unknown**

**no**

**no**

**Biocidal specific emission**

**pattern**

**yes**

**Biocide**

**use of a.s. < 10% of total?**

**yes**

Other regulatory areas

**Decision tree on need for estimation of aggregated exposure**

Annual tonnage of a.s. for biocide use

*No aggregated exposure estimation for a.s./b.p. required*

*Figure 1: Decision tree on the need for estimation of aggregated exposure*

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Paranix Environnement is a biocidal product containing 0.3% w/w sumithrin (sum of all isomers) (*i.e.* 0.28% w/w 1R-trans phenothrin) and 0.015% w/w pyriproxyfen as active substances.  The product Paranix Environnement is used indoors by non-professionals and is intended for the curative treatment of objects that could have been in contact with lice and nits (bedding, comb, armchair, helmet …) According to the label, the treated objects can’t be cleaned with wet methods. The product is applied by spray application at the dose of 26.7 g product/m².  Exposure of atmosphere can be expected considering the mode of application by spraying of the product Paranix Environnement resulting in direct emission to air. However, based on the indoor application of the product for the control of lice and nits, it is likely that emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the vapour pressures of 1R-trans phenothrin and pyriproxyfen are very low (2.37\*10-5 Pa at 20°C and < 1.33\*10-  5 Pa at 23°C, respectively) and 1R-trans phenothrin and pyriproxyfen are considered as non-persistent in air. Indeed, the estimated atmospheric photolytic half-lives in air equal to 3.63 hours and 0.307 day for 1R-trans phenothrin and pyriproxyfen, respectively, indicate a rapid degradation.  As the product is for indoor use only and directed onto objects that can’t be cleaned by wet methods once treated as stated in the label,, no contamination either directly or indirectly of the STP, the surface water (including sediment)  and the soil (including groundwater) is expected. |

**Infobox 22 - FR CA position**:

Proposed instruction of use and risk mitigation measure:

* Do not apply to washable surfaces or washable textiles.
* During application protect the adjacent surface with a non-washable plastic sheet.

Therefore, the risk for all compartments (air, water, sediment, soil and groundwater) and the risk of primary and secondary poisoning are considered acceptable when using the product Paranix Environnement according to the label recommendations. There is no need for conducting a mixture toxicity assessment and an estimation of aggregated exposure.

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| --- | --- | --- |
|  | **PARANIX ENVIRONNEMENT**  **Ready-for-use product used by non- professionals for the curative treatment of non-wet washable objects and furnishings against lice and nits infestations** | **Conclusion** |
| STP | Acceptable | **Unacceptable without risk mitigation measures** |
| Surface water | **Unacceptable** |
| Sediment | **Unacceptable** |
| Soil | **Unacceptable** |
| Groundwater | **Unacceptable** |
| Secondary poisoning | Acceptable |

## Measures to protect man, animals and the environment

See section 2.1.5.3, which is the Summary of Produxct Characteristics

## Assessment of a combination of biocidal products

Not relevant, as Paranix Environnement is not intended to be used with other biocidal products.

## Comparative assessment

Not relevant, as the active substances contained in the biocidal product Paranix Environnement are not candidates for substitution in accordance with Article 10 of Regulation (EC) No.528/2012. See also paragraph 2.1.2.2 of this document.

## ANNEXES

## List of studies for the biocidal product

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Part** | **Author** | **Year** | **Title** | **Owner** | **Data protection cliamed**  **(yes/No)** | **Essential for the assessment**  **(Yes/No)** |
| 2.2.2  Physico-chemical properties | Demangel B | 2016 | Physico-chemical tests on PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Study report No 15-912035-013 | Laboratoire Omega | Yes | Yes |
| 2.2.2  Accelerated storage stability study | Demangel B | 2016 | Physico-chemical tests and chemical analyses before and after an accelerated storage procedure for 8 weeks at 40°C on the aerosol PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Study report No 15-912035-015 | Laboratoire Omega | Yes | Yes |
| 2.2.2  Long terme stability study | Demangel B | 2016 | Physico-chemical tests and chemical analyses before and after a storage procedure for 36 months at 20°C on the aerosol PARANIX ENVIRONNEMENT NOUVELLE FORMULE  interim results after 6 and 12 months Study report No 15-912035-016 | Laboratoire Omega | Yes | Yes |
| 2.2.2  Long terme stability study | Demangel B | 2019 | Physico-chemical tests and chemical analyses before and after a storage procedure for 36 months at 20°C on the aerosol PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Study report No 15-912035-016 | Laboratoire Omega | Yes | Yes |

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| --- | --- | --- | --- | --- | --- | --- |
| 2.2.2  Low temperature stability study | Demangel B | 2016 | Physico-chemical tests before and after an low temperature stability test at 0°C for 7 days on the aerosol PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Study report No 15-912035-014 | Laboratoire Omega | Yes | Yes |
| 2.2.2  Technical characteristics | AEROFA RM | 2016 | Dossier de lot de répartition/conditionnement – atelier aerosols 1 – Nom de produit : PARANIX ENVIRONEMENT |  | Yes | Yes |
|  |  |  | Report : Edition du 04/07/2016 – Lot CC581 |  |  |
| 2.2.2  Technical characteristics | AEROFA RM | 2013 | Procedure Contrôle Qualité – Contrôles de fabrication et de conditionnement des aérosols |  | Yes | Yes |
|  |  |  | Report QLT814/13 |  |  |
| 2.2.3 | Detrimont | 2016 | Literature review on explosive | Laboratoire | Yes | Yes |
| Physical hazards | H. |  | properties, self-reactivity, oxidising | Omega |  |  |
|  | Ambrosi |  | properties, auto-flammability of the |  |  |  |
|  | D. |  | ingredients of the product PARANIX |  |  |  |
|  |  |  | ENVIRONNEMENT |  |  |  |
|  |  |  | ASC report No.15/80 |  |  |  |
| 2.2.4  Analytical method | Ricau H | 2016 | Validation of the analytical method for the determination of 1R-trans phenothrin in PARANIX ENVIRONNEMENT NOUVELLE FORMULE  Report no 15-912035-017 | Laboratoire Omega | Yes | Yes |
| 2.2.4  Analytical method | Ricau H | 2016 | Validation of the analytical method for the determination of pyriproxyfen in PARANIX ENVIRONNEMENT NOUVELLE FORMULE | Laboratoire Omega | Yes | Yes |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Report no 15-912035-018 |  |  |  |
| 2.3  Efficacy | E.  Brunton | 2015 | Report of tests of Paranix Environnement Nouvelle Formule spray against head lice  Report N°15/2027 | Laboratoire Omega | Yes | Yes |
| 2.3  Efficacy | B.  Toubate | 2016 | Rapport de l’efficacité lenticide du produit REF 1: PARANIX  ENVIRONNEMENT | Laboratoire Omega | Yes | Yes |
| 2.3  Efficacy | E.  Brunton | 2015 | Report of tests of Paranix Environnement Nouvelle Formule spray against head lice  Report N°15/2024A | Laboratoire Omega | Yes | Yes |

France PARANIX ENVIRONNEMENT PT18

## Output tables from exposure assessment tools

All the data entered in ConsExpo model for non-professional exposure assessment are listed in Table 2.2.6.2.5-1 and results are presented in Table 2.2.6.2.5-2.

For more details, please refer to the Excel data sheet “PARANIX\_Expo HH2”.



## New information on the active substance

Not relevant, as no additional data on the active substances have been generated.

## Residue behaviour

The product PARANIX ENVIRONNEMENT is intended for indoor spraying surface uses against lice and nits by non-professional on objects that could have been in contact with lice (bedding, comb, armchair, helmet...). No specific residue data were submitted in the context of this dossier.

As regards the intended use of the product PARANIX ENVIRONNEMENT, no direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statement is proposed:

“ Avoid any direct or indirect contact with food and feed.”

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

The efficacy studies are summarised in the IUCLID dossier (see Section 6.7).

## Confidential annex

The detailed composition of the product Paranix Environnement is presented in the confidential annex

This information is confidential and should not be disclosed to third parties Manufacturing site of the active substances: 1-R trans phenotrinand Pyriproxyfen:

⁻ Manufacturer: Sumitomo Chemical (UK) Plc – Hyte House, W7NL, London, UK

⁻ Manufacturing site: Aza-sabishirotai, 033-0022, Aomori, Japan

## Other

Not relevant.

1. Efficacy and safety of a combination regimen of phenothrin and ivermectin lotion in patients with head lice in Okinawa, Japan [↑](#footnote-ref-1)
2. First evidence of the mutations associated with pyrethroid resistance in head lice (Phthiraptera: Pediculidae) from Honduras [↑](#footnote-ref-2)