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

Product type 2

Nonanoic acid

Case Number in R4BP: BC-WQ019988-93

Evaluating Competent Authority: FR

Date: June 2018

Updated: May 2020

Table of Contents

[Table of Contents 2](#_Toc35943850)

[*1* CONCLUSION 5](#_Toc35943851)

[*2* ASSESSMENT REPORT 7](#_Toc35943852)

[2.1 Summary of the product assessment 7](#_Toc35943853)

[2.1.1 Administrative information 7](#_Toc35943854)

[**2.1.1.1** Identifier of the product 7](#_Toc35943855)

[**2.1.1.2** Authorisation holder 7](#_Toc35943856)

[**2.1.1.3** Manufacturer(s) of the products 7](#_Toc35943857)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 8](#_Toc35943858)

[2.1.2 Product composition and formulation 8](#_Toc35943859)

[**2.1.2.1** Identity of the active substance 8](#_Toc35943860)

[**2.1.2.2** Candidate(s) for substitution 9](#_Toc35943861)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 9](#_Toc35943862)

[**2.1.2.4** Information on technical equivalence 9](#_Toc35943863)

[**2.1.2.5** Information on the substance(s) of concern 9](#_Toc35943864)

[**2.1.2.6** Type of formulation 9](#_Toc35943865)

[2.1.3 Hazard and precautionary statements 9](#_Toc35943866)

[2.1.4 Authorised use(s) 10](#_Toc35943867)

[**2.1.4.1** Use description 10](#_Toc35943868)

[**2.1.4.2** Use-specific instructions for use 11](#_Toc35943869)

[**2.1.4.3** Use-specific risk mitigation measures 11](#_Toc35943870)

[**2.1.4.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc35943871)

[**2.1.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 11](#_Toc35943872)

[**2.1.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc35943873)

[2.1.5 General directions for use 12](#_Toc35943874)

[**2.1.5.1** Instructions for use 12](#_Toc35943875)

[**2.1.5.2** Risk mitigation measures 12](#_Toc35943876)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc35943877)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 13](#_Toc35943878)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc35943879)

[2.1.6 Other information 13](#_Toc35943880)

[2.1.7 Packaging of the biocidal product 13](#_Toc35943881)

[2.1.8 Documentation 14](#_Toc35943882)

[**2.1.8.1** Data submitted in relation to product application 14](#_Toc35943883)

[**2.1.8.2** Access to documentation 14](#_Toc35943884)

[2.2 Assessment of the biocidal product 14](#_Toc35943885)

[2.2.1 Intended use(s) as applied for by the applicant 14](#_Toc35943886)

[2.2.2 Physical, chemical and technical properties 15](#_Toc35943887)

[2.2.3 Physical hazards and respective characteristics 26](#_Toc35943888)

[2.2.4 Methods for detection and identification 30](#_Toc35943889)

[2.2.5 Efficacy against target organisms 32](#_Toc35943890)

[**2.2.5.1** Function and field of use 32](#_Toc35943891)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 33](#_Toc35943892)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 33](#_Toc35943893)

[**2.2.5.4** Mode of action, including time delay 33](#_Toc35943894)

[**2.2.5.5** Efficacy data 33](#_Toc35943895)

[**2.2.5.6** Occurrence of resistance and resistance management 36](#_Toc35943896)

[**2.2.5.7** Known limitations 36](#_Toc35943897)

[**2.2.5.8** Evaluation of the label claims 36](#_Toc35943898)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 37](#_Toc35943899)

[2.2.6 Risk assessment for human health 37](#_Toc35943900)

[**2.2.6.1** Assessment of effects on Human Health 37](#_Toc35943901)

[**2.2.6.2** Exposure assessment 45](#_Toc35943902)

[**2.2.6.3** Risk characterisation for human health 49](#_Toc35943903)

[2.2.7 Risk assessment for animal health 53](#_Toc35943904)

[2.2.8 Risk assessment for the environment 53](#_Toc35943905)

[**2.2.8.1** Effects assessment on the environment 53](#_Toc35943906)

[Aquatic compartment (incl. sediment) 53](#_Toc35943907)

[Sewage treatment plants (STP) 54](#_Toc35943908)

[Atmosphere 54](#_Toc35943909)

[Terrestrial compartment 54](#_Toc35943910)

[**2.2.8.2** Exposure assessment 59](#_Toc35943911)

[2.2.9 Measures to protect man, animals and the environment 100](#_Toc35943912)

[2.2.10 Assessment of a combination of biocidal products 100](#_Toc35943913)

[*3* Annexes 101](#_Toc35943914)

[3.1 List of studies for the biocidal product 101](#_Toc35943915)

[3.2 Output tables from exposure assessment tools 103](#_Toc35943916)

[3.3 New information on the active substance 103](#_Toc35943917)

[3.4 Residue behaviour 103](#_Toc35943918)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 103](#_Toc35943919)

[3.6 Confidential annex 103](#_Toc35943920)

[3.7 Other 103](#_Toc35943921)

**Note to the reader:**

This PAR proposed for the first authorisation of ENCLEAN, granted by France (FR) on 2018, has been updated after administrative change and mutual recognition in sequence.

In part 2.1 of the updated PAR the “proposal for decision” corresponds to the summary of product characteristics related to the updated decision.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-WQ019988-93 | 15/10/2018 | National authorisation |
| NA-TRS | *FR* | BC-HH050652-48 | 07/06/2019 | Transfer of a national authorization (JADE to Belchim Crop Protection NV) and addition of trade names |
| NA-ADC | *FR* | BC-JP052848-13 | 07/10/2019 | Addition of trade names |
| NA-ADC | *FR* | BC-KA056063-62 | 05/02/2020 | Addition of trade names |
| NA-APP | *FR* | BC-WQ019988-93 | 30/06/2020 | Updated of national authorisation following mutual recognitions in sequence and post-authorization data submission |
| NA-ADC | *FR* | BC-QQ060547-12 | 18/11/2020 | Addition of trade names |

# CONCLUSION

***Conclusion for Physico-chemical properties and analytical methods:***

The product ENCLEAN is an Emulsionable Concentrate (EC) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is 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, confirmed by the post-authorization data submitted, is 24 months. Its technical characteristics are acceptable for an EC formulation.

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

Analytical method for the determination of nonanoic acid in the biocidal formulation was provided and considered validated.

Methods for analysis of residues were validated for Nonanoic acid in air and water.

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.

***Conclusion for Efficacy:***

In conclusion, in accordance with the submitted tests, the product ENCLEAN is efficient against green algae (Chlorophyta spp.) by spraying after dilution 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 professional users, due to the classification of the product, facial exposure to splashes during mixing and loading has to be limited by the use of PPE (eye protection/goggles) and application of technical and organisational RMMs.

For practical reasons, the larger packaging sizes (over 1L) will be restricted to professional users only.

***Conclusion for Dietary risk assessment:***

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.

***Conclusion for Environment:***

Considering the intended use of ENCLEAN, the product shows unacceptable risks for terrestrial compartment via direct release.

Following risk mitigation measures shall be established in order to protect the environment:

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

Moreover, regarding the environmental profile of the a.s. (readily biodegradability, low potential of bioaccumulation, half-time life in soil and air...), the risk for environment can be considered acceptable.

This temporary exceedance of risk can only be accepted only for this product with nonanoic acid when considering all RMM.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| ENCLEAN | FR |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BELCHIM CROP PROTECTION NV  |
| **Address** | TECHNOLOGIELAAN 71840 LONDERZEELBELGIUM  |
| **Authorisation number** |  |
| **Date of the authorisation** |  |
| **Expiry date of the authorisation** |  |

#### 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** | Nonanoic acid (Pelargonic acid) |
| **Name of manufacturer** | Nantong Shenyu Green Medicine CO, Ltd |
| **Address of manufacturer** | D-E Block, 9th floor, 251, Ledu Road, songiiang District201600ShanghaiChina |
| **Location of manufacturing sites** | Yangkou Chemical Industry Zoon, Rudong County, Jiangsu Province201600ShanghaiChina |

### 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 [x]

#### 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 OAfficher 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[[2]](#footnote-3)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Nonanoic acid | Nonanoic acid | Active substance (technical) | 112-05-0 | 203-931-2 | 53.97 |

####

#### Information on technical equivalence

The decision on technical equivalence from ECHA published in January 2017 confirms that the alternative source of nonanoic acid 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[[3]](#footnote-4)

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

| **Classification** |
| --- |
| Hazard category | **Eye Irrit 2** |
| Hazard statement | **H412:** Harmful to aquatic life with long lasting effects.**H319:** Causes serious eye irritation. |
|  |
| **Labelling** |
| Signal words | Warning |
| Hazard statements | **H412:** Harmful to aquatic life with long lasting effects.**H319:** Causes serious eye irritation. |
| Precautionary statements | **P101:** If medical advice is needed, have product container or label at hand.**P102:** Keep out of reach of children.**P264:** Wash … thoroughly after handling.**P273:** Avoid release to the environment.**P280:** Wear protective gloves/protective clothing/eye protection/face protection.**P305 + P351 + P338:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.**P337 + P313:** If eye irritation persists get medical advice/attention.**P501**: Dispose of contents/container in accordance with local regulations. |
|  |
| Note | **EUH 066:** Repeated exposure may cause skin dryness or cracking. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Algaecide – Hard surfaces

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) |
| **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 after dilution directly on the surfaces to be treated. |
| **Application rate(s) and frequency** | Application rate: 0.0018 L (undiluted product)/m2The product should be diluted in water before application to obtain the application rate validated.Product must be diluted by mixing 1 part product to 28 parts of water.After dilution with water, the surface treated by packaging type is the following:F-HDPE bottles: * 0.125L is sufficient to treat 69 m2,
* 0.2L is sufficient to treat 111 m2,
* 0.25L is sufficient to treat 139 m2,
* 0.4L is sufficient to treat 222 m2,
* 0.5L is sufficient to treat 278 m2,
* 0.8L is sufficient to treat 444 m2,
* 1L is sufficient to treat 556 m2,

F-HDPE cans: * 3L is sufficient to treat 1667 m²,
* 5L is sufficient to treat 2778 m2,
* 10L is sufficient to treat 5556 m2,
* 15L is sufficient to treat 8333 m2,
* 20L is sufficient to treat 11111 m2,

F-HDPE barrels: * 200L is sufficient to treat 111111 m2,
* 640L is sufficient to treat 355556 m2,

F-HDPE tank: * 1000L is sufficient to treat 555556 m2,

Up to two applications per year  |
| **Category(ies) of users** | Non-professional, Professional |
| **Pack sizes and packaging material** | Professionnal:F-HDPE bottles: 125 mL, 200 mL, 250 mL, 400 mL, 500 mL, 800 mL, 1LF-HDPE cans: 3L, 5L, 10L, 15L, 20LF-HDPE barrels: 200L, 640LF-HDPE tank: 1000LNon-professional:F-HDPE bottles: 125 mL, 200 mL, 250 mL, 400 mL, 500 mL, 800 mL, 1L |

#### 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.
* The diluted solution should be used immediately.
* Only apply this product with a handheld manually operated low pressure (3 bar or below) device preferably in combination with a spraying shield.
* Stir during application.
* 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 ground and plants adjacent to the treated area shall be protected to avoid emission to environment.
* During the mixing and loading, facial exposure to splashes has to be limited.
* For professional users, the use of PPE and the application of technical RMM are required:
* Eye protection;
* Minimisation of splashes and spills;
* Minimise number of people exposed.
* For non-professional users:
* Minimisation of splashes and spills by pouring slowly the product from the bottle to the sprayer;
* Avoid contact with eyes.
 |

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

|  |
| --- |
| * 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.
* Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.
* Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting.
* Inhalation of dust: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
* In case of impaired consciousness place in recovery position and seek medical advice immediately.
* Keep the container or label available.
 |

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

|  |
| --- |
| * 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

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

### Other information

|  |
| --- |
| * The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).
* A measuring cap is attached to the bottles of the product for non-professional users.
* The dilution modalities of the product and the use rates of the diluted product must appear on the label.
 |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 125ml, 200ml, 250ml, 400ml, 500ml, 800ml, 1L | F-HDPE | Hermetically closed | Professional and non-professional users | Yes |
| Can | 3L, 5L, 10L, 15L, 20L | F-HDPE | Hermetically closed | Professional  | 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 1L are authorised.

### Documentation

#### Data submitted in relation to product application

***Physico-chemical properties:***

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

***Efficacy:***

The product ENCLEAN has been tested in following efficacy studies:

* For Algae:
* Three field studies conducted according to an in house method with the product ENCLEAN (54% w/w nonanoic acid) on hard surfaces (wood, plastic, concrete).

***Human health:***

Acute toxicity studies, skin and eye irritation studies and a skin sensitization study have been submitted for ENCLEAN.

For details, please refer to the reference list.

#### 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:* Pour the use dose in the sprayer already filled with ¼ of water
* Complete and mix with the recommended volume of water
* Spray by wetting the moss to destroy
* Let the product act for a few hours
 |
| **Application rate(s) and frequency** | 0.0018 L/m² - 6 -2 per year |
| **Category(ies) of users** | General public, Professional |
| **Pack sizes and packaging material** | HDPE fluorinated bottle: 125 mL, 200 mL, 250 mL, 400 mL, 500 mL, 800 mL, 1L, 3L, 5L, 10L, 15L, 20L, 200L, 640L, 1000L |

### Physical, chemical and technical properties

Type of formulation: Emulsion Concentrate EC

Concentration of use: 1.8%-6.0%

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 acidBatch 20111102 | Homogeneous liquid | Fieseler A., 2014Report number 82929204 | Acceptable |
| Colour at 20 °C and 101.3 kPa | yellowish |
| Odour at 20 °C and 101.3 kPa | Characteristic |
| Acidity / alkalinity | MT 191MT 75.3 | 502 g/l of nonanoic acidBatch 20111102 | 14.5% as H2SO4pH (1%): 3.8 at 20°C | Fieseler A., 2014Report number 82929204 | Acceptable |
| Relative density / bulk density | EU Method A.3 | Purity: 51.9% w/vBatch 20130226-2 | D20 = 0.963 | Fieseler A., 2014Report number 82921182 | Acceptable |
| Storage stability test – **accelerated storage** | MT 46.3GC-FID method (project 83241101) validated | 502 g/l of nonanoic acidBatch 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 creamAt 7.5 % v/v: max 12 mL of froth and cream**After 30 min in water D:**3% v/v: max 6mLof froth and creamAt 7.5 % v/v: max 10 mL of froth and cream | **After 30 min in water A:**3% v/v: max 7mLof froth and creamAt 7.5 % v/v: max 14 mL of froth and cream**After 30 min in water D:**3% v/v: max 5mLof froth and creamAt 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., 2014Report number 82929204 | The volumes of cream before and after accelerated and low temperature storages are outside the acceptable limits (>2 mL). A note on the label should be added: “stir during application”. |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No. 17 | 502 g/l of nonanoic acidBatch 20111102 |

|  |  |  |
| --- | --- | --- |
|  | **Initial** | **After 2years in F-HDPE** |
| **Appearance** | Yellow liquid with a characteristic odourPackaging: stable |
| **Content (%)** | 50.0 | 52.6 |
| **pH** | 1%: 3.8Neat:3.7 | 1%:3.9Neat:4.3 |
| **Acidity (% H2SO4)** | 14.2 | 12.2 |
| **Content of water (%)** | 0.9 | 1.0 |
| **Emulsion characteristics** | **After 30 min in water A:**3% v/v: max 6mLof froth and creamAt 7.5 % v/v: max 12 mL of froth and cream**After 30 min in water D:**3% v/v : max 6mLof froth and creamAt 7.5 % v/v: max 10 mL of froth and cream | **After 30 min in water A:**3% v/v: max 6mLof froth and creamAt 7.5 % v/v: max 15 mL of froth and cream**After 30 min in water D:**3% v/v: max 6mLof froth and creamAt 7.5 % v/v: max 10 mL of froth and cream |

 | Determination of the Long term Storage Stability of VVH 86087 at 20 °C, Fieseler A., 2017Study plan Report number 82920204 | AcceptableThe volume of froth and cream for the emulsion characteristics test are higher than the acceptable limits. A note on the label should be added: “stir during application”. |
| Storage stability test – **low temperature stability test for liquids** | MT 39.3MT 36.3MT 75.3 | 502 g/l of nonanoic acidBatch 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%, 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 creamAt 7.5 % v/v: max 12 mL of froth and cream**After 30 min in water D:**3% v/v : max 6mLof froth and creamAt 7.5 % v/v: max 10 mL of froth and cream | **After 30 min in water A:**3% v/v: max 3mLof froth and creamAt 7.5 % v/v: max 5 mL of froth and cream**After 30 min in water D:**3% v/v: max 3mLof froth and creamAt 7.5 % v/v: max 5 mL of froth and cream |

\*: Details of emulsion characteristics are described below the table. | Fieseler A., 2015Report number 82928204 | The volumes of cream before and after accelerated and low temperature storages are outside the acceptable limits (>2 mL).A note on the label should be added: “stir during application”. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  | 502 g/l of nonanoic acidBatch 20111102 | -Test substance thermally stable-Test substance stable to sunlight | Fieseler A., 2015Report N°82928204Report N°82929204Dornhagen, J., 2014, Report 201030452.01 | 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 acidBatch 20111102 | See detail results below table. | Fieseler A., 2014Report number 82929204 | The volumes of cream before and after accelerated and low temperature storages are outside the acceptable limits (>2 mL). A note on the label should be added: “stir during application”. |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not requiredENCLEAN is not sold in spray device.The MMAD is in that case not necessary for HH section since this information is not used in the local risk assessment that focus only on eye irritation.Concerning efficacy section, only an efficient quantity of undiluted product per surface area has been validated based on the efficacy data (without description of the MMAD used). From an efficacy point of view, MMDA is not relevant as long as the validated application rate is applied.Therefore, the MMAD/particle size test is not required. |  |  |
| Persistent foaming | MT 47.2 | 502 g/l of nonanoic acidBatch 20111102 | At 7.5% v/v:After 10 sec : 15.3 mLAfter 1 min : 14.7 mLAfter 3 min: 14.8 mLAfter 12 min : 10.0 mLAt 3.0% v/v:After 0 sec : 13.5 mLAfter 10 sec : 13.0 mLAfter 1 min : 12.5 mLAfter 3 min: 11.5 mLAfter 12 min : 9.0 mL | Fieseler A., 2014Report number 82929204Pointer C., 2016Report BT88JV | Acceptable |
| 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.5OECD 115 | Purity 51.9% w/vBatch 20130226-2 | Pure product: 28.7 mN/m at 20°C | Fieseler A., 2014Report number 82927184 | AcceptableSurface active product |
| Viscosity | MT 192OECD 114 | Purity 51.9% w/vBatch 20130226-2 | At shear rate 500 s-1: 53.44 mPa.s at 20°CAt shear rate 500 s-1: 23.46 mPa.s at 40°C | Fieseler A., 2014Report number 82926196 | Acceptable |

The product ENCLEAN is an Emulsionable Concentrate (EC) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is 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 is 24 months in F-HDPE. Its technical characteristics are acceptable for an EC formulation.

**As the volumes of cream before and after accelerated and low temperature storages are outside the acceptable limits (>2 mL), a note on the label should be added: “stir during application”.**

**Implication for labelling:**

* Keep in a dry, cool and ventilated area and in the original container
* Stir during application

**Emulsion characteristic before and after accelerated storage 14 days at 54°C**



**Emulsion characteristic after low temperature storage 7 days at 0°C**

****

****

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Method A.14OECD 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., 2014Study report 20130452.01 | AcceptableNo explosive properties |
| Flammable gases |  |  | Not relevant |  |  |
| Flammable aerosols |  |  | Not relevant |  |  |
| Oxidising gases |  |  | Not relevant |  |  |
| Gases under pressure |  |  | Not relevant |  |  |
| Flammable liquids |  |  | The study does not need to be conducted for the aqueous solution because the product only contains volatile organic components with flash-points above 100°C. |  | AcceptableThe flash point of biocide product is indicated in the SDS of biocide product as 135°C. This is in accordance with the flash point of formulants in the biocide products (lowest is 131°C in SDS of co-formulants). |
| 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; orb) 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; orc) 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/lBatch 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., 2014Study report 2013045203 | AcceptableNo oxidizing properties |
| Oxidising solids |  |  | Not relevant |  |  |
| Organic peroxides |  |  | Not relevant |  |  |
| Corrosive to metals | No guideline and method | ENCLEAN Batch : 8306282011 | Tests are provided on aluminium, zinc, stainless steel, copper and lead.On all metal samples, ENCLEAN product is pulverised. Samples are let dry (45° inclination) during 2h, 24h, 7days and 15days (with and without water rinsed after test). There is no loss of weight (0%) for all tests. | BEB6-C-3043/1 M. Guironnet, 2012 | AcceptableProduct is not corrosive to metal. Test is not in agreement with the CLP regulation.Moreover, according to test results and the safety data sheet, none of the component is classified corrosive to metals H290. Therefore, it can be considered sufficient to state the corrosive to metal classification.  |
| Auto-ignition temperatures of products (liquids and gases) | Method A15 | Purity 519 g/lBatch 20130226-2 | 345°C | Dornhagen J., 2014Study 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 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 Analytikund Consulting IBACON GmbHArheilger Weg 1764380 RossdorfGermany |
| 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 + 0.0143R2 = 0.9995N=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% |

**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.).

****

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Analytical method for the determination of nonanoic acid in the biocidal formulation was provided and considered 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 is a soluble concentrate to be diluted in water before 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 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 that 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 is used as algaecide on hard surfaces. The active substance nonanoic acid penetrates the organisms and destroy 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 within a period of some hours.

#### 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 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… | ENCLEANnonanoic acid500g/L | *Chlorophyta spp.* | Direct application by spraying on hard surface (concrete) covered with algae (9-17% of the total area).4 replicates per tested treatment (3 different application rates with ENCLEAN, a rate application with a reference product, a control without treatment) | diluted in water at the application rates of 15 L/ha, 18 L/ha, 22,5 L/ha for nonanoic acid (500g/L)at the application rate of 116 L/ha for reference treatment (186 g/L nonanoic acid)quotations (percentage of area covered by algae) were made at 7, 14, 28, 36, 136 days after application | 15L/ha: 79% efficacy at D7 and 70% efficacy at 136 DA 18L/ha: 86% efficacy at D7 and 92% efficacy at 136 DA 22,5L/ha: 96% efficacy at D7 and 98% efficacy at 136 DAReference treatment: 59% efficacy at D7 and 96% efficacy at 136 DApercentage of area covered by algae at 136 DA for untreated control: 48% (efficacy: 0%) | REYNENS P., 2017R027-17HIC: 1 |
| algaecide | *Walls, rooftops, pathway, driveway…* | ENCLEAN nonanoic acid500g/L | *Chlorophyta spp.**(Schizochlamys gelatinosa)* | Direct application by spraying on hard surface (plastic) covered with algae (66-93% of the total area).4 replicates per tested treatment (3 different application rates with ENCLEAN, a rate application with a reference product, a control without treatment) | diluted in water at the application rates of 15 L/ha, 18 L/ha, 22,5 L/ha for nonanoic acid (500g/L)at the application rate of 116 L/ha for reference treatment (186 g/L nonanoic acid)quotations (percentage of area covered by algae) were made at 7, 15, 30, 133 days after application | 15l/ha: 98% efficacy at D7 and 99% efficacy at 133 days18l/ha: 100% efficacy at 7 and 133 days 22,5l/ha: 100% efficacy at 7 and 133 daysReference treatment: 100% efficacy at 7 and 133 dayspercentage of area covered by algae at 133 DA for untreated control: 33% (66% at D0) | REYNENS P., 2017R028-17H, not publishedIC: 1 |
| algaecide | *Walls, rooftops, pathway, driveway…* | ENCLEAN nonanoic acid500g/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 (wood) covered with algae (80% of the total area).4 replicates per tested treatment (3 different application rates with ENCLEAN, a rate application with a reference product, a control without treatment) | diluted in water at the application rates of 15 L/ha, 18 L/ha, 22,5 L/ha for nonanoic acid (500g/L)at the application rate of 116 L/ha for reference treatment (186 g/L nonanoic acid)quotations (percentage of area covered by algae) were made at 7, 13, 61, 165 days after application | 15l/ha: 62.5% efficacy at D7 and 95,2% efficacy at 165 DA 18l/ha: 70.8% efficacy at D7 and 95,6% efficacy at 165 DA 22,5l/ha: 75% efficacy at D7 and 95,6% efficacy at 165 DAReference treatment: 79.2% at D7 and 96.8% efficacy at 165 DApercentage of area covered by algae at 165 DA for untreated control: 83.3% (80% at D0) | KEMEZYS H., 201794 17 05-01IC: 1 |

These trials showed that the product ENCLEAN is an effective algaecide (efficacy >90%) against green algae (i.e. Chlorophyta spp.) when applied on porous and non-porous hard surface (wood, plastic and concrete). The product has been tested in climatic conditions representative of uses (Belgium, Sweden) 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 15 L/ha showed a minimum efficiency (in the three efficacy studies submitted) of 62.5% at 7 days in curative treatment (70% at 136 days).

The product has been tested according to an in-house method and the application rate of 18 L/ha showed a minimum efficiency (in the three efficacy studies submitted) of 70.8% at 7 days in curative treatment (92% at 136 days).

The product has been tested according to an in-house method and the application rate of 22.5 L/ha showed a minimum efficiency (in the three efficacy studies submitted) of 75% at 7 days in curative treatment (95.7% at 165 days).

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the submitted tests, the product ENCLEAN is efficient against green algae (*Chlorophyta spp*.), at the application rate of 0.0018L product/m² (18 L of product/ha), by spraying after dilution 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) or other appointed bodies involved in resistance management.

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product ENCLEAN, diluted in water has shown a sufficient efficacy, for the uses in curative treatment against green algae (*Choloryphyta* *spp.*), at the application rate of 0.0018L product/m² (18 L of product/ha), 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.

Dilution table to be indicated in the label as proposed by the applicant:

|  |  |  |
| --- | --- | --- |
| Surface to be treated | ENCLEAN dose | Volume of water |
| 50 m² | 90 ml | 2,5 L |
| 100 m² | 180 ml | 5 L |
| 200 m² | 360 ml | 10 L |
| 500 m² | 900 ml | 25 L |

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

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

### Risk assessment for human health

ENCLEAN is a product used as algaecide for professional and non-professional users.

ENCLEAN contains 500 g/L a.s (pure) or 519.75 g a.s/L (technical) and should be used at the equivalent dose of 18L/ha and be diluted in water for a total volume of 300L to 1 000L.

The product is applied with a minimal interval of six months.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |
| --- |
| **Summary table of animal studies on skin corrosion /irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results***Average score**(24, 48, 72h)/**observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological**findings* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD 404GLPReliability 1 | New Zealand rabbits, female, three animals | Product ENCLEAN used as supplied0.5 mLUnder semi-occlusive dressing during 4 h | A well defined to moderate erythema, associated to a very slight to slight oedema, were noted on the treated area of all animals, 24 hours after the patch removal. The erythematous and oedematous reactions were totally reversible on day 7.On the cutaneous structure, dryness was noted from day 2 to day 7 in one animal, only on day 3 in a second one and on day 7 in the last one. | None | Richeux, F. 2014 |

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not skin irritant |
| Justification for the value/conclusion | According to the calculated means, the product ENCLEAN must not be classified. The classification criteria are not fulfilled. |
| Classification of the product according to CLP  | No classification as skin irritant is required for ENCLEAN. |

***Eye irritation***

|  |
| --- |
| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance,Dose levels, Duration of exposure** | **Results***Average score (24, 48, 72h)/**observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD 405GLPReliability 1 | New Zealand rabbits, female, three animals | Product ENCLEAN used as supplied0.1 mLTest item instilled into the conjunctival sac of one eye afterpulling the lower lid away from the eyeball. The lids were then gently held together for about onesecond. | The ocular reactions observed during the study have been slight to important and totally reversible:- at the conjunctivae level: a moderate to important redness noted 24 hours after the test item instillation and totally reversible between days 7 and 14, associated with a moderate chemosis noted 1 hour after the test item instillation and totally reversible between days 7 and 14;- at the iris level: a congestion, noted 1 or 24 hours after the test item instillation, and totally reversible on between days 2 and 3;- at the corneal level: a moderate corneal opacity, noted 1 or 24 hours after the test item instillation, and totally reversible between days 3 and 7. | None | Richeux, F. 2014 |

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Eye irritant |
| Justification for the value/conclusion | The classification criteria are fulfilled: corneal opacity ≥ 1 and redness of conjunctivae ≥ 2 are observed in 2 animals (mean value). The ocular reactions are totally reversible before the end of the observation period. |
| Classification of the product according to CLP  | According to the calculated means, the product must be classified as Eye Irrit 2 – H319 ”Causes serious eye irritation”. |

***Respiratory tract irritation***

|  |
| --- |
| **Data waiving** |
| Information requirement | Respiratory tract irritation |
| Justification | No study has been performed on the product ENCLEAN.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***

The skin sensitization study has been realised with a formulation containing 68% of a.s and the same co-formulants than ENCLEAN. This formulation has been considered as a worst-case to determine the skin sensitizing potential of the product ENCLEAN since in both formulations only the active substance is classified for toxicologic properties.

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method,Guideline, GLP status, . Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure**  | **Results**  | **Remarks** | **Reference**  |
| OECD 406 GLPReliability 2 | Dunkin-Hartley guinea pigsMale and female16 animals | VVH 86086 (corresponding to a formulation similar to ENCLEAN, containing 68% of a.s)**1st Intradermal Injection***Group 1* (Negative control): - 2 ID: Freund’s Complete Adjuvant diluted at 50 % in isotonic sodium chloride.- 2 ID: isotonic sodium chloride;- 2 ID: a mixture with equal volumes v/v of Freund’s Complete Adjuvant at 50% and isotonic sodium chloride,*Group 2* (Treated): - 2 ID: Freund’s Complete Adjuvant diluted by 50 % in isotonic sodium chloride,- 2 ID: test item at 0.5% in isotonic sodium chloride,- 2 ID: a test mixture in equal volumes v/v of Freund’s Complete Adjuvant at 50% and the test item at 1% in isotonic sodium chloride**2nd Topical Induction****GROUP 1 (Negative control)**: 0.5 mL of distilled water.**GROUP 2 (treated)**: 0.5 mL of the test item at 100%.Under occlusive dressing for 48h**Challenge Phase**Topical application of test item diluted at 12.5% and at 6.25%.Under occlusive dressing for 24h | **Induction phase Group 1**The induction phase was performed by intradermal injection on D0 with isotonic sodium chloride and by topical application on D8 with distilled water.No cutaneous reaction was recorded after the 1st induction phase. During the second induction, dryness was noted in 2 animals (2/5), 24 hours after the removal of the occlusive dressing.**Induction phase Group 2**The induction phase was performed by intradermal injection on D0 with the test item at 0.5% in isotonic sodium chloride and by topical application on D8 with the test item at 100%.No cutaneous reaction was recorded after the 1st induction phase. During the second induction, dryness was noted in all animals (11/11), 24 hours after the removal of the occlusive dressing.**Challenge phase Group 1 & 2**It was recorded a slight to moderate erythema in 27% (3/11), 18% (2/11) and 9% (1/11) of the animals from the treated group, 24, 48 and 72 hours after the challenge phase, respectively, on the treated area with the test item at 12.5%.It was recorded a slight to moderate erythema in 80% (4/5), 40% (2/5) and 20% (1/5) of the animals from the negative control group, 24, 48 and 72 hours after the challenge phase respectively, on the treated area with the test item at 12.5%.It was recorded a slight erythema in 27% (3/11) and 9% (1/11) of the animals from the treated group, 24 and 48 hours after the challenge phase, respectively, on the treated area with the test item at 6.25%.No cutaneous reaction was noted at the reading time 72 hours.It was recorded a slight erythema in 60% (3/5) of the animals from the negative control group, 24 hours after the challenge phase on the treated area with the test item at 6.25%. No cutaneous reaction was noted at the reading time 48 hours. | In the negative control group, the skin response in the challenge phase was relatively large. | Richeux, F. 2012 |

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not skin sensitizer |
| Justification for the value/conclusion | According to the classification criteria, , answer over at least 30% of animals is regarded as positive. Under these experimental conditions, this criteria is not fulfilled, therefore the product is not a skin sensitizer. |
| Classification of the product according to CLP | No classification for skin sensitization is required for ENCLEAN. |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Data waiving** |
| Information requirement | Respiratory sensitization |
| Justification | No study has been performed on the product ENCLEAN.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*

The acute oral toxicity study has been realised with a formulation containing 68% of a.s and the same co-formulants than ENCLEAN. This formulation has been considered as a worst-case to determine the acute oral toxicity potential of the product ENCLEAN since in both formulations only the active substance is classified for toxicologic properties.

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration**  | **Signs of toxicity**  | **ValueLD50****(mg/kg bw)** | **Remarks**  | **Reference**  |
| OECD 423GLPReliability 1 | Sprague Dawley rats6 females | The test item VVH 86086 (corresponding to a formulation similar to ENCLEAN, containing 68% of a.s) was used as supplied.Single dose of 2 000 mg/kg bw (gavage) | No mortality occurred during the study.No clinical signs related to the administration of the test item were observed.The body weight evolution of the animals remained normal throughout the study.The macroscopic examination of the animals at the end of the study did not reveal treatment related changes. | > 2000 | None | Richeux, F. 2012 |

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | > 2000 mg/kg bw |
| Justification for the selected value | No mortality has been observed after single administration of 2 000 mg/kg bw.In accordance with the OECD guideline No. 423, the LD50 cut-off of the test item may be considered higher than 5000 mg/kg body weight by oral route in the rat. |
| Classification of the product according to CLP | No classification for oral acute toxicity is required for ENCLEAN. |

*Acute toxicity by inhalation*

|  |
| --- |
| **Data waiving** |
| Information requirement | Inhalation acute toxicity |
| Justification | No study has been performed on the product ENCLEAN.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. The a.s being the only classified ingredient of the formulation and no classification for acute inhalation toxicity being reported for the a.s, no classification is required. |

*Acute toxicity by dermal route*

The acute dermal toxicity study has been realised with a formulation containing 68% of a.s and the same co-formulants than ENCLEAN. This formulation has been considered as a worst-case to determine the acute dermal toxicity potential of the product ENCLEAN since in both formulations only the active substance is classified for toxicologic properties.

|  |
| --- |
| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline,****GLP status,****Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity**  | **LD50****(mg/kg bw)** | **Remarks**  | **Reference** |
| OECD 402GLPReliability 1 | Sprague-Dawley rats5 males and 5 females | The test item VVH 86086 (corresponding to a formulation similar to ENCLEAN, containing 68% of a.s) was used as supplied.Single dose of 2 000 mg/kg bw | No mortality occurred during the study.No systemic clinical sign related to the administration of the test item was observed. Erythema was noted on the treated area in all females, 24 hours after the test item application. The cutaneous reactions were totally reversible on day 6.The body weight evolution of the animals remained normal throughout the study.The macroscopic examination of the animals at the end of the study did not reveal treatment-related changes. | > 2000 | None | Richeux, F. 2012 |

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | > 2000 mg/kg bw |
| Justification for the selected value | No mortality occured during the study after application of a dose of 2 000 mg/kg bw. |
| Classification of the product according to CLP  | No classification for dermal acute toxicity is required for ENCLEAN. |

***Information on dermal absorption***

Not applicable, only local risk assessment is performed.

***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 does not contain any substance of concern. Both co-formulants have no classification (harmonised classification of MSDS) and no Community Workplace Exposure value is available.

***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 | no |
| Dermal | No | yes | yes | no | yes | yes | no |
| Oral | No | no | no | no | no | no | no |

***List of scenarios***

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

In the CAR of the active substance nonanoic acid, no systemic effects 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 containing 53.97% of nonanoic acid (technical).

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 concentrated product classified Eye Irrit 2 – H319.

For details, please see the local RA in section 2.2.6.3.

*Scenario [2] – Application phase*

During the application phase, professional users are in contact with the diluted product.

An application rate of 18L p.b/ha is claimed by the applicant.

The product containing 519.75 g a.s (technical)/L has to be diluted in a total volume of 300 to 1 000L.

Therefore it is assumed that, in the dilution of 300L and 1000L, the content of a.s is of 3.1% (31.2 g a.s/L) and 0.94% (9.35 g a.s/L), respectively.

Considering the thereshold limit of classification of 10% for eye irritant category 2, the diluted formulation of ENCLEAN is not classified as eye irritant.

Since no classification is required, no risk assessment has to be performed.

For details, please see the local RA in section 2.2.6.3.

***Non-professional exposure***

*Scenario [1] – Mixing and loading phase*

During the mixing and loading phase, non-professional users are in contact with the concentrated product classified Eye Irrit 2 – H319.

For details, please see the local RA in section 2.2.6.3.

*Scenario [2] – Application phase*

During the application phase, non-professional users are in contact with the diluted product.

An application rate of 18L p.b/ha is claimed by the applicant.

The product containing 519.75 g a.s (technical)/L has to be diluted in a total volume of 300 or 1 000L.

Therefore it is assumed that, in the dilution of 300L and 1000L, the content of a.s is of 3.1% (31.2 g a.s/L) and 0.94% (9.35 g a.s/L), respectively.

Considering the thereshold limit of classification of 10% for eye irritant category 2, the diluted formulation of ENCLEAN is not classified as eye irritant.

Since no classification is required, no risk assessment has to be performed.

For details, please see the local RA in section 2.2.6.3.

***Monitoring data***

None

***Exposure of the general public***

Exposure to the general public occurs with the diluted product after application.

Considering that no classification is required for the diluted product, no qualitative risk assessment is necessary.

***Dietary exposure***

The product ENCLEAN 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*

| **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.

#### 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**

Not required.

***Risk for industrial users***

Not applicable

***Risk for professional users***

**Local effects**

For mixing and loading, as the concentrated product is irritant for eyes (Eye Irrit 2 – H319), a local risk assessment according to the guidance on the BPR: Volume III HH part B is realised (see table below).

For the application phase by spraying, the diluted product being not classified, no risk assessment is necessary.

|  |  |  |
| --- | --- | --- |
| Hazard | Exposure  | Risk |
| HazardCategory | Effectsintermsof C&L | Additionalrelevanthazardinformation | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route  | Frequency and duration of potential exposure  | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Eye Irrit 2 | - | 2 | Professional  | Mixing and loading concentrate product from a bottle to a knapsack sprayer | ocular | Few minutes per day  | Low  | **RMM Technics:**- Minimisation of splashes and spills;**RMM Organisation:**- Minimise number of staff exposed;-Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed;- Training for staff on good practice;- Good standard of personal hygiene**PPE**- Eye protection | The mixing and loading should be done cautiously in order to avoid any facial exposure via splashes. The effects are reversible.Considering that these recommendations can be followed during this task, ,the risk is acceptable according to RMM and PPE |

**Conclusion**

For professional users, due to the classification H319 of the product, facial exposure to splashes during mixing and loading has to be limited by the use of PPE (eye protection/goggles) and application of technical and organisational RMMs.

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

**Local effects**

For mixing and loading, as the concentrated product is irritant for eyes (Eye Irrit 2 – H319), a local risk assessment according to the guidance on the BPR: Volume III HH part B is realised (see table below).

For the application phase by spraying, the diluted product being not classified, no risk assessment is necessary.

|  |  |  |
| --- | --- | --- |
| Hazard | Exposure  | Risk |
| HazardCategory | Effectsintermsof C&L | Additionalrelevanthazardinformation | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route  | Frequency and duration of potential exposure  | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Eye Irrit 2 | - | 2 | Non professional  | Mixing and loading concentrate product from a bottle to a knapsack sprayer | ocular | Few minutes per day  | Low  | Labelling, instructions for use that minimise exposure or health effects**RMM Technics:*** Minimisation of splashes and spills by pouring slowly the product from the bottle to the knapsack
 | Considering that these instructions are followed during this task, the risk is acceptable |

**Conclusion**

For non professional users, labeling and instructions of use are necessary to minimise exposure and health effects during mixing and loading.

***Risk for the general public***

**Local effects**

Exposure of the general public occurs after application of the diluted product. No classification being required for the diluted product, no risk assessment is necessary.

**Conclusion**

An acceptable risk is assumed for general public.

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

The product ENCLEAN 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, if the FR CA does not agree with the applicant values or assessment, it is reported in the green boxes. Otherwise the values presented by the applicant are used. Please note that the defaultinput values are issued from ESD PT10. |

#### Effects assessment on the environment

### 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 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.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.kg soil dw-1 and up to 139 mg ENCLEAN.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 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 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 product. Therefore, ENCLEAN product is classified as H412 according to Regulation (EC) No.1272/2008 (CLP). |

***Further Ecotoxicological studies***

|  |
| --- |
| FR-CA box 4: *FR Opinion*No data is available. As the ENCLEAN 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 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 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 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 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 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 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 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 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 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 (500 ga.s.l-1) is an algaecide used for the curative treatment of construction materials. According to the claimed conditions of use, ENCLEAN 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 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 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 0.936 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 | 0.0018 | S |
| Content of active substance | F form | - | 0.54 | S |
| Product Density  | Density | g.l-1 | 963 | D |
| Quantity of active substance applied on area | M a.s. | g.m-2 | 0.936 | 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 |

In the CAR of the active substance (Doc IIC, p17), a worst case service-life scenario was calculated assuming that 100% of the applied amount will be washed off in one day immediately after application due to e.g. a heavy rain event and ignoring any possible RMM. However, in our assessment, the rinsing scenario is a worst-approach compared to the leaching scenario proposed in the CAR, therefore this approach covers the service life phase. Moreover, specifics RMM have been added to avoid the release to the environment during the day of application. In addition, if we change this value to 100% (representing the release to adjacent soil or STP of the whole amount of a.s. during the application), the risk is acceptable after 15 days (application + rinsing). The overall conclusions would remain the same.Even if a rinsing scenario has been assessed, it is important to underline that rinsing afterapplication is not allowed. **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] | 158.2 |
| 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 |
| Biodegradability | Readily biodegradable |
| DT50 soil [d] | 2.1 (12°C) |

|  |
| --- |
| **Calculated fate and distribution in the STP according to the CAR (EUSES model 2.1.2)** |
| **Compartment** | **Percentage [%]** |
| Degraded in STP | 86.72% |
| 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).

|  |
| --- |
| FR-CA box 19: *FR Opinion*Concerning the soil distant to a treated horizontal surface, the risk can be considered to be covered by the assessment of vertical surfaces as the spray drift will be lower. Regarding soil adjacent to a treated horizontal surface, run-off is more likely and cannot be mitigated. For vertical surfaces both facade and roof were considered for the risk assessment. Compared to a horizontal surface with a smaller treated area releasing product to the adjacent soil compartment, this assessment can be considered as a worst case situation. |

###### ***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 CAR (PT10) |
| Soil volume adjacent to surface treated | V soil(a) | m3 | 13 | D CAR (PT10) |
| 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 20: *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. The surface area of a facade (125 m2) and a roof (145 m2) were summed up. Concentrations in local soil and emission to local storm water have been revised considering a use quantity of 0.936 ga.s.m-2.**Concentrations in local soil due to direct emissions**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Concentration in local soil (mg.kgwwt-1)** |
| ESD PT10House in the countryside | Clocal soil(d) | Soil distant to treated surface | 1.04E-01 |
| Clocal soil(a) | Soil adjacent to treated surface | 2.29 |

**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) | 7.58E-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 PT10House 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 PT10House 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 PT10House 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).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 21: *FR Opinion***House scenario – Rinsing (by a rainfall event)**Considering a final use quantity of 0.936 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 PT10House in the countryside | Elocal rinse drift | 4.42E-02 |
| Elocal rinse runoff | 1.33E-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 PT10House in the countryside | Clocal soil (d) | Soil distant to treated surface | 1.82E-01 |
| Clocal soil (a) | Soil adjacent to treated surface | 6.00 |

**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 PT10House in the countryside | Clocal soil (d) | Soil distant to treated surface | 2.86E-01 |
| Clocal soil (a) | Soil adjacent to treated surface | 8.29 |

**Emission to local storm water following rinsing only**

|  |  |  |  |
| --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to waste water (kg.d-1)** |
| ESD PT10House in a city | Elocal water | Storm water(connected to the sewer system) | 1.77E-01 |

 |

######

|  |
| --- |
| FR-CA box 22: *FR Opinion*Please note that the emission estimation for “house in a city” was performed for a mixed sewer system, only. Direct release to surface water via separate sewer systems was not considered. However, since the submission of the product was in 2015, the scenario is not yet relevant regarding the decision on product authorisation. Note that the scenario will be relevant for reauthorisation of the product. |

###### ***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 23: *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):**2.81E-03 |
| Clocal water | Pond under bridge | **Concentration in water (mg.l-1):**2.81E-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 24: *FR Opinion***Bridge over pond scenario – Application + rinsing (by a rainfall event)**Considering a final use quantity of 0.936 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):**9.36E-03 |

 |

###### ***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 | DBased on ANSES recommandations for House scenarios \* | ESD PT10 |
| Soil volume adjacent to surface treated | V soil(a) | m3 | 0.26 | DBased 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 applicationPT8: Pond under bridge | Clocal soil(d) | Soil distant to treated surface | 5.2E-09 | 5.82E-03 |
| PT10 : Spray applicationPT8: 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 rinsedue to runoff | F runoff rinse | - | 0.75 | D | ESD PT10 |
| Fraction of rinsing solution lost during rinseby 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 applicationPT8: Pond under bridge | Clocal soil (d) | Soil distant to treated surface | 1.41E-08 | 1.60E-02 |
| PT10: Spray applicationPT8: Pond under bridge | Clocal soil (a) | Soil adjacent to treated surface | 7.69E-05 | 86.87 |

|  |
| --- |
| FR-CA box 25: *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 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[[4]](#footnote-5). 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). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[[5]](#footnote-6)). 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 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 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”[[6]](#footnote-7), 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 26: *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 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:$$n\_{house,application}=\frac{n\_{house,city}}{service life×365}$$Where:* Nhouse, city = number of houses in a city (4000);
* Service life = service life of the preserved products (0.5 year, the ENCLEAN 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 27: *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 | 8.34E-01 | 1.05E-01 |
| Application + rinsing | 5.56 | 2.78 | 3.50E-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 28: *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 | 1.05E-02 |
| Application + rinsing | 3.50E-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 | 2.81E-03 |
| Application and rinsing by a rainfall event | 9.36E-03 |

 |

###### ***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 29: *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 | 1.04E-01 |
| Soil adjacent to treated surface | 2.29 |
| Emission due to rinsing | Soil distant to treated surface | 1.82E-01 |
| Soil adjacent to treated surface | 6.00 |
| Emission due to application + rinsing | Soil distant to treated surface | 2.86E-01 |
| Soil adjacent to treated surface | 8.29 |

 |

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[[7]](#footnote-8), 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 30: *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. This results to a degradation rate of k=0.33 d-1.  *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 | 1.04E-01 | 1.03E-02 | 1.04E-03 |
| Soil adjacent to treated surface | 2.29 | 2.27E-01 | 2.27E-02 |
| Emission due to rinsing | Soil distant to treated surface | 1.82E-01 | 1.81E-02 | 1.79E-03 |
| Soil adjacent to treated surface | 6.00 | 5.96E-01 | 5.91E-02 |
| Emission due to application + rinsing | Soil distant to treated surface | 2.86E-01 | 2.84E-02 | 2.82E-03 |
| Soil adjacent to treated surface | 8.29 | 8.23E-01 | 8.16E-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 31: *FR Opinion*It has been considered that 22 houses are treated on a single day by ENCLEAN 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) | 1.84E-03 | 3.07E-04 |
| Emission due to application + rinsing (by a rainfall event) - 22 treated houses (per day) | 6.15E-03 | 1.02E-03 |

 |

According to the OECD ESD on wood preservatives (Appendix 4, p. 178)[[8]](#footnote-9) 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[[9]](#footnote-10), 2009[[10]](#footnote-11) and 2011[[11]](#footnote-12)).

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 product | 500 | g as.l-1 |
| Volume of ENCLEAN 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 32: *FR Opinion*A groundwater assessment via FOCUS PEARL was conducted for direct release to soil. Concerning the groundwater assessment after sewage sludge application, an assessment was not carried out as the application rate for arable land or grassland was substantially lower (0.208 kg.ha-1) than the one calculated for the direct release to the soil (0.732 kg.ha-1).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.Note that in the ESD PT 8, 16 treated houses per hectare and year are considered, so 2 applications on 16 houses are covered by the current assessment.

| **Input parameter PEARL 4.4.4** | **Unit** | **Value** | **Reference** |
| --- | --- | --- | --- |
| **Product name : ENCLEAN** |
| **Substance name : Nonanoic acid** |
| **Physicochemical parameters** |
| Molecular weight | g.mol-1 | 158.2 | 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 | 0.732 |  |
| D = (0.93 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-92) 7.50E-9 |

|  |
| --- |
| FR-CA box 33: *FR Opinion*As stated in the Assessment Report of nonanoic acid, with an half life in air of 39.4h, an accumulation of nanoic acid is not to be expected in the atmosphere. This is why air exposure is considered to be 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). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[[12]](#footnote-13)). 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 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 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”[[13]](#footnote-14), 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 34: *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-casePEC sed(mg.Kgwwt-1) | PNEC sed(mg.Kgwwt-1) | Worst-casePEC/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 35: *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 | 1.85E-01 |
| Releases during application + rinsing | 6.17E-01 |
| **Direct releases****Bridge over pond scenario PT8** | Releases during application | 4.94E-02 |
| Releases during application + rinsing | 1.65E-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-casePECSTP(mg.l-1) | PNECSTP(mg.l-1) | Worst-casePEC/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 36: *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 | 1.86E-02 |
| Releases during application + rinsing | 6.20E-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 37: *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 wort-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 product on urban houses, except for the unrealistic wort-case scenario which assumes a maximum of houses treated the same day, even with rinsing after treatment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 38: *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  | 1.86E-02 |
| Releases during application + rinsing | 6.21E-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 | **1.05** | 1.04E-01 | 1.05E-02 |
| Soil adjacent to treated surface | **23.1** | **2.29** | 2.29E-01 |
| Emission due to rinsing | Soil distant to treated surface | **1.84** | 1.83E-01 | 1.81E-02 |
| Soil adjacent to treated surface | **60.6** | **6.02** | 5.97E-01 |
| Emission due to application + rinsing | Soil distant to treated surface | **2.89** | 2.87E-01 | 2.85E-02 |
| Soil adjacent to treated surface | **83.74** | **8.31** | 8.24E-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. Moreover, nonanoic acid is readily biodegradable and has a DT50soil of 2.1 days at 12°C. Its potential for bioaccumulation is expected to be low based on the rapid metabolism within organisms via common pathways. Consequently the following risk mitigation measures and instructions of use are recommended, in order to avoid any possible harm:* + During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment.
* Products can only be used if the weather forecasts show no rain for the day of application.
* Do not clean the surface after treatment.

Based on the PEC/PNEC calculations in combination with the properties of Nonanoic acid and the proposed risk mitigation measures the risk for soil organisms through direct exposure to Nonanoic acid is considered to be acceptable.Therefore, calculating the risk by assuming a rinsing application (representative of a rain event) immediately after application is an overestimation of the risk for several reasons and only possibly if the proposed RMM above are ignored. Furthermore, in the CAR of nonanoic acid, a risk is pointed out in the adjacent soil, up to 15 days (included) after the product application. As the risk for the adjacent soil is acceptable after 14 days, the ENCLEAN product is compliant with the conditions of approval of the substance.Moreover, regarding the environmental profile of the a.s. (readily biodegradability, low potential of bioaccumulation, half-time life in soil and air...), the risk for soil organisms can be considered acceptable. Nevertheless, we underline the importance to clearly distinguish nonanoic acid from other products with algicide properties with a much worse environmental profile: the temporary exceedance of risk can only be accepted for this specific product with nonanoic acid considering all RMM.**Conclusion**: In accordance with the conclusions of Nonanoic acid CAR, the risk for soil organisms can be considered acceptable. |

**Primary and secondary poisoning**

|  |
| --- |
| FR-CA box39: *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. |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
|

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box40: *FR Opinion*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Phase | STP | Surface water | Sediment | Soil | Groundwater | Sec.Poisoning |
| Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | *Via* STP |
| ENCLEAN product |
| Application | Non acceptable risks without RMMs |
| Rinsing |

Following risk mitigation measures shall be established in order to protect the environment:* Products can only be used if the weather forecasts show no rain for the day of application.
* During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment.
 |

 |

### 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 (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Philippe REYNENS | 2017 | Determination of efficacy of biocide VVH 86 087 against Algae on impermeable surfaces, R027-17H, not published, Philippe REYNENS, 17 May 2017 | Yes | JADE |
| Philippe REYNENS | 2017 | Determination of efficacy of biocide VVH 86 087 against Algae on impermeable surfaces, R028-17H, not published, Philippe REYNENS, 17 May 2017 | Yes | JADE |
| Andrius Hansen KEMEZYS | 2017 | Determination of efficacy of biocide VVH 86 087 against Algae on impermeable surfaces, Trial no. 94 17 05-01, Andrius Hansen Kemezys, 28 April 2017 | Yes | JADE |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pointer C. | 2016 | Enclean: Persistent FoamingStudy Number: BT88JV | Y | Belchim Crop Protection NV |
| Fieseler A. | 2014 | Determination of the Accelerated Storage Stability of VVH 86087Report number 82929204 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Low Temperature Stability of VVH 86087Report number 82928204 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Relative Density of VVH 86087Report number 82921182 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Surface Tension of an aqueous solution of VVH 86087Report number 82927184 | Y | JADE |
| Fieseler A. | 2014 | Determination of the Viscosity of VVH 86087Report number 82926196 | Y | JADE |
| Dornhagen J. | 2014 | Oxidising propertiesStudy report 2013045203 | Y | JADE |
| Dornhagen J. | 2014 | Explosive propertiesStudy report 20130452.01 | Y | JADE |
| Dornhagen J. | 2014 | Auto-ignition temperatureStudy 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 86087Project 83241101 | Y | JADE |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title**  | **Owner of data** | **Data protection claimed** | **Essential studies for evaluation** |
|  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| F. RICHEUX | 2012 | VVH 86086EVALUATION OF ACUTE ORAL TOXICITY INRATS - ACUTE TOXIC CLASS METHOD | JADE | x |  | x |  |
| F. RICHEUX | 2012 | VVH 86086EVALUATION OF ACUTE DERMAL TOXICITYIN RATS | JADE | x |  | x |  |
| F. RICHEUX | 2014 | VVH 86087ASSESSMENT OF ACUTE DERMALIRRITATION | JADE | x |  | x |  |
| F. RICHEUX | 2014 | VVH 86087ASSESSMENT OF ACUTE EYE IRRITATION | JADE | x |  | x |  |
| F. RICHEUX | 2012 | VVH 86086ASSESSMENT OF SENSITISING PROPERTIESON ALBINO GUINEA PIGSMaximisation test according to MAGNUSSONAND KLIGMAN | JADE | x |  | x |  |

## Output tables from exposure assessment tools

Not applicable

## New information on the active substance

Not applicable

## Residue behaviour

The product ENCLEAN 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)[[14]](#footnote-15)

## Confidential annex

Please refer to the Confidential annex file.

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. 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-5)
5. Le parc de logements en France au 1er janvier 2014, INSEE Références, 2014 [(http://www.insee.fr/fr/themes/document.asp?ref\_id=if16)](http://www.insee.fr/fr/themes/document.asp?ref_id=if16) as consulted the 17th November 2016. [↑](#footnote-ref-6)
6. 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-7)
7. Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), V.1 April 2015, ECHA [↑](#footnote-ref-8)
8. Groundwater exposure assessment for wood preservatives Factors to consider [↑](#footnote-ref-9)
9. SANCO/321/2000 rev.2: FOCUS groudwater scenarios in the EU review of active substances. [↑](#footnote-ref-10)
10. 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-11)
11. FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater assessments, Version 2.0, January 2011. [↑](#footnote-ref-12)
12. 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-13)
13. 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-14)
14. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-15)