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

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



Brynsløkken AS – CuO - family

Product type(s) 21

Dicopper oxide

Case Number in R4BP3: BC-RT036764-05

Evaluating Competent Authority: Norway

Date: 26/May/2022

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# CONCLUSION

The biocidal product family Brynsløkken AS - CuO **–** familyconsists of products containing the active substance dicopper oxide. The product family is intended for treatment of nets used for offshore fish farming to prevent fouling. The treatment of the net is performed in specialised facilities, and the user category is industrial users.

It is concluded by the eCA that sufficient data have been provided to fulfil the conditions of Article 19 of regulation (EU) 528/2012.

The identity, physico-chemical properties and analytical methods are adequately addressed. The biocidal product family contains 12.00-27.64 dicopper oxide. The products may be yellow, red, or black in color with a pH range of 9.0-9.6. The average density is 1.31 g/ml for the representative concentrate product and approximately 1.13 g/ml for the representative RTU product. The products have a shelf life of 1 year when stored at temperatures above 5oC and below 30 oC.

The efficacy of the products has been demonstrated through field trials, assessing the efficacy of the net treatment under realistic conditions. The products are deemed to be sufficiently efficacious.

Exposure to human health from the use of the Brynsløkken AS - CuO- family (net treatment as well as net deployment) has been assessed in a tiered approach.

The risk to industrial workers involved in net impregnation activities was assessed using the Dipping model 4 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net dipping tasks. The risk was demonstrated to be acceptable for Meta SPC 1 and 3, provided that the workers wear impermeable coveralls and gloves and for Meta SPC 2 and 4 provided that the workers wear double coveralls and gloves.

The risk to professional workers involved in net deployment activities was assessed using the Handling model 2 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net deployment activities. The risk was demonstrated to be acceptable in the tier 1 assessment for Meta SPC 1 and 3, assuming use of gloves (the indicative hand exposure value in the exposure model was actual measured values inside gloves). A borderline risk was demonstrated for Meta SPC 2 and 4 in tier 1. Acceptable risk was demonstrated for all family members when gloves and (uncoated) coverall was used. Gloves are always worn when performing this task, due to mechanical strain, and in the Atlantic region usually also due to low temperatures.

Due to the classification of the products for Eye Dam. 1 (H318), eye protection should additionally be used.

Exposure to the environment from the use of the Brynsløkken AS - CuO- family has been assessed in a tiered approach. For the effects assessment, values agreed at the EU level have been used. For the exposure assessment, the EU fish farm scenario was used as a first tier. A second tier assessment with special regard to Norwegian fish farms has been conducted based on the Norwegian fish farm scenario document. This represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway.

In the tier 1 calculations, PECdissolved/PNECwater ratios based on PEC values calculated with the EU fish farm scenario were slightly above the trigger value for the Brynsløkken AS - CuO **-** family products. The PEC/PNEC ratios based on PEC values calculated with the Norwegian fish farm scenario, were found to be ≤ 1 indicating acceptable environmental risk.

In low-fouling conditions such as in the Baltic Sea, the products in Meta SPC 3 show acceptable risk to the environment. In order to avoid more use of copper in the Baltic Sea than what is necessary, and to limit release of copper to the environment, the products in Meta SPC 1, 2, and 4 should not be applied to nets meant for use in the Baltic Sea.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### 2.1.1.1 Identifier of the product / product family

| Identifier | **Trade Name** | **Country (if relevant)** |
| --- | --- | --- |
| Meta SPC 1 | Notorius A12 (Red/Black; Conc.)  Alpha Net Gard (Red/Black; Conc.) | Norway  Finland  Greece |
| Meta SPC 2 | Notorius A (Yellow/Black; Conc.)  Notorius A15 (Red/Black; Conc.) | Norway  Finland  Greece |
| Meta SPC 3 | Notorius A12  (Red/Black; RTU)  Alpha Net Gard (Red/Black; RTU) | Norway  Finland  Greece |
| Meta SPC 4 | Notorius A (Yellow/Black; RTU)  Notorius A15  (Red/Black; RTU) | Norway  Finland  Greece |

#### 2.1.1.2 Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Brynsløkken AS |
| **Address** | Delitoppen 3, 1540 Vestby, Norway |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Brynsløkken AS |
| **Address of manufacturer** | Delitoppen 3, 1540 Vestby, Norway |
| **Location of manufacturing sites** | Same as above |

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

|  |  |
| --- | --- |
| **Active substance** | Dicopper oxide |
| **Name of manufacturer** | NORDOX AS |
| **Address of manufacturer** | Østensjøveien 13 N-0661 Oslo Norway |
| **Location of manufacturing sites** | Same as above |

|  |  |
| --- | --- |
| **Active substance** | Dicopper oxide |
| **Name of manufacturer** | American Chemet Corporation |
| **Address of manufacturer** | 145 Highway 282, 59635 East Helena MT, The United States |
| **Location of manufacturing sites** | Same as above |

### Product (family) composition and formulation

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes

No

#### 2.1.2.1 Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Cuprous oxide, dicopper oxide |
| **IUPAC or EC name** | Copper (I) oxide |
| **EC number** | 215-270-7 |
| **CAS number** | 1317-39-1 |
| **Index number in Annex VI of CLP** | 029-002-00-X |
| **Minimum purity / content** | 942g/kg as cuprous oxide  837g/kg as copper (I) |
| **Structural formula** |  |

#### 2.1.2.2 Candidate(s) for substitution

Dicopper oxide is not a candidate for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Dicopper Oxide | Copper (I) oxide | Active substance | 1317-39-1 | 215-270-7 | 12.00 | 27.64 |
| Co-formulants |  | Non-active substance\* |  |  |  |  |

\*the full composition of the product family is provided in the confidential annex.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Overview table of the concentration of active substance and formulation types in the BPF** | | | | |
| **Meta-SPC number** | **1** | **2** | **3** | **4** |
| **Product name(s)** | Notorius A12 (Red/Black; Conc.)  Alpha Net Gard (Red/Black; Conc.) | Notorius A (Yellow/Black; Conc.)  Notorius A15 (Red/Black; Conc.) | Notorius A12 (Red/Black; RTU)  Alpha Net Gard (Red/Black) RTU | Notorius A (Yellow/Black; RTU)  Notorius A15 (Red/Black; RTU) | |
| **Dicopper oxide**  **Content (% w/w)** | 18.01-21.67 | 24.36-27.64 | 12.00-12.04 | 14.94-19.90 |
| **In-use concentration (Cu2O, % w/w)** | 12.29-12.35 | 15.12-20.00 |  |  |
| **Formulation type** | Suspension concentrate to be diluted with water (by volume) | Suspension concentrate to be diluted with water (by volume) | Suspension concentrate for direct application | Suspension concentrate for direct application |

#### 2.1.2.4 Information on technical equivalence

Nordox As is an approved active substance supplier in accordance with Article 95 of the Biocidal Products Regulation (BPR) and a participant in the Review Programme.

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

There are no substances of concern present in the products.

#### 2.1.2.6 Type of formulation

|  |
| --- |
| SD - Suspension concentrate for direct application  SC - Suspension concentrate (= flowable concentrate) |

### Hazard and precautionary statements

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

**Meta SPC 1**

Notorius A12 (Red; Conc.),Notorius A12 (Black; Conc.), Alpha Net Gard (Red; Conc.),

Alpha Net Gard (Black; Conc.)

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
| **Labelling** | | |
| Hazard Pictogram | pollut1 |  |
| GHS09 | GHS05 |
| Signal words | Danger | |
| Hazard statements | H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P273: Avoid release to the environment.  P280: Wear eye or face protection  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor.  P391: Collect spillage.  P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. | |
| Note |  | |

**Meta SPC 2**

Notorius A (Yellow; Conc.), Notorius A (Black; Conc.), Notorius A15 (Red; Conc.) and Notorius A15 (Black; Conc.)

| **Classification** | | | |
| --- | --- | --- | --- |
| Hazard category | Acute Tox. 4  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H302: Harmful if swallowed  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | | |
| **Labelling** | | | |
| Hazard Pictogram | pollut1 |  |  |
| GHS09 | GHS07 | GHS05 |
| Signal words | Danger | | |
| Hazard statements | H302: Harmful if swallowed  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | | |
| Precautionary statements | P264 Wash hands thoroughly after handling.  P273: Avoid release to the environment.  P280:Wear eye or face protection.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor.  P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell  P 330: Rinse mouth  P391: Collect spillage  P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation | | |
| Note |  | | |

**Meta SPC 3:**

Notorius A12 (Red; RTU), Notorius A12 (Black; RTU),

Alpha Net Gard (Red; RTU), Alpha Net Gard (Black; RTU)

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
| **Labelling** | | |
| Hazard Pictogram | pollut1 |  |
| GHS09 | GHS05 |
| Signal words | Danger | |
| Hazard statements | H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P273: Avoid release to the environment.  P280: Wear eye or face protection  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor.  P391: Collect spillage.  P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. | |
| Note |  | |

**Meta SPC 4:**

Notorius A (Yellow; RTU), Notorius A (Black; RTU), Notorius A15 (Red; RTU), Notorius A15 (Black; RTU)

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
| **Labelling** | | |
| Hazard Pictogram | pollut1 |  |
| GHS09 | GHS05 |
| Signal words | Danger | |
| Hazard statements | H318: Causes serious eye damag.  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P273: Avoid release to the environment.  P280: Wear eye or face protection  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor.  P391: Collect spillage.  P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. | |
| Note |  | |

### Authorised use(s)

#### 2.1.4.1 Use description

Table 1: Use PT 21 – Antifouling (for Meta SPC 1&2: Concentrates).

|  |  |
| --- | --- |
| **Product Type** | PT 21 |
| **Where relevant, an exact description of the authorised use** | The products are intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | Several species-all stages-algae  Several species-all stages-slimes  Several species-all stages-animals / other fouling organisms |
| **Field of use** | PT 21 – Antifouling products  The products are used in the control of fouling organisms in marine environment. |
| **Application method(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Approximately 0.9 liters / kg net (in-use concentration)- The products are all concentrates and are to be diluted with water.  Instructions for dilution:  Notorius A (Yellow/Black; Conc.): Add 500 L of Water to 1000 L of concentrate for the preparation of 1500 L of ready-to-use product.  Notorius A12 (Red/Black; Conc.): Add 1000 L of Water to 1000 L of concentrate for the preparation of 2000 L of ready-to-use product.  Notorius A15 (Red/Black; Conc.): Add 800 L of Water to 1000 L of concentrate for the preparation of 1800 L of ready-to-use product.  Alpha Net Gard (Red/Black; Conc.): Add 600 L of Water to 1000 L of concentrate for the preparation of 1600 L of ready-to-use product.  1 treatment per net. |
| **Category(ies) of users** | Industrial use |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

Table 2. Use PT 21 – Antifouling (for Meta SPC 3&4: RTU Products).

|  |  |
| --- | --- |
| **Product Type** | PT 21 |
| **Where relevant, an exact description of the authorised use** | The products are are intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | Several species-all stages-Algae  Several species-all stages-slimes  Several species-all stages-animals / other fouling organisms |
| **Field of use** | PT 21 – Antifouling products  The products are used in the control of fouling organisms in marine environment. |
| **Application method(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Approximately 0.9 liters / kg net - The products are all RTU (ready to use - not to be diluted).  1 treatment per net. |
| **Category(ies) of users** | Industrial use |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

#### 2.1.4.2 Use-specific instructions for use

|  |
| --- |
| See section 2.1.5.1. |

#### 2.1.4.3 Use-specific risk mitigation measures

|  |
| --- |
| Meta SPC 1 and 3:   * Wear suitable gloves; i.e. nitrile rubber, butyl-rubber, neoprene, polyethylene or PVC (EN 374). * A protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information). * Chemical goggles or face shield (EN 166). * Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.   Meta SPC 2 and 4   * Wear suitable gloves; i.e. nitrile rubber, butyl-rubber, neoprene, polyethylene or PVC (EN 374). * A double coverall, a chemically resistant (at least 3, EN 14605) coverall which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information) shall be worn with at least a long-sleeve, long-leg cotton coverall underneath. * Chemical goggles or face shield (EN 166). * Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. |

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

|  |
| --- |
| See section 2.1.5.3. |

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

|  |
| --- |
| See section 2.1.5.4 |

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

|  |
| --- |
| See section 2.1.5.5. |

### General directions for use

#### 2.1.5.1 Instructions for use

|  |
| --- |
| Description of dipping process (RTU Products):  Using a dipping chamber:  Empty the product from the IBC container into the dipping chamber (if needed rinse the IBC by use of approx 20L of water and empty the rinsing solution into the chamber as well). To assure homogenisation of the preparation stirring is required. Make sure that the nets are clean and dry before starting the treatment. The nets should stay immersed in the antifouling preparation for at least 15 minutes. Subsequent the nets are dried at a temperature below 60°C.  Using an impregnator:  For net impregnation the net must be placed into a bag (the impregnator). Air should be removed from the bag through a valve to create vacuum inside the bag. The bag must be held in place and the impregnator lid lowered on top of the impregnator and sealed so that no air enters the process. The IBC container must be connected to the pump and the antifouling product pumped into the bag to immerse the net in the product. The vacuum should then be re-established within the bag and allowed to stand for a few minutes. This process can be repeated up to 5 times. Any remaining product must be transferred from the bag back to the IBC for use later. The nets are then removed from the bag and dried at a temperature below 60°C.  Net dipping requires the use of lifting machinery (crane-assisted dipping is assumed to be the standard method for professional dipping of nets).  Description of dipping process (Concentrates):  Using a dipping chamber:  Empty the product from the IBC container into the dipping chamber and dilute with water as instructed (reference is made to the information concerning dilution listed under "Instructions for dilution").  Use the prescribed volume of water for dilution to rinse the IBC and empty the rinsing solution into the chamber as well. The concentrated antifouling paint and the correct load of water is mixed together in a dipping chamber with the use of a mobile dispersion mixer. The concentrated antifouling paint is mixed in a tank before adding the final mixture in the dipping chamber.  Density and viscosity must be measured to ensure that the product is homogeneous prior to treatment. Please follow the manufacturer's directions for how to measure density and viscosity.  Make sure that the nets are clean and dry before starting the treatment. The nets should stay immersed in the antifouling preparation for at least 15 minutes. Subsequent the nets are dried at a temperature below 60°C.  Using an impregnator:  For net impregnation the net must be placed into a bag (the impregnator). Air should be removed from the bag through a valve to create vacuum inside the bag. The bag must be held in place and the impregnator lid lowered on top of the impregnator and sealed so that no air enters the process. The IBC container must be connected to the pump and the antifouling product pumped into the bag to immerse the net in the product. The vacuum should then be re-established within the bag and allowed to stand for a few minutes. This process can be repeated up to 5 times. Any remaining product must be transferred from the bag back to the IBC for use later. The nets are then removed from the bag and dried at a temperature below 60°C.  Net dipping requires the use of lifting machinery (crane-assisted dipping is assumed to be the standard method for professional dipping of nets). |

#### 2.1.5.2 Risk mitigation measures

|  |
| --- |
| Avoid release to the environment  Application, maintenance and repair activities shall be conducted within a contained area to prevent losses and minimise emissions to the environment. This means that activities must take place on impermeable hard standing with bunding or on soil covered with an impermeable material. Any losses or waste containing antifouling biocides shall be collected for reuse or disposal.  High pressure water jet cleaning on site should not be performed. |

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

|  |
| --- |
| First aid measures  Description of first aid measures:  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.  IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.  IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance  Avoid release to the environment.  Emergency measures for the environment:  Application solutions must be collected and disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.   * Methods and material for containment and cleaning up: Use absorbent material and dispose of materials or solid residues at an authorized site. |

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

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| Product/Packaging: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.  Hazardous waste due to toxicity. Avoid release to the environment. Waste disposal number of unused product: UN number 3082/European waste code EWC 02 01 99. |

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

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| The product must be stored at temperatures above 5oC and below 30 oC.  The products are stable, when stored in the original packaging at ambient temperatures, for up to 12 months, provided that proper measures are taken to ensure that the product is homogeneous prior to application  Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. |

### Other information

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| The label of the biocidal product must provide advise on how to perform the deployment of the treated nets. As a minimum, the label must specify that suitable chemical protective gloves and eye protection (goggles) should be used during net deployment. Other PPE should be specified according to the authorisation holder's recommendations, including those needed based on the performed risk assessment.  Meta SPC 3:  The label of the biocidal product must provide advise on the deployment of treated nets in areas with low fouling, such as the Baltic sea,, i.e., that the nets be deployed for ca. 2 years before they are taken up to be cleaned and reimpregnated  Meta SPC 1, 2, 4:  Do not apply the products to nets meant for use in the Baltic Sea. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| IBC | 1000 L | HDPE | Standard closure / HDPE | Industrial | Yes |

### Documentation

#### 2.1.8.1 Data submitted in relation to product application

Reference is made to the Reference List in Annex 3.1.

#### 2.1.8.2 Access to documentation

An LoA to Annex II data for Dicopper oxide has been granted to Brynsløkken AS by the two suppliers of the a.s. (i.e. Nordox AS and American Chemet Corporation).

## Assessment of the biocidal product (family)

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

Table 2. Intended use - antifouling

|  |  |
| --- | --- |
| **Product Type** | 21 |
| **Where relevant, an exact description of the authorised use** | The products intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | Several species-all stages-Algae  Several species-all stages-slimes  Several species-all stages-animals / other fouling organisms |
| **Field of use** | PT 21 – Antifouling products  The products are used in the control of fouling organisms in marine environment. |
| **Application method(s)** | Net dipping: The product is pumped to a dipping tank where the net is lowered into the product using remotely operated cranes.  Vacuum treatment: The product is pumped into a sealed vacuum bag containing the net. Vacuum cycles are applied in order to evenly distribute the product into the net. |
| **Application rate(s) and frequency** | Approximately 0.9 L / kg net - The products are either RTU (ready to use - not to be diluted) or concentrates that are to be diluted with water.  Instructions for dilution:  Notorius A (Yellow/Black; Conc.): Add 500 L of Water to 1000 L of concentrate for the preparation of 1500 L of ready-to-use product.  Notorius A12 (Red/Black; Conc.): Add 1000 L of Water to 1000 L of concentrate for the preparation of 2000 L of ready-to-use product.  Notorius A15 (Red/Black; Conc.): Add 800 L of Water to 1000 L of concentrate for the preparation of 1800 L of ready-to-use product.  Alpha Net Gard (Red/Black; Conc.): Add 600 L of Water to 1000 L of concentrate for the preparation of 1600 L of ready-to-use product.  1 treatment per net. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

### Physical, chemical and technical properties

Validated data concerning physicochemical and technical properties of the products contained in the BPR family is available. The Danish Technological Institute (TI) was assigned to conduct new physicochemical and storage stability tests and the results for the two tested antifouling products is now available. For the physicochemical testing a concentrate and a RTU product were selected as representative products for the family. The concentrate and the RTU were selected for testing as they have the highest and lowest concentration of the active substances in the BPR family respectively. In this manner they are considered to cover the full range of the products contained in the family. The two selected products are: Notorius A (Yellow; Conc.) and Notorius A12 (Red; RTU).

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | water-based wax emulsions | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b;  Johannesen, S.A., 2019a  Johannesen, S.A., 2019b |
| Colour at 20 °C and 101.3 kPa | Visual inspection | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | Notorius A (Yellow; Conc.): Yellowish brown  Notorius A12 (Red, RTU): reddish brown | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b;  Johannesen, S.A., 2019a  Johannesen, S.A., 2019b |
| Odour at 20 °C and 101.3 kPa | Olfactometry | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | Odourless | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b;  Johannesen, S.A., 2019a  Johannesen, S.A., 2019b |
| Acidity / alkalinity | CIPAC MT 75.3 | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | The pH of the tested products were measured before and after 2 weeks of the accelrated storage stability test and 1 year of long term storage at ambient temperature.  **Notorius A (Yellow; Conc.):**  pH = 9.4  Accelrated storage: pH = 9.0.  Long term storage: pH = 9.3  **Notorius A12 (Red; RTU):**  pH = 9.6  Accelrated storage: pH = 9.2  Long term storage: pH = 9.2 | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b  Johannesen, S.A., 2019a  Johannesen, S.A., 2019b |
| Relative density | OECD 109 | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | The relative density was measured for the tested products.  **Notorius A (Yellow; Conc.):**  the average value is 1.31.  **Notorius A12 (Red; RTU):**  the average value is close to 1.13. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b; |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Stored for 2 weeks at 54 °C. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | The results indicate that the products are stable for the claimed shelf life of one year.  The packaging of the test material for both products was HDPE containers of 1 litre.  pH, pourability, suspensibility and spontaneity of dispersion were measured after storage, and the results are reported under each relevant endpoint.  **Notorius A (Yellow; Conc.):**  The change in the total content of the Cu2O in the test material was -4.9 % w/w and is below the accepted limit of 10 %.  An increase in viscosity was observed for the stored test material.  **Notorius A12 (Red; RTU):**  The change in the total content of the Cu2O in the test material was -9.4 % w/w and is below the accepted limit of 10 %.  The stored test material was seperated into two layers, a thick paste had setteled on the bottom of the cotainer during storage and minor lumps were observed. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b |
| Storage stability test – **long term storage at ambient temperature** | Guideline for specifying and managing shelf life and expiry date of crop  protection products. CropLife, Technical Monograph N°17, 2rd edition. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | The results of the succeeding one year storage stability tests confirm that the products of the Brynsløkken BPR-family are stable for the claimed shelf life of one year.  The packaging of the test material for both products was HDPE containers of 1 litre.  pH, pourability, suspensibility and spontaneity of dispersion were measured after storage, and the results are reported under each relevant endpoint.  **Notorius A (Yellow; Conc.):**  The change in the total content of the Cu2O in the test material was +4.9 % w/w and is below the accepted limit of 10 %.  No change in apperence was observed.  **Notorius A12 (Red, RTU):**  The change in the total content of the Cu2O in the test material was -0.8 % w/w and is below the accepted limit of 10 %.  The stored test material was seperated into two layers before homogenistation, a paste had setteled on the bottom of the container during storage. | Johannesen, S.A., 2019a; Johannesen, S.A., 2019b |
| Storage stability test – **low temperature stability test for liquids** | Not applicable |  | Justification for data waiving:  Test is not needed. Based on label instruction: To be stored above 5oC. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Not applicable |  | Justification for data waiving:  Dicopper oxide is not susceptible to degradation by UV light. Furthermore the thickness of the HDPE in the IBC container limits the amount of UV radiation reaching the contained product to a large extent. Furthermore, since the products are pigment dense the light that comes through the IBC container will not affect the product’s shelf life. Accordingly the other constituents of the antifouling product are only exposed to UV light in limited extent. Thereby the characteristics of the product is not expected to be affected.  However, as the storage stability studies were conducted in the dark, the statement "protect from sunlight" should be included on the label as a precautionary measure. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC MT 46.3 | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | **Concerning humidity:**  As the products are all water-based wax emulsions (and as they are stored in sealed IBC’s) air humidity is not expected to affect the technical characteristics of the products.  **Concerning temperature:**  For Notorius A (Yellow; Conc.) an increase in viscosity of the test material was observed.  For Notorius A12 (Red; RTU) tested in the accelerated storage stability test performed at 54° the high temperature seemed to affect the physical state of the product (the test material separated into two layers and an increase in the viscosity and minor lumps in the test material was observed.  The effects are not expected to occur when the products are stored at lower/ ambient temperature. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 / The effects on the selected packaging after storage were evaluated in accordance with Guidance on the BPR[[1]](#footnote-2), 3.4.2 Page 69. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | Each HDPE container of 1 litre filled with test material was weighed before and after storage prior to breaking the seal.  For Notorius A (Yellow; Conc.) and Notorius A12 (Red; RTU) no major weight change was observed for any of the products tested. Besides  discolouring of the interior of the container after 1 year of storage, no effects were obserevd for on the packaging selected for the storage stability studies. The discolouring is most likely caused by trace amount of test material which may optically appear different from larger amounts of the test material. When nothing else is stated in the reports the material of the container is not affected besides from discoloration. This means the material of the container appears intact. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b  Johannesen, S.A., 2019a;  Johannesen, S.A., 2019b |
| Wettability | Not relevant for SC/SD formulations |  |  |  |
| Suspensibility, spontaneity and dispersion stability | **Suspensibility**: CIPAC MT 161 (CSA 102, determining total Cu).  **Spontaneity of dispersion:** CIPAC MT 160  (CSA 102, determining total Cu) | Notorius A (Yellow; Conc.) | Only relevant for the concentrates (i.e. SC formulations).  **Suspensibility:**  The suspensibility of the active substance contained in the concentrate tested were in the accepted range of 60-110 %  Notorius A (Yellow; Conc.):  Accelerated storage:  66 % v/v: Cu: 99.3 %.  1 year storage:  66 % v/v: Cu: 99.4-100.9 %.  **Spontaneity of dispersion:**  The content of the active substances in the suspension are within the accepted range of 60 % to 105 %  Notorius A (Yellow; Conc.):  Accelerated storage:  66 % v/v: Cu: 95.3-95.8 %.  1 year storage:  66 % v/v: Cu: 95.9-99.4 %. | Johannesen, S.A., 2018a; |
| Wet sieve analysis and dry sieve test | Not relevant for SC/SD formulations |  |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability | Not relevant for SC/SD formulations |  |  |  |
| Disintegration time | Not relevant for SC/SD formulations |  |  |  |
| Particle size distribution, content of dust/fines, attrition, friability | Not relevant for SC/SD formulations |  |  |  |
| Persistent foaming | CIPAC MT 47.2 | Notorius A (Yellow; Conc.) | Only relevant for the concentrates (i.e. SC formulations).  The results show that the level of foam generated from the suspension of the test material does not exceed 60 ml after 1 minute.  Notorius A (Yellow; Conc.): 66 % v/v: Amount of foam after 1 min: 0 ml | Johannesen, S.A., 2018a |
| Pourability (rinsability) | CIPAC MT 148  The container was inversed for 70 times when determining the rinsed residue. This was a deviation from the normal prodecure of 10 times. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | **For the concentrate** the residue measured for the test material does exceed 5 %, and the rinsed residue does exceed 0.25 % (only for the stored product).  Notorius A (Yellow; Conc.): Accelerated storage:  Residue: 8.4-8.5 %\*;  Rinsed residue: 0.15-0.40 %\*.  1 year storage:  Residue: 8.4-11.8 %\*;  Rinsed residue: 0.15-0.27 %.\*  **For the RTU** The residue measured for the test material does not exceed 5 %, and the rinsed residue does not exceed 0.25 % (except for Notorius A12 (Red; RTU) stored for 1 year).  Notorius A12 (Red; RTU): Accelerated storage:  Residue: 1.1-1.8 %;  Rinsed residue: 0.17-0.20 %.  1 year storage:  Residue: 1.1-2.0 %;  Rinsed residue: 0.17-0.30 %.\*  \*See comments in the conclusion section. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b  Johannesen, S.A., 2019a;  Johannesen, S.A., 2019b |
| Burning rate — smoke generators | Not relevant |  |  |  |
| Burning completeness — smoke generators | Not relevant |  |  |  |
| Composition of smoke — smoke generators | Not relevant |  |  |  |
| Spraying pattern — aerosols | Not relevant |  |  |  |
| Physical compatibility | Not relevant – the products are not intended for use in combination with other products |  |  |  |
| Chemical compatibility | Not relevant – the products are not intended for use in combination with other products |  |  |  |
| Degree of dissolution and dilution stability | Not relevant for SC/SD formulations |  |  |  |
| Surface tension | EC method A.5 and OECD 115  The determination of the surface tension was performed in accordance with EC method A.5 and OECD 115. The test was conducted at the highest in-use concentration at 25°C using tensiometer K 20 from Krüss. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | The uncorrected surface tension is measured to be in the range of 38.3-45.3 mN/m (and  corrected by Harkin and Jordan in the range of 35.6-42.5 mN/m).  Notorius A (Yellow; Conc.):  Uncorrected: 45.3;  Corrected by Harkin and Jordan: 42.5.  Notorius A12 (Red; RTU):  Uncorrected: 38.3;  Corrected by Harkin and Jordan: 35.6. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b |
| Viscosity | OECD 114 / CIPAC MT 192  The determination of the viscosity of the test material was performed in accordance with CIPAC MT 192. The test was performed at five different shear rates, at 20°C and 40°C, respectively. Viscotester Rheolab QC from Anton Paar with measuring system DG42 was used. | Notorius A (Yellow; Conc.),  Notorius A12 (Red; RTU) | Notorius A (Yellow; Conc.):  20° C: 227.1-673.9 mPa\*s;  40° C: 214.9-676.3 mPa\*s.  Notorius A12 (Red; RTU):  20° C: 30.78-78.21 mPa\*s;  40° C: 27.88-73.83 mPa\*s. | Johannesen, S.A., 2018a;  Johannesen, S.A., 2018b |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The Brynsløkken antifouling products are viscous water based wax emulsions. The products are supplied as either suspension concentrates (SC formulations) or suspension concentrates for direct application (SC formulations; i.e. RTU products). The color of the products may be red, yellow or black. The pH is in the range of 9.0-9.6 and the relative density is approximately 1.13 g/ml for the RTU products and 1.31 g/ml for the concentrates. The surface tension is in the range of 35.6-42.5 mN/m (corrected by Harkin and Jordan), does not produce foam in the application process and are not able to burn.  After 12 months of storage at ambient temperatures, Notorius A12 separated into two layers and a paste had settled on the bottom of the container. It was possible to homogenise the sample by shaking and the settled material can be re-dispersed using a spatula. Hence, stirring by a mechanical stirrer will be necessary to ensure re-homogenisation of the product. The results of the storage stability tests show an increase in the total copper content after 12 months. The results may seem erroneous and is likely caused by difficulties when handling the samples. Since the products are wax emulsions, the solution can be inhomogeneous if it is not stirred properly, as observed in the storage stability test. Stirring prior to use is therefore a part of the user instructions, and it is suggested to allow a shelf life of 12 months for both the concentrate and RTU. The degradation of the active substances is less than 10 % after 12 months of storage. The claimed shelf life of one year is supported when stored at temperatures above 5oC and below 30 oC by the results of both accelerated and long term storage stability studies conducted on two of the products (one RTU and one concentrate) in the Brynsløkken BPR-family of antifouling products. As the storage stability studies was conducted in the dark, the label should state "protect against sunlight" as a precautionary measure.  As the pourability/rinsability is outside the requirements in the guidance document, actions must be taken to ensure that the dilution of the product is correct, and that the empty product containers are correctly disposed. The thorough rinsing described in the " Use-specific instructions for use" should minimize the residues in the container. As the products are supplied in IBC’s (with a much larger ratio of mass of product compared to the surface area of the container, when compared to a 1 litre HDPE bottle as used in the test) and as the IBC’s containing concentrates are to be flushed by the prescribed volume of water for dilution the unacceptable measured residue levels are not considered to be problematic. Furthermore, the measurement of viscosity of the concentrates after dilution will ensure that the proper dilution is achieved. As product residues in the packaging (containers) cannot be completely avoided, the empty containers must be disposed of in accordance with local regulations. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | UN Recommendations on the Transport of Dangerous Goods, 7th Ed., 2019, Appendix 6 DSC Screening determination for heat of decomposition. | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | Both products are not candidates for classification as UN Class 1 explosive substances as, in both cases, the total heat of decomposition was < 500 J/g. | Bee, T., 2022; |
| Flammable gases | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Flammable aerosols | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Oxidising gases | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Gases under pressure | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Flammable liquids | EC method A.9 (Pensky-Martens closed cup) | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | The flash point could not be determined as the products boiled prior to flashing.  Test temperature ranges employed:  Notorius A (Black; Conc.) = 20-72 ºC  Notorius A (Black; RTU) = 20-100 ºC | Bee, T., 2022 |
| Flammable solids | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Self-reactive substances and mixtures | UN Recommendations on the Transport of Dangerous Goods, 7th Ed., 2019, Appendix 6  DSC Screening determination for heat of decomposition. | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | The total heat of decomposition was determined to be 44.88 J/g for the concentrate and 102.58 J/gfor the RTU.  Both products are not candidates for classification as a UN Class 4, Division 4.1 self-reactive substances as, in both cases, the total heat of decomposition was < 300 J/g | Bee, T., 2022; |
| Pyrophoric liquids | Not relevant/Not applicable |  | Justification for data waiving:  Experience shows that the products are not pyrophoric liquids. |  |
| Pyrophoric solids | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Self-heating substances and mixtures | EC Method A.15 | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | The auto-ignition temperatures of Notorius A (Black; Conc.) and Notorius A (Black; RTU) was determined to be 549 ºC and >600 ºC respectively  Also, the products are all water-based wax emulsions (liquids)  which are not adsorbed on a large surface (e.g. on powder particles). | Bee, T., 2022; |
| Substances and mixtures which in contact with water emit flammable gases | Not relevant/Not applicable |  | Justification for data waiving:  The products are all water-based wax emulsions. No substances contained reacts with water and subsequent emits flammable gasses |  |
| Oxidising liquids | UN Test O.2 | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | A 1:1 mixture of Notorius A (Black; Conc.) & cellulose and 1:1 mixture of Notorius A (Black; RTU) & cellulose were observed to have a mean pressure rise time greater than that of a 1:1 mixture of 65 % nitric acid and cellulose. Both products are therefore exempt from classification as an oxidising liquids of UN Class 5, Division 5.1.J | Bee, T., 2022; |
| Oxidising solids | Not relevant/Not applicable |  | Not applicable to liquids. |  |
| Organic peroxides | Not relevant/Not applicable |  | Justification for data waiving:  The products do not contain any organic peroxides |  |
| Corrosive to metals | UN Test C.1 | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | In both cases, the percentage mass losses on steel and aluminium were found to be < 13.5 % over 7 days and the maximum pit depth on the aluminium / steel coupons was < 120 μm. Both products are therefore exempt from classification as corrosive substances of UN Class 8, Packing Group III (according to the UN Transport of Dangerous Goods Recommendations) | Bee, T., 2022; |
| Auto-ignition temperatures of products (liquids and gases) | EC method A.15 | Notorius A (Black; Conc.)  Notorius A (Black; RTU) | The auto-ignition temperature of Notorius A (Black; Conc.) and Notorius A (Black; RTU) was determined to be 549 ºC and >600 ºC respectively | Bee, T., 2022; |
| Relative self-ignition temperature for solids | Not relevant/Not applicable |  | Justification for data waiving:  Not applicable to liquids. |  |
| Dust explosion hazard | Not relevant/Not applicable |  | Justification for data waiving:  Not applicable to liquids. |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The Brynsløkken antifouling products are viscous water based wax emulsions. The products are supplied as either suspension concentrates (SC formulations) or suspension concentrates for direct application (SC formulations; i.e. RTU products). The products are non-flammable, not oxidising, not self-reactive or pyrophoric substances and are not corrosive to metals or present any other physical hazards. |

### Methods for detection and identification

Validated data concerning physiochemical- and technical properties of the products contained in the BPR-family are available. Brynsløkken AS assigned the Danish Technological Institute (TI) to conduct new physiochemical- and storage stability tests. This also includes method description and the corresponding method validation report for the analytical method CSA 102 used to determine the total content of copper in two products tested.

* **CSA 102** is used for the determination of the total content of copper (Cu) in Notorius A and Notorius A12 and aqueous dilutions of Notorius A. Quantification by AAS using external standards.

Concerning the analytical methods for measurement of dicopper oxide (i.e. copper) in all other matrices (i.e. for monitoring, in soil, air, water, animal and human body fluids and tissues as well as for monitoring of copper and residues in food and feeding stuff reference is made to the analytical methods listed in the EU Assessment Report for dicopper oxide.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | |  | |  | |
| Dicopper oxide (CAS No. 1317-39-1) | Analytical method CSA 102 Determination of the total content of copper (Cu) in Notorius A (24.1 % w/w) and Notorius A12 (10.5 % w/w) and aqueous dilutions of Notorius A (16.8 % w/w, 66 % dilution).  Quantification by AAS using external standards. | | 86.8-87.5 %  n = 3-5 | | Linear from 0.5 to 4 μg/ml Cu [[2]](#footnote-3);  5 calibration standards  r: 0.9995; slop: 0.0849; intercept: 0.0021 | | Any interference observed between the measured copper and formulation chemicals or possible contamination of glassware used is less than 0.4% at the specified wavelengths. Therefore, the analytical method CSA 102 is considered sufficiently specific for determination of the total content of copper in the test materials Notorius A, Notorius A12 and aqueous dilutions solutions of Notorius A (66% v/v). | | Notorius A:  99-101  Notorius A12: 101-102  Aqueous dilutions of Notorius A: 96.4-98.2 | | Notorius A: 100  Notorius A12: 102  Aqueous dilutions of Notorius A: 97.1 | | | Notorius A: RSD = 0.47  RSDr = 1.66.  RSD<RSDr  Notorius A12:  RSD =  1.26  RSDr = 1.86.  RSD<RSDr | | n/a | | Johannesen, S.A., 2018e;  Johannesen, S.A., 2018h |

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| **Conclusion on the methods for detection and identification of the product** |
| Concerning the analysis of the products as such (i.e. the methods used in both the accelerated storage stability test and for the long term test for determination of the content of dicopper oxide validated analytical methods are available.  The analytical method CSA 102 has been validated and includes the parameters specificity, linearity, recovery and precision. The validation was performed in accordance with Guidance on the Biocidal Products Regulation, vol. I, Part A, version 2.0, 2018 and SANCO/3030/99.  The results obtained of the validation of the analytical method CSA 102 is satisfactory as the requirements in the Guidance on the Biocidal Products Regulation, vol. I, Part A, version 2.0, 2018, have been met. Therefore, the analytical method can be used for the determination of copper in Notorius A and all other members of the BPR family of antifouling products. The analytical method is not specific for dicopper oxide as the form of the copper species added to the formulation cannot be identified. However, based on the product composition, the only source of copper in the product is dicopper oxide and the interference of the co-formulants has been addressed. Hence, the method can be considered as fit for the purpose.  Concerning the analytical methods for measurement of dicopper oxide (i.e. copper) in all other matrices (i.e. for monitoring, in soil, air, water, animal and human body fluids and tissues as well as for monitoring of copper and residues in food and feeding stuff reference is made to the analytical methods listed in the EU Assessment Report for Dicopper Oxide. |

### Efficacy against target organisms

#### 2.2.5.1 Function and field of use

The antifouling products are all water-based wax emulsions used to treat nets used for offshore fish farming by dipping. The active substance contained in the products is dicopper oxide. The purpose of coating the fishing nets with the products is to prevent/slow the growth of fouling organisms (i.e. slimes, algae and animals). As the nets are used for offshore fish farming a lower level of fouling on the nets results in a better/faster exchange of the water volume contained in the nets giving a better oxygen supply to the fish which again results in better conditions for the fish, higher growth rates (and better use of the feedstuff administered) and ultimately a higher output and profit for the fish farmer.

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

Organisms to be controlled:

Slimes (several species, all stages), Algae (several species, all stages) and other fouling organisms (several species, all stages).

Objects to be protected:

Nets used for offshore fish farming.

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

Cell death or inactivation, settlement inhibition or retardation. Target organisms are not expected to experience any unacceptable suffering. Reference is made to section 2.2.5.4 below.

#### 2.2.5.4 Mode of action, including time delay

As stated in section 2.2 in the EU Assessment report for Dicopper Oxide in the subsection “Mode of action”: “When copper from metallic copper, copper thiocyanate or cuprous oxide leaches into marine water in presence of oxygen, the predominant form of the copper is the active substance, the cupric ion, Cu2+. The cupric ion acts to retard settlement of the microscopic larvae of fouling organisms within a microlayer of water at the paint surface via two mechanisms:

(1) the ion retards organism's vital processes by inactivating enzymes;

(2) the ion acts more directly by precipitating cytoplasmic proteins as metallic

Proteinates”.

#### 2.2.5.5 Efficacy data

For a biocidal product family it is a prerequisite for authorisation that the efficacy of the family member with the lowest content of active substance has been proven by conducted efficacy trails. Using this approach all other members of the family are covered as well and are deemed to be efficient. For biocidal product family Brynsløkken AS - CuO - family the product Notorius A 12 is the product with the lowest content of active substance. However, all products except Alpha Net Gard have been tested for efficacy. Testing of the product Alpha Net Gard was omitted as the composition is almost identical to the product Notorius A12. Only the RTU versions of the products are tested, however, they are deemed to be representative for the concentrates. In addition, the different colour variations are deemed to be identical in composition except from the content of colour.

The efficacy trials cover the seasonal fouling peaks, but do not cover inter-season variation since all tests were conducted in the same year. Also, it is expected that the waters of the North Sea and connected fjords, have higher levels of nutrients and thereby sustains a more extensive growth of fouling organisms when compared to warmer and less nutritious waters as for instance the Mediterranean Sea. By selecting worst case scenarios for the efficacy trials the products are deemed to be efficient in waters less prone to growth of fouling organisms in case of a positive result at the worst-case location(s).

The protection goal with the use of antifouling coats on aquaculture nets differ between areas in Europe. The main objective is, nevertheless, to ensure an adequate water flow through the nets which is essential for fish health and wellbeing. Fish farms typically have oxygen meters permanently installed in the cages to indicate when the oxygen level is starting to decline so that cleaning or a change of net can be performed.

In Norwegian waters, the main objective is to control the level of salmon lice (*Lepeophtheirus salmonis*) in the cages. Salmon lice are normally not harmful to the farmed fish but exerts a threat to wild sea trout and wild salmon fry. Acceptable levels of sea lice in a farm is therefore strictly regulated and controlled, and too high levels may result in the farmer being imposed a reduced operation volume, or even a production quarantine. The predominant strategy used today to control salmon lice is by using cleaner fish. It is believed to be essential that the level of biofouling on the nets is kept at a low level to ensure that the cleaner fish eat salmon lice and not fouling organisms on the nets.

To the knowlegde of the rMS, a fouling level of 60 - 80% normally can be tolerated in countries without salmon lice issues. A defined upper tolerable fouling level is not possible to determine, as the farmers normally initiate measures on the basis of in-situ oxygen measurements in the cages and not on observed fouling levels. In areas with salmon lice issues, a fouling level equal to a score rank of 3 (10 – 34% of the surface) can be tolerated before measures, such as cleaning, need to be taken. In this respect, the practice between individual farms and farming companies differ.

No agreed guidance document on efficacy of PT21 products for use on aquaculture nets exists today. In 2017, the NO CA commissioned the development of such a guidance document in order to provide the applicants with an equal framework to base their efficacy studies upon, as well as to establish a framework to base their evaluation on (Guidelines for efficacy testing of antifouling coatings for nets in field tests; Developed by SINTEF Ocean on behalf of the Norwegian Environment Agency. Hereafter referred to as "SINTEF" with refrence to Bloecher and Floerl, 2018). The goal is to get this proposed guidance document included as an annex to the existing ECHA guidance document on efficacy and thereby completing the chapter on PT 21 products. The proposed guidance document has currently been discussed among the members of the ECHA working group on efficacy, but no final agreement has been reached at this point.

The efficacy study presented below was not conducted according to the proposed guidance document, as the guidelines were published after the study had been planned. However, the proposed guidance document has been used for the evaluation in this product family authorisation. As no agreement on its applicability has been reached some flexibility and pragmatism has been used during the evaluation.

The efficacy trials were conducted in 2018 in the field at three actual sites used for offshore fish farming in Norway. The testing was performed by use of static raft testing which resembles real life conditions for aquaculture use. Test surfaces were pieces of net attached to a frame (size 30 cm) suspended from a platform with the possibility of free floating. The frames were submerged to a depth of five meters (and the frames/nets were placed horizontally). The tests were performed in replicates of three – for each product three samples of net were impregnated with antifouling product and fixed to the frames after drying. Untreated samples of net were also attached to the frames as well (i.e. the negative reference samples). In total three frames were placed at each fish farm. The frames were inspected approximately every 3-4 week. At each date of inspection, the frames were surfaced, and pictures were taken of each sample of net on the three frames at the respective location.

The rMS has analysed the submitted photo evidence from the efficacy studies by quantifying the total biofouling load in accordance with the principles outlined in the proposed guidance document (Analysis of type A according to the SINTEF document). Basically, the submitted pictures were assigned a nominal rank score, ranging from 0 (free of biofouling) to 5 (>80% of the surface covered with biofouling organisms) by comparing them to the reference images presented in the SINTEF document, where possible. The reference pictures and the corresponding rank descriptions can be found in SINTEF document.

The efficacy criterium applied by the rMS was decided based on discussions between SINTEF Ocean and The Norwegian Environment Agency. The coating is assessed to be efficacious if the biofouling load on a sample is approximately 40% lower than the untreated control, equal to a difference in two ranks.

It is important to notice in this respect, that even when a coating has been deemed as not sufficiently effective, it still can perform much better than the untreated control. It is also to the knowlegde of the rMS, that the biofouling is more easier removed from a treated net than from an untreated net if the net is cleaned or at incidences with heavy weather. An untreated net in a peak fouling period can become fully overgrown in only one week.

The protection goal of the farmer is thus to postpone or delay the need for measures, such as cleaning or changing the net and to ensure fish health.

The applicant has received information from its distributor in Finland that after the nets are treated with Notorius A and deployd in the sea, the nets stay in the sea for around 2 years before they are taken up to be cleaned and re-impregnatet.The nets are not cleaned in situ during the production of the fish, but are kept clean by the antifouling. Brynsløkken AS therefore recommend that for areas with low fouling conditions, such as the Baltic Sea, the nets are deployed at sea for ca. 2 years.

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Notorius A12; Notorius A15 and Notorius A | Fouling organisms (i.e. slimes, algae and animals). | Static raft testing | Locations: In the field at three fish farms located in Norway: Lingalaks AS in Fuksesund, Hardangerfjorden in Norway,  Lærøy Vest AS at Skaftå in Osterøy and Blom Ljøsøy in Øygarden.  Material and methods:  The frames were submerged to a depth of five meters (and the frames/nets were placed horizontally). The tests were performed in replicates of three – for each product three samples of net were impregnated with antifouling product and fixed to the frames after drying. Untreated samples of net were also attached to the frames as well (i.e. the negative reference samples). In total three frames were placed at each fish farm.  The samples were prepared by submerging the pieces of net in the respective antifouling products for 20 minutes, then left to dry at room temperature for 24 hours. The samples were weighed before and after treatment with the antifouling (i.e. before treatment and after drying).  Evaluation: the frames were inspected every 3-4 week and documented by taking pictures of each sample. | By comparing the photos for treated and untreated nets taken over the course of the fouling season it shows a significantly visible less fouling on the nets treated with the antifouling products compared to the untreated nets. It can also be observed a variation in growth of fouling between locations.  In general, tested antifouling product demonstrate sufficient performance when the difference in the biofouling ranking score between the treated and untreated net is 2 ranks or more.  Notorius A demonstrated a better performance than Notorius A 12 and Notorius A 15 at two of three locations.  At Øygarden, all tested products demonstrated a sufficient performance at approx. 1 month of deployment. Notorius A 12 and Notorius A 15 demonstrated a sufficient performance for approx. 3 months and Notorius A demonstrated sufficient performance for approx. 5 months at this location.  At Fyksesund all products demonstrated sufficient performance at approx. 2 months.  Notorius A 12 and Notorius A 15 demonstrated a sufficient performance for approx. 4 months and Notorius A demonstrated a sufficient performance for at least 5 months at this location.  At Skaftå all products demonstrated a sufficient at approx. 3 months, and all products demonstrated a sufficient performance for at least 5 months at this locaton. | Pedersen, R.B., 2018  IUCLID 6.7 |

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| **Conclusion on the efficacy of the product** |
| The efficacy trials were all concucted at three actual sites used for offshore fish farming in Norway where the products are claimed to be efficient and are considered to be prone to growth of fouling organims.  **Notorius A 12 (RTU/concentrate, black/red)**  **Alpha Net Gard (RTU/concentrate, black/red)**  **Notorius A 15 (RTU/concentrate, black/red)**  The rMs concludes that an efficacy for upto 4 months has been demonstrated for the products Notorius A 12 and Notorius A 15 for all variations of RTU/concentrate and colour (black/red). This also apply to the product Alpha Net Gard since it is almost identical to Notorius A 12. However, due to physical factors (e.g. bad weather, heavy currents) influencing the study, it is not possible to determine the exact efficacy past 4 months. Hence, the product may still be efficacious.  **Notorius A (RTU/concentrates, black/yellow)**  The rMS concludes that an efficacy for upto 5 months has been demonstrated for the product Notorius A for all variations of RTU/concentrate and colour (black yellow).  However, due to physical factors (e.g. bad weather, heavy currents) influencing the study, it is not possible to determine the exact efficacy past 5 months. Hence, the product may still be efficacious.  **Overall conclusion**  Based on the results of the conducted efficacy trials it can be concluded that all the products of the biocidal product family demonstrate sufficient efficacy but for a worst-case location where more extensive growth of fouling is expected, a product with high content of dicopper oxide (i.e. Notorius A) should be selected. |

#### 2.2.5.6 Occurrence of resistance and resistance management

As stated in section 2.2 in the EU Assessment report for Dicopper Oxide in the subsection “Resistance”: “There have never been any recorded cases of resistance in populations of fouling organisms through the use of Copper based antifouling paints in the literature up to

now. However, some studies, in the literature, showed some impacts of copper pollution on

marine life and indicate that some hull-fouling species have copper tolerance”.

#### 2.2.5.7 Known limitations

None.

#### 2.2.5.8 Evaluation of the label claims

Brynsløkken AS products are not marketed with label claims on specific protection times as they are dependent upon the environmental conditions and growth in the area applied. Marine biofouling pressure is extremely variable with regards to season, location, temperature, sunlight, water nutrient level etc.

High pressure water jet cleaning on site should not be performed.

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

Not relevant. The antifouling products are not to be used in combination with other biocidal products.

### Risk assessment for human health

Dicopper oxide (CAS-no: 1317-39-1) is approved for use in product type PT21 under Regulation (EU) No.528/2012. The hazard assessment of dicopper oxide was conducted in line with the assessment of other copper compounds dossiers for PT21. The toxicological properties of the active substance are summarised in the assessment report on dicopper oxide in product type 21 (ECHA, 2016a).

The harmonised classification for human health hazards according to the CLP Regulation (Regulation (EC) No 1272/2008) is: Acute Tox 4; H332 (inhalation), Acute Tox 4; H302 (oral) and Eye Dam. 1; H318 (ECHA, 2014).

No oral repeated toxicity study was provided for the assessment of dicopper oxide in product type 21. It was decided, however, that it was applicable to read across from other relevant copper compound (e.g. copper sulphate pentahydrate). Further information can be found in the competent authority reports of dicopper oxide, as reflected in the assessment report (ECHA, 2016a).

Copper is a micronutrient, which is essential for life and necessary for all living cells. It is essential for a normal physiological function such as cellular respiration, free radical defence, synthesis of melanin, connective tissue, iron metabolism, regulation of gene expression, normal function of the heart, brain and immune system. On the other hand, copper transport mechanisms in the organism form part of the system of homeostasis, i.e., the body can maintain a balance of dietary copper intake and excretion that allows normal physiological processes to take place. Deficiency in copper is associated with growth retardation, anaemia, skin lesions, impaired immunity, intestinal atrophy, impaired cardiac function, reproductive disturbance, neurological defects and skeletal lesions. Additionally, copper is present in almost all foods, and some products. Most human diets naturally include between 1 and 2 mg/person/day of copper, with some containing up to 4 mg/person/day. Copper intake which exceeds the capacity of the endogenous homeostasis results in toxicity, or excess copper disease. Chronic copper toxicity is very rare, and the upper limit of homeostasis has never been strictly defined (ECHA, 2016a).

The key health effects, which were used for deriving the reference values for dicopper oxide, are the kidney and forestomachdamages observed in a 90-day rat study (on copper sulphate pentahydrate, via diet; ECHA, 2016 a). A NOAEL of 1000 ppm (16.3 and 17.3 mg Cu/kg bw/day in male and female rats respectively) was established based on the kidney effects. The lowest of these NOAEL values was used when the short-term and long term AEL values were derived.

**Reference values to be used in the Risk Characterisation (ECHA, 2016a)**

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| **Reference** | **Study** | **NOAEL** | **AF** | **Correction for oral absorption** | **Value** |
| **Reference values for copper (from dicopper oxide)** | | | | | |
| AELshort-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 50 | 25% | 0.082 mg Cu/kg bw/day |
| AELmedium-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 50 | 25% | 0.082 mg Cu/kg bw/day |
| AELlong-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 100 | 25% | 0.041 mg Cu/kg bw/day |
| ARfD | n.a. | | | | |
| ADI | EFSA (2008) | - | 0.15 mg Cu/kg bw/day | | |

#### 2.2.6.1 Assessment of effects on Human Health

The toxicological properties of the products of the biocidal product family are classified based on information on the ingredients in the products using the conventional calculation method in Regulation 1272/2008.

The toxicological data on all co-formulants have been compiled and assessed by the applicant and is presented in the confidential annex of the PAR together with the composition of the family members.

A more elaborate explanations of the proposed classification is provided in the confidential annex of the PAR (section 1.3).

All of the products in the product family will carry the classification Eye Dam. 1 (H318). In addition, the products in meta SPC 2 are also classified for acute oral toxicity (Acute Tox 4; H302), all based on the classification of the ingredients.

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The products contained in the BPR-family are not to be classified concerning skin irritation/skin corrosion. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin irritation/corrosion hazards based on the classification of the ingredient substances. The additivity principle of the CLP Regulation applies to the hazard class skin corrosion/irritation.  In accordance with Annex I section 3.2.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture, i.e. those ingredients which should be taken into account when classifying a mixture, are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for skin irritation/corrosion (see also 1.1.2.2.2 Cut off values in Annex I).  Table 3.2.3 of the regulation contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin.  Details of the product compositions are presented in the confidential annex of the PAR (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.   None of the ingredients classified for skin irritation are present in the products in the product family at 1% or greater. Therefore, none of the products require classification for skin irritation/corrosion according to Regulation (EC) No 1272/2008. |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are not to be classified concerning skin irritation/skin corrosion. |

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| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.1 Skin corrosion or skin irritation |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

***Eye irritation***

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The products contained in the BPR-family are to be classified concerning eye irritation - as Eye Dam. 1; H318. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for eye irritation hazards based on the classification of the ingredient substances. The additivity principle of the CLP Regulation applies to the hazard class eye irritation, such that each skin corrosive or serious eye  damaging/eye irritant ingredient contributes to the overall serious  eye damage/eye irritation properties of the mixture in proportion to its potency and concentration.  Details of the product compositions are presented in the confidential annex of the PAR (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  All of the products in the product family contains more than 3% of the active substance dicopper oxide (Eye Dam. 1). As the generic concentration limits of ingredients classified as serious eye damage (Category 1) is ≥ 3 %, all the products will carry the classification Eye Dam. 1 (H318). |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are to be classified as Eye Dam. 1; H318. |

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| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.2. Eye irritation |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

***Respiratory tract irritation***

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The products contained in the BPR-family are not to be classified concerning respiratory irritation. |
| Classification of the product according to CLP and DSD | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for respiratory tract irritation based on the classification of the ingredient substances.  In accordance with Annex I Section 3.8.3.4.1 of Regulation (EC) No 1272/2008, where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances.  Details of the product compositions are presented in the confidential annex of the PAR (section 1.1).There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

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| **Data waiving** | |
| Information requirement | Not an information requirement for biocidal products according to BPR |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

***Skin sensitization***

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| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | The products contained in the BPR-family are not to be classified concerning skin sensitisation. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient which has been classified as a skin sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limits presented in Table 3.4.6 of the regulation.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to Reg. (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Details of the product compositions are presented in the confidential annex of the PAR (section 1.1).   There are two ingredients which are classified as skin sens H317. However, none of these ingredients are above their respective concentration limits for H317 or EUH208 in any of the members of the product family. |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are not to be classified concerning skin sensitisation. |

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| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.3. Skin sensitisation |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to Reg. (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

***Respiratory sensitization (ADS)***

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| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | The products contained in the BPR-family are not to be classified concerning respiratory sensitisation. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for respiratory sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a respiratory sensitiser and is present at or above the appropriate generic concentration limit shown in Table 3.4.5. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limit presented in Table 3.4.6 of the regulation.  Details of the product compositions are presented in the confidential annex of the PAR (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected  There are no ingredients in the products which are classified for respiratory sensitisation. The products do not, therefore, require classification for respiratory sensitisation according to Regulation (EC) No 1272/2008. |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are not to be classified concerning Respiratory sensitisation. |

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| **Data waiving** | |
| Information requirement | Not a core information requirement for biocidal products according BPR; ANNEX III; TITLE 1; 8.4. Respiratory sensitization. |
| Justification | Not a core data requirement but there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

***Acute toxicity***

*Acute toxicity by oral route*

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| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | The four products in Meta SPC 2 *[Notorius A15 (Red; Conc.), Notorius A15 (Black; Conc.), Notorius A (Yellow; Conc.) and Notorius A (Black; Conc.)]* are all classified as Acute Tox 4; H302: Harmful if swallowed.  No classification for the products in Meta SPC 1, 3 and 4. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute oral toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredient should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  Details of the product compositions are presented in the confidential annex (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  The active substance dicopper oxide is present at a range of 12% to 27.64% w/w and is classified as Acute Tox 4: H302: Harmful if swallowed. An ATE of 500 for dicopper oxide is used in the calculation as given in ATP 17 to CLP. Some other ingredients in the products are also classified for acute oral toxicity, and have been taken into account where relevant. |
| Classification of the product according to CLP and DSD | The products in Meta SPC 2 are classified as Acute Tox 4; H302: Harmful if swallowed. The products in Meta SPC 1,3 and 4 in the BPR-family are not to be classified concerning acute toxicity by oral route. |

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| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.5. Acute toxicity; 8.5.1. By oral route |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. A study is not required, nor considered an appropriate use of animals. |

*Acute toxicity by inhalation*

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| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | The products contained in the BPR-family are not to be classified concerning acute toxicity by inhalation route. |
| Justification for the selected value | mixtures may be classified for acute inhalational toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredients should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  The active substance dicopper oxide is present at a range of 12% to 27.64% w/w and is classified as Acute Tox 4; H332. An ATE of 3.34 mg/l (dust or mists) as given in ATP17 to CLP is used in the calculation.  Details of the product compositions are presented in the confidential annex (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  Classification for acute inhalational toxicity is not warranted for products in the biocidal product family based on the calculation of the ATE of the mixtures. |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are not to be classified concerning acute toxicity by inhalation route. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.5. Acute toxicity; 8.5.2. By inhalation |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  A study is not required, nor considered an appropriate use of animals. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | The products contained in the BPR-family are not to be classified concerning acute toxicity by dermal route. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute dermal toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredients should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  Details of the product compositions are presented in the confidential annex (section 1.1). There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.  The ingredient classified for dermal toxicity are present at low concentration. Hence, it should not be taken into account (not relevant). |
| Classification of the product according to CLP and DSD | The products contained in the BPR-family are not to be classified concerning acute toxicity by dermal route. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | BPR; ANNEX III;  TITLE 1; 8.5. Acute toxicity; 8.5.3. By dermal route |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. A study is not required, nor considered an appropriate use of animals. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Dicopper oxide |
| Value(s) | 1.3% (Notorius M3 (RTU); to be used in the risk assessment for the whole BPR-family) |
| Justification for the selected value(s) | Brynsløkken AS has submitted BPR applications for two BPR-families of antifouling products – the one described in the present PAR containing only dicopper oxide as active substance (CuO BPF) and another BPR-family containing both dicopper oxide and copper pyrithione as active substances (CuO-CuPY BPF). Besides the coformulant containing the additional active substance copper pyrithione), the two families are similar and are made up of the same components in varying concentration.  When deciding on which formulations to be tested, considerations were given to the issue of selecting representative products, not just in terms of content of the active substance(s) but also with regards to the content of the co-formulants in the products.  The two concentrates Notorius A (Conc.) and Notorius M1 (Conc.) and the RTU Notorius M3 (RTU) were selected as they in combination represents (more or less) the full range of the content of the two active substances in the two BPR-families and represent both the concentrates and the RTU’s in terms of composition, i.e. content of the co-formulants. (See chapter 1.2 of the confidential annex to PAR for further information). However, as the exposure assessment is mainly dependent on the in use concentrations of the products, the in use concentrations of the products and not the concentration of the concentrates are important (and should have been tested rather than the concentrates).  It is a general observation that the percentage dermal absorption of a substance is inversely related to the concentration (area dose) of test material (EFSA, 2017). Of that reason, the potential dermal absorption value for the product with the lowest active substance concentration Notorius M3 (RTU) was used in the risk assessment for the whole BPR-family of antifouling product. Correction for variability was made according to the EFSA guidance (EFSA, 2017).  Description of study:  An *in vitro* dermal absorption study through human split thickness skin (Blackstock, 2019) was conducted on three net coating formulations from two biocidal product families from Brynsløkken.  The study was performed according to the OECD 428 test guideline, using flow-through diffusion cells (McGregor/Toner cells).  Absorption of the test item was assessed by collecting receptor fluid in four hourly fractions from 0 to 24 h post dose. The exposure was terminated at 8 h post dose by applying Permatex® Fast Orange Pumice followed by rinsing with water and drying the surface with tissue swabs. The skin wash solution and tissue swabs were retained for analysis. The exposure was followed by a 16 h post exposure monitoring period.  At 24 h post dose, the underside of the skin was rinsed with receptor fluid (receptor rinse).The *stratum corneum* was removed with 20 successive tape strips. The first tape strips were kept individual whereas the last tape strips were pooled (1, 2, 3, 4, 5, 6-10, 11-15 and 16-20).  The donor and receptor chambers were retained separately and analysed (receptor and donor wash).  The test system, especially the cell apparatus, can contain levels of endogenous copper. In addition, copper is naturally present in human skin. A second undosed group of skin samples (blank control) was included. These skin samples were handled as test preparation treated skin samples; i.e. set up, washed, terminated and analysed using the same methods. Based on the undosed group results (and the results of blank sample analysis), it was not considered necessary to adjust the data to account for intrinsic copper content rel. to the cell app. (donor and receptor chambers) since low background levels of copper were measured.  The total amount of copper (non-radiolabelled) was measured using ICP-MS (using the method validated under Charles River Study No. 422217; Oxenham, S., 2019). Where values measured were below the lower limit of quantification LLOQ, the appropriate LLOQ value was used in calculations as worst case predictions.  In addition to the test item, dicopper oxide, Notorius M1 and Notorius M3 also contains a second source of copper (copper pyrithione), at a concentration of 2.33 % and 1.17 % (w/w), respectively. Since ICP-MS analysis generates data in terms of elemental copper, it was not possible to determine the extent of copper absorption from the individual compounds. Therefore, it was assumed for the purposes of the OECD 428 study that all measured copper was derived from the dicopper oxide. This was justified as it resulted in a more conservative (worst-case) Risk Assessment for dicopper oxide.  It was not possible to determine the extent of absorption as defined in the EFSA guidance (EFSA, 2017) as almost all measurements in the receptor fluid for skin samples with applied test material were below the LLOQ. Consequently, it could not be concluded that the absorption was essentially complete at half of the study duration.  Including photographic evidence of the tape strips in dermal absorption studies was widely supported at the PT21 workshop as this could help in evaluating the amount of antifouling paint remaining in each tape strip (ECHA, 2016b and 2016c).  In the current study photo evidence was included for skin samples before and after washing to demonstrate the efficacy of washing.  One photograph of each skin sample was taken before tape stripping. An additional photograph of the skin sample (but not the tape strips) was taken after each tape strip until all of the paint formulation had been removed from the skin surface (according to the study director), unless no paint was present on pre-tape stripping image.  As for Notorius M3 (RTU), only photos of the skin sample before stripping was presented (except one cell where a photo of SC1 was included). Thus, based on the photo evidence, SC3+ could not be excluded.  A potential absorbable dose was calculated including tape strips 3+, correcting for variability in agreement with the EFSA guidance.  As expected, the percentage dermal absorption increase with decreasing content of the active substance in the test preparations. Notorius M3 (RTU – 12.95 % (w/w)) gives rise to the highest percentage dermal absorption.  See results in the table below. |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table of in vitro studies on dermal absorption** | | | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value**  **(values presented as % applied dose)** | | | **Remarks** *(e.g. major deviations)* | **Reference** |
| GLP Study performed in accordance with the guidance and guidelines detailed below[[3]](#footnote-4) | Eight samples of human split thickness membranes (390-400 µm depth) obtained from five different female donors (abdominal skin) were used per test preparation.  Undosed group: Additional 8 samples (to account for intrinsic copper levels associated with the test system)  + blank samples  8 h exposure  (terminated by applying Permatex® Fast Orange  Pumice and rinsing with water).  16 h post exposure monitoring period.  Photo evidence before and after washing and before and after each tape strips until all paint was removed  Flow-Through Diffusion Cell (McGregor/Toner cells)  Measurements of total copper by ICP-MS | CuO BPF:  **Notorius A**  Conc. (27.64%) w/w Cu2O)  CuO-CuPy BPF:  **Notorius M1 conc.**  (24.66%  w/w Cu2O + 2.33% w/w CuPT)  **Notorius M3 RTU**  (12.95% w/w Cu2O + 1.17%  w/w CuPT) | Test Preparation 1 **(Notorius A)**  Dislodgeable Dose 24h: 102.90%  Stratum Corneum: 0.37%  Total Unabsorbed Dose: 103.28%  Total Absorbed Dose: 0.10%  Dermal Delivery: 0.16%  Potentially Absorbable Dose: 0.35%  Mass Balance: 103.44%    Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  0.35 + (0.92 x 0.08)  ≈ **0.42 %** (n=7) | Test Preparation 2 **(Notorius M1)**  Dislodgeable Dose 24h: 103.82%  Stratum Corneum: 0.40%  Total Unabsorbed Dose: 104.24%  Total Absorbed Dose: 0.12%  Dermal Delivery: 0.26%  Potentially Absorbable Dose: 0.49%  Mass Balance: 104.50%  Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  0.49 + (0.84 x 0.19)  = **0.65 %** (n=8) | Test Preparation 3 **(Notorius M3)**  Dislodgeable Dose 24h: 101.91%  Stratum Corneum: 0.85%  Total Unabsorbed Dose: 102.80%  Total Absorbed Dose: 0.14%  Dermal Delivery: 0.29%  Potentially Absorbable Dose: 0.97%  Mass Balance: 103.10%  Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  0.97 + (0.92 x 0.37)  = **1.3 %** (n =7) | Based on the undosed group results and the blank sample analysis, not necessary to adjust the data to account for intrinsic copper contentrel. to the cell app. (donor and rec. chambers) since low backgr. levels of Cu were  measured. | Blackstock, 2019 |

Dislodgeable Dose 24h = 8h Skin wash + 8h +24h Tissue swabs + Donor chamber wash

*Stratum corneum* = tape strips 1 to 20

Total Unabsorbed Dose = Dislodgeable Dose 24h+ Stratum Corneum + Unexposed Skin

Total absorbed Dose: Cumulative Receptor Fluid + Receptor chamber wash

Dermal Delivery: Absorbed Dose + Exposed Skin

Potentially Absorbable Dose = Stratum Corneum 3-20 + Dermal delivery

Mass balance = Unabsorbed Dose + Dermal delivery

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

No substances of concern present in the antifouling products.

An ED Assessment of the co-formulants present in the BPR-family is presented in the Confidential Annex.

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

No data.

***Other***

***Endocrine disrupting potential***

According to the assessment performed as described in the CA-March21-Doc.4.3\_Final "Bridging Biocides with REACH"*,* none of the formulants contained in the products of the CuO Biocidal Product family are identified as endocrine disruptors.

The complete assessment is available in the confidential annex.

#### 2.2.6.2 Exposure assessment

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

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

Production and formulation of the antifouling products is addressed under other EU legislation (e.g. Directive 98/24/EC) and is not repeated under Regulation 528/2012.

This principle was agreed at the Biocides Technical Meeting in 2006 (TMI06).

The exposure assessment includes assessment of the risks to workers involved in the treatment and deployment of nets used for fish farming as well as post application processes.Treatment of nets with antifouling products is done industrially by specialised service companies employing professional operators whereas deployment of treated nets is undertaken by professional workers. The relevant work tasks are described below as well as the models used in the exposure assessment.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
|  | Mixing & loading | Primary – Mixing and loading of antifouling product  (covered by scenario 2) | Industrial workers |
| 2. | Application:  (including mixing &  Loading) | Primary exposure – Treatment of nets with antifouling product  Dipping model 4: Aquaculture – net dipping, dispensing to a pit from BIC, stirring and crane-assisted dipping, solvent-based and water-based products (ECHA, 2015a).  Describes the process of mixing/loading of antifouling product into treatment units, crane assisted net dipping, drying of treated nets and packaging of the treated nets for transport.  It is assumed that the Dipping model 4 covers treatment of nets using vacuum treatment. | Industrial workers |
| 3 | Post application | Primary – cleaning of treatment unit | Industrial workers |
| 4. | Contact with treated article | Secondary exposure – deployment of treated nets at fish farms:  Handling model 2 – Installing fish cages using lifting equipment and handling nets damp with sticky product (ECHA, 2015a).  Describes the process of deployment (or removal) of treated nets at fish farms. | professionals |
| 5 | Contact with treated article | Secondary -Washing and repairing of used nets | Industrial workers |
| 6. | Dietary | Secondary – Dietary exposure | General public |

**General assumptions**

Generic exposure data from the simple database models presented in the Biocides Human Health Exposure Methodology (ECHA, 2015a) are used as a basis for the exposure assessments, considering also the information provided in the surveys behind these models. The indicative values given in the guidance document (Biocides Human Health Exposure Methodology , ECHA, 2015a) are used as well as default physiological values.

The occupational risk is estimated by comparing the level of systemic exposure to copper from dicopper oxide with the relevant toxicological reference values for the active substance. Additionally, a local risk assessment has been performed due to the classification of all family members with H318 (Causes serious eye damage).

At the Technical Meeting III in 2011, it was agreed that the medium-term AEL should be used for risk characterization of professional workers applying or removing antifouling products, due to the expected periodic use of the antifouling agents (ref. Biocides Human Health Exposure Methodology, page 264, ECHA, 2015a). This decision concerned the use of antifouling products on boats.

Treatment of nets takes place year-round at dedicated service stations, according to our information 2-3 days/week (ref. also Biocides Human health Exposure Methodology, page 86-89, ECHA, 2015a where the task frequency is given as "some days a week"). Deployment of treated nets is on the contrary most intensive during springtime Hence, the AEL long term is considered most appropriate for the risk characterisation of net treatment, whereas AEL medium term is used in therisk characterisation of net deployment.

A tiered approach has been performed. Default assumptions and only minimal clothing is assumed in tier 1. This is unlikely to be representative of the normal workplace. Tier-2 refinements are performed for the estimation of a more realistic exposure assuming different types of PPE.

The exposure to the undiluted concentrates during mixing and loading is assumed to be very low due to the automated transfer of the product from the IBC (Intermediate bulk container) to the tank where the mixing take place. Thus, the exposure to the operator during net treatment will mainly be to the in-use concentration of the products.

A table with all products in the biocidal product family is included below. Exposure calculations have been made for all products in the different Meta SPCs (see 3.2.2). The results of the calculations for the product with the highest active substance concentration in each meta SPC are presented below.

**Overview table of the family members and concentrations of active substance**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Product** | **Formulation**  **and dilution**  (concentrate: water) | **Cu2O**  **(% w/w)** | **Cu2O**  **in use conc**  **(% w/w)1** | **Cu equiv**  **(%)2** | **Dermal abs (%)** |
| 1 | Notorius A12 (red/black) | Conc (1:1) | 21.67 | 12.29 | 10.91 | 1.3 |
| 1 | Alpha Net Guard (red/black) | Conc (1:0.6) | 18.01 | 12.35 | 10.97 | 1.3 |
| 2 | Notorius A 15 (red/black) | Conc (1:0.8) | 24.36 | 15.12 | 13.43 | 1.3 |
| 2 | Notorius A (yellow/black) | Conc (1:0.5) | 27.64 | 20.00 | 17.76 | 1.3 |
| 3 | Notorius A12 (red/black) | RTU | 12 | 12 | 10,66 | 1.3 |
| 3 | Alpha Net Guard (red/black) | RTU | 12,04 | 12,04 | 10,69 | 1.3 |
| 4 | Notorius A15 (red/black) | RTU | 14,94 | 14,94 | 13,27 | 1.3 |
| 4 | Notorius A (yellow/black) | RTU | 19,9 | 19,9 | 17,67 | 1.3 |

1 For concentrates, density has been taken into account when calculating the in-use concentrations.

2 Cu equivalents are calculated using the formula: [Cu2O]\*0,888

Conc = concentrates, RTU = ready to use products

Exposure calculations are presented in the tables below for products in grey colour.

***Industrial exposure***

***Scenario 1* – *Mixing/loading of antifouling product***

|  |
| --- |
| **Description of Scenario 1 – Mixing/loading of antifouling product** |
| Concentrates:  The concentrated product and the correct load of water are mixed together in a tank with the use of a mobile dispersion mixer. The concentrated product is transferred to the tank, and water is filled in the empty IBC to ensure that as much as possible of the product has been included in the diluted mixture. When the water and the concentrated product have been thoroughly mixed to assure homogenisation, the diluted product is transferred to the treatment unit through a pipe.  RTU products:  As for RTU products, the product is transferred to the treatment unit by connecting the IBC through a pipe. If needed, the IBC is rinsed with water (approximately 20 L/IBC) to facilitate the emptying of the IBC, and the rinsing solution is emptied into the treatment unit as well. Homogenisation of the diluted mixture is ascertained by stirring.  Minimal risk of exposure is expected during the mixing and loading process since there is no manual mixing or loading of the treatment unit. Exposure would be accidental and mainly associated to incidental exposure in connecting and disconnecting of transfer lines/pipes. Mixing/loading is included in Dipping model 4 and is not assessed separately. |

***Scenario 2:*** ***Treatment of nets with antifouling product (including mixing & loading)***

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 2 – Application – Treatment of nets with antifouling product** | | |
| Treatment of nets with antifoulant takes place year round by specialised service companies employing professional operators. The nets are treated when new as well as during service life (after washing and if needed repair).  According to the guidance document, it is assumed that one to two nets are treated during a working day and that the task is performed "some days a week" (page 86-89, EFSA, 2015a).  Net dipping:  Net dipping requires the use of lifting machinery (due to the size and weight of the nets). Crane-assisted dipping is assumed to be the standard method for dipping of nets.  The nets are lowered into a dipping tank/chamber containing the treatment solution. The nets should be clean and dry before dipping. The net should stay immersed in the treatment solution for at least 15 minutes. The net is left submerged in the product, held down by a weight. Subsequently, the nets are removed using the same lifting machinery used to place the net in the tank/chamber and put to dry at a temperature below 60° C, typically using a dry drum or free hanging system. The nets are packaged when dry and transported to the fish farms.    Figure 1: Net in dipping chamber Figure 2: Free hanging net system used following treatment    Figure 3: net hoisted after impregnation in the impregnator  Vacuum impregnation:  For net impregnation, the net is placed into a bag (the impregnator). Air is then removed from the bag through a valve to create vacuum inside the bag. The bag is then held in place and the impregnator lid is lowered on top of the impregnator and sealed so that no air enters the process. The IBC container is connected to the pump and the antifouling product is pumped into the bag to immerse the net in the product. The vacuum is then re-established within the bag and allowed to stand for a few minutes. This process can be repeated up to 5 times depending on which service station and company performs the process. Any remaining product is transferred from the bag back to the IBC for use at a later date. The nets are then removed from the bag and dried in a manner similar to the nets treated through the dipping process.    Figure 4: Net impregnation bag  There is a potential for dermal exposure (body and hands) through direct contact with treated nets when manually connecting/disconnecting the nets to lifting machinery (crane/hoist/winch)/drying drum etc. or whilst loading un-loading the vaccume bag as well as contact with contaminated surfaces and equipment.  **Description of model:**  The dipping models 1-4 in the Biocides Human Health Exposure Methodology describe professionals carrying out a range of dipping activities involving a variety of articles (ECHA, 2015a, page 199). The models reflect conditions where operators may contact treatment fluids as well as wet objects.  Dipping model 4 describes semi-automatic dipping of aquaculture nets in open vats (page 311, ECHA, 2015a). The scenario includes dispensing of product (both solvent-based and water-based products) from IBC, stirring and crane assisted dipping of the nets in the treatment solution.  The scenario is based on a survey from 1999 sponsored by HSE from the four major treaters of net in UK at the time. According to the guidance, the results reflect the true nature of the net dipping activity; i.e. an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated immersion of the nets in large vats of fluid and retrieval of the nets at the end of the process. The work is followed by the preparation of the nets and wrapping prior to transportation to the customer.  The indicative values are expressed as in-use product. Due to the high uncertainty in the figures (low number of measurements and variability of the data), the indicative values are the maximum values of the data set (ECHA, 2015a, page 199).  Indicative hands value (actual exposure inside protective gloves) = 16.7 mg/min  Indicative body values = 221 mg/min  Indicative inhalation value = 0.2 mg/m3  *(The indicative inhalation value is used in accordance with ad hoc recommendation 6 of the BPC Ad hoc Working Group on Human Exposure (page 11, version 4), following evaluation of dipping Model No.4 for the purposes of dipping of equipment for PT 2,3 and 4).*  The survey behind the model is old and with a low number of measurements (n=9). Large tanks (2000-7000 liters) were filled with antifouling products from intermediate bulk containers (IBC). The dipping and drying techniques differed between the sites with different degrees of automatization. Hence the potential for dermal exposure differed. Dermal exposure resulted from filling of the tanks, manually connecting/disconnecting of treated nets to fork lifts/hoists/drying drums, where relevant manually immersion of buoyant nets using sticks, incidental contact with contaminated surfaces/equipment and with nets during transfer to drying stations and packaging. The work performed during the survey was considered to be typical for all sites.  The workers wore coveralls, impervious/chemical resistant gloves and wellingtons and goggles/face protection were (usually) available.  Some of the measurements (n=5) are from dipping and packing of nets treated with solvent based products. These nets have to be packed and deployed in a damp state. A higher exposure to the involved personnel might therefore result. According to our information, solvent based products are no longer on the market in Europe. Nets treated with water-based products must be completely dry before they can be packed.  The process and procedures have developed since the performance of the study. The aquaculture business and its service providers have grown significantly and been professionalised since the performance of the study. To our knowledge, the service stations use treatment processes which involve little degree of physical contact with the nets during the treatment process. The exposure calculations must therefore be regarded as conservative.  Note on vacuum treatment of nets:  No exposure model or data exists for the assessment of exposure from vacuum treatment of nets. Many of the tasks with potential for exposure are identical as for dipping; connecting/disconnecting nets to cranes/winches, exposure to contaminated equipment and transferring of nets to the drying station.  It is assumed that the Dipping model 4 also covers treatment using the vacuum method. | | |
| **Tier** | **Parameters** | **Value** |
|  | Actual hand exposure  *(exposure inside protective gloves)1* | 16.7 mg/min (max values) |
| Potential body exposure1 | 221 mg/min (max values) |
| Potential inhalation exposure1 | 0.2 mg/m3 (max value) |
| Dermal absorption (dicopper oxide3) | 1.3% |
| Inhalation absorption | 100% |
| Inhalation rate2 | 1.25 m3/hr |
| Duration of exposure5 | 60 minutes |
| Body weight2 | 60 kg |
| Tier 2a | Gloves1 | Actual measurements inside gloves.  No further refinement possible |
| PPE (Coated coveralls)4 | 10% penetration |
| Tier 2b | Gloves1 | Actual measurements inside gloves.  No further refinement possible |
| PPE (Impermeable coveralls)4 | 5% penetration |
| Tier 2c | Gloves1 | Actual measurements inside gloves.  No further refinement possible |
| PPE (Double coveralls)4 | 1% penetration |

1 Biocides Human Health Exposure Methodology (ECHA, 2015a; page 199 + 311-312. Dipping model 4).

2 Ad hoc Working Group Recommendation 14: Default human factor values for use in exposure assessments for biocidal products (ECHA, 2017b)

3 Blackstock, 2019. The In Vitro Percutaneous Absorption of Dicopper Oxide in Three Formulations through Human Split-Thickness Skin

4 HEEG opinion 9, Default protection factors for protective clothing and gloves (HEEG, 2010) as also included in ECHA, 2015a (page 156-157).

5 Biocides Human Health Exposure Methodology (ECHA, 2015a; page 86-89).

**Calculations for Scenario 2 - Application – Treatment of nets with antifouling product**

The results of the calculations are presented below.

Full details of the exposure assessment calculations for all products can be found in a separate annex, see section 3.2.2.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Meta SPC 1 - Alpha Net Guard (conc.)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 4.61E-04 | 0.34 |  | **0.34** |
| Tier 2a/PPE  (gloves & coated coveralls) | 4.61E-04 | 0.055 |  | **0.056** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 4.61E-04 | 0.040 |  | 0.040 |
| Tier 2c/PPE  (gloves & double coveralls) | 4.61E-04 | 0.027 |  | 0.027 |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 7,46E-04 | 0.55 | - | **0.55** |
| Tier 2a/PPE  (gloves & coated coveralls) | 7,46E-04 | 0.090 | - | **0.090** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 7,46E-04 | 0.064 | - | **0.065** |
| Tier 2c/PPE  (gloves & double coveralls) | 7,46E-04 | 0.044 | - | 0.044 |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 4.5E-04 | 0.33 | - | **0.33** |
| Tier 2a/PPE  (gloves & coated coveralls) | 4.5E-04 | 0.054 | - | **0.054** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 4.5E-04 | 0.039 | - | 0.039 |
|  | Tier 2c/PPE  (gloves & double coveralls) | 4.5E-04 | 0.026 | - | 0.027 |
| **Meta SPC 4 - Notorius A (yellow&black)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 7.4E-04 | 0.55 | - | **0.55** |
| Tier 2a/PPE  (gloves & coated coveralls) | 7.4E-04 | 0.089 | - | **0.090** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 7.4E-04 | 0.064 | - | **0.064** |
|  | Tier 2c/PPE  (gloves & double coveralls) | 7.4E-04 | 0.043 | - | 0.044 |

\*Cu equivalents are calculated using the formula: [Cu2O]\*0,888

***Scenario 3: Post application - Cleaning of treatment unit***

|  |
| --- |
| **Description of Scenario 3 – Post-Application – Cleaning of treatment unit** |
| According to the applicant, the dip tank is cleaned periodically. Typically the dipping tanks or impregnators have a fully automated cleaning program and the vessels are cleaned by flushing, no manual removal is required.  However, in some instances, paint residues may be removed from the dipping tank/chamber by high pressure cleaning. Remains at the bottom of the dipping tank/chamber (sediment, dirt) are manually removed. The remains are gathered in an IBC and disposed.  Therefore, some contact with wet surfaces may occur during the process, and necessitates the use of appropriate PPE (such as boots, gloves, single use coveralls and goggles/face shield).  The task might be performed by the same workers that performs the net dipping. However, manually cleaning of the dipping tank/chamber is performed infrequent and is unlikely to take place at the same day as dipping of nets.  No appropriate exposure model or measurements exist for the process of cleaning the treatment unit. A description of the process and normally used PPE is included only.  The exposure is considered as being covered by the conservative assessment of dipping of nets (scenario 2). |

***Scenario 4******Deployment of treated nets at fish farms***

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 4 – Deployment of treated nets at fish farms** | | |
| The treated nets are transported to the fish farm and installed semiauotmatically.  Nets are manually fastened to the unfolding system which only takes place in the fastening loops on the bottom rope in the extension of the lifting rope. Once connected to the lifting equipment, the nets are automatically unfolded by the unfolding systems.  According to the guidance document, up to 6 persons are involved in the deployment of one net and the operators may deploy up to 3-7 nets in a day (ECHA, 2015a, page 86-89).  As the work is performed off-site, i.e. at the fish farm, scenario 4 is considered independently from the other scenarios.  **Description of model:**  A scenario to assess exposure to personnel from installation of a net treated with antifouling product at a fish farm is found in the Biocides Human Health Exposure Methodology (Handling model 2, page 303, ECHA, 2015a). The model includes measurements from semi-automated handling of the nets during the process of reconstructing cages around fish farms. The model reflects intermittent handling of treated nets at various stages of dryness.  The scenario is titled "installing fish cages using lifting equipment and handling nets damp with sticky product" and is based on a HSE sponsored survey of the major treaters and users of nets in the UK.  The original surveys are old, and the number of data points is low (n=9, two sites). Several of the data points were from personnel deploying nets treated with solvent based antifouling products. As nets treated with solvent based products are still damp with product at deployment, a somewhat higher exposure was observed, as expected, than when nets were treated with a water-based product. The latter nets are completely dry before they are installed. As solvent based products, according to our information, are no longer on the market in Europe, the assessment is regarded as conservative.  Penetration of clothing was not measured and was most unlikely as PVC coated suits were used for net deployment. Gloves were used to protect from abrasion by the nets. Gloves were tended to be used only once, eliminating secondary exposure from previously contaminated gloves.  The indicative values (expressed as in-use product) for this scenario are the 75 percentile values of the data set (page 198, ECHA, 2015a):  Indicative hands value (inside protective gloves) = 0.21 mg/min  Indicative body values = 7.55 mg/min  The resulting exposure values are reported below. | | |
| **Tier** | **Parameters** | **Value** |
| Tier 1 | Actual hands exposure (inside protective gloves)1 | 0.21 mg/min (75 percentile) |
| Potential body exposure1 | 7.55 mg/min (75 percentile) |
| Dermal absorption (dicopper oxide3) | 1.3% |
| Inhalation absorption | 100% |
| Inhalation rate2 | 1.25 m3/hr |
| Duration of exposure5 | 300 minutes (worst-case) |
| Body weight2 | 60 kg |
| Tier 2 | Hand exposure1 | Actual measurements inside gloves. No further refinement. |
| PPE (uncoated cotton coverall)4 | 25% penetration from dry substances |

1 Biocides Human Health Exposure Methodology (ECHA, 2015a; page 198 + 303. Handling model 2)

2 Ad hoc Working Group Recommendation 14: Default human factor values for use in exposure assessments for biocidal products (ECHA, 2017b)

3 Blackstock, 2019. The In Vitro Percutaneous Absorption of Dicopper Oxide in Three Formulations through Human Split-Thickness Skin

4 HEEG opinion 9, Default protection factors for protective clothing and gloves (HEEG, 2010) as also included in ECHA, 2015a (page 156-157).

5 Biocides Human Health Exposure Methodology (ECHA, 2015a; page 86-89).

**Calculations for Scenario 4 - Deployment of treated nets**

The results of the calculations are presented below.

Full details of the exposure assessment calculations for all products can be found in a separate annex, see section 3.2.2.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Meta SPC 1- Alpha Net Guard (conc.)** | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | - | 0.055 | - | 0.055 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.015 | - | 0.015 |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | - | 0.090 | - | 0.090 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.024 | - | 0.024 |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | - | 0.054 | - | 0.054 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.015 | - | 0.015 |
| **Meta SPC 4 - Notorius A (yellow&black) (RTU)** | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | - | 0.089 | - | 0.089 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.024 | - | 0.024 |

*\** \*Cu equivalents are calculated using the formula: [Cu2O]\*0,888

***Scenario 5: Washing and repairing used nets***

|  |
| --- |
| **Description of Scenario 5 – Washing and repairing used nets** |
| **Washing of nets after use:**  Following the requisite period at the sea, most of the dicopper oxide will have leached from the net matrix. Nets are returned to a service station for servicing.  The nets are taken to the service stations “dirty zone” and are washed in a suitable washing machine. The net is lifted into the net washing machine using a crane or a winch. After washing, the nets are transferred to the “clean zone”. The operation requires little or no physical contact with the net.  **Inspection and repair of nets**  The nets are inspected, repaired and refitted before the nets are retreated with antifouling product and reused. Some physical handling of the net will take place during the process, and appropriate PPE should be used.  At the point of inspection and repair most of the active substances are assumed to have leached out during service life of the nets (approximately 80% is assumed in the environmental risk assessment), and the residual amounts of products have been further reduced in the washing process. Thus, it is assumed that the potential for exposure is low compared to the task of handling newly treated nets (e.g. net deployment) The task is not further assessed. |

*Combined scenarios*

Mixing and loading and application is covered by the same scenario 2 (see further description above). Cleaning of the treatment unit and washing and repair of treated nets after service is considered as being covered by the conservative assessment of dipping.

Deployment of treated nets (scenario 4) is considered independently as this task is not performed at the service stations.

***Non-professional exposure***

Not relevant – industrial and professional use only.

***Exposure of the general public***

Not relevant – industrial and professional use only.

***Monitoring data***

No data.

***Dietary exposure***

|  |
| --- |
| **Description of Scenario 6 – Dietary exposure** |
| Copper is naturally present in the environment and also essential for many metabolic functions and reactions for both plants and animals. Copper is authorised as a feed additive under EU Reg. 479/20064 for nutrition of livestock including fish and shellfish and is routinely added to fish feed in order to prevent copper deficiency. The maximum content in the complete feeding stuffs is 25 mg/kg for fish and 50 mg/kg for crustaceans. It is also present in many food supplements for human consumption, according to Directive 2002/46/EC. Acceptable risks due to potential exposure of copper via food contamination was identified in the competent authority report for dicopper oxide based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force (ECHA, 2016a). However, it was indicated that exposure via food contamination might need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.  There is currently no harmonized methodology to assess the level in foodstuff of a PT21 active substance. The most relevant general approach available to estimate levels in fish and shellfish is based on a rough calculation using the highest Predicted Environmental Concentration (PEC) calculated from the marine environment with a Bio Concentration Factor (BCF). However, for copper this approach is not relevant. In the case of copper, the potential bioaccumulation cannot be established from the BCF values. This is due to copper being an essential metal for many organisms where a feedback regulation mechanism of the uptake exists. No concern is identified for copper, also due to its physico-chemical properties (high solubility/dilution in sea water, low bio-accumulation). See the Risk Assessment for the Environment section 2.2.8.1 for further information.  The levels of copper (Cu), as well as other metals and environmental pollutants, were analysed in a standardised muscle sample from both farmed (n=100) and wild (n=87) Atlantic salmon caught or produced in Norway in 2012 (Lundebye *et al*., 2017). The farmed Atlantic salmon were sampled at fish farms by inspectors from the Norwegian Food Safety Authority (NFSA) in 2012 (for the annual monitoring programme laid down in Directive 96/23 EC). Sampling locations represent regions with aquaculture activity along the Norwegian Coast accounting for at least 10 % of the total number of farm sites each year. The Wild Atlantic salmon were caught by nets in Norwegian northern coastal waters by commercial fishermen in 2012. Filets from the farmed salmon contained less copper than wild salmon. The mean cobber value ± SD from the farmed salmon was 0.38 ± 0.09 (with a min- max range of 0.27 - 0.95) and the mean value for the wild salmon was 0.57 ± 0.15 (with a min - max range of 0.4 - 1.8). The findings in Lundeby et al. (2017) gives no indication of elevated copper levels in farmed fish compared to wild caught fish.  Copper levels in farmed Atlantic salmon filets were also given in an annual report for 2019 provided by the Norwegian Institute of Marine Research. This report is part of the monitoring program for pharmaceuticals, illegal substances and contaminants in farmed fish (Bernhard *et. al*., 2020). Samples were taken from fish farms or slaughterhouses in all fish-producing regions in Norway by official inspectors from the NFSA. The sampling plan was randomised according to season and region. When analysing the Atlantic salmon filets from the fish included in this report (n = 52), the median value was 0.4 mg/kg w.w. and the max vale was 0.7 mg/kg w.w. copper.  No information was given regarding the biocide(s) used for net treatment. However, given that the samples were taken from different farms, and considering that copper containing antifoulants is the most frequently used antifoulant in Norway , it is reasonable to believe that nets treated with such products were used in a number of the selected farms. The results from both 2012 and 2019 seem to be in the same range with the mean of 0.38 vs a median of 0.4 mg/kg w.w.  If the maximum copper value in filets of 0.95 mg/kg w.w. given in the Lundebye study is used in a reverse reference exposure calculation, a 15-kilo child would have to consume approximately 2.4 kilos of salmon per day to exceed the ADI of 0.15 mg Cu/kg bw/day. The corresponding amount for an adult of 60 kg using the same maximum value, is 9.5 kilo salmon per day.  (0.15 mg/kg bw/day X 15 kg bw) / 0.95 mg /kg w.w. = 2.4 kg w.w./day (0.15 mg/kg bw/day X 60 kg bw) / 0.95 mg /kg w.w. = 9.5 kg w.w./day  Based on the information above, no concern in regard to exposure via food is identified. However, when a uniform methodology to assess dietary exposure induced by an antifouling application is available, this assessment may need to be updated. |

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment\*** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| **Meta SPC 1 - Alpha Net Guard (conc.)** | | | |
| 2 | Industrial users | Tier 2b/gloves & impermeable coveralls | 0.040 |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | |
| 2 | Industrial users | Tier 2c/gloves & double coveralls | 0.044 |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | |
| 2 | Industrial users | Tier 2b/gloves & impermeable coveralls | 0.039 |
| **Meta SPC 4 - Notorius A (yellow&black)** | | | |
| 2 | Industrial users | Tier 2c/gloves & double coveralls | 0.044 |
| **Meta SPC 1 - Alpha Net Guard (conc.)** | | | |
| 4 | professionals | Tier 1/Gloves | 0.055 |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | |
| 4 | professionals | Tier 2a/Gloves & uncoated coverall | 0.024 |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | |
| 4 | professionals | Tier 1/Gloves | 0.054 |
| **Meta SPC 4 - Notorius A (yellow&black)** | | | |
| 4 | professionals | Tier 2a/Gloves & uncoated coverall | 0.024 |

\*Values with acceptable/borderline risk included only2.2.6.3 Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF** | **Correction for oral absorption** | **Value** |
| **Reference value for copper** | | | | | |
| AELshort-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 50 | 25% | 0.082 mg/kg bw/day |
| AELmedium-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 50 | 25% | 0.082 mg/kg bw/day |
| AELlong-term | 90-day rat study | 16.3 mg Cu/kg bw/day | 100 | 25% | 0.041 mg/kg bw/day |
| ARfD | n.a. | | | | |
| ADI | EFSA (2008) | - | | | 0.15 mg Cu/kg bw/day |

**Specific reference value for groundwater**

Not relevant.

**Systemic effects**

***Risk for industrial users***

***Scenario 2: Dipping of nets in antifouling product (including mixing & loading)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg Cu/kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg Cu/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **Meta SPC 1 - Alpha Net Guard (conc.)** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.34 | **8.3** | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.056 | **1.4** | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.040 | 0.98 | Yes |
| Tier 2c/PPE  (gloves & double coveralls) | 0.027 | 0.67 | Yes |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.55 | **13** | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.090 | **2.2** | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.065 | **1.6** | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.044 | 1.08 | Yes (Borderline risk) |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.33 | **8.1** | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.054 | **1.3** | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.039 | 0.95 | Yes |
| Tier 2c/PPE  (gloves & double coveralls) | 0.027 | 0.65 | Yes |
| **Meta SPC 4 - Notorius A (yellow&black** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.55 | **13** | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.090 | **2.2** | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.064 | **1.6** | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.044 | 1.08 | Yes (Borderline risk) |

**Conclusion:**

Acceptable risk is demonstrated in the systemic risk assessment for industrial workers performing net treatment activities in tier 2b (impermeable coveralls and chemical resistant gloves) for Meta SPC 1 (Alpha Net Guard (conc)) and Meta SPC 3 (Alpha Net Guard (RTU)). As for the products in Meta SPC 2 and 4, a borderline risk was demonstrated in tier 2c assuming use of double coverall (1% clothing penetration) and chemical resistant gloves. Due to the conservatism of the risk assessment, the proposal is to accept this slight exceedance of the reference value.

***Risk for professional users***

***Scenario 4:* Deployment of treated nets**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg Cu/kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **Mg Cu/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **Meta SPC 1- Alpha Net Guard (conc.)** | | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.055 | 0.67 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.015 | 0.18 | Yes |
| **Meta SPC 2- Notorious A (yellow & black) (conc.)** | | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.090 | **1.09** | Yes (Borderline risk) |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.024 | 0.30 | Yes |
| **Meta SPC 3 - Alpha Net Guard (RTU)** | | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.054 | 0.66 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.015 | 0.18 | Yes |
| **Meta SPC 4 - Notorius A (yellow&black) (RTU)** | | | | | | |
| Scenario 4 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.089 | **1.09** | Yes (Borderline risk) |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.024 | 0.29 | Yes |

**Conclusion:**

Acceptable or borderline risk is demonstrated in the systemic risk assessment of professional workers performing net deployment in tier I (use of gloves only) for all products.

Acceptable risk is demonstrated with the use of gloves and uncoated coveralls for all products.

**Combined scenarios**

Mixing and loading and application is covered by the same scenario 2. Cleaning of the treatment unit and washing and repair of treated nets after service is considered as being covered by the conservative assessment of dipping of nets.

Deployment of treated nets (scenario 4) is considered independently as this task is not performed at the service stations.

**Local effects**

All products in the biocidal product family are classified with Eye Dam.1 (H318). The P-statements associated with H318 are:

P280 Wear protective eye/face protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor

The in use concentrations of dicopper oxide for all products are above the threshold value of 3% for classification as Eye Damage category 1 as defined in Regulation (EC) No 1272/2008 (CLP) Table 3.3.3.

A qualitative risk assessment is performed in accordance with the BPR Guidance (Chapter 4.3, ECHA, 2017a). The products in the biocidal product family are allocated to the hazard category "High" based on this guidance. Please refer to the table below for further information.

**Local effects – Qualitative assessment for industrial and professional use:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| Hazard cate-gory | Effects in terms of C&L | PT | Who is exposed | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM and PPE | Conclusion on risk |
| High | Eye dam. Cat 1, H318 | 21 | Industrial workers | Net dipping (incl. M&L)    (Washing and repair of used nets and cleaning equipment) | skin  Eye (splashes or hand to eye transfer during the task) | Estimated 2-3 days per weeks  Due to automated processes, only a few minutes potential exposure/day.  Intermittent handling of treated nets  Incidental contact with contaminated surfaces | - | Minimisation of manual operations (automatization incl. crane assisted lifting of nets)  Avoidance of contact with contaminated equipment and surfaces  Training of personnel  Instructions for use  PPE (Protection coveralls, chemical protective gloves, eye protection)  Good standard of personal hygiene   * Organisation   General safety and hygiene measures  Regular cleaning of equipment and work area  Labelling according to CLP   * Packaging and formulation that reduces the generation of aerosols and spray particles (Flow controlling, insert plug) | Acceptable  +Automated processes;  +Trained workers  +Use of appropriate PPE  + Good standard of personal hygiene. |
| 21 | Professional users | Net deployment (Installing and handling treated nets at fish farms) | Skin  Eyes (dust, hand to eye transfer) | Infrequent task (seasonal)  Dermal contact with dry treated nets  Practically no exposure to eyes due to use of goggles | - | Training for staff on good practise; instructions for use  Good standard of personal hygiene.  Personal protective equipment (coveralls, gloves, eye protection\*)  *\*goggles are worn during net deployment because of risk of debris from nets.* | Acceptable  +Exposure to dry nets  +Trained workers  +Use of appropriate PPE |

The potential for eye exposure is limited during the net treatment process as most of the process is operated remotely and does not involve contact with the treated nets or the treatment unit with the treatment solution. The risk of serous eye damage will be minimal if protective goggles or eye protection is used during the performance of these tasks.

**Conclusion**

***Industrial exposure***

*Net treatment activities:*

The risk to industrial workers involved in net impregnation activities (net dipping and vacuum impregnation) was assessed using the Dipping model 4 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net dipping tasks.

Acceptable risk is demonstrated in the systemic risk assessment for industrial workers performing net treatment activities in tier 2b (impermeable coveralls and chemical resistant gloves) for Meta SPC 1 (Alpha Net Guard (conc)) and Meta SPC 3 (Alpha Net Guard (RTU)). As for the products in Meta SPC 2 and 4, a borderline risk was demonstrated in tier 2c assuming use of double coverall (1% clothing penetration) and chemical resistant gloves. Due to the conservatism of the risk assessment, the proposal is to accept this slight exceedance of the reference value.

Due to the classification of the products for Eye damage 1 (H318), eye protection should additionally be used where eye exposure might take place.

***Professional exposure***

*Net deployment activities:*

The risk to professional workers involved in net deployment activities was assessed using the Handling model 2 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net deployment activities.

Acceptable or borderline risk is demonstrated in the systemic risk assessment of professional workers performing net deployment in tier I (use of gloves only) for all products. Acceptable risk is demonstrated with the use of gloves and uncoated coveralls for all products.

Gloves are always worn when performing net deployment, due to mechanical strain (and low temperature in the Atlantic region).

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

Not relevant – industrial and professional use only.

***Risk for the general public***

Not relevant – industrial and professional use only.

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

An acceptable risk is identified for potential exposure *via* food contamination. This is based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force. Exposure *via* food contamination may need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

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

Not relevant.

### Risk assessment for animal health

Not relevant for these products.

### Risk assessment for the environment

The environmental risk assessment covers the active substance dicopper oxide (Cu2O). The CuO BPF does not contain any substances of concern (SoC) for the environment.

Regarding the exposure to the environment from the use of the CuO BPF, the harmonised scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms (ECHA, 2015), hereafter referred to as the EU fish farm scenario, has been used for a first tier assessment at the EU level. In addition, an exposure assessment for Norwegian fish farms has been carried out, following the Norwegian environmental emission scenario for nets used in fish farms (NO, 2019), hereafter referred to as the Norwegian fish farm scenario. The latter represents an adjustment of the EU scenario to better reflect Norwegian fish farm conditions.

#### 2.2.8.1 Effects assessment on the environment

Dicopper oxide

An evaluation of the effect data for the active substance with relevance to the aquatic compartment can be found in the Competent Authority Report (CAR) for dicopper oxide (PT21, France, 2016).

The relevant ecotoxicological data and the calculated PNECs are summarized below:

**Predicted no effect concentrations for dicopper oxide used for the risk characterisation**

|  |  |  |
| --- | --- | --- |
| **PNEC** | **Result** | **Reference** |
| PNECmarina | 2.6 µg Cu/L | CAR dicopper oxide PT21, 2016 |
| PNECsurrounding waters | **1.15 µg Cu/L** | CAR dicopper oxide PT21, 2016 |
| PNECsea | 0.65 µg Cu/L | CAR dicopper oxide PT21, 2016 |
| PNECsediment | 98.8 mg Cu/kg sediment (dry weight) | CAR dicopper oxide PT21, 2016. |

For the marine compartment, 56 chronic NOEC/EC10 values, resulting in 24 different species-specific NOEC values covering different trophic levels (fish, invertebrates, algae), were retained for the PNEC derivation. NOEC values were related to the organic carbon (DOC) concentrations of the marine test media and species-specific NOECs were calculated after DOC normalizing of the NOECs. These species-specific NOECs were used for the derivation of species sensitivity distributions (SSD) and HC5-50 values, using statistical extrapolation methods. PNECs were derived for three different areas with differing DOC concentrations using an assessment factor of 2: harbours/marinas with a typical DOC concentration of 2 mg/L, surrounding waters with a typical DOC concentration of 0.5 mg/L and open sea with a typical DOC concentration of 0.2 mg/L. The emission scenario for fish nets (NO, 2015) assumes that the fish farm is located in coastal waters with low water flow velocities. Further, the EU emission scenario assumes water characteristics typical of more open waters. Therefore, for the purpose of the risk assessment, a PNECsurrounding water of 1.15 µg Cu/L is considered the most relevant for the fish farm scenario.

The PNECmarine sediment was calculated according to the equilibrium-partitioning concept based on a PNECwater using the 10th percentile of the Kd value for marine sediment according to the Guidance for environmental risk assessment for metals and metal compounds since no reliable toxicity data were available for the marine sediment compartment. The marine PNECsediment was determined to be 98.8 mg Cu/kg dw sediment (corresponding to 21.48 mg Cu/kg ww sediment)

Co-formulants

None of the co-formulants are regarded as substances of concern (SoC). Thus, no specific risk assessment of co-formulants has been carried out.

***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***

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to Reg. (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for Dicopper Oxide as well as the SDS for the components contained (attached in section 13 in substance/mixture dataset). The products contained in the BPR-family are to be classified concerning Acute and Chronic toxicity towards aquatic organisms.

Classification according to CLP:

Aquatic Acute 1; H400

Aquatic Chronic 1; H410

***Further Ecotoxicological studies***

No further ecotoxicological studies on CuOproducts are available.

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

There are no indications of non-target organisms believed to be at risk, which would justify further testing.

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

No supervised field trials to assess the risks to non-target organisms have been conducted.

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

No data available

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

Not relevant.

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

As described in the use instruction, the products are intended for professional use only and all industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place. Accordingly (and assuming the products are used as instructed) the only exposure of the (marine) environment identified is related to the release of Dicopper Oxide from the impregnated nets during deployment in the ocean as a result of leaching. No other environmental compartments are considered to be at risk.

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

Fate and behaviour of active substance dicopper oxide

The CAR for the active substance dicopper oxide (PT21, 2016) states that, because of the unique fate of copper in water, soil, sediment, and sludge, many of the data requirements listed in Section A7 of the Technical notes for Guidance are not applicable for inorganic compounds and metals; in particular e.g. hydrolysis, photodegradation and biodegradation. It is not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation. Subsequently, dicopper oxide, which is an inorganic salt, cannot be transformed into related degradation products other than copper ions (Cu2+) and water in solution. As with all metals, copper becomes complexed to organic and inorganic matter in waters, soil, and sediments and this affects copper speciation, bioavailability and thus toxicity, which mainly depends on the abundance of the copper ion. An important parameter determining the distribution of copper in the aquatic and soil environment is the adsorption onto solid materials and therefore partitioning coefficients. The concepts of octanol-water partitioning coefficient (Kow) and organic carbon partitioning coefficient (Koc) are not applicable to metals. Instead, the distribution of metals between the aqueous phase and soil/sediment/suspended matter could be described in terms of measured soil/water, sediment/water and suspended matter/water equilibrium distribution coefficients.

***Leaching behaviour (ADS)***

No data available

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

No data available.

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

No data available.

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

No data available.

**Aquatic bioconcentration**

Dicopper oxide

The CAR of the active substance dicopper oxide (PT21, 2016) states that copper becomes complexed to organic and inorganic matter in waters, soil, and sediments, and that this affects copper speciation, bioavailability, and thus toxicity, which mainly depends of the abundance of the copper ion. Because of the homeostasis of metals, BCF values are not indicative of the potential bioaccumulation. There is therefore limited evidence of accumulation and secondary poisoning of inorganic forms of metals, and also biomagnification in food webs. For the naturally occurring substances such as essential metals as copper, bioaccumulation is complex, and many processes are available to modulate both accumulation and potential toxic impact. Biota regulates their internal concentrations of essential metals through homeostatic control mechanisms (i.e. active regulation, storage). As a result of these processes, at low metal concentrations, organisms accumulate essential metals more actively in order to meet their metabolic requirements than when they are being exposed at higher metal concentrations. As a consequence of homeostatic processes, and unlike many organic substances, the BCF/BAF is not independent of exposure concentrations for metals and is rather inversely related to exposure concentrations. Thus, the use of ratios Cbiota/Cwater or Cbiota/Csediments as an overall approach for estimating copper bioconcentration factors is not appropriate.

***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)***

Not relevant.

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

Not relevant.

#### 2.2.8.2 Environmental exposure assessment and risk characterisation

Exposure to the environment from the use of the CuO BPF has been assessed in two tiers:

1. The first tier assessment is based on the EU fish farm scenario document agreed at EU level.
2. A second tier assessment with special regard to Norwegian fish farms has been conducted based on the Norwegian fish farm scenario document (available as an annex under section 3.7). This represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway. The most notable adjustments made in the Norwegian fish scenario as compared to the EU fish farm scenario, are that the net size (area) and sea depth is increased, the flow velocity is very slightly increased, and the parameters related to (suspended) organic matter have been adjusted. All the adjustments have been done following an investigation of information for 232 fish farm facilities which were considered relevant, i.e. they are marine salmon, trout and rainbow trout farms, and they have a moderate to high production capacity (in order to capture the trend towards larger fish farms). Please see the scenario document for details on the data gathering and selection of final values.

General information on the exposure assessment is given in the table below.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 21 |
| Assessed scenarios | Environmental emissions from nets used in fish farms, during the deployment time of the nets in the sea.  Only professional uses of the CuO products are envisaged and have been assessed. |
| Emission Scenario Document used | For the assessment covering use in the EU, the EU fish farm scenario was used, as a tier 1 assessment:  *Scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms. Norwegian Environmental Agency, 2015.*  For the assessment representative for Norway (i.e. a tier 2 assessment for the use in Norway), the Norwegian fish farm scenario was used:  *A Norwegian environmental emission scenario for fish farms - Adjustment of the EU scenario (2015) to better represent national conditions. Norwegian Environmental Agency, 2019.* |
| Approach | MAMPEC v.3.1 was used for the modelling.  For the active substance, agreed values from the CAR was used as input. For other environmental parameters, default values for the environmental parameters given in the above-mentioned scenario documents were used, in addition to product-specific values where applicable (e.g. the value “Coverage of product, COVERAGE” which has been replaced with a product specific value of 0.9 L/kg based on the input by the applicant). |
| Distribution in the environment | The PEC values in water and sediment were calculated with MAMPEC v.3.1 based on the input described above. |
| Life cycle steps assessed | Production: No  Formulation No  Use: No  Service life: Yes |

***Emission estimation***

In the following tables, some of the input parameters used for the calculations of daily local emissions (Elocal) and predicted environmental concentrations (PECs) are given. Elocal was calculated as follows, in accordance with the scenario documents:

Elocal (g/d) = (Nnet ∙ AREAnet ∙ Wnet ∙ COVERAGE ∙ Ca.i. ∙ Fa.i.) / Tdeployment

Subsequently, the Elocal values were entered into MAMPEC for the modelling of PECs. In the first table, Elocal input parameters and some input parameters for the PEC modelling are given, for both the EU fish farm scenario and the Norwegian fish farm scenario (for a full list of all input parameters and reasoning behind them, see the respective scenario documents). The second table lists the active substance input parameters, and the third table gives the concentrations of active substances used for the Elocal calculation of the different products.

All calculations of Elocal, and details on the MAMPEC modelling, can be found as annexes under section 3.2.1.

**Parameters for emission (Elocal) and PEC calculations**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **EU fish farm scenario1 (tier 1)** | **Norwegian fish farm scenario2 (tier 2)** |
| Concentration of a.i. in product, Ca.i. | *See table below* | *See table below* |
| Number of nets per fish farm area, Nnet | 10 | 10 |
| Area of each net, Areanet | 5103 m2 | 7770 m2 |
| Weight per m2 of net, Wnet | 0.36 kg/m2 | 0.36 kg/m2 |
| Coverage of product (amount of product used per kg net) | 1 L/kg\* | 1 L/kg\* |
| Fraction of released a.i. per deployment time of nets, Fa.i. | 0.8 | 0.8 |
| Time net is deployed in water, T deployment | 180 days | 180 days |
| Fish farm area (length [x] × width [y]) | 300 × 450 m | 280 × 610 m |
| Sea depth | 30 m | 60 m |
| Flow velocity | 3 cm/s | 3.2 cm/s |
| Salinity | 34 psu | 33.2 psu |
| Temperature | 9 °C | 8.6 °C |

1 Please see the [Emission scenario for nets used in fish farms (ECHA, 2015)](https://echa.europa.eu/documents/10162/16908203/esd_fish_net-aquaculture_2015_final.pdf/59cf4c4f-b04e-4006-baa7-de1965714c62) available from ECHA's webpage for the full set of parameters.

2 Please see the [Norwegian fish farm scenario (NO, 2019)](https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY) for the full set of parameters.

\*Coverage of 0.9 L/kg has been used in the calculations based on input on the application rate provided by the applicant.

**Active substance input parameters**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Active substance** | **Parameter** | **Unit** | **Value** | **Reference** |
| **Copper (total)** | Molecular mass | g/mol | 63.5 | PT 21 ESD excel copper |
| Saturized vapour pressure at 20°C | Pa | 0 |
| Solubility at 20°C | g/m3 | 0.001 |
| Kd | m3/kg | 132 |

**Concentration of active ingredient (Cu) in the CuO products**

|  |  |  |  |
| --- | --- | --- | --- |
| **RTU Products** | **Concentration of Cu2O in product (%, w/w)** | **Concentration of Cu2O in product (g/L)** | **Concentration of Cu in products (g/L)** |
| Notorius A (Yellow/Black; RTU) | 19.9 | 224.87 | 197.89 |
| Notorius A12 (Red/Black; RTU) | 12.00 | 135.60 | 119.33 |
| Notorius A15 (Red/Black; RTU) | 14.94 | 168.82 | 148.56 |
| Alpha Net Gard (Red/Black; RTU) | 12.04 | 136.05 | 119.73 |
| **Conc.** | **Concentration of Cu2O in product (%, w/w)** | **Concentration of Cu2O in product (g/L)** | **Concentration of Cu in products (g/L)** |
| Notorius A (Yellow/Black; Conc.) | 27.64 | 239.55 | 210.80 |
| Notorius A12 (Red/Black; Conc.) | 21.67 | 173.42 | 152.61 |
| Notorius A15 (Red; Conc.) | 24.36 | 140.86 | 123.95 |
| Alpha Net Gard (Red; Conc.) | 18.01 | 146.33 | 128.77 |

Following the approach described above, Elocal values were calculated for all the products. The table below gives the Elocal for both the EU fish farm scenario (tier 1) and the Norwegian fish farm scenario (tier 2).

**Daily Cu emission outputs (Elocal)**

|  |  |  |
| --- | --- | --- |
| **Product** | **EU fish farm scenario**  **(tier 1)** | **Norwegian fish farm scenario (tier 2)** |
| Notorius A (Yellow/Black) RTU | 14542 | 22142 |
| Notorius A12 (Red/Black) RTU | 8769 | 13352 |
| Notorius A15 (Red/Black) RTU | 10917 | 16622 |
| Alpha Net Gard (Red/Black) RTU | 8798 | 13396 |
| Notorius A (Yellow/Black) conc | 15490 | 23586 |
| Notorius A12 (Red/Black) conc | 11214 | 17075 |
| Notorius A15 (Red/Black) conc | 9108 | 13869 |
| Alpha Net Gard (Red/Black) conc | 9462 | 14408 |

**Background concentrations for Cu**

Background concentrations for Cu in water and sediment of **1.1 µg/L and 16.1 µg/g**, respectively, should be added to the predicted environmental concentrations. This is in line with the EU-agreed background concentrations used for the active substance evaluation for the marina scenarios for antifouling paints on recreational crafts, including the regional Atlantic marina scenario. It is not considered suitable to use the background values for open sea (0,5 µg/L for water and 3,5 µg/g for sediment), since the open sea background concentrations represent areas that are further away from the sources for release of Cu. The background concentrations can be integrated in the MAMPEC modelling or they can be added manually after calculating the steady-state PECs (without background concentrations) in MAMPEC. We chose the latter approach.

***Calculated PEC values and risk characterisation – Tier 1: the EU fish farm scenario***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.19 | 0.17 | 25.25 | 0.26 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.29 | **1.12** | 41.35 | 0,42 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.12 | 0.10 | 15.22 | 0.15 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.22 | **1.06** | 31.32 | 0.32 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.14 | 0.12 | 18.95 | 0.19 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.24 | **1.08** | 35.05 | 0.35 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.12 | 0.10 | 15.27 | 0.15 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.22 | **1.06** | 31.37 | 0.32 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) (conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.20 | 0.18 | 26.89 | 0.27 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) (conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.30 | **1.13** | 42.99 | 0.44 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.15 | 0.13 | 19.47 | 0.20 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.25 | **1.08** | 35.57 | 0.36 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.12 | 0.10 | 15.81 | 0.16 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.22 | **1.06** | 31.91 | 0.32 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.12 | 0.11 | 16.43 | 0.17 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 1.22 | **1.06** | 32.53 | 0.33 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

The resulting PEC/PNEC ratios without background concentrations were found to be below the trigger value of 1. However, in the tier 1 calculations, the PEC/PNEC ratios for PECdissolved/PNECwater ratios with background concentrations of Cu were slightly above the trigger value for the CuO products.

***Calculated PEC values and risk characterisation – Tier 2: the Norwegian fish farm scenario***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.07 | 0.06 | 9.32 | 0.09 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.17 | 1.02 | 25.42 | 0.26 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.04 | 0.04 | 5.62 | 0.06 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.14 | 0.99 | 21.72 | 0.22 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.05 | 0.05 | 6.99 | 0.07 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.15 | 1.00 | 23.09 | 0.23 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.04 | 0.04 | 5.64 | 0.06 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard RTU**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.14 | 0.99 | 21.74 | 0.22 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.08 | 0.07 | 9.92 | 0.10 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A (Yellow/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.18 | 1.02 | 26.02 | 0.26 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.05 | 0.05 | 7.18 | 0.07 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A12 (Red/Black) (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.15 | 1.00 | 23.28 | 0.24 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.04 | 0.04 | 5.84 | 0.06 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notorius A 15 (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.14 | 0.99 | 21.94 | 0.22 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.05 | 0.04 | 6.06 | 0.06 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Alpha Net Gard (Conc)**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.15 | 1.00 | 22.16 | 0.22 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

In the tier 2 calculations, the resulting PEC/PNEC ratios without and with background concentrations were found to be ≤ the trigger value of 1.

***Secondary poisoning***

Dicopper oxide

The CAR of the active substance dicopper oxide (PT21, 2016) states that because of the homeostasis of metals, BCF values are not indicative of the potential bioaccumulation. There is therefore limited evidence of accumulation and secondary poisoning of inorganic forms of metals, and biomagnification in food webs.

#### 2.2.8.3 Risk characterisation

***Atmosphere***

Not relevant.

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

Not relevant.

***Aquatic compartment***

**Risk characterisation for the EU fish farm scenario (tier 1)**

PEC/PNEC ratios based on PEC values calculated with the EU fish farm scenario are summarised in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values\*, EU fish farm scenario** | | |
|  | **PECdissolved/PNECwater** | **PECsuspended matter/ PNECsed** |
| **Notorius A (Yellow/Black) RTU** | | |
| Total copper | **1.12** | 0.42 |
| **Notorius A12 (Red/Black) RTU** | | |
| Total copper | **1.06** | 0.32 |
| **Notorius A15 (Red/Black) RTU** | | |
| Total copper | **1.08** | 0.35 |
| **Alpha Net Gard (Red/Black) RTU** | | |
| Total copper | **1.06** | 0.32 |
| **Notorius A (Yellow/Black) (conc)** | | |
| Total copper | **1.13** | 0.44 |
| **Notorius A12 (Red/Black) (conc)** | | |
| Total copper | **1.08** | 0.36 |
| **Notorius A15 (Red/Black) (conc)** |  |  |
| Total copper | **1.06** | 0.32 |
| **Alpha Net Gard (Red/Black) (conc)** |  |  |
| Total copper | **1.06** | 0.33 |

\*with background concentrations of copper

In tier 1 calculations, the PEC/PNEC ratios for PECdissolved/PNECwater were all slightly above the trigger value.

**Risk characterisation for the EU fish farm scenario (tier 2)**

New parameters have been included in MAMPEC after the development of the EU fish farm-scenario, and the EU fish farm scenario needs to be modified with respect to the inputs for *Wind speed* and *Fraction of time wind perpendicular*. The Norwegian Environment Agency has raised this issue with ECHA in order to get a harmonized solution for all PT 21 products used in aquaculture. For this BPF, the refMS has calculated the EU fish farm scenario with values for *Wind speed* (3.8 m/s) and *Fraction of time wind perpendicular* (0.5) from the [NORDIC ANTIFOULING PROJECT](http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1316151&dswid=-4507). However, these modifications did not impact the PEC/PNEC ratios.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values\*, EU fish farm scenario** | | |
|  | **PECdissolved/PNECwater** | **PECsuspended matter/ PNECsed** |
| **Notorius A (Yellow/Black) RTU** | | |
| Total copper | **1.12** | 0.42 |
| **Notorius A12 (Red/Black) RTU** | | |
| Total copper | **1.06** | 0.32 |
| **Notorius A15 (Red/Black) RTU** | | |
| Total copper | **1.08** | 0.35 |
| **Alpha Net Gard (Red/Black) RTU** | | |
| Total copper | **1.06** | 0.32 |
| **Notorius A (Yellow/Black) (conc)** | | |
| Total copper | **1.13** | 0.44 |
| **Notorius A12 (Red/Black) (conc)** | | |
| Total copper | **1.08** | 0.36 |
| **Notorius A15 (Red/Black) (conc)** |  |  |
| Total copper | **1.06** | 0.32 |
| **Alpha Net Gard (Red/Black) (conc)** |  |  |
| Total copper | **1.06** | 0.33 |

\*with background concentrations of copper

In tier 2 calculations, the PEC/PNEC ratios for PECdissolved/PNECwater were slightly above the trigger value.

The exceedances of PEC/PNEC are minor (PECdissolved/PNECwater are just over 1) based on conservative modelling which represents a worst case scenario.

**The Baltic Sea**

In areas with low fouling, such as the Baltic Sea, the applicant recommends that the nets are deployed for ca. 2 years before they are taken up to be cleaned and reimpregnated.  The default deployment period of 180 days used in this assessment is, therefore, considered to be worst case. In addition, as a risk mitigation measure, the applicant has added label restrictions against in-situ cleaning.

Applying the label restriction concerning in-situ cleaning as a risk management measure, as well as a deployment time of 2 years in areas with low fouling such as the Baltic Sea, , will ensure a safe use of the products in Meta SPC 3.

However, in order to avoid more use of copper in the Baltic Sea than what is necessary and to limit release of copper to the environment, the products in Meta SPC 1, 2, and 4 should not be applied to nets meant for use in the Baltic Sea.

**The Norwegian fish farm scenario**

Risk characterisation for the Norwegian fish farm scenario (tier 2)

PEC/PNEC ratios based on PEC values calculated with the Norwegian fish farm scenario are summarised in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values\*, Norwegian fish farm scenario** | | |
|  | **PECdissolved/PNECwater** | **PECsuspended matter/PNECsed** |
| **Notorius A (Yellow/Black) RTU** | | |
| Total copper | 1.0 | 0.26 |
| **Notorius A12 (Red/Black) RTU** | | |
| Total copper | 0.99 | 0.22 |
| **Notorius A15 (Red/Black) RTU** | | |
| Total copper | 1.0 | 0.23 |
| **Alpha Net Gard (Red/Black) RTU** | | |
| Total copper | 0.99 | 0.22 |
| **Notorius A (Yellow/Black) (Conc)** | | |
| Total copper | 1.0 | 0.26 |
| **Notorius A12 (Red/Black) (conc)** | | |
| Total copper | 1.0 | 0.24 |
| **Notorius A15 (Red/Black) (conc)** | | |
| Total copper | 1.0 | 0.23 |
| **Alpha Net Gard (Red/Black) (conc)** | | |
| Total copper | 1.0 | 0.22 |

\*with background concentrations of copper

For the Norwegian fish farm scenario, PEC/PNEC ratios were found to be ≤ 1.

All CuO BPF products therefore show acceptable risk to the aquatic environment.

***Terrestrial compartment***

Not relevant.

***Groundwater***

Not relevant.

***Primary and secondary poisoning***

Primary poisoning

Reference is made to the Risk characterisation for the aquatic compartment above.

Secondary poisoning

Not relevant. Dicopper oxide does not bioaccumulate.

Because of the homeostasis of metals, BCF values are not indicative of the potential bioaccumulation. There is therefore limited evidence of accumulation and secondary poisoning of inorganic forms of metals, and biomagnification in food webs.

***Mixture toxicity***

Not relevant.

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

Not relevant.

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

Reference is made to summary of the product assessment provided in section 2.1

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Not relevant.

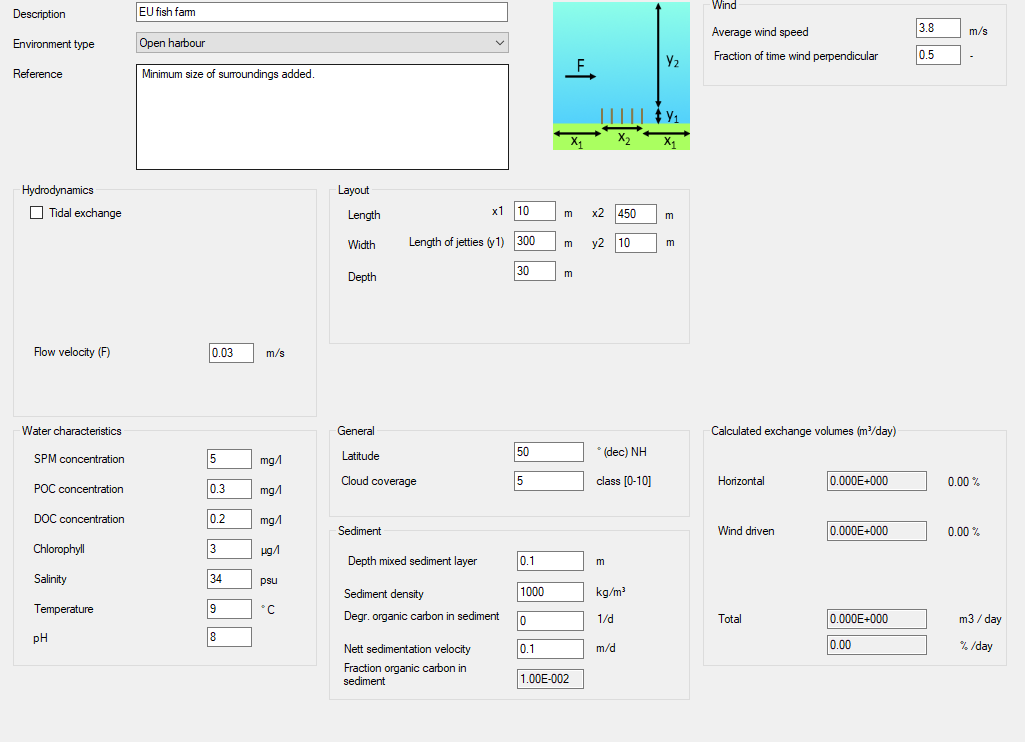
# Annexes

## List of studies for the biocidal product (family)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Legal entity owner for all references listed below is Brynsløkken AS | | | | | | | |
| Author | Year | Title | Bibliographic source | Testing laboratory | Report no. | Endpoint names | Endpoint UUIDs |
| Bee, T. | 2022 | Physico-chemical Testing on a Sample of Notorius A concentrate (black) and Notorius A RTU |  | DEKRA UK Ltd. | GLP3016010236R1/2021 | 4.1; 4.4; 4.6; 4.8; 4.16; 4.17.1 |  |
| Blackstock, C. | 2019 | The *In Vitro* Percutaneous Absorption of Dicopper Oxide in Three  Formulations through Human Split-Thickness Skin |  | Charles River Laboratories Edinburgh Ltd. | 784022 | 8.6 | 11b60a27-a84d-4ded-b044-348369b75591 |
| Johannesen, S.A. | 2018a | Test Report - 782237 Notorius A |  | Danish Technological Institute | 782237 | 3.1; 3.2; 3.3; 3.4.1; 3.5; 3.8; 3.9; 4.17; 12.3 | 34c16e33-61b1-4d45-baed-92c1566e5273; 5a59373a-7b98-4376-970f-7f57c6a2862d;  159120ab-2f2d-4e60-ba38-9ad3b8e5e1b9;  2484a569-bc46-4271-8efc-c0f6d097e8b7;  879953b0-98db-43c3-b993-83ebf8311a44;  a86373ab-83be-4845-9c86-f36f4c935adb;  43ca77a8-d363-4f35-8b68-356f5a20d54d;  52359686-8ff3-46cf-80b3-6c3a89093457;  ec807c1f-1e7b-451f-8a6c-36d477233088;  b5ea2503-6d4b-43f1-bab4-b144b07794d6;  883dd4ac-4172-42c9-9030-f821e5b843a3;  ec206ae9-3430-4c7a-861b-90fa294cde3b |
| Johannesen, S.A. | 2019a | Test Report - 782237-3 1Y Notorius A |  | Danish Technological Institute | 782237-3 1Y Notorius A | 3.1; 3.2; 3.4.1;  3.5 | 8ecccb0c-a78d-4284-adce-ea0e46ce59b2;  dd7d34ae-e0b5-4a9b-9962-e63708ce4602;  c5efca4f-20bc-423e-bbd3-2bb8c4ee6d9c;  64da8b68-033e-44ae-8a3b-892407d7107c;  92258a60-3918-4e7e-892a-cf9d10cbf425;  e11598ae-4927-4a79-9c84-ee8e62e6f771 |
| Johannesen, S.A. | 2018b | Test Report - 782237 Notorius A12 |  | Danish Technological Institute | 782237 | 3.1; 3.2; 3.3; 3.4.1; 3.5; 3.8; 3.9; 12.3 | ac188138-1905-444c-8693-c28e034ecd80;  2260222b-6981-47b5-a59c-40281293ebf2;  8a513ddf-e480-44bd-a380-91594a4c2c24;  425a41e6-d8fb-46be-b783-07304f9efdd0;  11fbac7f-9ad6-4ee9-b94b-3905ff22100d;  8227e966-f2a3-4778-8b51-671e1eadfe48;  f8752600-7ad4-4248-8ea8-4b07885d944d; |
| Johannesen, S.A. | 2019b | Test Report - 782237-4 1Y Notorius A12 |  | Danish Technological Institute | 782237-4 1Y Notorius A12 | 3.1; 3.2; 3.4.1;  3.5 | 2a6cb8d0-52fa-411d-beda-fb5323cd8b76;  da2b847d-e68d-45fb-864f-11713928057b;  71d8a01d-64b6-4df6-b598-23c92e402909;  5f9c8115-dc00-4a02-a7a2-875a43b09c20; |
| Johannesen, S.A. | 2018e | CSA 102 Determination of the total content of copper in Notorius  A and Notorius A12 and aqueous dilutions of Notorius A |  | Danish Technological Institute | 782237 | 5 | 15cbc6b1-a585-4d96-9b34-a4b8925a76a6 |
| Johannesen, S.A. | 2018h | Method Validation Report - 782237 MV CSA 102 |  | Danish Technological Institute | 782237 MV CSA 102 | 5 | 6c9afe0a-3249-4e32-a154-db546d032126 |
| Oxenham, S. | 2019 | 422217 - Validation of an Inductively Coupled Plasma – Mass Spectrometry Method for the Determination of Copper in Dermal Penetration Media Samples |  | Charles River Laboratories Edinburgh Ltd |  | 5 | 3cc1efe1-5fe4-48cd-9ffb-76ec3e62af1c |
| Pedersen, R.B.,. | 2018 | Efficacy studies for Notorius antifouling |  | Brynsløkken AS & mediator A/S |  | 6.7 | f5822c61-f054-4112-99c5-cc0a31464dc528251776-9252-42a4-9120-3c5b3ce60703 |
| Ohnstad, V. | 2018 | Application |  | Brynsløkken AS |  | 7.6 | e71add4c-f1b2-4321-8bdd-627a07f2cab6 |
| Ohnstad, V. | 2018 | Description of production |  | Brynsløkken AS |  | 7.6 | e71add4c-f1b2-4321-8bdd-627a07f2cab6 |

## Output tables from exposure assessment tools

### Output tables from the environment exposure assessments



The following excel-files have been uploaded to R4BP3 separately:

MAMPEC\_Alpha Net Gard conc\_EU.xlsx

MAMPEC\_Alpha Net Gard conc\_NO.xlsx

MAMPEC\_Alpha Net Gard RTU\_EU.xlsx

MAMPEC\_Alpha Net Gard RTU\_NO.xlsx

MAMPEC\_Notorius A\_conc\_EU.xlsx

MAMPEC\_Notorius A\_conc\_NO.xlsx

MAMPEC\_Notorius A\_RTU\_EU.xlsx

MAMPEC\_Notorius A\_RTU\_NO.xlsx

MAMPEC\_Notorius A12 conc \_EU.xlsx

MAMPEC\_Notorius A12 conc \_NO.xlsx

MAMPEC\_Notorius A12 RTU\_EU.xlsx

MAMPEC\_Notorius A12 RTU\_NO.xlsx

MAMPEC\_Notorius A15 conc \_EU.xlsx

MAMPEC\_Notorius A15 conc \_NO.xlsx

MAMPEC\_Notorius A15 RTU \_EU.xlsx

MAMPEC\_Notorius A15 RTU \_NO.xlsx

### Output tables from the human exposure assessments

The following excel-file has been uploaded to R4BP3 separately:

Brynsløkken\_Exposure dicopper oxide.xlsx

## New information on the active substance

Not relevant. No new data provided.

## Residue behaviour

Not relevant.

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

Please see section 2.2.5.5 and iuclid.

## Confidential annex

Please see the separate confidential annex.

## Other

**REFERENCES**

* Bernhard et al., 2020; Monitoring Program for Pharmaceuticals, illegal substances and contaminants in farmed fish – Annual Report for 2019.
* Bloecher, N, Floerl, O (2018) Guidelines for efficacy testing of antifouling coatings for nets in field tests. Technical paper, Norwegian Environment Agency, Oslo. <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB>
* European Chemicals Agency (ECHA), 2014. Committee for Risk Assessment; RAC opinion proposing harmonised classification and labelling at EU level of Dicopper oxide. Adopted 4 December 2014.
* European Chemicals Agency (ECHA), 2015. Emission scenario for nets used in fish farms.
* European Chemicals Agency (ECHA), 2015a. Biocides human health exposure methodology. Version 1. Helsinki.
* European Chemicals Agency (ECHA), 2016a. Assessment Report. Evaluation of the active substance Dicopper oxide. Product type 21. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
* European Chemicals Agency (ECHA), 2016b ECHA Report of Dermal Absorption of PT 21 Active Substances. Agreed at Human Health Working Group Meeting WG-V-2016 (9 December 2016).
* European Chemicals Agency (ECHA), 2016c. “Dermal absorption from antifouling products and other matrices that form a dry film during testing” Report of workshop held in Berlin 19 May 2016 Date of report 19 August 2016.
* European Chemicals Agency (ECHA), 2017a). Guidance on the Biocidal Products Regulation. Volume III. Human Health. Assessment & Evaluation (Part B+C), version 4.0, Helsinki.
* European Chemicals Agency (ECHA, 2017b). Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure. Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017).

European Chemicals Agency (ECHA, 2017c). Guidance on the Application of the CLP Criteria, Version 5.0.

* European Chemicals Agency (ECHA), 2019. Draft proposal: "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA".
* European Commission (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L 353, 1-1355
* European Food Safety Authority (EFSA); Buist, H. et al. 2017: Guidance on dermal absorption.. EFSA Journal, Volume 15, Issue 6, June 2017.
* Human Exposure Expert Group (HEEG) 2010. Opinion 9. Default protection factors for protective clothing and gloves. Ispra, 27.01.2010.
* Lundebye, A-K, et al (2017). Lower levels of Persistent Organic Pollutants, metals and the marine omega 3-fatty acid DHA in farmed compared to wild Atlantic salmon (Salmo salar), Environmental Research 155 (2017) 49–59.
* NO, 2019. A Norwegian environmental emission scenario for nets used in fish farms – Adjustment of the EU scenario (2015) to better reflect national conditions (Norwegian Environment Agency, 2019) <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY>
* OECD Guideline for Testing of Chemicals, Guideline 428: Skin Absorption: In Vitro Method (2004a)
* OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 28; Guidance Document for the Conduct of Skin Absorption Studies (2004b)
* Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment (CA-March21-Doc.4.3\_Final "Bridging Biocides with REACH) (available from: https://circabc.europa.eu/sd/a/987cb9c0-2c8e-45d6-b431-aa456d0584ea/CA-March21-Doc.4.3\_Final\_Bridging%20Biocides%20with%20REACH.docx)

1. Guidance on the Biocidal Products Regulation Volume I: Identity/physico-chemical properties/analytical methodology. Part A: Information Requirements Version 2.0. May 2018. [↑](#footnote-ref-2)
2. The minimum and maximum Cu concentration in µg/ml is 1.205-2.41 µg/ml for Notorius A (24.1 % w/w Cu) and 0.525-1.05 µg/ml for Notorius A12 (10.5 % w/w Cu). [↑](#footnote-ref-3)
3. OECD Guideline for Testing of Chemicals, Guideline 428: Skin Absorption: In Vitro Method (2004); OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 28; Guidance Document for the Conduct of Skin Absorption Studies (2004); Guidance on Dermal Absorption (EFSA Journal, 2017; 15(6): 4873); [↑](#footnote-ref-4)