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

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

(submitted by the evaluating Competent Authority)



ENCLEAN PAE

Product type 2

Nonanoic acid

Case Number in R4BP: BC-RCO19989-24

Evaluating Competent Authority: FR

Date: October 2018

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# CONCLUSION

***Conclusion for Physico-chemistry:***

The product ENCLEAN PAE is Another Liquid (AL) formulation, ready-to-use. 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 that of homogeneous yellowish liquid, with characteristic odour. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The shelf-life of the product is 24 months. **Final results of long term storage study should be provided in post-authorization.** Its technical characteristics are acceptable for an AL formulation.

The product ENCLEAN PAE is not explosive and has no oxidizing properties. The product is not considered as flammable.

***Conclusion for Efficacy:***

In conclusion, in accordance with the submitted tests, the product ENCLEAN PAE is efficient against green algae (*Chlorophyta spp*.) by spraying on hard porous and non-porous surfaces for use outdoor by professional and non-professional users.

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

***Conclusion for Human health:***

No unacceptable risk is observed for professional and non professional users.

*For practical reasons, the larger packaging sizes (over 20L) will be restricted to professional users only.*

***Conclusion for Environment:***

Considering the intended use of ENCLEAN PAE, risks are acceptable whatever the way of environmental release in considering the specific conditions of use.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| ENCLEAN PAE | FRANCE |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | JADE |
| **Address** | Parc Cadéra Sud - Avenue Ariane  33700  Merignac  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

Note to cMS : rMS has been informed that BELCHIM acquired JADE in 2017. The authorisation holder will thus have to change. However, JADE is still the authorisation holder indicated in R4BP dossier. Depending on whether it is possible to modify the case and change authorisation holder prior the authorisation is given, the name here above may be modified. Otherwise, a Na-TRS will have to be submitted.

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | IRIS |
| **Address of manufacturer** | 1126 avenue du Moulinas,  Route de saint privat-  30340 Salindres  France |
| **Location of manufacturing sites** | 1126 avenue du Moulinas,  Route de saint privat-  30340 Salindres  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | DIACHEM |
| **Address of manufacturer** | Via Mozzanica, 9/11  24043 Caravaggio  Italy |
| **Location of manufacturing sites** | Via Mozzanica, 9/11  24043 Caravaggio  Italy |

|  |  |
| --- | --- |
| **Name of manufacturer** | CHEMINOVA |
| **Address of manufacturer** | Stader Elbstraße 28  21683 Stade  Germany |
| **Location of manufacturing sites** | Stader Elbstraße 28  21683 Stade  Germany |

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

|  |  |
| --- | --- |
| **Active substance** | Acide nonanoïque, acide pélargonique |
| **Name of manufacturer** | Nantong Shenyu Green Medicine CO, Ltd |
| **Address of manufacturer** | D-E Block, 9th floor, 251, Ledu Road, songiiang District  201600  Shanghai  China |
| **Location of manufacturing sites** | Yangkou Chemical Industry Zoon, Rudong County, Jiangsu Province  201600  Shanghai  China |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Nonanoic acid (synonym: Pelargonic acid) |
| **IUPAC or EC name** | Nonanoic acid |
| **EC number** | 203-931-2 |
| **CAS number** | 112-05-0 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 962 g/kg |
| **Structural formula** | CH3(CH2)6CH2C OH O  Afficher l'image d'origine |

#### Candidate(s) for substitution

The active substance nonanoic acid contained in the biocidal products is not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Nonanoic acid | Nonanoic acid | Active substance (pure) | 112-05-0 | 203-931-2 | 2.16 |

#### Information on technical equivalence

The decision on technical equivalence from ECHA published in January 2017 confirms that the alternative source of nonanoic acic manufactured by Nantong Shenyu Green Medicine CO is considered technically equivalent compared to the reference source from Jade.

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

Please see the confidential annex for further details.

#### Type of formulation

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

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | None |
| Hazard statement | None |
|  | |
| **Labelling** | |
| Signal words | None |
| Hazard statements | None |
| Precautionary statements | None |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Algaecide – Hard surfaces

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | Curative, algaecide effect on building materials, on all hard surfaces (porous and non-porous) in green spaces, on every roof type (except thatched roof). |
| **Target organism (including development stage)** | Green algae (*Chlorophyta spp.)* |
| **Field of use** | Outdoor |
| **Application method(s)** | The product must be sprayed directly on the surfaces to be treated. |
| **Application rate(s) and frequency** | Application rate: 50 mL/m2  Up to two applications per year |
| **Category(ies) of users** | General public, Professional |
| **Pack sizes and packaging material** | Professionnal :  F-HDPE sprayers: 500 mL, 750mL, 1L  F-HDPE bottles: 1L  F-HDPE cans : 3L, 5L, 10L, 20L  F-HDPE barrels : 200L, 640L  F-HDPE tanks : 1000L  General public :  F-HDPE sprayers: 500 mL, 750mL, 1L  F-HDPE bottles: 1L  F-HDPE cans : 3L, 5L, 10L, 20L |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Avoid direct or indirect contact with food and feed. * Always read the label or leaflet before use and respect follow all the instructions provided. * Do not treat in rainy weather or on frozen surfaces. * Do not clean the surface after treatment. * Allow the product to take effect for at least several days. * The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

#### Risk mitigation measures

|  |
| --- |
| * Products can only be used if the weather forecasts show no rain for the day of application. * During the application, the soil and plants adjacent to the treated area shall be protected to avoid emission to soil compartment |

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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Mouth contact: Wash out mouth with water. Contact poison treatment specialist. * Keep the container or label available. * Keep the container or label available. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Dispose of unused product, its packaging (as the plastic film of soil protection) and all other waste, in accordance with local regulations. * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains |

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

|  |
| --- |
| * Shelf life: 2 years * Keep in a dry, cool and ventilated area and in the original container |

### Other information

|  |
| --- |
| * Final results of long term storage study should be provided in post-authorization * The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA). |

### 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)** |
| Sprayer | 0.5L, 0.75L, 1L | f-HDPE | Hermetically closed | Professional and non-professional users | Yes |
| Bottle | 1L | f-HDPE | Hermetically closed | Professional and non-professional users | Yes |
| Can | 3L, 5 L, 10L, 20L | f-HDPE | Hermetically closed | Professional and non-professional users | Yes |
| Barrel | 200L, 640L | f-HDPE | Hermetically closed | Professional | Yes |
| Tank | 1000L | f-HDPE | Hermetically closed | Professional | Yes |

For non-professional users, only packaging up to 20L are authorised.

### Documentation

#### Data submitted in relation to product application

***Physico-chemistry:***

Physico-chemical properties studies and analytical methods on the biocidal product ENCLEAN were provided by Jade.

***Efficacy:***

The product ENCLEAN PAE has been tested in following efficacy studies:

* For Algae:
* Three field studies conducted according to an in house method with the product ENCLEAN PAE (2.17% w/w nonanoic acid) on hard surfaces (cement pathway, plaster, glass)

***Residue data:***

No specific residue data were submitted in the context of this dossier. By definition, PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected. Considering the intended uses no data is required.

#### Access to documentation

Jade is one applicant of the active substance nonanoic acid and has access to data on this active substance.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – algaecide

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | Curative, algaecide effect on building materials, on all hard surfaces in green spaces, on every roof type (except thatched roof). |
| **Target organism (including development stage)** | algae |
| **Field of use** | Outdoor |
| **Application method(s)** | Spraying:   * Spray by wetting the moss to destroy * Let the product act for a few hours |
| **Application rate(s) and frequency** | 50.0 mL/m² - 100 –  2 per year |
| **Category(ies) of users** | General public, Professional |
| **Pack sizes and packaging material** | F-HDPE sprayers: 500 mL, 750mL, 1L  F-HDPE bottles: 1L  F-HDPE cans : 3L, 5L, 10L, 20L  F-HDPE barrels : 200L, 640L  F-HDPE tanks : 1000L |

### Physical, chemical and technical properties

The biocidal product is Another Liquid AL, ready-to-use.

Hydrocarbons and H304 co-formulant content : ≤10%

Packaging: f-HDPE

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 / 830.6303 / 830.6304 | 502 g/l of nonanoic acid  Batch 20111102 | Homogeneous liquid | Fieseler A., 2014  Report number 82929204 | Acceptable |
| Colour at 20 °C and 101.3 kPa | yellowish |
| Odour at 20 °C and 101.3 kPa | Characteristic |
| Acidity / alkalinity | MT 191  MT 75.3 | Enclean PAE  Batch 14090 | Acidity: 0.68 % w/w H2SO4 | C. Bär, 2016, S16-01013 | Acceptable |
| Relative density / bulk density | EU Method A.3 | Enclean PAE  Batch 14090 | D20: 1.0047 | C. Bär, 2016, S16-01010 | Acceptable |
| Storage stability test – **accelerated storage** | MT 46.3  GC-FID method (project 83241101) validated | 502 g/l of nonanoic acid  Batch 20111102 | |  |  |  | | --- | --- | --- | |  | **Initially** | **After 14 days at 54°C in 1L HDPE** | | Appearance (test item and container) | Homogeneous clear yellowish liquid with characteristic odour.  M=1074.5g (before and after storage).  No deformation of container. | | | Content of a.s. | 50.0 % w/w | 50.0 % w/w | | pH (1%, 20°C) | 3.8 | 3.8 | | Acidity (% H2SO4) | 14.2 | 14.5 | | Emulsion characteristics\* | **After 30 min in water A:**  3% v/v: max 6mLof froth and cream  At 7.5 % v/v: max 12 mL of froth and cream  **After 30 min in water D:**  3% v/v: max 6mLof froth and cream  At 7.5 % v/v: max 10 mL of froth and cream | **After 30 min in water A:**  3% v/v: max 7mLof froth and cream  At 7.5 % v/v: max 14 mL of froth and cream  **After 30 min in water D:**  3% v/v: max 5mLof froth and cream  At 7.5 % v/v: max 11 mL of froth and cream | | Persistent foaming (after 1 min at 7.5%) | 14.7 mL | - |   \*: Details of emulsion characteristics are described below the table. | Fieseler A., 2014  Report number 82929204 | Acceptable  The study was performed on the biocidal product ENCLEAN. Nevertheless, as the active substance content is above than ENCLEAN PAE product, the accelerated storage stability is considered acceptable. |
| Storage stability test – **long term storage at ambient temperature** |  |  | The study is on-going (started on 11/2014 and will finish in 2017). | Fieseler A.  Study plan Report number 82920204 | Final results of long term storage study, with spraying data before and post storage, should be provided in post-authorization. |
| Storage stability test – **low temperature stability test for liquids** | MT 39.3  MT 36.3  MT 75.3 | 502 g/l of nonanoic acid  Batch 20111102 | |  |  |  | | --- | --- | --- | |  | **Initially** | **After 7 days at 0°C** | | Appearance (test item and container) | Homogeneous yellowish liquid, no precipitation or separated material was observed after the storage | | | pH (1% and undiluted, 20°C) | 3.8 | 3.8 | | Acidity (% H2SO4) | 14.2 | 14.5 | | Emulsion characteristics | **After 30 min in water A:**  3% v/v: max 6mLof froth and cream  At 7.5 % v/v: max 12 mL of froth and cream  **After 30 min in water D:**  3% v/v : max 6mLof froth and cream  At 7.5 % v/v: max 10 mL of froth and cream | **After 30 min in water A:**  3% v/v: max 3mLof froth and cream  At 7.5 % v/v: max 5 mL of froth and cream  **After 30 min in water D:**  3% v/v: max 3mLof froth and cream  At 7.5 % v/v: max 5 mL of froth and cream | | Fieseler A., 2015  Report number 82928204 | Acceptable  Study was performed on the biocidal product ENCLEAN. Nevertheless, as the formulation of ENCLEAN PAE is an AL (ready-to-use), it considered acceptable. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  | 502 g/l of nonanoic acid  Batch 20111102 | The light, the temperature changes did not changed the content of active substance in the product. No degradation products are observed.  No reactivity towards material is present. | Fieseler A., 2014  Report number 82929204 | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See accelerated storage. |  |  |
| Wettability |  |  | Not required |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not required |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability | MT 36.3 | 502 g/l of nonanoic acid  Batch 20111102 | See detail results below table. | Fieseler A., 2014  Report number 82929204 | Acceptable  As the product is undiluted in water, the test is not required. |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required |  |  |
| Persistent foaming | MT 47.2 | 502 g/l of nonanoic acid  Batch 20111102 | At 7.5% v/v:  After 10 sec : 15.3mL  After 1 min : 14.7 mL  After 3 min: 14.8 mL  After 12 min : 10.0 mL | Fieseler A., 2014  Report number 82929204 | Acceptable  The test should be performed at maximum and minimum concentration application rate, but as the product is undiluted in water, the test is not required. |
| Flowability/Pourability/Dustability |  |  | Not relevant |  |  |
| Burning rate — smoke generators |  |  | Not relevant |  |  |
| Burning completeness — smoke generators |  |  | Not relevant |  |  |
| Composition of smoke — smoke generators |  |  | Not relevant |  |  |
| Spraying pattern — aerosols |  |  | Not relevant |  |  |
| Physical compatibility |  |  | Not required |  |  |
| Chemical compatibility |  |  | Not required |  |  |
| Degree of dissolution and dilution stability |  |  | Not required |  |  |
| Surface tension | Method A.5  OECD 115 | Enclean PAE  Batch 14090 | 71.6 mN/m at 20.5°C | C. Bär, 2016, S16-01006 | Acceptable |
| Viscosity | MT 192  OECD 114 | Enclean PAE  Batch 14090 | **At 20°C:**  12.63 mPa.s-1 at 5 s-1 shear rate to 10.36 mPa.s-1 at 100 s-1 shear rate  **At 40°C:**  10.74 mPa.s-1 at 5 s-1 shear rate to 8.62 mPa.s-1 at 100 s-1 shear rate | C. Bär, 2016, S16-01003 | Acceptable |

The product ENCLEAN PAE is Another Liquid (AL) formulation, ready-to-use. 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 that of homogeneous yellowish liquid, with characteristic odour. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. Shelf-life is 24 months. **Final results of long term storage study, with spraying data before and post storage, should be provided in post-authorization.** Its technical characteristics are acceptable for an AL formulation.

**Implication concerning labelling: None**

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Method A.14  OECD 113 | Batch 201302262 | A DSC-measurement in a closed glass crucible with the test item showed no thermal effect up to the final temperature range of 320 °C. The test was stopped due to pressure build up. Thus a total energy release of 328 J/g up to a temperature of 500 “C was recorded. | Dornhagen J., 2014  Study report  20130452.01 | Tests should be performed on the biocidal product ENCLEAN PAE.  Nevertheless, based on the MSDS, none of formulant has explosive properties. Therefore, it is not expected to have explosive properties. |
| Flammable gases |  |  | Not relevant |  |  |
| Flammable aerosols |  |  | Not relevant |  |  |
| Oxidising gases |  |  | Not relevant |  |  |
| Gases under pressure |  |  | Not relevant |  |  |
| Flammable liquids |  |  | Not required |  |  |
| Flammable solids |  |  | Not relevant |  |  |
| Self-reactive substances and mixtures |  |  | According to ECHA guidance on the application of the CLP criteria, section 2.8 and annex I, 2.8.4.2, nonanoic acid product based doesn't contain of chemical groups present in the molecule associated with explosive or self-reactive properties as indicated in tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria. |  | Acceptable |
| Pyrophoric liquids |  |  | According to the additional classification considerations in CLP Annex I, 2.9.4, the classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)). |  | Acceptable |
| Pyrophoric solids |  |  | Not relevant |  |  |
| Self-heating substances and mixtures |  |  | According to Annex I 2.11.4.2 of the CLP Regulation, A self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). Nonanoic Acid is not in this case.  In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. Furthermore, Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is drastically reduced. |  | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases |  |  | According to Annex I: 2.12.4.1.of CLP Regulation, The classification procedure for this class need not be applied if:  a) the chemical structure of the substance or mixture does not contain metals or metalloids; or  b) experience in handling and use shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or  c) the substance or mixture is known to be soluble in water to form a stable mixture. |  | Acceptable |
| Oxidising liquids | Method A.21 | Purity 519 g/l  Batch 20130226-2 | The test item has no oxidising properties under the test conditions in the sense of the European Commission Regulation (EC) No. 440/2008, Method A.21. | Dornhagen J., 2014  Study report  2013045203 | Tests should be performed on the biocidal product ENCLEAN PAE.  Nevertheless, based on the MSDS, none of formulant has oxidising properties. Therefore, it is not expected to have oxidising properties. |
| Oxidising solids |  |  | Not relevant |  |  |
| Organic peroxides |  |  | Not relevant |  |  |
| Corrosive to metals |  |  | Nonanoic Acid is classified as skin corrosive H314. For all ingredients regarding corrosivity to metals, no harmonised classification is listed in Annex VI to Regulation (EC) No. 1272/2008 'CLP' and no self-classification is notified in the ECHA CLP inventory.  According to CLP criteria (Annex I §2.16), no calculation method is available for extrapolation from ingredients, and there is no exemption procedure, especially as some of them may be of concern data on corrosivity to tissues are only provided as indicative information in the case of extreme values, but do not comply with specific criteria. |  | Acceptable  According to the safety data sheet, none of the component is classified corrosive to metals H290. The biocidal product is not considered as corrosive to metals. |
| Auto-ignition temperatures of products (liquids and gases) | Method A15 | Purity 519 g/l  Batch 20130226-2 | 345°C | Dornhagen J., 2014  Study report  20130452.02 | Acceptable |
| Relative self-ignition temperature for solids |  |  | Not relevant |  |  |
| Dust explosion hazard |  |  | Not relevant |  |  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product ENCLEAN PAE is not explosive and has no oxidizing properties. The product is not considered as flammable.  **Implication concerning labelling:**  **None** |

### Methods for detection and identification

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

|  |  |
| --- | --- |
| **Report:** | **Dr. Matthias Eichler.,** **Silke Herrmann, 2014** |
| Title: | Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087 |
| Document No | Project 83241101 |
| Test facility | Institut für Biologische Analytik  und Consulting IBACON GmbH  Arheilger Weg 17  64380 Rossdorf  Germany |
| Guidelines: | SANCO/3030/99 rev.4 |
| GLP | Yes |

**Preparation of accuracy samples:**

299.70 mg and 751.74 mg of the reference item Nonanoic Acid were weighed into separate 10 mL volumetric flasks and made up to the mark using methanol.

Approximately 70 mg of the blank formulation were weighed precisely into a centrifuge tube. 1 mL of the reference item stock solution (30 g/L) and 1 mL internal standard stock solution (Tridecanoic Acid) were added.

Approximately 25 mg of the blank formulation were weighed precisely into a centrifuge tube. 1 mL of the reference item stock solution (75 g/L) and 1 mL internal standard stock solution (Tridecanoic Acid) were added.

The solutions were derivatised with 2 mL of boron trifluoride-methanol solution were added to the tube. It was shaken and heated at 50 °C during 15 minutes. After half of the time had passed the solutions were stirred or swirled for a short time. At the end of the reaction the tubes were cooled at ~4° C for 30 minutes and then slightly shaken. Methanol (1.5 mL) was added for better phase separation in the following extraction step. Thus, iso-octane (10 mL) and saturated sodium chloride solution (3 mL) were added and the tubes were shaken vigorously by hand and then centrifuged for at least 15 minutes. The top layer was separated and the extraction repeated twice with 10 mL iso-octane each time. The extracts were combined and an aliquot was transferred into an autosampler vial and then analysed by GC-FID.

**Validation of the analytical method:**

|  |  |  |
| --- | --- | --- |
| Specificity | Interferences from impurities in control samples prepared from blank formulation and blank solvent (methanol) were evaluated by comparison of total mean peak area of the target analyte in the test item samples. No interference above 3% of total peak area for target analyte.  Blank, calibration and fortified samples chromatograms were provided. | |
| Linearity | The calibration curve was obtained by correlation of peak area of eight concentrations. | |
| Compound | Linearity data |
| Nonanoic acid | 10 to 100 mg  Y = 0.0187X + 0.0143 R2 = 0.9995  N=8 |
| Precision | Repeatability was evaluated with 5 independent determinations of the formulated product, no outlier. | |
| Compound | Repeatability (RSD) |
| Nonanoic acid | RSD = 0.7% < 1.48% (RSD calculated with modified equation of Horwitz) |
| Accuracy | Accuracy was determined by analysis of 10 independent determinations (five at 300 g a.s./kg and five at 750 g a.s./kg) in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. | |
| Compound | Accuracy (recovery ) |
| Nonanoic acid | 300 g a.s./kg: 101%  750 g a.s./kg: 98% |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **C. Pointer, 2016 : Ready to use (RTU): Method Validation**  **GLP** | | | | | | | |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | |
| Analytical method | Fortification range / Number of measurements | Linearity  N=6 | Specificity | Recovery rate (%) | | | Reference |
| Range | Mean  N=5 | RSD |
| GC-FID | Two fortification levels:  75% samples (approximately 16 g/L)  125% samples (approximately 27 g/L)  Five replicates per fortification levels | The calibration was found to be linear over a range 0.5-5mg, with a regression coefficient of 1.0000. | No interference | 98.99-100.6  100.8-101.7 | 99.79  101.1 | 0.59  0.35 | Pointer C., 2016  QR98RC |

**Specificity, linearity, precision and accuracy were checked and are found acceptable.**

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

**Residues in soil**

The degradation of Nonanoic acid applied to soil occurs very rapidly (DT50(12°C) = 2.1 days, DT90(12°C) = 3.4 days) by microbial means (Study A 7.2.1/02, Doc. III-A 7.2.1/02), not through hydrolysis or photolysis. In addition, Nonanoic acid is an active substance that has been found to occur naturally in low concentrations in soil.

The natural occurrence in the environment, and the rapid metabolism and degradation of Nonanoic acid to substances, of which no concern is to be expected (please see chapter 4.1.1.1 of this document), abrogates the need to quantify Nonanoic acid residues from applications as a biocide.

**Residues in animal and human body fluids and tissues**

As the active substance Nonanoic acid is not classified as toxic or very toxic an analytical method for the determination of residues in animal and human body fluids and tissues is not required (see also Doc. III-A

4.2.d).

**Residues in food/feedstuffs**

No analytical method for the determination of Nonanoic acid in plant material is presented, because the formulation (Katzenschreck) is not designed for the application on crops intended for food or feed. In addition, Katzenschreck is not foreseen to be used in a manner which may cause contact with food and feedstuffs (see also Doc. III-A 4.3.).

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|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| An analytical method for the determination of active substance in the formulation was provided and validated.  Methods for analysis of residues were validated for Nonanoic acid in air and water:  The determination of residues in air can be performed by air-sampling of the fatty acid ingredients (i.e. Nonanoic acid) followed by acidification and esterification and determination by gas chromatography. It has to be kept in mind that Nonanoic acid is a naturally occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of biocide usage.  Nonanoic acid has been found to occur naturally in low concentrations in water. Although the degradation of Nonanoic acid applied to water happens rapidly a LC/MS method has been developed to analyze residues in water with a limit of quantification of 10 μg/L.  As Nonanoic acid is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.  An analytical method for the determination of residues of Nonanoic acid in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs. |

### Efficacy against target organisms

#### Function and field of use

Main Group 01: Disinfectants

Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals

The product ENCLEAN PAE is ready-to-use and sprayed directly on hard surfaces to kill green algae by professional and non-professional users.

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

According to the uses claimed by the applicant, the product ENCLEAN PAE is intended to be used for curative treatment against green algae on hard surfaces.

The aim of using this product is to keep the surfaces free of algae in outdoor environment.

It is also claimed the product must be applied on the targets by spraying and one application is needed. A second application is sometimes needed (2 per year).

#### Effects on target organisms, including unacceptable suffering

The product ENCLEAN PAE is used as algaecide on hard surfaces. The active substance nonanoic acid penetrates the organisms and destroys the cell walls leading to a lysis.

#### Mode of action, including time delay

The mechanism of action of nonanoic acid is the destruction of algae cell membranes. This results in an unspecific and uncontrolled release of cell contents and photosynthesis can no longer take place. Due to its lipophilic characteristics the active substance quickly penetrates into the algal cells and disrupts cell membrane permeability. The result is the destruction of the photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell contents occurs.

After application of the biocidal product the treated area is not rinsed. As the active substance is a fatty acid it will not tend to stick to the treated surface.

Hence an application has to be done only if no rain is expected.

#### Efficacy data

There is no standard test method for algaecide efficacy testing that is currently recommended in the draft guidance on efficacy assessment of biocides PT 2.

Field studies were conducted with the product ENCLEAN PAE according to an in-house methodology.

The results are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| algaecide | Walls, rooftops, pathway, driveway… | ENCLEAN PAE  nonanoic acid  21.7g/L | *Chlorophyta spp.*  *Chaetophoraceae* (genus: *Pleurococcus*)  *Prasiolaceae* (species: *Desmococcus olivaceus*)    *Chlorellaceae* (genus: *Apatococcus*)    *Prasiolaceae* (species: *Stichococcus bacillaris Nageli*) | Direct application by spraying on hard surface (plaster) covered with algae (85-88% of the total area).  6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment) | At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L).  Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application. | 250L/ha (25 mL produit/m2): 95,5% efficacy at D7 and 99,7% efficacy at D14  519L/ha (52 mL de produit/m2): 100% efficacy at D7 and D14  percentage of area covered by algae at 14 DA for untreated control: 96.7% (85% at D0) | REYNENS P., 2017  H17NNNNN01-SE01  IC: 1 |
| algaecide | Walls, rooftops, pathway, driveway… | ENCLEAN PAE  nonanoic acid  21.7g/L | *Chlorophyta spp.*  *Chlorella vulgaris* | Direct application by spraying on hard surface (cement pathway) covered with algae (100% of the total area).  6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment) | At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L).  Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application. | 250L/ha (25 mL produit/m2): 39.2% efficacy at D7 and 41,7% efficacy at D14  519L/ha (52 mL de produit/m2): 80.8% efficacy at D7 and 90,8% efficacy D14    percentage of area covered by algae at 14 DA for untreated control: 100% | Mc CONNELL K., 2017  H17NNNNN01-UK01  IC: 1 |
| algaecide | Walls, rooftops, pathway, driveway… | ENCLEAN PAE  nonanoic acid  21.7g/L | *Chlorophyta spp.* | Direct application by spraying on hard surface (glass) covered with algae (62-73% of the total area).  6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment) | At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L).  Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application. | 250L/ha (25 mL produit/m2): 94% efficacy at D7 and 92% efficacy atD14  519L/ha (52 mL de produit/m2): 100% efficacy at D7 and D14  percentage of area covered by algae at 14 DA for untreated control: 83% (62% at D0) | KEMEZYS H., 2017  R042-17H  IC: 1 |

These trials showed that the product ENCLEAN PAE is an effective algaecide against green algae (*Chlorophyta spp.*) when applied on porous and non-porous hard surface (plaster, cement and glass). The product has been tested in climatic conditions representative of uses (Belgium, Sweden, UK) as well as on several genus and species of *Chlorophyta.*

The product has been tested according to an in-house method and the application rate of 250 L/ha (25 mL produit/m2) showed a minimum efficiency of 39.2% in curative treatment at 7 days (41.7% at 14 days).

The product has been tested according to an in-house method and the application rate of 519 L/ha (52 mL de produit/m2) showed a minimum efficiency of 80.8% at 7 days in curative treatment (90.8% at 14 days).

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the submitted tests, the product ENCLEAN PAE is efficient against green algae (*Chlorophyta spp.*), at the application rate of 50 mL product /m², by spraying on porous and non-porous hard surfaces for use outdoor by professional and non-professional users.  The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. |

#### Occurrence of resistance and resistance management

For algaecide application on hard surfaces with nonanoic acid-containing products, cases of resistances are not reported or known up to the time being.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product ENCLEAN PAE, ready-to-use, has shown a sufficient efficacy, for the uses in curative treatment against green algae (*Choloryphyta spp.*), at the application rate of 50 mL product/m², by spraying on hard surfaces in green spaces and on every roof type (except thatched roof) by professional and non-professional users.

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

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

The product ENCLEAN PAE is not intended to be used with another biocidal product.

### Risk assessment for human health

ENCLEAN PAE is a product used for the disinfection and acts like an algaecide for professional and non-professional users.

ENCLEAN PAE contains 2.27% a.s (technical) and should be used at the application rate of 50 mL pb/m2.

The product is applied up to twice per year with a minimal interval of six months.

#### Assessment of effects on Human Health

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on ENCLEAN PAE.

Classification of the products has been carried out according to the calculation rules laid down in the CLP regulation.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion and irritation |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin irritation. |

***Eye irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye irritation |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for eye irritation. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin sensitization. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for oral acute toxicity. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | No study has been performed on ENCLEAN PAE.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | Only local effect are considered.  Derma absorption value is not required. |

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, ENCLEAN PAE does not contain any substance of concern.

***Available toxicological data relating to a mixture***

None

#### Exposure assessment

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

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

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Mixing and loading | **Primary exposure – Dermal exposure**  Before application, the product may be loaded into a sprayer. | Professionals and non-professionals |
| 2. | Application by spraying | **Primary exposure – dermal and inhalation exposure**  The product is applied by spray application. | Professionals and non-professionals |

In the CAR of the active substance nonanoic acid, no systemic effect have been observed and no systemic reference toxicological value has been derived. Only a qualitative risk assessment (RA) has been performed. In this context, the same approach is performed for ENCLEAN PAE containing 2.27% of nonanoic acid.

Since the active substance approval of nonanoic acid, a discussion about the local risk assessment has been initiated at the WG II 2018. This discussion will be taken in consideration at the active substance renewal.

***Industrial exposure***

Not applicable

***Professional exposure***

*Scenario [1] – Mixing and loading phase*

During the mixing and loading phase, professional users are in contact with the product that is not classified. If there is no identified hazard for the handling of the product, no risk is expected and exposure assessment is not required.

*Scenario [2] – Application phase*

During the application phase, professional users are in contact with the product that is not classified. As there is no identified hazard during the handling of the product, no risk is expected and exposure assessment is not required.

***Non-professional exposure***

*Scenario [1] – Mixing and loading phase*

During the mixing and loading phase, non-professional users are in contact with the product that is not classified. If there is no identified hazard for the handling of the product, no risk is expected and exposure assessment is not required.

*Scenario [2] – Application phase*

During the application phase, non-professional users are in contact with the product that is not classified. As there is no identified hazard during the handling of the product, no risk is expected and exposure assessment is not required.

***Exposure of the general public***

Exposure to the general public occurs with the non classified product after application.

Considering that no hazard is identified with the product, no risk is expected.

***Monitoring data***

*[Please add any information on surveys or studies with the actual product or with a surrogate.]*

***Dietary exposure***

The product ENCLEAN PAE is intended to be used on building as disinfectant and algaecide. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

*Information of non-biocidal use of the active substance*

*[Please include a section for each area of other (non-biocidal) use of the active substance. Please insert or delete rows as needed.]*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection product | Fatty acids (C7 to C20): Herbicides, acaricides, insecticides, plant growth regulators on onamentals and lawns | No MRL required (annex IV of Regulation EU 396/2005) |
| 2. | Food additives | Fatty acids (E570): food additives | No limit required (Substances included in Annex IV without prejudice to Regulation (EC) No 1333/2008 on food additives) |

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

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

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant.

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

Not relevant.

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

Not relevant.

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

***Aggregated exposure***

Not applicable

***Summary of exposure assessment***

In the CAR of the active substance nonanoic acid, no systemic effect have been observed and no systemic reference toxicological value has been derived. Only a qualitative risk assessment has been performed.

In this context, the same approach is performed for ENCLEAN PAE conatining 2.27% of nonanoic acid.

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

No systemic reference values are available for nonanoic acid.

Only local effects have been considered in the CAR.

**Maximum residue limits or equivalent**

Not required.

**Specific reference value for groundwater**

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

***Risk for industrial users***

Not applicable

***Risk for professional users***

**Local effects**

The product ENCLEAN PAE being not classified, no hazard has been identified.

Therefore, no local risk assessment is required.

**Conclusion**

The risk is considered acceptabe for professioanl users.

***Risk for non-professional users***

**Local effects**

The product ENCLEAN PAE being not classified, no hazard has been identified.

Therefore, no local risk assessment is required.

**Conclusion**

The risk is considered acceptabe for non-professioanl users.

***Risk for the general public***

**Local effects**

The product ENCLEAN PAE being not classified, no hazard has been identified.

Therefore, no local risk assessment is required.

**Conclusion**

The risk is considered acceptabe for general public.

***Risk for consumers via residues in food***

The product ENCLEAN PAE is intended to be used on building. It will not get in contact with food or feed. Residue in food or feed are not expected.

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

Not applicable.

### Risk assessment for animal health

Not applicable.

### Risk assessment for the environment

The active substance, Nonanoic acid, is used as disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2).

|  |
| --- |
| FR-CA box 1: *FR Opinion*  Please notice that the environmental risk assessment is reported as provided by the applicant. The FR CA position is presented in green evaluation boxes. |

### Aquatic compartment (incl. sediment)

To determine the risks associated with potential exposure to Nonanoic acid in surface waters, the toxicity data are summarised in IUCLID Dataset Section 9. In accordance with the Guidance on the Biocidal Products Regulation Volume IV Environment - Part B Risk Assessment, assessment factors (AF) are applied to aquatic toxicity endpoints to derive a PNEC (predicted no effect concentration), which is compared to PEC (predicted environmental concentrations) data for surface waters.

Acute data are available for all three key trophic levels (fish, invertebrates and primary producers). Chronic data are available for all three key trophic levels (fish, invertebrates and primary producers). The selected endpoint for PNEC derivation was a 72-hour NOEyCof 0.46 mg Nonanoic acid.l-1 from an algal study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Taxonomic Group** | **Acute data**  **LC/EC50**  **(mg.l-1)** | **Chronic data**  **NOEC/EC10**  **(mg.l-1)** | **AF** | **PNEC**  **(µg.l-1)** |
| Fish | 41.9 | 21 | 10 | **46** |
| Invertebrates | 56.8 | 19.3 |
| Algae | 9.56 | 0.46 |

**PNEC aqua freshwater = 46 µg.l-1**

In the absence of ecotoxicological data, a provisional PNECsediment (freshwater) is calculated using the equilibrium partitioning method. The calculation is done as following: PNECsediment = (Ksusp-water\*PNECaqua\*1000)/RHOsusp with Ksusp-water = 2.08 m3.m-3 (with a Koc of 47.3 l.kg-1) and RHOsusp = 1150 kg.m-3.

|  |  |
| --- | --- |
| **Sediment organisms** | **PNECsed**  **(mg.kg sediment wwt-1)** |
| **0.0833** |

**PNEC freshwater sediment = 0.0833 mg.kg sediment wwt-1**

### Sewage treatment plants (STP)

Based on decision No. DSH-63-3-D-0009-2014 to grant permission to refer to the relevant study, the PNECstp is taken from the Competent Authority Report for Nonanoic acid as:

**PNEC microorganisms = 5.652 mg.l-1**

### Atmosphere

The vapour pressure of Nonanoic acid at ambient temperature is 0.9 Pa (20°C) and Henry's law constant is 0.33 Pa.m3.mol-1 at 20°C (with on a water solubility of 0.2027 g.l-1). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

### Terrestrial compartment

To determine the risks associated with potential exposure to Nonanoic acid in soil, the toxicity data are summarised in IUCLID Dataset Section 9.

In accordance with the Guidance on the Biocidal Products Regulation Volume IV Environment - Part B Risk Assessment, assessment factors (AF) are applied to terrestrial toxicity endpoints to derive a PNEC (predicted no effect concentration), which is compared to PEC (predicted environmental concentrations) data for the terrestrial compartment.

Terrestrial toxicity data are available for soil microorganisms (OECD 216 and OECD 217), plants (OECD 227 – 6 species and OECD 208 – 10 species) and earthworms (OECD 207). All these studies were performed with biocide product ENCLEAN PAE and results are converted to standard soil which is defined as a soil with an organic matter content of 3.4% using the following equation:

NOEC standard = NOEC exp x F om, soil standard / F om, soil exp

(BPR Guidance Vol IV, april 2015, Eq. 71, Infobox 9).

OECD 207 Short-term (14-day) toxicity to earthworms

Original data: 14d-EC50 = 908 mg ENCLEAN PAE.kg soil dw-1

(Test soil organic matter content: 5% sphagnum peat) equivalent to 14d-EC50 = 546.6 mg a.s.kg soil-1.

Normalised data: 14d-EC50 = 371.6 mg a.s.kg soil-1 (F om, soil standard = 3.4%).

OECD 216/217 Effects on soil microorganisms

Original data: No adverse effects observed down to 27.8 mg ENCLEAN PAE.kg soil dw-1 and up to 139 mg ENCLEAN PAE.kg soil dw-1 (test soil Total Organic Carbon content: 0.99%) equivalent to 21 mg a.s.kg soil-1 and 103 mg a.s.kg soil-1.

Normalised data: No adverse effects observed down to 42.4 mg a.s.kg soil-1 and 208 mg a.s.kg soil-1. (Foc, soil standard = 2%).

OECD 227 Acute toxicity to plants (6 species)

Original data: the lowest 21d-EC50 was 3862 g.ha-1 (*Cucumis sativus*, fresh weight) (F oc, test = 0.94%).

The original ecotoxicity values are provided as L.ha-1 of formulated product and were converted as g of active substance per hectare. Then, conversion of the test result expressed to g a.s.ha-1 to mg a.s.kg-1 are derived from the test by using a default soil depth of 10 cm and soil density of 1500 kg.m-³ dry soil as recommended in BPR Guidance Vol IV (April 2015, Infobox 11):

Original ecotoxicity value / (10,000 x 0.1 x 1,500).

21d-EC50 = 2.58 mg/kg soil dw (*Cucumis sativus*, fresh weight) (Foc, test = 0.94%).

Normalised data: 21d-EC50 = 9.31 mg.kg soil dw-1 (*Cucumis sativus*, fresh weight) (F om, soil standard = 3.4%).

OECD 208 Acute toxicity to plants (10 species)

Original data: the lowest 21d-EC50 was 15935 g.ha-1 (*Lolium perenne*, dry weight). The lowest 21d-

The original ecotoxicity values are provided as L/ha of formulated product and were converted as g of active substance per hectare. Then, conversion of the test result expressed to g a.s./ha to mg a.s./kg are derived from the test by using a default soil depth of 10 cm and soil density of 1500 kg/m³ dry soil as recommended in BPR Guidance Vol IV (April 2015, Infobox 11):

Original ecotoxicity value / (10,000 x 0.1 x 1,500).

21d-EC50 was 10.6 mg.kg soil dw-1 (*Lolium perenne*, dry weight)

Normalised data: 21d-EC50 was 14.4 mg.kg soil dw-1 (*Lolium perenne*, dry weight) (F om, soil standard = 3.4%)

Plants are significantly more sensible than microorganism and earthworm. Therefore, and in accordance with the European Assessment Report of Nonanoic Acid, the 21d EC50 value of 9.31 mg as/kg dwt-1 (Cucumis sativus) is chosen to derive the PNEC soil. An AF of 100 is applied still in accordance with the AR of Nonanoic Acid. The PNEC soil is then of, 0.0931 mg as/kg dwt-1.

**PNEC soil = 0.0931 mg as/kg dwt**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 2: *FR Opinion*  Applicant proposed to derive environmental PNEC values from new toxicity data supplied by JADE on nonanoic acid.  The alternative source of active substance, nonanoic acid, included in the formulation of ENCLEAN PAE product is considered technically equivalent compared to the reference source. Moreover the active substance supplied by JADE is included in the substances and suppliers list (Article 95 list).  Considering that data supplied by JADE falls within the range values of ecotoxicity data supplied in the assessment report of Nonanoic acid, PT2, July 2013, PNEC values derived from data of the JADE source have not been taken into account.  Consequently all the data are coming from the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013).  **Summary of PNECs of the active substance Nonanoic acid**   |  |  | | --- | --- | | **Compartment** | **Nonanoic acid** | | Freshwater | 5.68E-02 mg.l-1 | | Soil | 0.099 mg.kgwwt-1 | | STP | 5.652 mg.l-1 | | Oral bird | 0.331 mg.kg food-1 | | Oral small mammal | 5 mg.kg food-1 | |

***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***

|  |
| --- |
| FR-CA box 3: *FR Opinion*  The active substance nonanoic acid is classified according to Regulation (EC) No.1272/2008 (CLP) as Aquatic Chronic 3, H412, Harmful to aquatic life with long lasting effects.  The other co-formulants of the ENCLEAN PAE product are not classified for the environment and are not considered as substances of concern for the environment. Therefore, the co-formulants are not expected to have a significant impact on the ecotoxicological classification of the ENCLEAN PAE product. Therefore, ENCLEAN PAE product is not classified according to Regulation (EC) No.1272/2008 (CLP). |

***Further Ecotoxicological studies***

|  |
| --- |
| FR-CA box 4: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

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

|  |
| --- |
| FR-CA box 5: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

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

|  |
| --- |
| FR-CA box 6: *FR Opinion*  No data is available. This endpoint is relevant only for products in the form of bait or granules. The ENCLEAN PAE product is a liquid. |

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

|  |
| --- |
| FR-CA box 7: *FR Opinion*  No data is available. This endpoint is relevant only for products in the form of bait or granules. The ENCLEAN PAE product is a liquid. |

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

|  |
| --- |
| FR-CA box 8: *FR Opinion*  No data is available. The ENCLEAN PAE product is 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 will be treated with the ENCLEAN PAE product and it can be concluded that no secondary ecological effect is expected when using the product according to the label recommendations. |

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

|  |
| --- |
| FR-CA box 9: *FR Opinion*  Please refer to section Fate and distribution in exposed environmental compartments. |

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

|  |
| --- |
| FR-CA box 10: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

***Leaching behaviour (ADS)***

|  |
| --- |
| FR-CA box 11: *FR Opinion*  No relevant for this product. |

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

|  |
| --- |
| FR-CA box 12: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

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

|  |
| --- |
| FR-CA box 13: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

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

|  |
| --- |
| FR-CA box 14: *FR Opinion*  No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid. |

***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)***

|  |
| --- |
| FR-CA box 15: *FR Opinion*  Not relevant. |

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

|  |
| --- |
| FR-CA box 16: *FR Opinion*  Not relevant. |

#### Exposure assessment

**General information**

Product PT 2 ENCLEAN PAE (500 ga.s.l-1) is an algaecide used for the curative treatment of construction materials. According to the claimed conditions of use, ENCLEAN PAE product is diluted before application to obtain a final use concentration of 18 ga.s.l-1. The application rate of the diluted preparation is of 0.05 l.m-2.

There is no existing Emission Scenario Documents (ESD) for PT2 covering use of an algaecide on construction materials; therefore, the assessment of environmental emissions for ENCLEAN PAE product has been conducted using several guidance documents. The assessment is based on models simulating spray application on hard surfaces likely to be treated by non-professionals from ESD for PT10 (Emission scenario document for biocides used as masonry preservatives, EUBEES 2002) and ESD for Product Type 8 (Revised Emission Scenario Document for Wood Preservatives, OECD 2013).

Estimation of environmental concentrations due to use and service life of ENCLEAN PAE was conducted considering three hard surface models:

* House (walls and roof) from ESD PT10
* Fence, from ESD PT8
* Bridge over pond, from ESD PT8

Releases of product are expected during application due to spray drift and run-off. Releases are also expected during service life resulting from leaching of product from treated surfaces.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 17: *FR Opinion*  According to the claimed conditions of use a final use quantity of 1.093 ga.s.m-2 has been used in the environmental exposure assessment.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | | Volume of product applied on area | V form | l.m-2 | 0.05 | S | | Content of active substance | F form | - | 0.0227 | S | | Product Density | Density | g.l-1 | 963 | D | | Quantity of active substance applied on area | M a.s. | g.m-2 | 1.093 | O |   Fence scenario is covered by House scenario and consequently, Fence approach is not presented. |

**Fate and distribution in exposed environmental compartments**

A comprehensive review of the available information on the properties of the active substance Nonanoic acid is given here below.

A summary table of some of the key characteristics of the active substance used in the exposure assessments are given below.

Physico-chemical properties

|  |  |
| --- | --- |
| **Physical chemical properties** | **Values** |
| Molecular weight (g.mol-1) | 158.2 |
| Melting point | - |
| Boiling point | - |
| Vapour pressure (Pa, at 20°C) | 0.452 |
| Octanol-water partition coefficient (as log) | 2.4 |
| Water solubility (mg.l-1 at 25°C) | 202.7 |

Degradation properties

|  |  |  |  |
| --- | --- | --- | --- |
| **Degradation properties** | **Study results** | | **Values used** |
| **Half-lives** | **IUCLID-5 Dataset**  **Point** | **Half-lives** |
| Hydrolysis as a function of pH | No hydrolysis expected | 10.1.1.1.a | N/A |
| Ready biodegradability | Readily biodegradable | 10.1.1.1.b | 0.693 h in STP |
| Biodegradation in aerated sediment (biodegradability) | Waived | 10.1.1.2 | N/A(1) |
| Biodegradation in surface water | Waived | 10.1.1.2 | N/A(1) |
| Biodegradation in soil | 3 d (20°C) | 10.2.1 | N/A(1) |
| Degradation in air | 1.096 d | 10.3.1 | N/A |

(1): not defined since assessment is carried out at local scale

Partition coefficients (adsorption)

Study on adsorption/desorption as presented and reviewed in the DAR reviewed by EFSA.

An estimation of Koc by QSAR is obtained:

|  |  |
| --- | --- |
| **Adsorption properties** | **Values used** |
| Koc | 47.3 l.kg-1 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 18: *FR Opinion*   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Phase | STP | Surface water | | Sediment | | Soil | | Groundwater | | | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | | Application | yes | yes | yes | yes | yes | yes | yes | yes | yes | | Rinsing | yes | yes | yes | yes | yes | yes | yes | yes | yes |   **Active substance: Nonanoic acid**   |  |  | | --- | --- | | **Input parameters used in the environmental exposure assessments according to the CAR (July, 2013)** | | | **Input** | **Value** | | Molecular weight [g.mol-1] | 158.238 | | Vapour pressure [Pa] | 0.9 (20°C) | | Water solubility [mg.L-1] | 445 (25°C, pH 5) | | Henry’s law constant [Pa.m3.mole-1] | 0.33 | | Kow [Log 10] | 3.52 | | Koc [L.kg-1] | 63.1 | | SLUDGERATE [kg.d-1] | 790 | | DT50 soil [d] | 2.1 (12°C) |  |  |  | | --- | --- | | **Calculated fate and distribution in the STP (EUSES model 2.1.2)** | | | **Compartment** | **Percentage [%]** | | Water | 12.60% | | Sludge | 0.591% | | Air | 0.0894% | |

**Emission estimation**

###### ***House scenario***

In order to estimate emissions during service life, emissions during rinse right after application were considered as a worst-case.

According to ESD for PT10, assessment of emissions has been performed for two types of houses: house in the country side for which all loses of product during application go to local soil and house in a city for which all loses go to storm water.

|  |  |
| --- | --- |
| **Scenario** | **Receiving compartments** |
| House in a city | Surface water, Soil, Sediment |
| House in the countryside | Soil near to application area |

Calculations were done for an area of 270 m² (145 m² roof + 125 m² walls) according to the model house proposed in OECD (2002) (used in ESD PT10).

###### ***Emissions during application***

**Table 1 Emission scenario for calculating the releases from a house treated by sprayer (ESD PT10)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** |
| Treated area per day | AREA | m².d-1 | 270 | D |
| Volume of product applied on area | V form | l.m-2 | 0.05 | S |
| Concentration on active substance | C form | g.l-1 | 18 | S |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D |
| Soil volume distant to treated surface | V soil(d) | m3 | 142.81 | D ANSES recommendation |
| Soil volume adjacent to surface treated | V soil(a) | m3 | 13 | D ANSES recommendation |
| Bulk density of wet soil | RHO soil | kgwwt.m-3 | 1700 | D |

Model calculation for spray application:

Local emission of active substance during application due to spray drift

*Elocal drift = AREA x V form x C form x F drift E-3*

Local emission of active substance during application due to runoff

*Elocal runoff = AREA x V form x C form x F runoff E-3*

**House in the countryside:**

Concentration in distant soil due to spray application

*Clocal soil (d) = Elocal drift / (V soil (d)x RHOsoil)*

Concentration in adjacent soil due to spray application

*Clocal soil (a) = Elocal runoff / (V soil (a)x RHOsoil)*

**Table 2 Concentrations in local soil due to direct emissions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil (kg.kgwwt-1)** | **Concentration in local soil (mg.kgwwt-1)** | **Concentration in local soil (mg.kgdwt-1)** |
| ESD PT10 House in the countryside | Clocal soil(d) | Soil distant to treated surface | 1.00E-07 | 1.00E-01 | 1.13E-01 |
| Clocal soil(a) | Soil adjacent to treated surface | 2.20E-06 | 2.20 | 2.49 |

**House in a city:**

Local emission of active substance during application to storm water

*Elocal water = Elocal drift + Elocal runoff*

**Table 3 Emission to local storm water**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to waste water (kg.d-1)** |
| ESD PT10 House in a city | Elocal water | Storm water (connected to the sewer system) | 7.30 E-2 |

The potential environmental loadings from storm water are considered to determine PECs in STP, surface water and sediment.

Emission rate to storm water is used to calculate the PEC in the relevant compartments based on models described in EU Technical Guidance on Risk Assessment TGD (2003).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 19: *FR Opinion*  **House scenario – Application**  The equations from the ESD PT10 have been considered with the revised soil volumes as defined for the approbation of the active substance nonanoic acid. Concentrations in local soil and emission to local storm water have been revised considering a use quantity of 1.093 ga.s.m-2 following this approach:  **Concentrations in local soil due to direct emissions**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil (mg.kgwwt-1)** | | ESD PT10  House in the countryside | Clocal soil(d) | Soil distant to treated surface | 1.22E-01 | | Clocal soil(a) | Soil adjacent to treated surface | 2.67 |   **Emission to local storm water**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to waste water (kg/d)** | | ESD PT10 House in a city | Elocal water | Storm water (connected to the sewer system) | 8.85E-2 | |

###### ***Emissions during service-life: Rinse (100% wash-off)***

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost were not considered as application and rinse are performed during the same day.

**Table 4 Emission scenario for calculating the releases from a house during rinse (ESD PT10)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Treated area per day | AREA | m².d-1 | 270 | D | ESD PT10 |
| Concentration on active substance | C form | g.l-1 | 18 | S | ESD PT10 |
| Volume of diluted product applied on area | V form | l.m-2 | 0.05 | S |  |
| Fraction of rinsing solution lost during rinse due to runoff | F runoff rinse | - | 0.75 | D | ESD PT10 |
| Fraction of rinsing solution lost during rinse by spray drift | F drift rinse | - | 0.25 | D | ESD PT10 |
| Soil volume distant to treated surface | V soil(d) | m3 | 142.81 | D | ESD PT10 |
| Soil volume adjacent to surface treated | V soil(a) | m3 | 13 | D | ESD PT10 |
| Bulk density of wet soil | RHO soil | kgwwt.m-3 | 1700 | D | ESD PT10 |
| Concentration in soil distant to treated surface | Clocal soil(d) | Kg.Kgwwt-1 | - | O |  |
| Concentration in soil adjacent to treated surface | Clocal soil(a) | Kg.Kgwwt-1 | - | O |  |

Model calculation for releases during rinse

Local emission of active substance during rinse due to drift

*Elocal rinse drift =AREA x V form x C form x F drift rinse x (1-(F drift+ F runoff)) E-3*

Local emission of active substance during rinse due to runoff

*Elocal rinse runoff =AREA x V form x C form x F drift runoff x (1-(F drift+ F runoff)) E-3*

**Table 5 Emissions during rinse**

|  |  |  |
| --- | --- | --- |
| **Usage scenario** | **Symbol** | **Local emission of active substance during rinse**  **(kg.d-1)** |
| ESD PT10  House in the countryside | Elocal rinse drift | 4.26E-02 |
| Elocal rinse runoff | 1.28E-01 |

**House in the countryside:**

Concentration in distant soil due to spray application and rinse

*Clocal soil rinse (d) = Elocal rinse drift / (V soil (d) x RHO soil) + C local soil (d)*

Concentraton in adjacent soil due to spray application and rinse

*Clocal soil rinse (a ) = Elocal runoff drift / (V soil (a) x RHO soil) + C local soil (a)*

**Table 6 Concentrations in local soil due to direct emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil**  **(kg.kgwwt-1)** | **Concentration in local soil**  **(mg.kgdwt-1)** |
| ESD PT10  House in the countryside | Clocal soil (d) | Soil distant to treated surface | 2.76E-07 | 3.12E-01 |
| Clocal soil (a) | Soil adjacent to treated surface | 7.98E-06 | 9.02 |

**House in a city:**

Local emission of active substance during application to storm water

*Elocal water rinse = Elocal drift rinse + Elocal runoff rinse*

**Table 7 Emission to local storm water**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to waste water (kg.d-1)** |
| ESD PT10  House in a city | Elocal water | Storm water  (connected to the sewer system) | 1.28E-01 |

The potential environmental loadings for these usage scenarios are considered to determine the PECs in STP, surface water and sediment.

The emission rates are used to calculate the PEC in the relevant compartments based on models described in EU Technical Guidance on Risk Assessment TGD (2003).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 20: *FR Opinion*  **House scenario – Rinsing (by a rainfall event)**  Considering a final use quantity of 1.093 ga.s.m-2 , concentrations in local soil and emission to local storm water have been revised.  **Emissions during rinse**   |  |  |  | | --- | --- | --- | | **Usage scenario** | **Symbol** | **Local emission of active substance during rinse only (kg.d-1)** | | ESD PT10  House in the countryside | Elocal rinse drift | 5.16E-02 | | Elocal rinse runoff | 1.55E-01 |   **Concentrations in local soil due to direct emissions following rinsing only**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil**  **(mg.kgwwt-1)** | | ESD PT10  House in the countryside | Clocal soil (d) | Soil distant to treated surface | 2.13E-01 | | Clocal soil (a) | Soil adjacent to treated surface | 7.01 |   **Concentrations in local soil due to direct emissions following application and rinsing**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil**  **(mg.kgwwt-1)** | | ESD PT10  House in the countryside | Clocal soil (d) | Soil distant to treated surface | 3.34E-01 | | Clocal soil (a) | Soil adjacent to treated surface | 9.68 |   **Emission to local storm water following rinsing only**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to waste water (kg.d-1)** | | ESD PT10  House in a city | Elocal water | Storm water  (connected to the sewer system) | 2.07E-01 | |

###### ***Emissions due to the use of the product on bridge over pond***

Calculations were done considering two guidance documents. Characteristics of the bridge are from ESD PT8 and models and parameters governing spray application (losses of product, etc.) are from ESD PT10.

###### ***Emissions during application***

**Table 8 Emission scenario for calculating the releases from a bridge treated by sprayer (ESD PT10 and ESD PT8)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Treated area per day | AREA | m².d-1 | 10 | D | ESD PT8 |
| Volume of product applied on area | V form | l.m-2 | 0.05 | S | ESD PT8 |
| Concentration on active substance | C form | g.l-1 | 18 | S | ESD PT8 |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Water volume under bridge | V water | m3 | 1000 | D | ESD PT8 |

Fraction of product lost during brush application initially described in ESD PT8 is replaced by fractions of product lost due to spray drift and runoff described in ESD PT10 (spray application on House).

Local emission of active substance during application due to spray drift

*Elocal drift = AREA x V form x C form x F drift E-3*

Local emission of active substance during application due to runoff

*Elocal runoff = AREA x V form x C form x F runoff E-3*

Emission to local water during day of emission

*Elocal water = Elocal drift + Elocal runoff*

Local concentration in water (pond) during day of emission

*Clocal water = Elocal water / V water*

**Table 9 Emission to local water and concentration in water during application**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** |
| PT10: Spray application PT8: Pond under bridge | Elocal water | Pond under bridge | **Emission rate to water (kg.d-1):**  2.70 E-06 |
| Clocal water | Pond under bridge | **Concentration in water (Kg.l-1):**  2.70 E-09 |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 21: *FR Opinion*  **Bridge over pond scenario – Application**  Considering a final use quantity of 0.936 ga.s.m-2, emission to local water and concentration in water during application have been revised.  **Emission to local water and concentration in water during application**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** | | PT10: Spray application PT8: Pond under bridge | Elocal water | Pond under bridge | **Emission rate to water (kg.d-1):**  3.28E-03 | | Clocal water | Pond under bridge | **Concentration in water (mg.l-1):**  3.28E-03 | |

###### ***Emissions during service-life: Rinse (100% wash-off)***

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost during the same day were not considered as application and rinse are performed during the same day.

**Table 10 Emission scenario for calculating the releases from a bridge during rinse (ESD PT10)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Treated area per day | AREA | m².d-1 | 10 | D | ESD PT10 |
| Concentration on active substance | C form | g.l-1 | 18 | S | ESD PT10 |
| Volume of diluted product applied on area | V form | l.m-2 | 0.05 | S |  |
| Fraction of rinsing solution lost during rinse due to runoff | F runoff rinse | - | 0.75 | D | ESD PT10 |
| Fraction of rinsing solution lost during rinse by spray drift | F drift rinse | - | 0.25 | D | ESD PT10 |
| Water volume under bridge | V water | m3 | 1000 | D | ESD PT8 |

Model calculation for releases during rinse

Local emission of active substance during rinse due to drift

*Elocal rinse drift =AREA x V form x C form x F drift rinse x (1-(F drift + F runoff)) E-3*

Local emission of active substance during rinse due to runoff

*Elocal rinse runoff =AREA x V form x C form x F drift runoff x (1-(F drift + F runoff)) E-3*

*Clocal water rinse = Clocal water + (Elocal rinse drift  + Elocal rinse runoff )/ V water*

**Table 11 Concentration in local water due to spray application and rinse**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** |
| PT10 : Spray application PT8: Pond under bridge | Clocal water rinse | Pond under bridge | **Concentration in water (mg.l-1):**  9.01E-09 |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 22: *FR Opinion*  **Bridge over pond scenario – Application + rinsing (by a rainfall event)**  Considering a final use quantity of 1.093 ga.s.m-2, concentration in local water due to spray application and rinse (by a rainfall event) has been revised.  **Concentration in local water due to spray application and rinse**   |  |  |  |  | | --- | --- | --- | --- | | **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** | | PT10 : Spray application PT8: Pond under bridge | Clocal water rinse | Pond under bridge | **Concentration in water (mg.l-1):**  1.09E-02 | |

###### ***Emissions due to the use of the product on fence:***

Calculations were done considering two guidance documents. Characteristics of the fence are from ESD PT8 and models and parameters governing spray application (losses of product, volume of soil receiving product, etc.) are from ESD PT10.

###### ***Emissions during application***

**Table 12 Emission scenario for calculating the releases from a fence treated by sprayer (ESD PT10 and ESD PT8)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Treated area per day | AREA | m².d-1 | 2 | D | ESD PT8 |
| Volume of product applied on area | V form | l.m-2 | 0.05 | S | ESD PT8 |
| Concentration on active substance | C form | g.l-1 | 18 | S | ESD PT8 |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Soil volume distant to treated surface | V soil(d) | m3 | 2.85 | D  Based on ANSES recommandations for House scenarios \* | ESD PT10 |
| Soil volume adjacent to surface treated | V soil(a) | m3 | 0.26 | D  Based on ANSES recommandations for House scenarios \* | ESD PT10 |
| Bulk density of wet soil | RHO soil | kgwwt.m-3 | 1700 | D | ESD PT8 |

\*Input parameter calculated from default values of dimensions of receiving compartment considering spraying application, provided by ANSES for ESD PT 10 House model.

Concentration in distant soil due to spray application

*Clocal soil (d) = Elocal drift / (V soil (d) x RHO soil)*

Concentration in adjacent soil due to spray application

*Clocal soil (a) = Elocal runoff / (V soil (a) x RHO soil)*

**Table 13 Concentration in local soil due to direct emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil (mg.kgwwt-1)** | **Concentration in local soil (mg.kgdwt-1)** |
| PT10 : Spray application  PT8: Pond under bridge | Clocal soil(d) | Soil distant to treated surface | 5.2E-09 | 5.82E-03 |
| PT10 : Spray application  PT8: Pond under bridge | Clocal soil(a) | Soil adjacent to treated surface | 2.12E-05 | 23.96 |

###### ***Emissions during service-life: Rinse (100% wash-off)***

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost during the same day were not considered as application and rinse occurred during the same day.

**Table 14 Emission scenario for calculating the releases from a fence during rinse (ESD PT10)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Treated area per day | AREA | m².d-1 | 2 | D | ESD PT10 |
| Concentration on active substance | C form | g.l-1 | 18 | S | ESD PT10 |
| Volume of diluted product applied on area | V form | l.m-2 | 0.05 | S |  |
| Fraction of rinsing solution lost during rinse  due to runoff | F runoff rinse | - | 0.75 | D | ESD PT10 |
| Fraction of rinsing solution lost during rinse  by spray drift | F drift rinse | - | 0.25 | D | ESD PT10 |
| Concentration in soil distant to treated surface | Clocal soil (d) | Kg.kgwwt-1 | - | O |  |
| Concentration in soil adjacent to treated surface | Clocal soil (a) | Kg.kgwwt-1 | - | O |  |

Model calculation for releases during rinse

Local emission of active substance during rinse due to drift

*Elocal rinse drift =AREA x V form x C form x F drift rinse x (1-(F drift + F runoff))E-3*

Local emission of active substance during rinse due to runoff

*Elocal rinse runoff =AREA x V form x C form x F drift runoff x (1-(F drift + F runoff))E-3*

Concentration in distant soil due to spray application and rinse

*Clocal soil rinse (d) = Clocal soil (d) + Elocal rinse drift / (V soil (d) x RHO soil)*

Concentration in adjacent soil due to spray application and rinse

*Clocal soil rinse (a) = Clocal soil (a) + Elocal runoff drift / (V soil (a) x RHO soil)*

**Table 15 Concentration in local soil due to direct emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil (Kg.kgwwt-1)** | **Concentration in local soil (mg.kgdwt-1)** |
| PT10: Spray application  PT8: Pond under bridge | Clocal soil (d) | Soil distant to treated surface | 1.41E-08 | 1.60E-02 |
| PT10: Spray application  PT8: Pond under bridge | Clocal soil (a) | Soil adjacent to treated surface | 7.69E-05 | 86.87 |

|  |
| --- |
| FR-CA box 23: *FR Opinion*  **Fence scenario**  Emission scenario for calculating the releases from a fence is covered by house scenario. No further comments. |

**Calculated PEC values**

###### ***PEC in STP, surface water, and sediment***

PEC in STP, surface water and sediment have been calculated for “House in a city” scenario, where environmental emissions are made to the drains and potential concentrations of the active substance can be expected in these compartments.

Emissions due to losses during application and service life of ENCLEAN PAE product on houses in a city (270 m² of treated area) previously estimated were used for calculations. The predicted environmental concentration (PEC) of the active substance Nonanoic acid in STP, surface water and sediment has been determined using the general procedures for exposure to STP described in the Technical Guidance Document (TGD) on risk assessment[[2]](#footnote-2). This level of assessment is deemed adequate for the purposes of this exposure assessment and further refinements are not considered necessary.

The PEC calculations are based on the environmental emissions determined above. The local emissions are assumed to be discharged to a STP facility and the concentration of Nonanoic acid entering the STP is calculated using TGD models.

Emissions from indirect environmental exposure was calculated considering several number of potential treated houses connected to the same STP. The scenarios are described as below:

* One treated house per day connected to a STP
* *3152 treated houses per day connected to the same STP, based on 15 million of potentially concerned houses in France according to JADE’s previsions without any refinement (60 million of French people, divided by 4 manufacturers that produce similar biocide product as ENCLEAN PAE). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[[3]](#footnote-3)). The obtained fraction of potentially treated houses was then reported to the default number of 4000 houses connected to the same STP provided by ESD PT10 for city scenario. This simulation is considered as a worst case, as it considers that 100% (80% of French individual houses) the potentially concerned houses are treated the same day with ENCLEAN PAE product.*
* *57 treated houses per day connected to the same STP. Based on the maximum number of houses treated the same day leading to an acceptable risk for all environmental compartments without any refinement. A rate of 57 houses per STP corresponds to a number of 271 305.8 houses (based on the previous INSEE ref.) at a national scale (1% of French individual houses).*
* *1909 treated houses connected to the same STP. In order to provide a more realistic evaluation, a factor of simultaneity of treatments of houses with ENCLEAN PAE was taken into account as for a refinement. The number of 1909 houses corresponds to the maximum number of treated houses leading to acceptable risks for environmental compartments considering a factor of simultaneity of 0.03. This factor is provided by the ESD for PT18 “Emission Scenario Document For Insecticides, Acaricides and Products to control Arthropods for Household and Professional Uses”[[4]](#footnote-4), 2008. It is used to estimate emission rates of an active substance to the sewage system per day following applications of outdoor insecticides. This factor is considered as sufficiently conservative as outdoor algaecides are intended to be used at a lower frequency than outdoor insecticides. A rate of 1909 houses per STP corresponds to a number of 9 362 086.8 houses at a national scale (48 % of French individual houses which is a realistc worst case).*

|  |
| --- |
| FR-CA box 24: *FR Opinion*  Take into account a number of 3152 treated houses per day connected to the same STP, or of 1909 treated houses, appears unrealistic. A default number of houses connected to the same STP of 4000 is provided in the guidance on the Biocidal Products Regulation, Volume IV, Part B. That corresponds to 78.8 % and 47.72% of houses treated the same day by the ENCLEAN PAE Product, respectively. It is therefore not realistic to take these two values (3152 and 1909 treated houses) into account for the environmental evaluation.  According to the city scenario: leaching from paints, plasters and fillers applied in urban areas (2015), a number of houses treated daily (N house, application) depends on the service life of the product. N house, application is calculated by the formula below and the result will be rounded up:  Where:   * Nhouse, city = number of houses in a city (4000); * Service life = service life of the preserved products (0.5 year, the ENCLEAN PAE product is applied twice per year); * 365 = number of days in a year.   To conclude, emissions from indirect environmental exposure was calculated considering 22 treated houses per day connected to the same STP. |

**Table 16 PECstp**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | | **Local release to waste water (kg/d)** | **Local concentration in untreated wastewater Clocalinf (mg.l-1)** | **STP-effluent concentration (mg.l-1) (PECSTP)** |
| Emission due to application | One treated house (per day) | 7.30E-02 | 3.65E-02 | 4.58E-03 |
| 3152 treated houses (per day) | 2.30E+02 | 1.15E+02 | 1.44E+01 |
| 57 treated houses (per day) | 4.16 | 2.08 | 2.61E-01 |
| 1909 treated houses (refined with a simultaneity factor) | 4.18 | 2.09 | 2.62E-01 |
| Emission due to rinse (worst case) | One treated house (per day) | 1.28E-01 | 6.40E-2 | 8.04E-03 |
| 3152 treated houses (per day) | 4.03E+02 | 2.02E+02 | 2.53E+01 |
| 57 treated houses (per day) | 7.30 | 3.65 | 4.58E-01 |
| 1909treated houses (refined with a simultaneity factor) | 7.33 | 3.67 | 4.60E-01 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 25: *FR Opinion*  Application and rinsing are performed the same day; consequently emissions to STP can be added.  **PEC stp - (house scenario – application and rinsing by a rainfall event)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Usage scenario** | | **Local release to waste water (kg/d)** | **Local concentration in untreated wastewater Clocal inf (mg.l-1)** | **STP-effluent concentration (mg.l-1) (PECSTP)** | | 22 treated houses (per day) | Application | 1.67 | 9.74E-01 | 1.23E-01 | | Application + rinsing | 5.56 | 3.25 | 4.09E-01 | |

Using the effluent concentration estimated and the default dilution parameters, the surface water and sediment concentrations can be calculated as below:

**Table 17 PECsw**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | | **Local concentration in surface water Clocalwater**  **(mg.l-1) (PECsw)** | **Local concentration sediment**  **(mg.kg wwt-1) PECsed** |
| Emission due to application | One treated house (per day) | 4.58E-04 | 8.29E-04 |
| 3152 treated houses (per day) | 4.59E-03 | 8.31E-03 |
| 57 treated houses (per day) | 2.61E-02 | 4.73E-02 |
| 1909 treated houses (refined with a simultaneity factor) | 2.62E-02 | 4.75E-02 |
| Emission due to rinse (worst case) 100% wash-off | One treated house (per day) | 8.04E-04 | 1.46E-03 |
| 3152 treated houses (per day) | 2.53 | 4.58 |
| 57 treated houses (per day) | 4.58E-02 | 8.29E-02 |
| 1909 treated houses (refined with a simultaneity factor) | 4.60E-02 | 8.32E-02 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 26: *FR Opinion*  **PEC surface water *via* STP (house scenario – application and rinsing by a rainfall event)**   |  |  |  | | --- | --- | --- | | **Usage scenario** | | **Local concentration in surface water C local water (mg.l-1) (PEC sw)** | | 22 treated houses (per day) | Application | 1.23E-02 | | Application + rinsing | 4.09E-02 |   **PEC surface water – Direct release (Bridge scenario - application and rinsing by a rainfall event)**   |  |  | | --- | --- | | **Usage scenario** | **Local concentration in surface water C local water (mg.l-1) (PEC sw)** | | Application | 3.28E-03 | | Application and rinsing by a rainfall event | 1.09E-02 | |

###### ***PEC in soil and groundwater***

The use of the biocidal product leads to a soil exposure.

For “House in the countryside” and “Fence” scenario, direct emissions of Nonanoic Acid to soil are considered. A summary of results obtained previously is presented below;

In a first Tier, PEC soil due to direct releases to soil (Runoff and spray drift) were calculated without considering degradation of the substance in accordance with ESD PT10 and ESD PT8.

**Table 18 Tier 1, PEC soil for direct soil exposure**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | | **Receiving Compartment** | **Concentration in local soil (kg.kgwwt-1)** | **Concentration in local soil (mg.kgdwt-1)** |
| Application | House in the countryside | Soil distant to treated surface | 1.00E-07 | 1.13E-01 |
| Soil adjacent to treated surface | 2.20E-06 | 2.49E+00 |
| Fence | Soil distant to treated surface | 5.2E-09 | 5.82E-03 |
| Soil adjacent to treated surface | 2.12E-05 | 2.40 |
| Service life (rinse) 100% wash-off | House in the countryside | Soil distant to treated surface | 2.76E-07 | 3.12E-01 |
| Soil adjacent to treated surface | 7.10E-05 | 9.02 |
| Fence | Soil distant to treated surface | 1.24E-08 | 1.40E-02 |
| Soil adjacent to treated surface | 7.69E-05 | 8.69 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 27: *FR Opinion*  Application and rinsing (by a rainfall event) are performed the same day; consequently emissions to soil can be added. Fence scenario is covered by House scenario.  **Tier 1, PEC soil for direct soil exposure (house scenario)**   |  |  |  | | --- | --- | --- | | **Usage scenario** | **Receiving Compartment** | **Initial concentration in local soil (mg.kgwwt-1)** | | Emission due to application | Soil distant to treated surface | 1.22E-01 | | Soil adjacent to treated surface | 2.67 | | Emission due to rinsing | Soil distant to treated surface | 2.13E-01 | | Soil adjacent to treated surface | 7.01 | | Emission due to application + rinsing | Soil distant to treated surface | 3.34E-01 | | Soil adjacent to treated surface | 9.68 | |

In a second Tier, PEC soil were calculated taking degradation processes into account. A degradation rate of k = 0.231 d-1 was applied to initial concentrations in soil, based on a half-life of nonanoic acid in soil of 3 days. In accordance with the guidance on the Biocidal Products Regulation Volume IV[[5]](#footnote-5), concentrations in soil were averaged over 30 days in order to evaluate risk to terrestrial ecosystems.

The following equation was used to calculate concentrations in soil averaged over 30 days, taking degradation processes into account:

Concentration in receiving soils due over 30 days:

*C local soil (30 days) =C local soil (initial) \* Exp (-k/30)*

**Table 19 Tier 2, PEC soil for direct soil exposure**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | | **Receiving Compartment** | **Concentration in local soil (mg/kgdwt)** |
| Application | House in the countryside | Soil distant to treated surface | 1.0E-04 |
| Soil adjacent to treated surface | 2.43E-03 |
| Fence | Soil distant to treated surface | 4.10E-05 |
| Soil adjacent to treated surface | 8.99E-04 |
| Service life (rinse) 100% wash-off | House in the countryside | Soil distant to treated surface | 1.13E-04 |
| Soil adjacent to treated surface | 3.26E-03 |
| Fence | Soil distant to treated surface | 1.40E-02 |
| Soil adjacent to treated surface | 8.69 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 28: *FR Opinion*  According to the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013), a worst case scenario taking into account degradation processes has been carried out The calculations below demonstrate the degradation of this amount of the active substance as a function of time (days) aiming to present the number of days it will take to reach the PNEC soil meeting an acceptable risk.  A half-life of nonanoic acid in soil of 2.1 days is used to estimate PEC soil with degradation processes. *Clocal soil (30 days) =Clocal soil (initial) \*Exp(-k\*t)*  **Tier 2, PEC soil for direct soil exposure (application + rinsing)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Usage scenario** | **Receiving Compartment** | **Concentration in local soil (mg.kgwwt-1)** | | | |  | | 0 day | 7 days | 14 days | | Emission due to application | Soil distant to treated surface | 1.22E-01 | 1.21E-02 | 1.20E-03 | | Soil adjacent to treated surface | 2.67 | 2.65E-01 | 2.63E-02 | | Emission due to rinsing | Soil distant to treated surface | 2.13E-01 | 2.11E-02 | 2.09E-03 | | Soil adjacent to treated surface | 7.01 | 6.96E-01 | 6.90E-02 | | Emission due to application + rinsing | Soil distant to treated surface | 3.34E-01 | 3.32E-02 | 3.29E-03 | | Soil adjacent to treated surface | 9.86 | 9.61E-01 | 9.53E-02 |   Due to degradation and according to the half-life of 2.1 days, concentrations of Nonanoic acid in soil after 15 days is below the PNEC soil of 0.0990 mg.kgwwt-1, if 100% of the product leaches from 1 treated house in 1 day into the soil adjacent to the house. |

* For “House in a City” scenario where emissions are directed to sewage systems, indirect emissions via sludge loadings on soil must be determined. Therefore, PECs in soil were calculated using EU TGD models as it has been done previously for STP, surface water and sediment assessment.

**Table 20 PEC soil considering indirect exposure**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Usage scenario** | | | **Local PEC in agricultural soil averaged over 30 days (PECsoil) (mg.kgdwt-1)** | **Local PEC in agricultural soil averaged over 180 days (PECsoil) (mg.kgdwt-1)** | **Local PEC in grassland averaged over180 days (PECsoil) (mg.kgdwt-1)** |
| PT10 House in a city | Application | One treated house (per day) | 4.63E-04 | 1.35E-04 | 4.61E-05 |
| 3152 treated houses (per day) | 1.46 | 4.25E-01 | 1.45E-01 |
| 57 treated houses (per day) | 2.64E-2 | 7.70E-03 | 2.63E-03 |
| 1909 treated houses (refined with a simultaneity factor) | 2.65E-02 | 7.73E-03 | 2.64E-03 |
| Service-life (rinse) 100 % wash-off | One treated house (per day) | 8.11E-04 | 2.36E-04 | 8.08E-05 |
| 3152 treated houses (per day) | 2.56 | 7.46E-01 | 2.55E-01 |
| 57 treated houses (per day) | 4.63E-02 | 1.35E-02 | 4.61E-03 |
| 1909 treated houses (refined with a simultaneity factor) | 4.65E-02 | 1.36E-02 | 4.63E-03 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 29: *FR Opinion*  It has been considered that 22 houses are treated on a single day by ENCLEAN PAE product. Application and rinsing (by a rainfall event) are performed the same day; consequently emissions to soil can be added.  A fraction to sludge of 0.6% and a half-life of nonanoic acid in soil of 2.1 days have been considered according to Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013).  **PEC soil for indirect soil exposure**   |  |  |  | | --- | --- | --- | | **Usage scenario** | **Local PEC in agricultural soil averaged over 30 days (PEC soil) (mg.kgwwt-1)** | **Local PEC in agricultural soil averaged over 180 days (PEC soil) (mg.kgwwt-1)** | | Emission due to application - 22 treated houses (per day) | 2.15E-03 | 3.59E-04 | | Emission due to application + rinsing (by a rainfall event) - 22 treated houses (per day) | 7.18E-03 | 1.20E-03 | |

According to the OECD ESD on wood preservatives (Appendix 4, p. 178)[[6]](#footnote-6) for substances with low Kocs or high DT50s in soil there is a concern for groundwater and an assessment must be made.

Therefore, potential environmental emissions of nonanoic acid to groundwater have been assessed above, based on available guidances.

Simulations were conducted using two modelling softwares: FOCUS PELMO (v5.5.3) and FOCUS PEARL (4.4.4) and following the FOCUS working group recommendations (FOCUS, 2000[[7]](#footnote-7), 2009[[8]](#footnote-8) and 2011[[9]](#footnote-9)).

As realistic worst-case, an overall vulnerability corresponding to the 90th percentile of predicted concentration in groundwater is defined. This is approximated by combining a 80th percentile value for soil and a 80th percentile value for weather. The softwares and the different scenario properties are described in the FOCUS document (FOCUS, 2000).

Location of the scenarios and the main properties are shown in the table below.

**Figure 9.6-1 Location of the 9 groundwater scenarios (excerpt from FOCUS, 2009)**



**Table 21 Properties of the 9 groundwater scenarios**

| **Location** | **Mean Annual Temp. (°C)** | **Annual Rainfall**  **(mm)** | **Topsoil** | **Org. matter**  **(%)** |
| --- | --- | --- | --- | --- |
| Châteaudun | 11.3 | 648 + I\* | Silty clay loam | 2.4 |
| Hamburg | 9.0 | 786 | Sandy loam | 2.6 |
| Jokioinen | 4.1 | 650 | Loamy sand | 7.0 |
| Kremsmünster | 8.6 | 899 | loam/silt loam | 3.6 |
| Okehampton | 10.2 | 1038 | loam | 3.8 |
| Piacenza | 13.2 | 857 + I\* | Loam | 2.2 |
| Porto | 14.8 | 1150+ I\* | loam | 2.5 |
| Sevilla | 17.9 | 493+ I\* | Silt loam | 1.6 |
| Thiva | 16.2 | 500 + I\* | loam | 1.3 |

\* I: Irrigation

Groundwater assessment has been performed for a realistic worst-case scenario according to the guidance document “Groundwater exposure assessment for wood preservatives Factors to consider”. This worst-case scenario is defined by applications of a biocidal product on 35 houses per hectare, corresponding to a total treated area of 4375 m² per hectare. According to the guidance document, the assessment is based on ten applications a year of an intended rate of biocidal product split by ten.

Use conditions claimed by the Applicant are presented below:

|  |  |  |
| --- | --- | --- |
| **Conditions** | **Values** | **Unit** |
| Concentration on ENCLEAN PAE product | 500 | g as.l-1 |
| Volume of ENCLEAN PAE product used for 100 m² area to be treated | 0.18 | l |
| Volume of diluted product for 100 m² area to be treated | 5 | l |
| Surface to be treated | 100 | m² |
| Concentration in diluted product (ready to use) | 18 | g as.l-1 |
| Application rate of substance | 0.9 | g as.m-2 |

According to the worst-case scenario defined previously with a total treated area of 4375 m².ha -1, the application rate in kilograms per hectare taken into account for ground water assessment is about 3.39375 kg as.ha-1 per year (Application rate (g.m-²) x Area (m².ha-1) .1000-1).

In order to weight over time the exposition of Nonanoic Acid, the single application of 3.39375 kg as /ha per year is split into 10 applications about 0.3937 kg as /ha per year.

Parameters used for the groundwater assessment are presented below:

|  |  |
| --- | --- |
| **Input** | **Values** |
| Molecular weight (g.mol-1) | 158.2 |
| Vapour pressure (Pa, at 20°C) | 0.9 |
| Octanol-water partition coefficient (as log) | 2.4 |
| Water solubility (mg.l-1 at 25°C) | 202.7 |
| Koc (soil) (L/kg) | 47.3 |
| DT50soil (at 20°C) (d) | 3 |
| Freundlich exponent (-) | 0.9 |
| Split application rate (kg.ha-1) | 0.39375 |
| Nb applications (year-1) | 10 |
| Crop | Grass |

Chosen dates for split applications are presented below:

|  |  |
| --- | --- |
|  | **Date of split applications** |
| **1st Application** | 15/01 |
| **2nd Application** | 15/03 |
| **3rd Application** | 15/04 |
| **4th Application** | 15/05 |
| **5th Application** | 15/06 |
| **6th Application** | 15/07 |
| **7th Application** | 15/08 |
| **8th Application** | 15/09 |
| **9th Application** | 15/11 |
| **10th Application** | 15/12 |

Nine realistic worst-case scenarios have been defined, which collectively represent agricultural use in the EU.

Results for the two FOCUS models are presented in tables below.

| Scenario | **80th Percentile PECGW at 1 m Soil Depth (μg.l-1)** | |
| --- | --- | --- |
| **PELMO 5.5.4** | **PEARL4.4.4** |
| Châteaudun | <0.001 | <0.001 |
| Hamburg | <0.001 | 0.010 |
| Jokioinen | <0.001 | 0.001 |
| Kremsmünster | <0.001 | <0.001 |
| Okehamtpon | 0.001 | 0.014 |
| Piacenza | 0.001 | 0.020 |
| Porto | 0.002 | 0.063 |
| Sevilla | <0.001 | 0.003 |
| Thiva | <0.001 | <0.001 |

For both simulations, PECs gw are all below the threshold of 0.1 µg.l-1.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 30: *FR Opinion*  In a worst case approach, groundwater assessment has been revised considering the inputs parameters from the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013). Application dose has been estimated in taking into account the amount used for 35 houses spread over 12 annual applications per year.   | **Input parameter PEARL 4.4.4** | **Unit** | **Value** | **Reference** | | --- | --- | --- | --- | | **Product name : ENCLEAN PAE** | | | | | **Substance name : Nonanoic acid** | | | | | **Physicochemical parameters** | | | | | Molecular weight | g.mol-1 | 158.238 | AR | | Water solubility (20 °C, pH 5) | mg.l-1 | 415 | AR | | Molar enthalpy of dissolution | kJ.mol-1 | 27 | Default | | Saturated vapour pressure (20°C) | Pa | 0.9 | AR | | Molar enthalpy of vaporisation | kJ.mol-1 | 95 | Default | | Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 | Default | | Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 | Default | | **Degradation parameters** | | | | | Half-life (, pF2) (12°C) | d | 2.1 | AR | | Arrhenius activation energy | kJ.mol-1 | 65.4 | Default | | Exponent of moisture correction function | - | 0.7 | Default | | **Sorption parameters** | | | | | Koc value | l.kg-1 | 63.1 | AR | | Komvalue (20°C) | ml.g-1 | 36.6 | AR | | Freundlich exponent 1/n | - | 1 | Default | | Method of subroutine description | - | pH independent | - | | **Crop related parameters** | | | | | Crop uptake factor | - | 0 | Default | | **Application Schemes** | | | | | Dosage | kg.ha-1 | 0.861 |  | | D = (1.093 gas.m-2\*270 m2 \*35 houses) / 12 = 0.732 | | | | Application type | - | To the soil surface | / | | Repeat interval for years | - | 1 |  | | Date | - | 15/01 | The product can be applied anytime in the year. | | 15/02 | | 15/03 | | 15/04 | | 15/05 | | 15/06 | | 15/07 | | 15/08 | | 15/09 | | 15/10 | | 15/11 | | 15/12 | | **Crops Application** | | | | | Crop(s) | - | **Grassland** | | | Selected Locations | | CHATEAUDUN | | | HAMBURG | | | JOIKIONEN | | | KREMSMUENSTER | | | OKEHAMPTON | | | PIACENZA | | | PORTO | | | SEVILLA | | | THIVA | |   **Results**   | Scenario | **80th Percentile PECGW at 1 m Soil Depth (μg.l-1)** | | --- | --- | | **PEARL4.4.4** | | Châteaudun | <0.001 | | Hamburg | <0.001 | | Jokioinen | <0.001 | | Kremsmünster | <0.001 | | Okehamtpon | <0.001 | | Piacenza | <0.001 | | Porto | <0.001 | | Sevilla | <0.001 | | Thiva | <0.001 | |

###### ***PEC in air***

The vapour pressure of Nonanoic acid at ambient temperature 0.9 Pa (20°C) and Henry's law constant is 0.33 Pa.m3.mol-1 at 20°C (with a water solubility of 0.2027 g/L). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

|  |  |
| --- | --- |
| **Usage scenario** | **Concentration in air during emission episode (mg/m3)** |
| PT10: House in a city | 1) 2.78E-9  2) 7.50E-9 |

|  |
| --- |
| BOX 31: *FR Opinion*  Not relevant. |

#### Risk characterisation

Regarding cases as exposed in section 2.4 of the present document, risk characterisation for indirect environmental exposure was calculated considering several number of potential treated houses connected to the same STP. The scenarios are described as below:

* One treated house per day connected to a STP
* *3152 treated houses per day connected to the same STP, based on 15 million of potentially concerned houses in France according to JADE’s previsions without any refinement (60 million of French people, divided by 4 manufacturers that produce similar biocide product as ENCLEAN PAE). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[[10]](#footnote-10)). The obtained fraction of potentially treated houses was then reported to the default number of 4000 houses connected to the same STP provided by ESD PT10 for city scenario. This simulation is considered as a worst case, as it considers that 100% (80% of French individual houses) the potentially concerned houses are treated the same day with ENCLEAN PAE product.*
* *57 treated houses per day connected to the same STP. Based on the maximum number of houses treated the same day leading to an acceptable risk for all environmental compartments without any refinement. A rate of 57 houses per STP corresponds to a number of 271 305.8 houses (based on the previous INSEE ref.) at a national scale (1% of French individual houses).*
* *1909 treated houses connected to the same STP. In order to provide a more realistic evaluation, a factor of simultaneity of treatments of houses with ENCLEAN PAE was taken into account as for a refinement. The number of 1909 houses corresponds to the maximum number of treated houses leading to acceptable risks for environmental compartments considering a factor of simultaneity of 0.03. This factor is provided by the ESD for PT18 “Emission Scenario Document For Insecticides, Acaricides and Products to control Arthropods for Household and Professional Uses”[[11]](#footnote-11), 2008. It is used to estimate emission rates of an active substance to the sewage system per day following applications of outdoor insecticides. This factor is considered as sufficiently conservative as outdoor algaecides are intended to be used at a lower frequency than outdoor insecticides. A rate of 1909 houses per STP corresponds to a number of 9 086 362.8 houses at a national scale (48 % of French individual houses) which is a realistic worst case.*

|  |
| --- |
| FR-CA box 31: *FR Opinion*  An emission from indirect environmental exposure was calculated considering 22 treated houses connected to the same STP (Please see BOX 24 for more explanation). |

**Aquatic compartment**

Predicted Environmental Concentrations (PEC) for the aquatic compartment

Due to the highly conservative nature of the emission scenarios considered, the estimated PEC values are likely to be over estimates. Furthermore, as a worst-case situation, no removal or loss mechanisms are taken into account and due to the retentive properties of the active substance in the environment, it is considered that the majority of the emitted amounts will not actually make it from the point source to the STP location.

Assessment of risk for the aquatic compartment

The risk assessment is based on a comparison of the PNEC value for the aquatic compartment with the relevant PEC value. A PEC/PNEC ratio of less than one indicates that the risks are acceptable associated with the use of formulated products containing Nonanoic acid.

**Table 22 Summary of the PECsw and PNECsw values together with the PEC/PNEC values**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Used Scenario** | | | **Worst-case**  **PEC sw**  **(mg.l-1)** | **PNEC sw**  **(mg.l-1)** | **Worst-case**  **PEC/PNEC ratio** |
| **House scenario PT10** | One treated house (per day) | Releases during application | 4.58E-04 | 4.6E-2 | 9.96E-03 |
| Releases during rinsing | 8.04E-04 | 1.75E-02 |
| 3152 treated houses (per day) | *Releases during application* | *1.44* | *3.14E+01* |
| *Releases during rinsing* | *2.53* | *5.50E+01* |
| 57 treated houses (per day) | *Releases during application* | *2.61E-02* | *5.68E-01* |
| *Releases during rinsing* | *4.58E-02* | *9.95E-01* |
| 1909 treated houses (refined with a simultaneity factor) | *Releases during application* | *2.62E-02* | *5.70E-01* |
| *Releases during rinsing* | *4.60E-02* | *9.998E-01* |
| Bridge over pond scenario PT8 | | Releases during application | 2.70E-03 | 5.87E-02 |
| Releases during rinsing | 9.01E-03 | 1.96E-01 |

As PNECsed was calculating, the PECsed/PNECSed ratio is increased by a factor of 10 in order to take uptake via ingestion of sediment into account. (BPR: Volume IV Part B Risk Assessment Version 1.0 April 2015.).

**Table 23 Summary of the PECsed and PNECsed values together with the PEC/PNEC** **values**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Used Scenario** | | | Worst-case  PEC sed  (mg.Kgwwt-1) | PNEC sed  (mg.Kgwwt-1) | Worst-case  PEC/PNEC ratio x 10 |
| **House scenario PT10** | One treated house (per day) | Releases during application | 8.29E-04 | 0.0833 | 9.95E-03 |
| Releases during rinsing | 1.46E-03 | 1.75E-02 |
| 3152 treated houses (per day) | *Releases during application* | *2.61* | *3.14*E*+01* |
| *Releases during rinsing* | *4.58* | *5.50E+01* |
| 57 treated houses (per day) | *Releases during application* | *4.73E-02* | *5.67E-01* |
| *Releases during rinsing* | *8.29E-02* | *9.95E-01* |
| 1909 treated houses (refined with a simultaneity factor) | *Releases during application* | *4.75E-02* | *5.70E-01* |
| *Releases during rinsing* | *8.32E-02* | *9.99E-01* |
| Bridge over pond scenario PT8 | | Releases during application | 4.89E-03 | 5.87E-02 |
| Releases during rinsing | 0.0163 | 1.96E-01 |

These PEC/PNEC ratios indicate that no unacceptable risks to sediment dwelling biota arise from the use of the formulations containing Nonanoic acid, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day.

Considering the claim of the applicant, the risk for aquatic organisms is acceptable.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 32: *FR Opinion*  **PEC/PNEC values for surface water**   |  |  |  | | --- | --- | --- | | **Used Scenario** | | **PEC/PNEC ratio** | | **Indirect releases via the STP**  **House scenario PT10 -** 22 treated houses (per day) | Releases during application | 2.16E-01 | | Releases during application + rinsing | 7.20E-01 | | **Direct releases**  **Bridge over pond scenario PT8** | Releases during application | 5.77E-02 | | Releases during application + rinsing | 1.92E-01 |   The sediment risk assessment is equal to the aquatic risk assessment as both PEC sediment and the PNEC sediment have been calculated by EPM from the PEC local,water and the PNEC aquatic, respectively.  **Conclusion**: the risk for aquatic organisms is acceptable. |

**STP compartment**

Predicted environmental concentrations (PEC)

Summary of the PECSTP and PNECSTP values together with the PEC/PNEC values (Worst-case assumptions - STP compartment)

**Table 24 Summary of the PECstp and PNECstp values together with the PEC/PNEC values**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Used Scenario | | | Worst-case  PECSTP  (mg.l-1) | PNECSTP  (mg.l-1) | Worst-case  PEC/PNEC ratio |
| **House scenario PT10** | One treated house (per day) | Releases during application | 4.58E-03 | 5.652 | 8.10E-04 |
| Releases during rinsing | 8.04E-03 | 1.42E-03 |
| 3152 treated houses (per day) | *Releases during application* | *1.44E+01* | *2.55* |
| *Releases during rinsing* | *2.53E+01* | *4.48* |
| 57 treated houses (per day) | *Releases during application* | *2.62E-01* | *4.64E-02* |
| *Releases during rinsing* | *4.60E-01* | *8.14E-02* |
| 1909 treated houses (refined with a simultaneity factor) | *Releases during application* | *4.58E-01* | *8.10E-02* |
| *Releases during rinsing* | *8.03E-01* | *1.42E-01* |

For all scenarios, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day, the risk is acceptable for STP micro-organisms. The sub-scenario was adjusted considering use claimed by the applicant.

According to the Risk Assessment TGD supporting Commission Directive 93/67/EEC for new notified substances, Commission Regulation (EC) No 1488/94 for existing substances and Directive 98/8/EC for biocidal products, this indicates that no unacceptable risks to sewage micro-organisms arise from the use of the formulations containing Nonanoic acid.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 33: *FR Opinion*  **PEC/PNEC values for stp**   |  |  |  | | --- | --- | --- | | **Used Scenario** | | **PEC/PNEC ratio** | | **Indirect releases via the STP**  **House scenario PT10 -** 22 treated houses (per day) | Releases during application | 2.17E-02 | | Releases during application + rinsing | 7.24E-02 |   **Conclusion**: the risk for STP organisms is acceptable. |

**Atmosphere**

The vapour pressure of Nonanoic acid at ambient temperature is 0.9 Pa (20°C) and Henry's law constant is 0.33 Pa.m3.mol-1 at 20°C (with on a water solubility of 0.2027 g/L). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

|  |
| --- |
| FR-CA box 34: *FR Opinion*  Not relevant. |

**Terrestrial compartment**

According to usage patterns described, emissions of the active substance to soil are considered to occur via STP sludge loadings after STP treatment; therefore, PECs in soil and groundwater have been calculated.

***Indirect Emissions to soil***

PECsoil due indirect releases via sludge application were calculated for 1, 57 and 3152 houses considering releases to STP occurring the same day. PECsoil were also calculated for 1909 houses considering a simultaneity factor of 0.03.

Averaged over 30 days PECsoil due to indirect emission of substance to agricultural soil via sludge application and PEC/PNEC ratio are presented in table below:

**Table 25 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Indirect releases to soil**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Used Scenario | | | | PECsoil (30d)  (mg.Kgdwt-1) | PNECsoil (mg.Kgdwt-1) | PEC/PNEC ratio |
| **PT10 House** | **House in a city (agricultural soil)** | One treated house (per day) | Releases during application | 4.63E-04 | 0.0931 | 4.97E-03 |
| Releases during rinsing (100%wash-off) | 8.11E-04 | 8.71E-03 |
| 3152 treated houses (per day) | *Releases during application* | *1.46* | *1.57E+01* |
| *Releases during rinsing (100%wash-off)* | *2.56* | *2.75E+01* |
| 57 treated houses (per day) | *Releases during application* | *2.64E-02* | *2.83E-01* |
| *Releases during rinsing (100%wash-off)* | *4.63E-02* | *4.97E-01* |
| 1909 treated houses (refined with a simultaneity factor) | *Releases during application* | *2.65E-02* | *2.85E-01* |
| *Releases during rinsing (100%wash-off)* | *4.65E-02* | *4.99E-01* |

Regarding the scenario “House in a city” use, except the unrealistic scenario, all scenario lead to an acceptable risk regarding indirect release to soil after treatment even with rinsing.

***Direct Emissions to soil***

Tier 1 PECsoil due to direct emissions to adjacent soil and associated PEC/PNEC ratios are presented in table below. In Tier one, PECsoils were calculated without taking degradation processes into account.

**Table 26 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Direct releases to soil - T1, without degradation process.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Used Scenario | | PECsoil  (mg.Kgdwt-1) | PNECsoil  (mg.Kgdwt-1) | PEC/PNEC ratio |
| **House in the countryside**  (soil adjacent to the treated area application) | Releases during application | 2.49 | 0.0931 | 26.7 |
| Releases during rinsing (100%wash-off) | 9.02 | 96.9 |
| **Fence scenario PT8 (soil adjacent to the treated area)** | Releases during application | 0.92 | 9.89 |
| Releases during rinsing (100%wash-off) | 3.34 | 35.83 |

As a first-tier approach, and without taking into account degradation process, Risk to soil following a direct release is always unacceptable. A tier 2 approach with a refinement is therefore necessary and degradation properties of nonanoic acid are considered.

Tier 2 PECsoil due to direct emissions to adjacent soil and associated PEC/PNEC ratios are presented in table below. In second Tier, PECsoils were calculated taking degradation processes into account and averaged over 30 days.

**Table 27 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Direct releases to soil – T2 with degradation process as a refinement.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Used Scenario | | PECsoil  (mg.Kgdwt-1) | PNECsoil  (mg.Kgdwt-1) | PEC/PNEC ratio |
| **House in the countryside**  (soil adjacent to the treated area application) | Releases during application | 2.43E-03 | 0.0931 | 2.61E-02 |
| Releases during rinsing (100%wash-off) | 8.81E-03 | 9.46E-02 |
| **Fence scenario PT8**  (soil adjacent to the treated area) | Releases during application | 8.99E-04 | 9.65E-03 |
| Releases during rinsing (100%wash-off) | 3.26E-03 | 3.50E-02 |

According to the Risk Assessment TGD supporting Commission Directive 93/67/EEC for new notified substances, Commission Regulation (EC) No 1488/94 for existing substances and Directive 98/8/EC for biocidal products, this indicates that no unacceptable risks to terrestrial organisms arise from the use of the formulations containing Nonanoic acid when considering application on urban houses, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day.

All Tier 1 PEC/PNEC ratios for direct releases to soil are >1. In a higher tier, when taking degradation processes of nonanoic acid in soil into account, no unacceptable risks to terrestrial organisms.

No unacceptable risks to terrestrial organisms arise from the use of ENCLEAN PAE product on urban houses, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day, even with rinsing after treatment.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 35: *FR Opinion*  ***Indirect Emissions to soil - PEC/PNEC values***   |  |  |  | | --- | --- | --- | | **Used Scenario** | | **PEC/PNEC ratio** | | **House city scenario PT10 -** 22 treated houses (per day) | Releases during application | 2.18E-02 | | Releases during application + rinsing | 7.25E-02 |   **Indirect emission to soil:** the risk for soil organisms is acceptable.  ***Direct Emissions to soil - PEC/PNEC values - with degradation process as a refinement***   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Usage scenario** | **Receiving Compartment** | **PEC/PNEC ratio** | | | |  |  | **0 day** | **7 days** | **14 days** | | Emission due to application | Soil distant to treated surface | **1.23** | 11.22E-01 | 1.21E-02 | | Soil adjacent to treated surface | **26.97** | **2.68** | 2.66E-01 | | Emission due to rinsing | Soil distant to treated surface | **2.15** | 2.13E-01 | 2.11E-02 | | Soil adjacent to treated surface | **70.81** | **7.03** | 6.97E-01 | | Emission due to application + rinsing | Soil distant to treated surface | **3.37** | 3.35E-01 | 3.32E-02 | | Soil adjacent to treated surface | **99.60** | **9.71** | 9.63E-01 |   **Direct emission to soil:** PEC/PNEC ratio is acceptable on day 14 after application. According to Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013), the mode of action of the active substance is a physical effect on plant cell walls which affects cell wall integrity. Due to its lipophilic characteristics the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. Because of this quick penetration, it is expected that after 6 hours only a fractional amount is disposable. Consequently the following risk mitigation measures are recommended, in order to avoid any possible harm:   * During the application, the soil and plants adjacent to the treated area shall be protected to avoid emission to soil compartment * Products can only be used if the weather forecasts show no rain for the day of application.   Based on the PEC/PNEC calculations in combination with the proposed risk mitigation measures the risk for soil organisms through direct exposure to Nonanoic acid is considered to be acceptable.  **Conclusion**: In accordance with the conclusions of Nonanoic acid CAR, the risk for soil organisms can be considered acceptable. |

**Primary and secondary poisoning**

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| FR-CA box 36: *FR Opinion*  The log Kow of Nonanoic acid is 3.52, slightly higher than the threshold value of 3 indicates the substance may bioaccumulate (according to the guidance on the BPR: Volume IV – Part B).  However, it should be considered that :   * Nonanoic acid is rapidly biodegradable; * Nonanoic acid is a fatty acid. Fatty acids are ubiquitous available in the environment and important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems). Thus in predators no negative effects would be expected in concentrations higher than the concentrations tested and used for risk assessment accordingly. * Nonanoic acid is metabolized via ß-oxidation. This is quantitatively the most significant pathway for catabolism of fatty acids and results in the final products CO2 and acetyl-CoA which as such are further metabolized to CO2 and water.   The calculated BCF fish for Nonanoic acid is 195.88 l.kg-1 and the BCF in earthworms is 40.57 l.kg-1. In addition to the facts and arguments given above, together with the knowledge on metabolism and biological properties of fatty acids, sufficient evidence is given of the non-bioaccumulating properties of Nonanoic acid.  **Conclusion**: Considering all arguments above, the risk for fish eating and worm eating predators is acceptable. The non-compartment specific effects of secondary poisoning are low for the aquatic and terrestrial food chain. |

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| **Overall conclusion on the risk assessment for the environment of the product** |
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### Measures to protect man, animals and the environment

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

### Assessment of a combination of biocidal products

Not relevant.

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author(s) | Year | Title Source Company Report No. GLP or GEP Status (where relevant) Published or not | Member State Data Protection Claimed (Y/N) | **Owner** |
| Fieseler A. | 2014 | Determination of the Accelerated Storage Stability of VVH 86087  Report number 82929204 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Low Temperature Stability of VVH 86087  Report number 82928204 | Y | JADE |
| Dornhagen J. | 2014 | Oxidising properties  Study report 2013045203 | Y | JADE |
| Dornhagen J. | 2014 | Explosive properties  Study report 20130452.01 | Y | JADE |
| Dornhagen J. | 2014 | Auto-ignition temperature  Study report 20130452.02 | Y | JADE |
| Dr. Matthias Eichler., Silke Herrmann | 2014 | Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087  Project 83241101 | Y | JADE |
| C. Bär | 2016 | Determination of Free Acidity / Alkalinity of Enclean Prêt à l'emploi  S16-01013 | Y | JADE |
| C. Bär | 2016 | Relative Density of Enclean Prêt à l'emploi  S16-01010 | Y | JADE |
| C. Bär | 2016 | Surface Tension of Enclean Prêt-à-l'emploi  S16-01006 | Y | JADE |
| C. Bär | 2016 | Viscosity of Enclean Prêt à l'emploi  S16-01003 | Y | JADE |
| C. Pointer | 2016 | Ready to use (RTU): Method Validation | Y | Belchim |

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| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Philippe REYNENS | 2017 | Determination of efficacy of biocide  BCP1011H against Algae on impermeable surfaces, R042-17H, not published, Philippe REYNENS, 17 May 2017 | Yes | Jade | 2017.06.07 |
| McConnell Kirsty | 2017 | Determination of efficacy of biocide  BCP1011H against Algae on impermeable surfaces, H17NNNNN, not published, McConnell Kirsty,  26 April 2017 | Yes | Jade | 2017.06.07 |
| Andrius Hansen KEMEZYS | 2017 | Determination of efficacy of biocide  BCP1011H against Algae on impermeable surfaces (painted plaster wall), Trial no. H17NNNNN01-SE01, Andrius Hansen Kemezys, 28 April 2017 | Yes | Jade | 2017.06.07 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author(s) | Year | Title Source Company Report No. GLP or GEP Status (where relevant) Published or not | Member State Data Protection Claimed (Y/N) | **Owner** |
| Pointer C. | 2016 | Enclean: Persistent Foaming  Study Number: BT88JV | Y | Belchim Crop Protection NV |
| Fieseler A. | 2014 | Determination of the Accelerated Storage Stability of VVH 86087  Report number 82929204 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Low Temperature Stability of VVH 86087  Report number 82928204 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Relative Density of VVH 86087  Report number 82921182 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Surface Tension of an aqueous solution of VVH 86087  Report number 82927184 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Viscosity of VVH 86087  Report number 82926196 | Y | JADE |
| Dornhagen J. | 2014 | Oxidising properties  Study report 2013045203 | Y | JADE |
| Dornhagen J. | 2014 | Explosive properties  Study report 20130452.01 | Y | JADE |
| Dornhagen J. | 2014 | Auto-ignition temperature  Study report 20130452.02 | Y | JADE |
| Dr. Matthias Eichler., Silke Herrmann | 2014 | Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087  Project 83241101 | Y | JADE |

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| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of access** | | **Data protection claimed** | | **Essential studies for evaluation** | |
|  |  |  |  |  |  | **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
|  |  | F. RICHEUX | 2012 | VVH 86086  EVALUATION OF ACUTE ORAL TOXICITY IN  RATS - ACUTE TOXIC CLASS METHOD | JADE |  | x | x |  | x |  |
|  |  | F. RICHEUX | 2012 | VVH 86086  EVALUATION OF ACUTE DERMAL TOXICITY  IN RATS | JADE |  | x | x |  | x |  |
|  |  | F. RICHEUX | 2014 | VVH 86087  ASSESSMENT OF ACUTE DERMAL  IRRITATION | JADE |  | x | x |  | x |  |
|  |  | F. RICHEUX | 2014 | VVH 86087  ASSESSMENT OF ACUTE EYE IRRITATION | JADE |  | x | x |  | x |  |
|  |  | F. RICHEUX | 2012 | VVH 86086  ASSESSMENT OF SENSITISING PROPERTIES  ON ALBINO GUINEA PIGS  Maximisation test according to MAGNUSSON  AND KLIGMAN | JADE |  | x | x |  | x |  |

## Output tables from exposure assessment tools

## New information on the active substance

## Residue behaviour

The product ENCLEAN PAE is intended to be used on building as disinfectant and algaecide. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

## Summaries of the efficacy studies (B.5.10.1-xx)[[12]](#footnote-12)

## Confidential annex

Please refer to the Confidential annex file.

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Technical Guidance document (TGD) on Risk Assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Part II (2003). [↑](#footnote-ref-2)
3. Le parc de logements en France au 1er janvier 2014, INSEE Références, 2014 (<http://www.insee.fr/fr/themes/document.asp?ref_id=if16>) as consulted the 17th November 2016. [↑](#footnote-ref-3)
4. OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18. EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES, IOMC, 2008 [↑](#footnote-ref-4)
5. Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), V.1 April 2015, ECHA [↑](#footnote-ref-5)
6. Groundwater exposure assessment for wood preservatives Factors to consider [↑](#footnote-ref-6)
7. SANCO/321/2000 rev.2: FOCUS groudwater scenarios in the EU review of active substances. [↑](#footnote-ref-7)
8. FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp [↑](#footnote-ref-8)
9. FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater assessments, Version 2.0, January 2011. [↑](#footnote-ref-9)
10. Le parc de logements en France au 1er janvier 2014, INSEE Références, 2014 (http://www.insee.fr/fr/themes/document.asp?ref\_id=if16) [↑](#footnote-ref-10)
11. OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18. EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES, IOMC, 2008 [↑](#footnote-ref-11)
12. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-12)