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

**DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the eCA)



Product family name: COM 508

Product type 2

Nonanoic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-FH019954-39

Evaluating Competent Authority: The Netherlands

Date: 01/02/2019

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# CONCLUSION

Based on the risk assessment, no unacceptable risk for human health is identified for the unprotected non-professional user by exposure to nonanoic acid contained in the biocidal product family, COM 508, consisting of two biocidal products containing the active substance nonanoic acid, when the products are used according to the instructions for use. No unacceptable risk for human health is identified for the general public due to secondary exposure to the products either.

No unacceptable risks are identified for the environment when the products are used according to the instructions for use and when the risk mitigation measures as indicated in the SPC are taken into account.

Data on the biocidal product have demonstrated sufficient efficacy against green algae and lichens. Nonanoic acid has a specific mode of action that penetrates into the plant tissue and disrupts the cell membrane and consequently leads to inhibition of photosynthesis. Resistance development is not expected since it does not affect a functional group.

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

The eCA concludes that the products of the biocidal product family fulfil the requirements of article 19, and authorisation can be granted.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product family (trade names)

| **Identifier** | **Country (if relevant)** | **Remark(\*)** |
| --- | --- | --- |
| COMPO Groene aanslagreiniger concentraat | Netherlands | name of the concentrate |
| COMPO Groene aanslagreiniger klaar voor gebruik | Netherlands | name of the RTU product |
| Groene aanslagreiniger concentraat / Anti-dépôts verts concentré | Belgium | name of the concentrate |
| Groene aanslagreiniger klaar voor gebruik / Anti-dépôts verts prêt à l'emploi | Belgium | name of the RTU product |
| Groene aanslagreiniger concentraat / Anti-dépôts verts concentré | Luxembourg | name of the concentrate |
| Groene aanslagreiniger klaar voor gebruik / Anti-dépôts verts prêt à l'emploi | Luxembourg | name of the RTU product |
| Grünbelag-Reiniger | Austria | name of the concentrate |
| Grünbelag- & Algenreiniger | Austria | name of the concentrate |
| Grünbelag-Frei | Austria | name of the concentrate |
| COMPO Grünbelag-Frei | Austria | name of the concentrate |
| Algen-Frei | Austria | name of the concentrate |
| Nonan Grünvernichter | Austria | name of the concentrate |
| Nonan Grünbelag-Reiniger | Austria | name of the concentrate |
| Grünvernichter | Austria | name of the concentrate |
| Algen-EX | Austria | name of the concentrate |
| Algen- & Flechten-EX | Austria | name of the concentrate |
| COMPO Algen- & Flechten-EX | Austria | name of the concentrate |
| Grünbelag-EX | Austria | name of the concentrate |
| Terrassen und Wege Grünbelag-Frei | Austria | name of the concentrate |
| VOROX Terrassen und Wege | Austria | name of the concentrate |
| Grünbelag-Reiniger AF | Austria | name of the RTU product |
| Grünbelag- & Algenreiniger AF | Austria | name of the RTU product |
| Grünbelag-Frei AF | Austria | name of the RTU product |
| COMPO Grünbelag-Frei AF | Austria | name of the RTU product |
| Algen-Frei AF | Austria | name of the RTU product |
| Nonan Grünvernichter AF | Austria | name of the RTU product |
| Nonan Grünbelag-Reiniger AF | Austria | name of the RTU product |
| Grünvernichter AF | Austria | name of the RTU product |
| Algen-EX AF | Austria | name of the RTU product |
| Algen- & Flechten-EX AF | Austria | name of the RTU product |
| COMPO Algen- & Flechten-EX AF | Austria | name of the RTU product |
| Grünbelag-EX AF | Austria | name of the RTU product |
| Terrassen und Wege Grünbelag-Frei AF | Austria | name of the RTU product |
| VOROX Terrassen und Wege AF | Austria | name of the RTU product |
| Grünbelag-Reiniger | Germany | name of the concentrate |
| Grünbelag- & Algenreiniger | Germany | name of the concentrate |
| Grünbelag-Frei | Germany | name of the concentrate |
| COMPO Grünbelag-Frei | Germany | name of the concentrate |
| Algen-Frei | Germany | name of the concentrate |
| Nonan Grünvernichter | Germany | name of the concentrate |
| Nonan Grünbelag-Reiniger | Germany | name of the concentrate |
| Grünvernichter | Germany | name of the concentrate |
| Algen-EX | Germany | name of the concentrate |
| Algen- & Flechten-EX | Germany | name of the concentrate |
| COMPO Algen- & Flechten-EX | Germany | name of the concentrate |
| Grünbelag-EX | Germany | name of the concentrate |
| Terrassen und Wege Grünbelag-Frei | Germany | name of the concentrate |
| VOROX Terrassen und Wege | Germany | name of the concentrate |
| Grünbelag-Reiniger AF | Germany | name of the RTU product |
| Grünbelag- & Algenreiniger AF | Germany | name of the RTU product |
| Grünbelag-Frei AF | Germany | name of the RTU product |
| COMPO Grünbelag-Frei AF | Germany | name of the RTU product |
| Algen-Frei AF | Germany | name of the RTU product |
| Nonan Grünvernichter AF | Germany | name of the RTU product |
| Nonan Grünbelag-Reiniger AF | Germany | name of the RTU product |
| Grünvernichter AF | Germany | name of the RTU product |
| Algen-EX AF | Germany | name of the RTU product |
| Algen- & Flechten-EX AF | Germany | name of the RTU product |
| COMPO Algen- & Flechten-EX AF | Germany | name of the RTU product |
| Grünbelag-EX AF | Germany | name of the RTU product |
| Terrassen und Wege Grünbelag-Frei AF | Germany | name of the RTU product |
| VOROX Terrassen und Wege AF | Germany | name of the RTU product |
| Clairland net | France | name of the concentrate |
| Pelargo | France | name of the concentrate |
| Clairland net spray | France | name of the RTU product |
| Pelargo Spray | France | name of the RTU product |
| Gesal Super Rapid Algen- und Moosvertilger für Wege und Plätze Konzentrat | Switzerland | name of the concentrate |
| Gesal Super Rapid Algen- und Moosvertilger für Wege und Plätze | Switzerland | name of the RTU product |

(\*) RTU = Ready-to-use

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | COMPO Benelux N.V. |
| **Address** | Filliersdreef 14  9800 Deinze  Belgium |
| **Authorisation number** | NL-0015018-0000 | |
| **Date of the authorisation** | 1 February 2019 | |
| **Expiry date of the authorisation** | 1 February 2029 | |

#### Applicant

|  |  |
| --- | --- |
| **Company Name:** | COMPO GmbH |
| **Address:** | Gildenstr. 38 |
| **City:** | Münster |
| **Postal Code:** | 48157 |
| **Country:** | Germany |
| **Telephone:** | +49 251 3277-368 |
| **Fax:** | +49 251 3277-1368 |
| **E-mail address:** | [Regulatory@compo.de](mailto:Regulatory@compo.de) |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | COMPO GmbH |
| **Address of manufacturer** | Gildenstr. 38  48157 Münster  Germany |
| **Location of manufacturing sites** | Schirm GmbH  Dieselstr. 8  85107 Baar-Ebenhausen  Germany |

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

|  |  |
| --- | --- |
| **Active substance** | Nonanoic acid |
| **Name of manufacturer** | Emery Oleochemicals LLC |
| **Address of manufacturer** | 4900 Este Avenue  45232 Cincinnati, Ohio  United States |
| **Location of manufacturing sites** | 4900 Este Avenue  45232 Cincinnati, Ohio  United States |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Nonanoic acid |
| **IUPAC or EC name** | Nonanoic acid |
| **EC number** | 203-931-2 |
| **CAS number** | 112-05-0 |
| **Index number in Annex VI of CLP** | 607-197-00-8 |
| **Minimum purity / content** | ≥ 89.78% |
| **Structural formula** |  |

#### Candidate(s) for substitution

Not applicable.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Nonanoic acid  **pure a.s.** | Nonanoic acid | Active substance | 112-05-0 | 203-931-2 | 3.1 | 24.3 |
| Nonanoic acid (\*)  **techn. grade a.s. (≥ 89.78%)** | Nonanoic acid | active substance | 112-05-0 | 203-931-2 | 3.5 | 27.0 |

(\*) The composition is based on the techn. grade a.s. (≥ 89.78%).

The biocidal product family, COM 508, consists of two meta SPC’s, each containing one biocidal product. Meta SPC 1 contains a ready-to-use product and meta SPC 2 contains a concentrate. All products in the family contain the active substance nonanoic acid. The products are:

Meta SPC 1: COMPO Groene aanslagreiniger klaar voor gebruik (product code COM 508 09 AL B).

Meta SPC 2: COMPO Groene aanslagreiniger concentraat (product code COM 508 16 EW B).

The product code COM 508 16 EW B is identical to the product code COM 508 16 H EW and product code COM 508 09 AL B is identical to product code COM 508 09 H AL.

Please see the confidential annex for further details.

#### Information on technical equivalence

COMPO GmbH obtains the active substance nonanoic acid (product code Emery 1202) from the manufacturer Emery Oleochemical LLC, USA, from whom also the submitter of the active substance dossier in the Review Program, W. Neudorff GmbH KG, Germany, obtains his active substance nonanoic acid. As the source of the active substance is the same for COMPO GmbH and W. Neudorff GmbH KG, the technical equivalence of both sources for nonanoic acid is given.

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

Polyethylene glycol monoalkyl ether (CAS 9043-30-5) is identified as a SoC for human health.

#### Type of formulation

|  |
| --- |
| AL - Any other liquid (ready-to-use product Meta SPC 1)  EW - Emulsion, oil in water (concentrate Meta SPC 2) |

### Hazard and precautionary statements

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

**For metaSPC 1 (RTU)**

| **Classification** | |
| --- | --- |
| Hazard category | - |
| Hazard statement | EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.- |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P270: Do not eat, drink or smoke when using this product. |
|  | |
| Note | **-** |

**For metaSPC 2 (concentrate)**

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit. 2 |
| Hazard statement | H319: Causes serious eye irritation. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | 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 skin thoroughly after handling.  P270: Do not eat, drink or smoke when using this product.  P280: Wear eye 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. |
|  | |
| Note | **-** |

### Authorised use(s)

**Table 1. Use # 1.1 – algaecide, ready-to use, outdoor use (meta SPC 1)**

|  |  |
| --- | --- |
| **Product Type** | 2 - Disinfectants and algaecides not intended for direct application to humans or animals. |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Green algae - Green algae – No data  Lichen – Lichens – No data |
| **Field of use** | Outdoor use  The biocidal product is used for remedial treatment of rocks, wood and natural stones to remove green surface discolouration on patios, paths, car parks, masonry, steps, and other hard porous surfaces. |
| **Application method(s)** | Trigger spraying |
| **Application rate(s) and frequency** | One spray bottle is sufficient to treat 7.5 m2. In case of very light surface discolouration, one spray bottle is sufficient to treat 15 m2.  Frequency: once per year |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 750 mL bottle made of HDPE or PET. |

#### MetaSPC 1, use 1: Instructions for use

|  |
| --- |
| Always read the label or leaflet before use and respect/follow all the instructions provided.  The ready-to-use product (nonanoic acid concentrations of 31 g/l) is used undiluted.  Dry contaminated surfaces are sprayed evenly from a distance of about 30 cm until they are completely dampened. Do not apply more fluid than necessary and avoid that droplets runoff from surfaces during application.  Allow the product to take effect for at least 48 hours. Do not rinse with water afterwards. Do not apply in windy conditions.  Do not spray on non-target plants during application to prevent irreversible damage.  The soil next to the treated surface should be covered with plastic sheets (at least 50 cm width) during application to avoid emissions to soil. |

#### MetaSPC 1, use 1: Risk mitigation measures

|  |
| --- |
| Keep children and pets away until surface is dried.  Do not apply when rain is expected within 48 hours and/or in windy conditions.  Do not apply this product to surfaces near or above surface water. Avoid release to drains.  Cover soils adjacent of the objects to be treated with plastic of at least 50 cm width. |

#### MetaSPC 1, use 1: Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.  Description of first aid measures General advice: First aid personnel should pay attention to their own safety. If you feel unwell, seek medical advice (show the label where possible). If inhaled: Keep patient calm, remove to fresh air, seek medical attention. In case of skin contact: Wash off immediately with soap and plenty of water. In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If swallowed: Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Consult a physician if necessary.  Emergency measures to protect the environment: Should not be released into the environment. Do not flush into surface water or sanitary sewer system. |

#### MetaSPC 1, use 1: The instructions for safe disposal of the product and its packaging

|  |
| --- |
| Dispose concentrated product and empty packaging material according to national regulation |

#### MetaSPC 1, use 1: Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Requirements for storage areas and containers:  Store protected against frost. Keep in a cool place. Keep in the original container.  Further information on storage conditions: Keep away from food, drink and animal feed.  Storage period: 4 years  Storage temperature: 2 -25 °C |

**Table 2. Use # 2.1 – algaecide, concentrate, outdoor use (meta SPC 2)**

|  |  |
| --- | --- |
| **Product Type** | 2 - Disinfectants and algaecides not intended for direct application to humans or animals. |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Green algae - Green algae – No data  Lichen – Lichens – No data |
| **Field of use** | Outdoor use:  The biocidal product is used for remedial treatment of rocks, wood and natural stones to remove green surface discolouration on patios, paths, car parks, masonry, steps, and other hard porous surfaces. |
| **Application method(s)** | Spraying (diluted concentrate) |
| **Application rate(s) and frequency** | Dilution: 13%  Add 1 liter of water to 150 mL of concentrate to create the diluted concentrate solution. This amount of solution is sufficient to treat 11.5 m2. In case of very light surface discolouration this amount is sufficient to treat 20 m2.  Frequency: once per year |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 500 mL bottle made of HDPE or PET. |

#### MetaSPC 2, use 1: Instructions for use

|  |
| --- |
| Always read the label or leaflet before use and respect/follow all the instructions provided.  For this product a dilution should be made with clean water to an end concentration of 31 g/l nonanoic acid. Add 1 liter of water to 150 mL of concentrate to create the diluted concentrate solution.  This amount of solution is sufficient to treat 11.5 m2. In case of very light surface discolouration this amount is sufficient to treat 20 m2.  The equipment to be used for spraying must be a handheld manually operated low pressure (3 bar or below) device. This device should be used in combination with a spraying shield.  Dry contaminated surfaces are sprayed or doused evenly from a distance of about 30 cm until they are completely dampened. Do not apply more fluid than necessary and avoid that droplets runoff from surfaces during application.  Allow the product to take effect for at least 48 hours. Do not rinse with water afterwards.  Do not apply in windy conditions.  Do not spray on non-target plants during application to prevent irreversible damage.  The soil next to the treated surface should be covered with plastic sheets (at least 50 cm width) during application to avoid emissions to soil. |

#### MetaSPC 2, use 1: Risk mitigation measures

|  |
| --- |
| Avoid contact with eyes.  Avoid splashes when making a dilution.  Keep children and pets away until surface is dried.  Do not apply when rain is expected within 48 hours and/or in windy conditions.  Do not apply this product to surfaces near or above surface water. Avoid release to drains.  Cover soils adjacent of the objects to be treated with plastic of at least 50 cm width.  The equipment to be used for spraying must be a handheld manually operated low pressure (3 bar or below) device. This device should be used in combination with a spraying shield. |

#### MetaSPC 2, use 1: Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.  Description of first aid measures General advice: First aid personnel should pay attention to their own safety. If you feel unwell, seek medical advice (show the label where possible). If inhaled: Keep patient calm, remove to fresh air, seek medical attention. In case of skin contact: Wash off immediately with soap and plenty of water. In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If swallowed: Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Consult a physician if necessary.  Emergency measures to protect the environment: Should not be released into the environment. Do not flush into surface water or sanitary sewer system. |

#### MetaSPC 2, use 1: Instructions for safe disposal of the product and its packaging

|  |
| --- |
| Dispose concentrated product and empty packaging material according to national regulation |

#### MetaSPC 2, use 1: Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Requirements for storage areas and containers:  Store protected against frost. Keep in a cool place. Keep in the original container.  Further information on storage conditions: Keep away from food, drink and animal feed.  Storage period: 4 years  Storage temperature: 2 - 25 °C |

### General directions for use

#### Instructions for use

|  |
| --- |
| Please refer to chapter 2.1.4 |

#### Risk mitigation measures

|  |
| --- |
| Please refer to chapter 2.1.4 |

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

|  |
| --- |
| Please refer to chapter 2.1.4 |

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

|  |
| --- |
| Please refer to chapter 2.1.4 |

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

|  |
| --- |
| Please refer to chapter 2.1.4 |

### Other information

|  |
| --- |
| metaSPC 2: The products should have child-proof closure. |

### Packaging of the biocidal product

Packaging of the ready-to-use product (metaSPC 1)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 with trigger sprayer | 750 mL | HDPE or PET | HDPE or PET | non-professional | Yes |

Packaging of the concentrate (metaSPC 2)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | 500 mL | HDPE or PET | HDPE or PET | non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

Not applicable

#### Access to documentation

No letter of access has been submitted by the applicant to the dossier that supported the registration of the active substance nonanoic acid under the Biocidal Product Directive 98/8/EC to get Annex I inclusion. Instead, the applicant has submitted an own full dossier (alternative dossier) according to Article 95 of the Biocidal Product Regulation (EU) No 528/2012. Nonanoic acid for PT2 from COMPO GmbH is on the Article 95 list. The eCA has evaluated the alternative dossier according to the guidance document AP 13.2.-CG-16-2016-14, please refer to the confidential annex of the PAR for the results.

The applicant has submitted a letter of access from the submitter of the active substance dossier in the Review Program, W. Neudorff GmbH KG, Germany, which grants data access to a 28-day prolonged toxicity test of nonanoic acid in rainbow trout (*Oncorhynchus mykiss*).

## Assessment of the biocidal product family

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

[See 2.1.4 for the authorised uses, after assessment of the dossier.]

**Table 3. Intended use # 1 –** **algaecide, ready-to use, outdoor use**

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Green algae and lichens. |
| **Field of use** | Outdoor use: patios, paths, car parks, masonry, steps (includes rocks, wood and natural stone) |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | One spray bottle is sufficient to treat 7.5 m2. In case of very light surface discolouration, one spray bottle is sufficient to treat 15 m2.  Repeat treatment if necessary (no more than two treatments at an interval of 20 to 60 days) |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 750 mL bottle made of HDPE or PET. |

**Table 4. Use # 2 – algaecide, concentrate, outdoor use**

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Green algae and lichens. |
| **Field of use** | Outdoor use: patios, paths, car parks, masonry, steps (includes rocks, wood and natural stone) |
| **Application method(s)** | Pouring or spraying (diluted concentrate) |
| **Application rate(s) and frequency** | Add 1 liter of water to 150 mL of concentrate to create the diluted concentrate solution. This amount of solution is sufficient to treat 11 m2. In case of very light surface discolouration this amount is sufficient to treat 20 m2.  Repeat treatment if necessary (no more than two treatments at an interval of 20 to 60 days) |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 500 mL bottle made of HDPE or PET. |

### Physical, chemical and technical properties

**Structure of the biocidal product family**

|  |  |  |
| --- | --- | --- |
| *Meta SPC* | *Name* | *Product code* |
| 1 | COMPO Groene aanslagreiniger klaar voor gebruik | COM 508 09 AL B  COM 508 09 H AL |
| 2 | COMPO Groene aanslagreiniger concentraat | COM 508 16 EW B  COM 508 16 H EW |

| **Property** | **Guideline and Method** | **Tested product** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Liquid | Schieck, 2010a |
|  | Visual inspection | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | Liquid | Schieck, 2010b |
| Colour at 20 °C and 101.3 kPa | Visual inspection | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | White milky | Schieck, 2010a |
|  | Visual inspection | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | White milky | Schieck, 2010b |
| Odour at 20 °C and 101.3 kPa | Olfactory inspection | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Sour odour and like coconut. | Schieck, 2010a |
|  | Olfactory inspection | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | Aromatic odour like coconut | Schieck, 2010b |
| Acidity / alkalinity | CIPAC method 75.3 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Results of pH at 20 °C:  4.55 (undiluted)  4.09 (diluted, 1% in water) | Schieck, 2010a |
|  | CIPAC method 75.3 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | Results of pH at 20 °C:  4.47 (undiluted)  4.12 (diluted, 1% in water) | Schieck, 2010b |
|  | − | − | The acidity was not determined because the pH value was between 4 and 10. | − |
| Relative density / bulk density | EU method A.3 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Density:  0.9793 g/cm3 at 19.7 °C  D420: 0.9793 (calculated) | Schieck, 2010c |
|  | EU method A.3 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | Density:  0.9958 g/cm3 at 19.7 °C  D420: 0.9958 (calculated) | Schieck, 2010d |
|  | − | − | The bulk density must be determined for solids. Since the biocidal products are liquid this test does not apply. | − |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.3  2 weeks at 54 °C | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The formulation is stable in HDPE at 54 °C for 2 weeks. No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 23.821 g before storage and 22.966 g after storage. The appearance of the product and packaging, pH, emulsion characteristics as well as pourability, were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2010a |
|  |  |  | Appearance of the product before and after storage: White milky formulation with a sour odour and like coconut. |  |
|  |  |  | Stability of the HDPE packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 565.1 g, weight after storage: 564.5 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product was 4.09 before storage and 4.20 after storage.  The pH value of the undiluted product was 4.55 before storage and 4.65 after storage. |  |
|  |  |  | Emulsion characteristics: At the initial emulsification, all samples were emulsified spontaneously and they were all still emulsified after standing for 30 min.  After standing for 2 h and 24 h a small creamy phase (~0.2mL) could be observed. The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. |  |
|  |  |  | Pourability:  Before storage:  Residue: 0.6701%  Rinsed residue: 0.2742%  After storage:  Residue: 0.5347%  Rinsed residue: 0.1615% |  |
|  | CIPAC method MT 46.3  2 weeks at 54 °C | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The formulation is stable in HDPE at 54 °C for 2 weeks. No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 2.871 g before storage and 2.901 g after storage. The appearance of the product and packaging as well as pH were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2010b |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour like coconut. |  |
|  |  |  | Stability of the HDPE packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 826.3 g, weight after storage: 825.4 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product was 4.12 before storage and 4.19 after storage.  The pH value of the undiluted product was 4.47 before storage and 4.49 after storage. |  |
|  | CIPAC method MT 46.3  8 weeks at 40 °C  Spray diameter and discharge rate: PSD, Data Requirements Handbook, Point 4.17  Clogging: Manual on Development and use of FAO and WHO Specifications for Pesticides, chapter 8.11.4.5 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The biocidal product is stable for 8 weeks at 40 °C in the tested packaging (HDPE bottle with three different trigger sprayer: Trigger Sprayer SP05 of Spray Plast, Trigger Sprayer T95 of Canyon and Trigger Sprayer “Mixor” of Calmar).  No clogging could be observed. There were no noticeable problems in the spray behaviour. No formation of droplets could be observed during operating. No significant changes occurred with regards to the spray diameter and the discharge rate.  Results for the three trigger sprayer:  The distance between spray nozzle and paper was about 30 cm ± 0.5 cm.  Trigger sprayer SP05:  The discharge rate is the same at T=0 and after storage, namely 1.17g/operation.  The spray diameter at T=0 is 42.4 cm. After storage the spray diameter is 36.5 cm.  Trigger sprayer mixor:  The discharge rate at T=0 is 1.25g/operation. After storage the discharge rate is 1.28g/operation  The spray diameter is the same T=0 and after storage, namely 21.2 cm.  Trigger sprayer T95:  The discharge rate at T=0 is 1.06g/operation. After storage the discharge rate is 1.05g/operation  The spray diameter at T=0 is 35.9 cm. After storage the spray diameter is 31. cm. | Schieck, 2010g, h, i |
| **eCA remark:**  Despite the fact that accelerated storage stability studies at elevated temperature show acceptable results, the applicant wishes to put on the label the storage condition ‘Store between 2-25°C’. As the eCA does not see any issues with including this sentence it is included in the SPC. | | | | |
| Storage stability test – **long term storage at ambient temperature** | GCPF (former GIFAP) Monograph No. 17  2 years at ambient temperature | Concentrate (COM 508 16 EW B), content a.s.: 24.26% (237.59 g/L) | The formulation is stable in HDPE at ambient temperature for 2 years. No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 24.14% before storage and 23.20% after storage. The appearance of the product and packaging, pH, emulsion characteristics as well as pourability were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2014 |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). The odour is also a little bit sourish. |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 558.7 g, weight after storage: 557.4 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product was 4.02 before storage and 3.88 after storage.  The pH value of the undiluted product was 4.57 before storage and 4.61 after storage.  No significant changes occurred during storage. |  |
|  |  |  | Emulsion characteristics: At the initial emulsification, all samples were emulsified spontaneously and they were all still emulsified after standing for 2 h.  After standing for 24 h a small creamy phase (~0.2mL) could be observed partially. The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. |  |
|  |  |  | Pourability:  Before storage:  Residue: 0.39%  Rinsed residue: 0.11%  After storage:  Residue: 0.46%  Rinsed residue: 0.17% |  |
|  | GCPF (former GIFAP) Monograph No. 17  3 years at ambient temperature | Concentrate (COM 508 16 EW B), content a.s.: 24.26% (237.59 g/L) | The formulation is stable in HDPE at ambient temperature for 3 years (interim results). No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 23.36% before storage and 24.47% after storage. The appearance of the product and packaging, pH, emulsion characteristics as well as pourability were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2016a |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 564.1 g, weight after storage: 561.7 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product (1% in water) at 20 !C was 4.14 before storage and after storage.  The pH value of the undiluted product at 20 °C was 4.64 before storage and 4.54 after storage.  No significant changes occurred during storage. |  |
|  |  |  | Emulsion characteristics: At the initial emulsification, all samples were emulsified spontaneously and they were all still emulsified after standing for 2 h.  After standing for 24 h a small creamy phase (~0.2mL) could be observed partially at the beginning of the study. The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. |  |
|  |  |  | Pourability:  Before storage:  Residue: 0.54%  Rinsed residue: 0.17%  After storage:  Residue: 0.50%  Rinsed residue: 0.13%  No significant changes occurred during storage. |  |
|  | GCPF (former GIFAP) Monograph No. 17  4 years at ambient temperature | Concentrate (COM 508 16 EW B), content a.s.: 24.26% (237.59 g/L) | The formulation is stable in HDPE at ambient temperature for 4 years (interim results). No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 23.36% before storage and 22.39% after storage. The appearance of the product and packaging, pH, emulsion characteristics as well as pourability were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2018 |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 565.3 g, weight after storage: 561.7 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product (1% in water) at 20 °C was 4.14 before storage and 4.08 after storage.  The pH value of the undiluted product at 20 °C was 4.64 before storage and 4.60 after storage.  No significant changes occurred during storage. |  |
|  |  |  | Emulsion characteristics: At the initial emulsification, all samples were emulsified spontaneously and they were all still emulsified after standing for 2 h.  After standing for 24 h a small creamy phase (~0.2mL) could be observed partially at the beginning of the study. The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. |  |
|  |  |  | Pourability:  Before storage:  Residue: 0.54%  Rinsed residue: 0.17%  After storage:  Residue: 0.60%  Rinsed residue: 0.34%  No significant changes occurred during storage. |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | GCPF (former GIFAP) Monograph No. 17  2 years at ambient temperature | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The formulation is stable in PET at ambient temperature for at least 2 years. No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 3.09% before storage and 2.99% after storage. The appearance of the product and packaging, pH, clogging, spray diameter and discharge rate were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2015 |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 816.5 g, weight after storage: 814.3 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product was 4.10 before storage and 4.11 after storage.  The pH value of the undiluted product was 4.53 before storage and 4.55 after storage.  No significant changes occurred during storage. |  |
|  |  |  | No clogging could be observed before and after storage. A few drops collected at the spray nozzle during pumping.  The spray diameter was 31.4 cm before and 30.4 cm after storage.  The discharge rate was 1.11 g before and 1.28 g after storage.  No significant changes occurred during storage. |  |
|  | GCPF (former GIFAP) Monograph No. 17  3 years at ambient temperature | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The formulation is stable in PET at ambient temperature for at least 3 years (interim results). No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 3.09% before storage and after storage. The appearance of the product and packaging, and pH were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2016b |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 816.3 g, weight after storage: 796.3 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product (1% in water) at 20 °C was 4.10 before storage and 4.13 after storage.  The pH value of the undiluted product at 20 °C was 4.53 before storage and 4.44 after storage.  No significant changes occurred during storage. |  |
|  | GCPF (former GIFAP) Monograph No. 17  4 years at ambient temperature | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The formulation is stable in PET at ambient temperature for at least 4 years. No significant changes of physical-chemical properties and packaging stability occurred during the test. The nonanoic acid content was 3.09% before storage and 3.02% after storage. The appearance of the product and packaging, and pH were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2018 |
|  |  |  | Appearance of the product before and after storage: White milky formulation with an aromatic odour (like coconut). |  |
|  |  |  | Stability of the packaging before and after storage: The bottles are practically new without any traces of usage. During storage no changes occurred. There are no signs that the quality of the material has changed.  Weight change of unopened container: Weight before storage: 815.5 g, weight after storage: 789.5 g. No significant changes occurred during storage. |  |
|  |  |  | The pH value of the diluted product (1% in water) at 20 °C was 4.10 before storage and 4.04 after storage.  The pH value of the undiluted product at 20 °C was 4.53 before storage and 4.47 after storage.  No significant changes occurred during storage. |  |
|  |  |  | No clogging could be observed before and after storage. A few drops collected at the spray nozzle during pumping.  The spray diameter was 31.4 cm before and 27.3 cm after storage.  The discharge rate was 1.11 g before and 1.21 g after storage.  No significant changes occurred during storage. |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC method MT 39.3 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The formulation is stable at 0 °C for 7 days. No material was separated after storage, the volume of the formulation has not changed. The pH and emulsion characteristics were determined before and after storage. Results for these tests were considered acceptable. | Schieck, 2010e |
|  |  |  | The pH value of the diluted product (1% in water) was 4.16 before and after storage.  The pH value of the undiluted product was 4.58 before storage and 4.62 after storage. |  |
|  |  |  | Emulsion characteristics: At the initial emulsification, all samples were emulsified spontaneously and they were all still emulsified after standing for 2 h.  After standing for 24 h a small creamy phase (~0.2mL) could be observed. The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. |  |
|  | CIPAC method MT 39.3 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The formulation is stable at 0 °C for 7 days. No material was separated after storage, the volume of the formulation has not changed. The pH was determined before and after storage. Results for this test were considered acceptable. | Schieck, 2010f |
| **eCA remark:**  Despite the fact that low temperature stability tests show acceptable results, the applicant wishes to put on the label the storage condition ‘Protect from frost’. As the eCA does not see any issues with including this sentence it is included in the SPC. | | | | |
|  |  |  | The pH value of the diluted product (1% in water) was 4.17 before and after storage.  The pH value of the undiluted product was 4.43 before and after storage. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | − | − | Not applicable as the packaging is light-proof. Therefore, the formulations are not exposed to light during storage. | − |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | − | − | Not applicable because according to the label instructions the biocidal products have to be kept in a cool place. | − |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | − | − | The products are stable for at least 4 years in PET and HDPE.  Please refer to the results of the storage stability studies summarised above. | − |
| Wettability | − | − | The wettability must be determined for solid preparations which are to be dispersed in water. Since the biocidal products are liquid this test does not need to be performed. | − |
| Suspensibility, spontaneity and dispersion stability | − | − | The suspensibility, spontaneity and dispersion stability must be determined for solid biocidal products or suspensions, respectively. Since the biocidal products are liquid and no suspensions these tests do not need to be performed. | − |
| Wet sieve analysis and dry sieve test | − | − | The wet sieve and dry sieve test must be performed for solid biocidal products, dispersible concentrates or suspensions, respectively. Since the biocidal products are not solid, no dispersable concentrates and no suspensions, these tests do not need to be performed. | − |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC method MT 36.3 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The analyses were carried out at the highest (13%) and at the lowest (0.7%) application concentration levels of the biocidal product and with two standard waters (CIPAC water A and D).  All samples were emulsified spontaneously and they were all still emulsified after standing for 30 min.  After standing for 2 h and 24 h a small creamy phase (~0.2mL) could be observed.  The re-emulsification was done and all samples were totally re-emulsified. The samples were still emulsified until the end of the determination. | Schieck, 2010a |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The data on emulsifiabilty, re-emulsifiabilty and emulsion stability are required to determine whether a preparation forms and maintains a stable emulsion. Since the biocidal product COM 508 09 AL B is a ready-to-use product these tests do not need to be performed. | − |
| Disintegration time | − | − | The disintegration time must be determined for biocidal products supplied as tablets. Since the biocidal products are liquid this test does not need to be performed. | − |
| Particle size distribution, content of dust/fines, attrition, friability | − | − | The data on particle size distribution, content of dust/fines, attrition, and friability are required for solid biocidal products. Since the biocidal products are liquid formulations these tests do not need to be performed. | − |
| Persistent foaming | CIPAC method MT 47.2 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Tested concentration:  13% (CIPAC water C was used)  Volume of foam after  10 sec: 33 mL  1 min: 29.5 mL  3 min: 28.0 mL  12 min: 26.0 mL | Schieck, 2010j |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The persistence of foaming must be investigated for biocidal products which have to be diluted with water before application. Since the biocidal product COM 508 09 AL B is not intended for dilution with water before use, this test does not need to be performed. | − |
| Flowability/Pourability/Dustability | CIPAC method MT 148 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | Result of pourability:  Residue: 0.6701%  Rinsed residue: 0.2742%  The flowability has to be determined for granular formulations and the dustability for dusts. Since no equipment is needed for the application of the biocidal product and since the biocidal product is no dust these tests do not need to be performed. | Schieck, 2010a |
|  |  |  | **eCA remark**  The rinsed residue was slightly above 0.25% in some cases. In the instructions for safe disposal, the applicant has recommended to offer rinsed packaging to local recycling facilities. |  |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The flowability has to be determined for granular formulations. The pourability must be investigated for suspension concentrates, capsule suspensions and suspo-emulsions and the dustability for dusts. Since the biocidal product COM 508 09 AL B is no granular formulation, no suspension, emulsion, or dust these tests do not need to be performed. | − |
| Burning rate — smoke generators | − | − | The burning rate must be determined for biocidal products intended to be used as smoke generators. Since the biocidal products are not smoke generators this test does not need to be performed. | − |
| Burning completeness — smoke generators | − | − | The burning completeness must be determined for biocidal products intended to be used as smoke generators. Since the biocidal products are not smoke generators this test does not need to be performed. | − |
| Composition of smoke — smoke generators | − | − | The composition of smoke must be determined for biocidal products intended to be used as smoke generators. Since the biocidal products are not smoke generators this test does not need to be performed. | − |
| Spraying pattern — aerosols | − | − | The spraying pattern must be determined for aerosols. Since the biocidal products are not aerosols this test does not need to be performed. | − |
| Clogging, Spray diameter and discharge rate | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | For results of clogging, spray diameter and discharge rate of the ready-to-use spray, please refer storage stability tests summarised above. | − |
|  | − | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The clogging of dispenser valve, spray diameter and discharge rate must be investigated for biocidal products supplied in bottles with trigger sprayer. Since the biocidal product COM 508 16 EW B is not supplied in such a bottle, this test does not need to be performed. | − |
| Physical compatibility | − | − | The biocidal products are not intended to be used with other products including other biocidal products. Therefore no information is submitted about their physical compatibility with other products. | − |
| Chemical compatibility | − | − | The biocidal products are not intended to be used with other products including other biocidal products. Therefore no information is submitted about their chemical compatibility with other products. | − |
| Degree of dissolution and dilution stability | − | − | The degree of dissolution must be determined for water soluble bags and tablets, the dilution stability for water-soluble preparations. Since the biocidal products are not water soluble bags, tablet or a water-soluble preparations these tests do not need to be performed. COM 508 09 AL B is a liquid ready-to-use formulation and COM 508 16 EW B is an oil in water emulsion. | − |
| Surface tension | EC method A.5 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The surface tension of the biocidal product is 25.56 mN/m at 20.4 °C and 26.29 mN/m at 40 °C.  The highest in use concentration of the concentrate is equal to the ready-to-use product concentration (30.99 g/L). | Schieck, 2010c |
|  | EC method A.5 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The surface tension of the biocidal product is 27.01 mN/m at 20.5 °C and 27.42 mN/m at 39.6 °C. | Schieck, 2010d |
| Viscosity | CIPAC method MT 192 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The viscosity was measured at different shear rates (beginning with the lowest one). To determine the suitable shear rate, a plot was created (viscosity against shear rate). Three suitable shear rates were selected within the relevant measuring range. The measurement was carried out at each of the selected shear rates for six times. The result is that one with the lowest standard deviation.  The viscosity of the biocidal product is 21.5 mPa\*s at 20 °C and a shear rate of 28.7 s-1 and 10.8 mPa\*s at 40 °C and a shear rate of 51.6 s-1. | Schieck, 2010c |
|  | CIPAC method MT 192 | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | The viscosity of the biocidal product is 2.40 mPa\*s at 20.1 °C and a shear rate of 0.57 s-1 and 0.96 mPa\*s at 39.9 °C and a shear rate of 2.87 s-1. | Schieck, 2010d |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Both biocidal products (concentrate COM 508 16 EW B and ready-to-use COM 508 09 AL B) are white milky liquids with an odour like coconut. The concentrate has also a sour odour. The pH value of the undiluted concentrate is 4.64 and of the undiluted ready-to-use product 4.53. The pH value of a 1% v/v solution of the concentrate in water is 4.14 and of the ready-to-use product 4.10. The relative density of the concentrate is 0.9793 and of the ready-to-use product 0.9958. Both products can be regarded as surface active. The biocidal products are stable at 54 °C for 2 weeks, at 0 °C for 7 days and for at least 4 years at ambient temperature in PET and HDPE packaging. No significant changes of physical-chemical properties and packaging stability occurred during the tests.  The provided data are representative for the biocidal product family. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Tested product** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | EU method A.14 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The biocidal product has no explosive properties. | Krack, 2010a |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | As COM 508 09 AL B is a dilution of COM 508 16 EW B in water it can be concluded, that COM 508 09 AL B has no explosive properties. | − |
| Flammable gases | − | − | The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal products are not gases this test does not need to be performed. | − |
| Flammable aerosols | − | − | The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal products are not aerosols this test does not need to be performed. | − |
| Oxidising gases | − | − | The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal products are liquids this test does not need to be performed. | − |
| Gases under pressure | − | − | The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal products are liquid this test does not need to be performed. | − |
| Flammable liquids | EU method A.9 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | No flash point was observed up to 100 °C. The biocidal product is not flammable. | Krack, 2010b |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | As COM 508 09 AL B is a dilution of COM 508 16 EW B in water it can be concluded, that COM 508 09 AL B neither has a flash point up to 100°C. | − |
| Flammable solids | − | − | The parameter flammable solids must be determined for solid biocidal products. Since the biocidal products are liquid this test does not need to be performed. | − |
| Self-reactive substances and mixtures | − | − | There are no ingredients with explosive or self-reactive properties present in the biocidal products. Therefore the formulation is not self-reactive. | − |
| Pyrophoric liquids | − | − | The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected. | − |
| Pyrophoric solids | − | − | The parameter pyrophoric solids must be determined for solid biocidal products. Since the biocidal products are liquid this test does not need to be performed. | − |
| Self-heating substances and mixtures | − | − | The study does not need to be conducted as the biocidal products are liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface. | − |
| Substances and mixtures which in contact with water emit flammable gases | − | − | The biocidal products contain water. Therefore an emission of flammable gases is not expected when the preparations come in contact with water. | − |
| Oxidising liquids | EU method A.21 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The biocidal product has no oxidising properties. | Krack, 2010c |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | As COM 508 09 AL B is a dilution of COM 508 16 EW B in water it can be concluded, that COM 508 09 AL B has no oxidising properties. | − |
| Oxidising solids | − | − | The parameter oxidising solids must be determined for solid biocidal products. Since the biocidal products are liquid this test does not need to be performed. | − |
| Organic peroxides | − | − | Since the biocidal products are not organic peroxides, tests do not need to be performed. | − |
| Corrosive to metals | − | − | The products have been known since many years. It has never been reported any significant corrosion with tank or applicability material which are partially made of metal. The products are not significantly corrosive to metals. Furthermore containers made of carbon steel or aluminium are not recommended. The packaging material is HDPE and PET, respectively. | − |
| Auto-ignition temperatures of products (liquids and gases) | EU method A.15 | Concentrate (COM 508 16 EW B), content a.s.: 24.37% (237.59 g/L) | The auto-ignition temperature of the biocidal product is 430 °C. | Krack, 2010d |
|  | − | Ready-to-use product (COM 508 09 AL B), content a.s.: 3.1% (30.99 g/L) | As COM 508 09 AL B is a dilution of COM 508 16 EW B in water it can be concluded, that COM 508 09 AL B is not auto-flammable. | − |
|  | − | − | The auto-ignition temperature must be determined for gases. Since the biocidal products are liquid this test does not need to be performed. | − |
| Relative self-ignition temperature for solids | − | − | The parameter self-ignition solids must be determined for solid biocidal products. Since the biocidal products are liquid this test does not need to be performed. | − |
| Dust explosion hazard | − | − | The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal products are liquid this test does not need to be performed. | − |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Both biocidal products (concentrate COM 508 16 EW B and ready-to-use COM 508 09 AL B) have no explosive, flammable, or oxidizing properties.  The provided data are sufficient to cover the biocidal product family. |

### Methods for detection and identification

| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Concentrate (COM 508 16 EW B), content a.s. nonanoic acid: 24.37% (237.59 g/L) | GC-FID | Two synthetic samples were prepared for each fortification level. Each sample was measured twice.  Fortification levels: 17.06, 24.37, 31.68%, corresponding to commercial formulation -30%, like commercial formulation and commercial formulation + 30%, respectively. | Six concentration levels over the range 0.125% - 1.25% (app. 5% - 50% in formulation) were measured. Each concentration was measured two times. Correlation coefficient: 0.999 | No interference with other peaks. | Results of recoveries determined for each fortification level:  Range: 97.88 - 100.12%, Mean: 99.03% (n=4), (fortification level 17.06%) Range: 100.94 - 102.68%, Mean: 101.90% (n=4), (fortification level 24.37%) Range: 99.24 - 101.83%, Mean: 100.60% (n=4), (fortification level 31.68%)  The mean recovery over all levels was 100.51% with a relative standard deviation of 1.59%. | | | Limit of detection: 0.5%  Limit of quantification: 1.5% | Schieck, 2010k |
| Ready-to-use product (COM 508 09 AL B), content a.s. nonanoic acid: 3.1% (30.99 g/L) | GC-FID | Two synthetic samples were prepared for each fortification level. Each sample was measured twice.  Fortification levels: 2.17, 3.1, 4.03%, corresponding to commercial formulation -30%, like commercial formulation and commercial formulation + 30%, respectively. | Six concentration levels over the range 0.125% - 1.25% (app. 0.78125% - 7.8125% in formulation) were measured. Each concentration was measured two times. Correlation coefficient: 1.000 | No interference with other peaks. | Results of recoveries determined for each fortification level:  Range: 96.13 - 98.14%, Mean: 97.13% (n=4), (fortification level 2.17%)  Range: 96.90 - 98.88%, Mean: 97.79% (n=4), (fortification level 3.1%)  Range: 96.67 - 99.10%, Mean: 97.58% (n=4), (fortification level 4.03%)  The mean recovery over all levels was 97.50% with a relative standard deviation of 0.93%. | | | Limit of detection: 0.02%  Limit of quantification: 0.07% | Schieck, 2010l |

Analytical methods or justifications for non-submission of them for the determination of nonanoic acid residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. Please refer to the dossier submitted for the active substance for its inclusion in the list of Article 95 BPR. Analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or is intended to be placed on, in or near soils in agricultural or horticultural use. The active substance nonanoic acid is not intended for direct application to foods or feedingstuffs or to surfaces and areas where foods or feedingstuffs are prepared or stored. The biocidal products should be kept away from food, drink and animal feed. Exposure of food and feedstuffs to nonanoic acid can be excluded when applied according to the recommended use. An analytical method for the determination of active substance residues in/on food and feedstuffs is therefore not necessary.

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| **Conclusion on the methods for detection and identification of the product** |
| The analytical methods have been successfully validated for specificity, linearity, repeatability, accuracy and limit of determination / detection and are therefore regarded valid for the determination of the active substance content in the biocidal products. |

### Efficacy against target organisms

#### Function and field of use

The biocidal product family COM 508 consists of a biocidal product concentrate COM 508 16 EW B and the ready-to-use formulation COM 508 09 AL B which contain the active substance nonanoic acid.

The biocidal products are used for remedial treatment of rocks, wood and natural stones to remove stubborn green surface discolouration on patios, paths, car parks, masonry, steps, and other hard surfaces. The products are used outdoors by non-professionals.

The ready-to-use solution is sprayed evenly over the dry surface to be treated. After diluting the EW concentrate, the dilution is sprayed or poured evenly over the dry surface. After treatment the surface is not rinsed and the biocidal product should be incubated for at least 24 hours. An application has to be done only if no rain is expected for the day of application.

Algae and lichens (algae or cyanobacteria living in a symbiotic relationship with fungi) are expected not to destroy the material as such, but to cause unwanted visual and hygienic effects. Thus, algaecides are not considered to be acting as preservatives in the sense of the current Biocidal Product Regulation (BPR), but as general purpose biocides within product-type 2. In the BPR, products used against algae for remedial treatment of construction materials belong to product type 2 “Disinfectants and algaecides not intended for direct application to humans or animals”.

The emulsion oil in water formulation COM 508 16 EW B contains 237.59 g/L nonanoic acid and the ready-to-use formulation COM 508 09 AL B contains 30.99 g/L nonanoic acid.

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

The biocidal products are intended to be used to remove green algae and lichens on rocks, wood and natural stones of e.g. patios, paths, car parks, masonry, steps.

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

Nonanoic acid is a naturally occurring fatty acid found in plants and animals. When applied to growing plants (including algae and the photobiont (algae, cyanobacteria) in lichens) in sufficient quantities, nonanoic acid causes tissue death.

#### Mode of action, including time delay

The active substance nonanoic acid is a naturally occurring fatty acid found in plants and animals. When applied to growing plants the active substance nonanoic acid quickly penetrates into the plant tissue and disrupts cell membrane. This results in an unspecific and uncontrolled release of cell contents and in an inhibition of photosynthesis which consequently leads to cell death. Due to its lipophilic characteristics the active substance quickly penetrates into the cells and disrupts cell membrane permeability. The result is the destruction of the photosynthesis mechanisms and other membrane bound physiological processes in both algae and cyanobacteria. Finally, an uncontrolled leakage of cell contents occurs.

In addition, lichen are algae or cyanobacteria (the so called photobiont) living in a symbiotic relationship with fungi (mycobiont). The majority of lichens (approx. 90%) have a symbiotic relationship with algae and only 10% with cyanobacteria. By killing the algae or cyanobacteria, the lichen is hindered in growth due to the lack of organic products, deriving from the algae or cyanobacteria (photosynthesis products). As a result the lichen will be killed.

#### Efficacy data

| **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 | non crop areas, farmyard paved with cobblestones | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae, *Desmodesmus subspicatus* | Suspension test (in-house method, algae inhibition) | Algae suspension  Test substance application: 130 mL/L, 40.36 mL/L and 10.48 mL/L (corresponding to 3.1%, 0.77% and 0.2% a.s. concentration)  Test substance contact time: 10 min, 8 h, 24 h  Incubation temperature: 23 °C ± 2 °C  Neutralization: membrane filtration  Incubation time after resuspension: 72 h (96)  Evaluation: Fluorometric measurement, determination of % inhibition in relation to control | On the basis of obtained results the test formulations COM 508 16 H (0.2, 0.77 and 3.1%) has been active against algae in the suspension test under experimental conditions.   |  |  |  | | --- | --- | --- | |  | % inhibition after 10 min | | | Product concentration | Acute | 72h algae incubation | | 3.1% | 27.3 | 55.9 | | 0.77% | 31.2 | 77.4 | | 0.2% | 38.5 | 42.9 |  |  |  |  | | --- | --- | --- | |  | % inhibition after 8 h | | | Product concentration | Acute | 72h algae incubation | | 3.1% | 80.8 | 99.9 | | 0.77% | 83.3 | 99.9 | | 0.2% | 84.0 | 99.8 |  |  |  |  | | --- | --- | --- | |  | % inhibition after 24 h | | | Product concentration | Acute | 72h algae incubation | | 3.1% | 96.7 | 99.7 | | 0.77% | 99.0 | 99.6 | | 0.2% | 98.6 | 99.6 | | Allerdings, E. & Lebertz, H. (2016) |
| Algaecide | non crop areas, farmyard paved with cobblestones | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (2) | Test system: farmyard paved with cobblestones covered with algae between the stones Location: Upper Austria  Application: single application, spray, 25 °C  Test substance concentration: 130 L/ha (31000 g nonanoic acid/ha)= 13 mL/m2  Replicates: 3  Controls: Untreated plot (negative control), Finalsan Unkrautfei (166 L/ha, 31000 g nonanoic acid/ha) (positive control)  Evaluation: visual % of control recorded (2, 9, 16, 28 days) | On the basis of obtained results the test formulations COM 508 16 H (130 L/ha) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 2 | 9 | 16 | 28 | | 130 l/ha = 13 mL/m2 | 100 | 100 | 100 | 100 | | Finalsan Unkrautfrei (positive control) | 76.7 | 83.3 | 66.7 | 63.3 | | Stratmann, B. & Anzengruber, J. (2011) |
| Algaecide | non crop areas (pathways with trees), sandy silt soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (3),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas (pathways with trees), sandy silt soil Location: Germany  Randomized Complete Block (RCB) with a plot size of 1 x 12.5 m  initial density: Algae: 88.75%  Application: single application, spray, 24.2 °C  Application rate: 65, 97 and 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 9, 15, 27 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.  Algae:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 3 | 9 | 15 | 27 | | 65 L/ha = 6.5 mL/m2 | 92.50 | 97.75 | 95.00 | 67.50 | | 97 L/ha = 9.7 mL/m2 | 96.50 | 99.00 | 97.25 | 83.25 | | 130 L/ha = 13 mL/m2 | 98.25 | 99.00 | 99.00 | 91.75 | | Rohr, J. (2010a) |
| Algaecide | non crop areas (pathways with trees), sandy silt soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (3),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas (pathways with trees), sandy silt soil Location: Poland Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 12.50%  Application: single application, spray, 16.7 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (2, 7, 14, 28 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial up to 14 days under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 2 | 7 | 14 | 28 | | 130 L/ha = 13 mL/m2 | 93.25 | 96.50 | 96.25 | 82.50 | | Rohr, J. (2010b) |
| Algaecide | non crop areas (pathways with trees), sandy silt soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (3),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas (pathways with trees), sandy silt soil Location: Poland Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 37.50%  Application: single application, spray, 17.1 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (2, 7, 14, 28 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial up to 14 days under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 2 | 7 | 14 | 28 | | 130 L/ha = 13 mL/m2 | 83.25 | 98.25 | 97.00 | 72.50 | | Rohr, J. (2010c) |
| Algaecide | non crop areas, sandy silt soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, sandy silt soil Location: Poland Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 5.75%  Application: single application, spray, 23.3 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 10, 22, 49 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 3 | 10 | 22 | 49 | | 130 L/ha = 13 mL/m2 | 93.25 | 99.00 | 95.00 | 88.75 | | Rohr, J. (2010d) |
| Algaecide | non crop areas (pathways with trees), silty clay soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (3),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas (pathways with trees), silty clay soil Location: Germany  Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 71.25%  Application: single application, spray, 23.4 °C  Application rate: 65, 97 and 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 9, 15, 27 days) | On the basis of obtained results the test formulations COM 508 16 H EW has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.  Algae:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 3 | 9 | 15 | 27 | | 65 L/ha = 6.5 mL/m2 | 97.00 | 96.50 | 93.25 | 57.50 | | 97 L/ha = 9.7 mL/m2 | 98.00 | 98.50 | 95.00 | 73.25 | | 130 L/ha = 13 mL/m² | 99.00 | 99.00 | 97.25 | 90.00 | | Rohr, J. (2010e) |
| Algaecide | non crop areas (pathways with trees), silty loam soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (3),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas (pathways with trees), silty loam soil Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 7 m  Initial density: Algae: 44.25%  Application: single application, spray, 27.9 °C  Application rate: 65, 97 and 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (2, 7, 13, 27 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.  Algae:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 2 | 7 | 13 | 27 | | 65 L/ha = 6.5 mL/m2 | 85.25 | 96.25 | 93.25 | 80.25 | | 97 L/ha = 9.7 mL/m2 | 92.50 | 97.50 | 94.00 | 83.00 | | 130 L/ha = 13 mL/m2 | 96.25 | 98.25 | 96.25 | 87.75 | | Rohr, J. (2010f) |
| Algaecide | non crop areas (path and places) | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guideline PP 1/117 (3) | Test system:  non crop areas (path and places) Location: Germany Randomized Complete Block (RCB) with 2 m2  Application: single application, spray, 10.8 - 26 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (2, 7, 14, 21 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae under the experimental conditions according to the EPPO guideline PP 1/117 (3).   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Evaluation time (days) | 2 | 7 | 14 | 21 | | Pest density (control), % | 97.0 | 97.5 | 86.3 | 91.3 | | Reduction (% of untreated control) | 98.75 | 99.50 | 99.50 | 100.00 | | LWK Niedersachsen (2010) |
| Algaecide | non crop areas, silt loam soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, silt loam soil Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 47.50%  Application: single application, spray, 17.7 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3 and 7 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  | | --- | --- | --- | |  | % of untreated check | | | Evaluation time (days) | 3 | 7 | | COM 508 16 H, 130 L/ha = 13 mL/m2 | 97.00 | 93.75 | | Rohr, J. (2011g) |
| Algaecide | non crop areas, silt loam soil | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, silt loam soil  Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: 80%  Application: single application, spray, 19.1 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3 and 7 days) | On the basis of the obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid) has been active against algae at silt loam soil in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  | | --- | --- | --- | |  | % of untreated check | | | Evaluation time (days) | 3 | 7 | | COM 508 16 H EW, 130 L/ha = 13 mL/m2 | 98.00 | 95.00 | | Rohr, J. (2011h) |
| Algaecide | Wall – hard surfaces | COM 508 16 H EW (nonanoic acid content: 237.59 g(L) | Algae and lichens | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3) | Test system:  wall – hard surfaces  Location: France Randomized Complete Block (RCB) with a plot size of 2 x 2 m  Initial density: about 32% cover on wall  Application: single application, spray, 23.7 °C  Application rate: 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 7, 14, 29 and 45 days) | On the basis of obtained results the test formulations COM 508 16 H EW (237.59 g/L nonanoic acid has been active against algae and lichens in the field trial on day 29 to day 45 under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | | Eval-uation time (days) | 3 | 10 | 14 | 29 | 45 | | Algae  130 l/ha = 13 mL/m2 | 0 | 0 | 0 | 94.5 | 98.8 | | Lichen  130 l/ha = 13 mL/m2 | 0 | 0 | 0 | 94.5 | 98.8 | | Bersegeay, A. & Viard, J.B. (2011) |
| Algaecide | Interlocking paver – hard surfaces | COM 508 16 H EW (nonanoic acid content: 237.59 g/L) | Algae and lichens | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (2) | Test system:  utility yard , interlocking paver (hard surface) Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 6 m  Initial density: about 13.5% for lichen and 38.2% for algae  Application: 5 treatment levels (see application rate), one application per treatment level, applied by spraying  Application rate: 45, 65. 100 or 130 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot  Evaluation: visual % of control recorded (2, 7, 13, and 23 days after application) | On the basis of obtained results the test formulations COM 508 16 H EW has been active against algae and lichens in the field trial under the experimental conditions according to the EPPO guidelines.  All application rates were efficacious against algae and lichen. For lichens the two lower rates were significantly less efficacious. Maximum effect was observed 7 days after treatment for algae and 23 days after treatment for lichens.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Lichens | % of untreated check | | | | | Evaluation time(days) | 2 | 7 | 13 | 23 | | 130 L/ha = 13 mL/m2 | 70.25 | 91.75 | 96.00 | 98.00 | | 97 L/ha = 9.7 mL/m2 | 63.75 | 83.25 | 93.00 | 96.75 | | 65 L/ha = 6.5 mL/m2 | 58.25 | 80.00 | 88.25 | 91.75 | | 45 L/ha = 4.5 mL/m2 | 52.00 | 76.75 | 82.50 | 83.25 | | Rohr, J. (2016) |
|  |  |  |  |  |  | |  |  |  |  |  | | --- | --- | --- | --- | --- | | Algae | % of untreated check | | | | | Evaluation time (days) | 2 | 7 | 13 | 23 | | 130 L/ha = 13 mL/m2 | 93.25 | 97.50 | 97.00 | 94.75 | | 97 L/ha = 9.7 mL/m2 | 88.25 | 96.25 | 92.50 | 92.00 | | 65 L/ha = 6.5 mL/m² | 80.00 | 90.50 | 85.25 | 81.75 | | 45 L/ha = 4.5 mL/m² | 72.75 | 87.75 | 85.00 | 78.25 | |  |
| Algaecide | non crop areas, farmyard paved with cobblestones | COM 508 09 H AL  (nonanoic acid content: 30.99 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (2) | Test system: farmyard paved with cobblestones covered with algae between the stones Location: Upper Austria  Application: single application, spray, 25 °C  Test substance concentration:  1000 L/ha (31000 g nonanoic acid/ha)  Replicates: 3  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 31000 g nonanoic acid/ha)  Evaluation: visual % of control recorded (2, 9, 16, 28 days) | On the basis of obtained results the test formulations COM 508 09 H AL (1000 L/ha) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 2 | 9 | 16 | 28 | | Algae  1000 l/ha = 100 mL/m2 | 100 | 100 | 100 | 100 | | Stratmann, B. & Anzengruber, J. (2011) |
| Algaecide | non crop areas, sandy silt soil | COM 508 09 H AL  (nonanoic acid content: 30.99 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, sandy silt soil Location: Poland Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 5.75%  Application: single application, spray, 23.3 °C  Application rate: 1000 L/ha 100% (v/v)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 10, 22, 49 days) | On the basis of obtained results the test formulations COM 508 09 H AL (30.99 g/L nonanoic acid) has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | Evaluation time (days) | 3 | 10 | 22 | 49 | | Algae  1000 l/ha = 100 mL/m2 | 91.25 | 95.75 | 95.00 | 82.50 | | Rohr, J. (2010d) |
| Algaecide | non crop areas, silt loam soil | COM 508 09 H AL (nonanoic acid content: 30.99 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, silt loam soil Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: Algae: 47.50%  Application: single application, spray, 17.7 °C  Application rate: 1000 L/ha  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3 and 7 days) | On the basis of obtained results the test formulations COM 508 09 H AL (30.99 g/L nonanoic acid has been active against algae in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  | | --- | --- | --- | |  | % of untreated check | | | Evaluation time (days) | 3 | 7 | | COM 508 09 H AL, 1000 L/ha = 100 mL/m2 | 96.00 | 93.75 | | Rohr, J. (2011g) |
| Algaecide | non crop areas, silt loam soil | COM 508 09 H AL (nonanoic acid content: 30,99 g/L) | Algae | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3),  PP 1/181 (3),  PP 1/135 (3) | Test system:  non crop areas, silt loam soil  Location: Germany Randomized Complete Block (RCB) with a plot size of 2.5 x 5 m  Initial density: 80%  Application: single application, spray, 19.1 °C  Application rate: 1000 L/ha (carrier: water)  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3 and 7 days) | On the basis of the obtained results the test formulations COM 508 09 H AL (30.99 g/L nonanoic acid) has been active against algae at silt loam soil in the field trial under the experimental conditions according to the EPPO guidelines.   |  |  |  | | --- | --- | --- | |  | % of untreated check | | | Evaluation time (days) | 3 | 7 | | COM 508 09 H AL, 1000 L/ha = 100 mL/m2 | 97.25 | 91.25 | | Rohr, J. (2011h) |
| Algaecide | Wall – hard surfaces | COM 508 09 H AL (nonanoic acid content: 30.99 g/L) | Algae and lichens | EPPO Guidelines  PP 1/117 (2),  PP 1/152 (3) | Test system:  wall – hard surfaces  Location: France Randomized Complete Block (RCB) with a plot size of 2 x 2 m  Initial density: about 32% cover on wall  Application: single application, spray, 23.7 °C  Application rate: 1000 L/ha  Replicates: 4  Controls: Untreated plot, Finalsan Unkrautfei (166 L/ha, 186. 7 g/L nonanoic acid)  Evaluation: visual % of control recorded (3, 7, 14, 29 and 45 days) | On the basis of obtained results the test formulations COM 508 09 H AL (30.99 g/L nonanoic acid) has been active against algae and lichens in the field trial on day 29 to day 45 under the experimental conditions according to the EPPO guidelines.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | % of untreated check | | | | | | Eval-uation time (days) | 3 | 10 | 14 | 29 | 45 | | Algae  1000 l/ha = 100 mL/m2 | 0 | 0 | 0 | 89.5 | 96.5 | | Lichen  1000 l/ha = 100 mL/m2 | 0 | 0 | 0 | 89.5 | 96.5 | | Bersegeay, A. & Viard, J.B. (2011) |

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| **Conclusion on the efficacy of the product** |
| For the assessment of the efficacy of algaecidal products no criteria are included in the  ”Transitional guidance on efficacy for product types 1-5, disinfectants”. When assessing the efficacy of such products and choosing efficacy criteria, the intended use of the products should be taken into account. The removal of algae and lichens is desired to remove discolouration from surfaces or to remove slippery (and thus dangerous) layers of microorganisms from surfaces. The target organisms are not pathogenic or dangerous for human health.  To prove the basic efficacy of the product an adapted phase 2 step 1 test was provided using al algal species that can be grown under the test conditions. In this test a log reduction of >2 was observed, which is deemed sufficient considering the intended use of the product.  The provided field studies were performed according to guidelines as available via the European and Mediterranean Plant Protection Organisation (EPPO). These guidelines are used in assessing the efficacy of plant protection products for the control of weeds on hard and semi-permeable surfaces. Efficacy is assessed by visually measuring the percentage of target organisms in treated versus untreated plots. This test method is very much in line with the intended use and application of the algaecidal product under consideration. The EPPO guidelines do not offer efficacy criteria to be met, but from the SANCO E3 a document (GUIDANCE DOCUMENT ON THE EFFICACY COMPOSITION OF CORE DOSSIER AND NATIONAL ADDENDA SUBMITTED TO SUPPORT THE AUTHORIZATION OF PLANT PROTECTION PRODUCTS UNDER REGULATION (EC) NO 1107/2009 OF THE EU PARLIAMENT AND COUNCIL ON PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET, SANCO/10055/2013 Rev. 4) is available that sets criteria for the interpretation of results from efficacy tests against weeds. The following scale is provided to assess the efficacy against weeds (the right column represents the amount of reduction of the target organism compared to the untreated control):    As weeds have a direct negative effect on e.g. crop yield, relatively high reductions of weeds in treated plots are desired to provide a meaningful level of efficacy. For algae, where the negative effect is mostly visual (discolouration), an efficacy (reduction) level of 80% could be deemed acceptable.  The efficacy tests were performed with the products COM 508 16 H (EW) and COM 508 09 H (AL) which are identical in composition to COM 508 16 EW B and COM 508 09 AL B, respectively. The ready-to-use product is a dilution of the concentrate, but is otherwise identical in composition (with 0.05% w/w preservative added to the RTU product which is not present in the concentrate). As such, results from studies with the (diluted) concentrate can be read-across to the RTU product.  Efficacy against green algae under laboratory conditions was demonstrated in a suspension test. No standard test guideline exists for this group of organisms (algae), so an adapted test was used with *Desmodesmus subspicatus*, a standard test organism from the OECD 201 (ecotoxicity) test. The test was performed without soiling and at a relatively high temperature of 23ºC. At a concentration of 10.48 mL/l (compared to the 130 mL/l as the actual use concentration) a reduction >99% was demonstrated after a contact time of 24 hours. Considering the application of the product (removal of visual discoloration of surfaces), basic efficacy of the product is sufficiently demonstrated in this suspension test.  No suspension test demonstrating efficacy against lichens was provided as this test is technically not feasible. Efficacy against lichens was sufficiently demonstrated in field trials.  The efficacy of the concentrate COM 508 16 EW B was demonstrated against green algae on hard surfaces such as paved farmyards, cobblestones and walls at a final nonanoic acid concentration of 3.1 g/m2 (13 mL/m2 of the concentrate). In addition, in a field trial on interlocking paver with lichen and algae COM 508 16 EW B was tested at the following application rates: 4.5, 6.5, 10 and 13 mL/m² (1.1 – 3.1 g nonanoic acid/m²). An acceptable efficacy (reduction > 90% in 50% of the algae test results and in 37.5% of the lichen test results) level was shown for all application rates.  At sandy silt or silty loam soil efficacy of COM 508 16 EW was tested at final nonanoic acid concentrations of 1.5 to 3.1 g/m² (6.5 – 13 mL/m² of the concentrate). Best reductions of algae were demonstrated with 13 mL/m² concentrate. The field trial on silty loam soil showed an acceptable efficacy (reduction) level at application rates of 6.5 to 13 mL/m² of the concentrate. On sandy silt soil/silty clay soil acceptable efficacy was found at 15 days after application for all application rates but declined towards 27 days after application. Although acceptable reduction levels at all days of examination was demonstrated only with 13 mL/m², lower application rates up to 6.5 mL/m² are sufficient in case of very light surface discolouration.  Thus, the overall efficacy of the concentrate COM 508 16 EW B was demonstrated against algae and lichen at application rates of 6.5 to 13 mL/m² (1.5 – 3.1 g nonanoic acid/m²).  The efficacy of the ready-to-use product COM 508 09 AL B was demonstrated at a final concentration of 3.1 g nonanoic acid/m2 (100 mL/m2 of the ready-to-use formulation) against algae and lichens at hard surfaces, e.g. paved farmyards, cobblestones or walls.  At sandy silt soil and silty loam soil the product was effective against algae at a final nonanoic acid concentration of 3.1 g/m² (100 mL/m² of ready to use formulation). Results from studies with the (diluted) concentrate can be read-across to the ready-to-use product. Therefore, efficacy against algae was demonstrated also at lower doses (1.5 – 3.1 g nonanoic acid/m²) using the concentrate COM 508 16 EW B for which similar application rates based on the a.s. were tested.  Thus, the overall efficacy of the ready-to-use product COM 508 09 AL B was demonstrated against algae and lichen at application rates of 48 - 100 mL/m² (1.5 – 3.1 g nonanoic acid/m²) |

#### Occurrence of resistance and resistance management

Nonanoic acid has a specific mode of action (destruction of cell membranes) but development of resistance is not expected, since it does not affect a functional group but it quickly penetrates into the tissue and disrupts normal cell membrane permeability. This causes a destruction of photosynthesis mechanisms and other membrane bound physiological processes.

#### Known limitations

Lawn grass, weeds, wild plants and garden plants that are treated inadvertently will be destroyed or at least severely damaged. On the other hand, the woody parts of a plant will not be damaged. Not to be applied for algae control in the lawn.

The product should only be applied if no rain is expected for the day of application and when wind is not blowing.

#### Evaluation of the label claims

The label claims as stated in the SPC reflect the efficacy of the biocidal product.

COM 508 16 EW (concentrate): The overall efficacy was demonstrated against green algae and lichens for 6.5 to 13 mL concentrate/m2, corresponding to 1.5 to 3.1 g a.s./m2. These application rates are similar to those recommended to the users. On the label it is indicated that 150 mL of the concentrate should be diluted with 1 liter of water to create the diluted concentrate solution, which is sufficient for the treatment of 11.5 m2 (13 mL concentrate/m2). In case of light discoloration it is possible to treat up to 20 m² with 1150 mL solution (similar to 6.5 mL concentrate/m2).

For COM 508 09 H AL 100 mL/m2 is recommended as the maximum dose. This application rate was efficacious in the field trials. The low application rate recommended (treatment of up to 15 m2 with 750 mL ready-to-use solution) is demonstrated by transferring data of the concentrate (6.5 mL concentrate /m2).

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

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

### Risk assessment for human health

The toxicological properties of the active substance nonanoic acid are summarised in the Assessment Report (RMS AT, 2013). The applicant submitted an Article 95 dossier with different human health toxicity studies. These studies were examined by the eCA in accordance with procedures described in document ap 13.2-CG-16-2016-14 and accepted. See also the appendix “List of endpoints alternative dossier Nonanoic acid”. In line with the CG guidance, only the latest LoEP agreed by the BPC in the context of the (initial or reviewed) approval of the active substance is taken into account for the product authorisation.

Regarding toxicity of the biocidal product family, acute toxicity tests as well as tests for skin and eye irritation and skin sensitisation have been conducted with the worst case product COM 508 16 EW B (concentrate).

Based on the results of the toxicity studies the biocidal products of the biocidal product family do not need to be classified for Acute Toxicity, Skin Irritation/Corrosion. According to the Regulation (EC) 1272/2008 (CLP) a classification for Eye Irrit. 2; H319 is required for metaSPC 2 (concentrate), and for metaSPC 1 (ready-to-use product) EUH208 is assigned due to the presence of a skin sensitizer 1,2-benzisothiazol-3(2H)-one.

#### Assessment of effects on Human Health

**General remarks**

Except for a modified Local Lymph Node Assay no studies with the biocidal product (b.p.) COM 508 09 AL B (ready-to-use) were conducted. However, the ready-to-use product COM 508 09 AL B is a dilution of the concentrate COM 508 16 EW B in water. Therefore, it is assumed that the toxicological characteristics of COM 508 16 EW B represents a worst case for the related b.p. COM 508 09 AL B allowing bridging of the toxicological properties.

As a minor change a preservative is added to the ready-to-use product, and this should be accounted for in the classifications in addition to the conclusion drawn from the bridging.

***Skin corrosion and irritation***

(*cf.* IUCLID Section 8.1)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** |
| Skin irritation *in vivo*,  OECD 404,  GLP: yes,  RL 1 | Rabbit,  Himalayan,  3 males | COM 508 16 H EW,  Unchanged (no vehicle), 100%,  4 h | Mean scores per animal (24, 48, 72h):  Erythema: 1.7, 1.0, 1.0  Edema: 0.0, 0.0, 0.0,  Fully reversible | Erythema were fully reversible within 6 days | Leuschner, 2009a |

For skin corrosion and irritation no human data is available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritating. |
| Justification for the value/conclusion | The worst case b.p. COM 508 16 EW B was not irritating to the skin of rabbits. |
| Classification of the product according to CLP | Not classified. |

***Eye irritation***

(*cf.* IUCLID Section 8.2)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** |
| Eye Irritation *in vivo*,  OECD 405,  GLP: yes,  RL 1 | Rabbit, Himalayan, 3 males | COM 508 16 H EW,  Unchanged (no vehicle), 100%,  24 h | Mean scores per animal (24, 48, 72h):  Cornea: 1.0, 1.0, 1.0  Iris: 0.7, 0.7, 0.7  Conjuctivae: 1.7, 1.7, 1.0  Chemosis: 1.0, 0.7, 0.7  Fully reversible | Reversible within:  Iris: 72 h Chemosis: 72 h Cornea: 5 days  Conjunctiva:6 days | Leuschner, 2009b |

For serious eye damage and irritation no human data is available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | metaSPC 2: Irritating to eyes |
| Justification for the value/conclusion | metaSPC 1: Based on the calculation in accordance with the CLP guidance for the RTU product no classification is required.  metaSPC 2: The worst case b.p. COM 508 16 EW B was irritating to the eye of rabbits. |
| Classification of the product according to CLP | metaSPC 1: no classification  metaSPC 2: Eye Irrit. 2, H319 |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the conclusion | No data on respiratory tract irritation is available for the biocidal products (b.p.) of the biocidal product family. Toxicological properties and classification of the b.p. was deduced from the respective properties of the active substance (a.s.) and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

For respiratory tract irritation no human data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal products (b.p.) of the biocidal product family (BPF) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Within the acute inhalation toxicity study with COM 508 16 EW B in rats no signs of respiratory tract irritation were observed although the b.p. contains a co-formulant being classified for STOT SE 3, H335 and neat nonanoic acid being classified for skin irritation and severe eye damage. Thus, synergistic effects did not occur.  Data of the a.s. nonanoic acid were evaluated by the Rapporteur Member State (RMS) Austria and published as Chemical Assessment Report (RMS AUT, 2013). This evaluation is confirmed by the data submitted by Compo for Article 95 listing. Nonanoic acid is not classified for respiratory tract irritation. According to the MSDS the co-formulant n-lauroylsarcosine (CAS no. 97-78-9) is classified as STOT SE 3, H335 – May cause respiratory irritation. No specific concentration limits are specified for n-lauroylsarcosine in Annex VI of CLP, so that the generic concentration limit of the CLP applies. According to the criteria for classifying mixtures under CLP, components with a concentration equal to or greater than the generic concentration limit (20% for STOT SE Category 3 components) will be taken into account for classification purposes. Since n-lauroylsarcosine is present at a concentration below this concentration limit in both b.p. of the BPF, the b.p. do not need to be classified for specific target organ toxicity – single exposure. The absence of local respiratory tract irritation is also evident in the aforementioned acute inhalation toxicity study in rats.  Therefore, the b.p. of the BPF do not need to be classified for respiratory tract irritation. |

***Skin sensitization***

(*cf.* IUCLID Section 8.3)

| **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**  *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks**  *(e.g. major deviations)* | **Reference** |
| GPMT,  OECD 406,  GLP: yes  RL 2 | Guinea pig,  Dunkin-Hartley,  Male,  5 (vehicle control), 10 (test group), 20 (positive control) | COM 508 16 H EW, water,  Intradermal induction: 0.5%, single injection,  Epicutaneous induction: 50%, 48 h,  Epicutaneous challenge: 5%, 24 h | No. with positive reactions / total no. in group  1st reading (48 h):  Negative control: 0 / 5,  Test group: 0 / 10,  Positive control: 20 / 20,  2nd reading (72 h):  Negative control: 0 / 5,  Test group: 0 / 10  Positive control: 20 / 20 | Smaller number of animals (10 instead of 20 in the test group) | Haferkorn, 2010a |
| Modified LLNA,  Similar to OECD 429,  GLP: yes  RL 2 | Mouse,  NMRI / Crl:NMRI  Female  6 / group | COM 508 09 H AL,  Acetone/olive oil (4:1 v/v),  100%, 50%, 25%,  Open application to the dorsum of each ear | Stimulation indices:  Lymph node cell count, Lymph node weight, Ear weight, Ear thickness:  Vehicle control: 1, 1, 1, 1  25% test item: 1.002, 1.018, 1.040, 1.034  50% test item: 0.926, 1.036, 0.980, 1.009  100% test item: 1.127, 1.143, 0.980, 1.043  Positive control: 1.841, 1.411, 1.177, 1.216 | excision of lymph nodes at day 4; cut-off at stimulation index of 1.4 (sensitising)and 1.1 (irritating), Method established by an European interlaboratory validation exercise.  Cell proliferation was counted by cell-counting instead of radio active labelling | Haferkorn, 2015 |

For skin sensitisation no human data is available.

**metaSPC 2 (concentrate)**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | The representative b.p. COM 508 16 EW B was not sensitising in GPMT test (Haferkorn, 2010a)). Additionally, nonanoic acid is not classified for skin sensitisation and the b.p. contains no further co-formulants that are classified for skin sensitisation at concentrations leading to a classification of the b.p. |
| Classification of the product according to CLP | No classification |

**metaSPC 1 (RTU)**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | The representative b.p. COM 508 09 AL B was not sensitising in a LLNA (Haferkorn, 2015). Nonanoic acid is not classified for skin sensitisation and the b.p. contains no further co-formulants that are classified for skin sensitisation at concentrations leading to a classification of the metaSPC contains 1,2-benzisothiazol-3(2H)-one, which is classified as a skin sensitizer (H317). Because tThe concentration of 1,2-benzisothiazol-3(2H)-one in metaSPC 1 exceeds the concentration limit for elicitation (10% of the SCL for H317), EUH208 is required in accordance with Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | EUH208 |

***Respiratory sensitisation (ADS)***

(*cf.* IUCLID Section 8.4)

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | No data on respiratory sensitisation is available for the biocidal products (b.p.). Toxicological properties and classification of the b.p. was deduced from the respective properties of the active substance (a.s.) and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

For respiratory sensitisation no human data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal products (b.p.) of the biocidal product family (BPF) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Synergistic effects do not need to be expected. Within the Guinea Pig Maximisation Test, which is designed to maximise the skin reaction to applied chemicals, the concentrated b.p. (COM 508 16 EW B) did not result in any positive skin reaction. Additionally the modified Local Lymph Node Assay with the diluted b.p (COM 508 09 AL B), did reveal a negative outcome. Therefore, a synergistic effect with regard to sensitisation is very unlikely. Additionally the additivity concept is not applicable for respiratory or skin sensitisation, meaning that if the mixture contains two substances each below the generic or specific concentration limits, the mixture will not be classified.  Data of the a.s. nonanoic acid were evaluated by the Rapporteur Member State (RMS) Austria and published as Chemical Assessment Report (RMS AUT, 2013). Further data submitted by the applicant for Article 95 listing confirmed this evaluation. Nonanoic acid is not classified for respiratory sensitisation. No co-formulant is classified for respiratory sensitisation.  Therefore, the b.p. of the BPF do not need to be classified for respiratory tract sensitisation. |

***Acute toxicity***

*Acute toxicity by oral route*

*(cf. IUCLID Section 8.5.1)*

| **Summary table of animal studies on acute oral toxicity** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Method Guideline**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance**  **Dose levels Type of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **Value LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute toxic class method, Limit test,  OECD 423,  GLP: yes,  RL 1 | Rat,  CD / Crl: CD(SD),  6 females | COM 508 16 H EW,  Unchanged (no vehicle),  2000 mg/kg bw,  gavage | No mortality,  No clinical signs,  No effect on body weight | > 2000 mg/kg bw |  | Haferkorn, 2010b |

For acute oral toxicity no human data is available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not harmful. (LD50 >2000 mg/kg bw) |
| Justification for the selected value | According to an acute oral toxicity study (OECD Guideline 423), the oral LD50 of the worst case b.p. COM 508 16 EW B exceeds 2000 mg/kg bw. As COM 508 16 EW B represents the worst case in the BPF, the absence in the classification for this endpoint is valid for all metaSPCs. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by inhalation*

*(cf. IUCLID Section 8.5.2)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on acute inhalation toxicity** | | | | | | |
| **Method, Guideline,**  **GLP status , Reliability** | **Species, Strain, Sex, No/group** | **Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD)**  **Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LC50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Standard acute method, limit test,  OECD 403,  GLP: yes,  RL 1 | Rat,  CD / Crl: CD/SD),  Male/female,  5 / sex / group | COM 508 16 H EW,  Aerosol, MMAD: 3.711 µm, GSD: 2.84 µm,  Nominal: 5.0 mg/L, actual: 5.10 ± 0.05 mg/L,  Nose only,  4 h | No mortality,  Slight ataxia, tremor and dyspnoea up to 3 h after exposure,  3 of 5 females with reduced body weight gain,  No pathological findings | > 5.1 mg/L | The test item was diluted in water to allow generation of the test atmosphere. No signs of local effects were observed. | Haferkorn, 2010c |

For acute inhalation toxicity no human data is available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not harmful. (LD50 > 5.1 mg/L (aerosol)) |
| Justification for the selected value | According to an acute inhalation toxicity study (OECD Guideline 403), the 4 h inhalative LC50 value of the worst case b.p. COM 508 16 EW B exceeds 5.10 mg/L air. As COM 508 16 EW B represents the worst case in the BPF, the absence in the classification for this endpoint is valid for all metaSPCs. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by dermal route*

*(cf. IUCLID Section 8.5.3)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on acute dermal toxicity** | | | | | | |
| **Method, Guideline,**  **GLP status,**  **Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Standard acute method, limit test,  OECD 402,  GLP: yes,  RL 1 | Rat,  CD / Crl: CD(SD),  Male/female,  5 / sex / group | COM 508 16 H EW,  Unchanged (no vehicle),  2000 mg/kg bw,  5 cm x 6 cm clipped skin on the animals’ back | No mortality,  No clinical signs,  No effects on body weight, No skin reactions | > 2000 mg/kg bw |  | Haferkorn, 2010d |

For acute dermal toxicity no human data is available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not harmful. (LD50 > 2000 mg/kg bw) |
| Justification for the selected value | According to an acute dermal toxicity study (OECD Guideline 402), the dermal LD50 value of the worst case b.p. COM 508 16 EW B exceeds 2000 mg/kg bw. As COM 508 16 EW B represents the worst case in the BPF, the absence in the classification for this endpoint is valid for all metaSPCs. |
| Classification of the product according to CLP | Not classified. |

***Information on dermal absorption***

(*cf.* IUCLID Section 8.6)

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Nonanoic acid |
| Value | 100% |
| Justification for the selected value | The dermal absorption value of 100% nonanoic acid as set by the RMS Austria was adopted for the biocidal products. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Other justification. |
| Justification | Data of the active substance (a.s.) nonanoic acid were evaluated by the Rapporteur Member State (RMS) Austria and published as Assessment Report (RMS AUT, 2013). Further data submitted by the applicant for Article 95 listing confirmed this evaluation.  Nonanoic acid is a single chain saturated fatty acid. Quantitative dermal absorption data are not available from *in vivo* or *in vitro* dermal absorption studies. Considering the physical-chemical properties a default value for dermal absorption of 100%, as assumed in the Assessment Report, will be used for the risk assessment of the biocidal products. |

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

Two substances of concern are identified in the BPF: ethane-1,2-diol in metaSPC 1 and polyethylene glycol monoalkyl ether in metaSPC 2.

According to the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) (version 2.1, ECHA February 2017) a co-formulant present in a b.p. should be considered as substance of concern (SoC) if for the co-formulant a Community workplace exposure limit value is established. RTU products in metaSPC1 contain up to 0.025% ethane-1,2-diol (CAS 107-21-1) for which an 8-hour time-weighted average (TWA) of 52 mg/m³ was recommended by the Scientific Committee for Occupational Exposure Limits (SCOEL). The critical effect of ethane-1,2-diol is irritation of the mucous membranes. A short-term exposure limit (STEL, 15 min) of 104 mg/m³ was proposed to limit peaks of exposure which could result in irritation.

The BPR guidance document further states “that a generic concentration cut-off value (for their [i.e. substances for which an occupational exposure limit value is established] presence in a product) applicable to all such substances cannot be specified. This should be determined on a case-by-case basis depending on the hazard profile, potency and exposure potential of the substance.” Therefore, instead of considering a substance for which a community workplace exposure limit value is established by default as SoC the hazard profile, the toxicological potency and the potential exposure should be taken into account to assess whether or not the substance is of concern in the concentration and the use conditions of the b.p.

Since for ethane-1,2-diol relatively high exposure limit values (TWA, STEL) are established, this substance can be considered to have a rather low toxicological potency. In addition, the concentration of ethane-1,2-diol in this BPF is very low (0.025%) and it is not likely that the exposure to ethane-1,2-diol would reach the SCOEL value from the use of the b.p. of this BPF, when the products are used in accordance with the SPC. Overall it is concluded that ethane-1,2-diol is not a SoC in this BPF.

Furthermore, polyethylene glycol monoalkyl ether (CAS 9043-30-5) is identified as a SoC (Band A) in metaSPC 2. The co-formulatn with H318 is present at a concentration that is taken into account for the classification of eye irrit cat 2 (H319) of metaSPC 2. Although metaSPC 2 is assigned with H319 based on an in vivo study, it cannot be excluded that polyethylene glycol monoalkyl ether contributes to the classification. According to the above mentioned Guidance, a SoC that falls in Band A can be addressed by applying P-statements associated with concerned hazard classification. As relevant P-statements are already assigned for the BPF, no additional risk assessment or RMMs are required.

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

Toxicological data relating to a mixture that a substance of concern is a component of are not required.

***Other***

In the ready-to-use product ethane-1,2-diol is present. According to the MSDS, ethane-1,2-diol (CAS no. 107-21-1, ingredient of the co-formulant Acticide B 20), is classified as STOT RE 2, H373 - May cause damage to organs (kidney) through prolonged or repeated exposure. No specific concentration limits are specified for ethane-1,2-diol in Annex VI of CLP, so that the generic concentration limit of the CLP applies. Since, ethane-1,2-diol is present at a concentration well below the concentration limit of 1%, the b.p. does not need to be classified for specific target organ toxicity – repeated exposure.

The b.p. are used as algaecide for the treatment of surfaces such as terraces, pathways, parking lots and walls outdoors. Other test(s) related to the exposure to humans are not available for the proposed biocidal use pattern. Exposure estimates and risk characterisations are given in the human risk assessment. The risk characterisation, showed no concern when the b.p. are handled and applied. Therefore no other test related to the exposure to humans is necessary.

The b.p. is not intended for direct application to foods or feeding stuff or to surfaces and areas where foods or feeding stuffs are prepared or stored. Hence, an exposure of food and feeding stuff can be excluded when applied according to the instructions for use. Additional food or feeding stuffs studies are not required.

#### Exposure assessment

The biocidal products (b.p.) of the biocidal product family (BPF) which contain the active substance (a.s.) nonanoic acid (product type 2) are applied against green algae and are used for the treatment of surfaces such as terraces, pathways, parking lots and walls outdoors. The b.p. will be used by non-professional users (general public).

Products in metaSPC 2 are sold in the form of a concentrate (emulsion: oil in water) and contains 24.3-27% (w/w) a.s. The product needs to be diluted to a final in-use concentration of 30.99 g/L a.s. (3.11% (w/w)). One liter water is needed for the treatment of 11 to 15 m² surface. The b.p. can be applied either via spraying or via pouring. After use, the product is left on the surfaces at minimum for 24 hours. The treatment may be repeated 2 times with an application interval of 20 to 60 days.

Products in metaSPC 1 are sold in the form of a ready-to-use product and contains 3.1-3.5% (w/w) a.s.. 750 mL of undiluted b.p. is intended for the treatment of minimum 7.5 m2. Depending on the grade of infestation the b.p. may be sufficient for up to 15 m² surface. The b.p. is applied via spraying. After use, handling of the b.p. is the same as for metaSPC 2.

Due to the application type exposure of non-professionals occurs predominantly via dermal route. The vapour pressure of nonanoic acid is 0.42 Pa at 20 °C for the pure a.s. Very small amounts of vapour may be inhaled when the concentrate product is poured from its container into spraying or pouring equipment or during spray application. Respiratory exposure is expected to be low due to handling of small volumes outdoors for short times, low vapour pressure of nonanoic acid and the type of spray used (trigger spray). Exposure via hand-to-mouth contact is unlikely because hands and exposed skin areas are washed with water and soap after use so that the skin surface is free of saliva-dislodgeable a.s.

Secondary exposure of children to the BPF by touching treated surfaces will take place via the dermal route. Additionally, oral exposure via hand-to-mouth transfer may occur.

**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 | n.r. | n.r. | yes | n.r. | n.r. | no | n.r. |
| Dermal | n.r. | n.r. | yes | n.r. | n.r. | yes | n.r. |
| Oral | n.r. | n.r. | no | n.r. | n.r. | yes\* | n.r. |

\* Accidental hand-to-mouth contact of infants was considered as worst case assumption.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Mixing and loading | Primary exposure,  Dilution of the concentrate product with water | Non-professionals |
| 2. | Pouring | Primary exposure,  Pouring the solution of concentrate product using a watering can | Non-professionals |
| 3. | Spraying | Primary exposure,  Spraying using spray pressures from 1 to 3 bars | Non-professionals |
| 4. | Cleaning of equipment | Primary exposure,  Cleaning of the pouring or spraying equipment after application | Non-professionals |
| 5. | Child walking through wet b.p. | Secondary exposure,  A treated area is walked upon bare feet by toddlers | General public (child) |
| 6. | Infant  touching treated area | Secondary exposure,  An infant re-enters the treated area. Hand-to-mouth transfer of the b.p. by infants after contact to treated area | General public (child) |

***Monitoring data***

No further information on surveys or studies with the actual products or with a surrogate is submitted.

***Dietary exposure***

The b.p. is not intended for direct application to foods or feeding stuff or to surfaces and areas where foods or feeding stuff are prepared or stored. Hence, an exposure of food and feeding stuff to nonanoic acid can be excluded when applied according to the instructions for use.

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

Residue definitions

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection products | MRL in crops and in products of animal origin | No MRL required1 |
| ADI | Not applicable2 |
| 2. | Feed additive | All animal species | 5 mg/kg complete feed3 |

1 EU Pesticide database, Current Maximum Residue Levels (MRL) values for fatty acids C7-C20, Reg. (EC) No 839/2008, Entry in force: 01.09.2008 (<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1676>)

2 Directive 2008/127/EC

3 Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01) and Scientific opinion EFSA Journal 2013;11(4):3169 (http://www.efsa.europa.eu/sites/default/files/scientific\_output/files/main\_documents/3169.pdf)

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

Livestock exposure of nonanoic acid can be excluded when applied according to the instructions for use.

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

Not relevant. The BPF is for non-professional use.

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

Food, drinking water or livestock exposure of nonanoic acid can be excluded when applied according to the instructions for use.

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

Formulation, packing and re-packing of nonanoic acid and mixtures of nonanoic acid is already addressed under Regulation (EC) No 1907/2006 (REACh, EC Number: 203-931-2). Therefore this risk assessment was not repeated for submission of nonanoic acid under Regulation (EU) 528/2012 (BPR).

The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance is not required, unless the active substance is totally new to the EU market and manufactured in the EU. This is not the case for nonanoic acid which is an existing biocidal active substance within the EU.

#### Risk characterisation for human health

Nonanoic acid is the active substance used in this BPF. The Assessment Report of nonanoic acid states that no adverse systemic effects are apparent from the toxicological data up to high doses, but irritant properties of nonanoic acid are evident. No classification is warranted for metaSPC 1 for local effects. MetaSPC 2 is classified as eye irritant according to the results in animal studies performed with the undiluted concentrate COM 508 16 EW B. Consequently the risk characterisation focuses only on local effects of metaSPC 2. Data allowing reliable quantitative estimates for local irritation thresholds of nonanoic acid or the biocidal products are absent, and therefore a qualitative assessment is provided. This approach is in accordance with the Assessment Report.

***Risk for industrial users***

Not relevant as the biocidal products of the BPF are intended for non-professional uses only.

***Risk for professional users***

Not relevant as the biocidal products of the BPF are intended for non-professional uses only.

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

**Local effects (metaSPC 2)**

|  |  |  |
| --- | --- | --- |
| **Hazard** | Hazard Category | Low |
| Effects in terms of C&L | Eye irrit. Cat 2, H319 |
| **Exposure** | PT | 2 |
| Who is exposed? | Non-professional |
| Task, uses, processes | [1] Mixing & Loading  [2] Pouring  [3] Spraying  [4] Cleaning of Equipment |
| Potential exposure route | Skin  Eye (splashes, hand to eye transfer)  Respiratory tract |
| Frequency and duration of potential exposure | 2/year,  [1] 5 min  [2] 5 min  [3] 60 min  [4] 10 min |
| Relevant RMM | Labelling as eye irritant,  Instructions for use that minimize exposure (“Avoid splashes when making a dilution”, “Avoid contact with eyes.”) |
| **Risk** | Conclusion of risk | Acceptable since:  + Reversible effect  + Low frequency and short duration  + Low vapour pressure of the a.s.  + High ventilation expected due to outdoor use  + The label instructs to minimise contact to b.p.  + Child-proof closure |

**Conclusion**

Based on the qualitative risk assessment, no unacceptable risk is identified for the unprotected non-professional user from the use of the biocidal product family COM 508, when used according to the instructions for use.

***Risk for the general public***

**Local effects**

Dermal secondary exposure may occur for toddlers who walk across the treated surface with bare feet and for infants touching the treated surface. The metaSPC 2 of the BPF COM 508 are classified for eye irritation (Category 2, H319) based on the study that has been performed with the concentrate product (COM 508 16 EW B). In this study all symptoms were reversible within 6 days, indicating rather slight irritation properties for the concentrate. No study on the eye irritation properties of the RTU products in metaSPC 1 is available. Since the in-use concentration of the products of the BPF COM 508 is 8 times lower than what is tested in the eye irritation study, local irritation caused by secondary exposure will be even less severe than what the eye irritation study has suggested. Based on the calculation rule, no classification for eye damage/irritation is required for metaSPC 1. As the products are not classified for skin irritation no local skin effects are expected by the secondary exposure.

Exposure of infants, who exhibit a great deal of hand-mouth and hand-to-eye contact, is considered negligible as infants are expected to be efficiently kept away from wet surfaces outdoors because of P102 ‘Keep out of reach of children’ and the risk mitigation measure ‘Keep children and pets away until surface is dried’. Still, accidental exposure of infants to a certain amount of the b.p. may occur after touching treated, wet surfaces. Although this might (theoretically) cause slight irritations at the mouth mucosa or in the eyes, considering the relative low volume of product that will be transferred the potential effects, if any occurs, will be very mild and reversible.

**Local effects (metaSPC 2)**

|  |  |  |
| --- | --- | --- |
| **Hazard** | Hazard Category | Low |
| Effects in terms of C&L | Eye irrit. Cat 2, H319 |
| **Exposure** | PT | 2 |
| Who is exposed? | Child including toddlers (secondary exposure) |
| Task, uses, processes | [5] Child walking through wet treated surfaces with b.p.  [6] Hand-to-mouth transfer  [7] Hand-to-eye transfer |
| Potential exposure route | Skin [5] + [6] + [7]  Oral [6]  Eye [7] |
| Frequency and duration of potential exposure | 1/year,  [5] Few minutes or less  [6] Few minutes or less  [7] Few minutes or less |
| Relevant RMM | Labelling as eye irritant,  Instructions for use that minimize exposure   * keep out of reach children (P102) * ‘Keep children and pets away until surface is dried’ |
| **Risk** | Conclusion of risk | Acceptable since:  + Reversible effect  + Low likelihood for exposure of critical initial sites of contact (i.e. eye)  + Short exposure duration  + Low exposure frequency  + The label instructs to minimise contact to b.p. |

**Conclusion**

Based on the qualitative risk assessment no unacceptable risk for adverse effects are identified for general public from secondary exposure to the biocidal product family COM 508, when used according to the instructions for use.

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

Food, drinking water or livestock exposure of nonanoic acid can be excluded when applied according to the instructions for use. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

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

The b.p. of the BPF do not contain substances of concern. Therefore exposure to several active substances or substances of concern within the products is not relevant.

### Risk assessment for animal health

Animals such as dogs and cats may be exposed to the nonanoic acid and the b.p. by walking over wet treated surfaces. A risk mitigation measure “‘Keep children and pets away until surface is dried’” is included to minimise such contact of domestic animals. As the risk of secondary exposure of general public was considered acceptable, no adverse health effects are expected also for the animals, when applied according to the instructions for use.

### Risk assessment for the environment

The biocidal products within the nonanoic acid biocidal product family are all used by non-professionals as algaecide in the product type (PT) 02 for the treatment of surfaces such as terraces, pathways, parking lots and walls outdoors.

The b.p. are the following:

Meta SPC 1:

COM 508 09 AL B containing 3.1% of the a.s. nonanoic acid is sold in the form of a ready-to-use product. The b.p. can be applied via spraying. The maximum applied amount of b.p. is 100 mL per m². After use, the product is left on the surfaces at minimum for 24 hours. The treatment may be repeated 2 times with an application interval between 20 and 60 days.

For algaecide use, the b.p. COM 508 09 AL B is chosen as the worst case product, as the application amount of the a.s. per m2 is slightly higher compared to COM 508 16 EW B.

Meta SPC 2:

COM 508 16 EW B containing 24.3% of the active substance (a.s.) nonanoic acid is sold in the form of a concentrate (emulsion: oil in water) and 150 mL is to be added to 1000 mL water for the treatment of 11 to 20 m² surface. The b.p. can be applied either via spraying or via pouring. After use, the product is left on the surfaces at minimum for 24 hours. The treatment may be repeated 2 times with an application interval between 20 and 60 days.

#### Effects assessment on the environment

The applicant submitted an Article 95 dossier with different fate&behaviour and ecotoxicity studies. These studies were checked by the eCA in accordance with procedures described in document ap 13.2-CG-16-2016-14 and accepted see also the appendix “List of endpoints alternative dossier Nonanoic acid”. It was noted that without taking into account the agreed endpoints of nonanoic acid, the endpoints from the submitted studies would result in higher (less strict) PNEC values as compared to those included in the AR (2013) of nonanoic acid. Considering that the PNEC values for the a.s. nonanoic acid taken from the AR (2013) are worst case and also in line with the CG guidance, only the latest LoEP agreed by the BPC in the context of the (initial or reviewed) approval of the active substance is taken into account for the product authorisation.

|  |  |  |
| --- | --- | --- |
| **PNEC values for the a.s. nonanoic acid** | | |
| **Compartment** | **Value** | **Unit** |
| Fresh water | 0.0568 | mg/L |
| Sediment | \* | |
| STP | 5.652 | mg/L |
| Soil | 0.112 / 0.099 | mg/kgdwt /wwt\*\* |

\* Because ecotoxicity data are not available for sediment organisms, the PNEC have to be derived from the PNECfreshwater using equilibrium partitioning. However, PECsediment is also derived by using equilibrium partitioning from PECfreshwater and therefore the ratio PEC:PNEC for freshwater covers that of sediment as well. Calculation of PECsediment is therefore not included in the current risk assessment.

\*\* Dwt converted to wwt using conversion factor of 1.13 (ESD PT8, 2013[[1]](#footnote-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***

The exposure assessment is based on data for the active substance. There are no fate or ecotoxicity data available for the product. The biocidal products within the nonanoic acid biocidal product family do not contain substances of concern, which result in a further classification of these products. Therefore the assessment for nonanoic acid covers for the whole product.

***Further Ecotoxicological studies***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | The original data and PNECs from the assessment report are used for the risk assessment. No further ecotoxicological studies are required |
| Justification | - |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Bioaccumulation |
| Justification | No experimental studies investigating the bioaccumulation potential of the biocidal products (b.p.) within the nonanoic acid biocidal product family are available. The active ingredient nonanoic acid is not considered to be bioaccumulative. Fatty acids are a nutritional energy source for organisms. Under environmental conditions fatty acids are readily biodegraded in an aerobic environment by microorganisms. Therefore, the potential for bioaccumulation is expected to be low based on the rapid metabolism within organisms via common pathways. Hence, fatty acids are considered no risk to organisms from their bioconcentration and biomagnification properties. The calculated BCF values for fish (195.88 L/kg wwt) and earthworms (40.57 L/kg wwt) from the Assessment Report (Austria, 2013) of the active substance confirm this. The biocidal products within the nonanoic acid biocidal product family do not contain any substance of concern for the environment. None of the constituents is classified as PBT/vPvB substance. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS) |
| Justification | No specific non-target organisms believed to be at risk were identified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, ecotoxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Relevant and reliable ecotoxicological data of the a.s. nonanoic acid are available from the Assessment Report (Austria, 2013).  The STP and soil were identified as the only receiving environmental compartments after application of the biocidal products (b.p.) within the nonanoic acid biocidal product family.  Since the environmental risk assessment has demonstrated a safe use for these two compartments considering risk mitigation measures and no further environmental compartments were identified to be of concern, no additional studies are considered to be necessary. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on the risks to non-target organisms under field conditions is not required. |
| Justification | Risks to non-target organisms is covered in the risk assessment for soil and aquatic compartment, which does not trigger further higher tier tests. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on the acceptance by ingestion of the biocidal product by any non-target organisms is not required. |
| Justification | The biocidal products (b.p.) within the nonanoic acid biocidal product family do not contain any lure which could be attractive for non-target organisms. Therefore, ingestion by non-target organisms is no matter of concern. Moreover, the product is not marketed in the form of granules. |

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

The intended use of the biocidal products (b.p.) within the nonanoic acid biocidal product family is limited to the outdoor application on paved terraces, pathways, parking lots or walls on a small scale and not on bare soil. Therefore, exposure of the environment is only possible via spray drift or run-off from treated surfaces. A large space application of the biocidal product to water body, wetland, forest or field is not intended and information on secondary ecological effects is not required.

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

Formulation of the biocidal product

From the formulation of the b.p., no emissions to the environment are to be expected and therefore, no risk assessment is conducted for this life cycle stage. Furthermore, the formulation is not covered by the ESD PT10 (2002)[[2]](#footnote-2) on masonry preservatives.

Application and use of the biocidal product

The b.p. is applied via spray or pouring application. For worst case considerations, spray application is assessed. Emissions may occur from the treated surfaces such as terraces, pathways, parking lot and walls outdoors during application due to runoff or spray drift.

The ESD for PT10 (2002) differs between the places countryside and city, where the treatment is performed. The emissions from runoff may reach soil adjacent to treated surface if the treated surface is located in the countryside; if it is located in the city, the fraction ends up in the waste/storm water via sewage treatment plants (STP) or directly into the surface water via STP bypass or direct rainwater discharge. When considering spray drift, releases to air are possible. However, an accumulation of nonanoic acid in the air is not expected due to its short half-life in air of 39.4 h according to the AR (2013). But after spray drift, there can be deposition of droplets onto soil. If the treated surface is located in the countryside, the spray drift reaches soil at some distance to the treated surface which is often unpaved. If the treated surfaces are located in a city, the ground is mostly paved. Therefore, releases reach waste water and can be added to the releases due to runoff.

The releases during service life are potential emissions to the environment resulting only from leaching of a substance from treated substrates. The cumulative quantity of an active ingredient, emitted to the relevant environmental compartment due to leaching from a treated surface, is considered for the assessment. The soil adjacent to the treated surface and the STP or surface water in the city are the primary compartments where the active substance is discharged during service life.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies on fate and behaviour in the environment are not required. |
| Justification | The data on the distribution and fate of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p. Furthermore, the components of the product do not influence the distribution characteristics of the a.s., which is also classified as readily biodegradable in active sludge. According to the assessment report (2013), the toxicity of metabolites is not relevant for the environmental risk assessment as the final degradation product are CO2 and water due to metabolisation by beta-oxidation in organisms.  Further testing for distribution and dissipation in the environment is therefore not deemed reasonable. |

***Leaching behaviour (ADS)***

**Laboratory immersion test**

Two laboratory immersion tests have been conducted with the b.p. COM 508 09 HAL according to OECD guideline 107 (Iuclid section 10.3: Wegner, R., 2017a, Wegner, R., 2017b). The test specimens were fibre cement (143 mm x 35 mm x 8 mm; Wegner, R., 2017a) and clinker straps (143 mm x 70 mm x 14 mm; Wegner, R., 2017b). The applied amount accounted for 99.8 mL b.p./m²; i.e. 3.078 g a.s./m². The treated specimens were immersed in demineralised water twice for 60 minutes per immersion cycle. Immersion cycles took place on day 1, day 3, day 5, day 8, day 10, day 12, day 15, day 17, and day 19. The eluates of the immersion cycles were analysed for the a.s. nonanoic acid. The results are shown in the following table.

| **Immersion cycle (2 x 60 min)** | | | **Quantity of nonanoic acid emitted per immersion cycle (mg/m2) / percentage of applied a.s. (%)** | |
| --- | --- | --- | --- | --- |
| **No** | **Day** | **Time interval** | **Fibre cement** | **Clinker straps** |
| 1 | 1 | 1 | 13.1 / 0.43 | 272.1 / 8.84 |
| 2 | 3 | 2 | 17.5 / 0.57 | 62.8 / 2.04 |
| 3 | 5 | 2 | 31.7 / 1.03 | 25.6 / 0.83 |
| 4 | 8 | 3 | 18.9 / 0.62 | 2.79 / 0.09 |
| 5 | 10 | 2 | 11.6 / 0.38 | 5.23 / 0.17 |
| 6 | 12 | 2 | 14.4 / 0.47 | 7.72 / 0.25 |
| 7 | 15 | 3 | 13.3 / 0.43 | 4.95 / 0.16 |
| 8 | 17 | 2 | 18.4 / 0.60 | 4.06 / 0.13 |
| 9 | 19 | 2 | 3.60 / 0.12 | 1.24 / 0.04 |
| **Quantity of active substance emitted during all immersion cycles (mg/m2)** | | | **142.5** | **386.5** |
| **Quantity of active substance emitted during all immersion cycles (% of applied)** | | | **4.6** | **12.6** |

Total leaching

The total leaching for nonanoic acid amounts to 142.5 mg a.s./m² (fibre cement) and 386.5 mg a.s./m² (clinker straps) treated fibre cement, respectively.

Relative leaching

After 19 days and 9 immersion cycles (2 x 60 min), 4.6% of the a.s. inventory (fibre cement) and 12.6% (clinker straps) leached from the treated test specimens.

The specific emissions of nonanoic acid per immersion cycle and are shown in the following two figures (Figure 1 and Figure 2).

Figure 1: Emission of nonanoic acid per immersion cycle (laboratory immersion test – fibre cement)

Figure 2: Emission of nonanoic acid per immersion cycle (laboratory immersion test – clinker straps)

The results reveal a strong decline in leaching for the clinker straps – treatment with the lowest quantity of nonanoic acid emitted at the last immersion cycle. During the first immersion cycle, 8.84 of the applied a.s. leached from the test specimens, which is 70.2% of the total leaching. For fibre cement, lower emissions could be observed with the lowest quantity of a.s. emitted at the last immersion cycle. In general, leaching from clinker straps was approximately three times higher than leaching from fibre cement presumably caused by the higher porosity of the fibre cement test specimens.

In accordance with the outcome from the 2nd EU Leaching Workshop (2013), the leaching rates are derived from a first order decay curve fitting the cumulative quantities leached versus time plot. The resulting logarithmic function (ln) is a trendline, which fits closely the cumulative long term leaching date. The trendline with the corresponding regression equation and coefficient of variation can be found for nonanoic acid (laboratory immersion test with fibre cement and clinker straps) in the following figures.

Figure 3: Fitted quantity of nonanoic acid leached versus time (fibre cement; laboratory immersion test)

Figure 4: Fitted quantity of nonanoic acid leached versus time (clinker straps; laboratory immersion test)

An acceptable fit can be achieved by first order decay curve fitting (Figure 3). Therefore, leaching rates can be determined by the equation:

FLUX(t) = a + b \* ln(t) / TIME1/2

The derived leaching rates are the following for fibre cement specimens (Figure 3):

TIME 1 (30 d): 5.59 mg/m²/d, resulting in a Qleach1 (0-30days) of 167.7 mg/m² (5.45% of nominally applied) and

TIME 2 (365 d): 0.89 mg/m²/d resulting in a Qleach2 (30-365 days) of 155.1 mg/m² (5.05% of nominally applied). Total amount leached in a year 323.2 mg/m2 (10.5% of total applied)

For clinker straps, the derived leaching rates are the following (Figure 4)Figure 4:

TIME 1 (30 d): 14.0 mg/m²/d, resulting in a Qleach1 (30 days) of 420.00 mg/m² (28.5% of nominally applied) and

TIME 2 (365 d): 1.48 mg/m²/d, resulting in a Qleach2 (30-365 days) of 120.12 mg/m² (8.13% of nominally applied). Total amount leached in a year 540.68 mg/m2 (36.6% of total applied)

The RMS has evaluated these studies and agrees with the conclusions but has the following observations which partially could have improved the quality and representativeness of this test:

• Duration of the test (19 days) was some cases insufficient to reach a plateau, which makes it difficult to extrapolate to TIME2.;

• Information on the influence of different cleaning processes like high pressure or brushing on leaching is lacking. This is caused by the default small size of the test specimen in the immersion tests, making it technically not feasible to use high pressure techniques and capture the washwater in order to quantify the influence of cleaning.

• Especially in the clinker straps study the nonanoic acid was detected at all days, also in the water of untreated specimen. Release rates were 1.72 mg/m2 per day at start to 0.21 mg/m2 per day at the end of the test period. The applicant explained this by noting that fatty acids like nonanoic acid are ubiquitous in nature. According to the AR, the background concentrations in soils vary between 0.35 - 0.65 mg/kg soil. Considering that clinkers consist of soil components, also the water of untreated specimen contains of nonanoic acid. Furthermore, the clinkers were not pre-treated prior to use.

**Semi-field leaching study**

The leaching of nonanoic acid, a.s. of the b.p of the BPF, from treated fibre cement (vertical and horizontal orientation) was investigated in a semi-field study (Iuclid section 10.3: Wegner, R., 2017c, Wegner, R., 2017d) at Wald Campus of FH Eberswalde, Germany. The test design is in accordance with NT Build 509, developed by the Nordic Innovation Centre (approved 2005-03). Fibre cement was treated with COM 508 09 HAL(nominal 3.1% a.s.; w/w) by spraying two times, resulting in a final product retention of mean 99.8 g/m², corresponding to a nominal retention of 3.094 g a.s./m² fibre cement – vertical orientation and 3.109 g a.s./m² fibre cement – horizontal orientation, respectively.

A total of three preservative treated test set-ups was established each consisting of 7 replicates. Additionally one untreated test set-up with 7 replicates was installed. The fibre cement test specimens were exposed outdoor above ground vertically and horizontally facing south-west at the field test site. Run-off leachates were continuously collected after each major rain event and analysed for nonanoic acid. The experiment started in 2017 and results are available now for 223 days comprising 584 mm precipitation.

Total leaching

The total leaching for nonanoic acid amounts to 92.05 mg a.s./m² (vertical orientation) and 52.48 mg a.s./m² (horizontal orientation) treated fibre cement , respectively.

Relative leaching

During the study duration of 223 days, 2.975% of the a.s. inventory (vertical orientation of test specimens) and 1.69% of a.s. inventory leached from the horizontal orientation, respectively.

For determination of the leaching rates, the experimental leaching rates were normalised to a yearly precipitation of 700 mm and are summarized in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **FLUX values (mg/m2/d) for nonanoic acid (vertical and horizontal orientation) normalised to a precipitation of 700 mm / year** | | | | | |
| **Cum. sampling time (d)** | **Cum. \* precipitation (mm)** | **Cum. normalised precipitation (mm)** | **Cum. normalised sampling time (d)** | **Normalised FLUX Nonanoic acid – Vertical (mg/m2/d)** | **Normalised FLUX Nonanoic acid – Horizontal (mg/m2/d)** |
| 7 | 5 | 13 | 3 | 0.43 | 13.2 |
| 16 | 23 | 31 | 12 | 0.03 | 1.40 |
| 42 | 50 | 81 | 26 | 0.68 | 0.06 |
| 68 | 124 | 130 | 65 | 1.43 | 0.02 |
| 72 | 201 | 138 | 105 | 0.32 | 0.03 |
| 149 | 413 | 286 | 215 | 0.11 | 0.01 |
| 223 | 584 | 428 | 305 | 0.01 | 0.01 |

\* Cum. = cumulative

As can be seen from the study results, the rainfall was quite high between day 42 and day 68 (2.85 mm/d) and extraordinary high (19.25 mm/d) during 4 days from day 68 till day 72 of the test. The duration of the study and the number of samplings can be considered as sufficient to derive short term leaching rates for tim1 (30 days) and long-term leaching rates for time 2 (365 days).

In accordance with the outcome from the 2nd EU Leaching Workshop (2013), the leaching rates are derived from a first order decay curve fitting the cumulative quantities leached versus time plot. The resulting logarithmic function (ln) is a trendline, which fits closely the cumulative long term leaching date. The trendline with the corresponding regression equation and coefficient of variation can be found for nonanoic acid (semi-field studies with vertical;

Figure 5 and horizontal orientation;

Figure 6 of test specimens) in the following figures.

Figure 5: Fitted quantity of nonanoic acid leached versus time (fibre cement; semi-field study: vertical orientation)

For short-term leaching, the derived FLUX values are applicable as the resulting function overestimates the real leached amounts. Therefore, the leaching rate for TIME 1 (0-30 d) has been determined by the equation:

FLUX(t) = a + b \* ln(t) / TIME1/2

This results in the following leaching rate:

TIME 1 (0-30 d): 1.32 mg/m²/d

The fit is also valid to estimate long term leaching with the following leaching rate:

TIME 2 (30-365 d): 0.17 mg/m²/d

Figure 6: Fitted quantity of nonanoic acid leached versus time (fibre cement; semi-field study: horizontal orientation)

An acceptable fit was achieved for the horizontal orientation by first order decay curve. The derived leaching rates for TIME 1 and TIME 2 are:

TIME 1 (0-30 d): 1.55 mg/m²/d

TIME 2 (30-365 d): 0.02 mg/m²/d

Figure 6 shows that especially at the start of the experiment the first order fit underestimates of the leaching rate. Therefore as an alternative also a log transformed second order fit was derived (see Figure 7). The obtained trend line was used to calculate a TIME 1 (0-30 d) leaching rate of 1.66 mg/m2/d

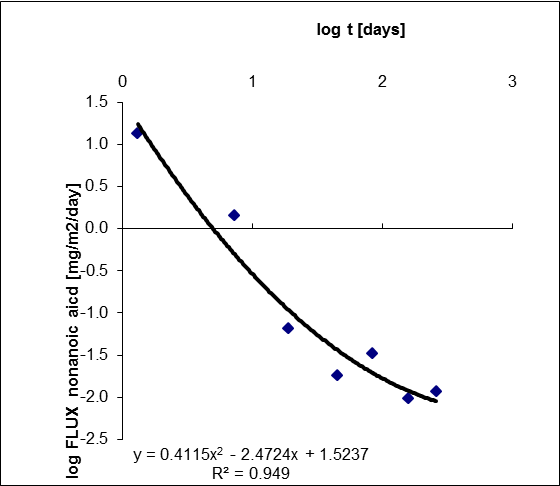


Figure 7: second order Fitted log transformed quantity of nonanoic acid leached versus log transformed time (fibre cement; semi-field study: horizontal orientation)

**Leaching rates used for the risk assessment**

The leaching rates (flux values) derived from the several leaching tests are summarized in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Derived FLUX values (mg/m2/d) and cumulative leaching (mg/m2) for nonanoic acid derived from leaching tests** | | | | |
| **Leaching test** | **Test specimen** | **Time\* (d)** | **Leaching rates** | **Qleaching** |
| Laboratory immersion | Fibre cement | 0-30 | 5.59 | 167.70 |
| 30-365 | 0.46 | 154.1 |
| Laboratory immersion | Clinker straps | 0-30 | 14.0 | 420.56 |
| 30-365 | 0.36 | 120.12 |
| Semi-field | Fibre cement – vertical orientation | 0-30 | 1.32 | 39.5 |
| 30-365 | 0.17 | 57.0 |
| Semi-field | Fibre cement – horizontal orientation | 0-30 | First.1: 1.55 | 46.4 |
| Sec.2: 1.66 | 49.8 |
| 30-365 | First.1: 0.02 | 8.10 |

\*: PECs in soil were calculated distinguishing two phases. First phase includes the runoff at t=0 and the leaching during the first 30 days. The concentration in soil at day 30 is used in the formula for the remaining period to calculate the concentration at day 365.  
PECs in surface water are calculated assuming a fraction that leached from houses and objects that were recently treated (0-30 days) and after a longer period (30-365).

1: modelled after first order decay curve; 2: modelled after a second order function.

Leaching rates for TIME 1 derived from the semi-field leaching test and calculated by different models vary between 0.43 mg/m2/d and 1.66 mg/m2/d. For worst-case consideration a FLUX value of 1.66 mg/m2/d is taken. As the laboratory immersion test shows, that clinker straps reveals higher leaching rates during the first two immersion cycles compared to fibre cement a correction factor must be implemented. This factor can be obtained by dividing 14.0 by 5.59, resulting in 2.5. Multiplication of the factor with the maximum FLUX (1.66 mg/m²/d) results in a FLUX value of 4.15 mg/m2/d. The amount leached over the first 30 days (Qleach1) is therefore **124.5 mg/m²**.

As indicated above, the semi-field test results are appropriate for TIME 2 FLUX calculations as seven measurements are available comprising a study duration of 223 days (61% of TIME 2 duration). Leaching rates for TIME 2 derived from the semi-field leaching test and calculated by different models vary between 0.01 mg/m2/d and 0.17 mg/m2/d. For worst-case consideration, a rate of 0.17 mg/m2/d is taken into account derived from the semi-field study with fibre cement and vertical orientation. No correction factor needs to be applied, as in the laboratory immersion tests, the TIME 2 leaching rate for fibre cement (0.46 mg/m²/d) was already from the third immersion cycle onwards higher compared to clinker straps (0.36 mg/m²/d).

Therefore, the leaching rate decreases to 0.17 mg/m²/d after 30 days, i.e. 57.0 mg/m² is additionally lost over the remaining 335 days. Consequently, the total amount leached over one year (Qleach2) is **184.5 mg/m²**.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on distribution and dissipation in soil is not required. |
| Justification | The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p. Furthermore, the components of the product do not influence the distribution characteristics of the a.s., which is also classified as readily biodegradable. The formulation types are not expected to change the model of action of the a.s. or its bioavailability.  Further testing for distribution and dissipation in the environment is therefore not deemed necessary. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on distribution and dissipation in water and sediment is not required. |
| Justification | The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p. Furthermore, the components of the product do not influence the distribution characteristics of the a.s., which is also classified as readily biodegradable.  Further testing for distribution and dissipation in the environment is therefore not deemed necessary. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on distribution and dissipation in air is not required. |
| Justification | It is considered that volatilisation to the atmosphere following normal biocidal use of the products may occur due to the vapour pressure (0.9 Pa at 20°C and 1.4 Pa at 25°C) and Henry’s Law constant (0.33 Pa m³/mol at 20°C) of the a.s. The potential for atmospheric exposure is considerably limited by the rapid breakdown of fatty acids by microbial action. Accumulation in air does not occur due to atmospheric gas-phase reaction (DT50 = 39.4 h on basis of OH time frame 24 hrs/day, 5 x 105 OH radicals/cm3).  Thus, accumulation and transport in air can be excluded and further testing is not deemed necessary. |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on risks to aquatic organisms or plants under field conditions in not required. |
| Justification | The b.p. are applied via spraying on terraces, pathways, parking lots or walls on a small scale. An overspray study is therefore considered to be unnecessary. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on aquatic chronic toxicity is not required. |
| Justification | Direct emissions of the products to surface water (incl. sediment) are unlikely. The data on aquatic toxicity of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the biocidal products. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Information on aquatic bioconcentration is not required. |
| Justification | Direct emissions of the products to surface water (incl. sediment) are unlikely. The data on the bioconcentration of the a.s. give sufficient information and there are no indications of risk due to specific properties of the biocidal products. |

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

The biocidal products are liquid formulations and there is no potential for large scale formation of dust. However, the products are to be sprayed or poured outside but the intended field of application is in small surface treatments of terraces, pathways or walls and the use is restricted to non-professionals. A large space application of the biocidal product is not intended and an overspray behavior is therefore not required under field conditions.

#### Exposure assessment

In the context of the Biocidal Products Regulation (BPR), ESDs have been prepared for a number of product types, among them for products used as masonry preservatives (ESD PT 10, 2002) to assess the emissions from products used for preservation and remedial treatment of masonry or construction materials for the control of microbiological and algal attach.

Due to the lack of an appropriate scenario for the use of nonanoic acid as surface treatment on surfaces in PT 02, the scenarios described in the ESD PT 10 (2002), ESD for PT 8 (2013), “Leaching from paints, plasters, and fillers applied in Urban areas” (Version 6, 2015) and “The assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10, Version 3, 2014) were applied. The environmental risk assessment for the b.p. is based on this document as well as on Volume IV Environment - Part B Risk Assessment version 1.0 2015)[[3]](#footnote-3) and ECHA technical agreements for biocides (TAB, version 1.2 December 2016)

The ESD PT10 (2002) on masonry preservatives covers the two life-cycle steps: application and releases from outdoor treated surface during service life due to application and leaching as being potentially relevant for environmental emissions. The assessment of emissions is based on the product COM 508 09 AL B (meta SPC 1), as the application amount of the active substance per m2 is slightly higher compared to COM 508 16 EW B (meta SPC 2) (COM 508 09 AL B: 3.099 g a.s./m²; COM 508 16 EW B: 3.089 g a.s./m²).

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Scenario 1: City   1. Emission via STP to surface water and sludge 2. Direct emission to surface water via mixed sewer systems during storm event and via separate sewer system   Scenario 2: Countryside direct emission to soil |
| ESD(s) used | Emission scenario document for biocides used in masonry preservatives (product type 10), 2002  Revised Emission Scenario Document for Wood Preservatives (2013)  Scenario for uses on parking lots and terraces developed by the applicant;  Leaching from paints, plasters, and fillers applied in urban areas (Muijs, B., Okkerman, P., Version 6, 2015)  The assessment of direct emissions to surface water in urban areas (PT 6.2/6.3 and 7-10, Ahting, M., Mueller, S., Version 3, 2014) |
| Approach | Scenario 1: Average consumption  Scenario 2: Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV/B (2015) and ESD PT10, 2002 and ESD PT 8 (2013) |
| Groundwater simulation | Higher tier groundwater modelling with FOCUS PEARL 4.4.4 was performed for the countryside scenario. The relevant input parameters are described in annex section 3.7. |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1 and 2:  Production: No  Formulation No  Use: Yes  Service life: Yes |
| Remarks | No remarks |

***Emission estimation***

Due to the lack of an appropriate scenario for the use of nonanoic acid as algaecide on surfaces such as terraces, pathways, parking lots and walls in PT 02, the PT 10 and PT 8 scenario was applied dealing with the façade of a house being the representative vertical surface to be treated.

Emissions of nonanoic acid to the environment may occur from product application due to runoff and spray drift and from leaching during service life. Spray application is assumed for worst case considerations.

For the treated façade, the dimensions of the model house already proposed in the ESD for PT 8 (OECD, 2013) are used. The height of the house is 2.5 m and its perimeter is 50 m (17.5 m long and 7.5 m wide). So, the total treated surface of the house is 125 m². The default values for the size of the soil receiving runoff according to the ESD for PT 8 (2013) are 50 cm distance from the house and 50 cm deep. This results in a soil volume adjacent to the house of 13 m³ and a treated area to soil volume ratio of 9.6. When considering spray drift, a drift length of 4.07 m is calculated resulting in a potentially exposed soil volume distant to the house of 142.8 m³ according to the ESD for PT 10 (2003) . The soil volume of 142.8 m³ is based on the following assumptions:

According to TAB (2016), a soil depth of 50 cm for “spraying” can be used to calculate the volume distant to the house Vsoil(d). The distance travelled by drift can be calculated according to equation presented on page 21 of the ESD for PT (2002). Applying a height release of 2.5 m (no roof treatment), it results in a drift of 4.07 m. Taking both values into account, it results in a total soil volume of 142.8 m³ (based on Figure 5 of the ESD for PT 10).

Vsoil(d) = (2 x ((17.5 m + 0.5 m + 0.5 m + 4.07 m + 4.07 m) x 4.07 m x 0.5 m)) + (2 x (4.07 x (7.5 + 0.5 + 0.5) x 0.5)) = 142.8 m³

However, an in-situ spraying scenario is described in the ESD for PT 8 (2013) paragraph 4.4.5), which is more appropriate for the assessment. According to the label, the product should be applied when there is no wind. In this case, spray drift will only deposit within the 50 cm-zone adjacent to the treated surface (ESD for PT 8, 2013), which also represents a worst case. Therefore, the assessment is done using both calculation approaches.

Next to vertical surface, the products of the BPF may also be applied to horizontal surfaces like terraces, pathways and parking lots. Therefore, the treatment of horizontal surfaces is considered for the emission estimation as well.

According to ESD for PT 18 (2008), the typical size of a terrace is 6% of a garden with a size of 500 m² resulting in an area to be treated of 30 m². Regarding the size of pathways in garden, 5% of 500 m²; i.e., 25 m², is a typical size according to the ESD for PT 18 (2008). For the treatment of parking lots, no default values are available in official guidance documents. For the assessment, a parking lot for 2 cars per private house is assumed, which is a realistic worst case. The length of a parking lot is assumed to be 5 m and the width per car is 2.5 m resulting in a parking lot size of 25 m², which is a realistic size for parking lots in Germany[[4]](#footnote-4).

This results in a total treated area for horizontal surfaces of 80 m², which is used for the assessment, corresponding to a receiving (surrounding) soil volume of 9.5 m3 and a treated area to soil volume ratio of 8.4.

Releases during treatment (application)

Releases may occur from surfaces such as terraces, pathways, parking lots, and walls outdoors during application due to runoff or spray drift.

The emissions from runoff may reach soil adjacent to treated surface if the treated surface is located in the countryside; if it is located in the city, the fraction ends up in the waste water and adjacent STP or directly in surface water in case of direct emissions via direct rainwater discharge (separate sewer system).

When considering spray drift, releases to air are possible. However, emissions to air are expected to be low and an accumulation of nonanoic acid in the air is not to be expected due to its short half-life in air of 39.4 h. But after spray drift, there can be a deposition of droplets onto soil.

If the treated surfaces are located in a city, the ground is mostly paved. Therefore, releases due to drift reach waste water and are added to the releases due to runoff.

Releases from treated surfaces outdoors during service life due to leaching

Emissions during service life result from leaching of a substance from treated substrates. The cumulative quantity of an active ingredient emitted to the relevant environmental compartment due to leaching from a treated surface, is considered for the assessment. The soil adjacent to the treated surface in the countryside scenario and the paved ground in the city scenario are the compartments, where emissions may occur.

In summary, emissions may occur due to application losses due to runoff or spray drift and leaching during service life. The receiving environmental compartments are either soil (countryside scenario 2) or STP/surface water (city scenario 1).

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission during application and service life** | | | |
| **Input** | **Definition** | **Value** | **Unit** |
| Scenario:1 and 2 | | | |
| **Product-dependent input variables** | | | |
| Fraction of active substance in product (30.99 g/L] | Fform | 0.03099 | [-] |
| Volume of product applied on area | Vform | 0.1 | L/m² |
| Amount leached over the first 30 days | Qleach1 | 124.5 | mg/m² |
| Amount leached over 30-365 days | Qleach2 | 181.45 | mg/m² |
| **General defaults** | | | |
| Treated area of a façade per day | AREAfaçade | 125 | m²/d |
| Treated area of horizontal surfaces per day (parking lots, terraces and pathways)\* | AREAhorizontal | 80 | m²/d |
| Fraction of product lost during application by spray drift | Fdrift | 0.1 | [-] |
| Fraction of product lost during application by runoff | Frunoff | 0.2 | [-] |
| Duration of the initial assessment period (service life - leaching) | TIME1/Tinitial | 30 | d |
| Duration of the longer assessment period (service life - leaching) | TIME 2 | 365 | d |
| **Emission to the sewer (City scenario)** | | | |
| Time for longer assessment period | Tlonger | 335 | d |
| Number of houses that are treated | Nhouse, application | 6 | /d |
| Number of houses in a city recently treated | Nhouse,initial | 164 | - |
| Number of houses in a city treated more than 30 days ago | Nhouse,longer | 1836 | - |
| **Direct emission to soils (House scenario)** | | | |
| Soil volume | Vsoil | 13 | m³ |
| Density of the soil | RHOsoil | 1700 | kg/m³ |
| Half-life for degradation in soils | DT50 | 2.1 | d |

\* The horizontal surfaces are only relevant for the calculations for scenario 1 (city scenario, emission to the sewer). For scenario 2 (countryside, direct emission to soils), the house scenario is calculated as worst case scenario.

Calculations for Scenario 1(city scenario)

The ESD for PT 10 differs between the places countryside and city, where the treatment is performed. The city (scenario 1 in this document) is assessed and calculated according to the agreed city scenario “Leaching from paints, plasters, and fillers applied in urban areas” (Muijs, B., Okkerman, P., Version 6, 2015).

In the city scenario, losses due to spray drift and runoff during application (Elocalspray.façade.water) and leaching over the assessment period are likely to enter paved ground and are washed either with rain to the sewer system subsequently reaching the STP or directly to surface water in case when rain water is collected separately without being mixed with other waste water (separate sewer systems). Emission to separate sewer systems is calculated according to the agreed scenarios described in “The assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10, Ahting, M., Mueller, S., Version 3, 2014).

According to the city scenario (2015), emissions during application have to be multiplied by 6 taking the treatment of six houses per day into account (due to the service life of 365 days). Furthermore, spray application is assessed, as the product is not applied via the proposed brush application. The same assumptions are applied to the treatment of horizontal surfaces (parking lots, pathways and terraces) in urban areas (Fdrift: 0.1 and Frunoff: 0.2).

For tier 1, emissions via leaching during service life of 365 days are assessed assuming a 100% a.s. leaching during this period (50% during the first 30 days and 50% during the remaining service life of the product).

For tier 2, the leaching is refined with the leaching rates derived from the semi-field studies and laboratory immersion tests, i.e., 4.15 mg/m²/d for surfaces recently treated (less than 30 days ago) and 0.17 mg/m²/d for surfaces that are treated more than 30 days ago. These figures corresponds to a cumulative leaching of 124.5 mg/m2 and 56.95 mg/m2 for recent treatments (1-30 days) and older treatments (30-365 days), respectively.

The calculations are performed according to the sub scenario “paints applied on façade” taking a service life Tservice life of 365 days, and a volume applied Vformof 0.1 L/m² into account.

It must be pointed out, that the city scenario (2015) is applicable only up to a certain point for the intended use of the b.p. The underlying assumptions are not realistic for the b.p as the service life of the product is significantly lower and the assumed treatment of 4000 houses within 30 days or 365 days (service life) is hardly reasonable for the intended use of the b.p. Therefore, the treatment of only half of the houses (2000) over a period of 365 days is more realistic and used for assessment taking into consideration, that the use is clustered to weekends or certain periods in spring and autumn. Furthermore, the b.p. are only applied by non-professionals.

| **Resulting local emission to relevant environmental compartments for scenario 1 (city scenario)** | | | |
| --- | --- | --- | --- |
| **Parameter** | **Definition** | **Compartment** | **Value [kg/d]** |
| Total emissions resulting from application and leaching – Houses and horizontal surfaces (pathways, parking lots, terraces) – Tier 1 (100% Leaching after 1 year) | Elocalwater\_tier 1 | STP/Surface water | Runoff+drift: 1.14  1-30d: 1.74  30-365d: 1.74  Total: 4.62 |
| Total emissions resulting from application and leaching – Houses and horizontal surfaces (pathways, parking lots, terraces) – Tier 2 (Refinement with leaching studies) | Elocalwater\_tier 2 | STP/Surface water | Runoff+drift: 1.14  1-30d: 0.14  30-365d: 0.06  Total: 1.35 |

Calculations for Scenario 2 (rural scenario)

In the countryside, spray drift and runoff during application (Elocalrunoff.façade / Elocalspray\_drift.façade) and service life are separate scenarios to calculate PECs for the soil compartment. Runoff reaches soil adjacent to the treated house according to ESD for PT 8 (2013). According to ESD for PT 10 (2002), the deposition of spray drift reaches soil distant from the house (distant soil).

The soil adjacent to the house is the only compartment where a substance can accumulate. This results in the following local emissions for scenario 2, which are calculated according to the ESD for PT 8 (2013) and the ESD for PT 10 (2002).

| **Resulting local emission to relevant environmental compartments for scenario 2 (countryside scenario)** | | | |
| --- | --- | --- | --- |
| **Parameter** | **Definition** | **Compartment** | **Value [kg/d]** |
| Local emission of a.s. during application due to runoff | Elocalrunoff.façade | Adjacent soil | 0.077 |
| Local emission of a.s. during application due to spray drift | Elocaldrift.façade | Distant soil | 0.039 |
| Local emission of a.s. due to leaching– Tier 1 (100% leaching after 1 year)\* | Esoil(a)leach.time1,tier1 | Adjacent soil | 1-30d: 6.46 x 10-3  30-365d: 5.78 x 10-3 |
| Local emission of a.s. due to leaching – Tier 2 (Refinement with leaching studies) | Esoil(a)leach.time1,tier2 | Adjacent soil | 1-30d: 5.19 x 10-4  30-365d: 2.13 x 10-5 |

Cumulative leaching over the initial assessment period (0-30 days) and remaining assessment period (30 – 365 days) is calculated according to the following formulas (modified from formulas 3.5 and 3.6 from the revised ESD for PT 8 (version 2013):





where:

* Ecomp, leach, time1 average daily emission (mg/d) to compartment X (water or soil) of the active ingredient due to leaching over the first 30 days;
* Ecomp, leach, time2 average daily emission (mg/d) to compartment X (water or soil) of the active ingredient due to leaching over the remaining assessment period (product’s service life minus 30 days);
* AREA surface area (m²) of the treated object (see ESD);
* Qleach, time1 cumulative quantity of an active ingredient leached out over the first 30 days (mg/m²);
* Qleach, time2 cumulative quantity of an active ingredient leached out during the remaining assessment period (mg/m²);
* time1 duration of the initial assessment period (30 days);
* time2 duration of the remaining assessment period (product’s service life minus 30 days).

The PECs for the soil compartment at day 30 and 365 were subsequently calculated as follows:

*initial assessment period (0 ≥ t ≤ TIME1):*



*second assessment period (TIME1 ≥ t ≤ TIME2):*



where:

* Clocalsoil, applic Concentration in soil during application (mg/kg wwt)
* Vsoil Volume of the receiving soil compartment (13 m³);
* RHOsoil Bluk soil density (1700 kg/m³);
* Ksoil Total rate constant for disappearance for soil calculated according to the guidance. Only degradation (DT50=2.1 d) and leaching (calculated from the active substance physical-chemical properties as listed elsewhere) to deeper soil layers was considered as the active substance does not evaporate from soils (0.331/d).

PECs were calculated without and with precautionary measures, i.e. covering of adjacent soils with plastic. The latter was calculated by assuming that the initial concentration is equal to zero. Considering that the product is applied annual, the concentration after ten years was calculated summarising the residual fraction from previous treatments. Horizontal surfaces were not considered for direct emission to soils as the surface:soil ratio is disadvantageous for vertical surfaces. Therefore, the default house scenario sufficiently covers emission from terraces etc.

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Fresh-water** | **Freshwater sediment** | **STP** | **Air** | **Soil** | **Groundwater** |
| Scenario 1 | Yes | covered by freshwater | Yes | Not relevant | Yes | Yes |
| Scenario 2 | Not relevant | Not relevant | No | Not relevant | Yes | Yes |

Relevant and reliable environmental fate parameter of the a.s. nonanoic acid are taken from the AR (2013).

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for nonanoic acid for calculating emissions to the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 158.2 | g/mol |  |
| Melting point | 11.7 - 12.5 | °C |  |
| Vapour pressure (at 20°C) | 0.9 | Pa |  |
| Water solubility (at 20°C) | 0.415 | g/L | pH 5 |
| Log Octanol/water partition coefficient | 3.52 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 63.1 | L/kg |  |
| Henry’s Law Constant | 0.33 | Pa m3/mol |  |
| Biodegradability | Ready biodegradable |  |  |
| DT50 for biodegradation in surface water | 15 days |  | Table 7 in Vol IV Part B |
| DT50 for hydrolysis in surface water | Expected to be stable |  |  |
| DT50 for photolysis in surface water | No phototransformation can be expected |  |  |
| DT50 for degradation in soil | 2.1 | d (at 12ºC) |  |
| DT50 for degradation in air | 19.73 | hr | OH time frame 24 hrs/day, 0.5×106 OH radicals/cm3 |
| Bioconcentration factor in earthworm/fish | 40.57/195.88 | L/kg wwt | Calculated value (Expected to be low based on the rapid metabolism within organisms) |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| **Compartment** | **Percentage [%]** | **Remarks** |
| Air | 0.00 | Estimated using SimpleTreat 3.1 |
| Water | 12.6 |
| Sludge | 0.59 (primary sludge: 0.6; surplus sludge: 0.0) |
| Degraded in STP | 86.8 |

***Calculated PEC values***

**Scenario 1 Urban emission to sewer**

Based on the ESD PT10 and the city scenario (2015), releases to STP are only considered relevant for the treatment of houses in the city (scenario 1). The distribution of the a.s. nonanoic acid in the STP was calculated according to the Guidance BPR IV/B (2015).

PEC in STP

The PECSTP is calculated using equation 33 of the Guidance for BPR IV/B (2015). Assuming a total emission of 4.62 kg/d (tier 1; 100% leaching) and 1.35 kg/d (tier 2; derived from leaching studies) to waste water during application and leaching, the concentration in the STP effluent (PECSTP) is **0.29 mg/L** and **0.085 mg/L**, respectively.

PEC in water

The effluent of the STP is diluted into the surface water. The PECwater is calculated according to equation 45 of the Guidance BPR IV/B (2015).) using a solid-water partition coefficient in suspended matter of 6.31 L/kg (worst case Koc resulting in highest PECwater: 63.1 L/kg). The calculated local concentration in surface water during emission episode (PECwater) is **0.029 mg/L** (tier 1) and 8.5**x 10-3 mg/L** (tier 2), respectively.

| **Resulting local concentrations of nonanoic acid in STP and surface water for scenario 1 (city scenario) resulting from application and leaching.** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario 1 City scenario** | **PEC STP (mg/L)** | | **PEC fresh water (mg/L)** | |
| **Tier 1** | **Tier 2** | **Tier 1** | **Tier 2** |
| During application | 7.19 X 10-02 | 7.19 X 10-02 | 7.19 X 10-03 | 7.19 X 10-03 |
| leached from recently treated houses and horizontal surfaces (pathways, parking lots, terraces) | 1.09 X 10-01 | 8.78 X 10-03 | 1.09 X 10-02 | 8.78 X 10-04 |
| leached from not recently treated houses and horizontal surfaces | 1.09 X 10-01 | 4.02 X 10-03 | 1.09 X 10-02 | 4.02 X 10-04 |
| leached from all treated houses and horizontal surfaces | 2.19 X 10-01 | 1.28 X 10-02 | 2.19 X 10-02 | 1.28 X 10-04 |
| **Total** | **2.91 X 10-01** | **8.47 X 10-02** | **2.91 X 10-02** | **8.47 X 10-03** |

PEC in sediment

The sediment is not considered due to the calculation of PNECsediment using the equilibrium partitioning method. Therefore, the risk characterisation ratio is the same like for surface water.

PEC in soils

For the soil compartment, emission of the a.s. occurs due to the indirect release via sewage sludge application from a STP. The rate of sewage sludge production is 790 kg/d. The initial concentration in soil following 10 sludge applications is used to calculate average residues in soils (PECsoil) of terrestrial ecosystems assuming an averaging time of 30 days and a first order rate constant for removal from top soil of 0.33 d-1. The calculated PECsoil after 10 years of use is **5.84 x 10-2 mg/kg** **wwt** (tier 1) and **1.70 x 10-2 mg/kg wwt** (tier 2) using equation 55 of Guidance BPR IV/B (2015), respectively.

PEC in groundwater

The soil pore water concentration is assessed using Guidance BPR IV/B (2015) default values for the PEC calculation in soil pore water according to equation 20-22 and using time weighted concentration in soil for 30 days after the sludge application. Furthermore, an air-water partitioning coefficient of Kair\_water 9.13 x 10-5 and a partitioning coefficient solid-water in soil of 1.26 L/kg (worst case Koc resulting in highest PECgw: 63.1 L/kg) are used to calculate a soil-water partitioning coefficient of 2.09 m³/m³. As result, the soil-water partitioning coefficient is used as input parameter to calculate the local pore water concentration (PECgw) of **4.77 µg/L** (tier 1) and **1.39 µg/L** (tier 2) according to Guidance BPR IV/B (2015)3 equation 67, respectively.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resulting local concentrations of nonanoic acid in soil and ground water for scenario 1 (city scenario) resulting from application and leaching discharged to sewer.** | | | | |
|  | **soila PEC (mg/kg wwt)A** | | **Groundwater (ug/L)B** | |
|  | Tier I | Tier 2 | Tier I | Tier 2 |
| Concentration in soil and groundwater after sludge application | 5.84 x 10-2 | 1.70 x 10-2 | 4.7 | 1.39 |

A concentration in top soils after ten successive sludge applications - initial concentration. Note that at WG the PEC to be used for the risk assessment is under discussion. Here is chosen to use the initial PEC as it corresponds with the PNEC wich is also based on initial concentrations.

B Concentration is averaged over 30 days after the 10th sludge application

Scenario 1 direct emission to surface water from a. mixed sewer systems and b. separate sewer systems

The direct emissions to surface water in urban areas are calculated according to the equations described in the storm water scenario document (UBA, 2014). According to TAB (2016), the application step should not be considered for mixed sewer systems, although this agreement relates only to the application of paint. One may consider this also could be relevant for the treatment of walls and horizontal surfaces around the house **by adding a risk mitigation sentence to the label** “do not apply this product during or shortly before rain events” . On the other hand the amount emitted from surfaces due to runoff and drift will be combined with the amount that specifically was applied to walls and horizontal surfaces and therefore be part of the total emission. Therefore, the relevant emissions occur during during application and service life.

For direct rainwater discharge, the effluent discharge rate of rainwater sewer is decreased from the default value of 2 x 106 L/d to 0.6 x 106 L/d, which is in accordance to the scenario document.

The concentrations in surface water are **0.772 mg/L** (tier 1) and **0.23 mg/L** (tier 2).

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations of nonanoic acid in surface water for scenario 1 (stormwater scenario) resulting from application and leaching.** | | |
| **Scenario** | **fresh water PEC (mg/L)** | |
| **Tier 1** | **Tier 2** |
| during application | 1.91 X 10-01 | 1.91 X 10-01 |
| leached from recently treated façades and horizontal surfaces | 2.91 X 10-01 | 2.33 X 10-02 |
| leached from not recently treated treated façades and horizontal surfaces | 2.91 X 10-01 | 1.07 X 10-02 |
| leached from all treated façades and horizontal surfaces | 5.81 X 10-01 | 3.40 X 10-01 |
| **total** | **7.72 X 10-01** | **2.25 X 10-01** |

**Scenario 2 rural scenario (direct emission to soil)**

PEC in soil

Algal treatment of buildings in the countryside may result in direct releases to the soil during application and leaching during service life. The biocidal product is intended for the treatment of surfaces such as terraces, pathways, parking lots and walls; thus, the façade scenario was considered as an appropriate scenario for the emission estimation. Treatment of the roof is not considered in the present risk assessment since the b.p. are not intended for roof treatment.

Below the results of the two tier approaches are included distinguishing 1 time application. 2 applications per year for 10 years.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resulting local concentrations of nonanoic acid in adjacent and distant soil for scenario 2 (countryside scenario) from application and leaching during service life over the initial and longer assessment period assuming removal in soil** | | | | |
| **Parameter** | **Compartment** | **Period** | **Value [mg/kg wwt]** | |
| **Tier 1** | **Tier 2** |
| Local concentration of a.s resulting from one application | Adjacent soil | during application | 3.51 | 3.53 |
| after 30 days | 8.85 x 10-1 | 7.12 x 10-2 |
| after 365 days | 7.93 x 10-2 | 2.91 x 10-3 |
| Local concentration of a.s resulting from 1 application per year over 10 years | Adjacent soil | during application | 3.59 | 3.57 |
| 30 days after last application | 9.66 x 10-1 | 9.75 x 10-2 |
| 365 days after last application | 1.59 x 10-1 | 2.91 x 10-2 |
| Local concentration of a.s resulting from one application | Distant soil | during application | 8.4 x 10-1 | |
| TWA after 30 days (according to ESD for PT 10, 2002) | 8.4 x 10-2 | |

The time weighted concentrations in soil are used for the calculation of groundwater concentrations as they represent the worst case.

PEC in groundwater

The predicted environmental concentration in groundwater are calculated according to the ESD for PT 8 (2013), i.e., equations 3.9 and 3.10), which is comparable to the groundwater assessment according to the Guidance for BPR IV/B (2015). The groundwater concentrations after in-situ application and leaching during service life are derived from the TWA soil concentrations calculated using equations 3.7 and 3.8 of the ESD for PT 8 (2013).

| **Resulting local concentrations of nonanoic acid in soil pore water for scenario 2 (countryside scenario) due to release during application and service life** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | | **Compartment** | **Period** | **Definition** | **Value [µg/L]** | |
| **Tier 1** | **Tier 2** |
| Local concentration of a.s resulting from one application | | Adjacent soil | during application | **Clocalspray, façade. soil** | 2850.9 | 2850.9 |
| after 30 days | 718.8 | 57.8 |
| after 365 days | 64.4 | 2.4 |
| Local concentration of a.s resulting from 1 application per year over 10 years | | Adjacent soil | during application | **Clocalspray, façade. Porewater** | 2915.9 | 2872 |
| after 30 days | 784.6 | 79.3 |
| after 365 days | 129.1 | 23.7 |

Predicted environmental concentrations in pore water amount to >0.1 µg/L. According to Council Directive 98/83/EC[[5]](#footnote-5) (1993) relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L for substances considered separately. The calculated pore water concentrations for nonanoic acid (as an indicator of the potential concentrations in groundwater) do not comply with this criterion.

Therefore FOCUS PEARL 4.4.4 simulations are performed according to the PT 08 scheme with a density of 16 treated houses per ha and a leachable area of 125 m² per house as well as a fraction for weather side of 1(worst case) resulting in a total leachable area of 2000 m² per ha. Considering a product application rate of 100 mL/m² and an a.s. concentration of 30.99 g/L, it results in a total amount of 6.20 kg nonanoic acid leached per ha per year (100% leaching during service life of one year; worst case). The application scheme described in the ESD for PT 8 (2003) is applied, i.e.; ten events evenly distributed over the year (10.01; 15.02; 24.03; 29.04; 05.06; 11.07; 17.08; 22.09; 29.10; 04.12) resulting in a dosage of 0.62 kg/ha per event. The assessed crop type is alfalfa/grass and the application mode is surface application. The FOCUS PEARL parameters are summarized in annex section **Fout! Verwijzingsbron niet gevonden.**.

The FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of <0.0001 µg/L for all nine FOCUS scenarios (Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva) and an acceptable risk to the groundwater compartment.

In the calculations a Freundlich sorption exponent of 1 is used, indicating that a doubling of the dosage will lead to a doubling in groundwater concentrations. The present calculations relate only to the treatment of houses, although also terraces and parking lots can be treated. The outcome of the calculations, however, shows that that even when doubling the treated surface area the 0.1 µg/L standard is not exceeded. Due to the low concentrations derived, it is assumed that an additional release from the horizontal surfaces will not result in an exceeding of the trigger value.

**Summary tables**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for scenario 1** | | | | |
| **Scenario 1** | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [µg/L] |
| City Scenario – Aggregated (vertical + horizontal surfaces) – Tier 1 (100% leaching during service life) | 0.29 | 0.029 | 5.84 x 10-2 | 4.74 |
| City Scenario – Aggregated (vertical + horizontal surfaces) – Tier 2 (Leaching rates derived from leaching studies) | 8.47 x10-2 | 8.47 x 10-3 | 1.70 x 10-2 | 1.39 |
| Direct discharge (separate system) – Aggregated (vertical + horizontal surfaces) – Tier 1 (100% leaching during service life) | Not relevant | 0.77 | Not relevant | Not relevant |
| Direct discharge (separate system) – Aggregated (vertical + horizontal surfaces) – Tier 2 (Leaching rates derived from leaching studies) | Not relevant | 0.23 | Not relevant | Not relevant |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for scenario 2** | | | | | |
| **Parameter** | **Period** | **PECsoil [mg/kg wwt]** | | **PECporewater [µg/L]** | |
| **Tier 1** | **Tier 2** | **Tier 1** | **Tier 2** |
| Concentration in ajacent soil resulting from one application | during application | 3.51 | 3.51 | 2850.9 | 2850.9 |
| after 30 days | 8.85 x 10-01 | 7.12 x 10-2 | 718.8 | 57.8 |
| after 365 days | 7.93 x 10-02 | 2.91 x 10-3 | 64.4 | 2.4 |
| Concentration in ajacent soil resulting from 1 application per year over 10 years | during application | 3.59 | 3.53 | 2915.9 | 2873 |
| after 30 days | 9.66 x 10-01 | 9.75 x 10-2 | 784.6 | 79.3 |
| after 365 days | 1.59 x 10-01 | 2.91 x 10-2 | 129.1 | 23.7 |

|  |  |
| --- | --- |
| **Summary table on calculated PECGW values using FOCUS Pearl for scenario 2 (countryside, crop type: alfalfa/gras)** | |
| **FOCUS scenario** | **PECGW** |
| [μg/L] |
| Chateaudun | < 10-4 |
| Hamburg | < 10-4 |
| Jokioinen | < 10-4 |
| Kremsmünster | < 10-4 |
| Okehampton | < 10-4 |
| Piacenza | < 10-4 |
| Porto | < 10-4 |
| Sevilla | < 10-4 |
| Thiva | < 10-4 |

***Primary and secondary poisoning***

Primary and secondary poisoning

Fatty acids are a nutritional energy source for organisms. Under environmental conditions fatty acids are readily biodegraded in an aerobic environment by microorganisms. Therefore, the potential for bioaccumulation is expected to be low based on the rapid metabolism within organisms via common pathways. Hence, fatty acids are considered to pose no real risk to organisms from their bioconcentration and biomagnification properties. There is no need to assess this route further.

#### Risk characterisation

***Atmosphere***

Conclusion:It is considered, that any potential for atmospheric exposure will be limited by the rapid breakdown of fatty acids by microbial action. Thus, accumulation and transport in air can be excluded.

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 – Tier 1 (100% leaching) | 0.051 |
| Scenario 1 – Tier 2 (Leaching rates derived from leaching studies) | 0.015 |
| Scenario 2 | Not relevant |

Conclusion: Risk ratio for scenario 1 is << 1 indicating no unacceptable risk for STP.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values Surface water** | | |
|  | **Tier 1** | **Tier 2** |
| Scenario 1 – City Scenario | 0.51 | 0.15 |
| Scenario 1 – Direct discharge (separate systems) | **13.6** | **3.96** |
| Scenario 2 | Not relevant | |

Conclusion: For the city scenario, where indirect emissions to the surface water via STP occur, the risk ratio is < 1 indicating no unacceptable risk for surface water inhabiting organisms.

For direct rainwater discharge, the PEC/PNEC ratio is above 1 for the tier 1 and 2 approach. It should be noted that the storm water scenario was developed <2 years after approval of the substance, therefore is not fully in force and cannot be used to remove certain uses from the proposed label. Nevertheless emission to surface water should be prevented as much as possible and the label of the b.p. should contain the following instructions:

* + Do not rinse treated surfaces with water afterwards;
  + Allow the product to take effect for at least 24 hours;
  + Do not apply just before or during rain;
  + Do not apply this product to surfaces near or above surface water;
  + Avoid release to drains

Note that at the active substance renewal stage the storm water scenario will be enforced and it will require further refinement to show that the assessed use is safe for the environment.

Based on the PEC/PNEC-ratios in combination with a more realistic worst-case parameter setting for the risk assessment, risks for surface water are considered to be acceptable.

***Terrestrial compartment***

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated PEC/PNEC values in soil** | | | |
|  | | **Tier 1** | **Tier 2** |
| Scenario 1 (city) – contaminated sewer sludge on land | | 0.589 | 0.172 |
| Scenario 2 (countryside) – runoff and spraydrift during application and leaching from treated surfaces to soil | |  |  |
| **Adjacent soil** | **Period** | **Tier 1** | **Tier 2** |
| Local concentration of a.s resulting from one application | during application | **35.4** | **35.4** |
| after 30 days | **8.9** | 0.72 |
| after 365 days | 0.80 | 0.029 |
| Local concentration of a.s resulting from 2 applications per year over 10 years | during application | **36.2** | **35.7** |
| after 30 days | **9.7** | 0.98 |
| after 365 days | **1.6** | 0.29 |
| **Distant soil** | **period** |  | |
| Local concentration of a.s resulting from one application | during application | **8.91** | |
| TWA after 30 days (according to ESD for PT 10, 2002) | 0.891 | |

Conclusion: For scenario 1 (city scenario), a safe use is demonstrated due to the release of the a.s. to the soil after sludge application.

Regarding the country scenario and the soil distant to the house (ESD PT 10 approach), PEC/PNEC ratios do indicate a risk for soil inhabiting organisms during the first period. The applicant proposes to state at the label that the b.p. should not be applied when there is wind. Therefore, a considerable drift to areas distant to a house is not expected. This assumption is in accordance to the ESD for PT 8 (2013; in-situ spraying).

**The RMS** concludes that spray drift has to be taken into account in the risk assessment of this product. Concerning the fact that a risk is identified for adjacent soils, which was based on average wind speed is 5.5 m/s at 10 m height, we propose to include a recommendation in the use instructions only to apply the product when there is no wind.

Regarding the country scenario and the soil adjacent to the house related to run-off, PEC/PNEC ratios are >1. Therefore, the applicant has proposed for safety reasons the following risk mitigation measures to be included on the label for the application step:

- Do not spray on non-target plants during application to prevent irreversible damage.

- The soil next to the treated surface should be covered during application to avoid emissions to soil.

**The RMS** hasaccepted these sentences, as they were also accepted in the assessment report for approval of the active substance.

Additionally, the RMS has included an instruction that the user should avoid the application of excess fluid and run off.

Additionally, the applicant proposes the following: Assuming that the a.s. will be bound to the target organisms within some hours, the following risk mitigation measure is further proposed:

- Products can only be used if the weather forecasts show no rain for the day of application.

**The RMS** accepts this RMM as it was also accepted in the assessment report for approval of the active substance. It should however be noted that the product is inefficacious when it is applied shortly before or during rain.

To avoid spray drift during application of the diluted concentrate (meta-SPC 2), the following risk mitigation measure was added:

The equipment to be used for spraying must be a handheld manually operated low pressure (3 bar or below) device. This device should be used in combination with a spraying shield.

***Groundwater***

Conclusion: For scenario 1 (city), the calculated pore water concentrations for nonanoic acid (as an indicator of the potential concentrations in groundwater) are above the maximum admissible concentration for pesticides in drinking water of 0.1 µg/L. However, a higher FOCUS PEARL4.4.4 calculation would result in groundwater values < 10-4 as the worst case application rate is 0.30 kg/ha (assuming a sludge concentration of 60.6 mg/kg and an annual sewage sludge application rate of 5000 kg/ha for arable soil) and therefore considerably lower compared to the scenario 2 (countryside) calculations with a rate of 6.2 kg/ha, where no risk for the groundwater could be demonstrated.

For scenario 2 (countryside), the higher tier FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of < 10-4 µg/L for all nine FOCUS scenarios (Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva) and an acceptable risk to the groundwater compartment.

***Surface water intended for the abstraction of drinking water***

In The Netherlands next to groundwater for the abstraction of drinking water also surface water for the abstraction of drinking water is relevant as National specific issue. From the general scientific knowledge collected by the NL-eCA about the products and the active substance, the RMS concludes that there are in this case no concrete indications for concern about the consequences of the products for surface water from which drinking water is produced, when used in compliance with the directions for use. The existing active substance nonanoic acid is not included in the list of substances of concern due to their presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb. In addition, nonanoic acid nor their metabolites are on the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). Hence, the standards for surface water destined for the production of drinking water are met.

***Primary and secondary poisoning***

Primary and secondary poisoning

Fatty acids are a nutritional energy source for organisms. Under environmental conditions fatty acids are readily biodegraded in an aerobic environment by microorganisms. Therefore, the potential for bioaccumulation is expected to be low based on the rapid metabolism within organisms via common pathways. Hence, fatty acids are considered to be no real risk to organisms from their bioconcentration and biomagnification properties. There is no need to assess this route further.

***Mixture toxicity***

Mixture toxicity is not of relevance as the b.p. within the BPF only contain nonanoic acid as a.s. and none of the b.p. contains any substance of concern for the environment.

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

The applicant only supports underlying use and therefore an aggregated exposure is not relevant.

|  |
| --- |
| **Overall conclusions on the risk assessment for the environment of the product** |
| * The risk assessment for **sewage treatment plants** indicates safe use for the b.p. and scenario 1. * **Surface water:**   Risk mitigation measures are needed to prevent adverse effects due to direct release to surface water   * **Soil:**   Regarding scenario 1 (city), the PEC/PNEC values for nonanoic acid are below the trigger value of 1.  Regarding scenario 2 (countryside) and the soil adjacent and distant to the house and other treated objects such as terrasses, pathways and parking lots, PEC/PNEC ratios > 1 indicate potential adverse effects for soil organisms. The risks for organisms in soil adjacent and distant from treated objects are considered to be acceptable after a short period (40 days).   * Higher tier FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of <10-4 µg/L for all nine FOCUS scenarios and an acceptable risk for the **Groundwater**. * Considering the risks identified the following risk mitigation measures and directions for use are to be indicated in the SPC:   **Generic:**   * + The biocidal product is used only for remedial treatment of hard porous surfaces to remove green surface discolouration on patios, paths, car parks, masonry and steps. Relevant materials to be treated are for example bricks, concrete, rocks, wood and natural stone.);   + Do not apply more fluid than prescribed and avoid that droplets runoff from surfaces during application;   + This Product can only be used if the weather forecasts show no rain for the day of application;   + Pay attention to wind-induced drifting; it is advisable to apply when there is no wind;   + Allow the product to take effect for at least 24 hours;   + Do not rinse treated surfaces with water afterwards.   **Surface water**   * + Do not apply this product to surfaces near or above surface water;   + Avoid release to drains.   **Soil**   * + Do not spray on non-target plants during application to prevent irreversible damage;   + The soil next to the treated surface should be covered during application to avoid emissions to soil. |

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

Please refer to the summary of the product assessment, section 2.1.

### Assessment of a combination of biocidal products

Not applicable.

For biocidal products that are intended to be authorised for the use with other biocidal products.

### Comparative assessment

Not applicable.

# Annexes

## List of studies for the biocidal product family

| **Author(s)** | **Year** | **Title** | **Testing Company** | **Report No.** | **GLP Study (Yes/No)** | **Published (Yes/No)** | **Data Protection Claimed (Yes/No)** | **Data Owner** | **Section No. in IUCLID /  Non-key study/ Published** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Allerdings, E. & Lebertz, H. | 2016 | Proof of efficacy on algae (algicidal suspension test) | SGS INSTITUT FRESENIUS GmbH, Taunusstein, Germany | 3746541-01 | No | No | Yes | COMPO GmbH | 6.7 |
| Bersegeay, A. & Viard, JB | 2011 | Herbicide Field Trial – Hard Surface – Algae. | Solevi, Ruy, France | H11COM508\_Alg1 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Haferkorn, J. | 2010a | Examination of COM 508 16 H EW in the skin sensitisation test in guinea pigs according to Magnusson and kligman (maximisation test). | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 25201 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.3 |
| Haferkorn, J. | 2010b | Acute oral toxicity study of COM 508 16 H EW in rats. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 25543 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.5.1 |
| Haferkorn, J. | 2010c | Acute inhalation toxicity study of COM 508 16 H EW in rats. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 25678 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.5.2 |
| Haferkorn, J. | 2010d | Acute dermal toxicity study of COM 508 16 H EW in CD rats. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 25544 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.5.3 |
| Haferkorn, J. | 2015 | COM 508 09 H AL Skin Sensitisation: modified local lymph node assay in NMRI mice. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 31876 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.3 |
| Krack, M. | 2010a | COM 508 16 H EW, Batch No.: 07/014, Explosive properties A.14 (OPPTS 830.6316). | Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany | 20100186.02 | Yes | No | Yes | COMPO GmbH & Co. KG | 4.1 |
| Krack, M. | 2010b | COM 508 16 H EW, Batch No.: 07/014, Flash point A.9. | Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany | 20100186.01 | Yes | No | Yes | COMPO GmbH & Co. KG | 4.2 |
| Krack, M. | 2010c | COM 508 16 H EW, Batch No.: 07/014, Oxidising properties of liquids A.21. | Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany | 20100186.04 | Yes | No | Yes | COMPO GmbH & Co. KG | 4.4 |
| Krack, M. | 2010d | COM 508 16 H EW, Batch No.: 07/014, Auto-flammabiliy (determination of the temperature of self-ignition of volatile liquids and of gases) A.15. | Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany | 20100186.03 | Yes | No | Yes | COMPO GmbH & Co. KG | 4.17.1 |
| Leuschner, J. | 2009a | Acute dermal irritation/corrosion test (patch test) of COM 508 16 H EW in rabbits. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 24959 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.1 |
| Leuschner, J. | 2009b | Acute eye irritation/corrosion test of COM 508 16 H EW in rabbits. | LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany | 25103 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.2 |
| LWK Niedersachsen | 2010 | Algen auf Nichtkulturland. | Prüfstelle Oldenburg, Landwirtschaftskammer Niedersachsen, Germany | H10COM508\_Alg1\_03 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| RMS AUT | 2013 | Assessment Report Nonanoic acid  Product-type 2  (Disinfectants and algaecides not intended for direct application to humans or animals)  September 2013 | – | – | No | Yes | No | – | Published |
| Rohr J. | 2010a | COM 508 use against algae in non crop areas (pathways with trees). | Agrartest GmbH, Aarbergen-Panrod, Germany | H10COM508\_Alg2\_01 (DEU) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2010b | COM 508 use against algae in non crop areas (pathways with trees). | Agrartest Sp.zo.o., Domaniow, Poland | H10COM508\_Alg1\_01 (POL) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2010c | COM 508 use against algae in non crop areas (pathways with trees). | Agrartest Sp.zo.o., Domaniow, Poland | H10COM508\_Alg1\_02 (POL) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2010d | COM 508 use against broad leaf weeds and grasses (2nd priority: mosses) in non crop land. | Agrartest Sp.zo.o., Domaniow, Poland | H10COM508\_B+G7\_03 (POL) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2010e | COM 508 use against algae in non crop areas (pathways with trees). | Agrartest GmbH, Aarbergen-Panrod, Germany | H10COM508\_Alg2\_02 (DEU) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2010f | COM 508 use against algae in non crop areas (pathways with trees). | Agrartest GmbH, Aarbergen-Panrod, Germany | H10COM508\_Alg2\_03 (DEU) | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2011g | COM 508 use against algae in non crop areas. | Agrartest GmbH, Aarbergen-Panrod, Germany | H11COM508\_Alg1\_55 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2011h | COM 508 use against algae in non crop areas. | Agrartest GmbH, Aarbergen-Panrod, Germany | H11COM508\_Alg1\_03 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Rohr J. | 2016 | COM 508 use against lichens in non crop areas. | Agrartest GmbH, Aarbergen-Panrod, Germany | H16COM508\_Lich1\_01 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Scheerbaum, D. | 2010 | Fish (Rainbow trout), Acute Toxicity Test, Semi-Static, 96 h. | Dr. U.Noack Laboratorien, Käthe-Paulus-Straße 1, 31157 Sarstedt, Germany | FAR14012 | Yes | No | Yes | COMPO GmbH & Co. KG | 9.2.1.1 |
| Schieck, S. | 2010a | COM 508 16 H EW - Accelerated storage test (54 °C / 2 weeks). | Intertek Food Services GmbH, Linden, Germany | 57161 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.1  3.2  3.4.1\_01  3.5\_01 |
| Schieck, S. | 2010b | COM 508 09 H AL - Accelerated storage test (54 °C / 2 weeks). | Intertek Food Services GmbH, Linden, Germany | 57162 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.1  3.2  3.4\_02 |
| Schieck, S. | 2010c | COM 508 16 H EW - Physical analysis. | Intertek Food Services GmbH, Linden, Germany | 60287 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.3  3.8  3.9 |
| Schieck, S. | 2010d | COM 508 09 H AL - Physical analysis. | Intertek Food Services GmbH, Linden, Germany | 57176 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.3  3.8  3.9 |
| Schieck, S. | 2010e | COM 508 16 H EW - Determination of low temperature stability. | Intertek Food Services GmbH, Linden, Germany | 57174 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_03 |
| Schieck, S. | 2010f | COM 508 09 H AL - Determination of low temperature stability. | Intertek Food Services GmbH, Linden, Germany | 57177 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_04 |
| Schieck, S. | 2010g | COM 508 09 H AL - Accelerated storage test (40 °C / 8 weeks) - Determination of the "clogging test", spray diameter and discharge rate (HDPE-bottle with trigger sprayer SP05 of Spray Plast). | Intertek Food Services GmbH, Linden, Germany | 57179 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_05 |
| Schieck, S. | 2010h | COM 508 09 H AL - Accelerated storage test (40 °C / 8 weeks) - Determination of the "clogging test", spray diameter and discharge rate (HDPE-bottle with trigger sprayer T95 of Canyon). | Intertek Food Services GmbH, Linden, Germany | 57180 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_06 |
| Schieck, S. | 2010i | COM 508 09 H AL - Accelerated storage test (40 °C / 8 weeks) - Determination of the "clogging test", spray diameter and discharge rate (HDPE-bottle with trigger sprayer / "Mixor" of Calmar). | Intertek Food Services GmbH, Linden, Germany | 57181 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_07 |
| Schieck, S. | 2010j | COM 508 16 H EW - Determination of the persistent foaming. | Intertek Food Services GmbH, Linden, Germany | 57175 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.5\_02 |
| Schieck, S. | 2010k | Validation of an analytical method: Determination of pelargonic acid in formulation COM 508 16 H EW by GC-FID. | Intertek Food Services GmbH, Linden, Germany | 57127 | Yes | No | Yes | COMPO GmbH & Co. KG | 5\_01 |
| Schieck, S. | 2010l | Validation of an analytical method: Determination of pelargonic acid in formulation COM 508 09 H AL by GC-FID. | Intertek Food Services GmbH, Linden, Germany | 57128 | Yes | No | Yes | COMPO GmbH & Co. KG | 5\_02 |
| Schieck, S. | 2014 | COM 508 16 H EW - Storage stability testing (2 years). | Intertek Food Services GmbH, Linden, Germany | 64769 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_08 |
| Schieck, S. | 2015 | COM 508 09 H AL - Storage stability testing (4 years). Interim report after 2 years. | Intertek Food Services GmbH, Linden, Germany | 75209 | Yes | No | Yes | COMPO GmbH & Co. KG | 3.4.1\_09 |
| Schieck, S. | 2016a | COM 508 16 H EW Storage stability testing (4 years) | Intertek Food Services GmbH, Linden, Germany | 75210 | Yes | No | Yes | COMPO GmbH | 3.4.1\_10 |
| Schieck, S. | 2016b | COM 508 09 H AL Storage stability testing (4 years) | Intertek Food Services GmbH, Linden, Germany | 75209 | Yes | No | Yes | COMPO GmbH | 3.4.1\_11 |
| Stratmann, B. & Anzengruber, J. | 2011 | COM 508 use against algae in non crop areas. | ATC – Agro Trial Center GmbH, Versuchsstation Gerhaus, Rohrau, Austria | H-11-S-099 | Yes (GEP) | No | Yes | COMPO GmbH & Co. KG | 6.7 |
| Walker, M. et al. | 1991 | Significance of vehicle thickness to skin penetration of halcinonide. | – | Int. J. Pharma., 70, 167-172 | No | Yes | No | – | Published |
| Wegner, R. | 2017a | Test Report – COM 508 09 H AL – OECD Guidance No. 107 - 31/17/3025/01 | Materialprüfanstalt Brandenburg GmbH, Eberswalde | 31/17/3025/01 | No | No | Yes | COMPO GmbH & Co. KG | 10.3 |
| Wegner, R. | 2017b | Test Report – COM 508 09 H AL – OECD Guidance No. 107 - 31/17/3025/02 | Materialprüfanstalt Brandenburg GmbH, Eberswalde | 31/17/3025/02 | No | No | Yes | COMPO GmbH & Co. KG | 10.3 |
| Wegner, R. | 2017c | Test Report – COM 508 09 H AL – NT Build 509 - 31/17/3025/03A | Materialprüfanstalt Brandenburg GmbH, Eberswalde | 31/17/3025/03A | No | No | Yes | COMPO GmbH & Co. KG | 10.3 |
| Wegner, R. | 2017d | Test Report – COM 508 09 H AL – NT Build 509 - 31/17/3025/04A | Materialprüfanstalt Brandenburg GmbH, Eberswalde | 31/17/3025/04A | No | No | Yes | COMPO GmbH & Co. KG | 10.3 |

**REFERENCE list of guidances that were used for the evaluation**

|  |
| --- |
| List with problem substances for the abstraction of drinking water from surface water. VEWIN, 2016, http://www.vewin.nl/probleemstoffen |
| Bakker, J. Biociden in oppervlaktewater voor drinkwaterproductie, National Institute of Public Health and the Environment, RIVM report 601712007, 2010, Bilthoven, The Netherlands. |
| Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer. |
| ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013 |
| Technical Agreements for Biocides. European Chemicals Agency, Helsinki, Finland, June 2016. |
| Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B: Risk Assessment (Active Substances). European Chemicals Agency, Report no. ECHA-15-G-01-EN, Helsinki, Finland, 2015. |

## Output tables from exposure assessment tools

Not relevant because the qualitative risk assessment was performed on local effects that may be caused by the a.s. nonanoic acid.

## New information on the active substance

Not applicable

## Residue behaviour

Not applicable

## Summaries of the efficacy studies (B.5.10.1-xx)[[6]](#footnote-6)

Summaries of the efficacy studies are provided in IUCLID section 6.7. Please refer to the respective IUCLID section.

## Confidential annex

Please refer to the separate document.

## Other

Input parameters for Pearl groundwater calculations

| **Parameter** | **Value** |
| --- | --- |
| **Tab Scenario** | |
| Location | all 9 EU scenarios |
| Crop Calendar | GRASS |
| Irrigation | no irrigation |
| Tillage | no tillage |
| Repeat interval for application events (years)**-** | 1 |
| **Parent substance** | |
| Substance | Nonanoic acid |
| Application | xxx |
| Deposition | no deposition |
| **Tab Simulation control** | |
| Start date | 01/01/1901 |
| Stop date | 31/12/1926 |
| Stop criterion (kg/ha) | 0 |
| Repeat hydrology | unchecked |
| **Tab Output control** | |
| Format of time column | Number of days since start of simulation |
| Print method | other |
| Print step (d) | 30 |
| Depth of Focus target layer (m) | 1 |
| Format for reals in output file | G12.4 |
| Summary output | checked |
| Detailed output | unchecked |
| Output cumulative | checked |
| Summary report | FOCUS report |
| **Tab SWAP hydrological module** | |
| Minimum timestep (d) | 1E-07 |
| Maximum timestep (d) | 0.2 |
| Tolerance in SWAP (-) | 0.001 |
| Tolerance for groundwater level (m) | 1 |
| Maximum number of iterations (-) | 1000 |
| Option hydrology | Run SWAP and the PEARL |
| Option hysteresis | Not considered |
| Minimum pressure head to switch drying/wetting (cm) | 0.2 |
| **Tab Diffusion** | |
| Reference temperature for diffusion (°C) | 20 (default) |
| Reference diffusion coefficient in water (m2/d) | 4.3E-5 (default) |
| Reference diffusion coefficient in air (m2/d) | 0.43 (default) |
| **Tab Crop** | |
| Wash-off factor (/m) | 0.0001 |
| Canopy process option | lumped |
| Half-life at crop surface (d) | 1000000 |
| Coefficient for uptake by plant (-) | 0 (no uptake by plants) |
| **Application** | |
| Application type | To the soil surface |
| Date: | 10/01/1906; 15/02/1906; 24/03/1906; 29/04/1906; 05/06/1906; 11/07/1906; 17/08/1906; 22/09/1906; 29/10/1906; 04/12/1906 |
| Dosage (kg/ha) | 0.62 |
| **Substances** | |
| **Active substance** | |
| **Tab General** | |
| Code | Nonanoic |
| Parent | unchecked |
| Name | Nonanoic acid |
| Molar mass (g· mol-1) | 158.2 |
| Saturated vapour pressure (Pa) | 0.9 |
| Measured at (°C) | 20 |
| Molar enthalpy of vaporisation (kJ/mol) | 95 |
| Solubility in water (mg/L) | 415 |
| Measured at (°C) | 20 |
| Molar enthalpy of dissolution (kJ/mol) | 27 (default) |
| **Tab Freundlich sorption** | |
| Option | Kom, pH-independet |
| Kom | 36.6 |
| Measured at (°C) | 20 |
| Molar enthalpy of sorption (kJ/mol) | 0 |
| Reference concentration in liquid phase (mg/L) | 1 (default) |
| Freundlich sorption exponent (-) | 1 |
| Desorption rate coefficient(/d) | 0 (default) |
| Factor relating CofFreNeq and COFFreEql (-) | 0 (default) |
| **Tab Transformation** | |
| Half-life (d) | 2.1 |
| Measured at (°C) | 12 |
| Optimum moisture conditions (pF2 or wetter) | unchecked |
| Liquid content in incubation experiment (mg/kg) | 1 (default) |
| Exponent for the effect liquid (-) | 0.7 (default) |
| Molar activation energy (kJ/mol) | 54 (default) |
| **Metabolites are not relevant and therefore not further assessed.** | |

1. OECD series on emission scenario document Number 2, 2013. Revised emissions scenario document for wood preservatives, ENV/JM/MONO(2013)21. OECD. [↑](#footnote-ref-1)
2. Emission scenario document for biocides used as masonry preservatives (product type 10), 2002. INERIS-DRC-02-25582-ECOT-VMi-n°02DR0270.doc. [↑](#footnote-ref-2)
3. Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B: Risk Assessment (Active Substances). European Chemicals Agency, Report no. ECHA-15-G-01-EN, Helsinki, Finland, 2015. [↑](#footnote-ref-3)
4. http://www.parken.de/cms/Media/GarVO/GarVO%20B-W.pdf [↑](#footnote-ref-4)
5. Council Directive 93/83/EC on the quality of water intended for human consumption, 1993. Official Journal of the European Communities. [↑](#footnote-ref-5)
6. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-6)