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**



Aquanet Northsea Product Family

Product type(s) 21

Dicopper oxide

Case Number in R4BP3:[BC-QX036506-04]

Evaluating Competent Authority: Norway

Date: [11/10/2022]

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# CONCLUSION

The biocidal product family AquaNet Northsea Product Familycontains the active substance dicopper oxide. The product family is intended for treatment of fish nets to prevent fouling of the nets during use. The treatment of the net is performed in specialised facilities, and the user categories are 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. When using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

Toward the end of the evaluation phase, a risk for human health was identified for the product named AquaNet NorthSea Ultra. Therefore, the product named AquaNet NorthSea Ultra was modified, and the amount of active substance content was reduced to an acceptable level. The active substance dicopper oxide was reduced from 29.5%(w/w) to 21.80%(w/w). Please note that the studies performed on the old version of AquaNet NorthSea Ultra may be used for some endpoints. It is specified in the text whether the new or old formulation has been used, and the postfix "old" has been added to the name (i.e. " AquaNet NorthSea Ultraold"). In those cases, read across from the old to the new formulation has been evaluated and deemed acceptable. The composition of AquaNet NorthSea Ultra old can be found in the confidential annex.

The identity, physico-chemical properties and analytical methods were adequately addressed. The biocidal product family contains 14.23 -26.42%w/w dicopper oxide. The representative products are liquids, red in color with at pH of 9.1. The density of the concentrated products is 1.32 g/cm3 for the in-use concentrations. The products have a shelf life of 12 months when stored protected from frost.

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 AquaNet NorthSea BPF (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 AquaNet NorthSea CCT 100 plus and AquaNet NorthSea C50 provided that the workers wear coated coveralls and gloves and for AquaNet NorthSea Standard provided that the workers wear double coveralls and gloves.

Safe use could not be demonstrated for AquaNet NorthSea Ultraold even with use of double coveralls and gloves (see above). An acceptable risk was demonstrated with NorthSea Ultra with the use of 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 for all family members except for AquaNet NorthSea Ultraold, provided that the workers wear gloves (the indicative hand exposure value in the exposure model was actual measured values inside gloves). Acceptable risk for AquaNet NorthSea Ultraold was demonstrated provided the use of uncoated cotton coveralls (25% penetration) in addition to gloves. 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 damage 1 (H318), protective goggles or similar eye protection should be used for the tasks where the workers may be at risk to be exposed to the product.

Risk to the environment from the use of the Aquanet NorthSea BPF has been assessed in two tiers. For the effects assessment, values agreed at EU level have been used. For the exposure assessment, both the EU fish farm scenario and the Norwegian fish farm scenario were used in the assessment. The latter represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway. A higher tier assessment based on field data has also been conducted.

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 all North Sea products. In the EU scenario, refined calculations based on leaching rates in a field study with nets that were not in-situ cleaned, the PEC/PNEC ratios were found to be ≤ 1, indicating acceptable environmental risk. For all products, PEC/PNEC ratios were ≤ 1 also in the Norwegian fish farm scenario, indicating acceptable environmental risk.

In low-fouling conditions such as in the Baltic Sea, the product 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 and 2 should not be applied to nets meant for use in the Baltic Sea.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative Information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| Product family: North Sea products, consisting of | NO, DK, FI, EL, ES |
| AquaNet Northsea STANDARD |  |
| AquaNet Northsea ULTRA |  |
| AquaNet Northsea CCT100PLUS |  |
| AquaNet Northsea C50 |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Steen-Hansen A/S |
| **Address** | Ulsmågveien 24, NO-5224 Nesttun  Norway |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Steen-Hansen A/S |
| **Address of manufacturer** | Ulsmågveien 24, NO-5224 Nesttun, Norway |
| **Location of manufacturing sites** | Ulsmågveien 24, NO-5224 Nesttun, Norway |

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

|  |  |
| --- | --- |
| **Active substance** | Dicopper oxide |
| **Name of manufacturer** | Spiess-Urania Chemicals GmbH |
| **Address of manufacturer** | Frankenstraβe 18b 20097 Hamburg Germany |
| **Location of manufacturing sites** | c/o Aurubis AG  Müggenburger Hauptdeich 2  20539 Hamburg |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substances

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Dicopper oxide |
| **IUPAC or EC name** | Dicopper oxide, copper (1) 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** | 94.2% |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance is not considered as a candidate for substitution.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Common name | IUPAC name | Function | CAS number | EC number | Content (% w/w) |
| Dicopper oxide | Copper(I)oxide | Active substance | 1317-39-1 | 215-270-7 | 17.46 - 26.42 |
| Silicon dioxide | - | Non-active substance (substance of concern) | 7631-86-9 and 112945-52-5 | 231-545-4 | 0.171 – 0.244 |

The full composition of the biocidal product family can be found in the confidential annex.

**Overview of the meta-SPCs**

|  |  |  |  |
| --- | --- | --- | --- |
| **meta-SPC number** | **1** | **2** | **3** |
| **Product name(s)** | Aquanet NorthSea Standard  Aquanet NorthSea Ultra | Aquanet NorthSea CCT 100 plus | Aquanet NorthSea C50 |
| **In use concentration**  **Cu2O (% w/w)** | 17.46-21.8 | 15.23 | 14.23 |
| **Concentrate concentration**  **Cu2O (% w/w)** | - | 26.42 | 19.83 |
| **Formulation type** | SD – Suspension concentrate for direct application | SC – Suspension concentrate (= flowable concentrate) | SC – Suspension concentrate (= flowable concentrate) |

-

**Overview of the individual products in the family**

|  |  |  |  |
| --- | --- | --- | --- |
| Product name | Formulation | Dicopper oxide (Cu2O, % w/w) | In-use concentration (Cu2O, % w/w) |
| AquaNet NorthSea product family |  | 17.46 – 26.42 | 14.23 – 21.8 |
| Aquanet NorthSea Standard | Ready for use | 17.46 | 17.46 |
| Aquanet NorthSea Ultra | Ready for use | 21.8 | 21.8 |
| Aquanet North ea CCT 100 plus | Concentrate (1:1 dilution) | 26.42 | 15.23 |
| Aquanet NorthSea C50 | Concentrate (1:0.5 dilution) | 19.83 | 14.23 |

The full composition details of the formulations are contained within the confidential annex of this PAR.

#### Information on technical equivalence

Spiess-Urania Chemicals GmbH is listed as an approved supplier. The source of the active substance is the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation No. 528/2012. Thus, no assessment for TE is needed.

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

See the Confidential annex for an evaluation of substances of concern present in the biocidal product family.

#### Type of formulation

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

### Hazard and precautionary statements

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

**Meta SPC 1**

| **AquaNet Northsea Standard and AquaNet Northsea Ultra** | | |
| --- | --- | --- |
| **Classification** | | |
| Hazard category | Met. Corr. 1  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H290: May be corrosive to metals  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
|  | | |
| **Labelling** | | |
| Hazard pictograms |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger | |
| Hazard statements | H290: May be corrosive to metals  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P234 - Keep only in original packaging.  P390 - Absorb spillage to prevent material damage  P406 - Store in corrosion- resistant/… container with a resistant inner liner.  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 | This mixture does not contain substances which meet the PBT or vPvB criteria of REACH regulation, annex XIII | |

**Meta SPC 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **AquaNet Northsea CCT100 Plus** | | | |
| **Classification** | | | |
| Hazard category | Met. Corr. 1  Acute Tox. 4 (Oral)  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H290: May be corrosive to metals  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 Pictograms |  |  | pollut1 |
| GHS07 | GHS05 | GHS09 |
| Signal words | Danger | | |
| Hazard statements | H290: May be corrosive to metals  H302: Harmful if swallowed  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | | |
| Precautionary statements | P234 - Keep only in original packaging.  P390 - Absorb spillage to prevent material damage  P406 - Store in corrosion- resistant/… container with a resistant inner liner.  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  P330: 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 | | |
| Supplemental hazard information | EUH208: Contains a mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one (CMIT/MIT) 3:1. May produce an allergic reaction. | | |
|  | | | |
| Note | This mixture does not contain substances which meet the PBT or vPvB criteria of REACH regulation, annex XIII | | |

**Meta SPC 3**

| **AquaNet Northsea C50** | | |
| --- | --- | --- |
| **Classification** | | |
| Hazard category | Met. Corr. 1  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H290: May be corrosive to metals  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
|  | | |
| **Labelling** | | |
| Hazard pictograms |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger | |
| Hazard statements | H290: May be corrosive to metals  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P234 - Keep only in original packaging.  P390 - Absorb spillage to prevent material damage  P406 - Store in corrosion- resistant/… container with a resistant inner liner.  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. | |
| Supplemental hazard information | EUH208: Contains a mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one (CMIT/MIT) 3:1. May produce an allergic reaction. | |
|  | | |
| Note | This mixture does not contain substances which meet the PBT or vPvB criteria of REACH regulation, annex XIII | |

### Authorised use(s)

#### Use description

Table 1. Use PT 21 – Antifouling coating (Meta SPC 1 – RTU)

|  |  |
| --- | --- |
| **Product Type** | 21 |
| **Where relevant, an exact description of the authorised use** | The Aquanet Northsea product family is intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | There are over 4000 fouling species from a variety of phyla   1. Slime, *e.g.* bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, *e.g.* barnacles,mussels and hydrozoans species |
| **Field of use** | PT 21 – Antifouling products  The Aquanet Northsea products are used in the control of fouling organisms in marine environment. |
| **Application methods** | AquaNet Northsea Standard and AquaNet Northsea Ultra are ready-for-use products marketed in 1000 litre IBC HDPE containers as liquid formulations.  The products are intended to be applied by dipping or by vacuum treatment |
| **Application rate and frequency** | AquaNet NorthSea Standard: 1.0 litre of product per kg of net.  AquaNet NorthSea Ultra: 1.0 litre of product per kg of net. |
| **Category of users** | Industrial use only |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

Table 2. Use PT 21 – Antifouling coating (Meta SPC 2 – concentrate 1:1 dilution)

|  |  |
| --- | --- |
| **Product Type** | 21 |
| **Where relevant, an exact description of the authorised use** | The Aquanet Northsea product family is intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | There are over 4000 fouling species from a variety of phyla   1. Slime, *e.g.* bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, *e.g.* barnacles,mussels and hydrozoans species |
| **Field of use** | PT 21 – Antifouling products  The Aquanet Northsea products are used in the control of fouling organisms in marine environment. |
| **Application methods** | AquaNet Northsea CCT 100 Plus is a concentrate marketed in 1000 litre IBC HDPE containers as liquid formulation.  Aquanet Northsea CCT 100 plus is diluted 1:1 with water (v/v).  The product is intended to be applied by dipping or by vacuum treatment |
| **Application rate and frequency** | AquaNet NorthSea CCT 100 plus: 1.0 litre of product (ready to use concentration) per kg of net. |
| **Category of users** | Industrial use only |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

Table 3. Use PT 21 – Antifouling coating (Meta SPC 3 – Concentrate 1:0.5 dilution)

|  |  |
| --- | --- |
| **Product Type** | 21 |
| **Where relevant, an exact description of the authorised use** | The Aquanet Northsea product family is intended to be used for the protection of nets used in aquaculture against fouling. |
| **Target organism (including development stage)** | There are over 4000 fouling species from a variety of phyla   1. Slime, *e.g.* bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, *e.g.* barnacles,mussels and hydrozoans species |
| **Field of use** | PT 21 – Antifouling products  The Aquanet Northsea products are used in the control of fouling organisms in marine environment. |
| **Application methods** | Aquanet Northsea C50 is a concentrate marketed in 1000 litre IBC HDPE containers as liquid formulation. Aquanet Northsea C50 is diluted 1: 0.5 with water (v/v).  The product is intended to be applied by dipping or by vacuum treatment |
| **Application rate and frequency** | AquaNet NorthSea C50: 1.0 litre of product (ready to use concentration) per kg of net. |
| **Category of users** | Industrial use only |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

#### Use-specific instructions for use

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

#### Use-specific risk mitigation measures

|  |
| --- |
| Meta-specific PPE to be worn:  **RTUs: Meta SPC 1 (AquaNet Northsea Standard and AquaNet Northsea Ultra):**  Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves (EN 374).  A double coverall, a chemically resistant (at least type 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.  Use eye protection to EN 166, designed to protect against liquid splashes.  See also section 2.1.5.2.  **Concentrates: Meta SPC 2 (AquaNet Northsea CCT 100 Plus) and 3 (AquaNet Northsea C50):**  Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves (EN 374).  A protective coverall (at least type 6, EN-13034) shall be worn (coverall material to be specified by the authorisation holder within the product information).  Use eye protection to EN 166, designed to protect against liquid splashes.  See also section 2.1.5.2. |

#### 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 |

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

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

#### 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

#### Instructions for use

|  |
| --- |
| Ready for use-products must be stirred well before use.  Concentrates must be diluted with the correct amount of water, as specified on the label. The products must be stirred well after addition of water. Dipping tanks with stirring or pumping equipment must be used.  Density and viscosity must be measured prior to dipping, the measured values must be within the technical specification for the individual products. Density and viscosity must be measured to ensure that the product is homogeneous prior to dipping. Please follow the manufacturer's directions for how to measure density and viscosity.  Dilution procedure:  After transferring the concentrated product to either a holding tank or a dipping tank, the IBC must be filled with the correct amount of water. The water is then transferred to the holding or dipping tank, followed by stirring of the mixture.  Dipping of nets:  Lower the net in the dipping tank using remotely operated net rollers and dip the net in the product for a minimum of 30 minutes whilst it is being held down by a weight attached to a crane.  Ensure the net to be treated is completely wetted with the product.  After treatment, remove the weight, roll back the net onto the roller and leave to dry by injecting dried air into the net rolls.  Vacuum treatment of nets:  The lid of the net-bag is opened, and the net lowered into the vacuum bag using a remotely operated net rollers or a crane. Transport a specified amount of product from the vacuum-tank to the vacuum-bag, through the lid on the top. Start the program of “vacuuming the bag” so that the product enters through the net to be treated. Regardless of the size of the vacuum-bag, lowest pressure >0.8 bar. To ensure that the net to be treated is completely wetted with the product. Apply the following program setting for the vacuum equipment "run x number of cycles (>4)". Set on the program of “drying” so that the rest of the product left in the bag is transported back to the tank, through the bottom of the vacuum-bag. After finishing treatment, open the lid and lift the net off the bag using a crane or remote-controlled net rollers to the next process (drying-process).  Lowest pressure during vacuum cycles: 0.8 bar  Max amount of application cycles: 4  Max amount of drying cycles: 4  Avoid pushing paint above the vacuum bag  Allow leftover paint to reset for 2-3 days before re-use |

#### Risk mitigation measures

|  |
| --- |
| Avoid breathing dust/mist  Use only outdoors or in a well-ventilated area  No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation  Avoid contact with skin and eyes.    Wash hands after handling/use  Avoid release to the environment.  The person responsible for the placing on the market of an article treated with this product, shall include the following RMM on the label:   * "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." |

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

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| IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.  If symptoms: Call 112/ambulance for medical assistance.  If no symptoms: 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. |

#### 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. |

#### 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. Protect against sunlight.  The AquaNet Northsea BPF 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. |

### 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 1, 2:  Do not apply the products to nets meant for use in the Baltic Sea.  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. |

### 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 | Lid | Industrial | Yes |

### Documentation

#### Data submitted in relation to product application

Please see reference list

#### Access to documentation

The applicant has access to all the data submitted for the approval of the active substance dicopper oxide. A letter of access is provided.

The applicant is the owner of all data submitted on the AquaNet Northsea product family.

## Assessment of the biocidal product (family)

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

Table 2. Intended use # 21 – Antifouling coating

|  |  |
| --- | --- |
| Product Type | 21 |
| Where relevant, an exact description of the authorised use | The AquaNet Northsea products are intended to be used for the protection of nets used in aquaculture against fouling. |
| Target organism (including development stage) | There are over 4000 fouling species from a variety of phyla   1. Slime, *e.g.* bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, *e.g.* barnacles,mussels and hydrozoans species |
| Field of use | PT 21 – Antifouling products  AquaNet Northsea products are used in the control of fouling organisms in marine environment. |
| Application method(s) | AquaNet Northsea Standard and AquaNet Northsea Ultra are ready-for-use products marketed in 1000 litre IBC HDPE containers as liquid formulations.  AquaNet Northsea CCT100 Plus and Aquanet Northsea C50 are concentrates marketed in 1000 litre IBC HDPE containers as liquid formulation. Aquanet Northsea CCT 100 plus is diluted 1:1 with water and Aquanet Northsea C50 is diluted 1: 0.5 with water.  The products are intended to be applied by dipping or by vacuum treatment. |
| Application rate(s) and frequency | AquaNet NorthSea Standard: 1.0 litres of product per kg of net.  AquaNet NorthSea Ultra: 1.0 litres of product per kg of net.  AquaNet NorthSea CCT100plus: 1.0 litres of product (ready to use concentration) per kg of net.  AquaNet NorthSea C50: 1.0 litres of product (ready to use concentration) per kg of net. |
| Category(ies) of users | Industrial use only |
| Pack sizes and packaging material | 1000 L IBC containers |

### Physical, chemical and technical properties

The physical, chemical and technical properties were mainly determined for the representative product of the Aquanet Northsea BPF, AquaNet Northsea Ultraold. All products in the family are composed of the same components, but in varying concentrations of active substance. AquaNet North Sea Ultraold is the product with the highest content of active substance. Please note that all studies are performed on the old formulation of AquaNet Northsea Ultra. However, this product is deemed as representative for the biocidal products family, and therefore also representative for the new version of AquaNet Northsea Ultra. Physical, chemical and technical properties were also determined for the concentrate Aquanet Northsea CCT 100 Plus. In addition, the persistent foaming tests were conducted on all the products of the product family; Northsea Standard, AquaNet Northsea Ultra, AquaNet Northsea CCT100 Plus and AquaNet Northsea C50.

| **Property** | **Guideline and Method** | **Results** | **Reference** |
| --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | EPA OPPTS 830.6303 | **AquaNet North Sea Ultraold**  Liquid aqueous suspension concentrate  T=6 months storage: Some phase separation could be observed (green liquid phase on the top)  T=12 months Clumping and some phase separation could be observed (green liquid phase on the top). The product re-homogenised after stirring with an impeller attached to a drilling machine  **Aquanet Northsea CCT 100 Plus:**  Liquid aqueous suspension concentrate.  T=6 months storage: No change in physical state.  T= 12 months storage: Liquid aqueous suspension  concentrate. Clumping and some phase separation could be observed (dark brown liquid phase on the top). The product re-homogenised after stirring with an impeller attached to a drilling machine. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Colour at 20°C and 101.3 kPa | EPA OPPTS 830.6302 | **AquaNet North Sea Ultraold**  Red  No significant change after 6 and 12 months of storage.  **Aquanet Northsea CCT 100 Plus:**  Dark reddish brown.  No significant change after 6 and 12 months of storage. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | **AquaNet North Sea Ultraold**  Odourless to slight damp odour  No significant change after 6 and 12 months storage.  **Aquanet Northsea CCT 100 Plus:**  Odourless to slight damp odour  No significant change after 6 and 12 months storage. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| pH | CIPAC MT 75.3 | **AquaNet North Sea Ultraold**  T=0 months,  pH = 9.1  T= 6 months:  pH = 9.2  T = 12 months:  pH = 8.9  **Aquanet Northsea CCT 100 Plus:**  T=0 months,  pH = 9.0  T= 6 months:  pH = 8.9  T = 12 months:  pH = 8.8 | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Acidity/alkalinity | Not required as pH >4 <10. | | |
| Relative density | ISO 2811-1 | **AquaNet Northsea Ultraold**  T = 0 months,  density = 1.32 g/cm3  T = 6 months: density = 1.36 g/cm3  T = 12 months: density = 1.34 g/cm3  **Aquanet Northsea CCT 100 Plus:**  T = 0 months,  density = 1.36 g/cm3  T = 6 months: density = 1.36 g/cm3  T = 12 months: density = 1.35 g/cm3 | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Storage stability test – **accelerated storage** | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | | |
| Storage stability test – **long-term storage at ambient temperatures** | According to requirements of regulation 528/2012  Active Ingredient Content (Internal Analytical Method SP 5458) | The packaging of the test material was HDPE (1L bottles).  The tested products are Aquanet Northsea Ultraold (29 % w/w Cu2O) % w/w Cu2O) and Aquanet Northsea CCT 100 Plus (26.42 % w/w Cu2O).  **Aquanet Northsea Ultraold**  T=0 months:  Cu2O content = 28% w/w.  T= 6 months:  Cu2O content = 31% w/w. The Cu2O content has increased by 10.7\* %.  T = 12 months: Cu2O content = 32% w/w. The Cu2O content was increased by 14.3\* %.  No significant weight variation is reported.  Appearance and measurements of pH, relative density, pourability, suspensibility and spontaneity of dispersion were documented after storage and the results are reported under each relevant endpoint.  \*See comments in the conclusions section  **Aquanet Northsea CCT 100 Plus:**  T=0 months:  Cu2O content = 26% w/w.  T= 6 months:  Cu2O content = 25% w/w. The Cu2O content has decreased by 4 %.  T = 12 months: Cu2O content = 25% w/w. The Cu2O content was increased by 4 %.  No significant weight variation is reported.  Appearance and measurements of pH, relative density, pourability, suspensibility and spontaneity of dispersion were documented after storage and the results are reported under each relevant endpoint. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Storage stability test – **low-temperature stability test for liquids** | Not performed. The products shall not be stored at temperatures below 5 °C. This will be clearly stated on the label. | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Not performed. The statement "Protect from sunlight" will be clearly stated on the label. | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Not performed. The products will not be stored at temperatures above 30 °C. Humidity is not expected to affect the technical properties of the products as they are water based and stored in sealed containers. | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | According to requirements of regulation 528/2012 | No noticeable physical change of the packaging could be observed after 6 and 12 months for Aquanet Northsea Ultraold and Aquanet Northsea CCT 100 Plus. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Wettability | Not performed as not applicable to this formulation type. | | |
| Suspensibility, spontaneity and dispersion stability | CIPAC MT 184, CIPAC MT 160 | **Aquanet Northsea Ultraold**  T = 0 months:  Suspensibility: 100%  Spontaneity of dispersion: 98%  T= 6 months: Suspensibility = 105%, spontaneity of dispersion = 83%.  T = 12 months: Suspensibility = 103%, spontaneity of dispersion = 95%.  **Aquanet Northsea CCT 100 Plus:**  T = 0 months:  Suspensibility: 101%  Spontaneity of dispersion: 94%  T= 6 months: Suspensibility = 107%, spontaneity of dispersion = 69%.  T = 12 months: Suspensibility = 101%, spontaneity of dispersion = 80%. | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |
| Wet sieve analysis and dry sieve test | Not performed. Justification: Wet sieve analysis is not applicable in this case when considering the application method of the products. There are no nozzles or filters on the application equipment and the relevant valves are of large dimensions with no risk of blockage by residues. Therefore, wet sieve analysis are not relevant for these products.  Furthermore, the viscosity and density are measured prior to use to ensure that the products are sufficiently re-homogenised after storage. | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Not performed as not applicable to this formulation type. | | |
| Disintegration time | Not performed as not applicable to this formulation type. | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not performed as not applicable to this formulation type. | | |
| Persistent foaming | CIPAC MT 47.3 | Tested on the products AquaNet Northsea Standard, AquaNet Northsea Ultra, AquaNet Northsea CCT100 Plus and AquaNet Northsea C50.  The results for all products show that the level of foam generated from the suspensions of the test material does not exceed 60 ml after 1 minute. | AquaNet North Sea Persistent Foaming Testing, 2022, study number RH/17/005-2022 |
| Flowability/Pourability/Dustability | CIPAC MT 148 | **Aquanet Northsea Ultraold**  T = 0 months:  Pourability= 1.36%  Rinsability= 0.09%  T= 6 months: Pourability = 1.25%, Rinsability = 0.09%.  T = 12 months: Pourability = 1.22%, Rinsability = 0.06%.  **Aquanet Northsea CCT 100 Plus:**  T = 0 months:  Pourability= 3.84%  Rinsability= 2.32%\*  T= 6 months: Pourability= 3.94%, Rinsability= 2.17%\*  T = 12 months: Pourability= 4.52%, Rinsability= 2.86%\*  \*See comments in the conclusions section | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b |
| Burning rate — smoke generators | Not performed as not applicable to this formulation type. | | |
| Burning completeness — smoke generators | Not performed as not applicable to this formulation type. | | |
| Composition of smoke — smoke generators | Not performed as not applicable to this formulation type. | | |
| Spraying pattern — aerosols | Not performed as not applicable to this formulation type. | | |
| Physical compatibility | AquaNet North Sea Ultra is not used in combination with any other product therefore physical and chemical compatibility tests are not relevant. | | |
| Chemical compatibility | AquaNet North Sea Ultra is not used in combination with any other product therefore physical and chemical compatibility tests are not relevant. | | |
| Degree of dissolution and dilution stability | Not performed as not applicable to this formulation type. | | |
| Surface tension | EC A5 1.6.4 (OECD 115) | Surface Tension (mN/m): 35.0 | Final report # RH/20/001 (2019) |
| Viscosity | ISO 2431 | **Aquanet Northsea Ultraold**   |  |  | | --- | --- | | 20°C Cup ISO 3 | 40°C Cup ISO 3 | | >100 s | >100 s |  |  |  | | --- | --- | | 20°C Cup ISO 4 | 40°C Cup ISO 4 | | 38 s | 30 s |   **Aquanet Northsea CCT 100 Plus:**   |  |  | | --- | --- | | 20°C Cup ISO 3 | 40°C Cup ISO 3 | | 41 s | 37 s |  |  |  | | --- | --- | | 20°C Cup ISO 4 | 40°C Cup ISO 4 | | 19 s | 16 s | | Interim report 6 months AquaNet North Sea Ultra, 2018, report number 7P04987-03  Final report 12 months AquaNet North Sea Ultra, 2018, 7P04987-03b  Interim report 6 months AquaNet CCT100 Plus, 2018, report number 7P04987-01  Final report 12 months AquaNet CCT100 Plus, 2018, 7P04987-01b |

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| **Conclusion Mon the physical, chemical and technical properties of the product** |
| The RTU product Aquanet Northsea Ultraold is a red aqueous suspension concentrate with slight damp odour. It has a density of 1.32 g/cm3, a pH of 9.1 and a viscosity at 20ºC (ISO3) >100 s and at 40ºC (ISO4) is 40 s respectively. Data are presented after 6 and 12 months storage.  The concentrate Aquanet Northsea CCT 100 Plus is a dark reddish brown aqueous suspension concentrate with slight damp odour. It has a density of 1.36 g/cm3, a pH of 9.0 and a viscosity at 20ºC (ISO3) 41 s and at 40ºC (ISO4) is 16 s respectively. Data are presented after 6 and 12 months storage.  Generally, the physicochemical and technical properties remain stable after storage in both products. Some phase separation and clumping are observed at 12 months, but this can be re-homogenised. Thusly, the products can only be used in facilities with proper stirring equipment, or where the diluted product is pumped between tanks (which ensures proper mixing). Furthermore, the quality of the product must be assessed prior to application. According to the use description provided by the applicant, both viscosity and density of the diluted product is measured. Both the viscosity and the density must be within a range specified by the authorisation holder.  The content of active substance, dicopper oxide, seems to increase during storage for AquaNet Northsea Ultraold. However, as copper is an element, an increase in the copper content is not possible. None of the co-formulants is suspected to contain copper in any measurable level and should therefore not be able to explain this. Also, it should be noted that there is no change in the weight of the sample after 6 and 12 months of storage. The rMS ascribes the observed change to difficulties in sample handling, or to insufficient stirring of the stored product prior to sampling. The test samples are paint-like formulations which is a challenging sample material to analyse. Measures are taken in the use instruction to ensure that the product is sufficient re-homogenised after storage as mentioned above. Considering the measurements taken in the user instructions and the difficult sampling material, the rMS is of the opinion that the long-term storage stability studies are acceptable.  As the rinsability measured for Aquanet Northsea CCT 100 Plus is outside the requirements in the guidance documents, actions must be taken to ensure that the dilution of the product is correct, and that the empty product containers are disposed of correctly. The thorough rinsing described in the "Instruction for use" should minimize the residues in the container. Furthermore, the measurement of viscosity and density 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 to hazardous or special waste collection point in accordance with local regulations.  In conclusion, the products can be stored for 12 months under ambient conditions, provided that proper measures are taken to ensure that the product is homogeneous prior to application. The products must be protected from direct sunlight and at temperatures above 5oC and below 30 oC.  AquaNet NorthSea Ultraold and Aquanet Northsea CCT 100 Plus are considered to be representative products for the product family concerning the physical, chemical and technical properties and a read-across of the results are considered acceptable. Further justification on the read-across can be found in the confidential PAR. |

### Physical hazards and respective characteristics

The physical hazards and respective characteristics were determined for the representative product of the Aquanet Northsea BPF, Aqua Net CCT100 Plus.

| **Property** | **Guideline and Method** | **Results** | **Reference** |
| --- | --- | --- | --- |
| Explosiveness | Not performed | Initial DSC screening shows that the heat of decomposition is 152.6 J/g. As <500 J/g the test item is not considered to be explosive. | Initial DSC scan in: Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus,2017 report number GLP3016001671CR1V1/2017 |
| Flammable gases | Not performed as not relevant for this product | | |
| Flammable aerosols | Not performed as not relevant for this product | | |
| Oxidising gases | Not performed as not relevant for this product | | |
| Gases under pressure | Not performed as not relevant for this product | | |
| Flammable liquids | CTL SOP No. 408 : ASTM D93 (PENSKY-MARTENS METHOD) | The test temperature range was 40 to 360°C. Boling was observed at approx. 98 °C, and further testing was not possible.  In conclusion, no flash point before boiling. The test item is not considered to be flammable. | Flash point measured in: Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus,2017 report number GLP3016001671CR1V1/2017 |
| Flammable solids | Not performed as not relevant for this product | | |
| Self-reactive substances and mixtures | Not performed | The study does not need to be conducted because the exothermic decomposition energy is less than 300 J/g and hence, the classification procedure does not need to be applied | Exothermic decomposition measured in: Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus,2017 report number GLP3016001671CR1V1/2017 |
| Pyrophoric liquids | Not performed | No ignition of the product by air at ambient temperatures is expected. Also, experience from practical handling shows that the products are not pyrophoric liquids. |  |
| Pyrophoric solids | Not performed as not relevant for this product | | |
| Self-heating substances and mixtures | Not performed | Not applicable because the products are liquids which are not absorbed on a large surface (e.g., on powder particles). |  |
| Substances and mixtures which in contact with water emit flammable gases | Not performed as not relevant for this product, the product is already as a dilution in water. | | |
| Oxidising liquids | Not performed | Justification:  None of the components, or mixtures, in the biocidal product is classified as oxidising. The active substance contains oxygen, but is harmonized classified as not oxidising. Furthermore, the product is an aqueous solution and according to the guidance on application of CLP-criteria (ver. 5.0, 2017) it is not necessary to test if the product contains less than 20% of an oxidising solid in aqueous solution. As none of the components are classified as oxidising, there cannot be more than 20% of an oxidising substance present. Hence, a test is not necessary. |  |
| Oxidising solids | Not performed as not relevant for this product | | |
| Organic peroxides | Not classified as there are no organic peroxides present in the product. | | |
| Corrosive to metals | UN Manual of Tests and Criteria: Part III, 37.4: Test methods for corrosion to metals | The percentage mass losses on steel[[2]](#footnote-3) and aluminium were found to be < 13.5 % over 7 days, however, the maximum pit depth on the aluminium coupons was > 120 μm. The sample is therefore a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations). | Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus,2017 report number GLP3016001671CR1V1/2017 |
| Auto-ignition temperatures of products (liquids and gases) | ASTM E659 (Standard test method for autoignition temperature of liquid chemicals) | The autoignition temperature of Aqua Net CCT100 Plus has been determined to be 540◦C | Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus,2017 report number GLP3016001671CR1V1/2017 |
| Relative self-ignition temperature for solids | Not performed as not relevant for this product | | |
| Dust explosion hazard | Not performed as not relevant for this product | | |

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| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| Aquanet CCT100 PLUS product are candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations).  They are not explosive or oxidising and have an auto ignition temperature of 540ºC. |

### Methods for detection and identification

**Analytical methods for the analysis of the product as such including the active**

Methods for determining dicopper oxide in the product:

Samples are dried and digested in a mixture of nitric acid and hydrogen peroxide in closed containers that are heated using microwaves. Copper (Cu) is then determined by the resulting solutions using inductively coupled plasma – optical emission spectrometry (ICP-OES). Cu can be recalculated to Cu2O by assuming that all Cu is present as Cu2O (depending on the composition of the formulation). This internal method is based on several well-established standard methods: EN 13656, EPA Method 3052, and EN ISO 11885 that are fully validated. Precision (as repeatability), accuracy (as recovery), and linearity and selectivity/specificity have been investigated as described in SANCO/3030/99 rev.4 11/07/00 and all requirements have been fulfilled. 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 analytical method is suitable for the determination of dicopper oxide in the formulation.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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) | ICP-OES (Method SP5458)  Determination of the total content of Cu in Aquanet CCT 100 Plus and Aquanet Northsea Ultra for the trueness and Aquanet HG 360[[3]](#footnote-4) for the repeatability. | n = 5 | Linear from 0 to 30 mg/L  ; 6 calibrations  Emission line for Cu =327.393    R = 0.9997; slop = 122510; intercept = 11923;  Emission line for Cu =324.752    R = 0.9994; slop = 282543; intercept = 39433; | No interference  In general, the selectivity of ICP-OES instrumentation is high in an organic  matrix. Furthermore, the analyte is one of the main components in the samples, i.e. it is typically present at concentrations higher than concentrations of possible  interfering compounds. In addition, each analyte is determined using two  different emission lines and the result for the second line is used to confirm the  result for the first line. The used emission lines are the recommended and known  to have no or few interferences from other compounds. | 96.16 – 100.97 %[[4]](#footnote-5) | 98.6 % | 1.41 % | n/a | Fischer (2017b) |

**Analytical methods used for monitoring:**

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint.

**Analytical methods used for soil:**

The applicant has letters of access issued by Spiess Urania to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

**Analytical methods used for air:**

The applicant has letters of access issued by Spiess Urania to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

**Analytical methods used for water:**

The applicant has letters of access issued by Spiess Urania to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

**Analytical methods used for animal and human body fluids and tissues:**

The applicant has letters of access issued by Spiess Urania to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

**Analytical methods for monitoring of active substances and residues in food and feeding stuff**

The applicant has letters of access issued by Spiess Urania to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

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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 for the long term test for determination of the content of Dicopper oxide) validated analytical method is available. The validated method includes the parameters specificity, linearity, recovery and precision, and were performed according to SANCO/3030/99 rev.4 11/07/00. Therefore, the analytical methods can be used for the determination of Copper in the the BPR family of antifouling products.    Concerning the analytical methods for measurement of Dicopper Oxide (i.e. Copper) in all other matrixes (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

#### Function and field of use

**Function:** Antifoulant

**Field of use:** Aquaculture

The Aquanet North Sea BPF is intended to be used for the protection of nets used in aquaculture against fouling organisms in marine environments.

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

The number of fouling organisms to which an aquaculture net may be exposed is large. Over 4000 fouling species with representatives from a variety of phyla, for example; slime, diatoms species (*e.g.* *Achnanthes* and *Amphora* species), algae such as green, brown and red algae spores (*e.g.* *Enteromorpha* spp, *Polysiphonia*), animals such as barnacles, mussels, tubeworms (*e.g.* Serpulids), sponges.

#### 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.

#### Mode of action, including time delay

Dicopper oxide:

When copper from 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.

#### Efficacy data

Biofouling in marine aquaculture is one of the main barriers to efficient and sustainable production (Dürr and Watson 2010), and the direct economic cost of managing biofouling in the aquaculture industry is estimated to be 5-10% of the production costs (Lane and Willemsen 2004).

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"). The proposed guidance document is included as a separate attachment to this PAR (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 proposed guidance document has been used for the evaluation this product family authorisation. However, as no agreement on its applicability has been reached some flexibility and pragmatism has been used in the assessment.

The first efficacy studies performed for these products were performed in 2017 before the proposed guidance document was finalised and were thus performed according to the applicants own internal routines. After the proposed guidance document was finalised / drafted, a new set of efficacy studies was performed in 2018, where the methodology and principles given in the proposed guidance document was largely followed.

The first set of efficacy studies performed for this product family deviate from the principles in the proposed guidance document in that the samples are not tested in randomised triplicates. Only single samples of each product were tested. This was reported to be due to capacity problems at the fish farms due to the commercial activities, such as boat traffic and other farm operations taking place. The applicant therefore chose to use larger sample panels (80 x 40 cm) than the minimum size recommended in the proposed by SINTEF (25 x 25 cm). The total tested areas are thus larger in these studies than recommended in the SINTEF document. The samples were scored in accordance with the applicants own internal procedure which is presented in the individual study reports.

The submitted photo evidence from the 2017 efficacy tests were unfortunately of too poor quality and resolution for a proper evaluation to be performed by the rMS. The tests are generally well performed and to a large extent follow the principles given in the SINTEF document. Due to the poor image quality, these tests have been given a reliability score of 3. They are nevertheless included in order to provide supplemental information.

The second set of efficacy test were performed largely in line with the principles given in the SINTEF document. The samples are tested in four parallels and all samples were randomised in the frames. The application data for the efficacy studies is provided below. The frames were placed in the sea at an active fish farm and were located approximately 1 meter away from an active producing fish cage. The samples were inspected and photographed approximately every 4 weeks. The applicant has also analysed the samples according to their own internal standard, and not according to the standard proposed by SINTEF.

**Application data for 2018 efficacy studies**

**Application rate:** 1L / kg net

**Dilution (if used):** AquaNet CCT100plus: 1:1 (v/v)   
(concentrate/water)

AquaNet C50: 1:0.5 (v/v) (concentrate/water)

**Concentration of Active Substance in the studies:**

AquaNet Standard: 17.5% Cu2O

AquaNet C50: 14.2% Cu2O

AquaNet Ultra: 29.5% Cu2O

AquaNet CCT100: 15.2% Cu2O

**How were the nets treated:** Vacuum

All the submitted efficacy studies were performed at active fish farms with the test panels were placed in close proximity from an active producing fish cage. This gives very realistic conditions with regard to the natural conditions in a producing cage with respect to fouling pressure and exposure to nutrients from food spillage and faeces. The fouling pressure under such conditions is extreme and has been reported to be up to 49 times higher than in the surrounding sea (Bloecher et al 2015).

The rMS has analysed the submitted 2018 efficacy studies by quantifying the total biofouling load in accordance with the principles outlined in the SINTEF document. The submitted photo evidence was unfortunately of to poor quality to allow for a detailed analysis of the % biofouling cover (Analysis of type B according to the SINTEF document). Instead, the biofouling load was estimated (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 Bloecher and Floerl 2018.

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.

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 are 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.

The applicant has informed us that 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 differs. For areas of low salinity environment, the products with lower levels of copper are preferred.

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 experienced by the farmers that the biofouling falls easier off from a treated net than from an untreated net at for instant 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. According to information from the applicant, the fish farm companies are to a large extent very professional businesses which often have a high degree of competence of the biofouling issues in the area where they operate. They have thus much experience and expertise on the farming strategies that gives the biggest production advantages in their farms.

In general the EFF WG supported that testing should be done in the region for which the claim is made by the applicant. However, there is no final decision or agreement regarding this matter and further discussion at the EFF WG is needed.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Anti-foulant* | PT21 | AquaNet Standard | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Horgefjorden at 80 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 44 – 64 – 85 – 104 – 127 – 162 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Hope, B (2017)* |
| *Antifoulant* | PT21 | AquaNet Standard | *Wide range of marine fouling organisms in the Mediterranean Sea (Greece)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Galaxidi at 100 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 27 - 40 – 54 – 68 – 83 – 96 – 111 – 125 – 139 – 152 – 167 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Fagerlid, S (2017)* |
| *Antifoulant* | PT21 | AquaNet Ultra | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Horgefjorden at 80 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 44 – 64 – 85 – 104 – 127 – 162 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Hope, B (2017)* |
| *Antifoulant* | PT21 | AquaNet Ultra | *Wide range of marine fouling organisms in the Mediterranean Sea (Greece)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Galaxidi at 100 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 27 - 40 – 54 – 68 – 83 – 96 – 111 – 125 – 139 – 152 – 167 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Fagerlid, S (2017)* |
| *Anti-foulant* | PT21 | AquaNet CCT100 Plus | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Horgefjorden at 80 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 44 – 64 – 85 – 104 – 127 – 162 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Hope, B (2017)* |
| *Antifoulant* | PT21 | AquaNet CCT100 Plus | *Wide range of marine fouling organisms in the Mediterranean Sea (Greece)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Galaxidi at 100 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 5 months (0 – 27 - 40 – 54 – 68 – 83 – 96 – 111 – 125 – 139 – 152 – 167 d) | Indicated active protection time of > 5 months  (the applicant's own assessment)  Reliability: 3 | *Fagerlid, S (2017)* |
| *Antifoulant* | PT21 | AquaNet Ultra | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in Syltøy at 70 m depth from Apr. to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 24.8% dicopper oxide + 2% tralopyril / 7 months (0 – 23 – 58 – 77 – 116 – 134 – 169 – 205 d | Indicated active protection time of > 7 months  (the applicant's own assessment)  Reliability: 3 | Ulriksen, U (2017) |
| Antifouling | PT21 | AquaNetStandard | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  CEPE-method (antifouling coatings-methods for the generation of antifouling efficacy data)-for aquaculture nets developed by SINTEF Ocean on behalf of the Norwegian Environment Agency  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in South-West Norway at 80 m depth from April 2018 to November 2018, 1 meter from high production cages where fouling pressure is greater than surrounding areas. Test units comprised of nets on stainless steel cages treated with test substance (2 replicates) or control (7 replicates) | Results indicates a protection time of at least 14 weeks in North Atlantic waters  Reliability: 2 | Hope, B (2018) |
| Antifouling | PT21 | AquaNet Ultra | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  CEPE-method (antifouling coatings-methods for the generation of antifouling efficacy data)-for aquaculture nets developed by SINTEF Ocean on behalf of the Norwegian Environment Agency  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in South-West Norway at 80 m depth from April 2018 to November 2018, 1 meter from high production cages where fouling pressure is greater than surrounding areas. Test units comprised of nets on stainless steel cages treated with test substance (2 replicates) or control (7 replicates) | Results indicates a protection time of > 5 months in North Atlantic waters  Reliability: 2 | Hope, B (2018) |
| Antifouling | PT21 | AquaNet CCT100 Plus | *Wide range of marine fouling organisms in North European waters (Norway)* | ISO 4628/3  SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests  CEPE-method (antifouling coatings-methods for the generation of antifouling efficacy data)-for aquaculture nets developed by SINTEF Ocean on behalf of the Norwegian Environment Agency  Internal procedures DOKID-1294561088-104  Internal procedures: DOKID-1294561088-103 | Seawater column located in South-West Norway at 80 m depth from April 2018 to November 2018, 1 meter from high production cages where fouling pressure is greater than surrounding areas. Test units comprised of nets on stainless steel cages treated with test substance (2 replicates) or control (7 replicates) | Results indicates a protection time of at least 14 weeks in North Atlantic waters  Reliability: 2 | Hope, B (2018) |

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| **Conclusion on the efficacy of the product** |
| Please observe that only the efficacy studies performed in 2018 has been evaluated by the rMS and the fouling levels assigned a rank according to the SINTEF document.  The efficacy studies performed in 2017 could not be evaluated by the rMS. These tests were evaluated and scored by the applicant according to their own internal procedure. As the applicant has used the term "score" in their assessment of the 2017 studies, this term has been kept in the description of the studies.  The referred scores do not correlate directly to the ranks given in the SINTEF document. Please see the SINTEF document and the study reports for further information.  **Aquanet North Sea Standard:**  **Norwegian south-western coast, April to November 2018.**  In the efficacy test performed on AquaNet NorthSea Standard on the Norwegian south-western coast from April to November 2018 (Hope, B.; 2018), the product showed very good protection up to, and including, the sampling date after 98 days (14 weeks) in the sea. The samples at 28 days and 58 days were assigned a rank of 0, while the sample at 98 days was assigned a rank of 1 (< 20% biofouling cover). The control samples at 98 days were assigned a rank of 4.  At the next time point at 134 days, the samples had accumulated a significant amount of fouling organisms (Hydroids and skeleton shrimp were most abundant). These samples were evaluated to a rank of 4 (60 – 80% growth cover), while the controls were assigned a rank of 5 (> 80%).  At the sampling point at 176 days, much of the fouling had fallen off. This was also the case for the control samples, although they still contained considerably more fouling than the test samples. It was noted in the test report that some skeleton shrimps were still observed, and that new settlement of hydroids had started. The 176 days samples were assigned a rank of 3, while the controls were assigned a rank of 5.  The fact that a new population of hydroids was being established at this timepoint, is taken as a clear indication that the efficacy of the coating at this time had declined to a level where it no longer provided sufficient protection against fouling.  The shredding of fouling at this sampling day is shared by all samples, across products and product families and includes the control samples. No explanation to this shredding event was presented. It is therefore considered likely that this shredding of the fouling species was caused by an external factor, such as bad weather, and not by the biocidal effect of the product. The antifouling coat may, nevertheless, cause the fouling to fall off easier than it would from an untreated net.  At the last sampling day, at 231 days, the samples are heavily fouled, primarily by skeleton shrimp and hydroids. These samples were assigned a rank of 4 and 5, while the control samples were assigned a rank of 5. This development is taken as evidence that the antifouling effect was significantly reduced sometime between sampling day 98 and sampling day 134.  **Horgefjorden on the Norwegian south-western coast, May to October 2017:**  In the efficacy test performed on AquaNet North Sea Standard in Hognefjorden on the Norwegian south-western coast in 2017 (Hope, B.; 2017), the results are comparable to the 2018 test. The samples analysed up to day 104 shows a very good protection against biofouling, while the control sample is heavily fouled. After 127 days in the sea the test panel had acquired a considerable level of fouling. The applicant gave this sample a score of 4 (35-64% biofouling cover; scored according to the applicant's own procedure). Much of the fouling visible in the pictures was described by the applicant to consist of non-sessile algae. The submitted pictures are, unfortunately, of too poor quality for the rMS to be able to perform an independent assessment of this study. The study and the applicant's assessment are included to provide supplemental information.  **Galaxidi, central Greece May to November 2017:**  In the 2017 test on Aquanet North Sea Standard performed in Galaxidi in central Greece (Fagerlid, S.; 2017), the product provides good protection against fouling organisms throughout the whole study period (139 days). The sample was given a score of 2 (< 10% biofouling cover) at the last sampling point after 139 days, and this seems to be justified by the picture evidence.  According to the applicant, this test demonstrates that Aquanet North Sea Standard is efficient in Greek Mediterranean waters for up to 5 months.  The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information.  **Conclusion:**  The rMS concludes that an approximate protection time of at least 14 weeks depending on the degree of biofouling pressure for Aquanet North Sea Standard in North Atlantic waters is demonstrated based on the results in the submitted efficacy study. Note that the product may still be efficacious after 14 weeks.  According to the applicant Aquanet North Sea Standard is efficient in Greek Mediterranean waters for more than 4.5 months. The rMS has not been able to perform an independent assessment of this study.  **Aquanet North Sea Ultraold:**    Although the product AquaNet North Sea Ultraold is not authorised, the efficacy data are still included for reference. The efficacy of the new product AquaNet North Sea Ultra is covered by the efficacy tests performed on the products with lower copper content.  **Norwegian south-western coast, April to November 2018.**  In the efficacy test performed on AquaNet North Sea Ultraold on the Norwegian south-western coast from April to November 2018 (Hope, B.; 2018), the product showed very good protection against fouling organisms for the whole span of the test, 231 days (33 weeks). The samples were assigned a rank of 1 (< 20% biofouling cover) after 58 and 98 days in the sea. The control samples were assigned a rank of 3 and 4, respectively, at these sample points.  After 134 days in the sea, some skeleton shrimp were observed, and these samples were assigned a rank of 2 (20-39% biofouling cover). At this time point, the controls were assigned a rank of 5 (> 80% biofouling cover). The fouling level remained at this level (rank 2) throughout the test period of 231 days, while the controls remained heavily fouled with a rank of 5.  **Syltøy on the Norwegian south-western coast, April to November 2017:**  In the 2017 efficacy test performed on AquaNet North Sea Ultraold at Syltøy on the Norwegian south-western coast (Hope, B.; 2017), the results are comparable to the 2018 test. Aquanet North Sea Ultraold provided very good protection against biofouling throughout the whole timespan of the test (205 days). The score assigned by the applicant reached a maximum level of 4 (35-64 % fouling) after 134 and 169 days, after which the levels decline again (samples were scored according to the applicant's own standard).  The pictures submitted with this study were unfortunately of too poor quality for the rMS to be able to perform an independent assessment of the study. It is, nevertheless, noted that the assessment performed by the applicant seems reasonable.  The test is included in order to provide supplemental information  **Horgefjorden on the Norwegian south-western coast, April to November 2017:**  In the 2017 efficacy test performed on AquaNet North Sea Ultraold in Horgefjorden on the Norwegian south-western coast (Hope, B.; 2017), the results are also comparable to the 2018 test of this product. Aquanet North Sea Ultraold provided very good protection against biofouling throughout the whole timespan of the test (162 days). The assigned scores reached a maximum level of 1 in the run of the study, while the concurrent control is heavily fouled.  The rMS was not able to perform an independent assessment of this study. It is, nevertheless, included to provide supplemental information.  **Galaxidi, central Greece May to November 2017:**  The 2017 test on AquaNet North Sea Ultraold, performed in Galaxidi in central Greece (Fagerlid, S.; 2017), the product demonstrated very good protection against fouling throughout the whole test period of 167 days (24 weeks). The samples throughout the whole test period were given a score of 1 by the applicant, and the majority of the visible fouling was described to consist non-sessile green algae.  The pictures submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the assigned score values. It is, nevertheless, evident that the samples indeed seem to harbour a very low level of fouling.  The applicant's conclusion from this efficacy study is that the product is efficacious for more than 5.5 months in Greek Mediterranean waters.  **Conclusion:**  The rMS concludes that a protection time of more than 7 months depending on the degree of biofouling pressure for Aquanet North Sea Ultraold in North Atlantic waters is demonstrated based on the results in the submitted efficacy studies.  The applicant claims a demonstrated efficacy of more than 5 months in Greek Mediterranean waters. The rMS has not been able to perform an independent assessment of this test due to low picture quality. The conclusions drawn by the applicant does, however, seem reasonable.  **Aquanet North Sea CCT 100 plus:**  **Norwegian south-western coast, April to November 2018**  In the efficacy test performed onAquanet CCT 100 plus on the Norwegian south-western coast in 2018 (Hope, B.; 2018), the product showed very good protection up to the sampling date at 98 days (14 weeks) in the sea. The samples up to and including this sampling date were assigned a rank not exceeding 1 (<20% biofouling cover), while the control samples showed a steady increase in biofouling level to a rank of 3 (40-59% biofouling cover) after 58 days and 4 (60-80% biofouling cover) after 98 days  At the sampling point at 134 days, the samples had accumulated a significant amount of fouling organisms (Hydroids and skeleton shrimp were most abundant). The 134 days samples were assigned a rank of 4 (60-80% biofouling cover), while the concurrent controls were assigned a rank of 5 (> 80% biofouling cover).  At the 176 days sampling point, much of the biofouling had fallen off. It was noted in the report that new settlement of hydroids had started, and that skeleton shrimp were observed. The 176 days samples were assigned a rank of 3 (40-59% biofouling cover), while the control sample at this point was still regarded as a rank 5. The active re-settlement of hydroids noted in these samples, is in the rMS' opinion a clear indication that the antifouling protection at this point had decreased to a level where it no longer provided sufficient protection against fouling.  At the last sampling point at 231 days, the samples assigned a rank 5, indicating indeed that the protective effect against fowling had been lost.  **Horgefjorden on the Norwegian south-western coast, April to November 2017:**  In the 2017 efficacy test performed with Aquanet North Sea CCT 100 plus in Horgefjorden on the Norwegian south-western coast (Hope, B.; 2017), the product seems to perform very good throughout the test period. The photographic evidence submitted with this study were, unfortunately, of too poor quality for the rMS to perform an independent assessment. The test samples were given a score by the applicant (according to their own internal procedure) not exceeding 1 throughout the test period of 162 days.  The photographic evidence submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the study. The study is, nevertheless, included to provide supplemental information.  **Galaxidi, central Greece May to November 2017:**  The 2017 test on Aquanet North Sea CCT 100 plus performed in Galaxidi, central Greece, show a level of biofouling which gradually increased up to a score of 4 (35 – 64% biofouling cover) after 139 days (20 weeks) in the sea. The final sampling point at 152 days was given a score of 5 (65-90% biofouling cover).  The photographic evidence submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the study. The study is, nevertheless, included to provide supplemental information.  **Conclusion:**  The rMS concludes that an approximate protection time of at least 14 weeks depending on the degree of biofouling pressure for Aquanet North Sea CCT 100 plus in North Atlantic waters is demonstrated based on the results in the submitted efficacy studies. However, the product may still be efficacious beyond 14 weeks.  The applicant claims a demonstrated efficacy of more than 5 months in Greek Mediterranean waters. The pictures submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the reported score values.  **AquaNet North Sea C50:**  No efficacy studies on AquaNet North Sea C50 were submitted.  AquaNet North Sea C50 is formulated as a concentrate, and the in-use concentration of Cu2O is 14.23 % (w/w). This is just slightly less than the in-use concentration of Cu2O in AquaNet North Sea CCT100 plus of 15.23% (w/w). Further, AquaNet North Sea C50 is comparable to the concentrated members of the related AquaNet 360 BPF, AquaNet LG360 and AquaNet HG 360, for which efficacy studies have been submitted.  The Aquanet 360 family members contain in addition to Cu2O a small amount of copper thiocyanate (CuSCN). The active moiety in CuSCN is also the cuprous ion (Cu2+). The in-use concentration of total Cu2+ in the AquaNet 360 family members are: Aquanet LG 360, 7.83% (w/w) and AquaNet HG 360: 15.06% (w/w).  There is a high level of similarity in the composition between these two product families (please see the confidential annex for more details on composition). The efficacy of these products is very much decided by the concentration of active substance. In this respect, AquaNet North Sea C50 is intermediate between the two AquaNet 360 family members. As all the comparable products mentioned have demonstrated an approximate protection time of at least 14 weeks in North Atlantic waters depending on the degree of biofouling pressure, it is reasonable to believe that this also will be the case for AquaNet North Sea C50. On the basis of active substance content and similarity in product composition, the rMS concludes that read across of efficacy data from the mentioned formulations to AquaNet North Sea C50 can be accepted and an approximate protection time of at least 14 weeks in North Atlantic waters, depending on the degree of biofouling pressure, can reasonably be expected. Again, the product may still be efficacious beyond 14 weeks.  **Overall conclusion**  According to the applicant, the efficacy trials were conducted for the North Sea products in exposed open sea conditions in the North Atlantic. Due to physical factors (e.g. bad weather, heavy currents) it is not possible to determine the exact efficacy past 14 weeks (3 ½ months), hence, the product may still be efficacious. 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. Although, based on a worst-case location where more extensive growth of fouling is expected. The applicant states based on experience that products used in the Baltic Sea demonstrate sufficient efficacy for longer than the 180 days deployment time used in Risk Assessment. Also, the applicant has experience with deployment of AquaNet Standard in the Atlantic Ocean demonstrating that the product is efficacious for >98 days.  Overall, the rMS concludes that all the products of the biocidal product family demonstrate sufficient efficacy. |

#### Occurrence of resistance and resistance management

Considering the non-selective mode of action of the active substances (dicopper oxide), development of resistance against AquaNet North Sea BPF product is unlikely.

Dicopper oxide:

As stated in the CAR (PT21, 2016), there have never been any recorded cases of resistance in populations of fouling organisms using copper based anti-fouling 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.

#### Known limitations

None reported

#### Evaluation of the label claims

The AquaNet products are not marketed with label claims on specific protection times. Marine biofouling pressure is extremely variable with regards to location, season, temperature, sunlight, water nutrient level etc. so no specific claims regarding protection time are possible to make, except for reduced growth relative to an untreated net.

According to Steen-Hansen's internal procedure, nets treated with Aquanet North Sea antifouling products cannot be used together with high pressure water jetting on site. This is detailed in the Steen-Hansen Compliance Document: ‘Cleaning restrictions for treated nets’ (2019).

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

The Aquanet North Sea BPF product family are not intended to be used in combination with other biocidal products.

### Risk assessment for human health

The toxicology of the active substance, dicopper oxide (Cu2O), was examined according to standard requirements in the review programme under BPR. The toxicological properties of the active substance summarised in the CA report, as reflected in the assessment report:

* Assessment report on Dicopper oxide (CAS-no: 1317-39-1), Product type 21, eCA FR, January 2016 (ECHA, 2016a)

Toxicological testing (acute toxicity tests and tests for skin or eye irritation and skin sensitisation) have not been performed for the products in the AquaNet North Sea biocidal product family.

In the absence of such test results, the products are classified based on information on the ingredients in the products using the conventional calculation method in Regulation 1272/2008 (CLP) (cf. 2.2.6.1.).

The AquaNet North Sea CCT 100 plus product is classified for acute oral toxicity (Cat 4, H302) and serious eye damage (Cat 1, H318), whereas the AquaNet North Sea Standard, the AquaNet North Sea Ultra and the AquaNet North Sea C50 products are classified for serious eye damage (Eye dam. Cat 1; H318) based on the respective classification of the ingredients.

The composition and CLP classification for human health hazards of the co-formulants are presented in the confidential Annex to this PAR.

**Background information on the active substances:**

Dicopper oxide is approved for use in product-type PT21 in the context of Regulation (EU) No.528/2012 by Implementing Regulation (EU) 2016/1089. To support the decision on approval, the hazard assessment of dicopper oxide was conducted in line with the assessment of other copper compounds dossiers for PT21.

The harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) of the active substance is available (17 ATP). The human hazards related to this substance are the following Acute Tox (Cat 4, H332, Inhalation), Acute Tox. (Cat 4, H302, oral) and Eye Dam. (Cat 1, H318).

No repeated toxicity study by oral route was provided for dicopper oxide. However, it was decided that read across to other relevant copper compound (e.g., copper sulphate pentahydrate) was applicable. Further information can be found in the assessment report (ECHA, 2016a). as further elaborated in the competent authority reports of dicopper oxide.

Copper is a micronutrient, essential for life and necessary for all living cells. It is essential for a normal physiological function such as cellular respiration, free radical defense, synthesis of melanin, connective tissue, iron metabolism, regulation of gene expression, and 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).

Based on the CA report on dicopper oxide, the key health effects to consider in the risk assessment are the kidney and forestomachdamages observed in the 90-day dietary study in rats (with the test material copper sulphate pentahydrate). 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 deriving the short-term and long term AEL values.

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

**(ref: Assessment report for dicopper oxide (ECHA, 2016a))**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **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 |

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No studies for the assessment of skin irritation/corrosion of The North Sea BPF products are available.

The additivity principle of the CLP Regulation applies to the hazard class skin corrosion/irritation with a generic cut off for when the substances should be taken into account of 1 % (Table 1.1, in Annex I to Reg. no 1272/2008).

The active substances, dicopper oxide is not classified for skin irritation/corrosion. One co-formulant is classified with Skin irrit. 2 (H315) but is present in a concentration that will not result in classification of the products.

According to Annex III, point 8.1, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the skin irritating effects of the AquaNet North Sea products is not considered necessary.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive or irritating to skin |
| Justification for the value/conclusion | The active substance is not classified for skin irritation/corrosion. One co-formulant is classified as skin irritating but is present in a concentration that will not lead to classification of the product. |
| Classification of the product according to CLP | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion or skin irritation |
| Justification | Waiving according to No. 8.1, Column 3 of Annex III of BPR regulation:  There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected. |

***Eye irritation***

No studies for the assessment of eye irritation/corrosion of AquaNet 360BPF are available.

The additivity principle of the CLP Regulation applies to the hazard class serious eye damage/eye irritation with a generic cut off for when the substances should be taken into account of 1 % (Table 1.1, in Annex I to Reg. no 1272/2008).

Since dicopper oxide is contained in the products in a range of concentrations between 17.5 and 26.4% (w/w), this triggers a classification of the products with Cat 1, H318 “Causes serious eye damage” irrespectively of the co-formulants (Table 3.3.3 in Annex I to Reg. no 1272/2008).

Two co-formulants are classified as eye irritants (Cat.2, H319) and two co-formulants as serious eye damaging (Cat.1, H318). However, the concentrations of the latter two substances are below the cut off concentration for when the substances should be taken into account. Thus, none of these co-formulants contributed to the overall classification of the products as eye damaging.

According to Annex III, point 8.2, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the eye irritating effects of the AquaNet North Sea BPF is not considered necessary.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Causes serious eye damage |
| Justification for the value/conclusion | Classification of the product family is based on classification of the active ingredient, dicopper oxide |
| Classification of the product according to CLP | Cat 1, H318 |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye irritation or damage |
| Justification | Waiving according to No. 8.2, Column 3 of Annex III of BPR regulation:  There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected |

***Skin sensitisation***

No studies for the assessment of skin sensitization of the AquaNet North Sea products are available.

The active substance, dicopper oxide, is not classified for skin sensitisation (17 ATP to CLP). Two co-formulants do however contain a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one; 3:1 (CMIT/MIT) in concentrations which triggers labelling of the family members AquaNet North Sea CCT 100 plus and AquaNet North Sea C50 with the sentence EUH 208; Contains a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (CMIT/MIT) 3:1 May cause an allergic skin reaction.

According to Annex III, point 8.3, Column 3 of the BPR, as sufficient information is available for the active substances and the co-formulants a study investigating the skin sensitizing effects of AquaNet North Sea BPF is not considered necessary.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not skin sensitising |
| Justification for the value/conclusion | The active substance, dicopper oxide, is not classified for skin sensitisation. Two co-formulants do however contain a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one; 3:1 (CMIT/MIT) in concentrations which triggers labelling of the family members AquaNet North Sea CCT 100 plus and AquaNet North Sea C50 with the sentence EUH 208 (see below). |
| Classification of the product according to CLP and DSD | Not classified  EUH 208; Contains a mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (CMIT/MIT) 3:1. May cause an allergic skin reaction.  (Only relevant for the AquaNet North Sea CCT 100 plus and the AquaNet North Sea C50 family members) |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitisation |
| Justification | Waiving according to No. 8.3, Column 3 of Annex III of BPR regulation:  There are sufficient data available on the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected. |

***Respiratory sensitisation (ADS)***

No studies for the assessment of respiratory sensitisation of the AquaNet North SeaBPF are available. The active substance dicopper oxide is not classified for respiratory sensitisation (17 ATP to CLP). In addition, none of the co-formulants are classified for this endpoint. A study investigating the respiratory sensitising effects of AquaNet North Sea products is not considered necessary.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not respiratory sensitiser |
| Justification for the value/conclusion | No substance present in the AquaNet North Sea Product Family is classified for respiratory sensitisation. Therefore, this BPF is not classified for this endpoint. |
| Classification of the product according to CLP and DSD | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | ADS - Respiratory sensitization |
| Justification | No test guideline available |

***Acute toxicity***

*Acute toxicity by oral route*

No studies for the assessment of acute oral toxicity of AquaNetNorth Sea BPF are available. Harmonised classification exists for the active substance, dicopper oxide, which is classified with Acute Tox 4, H302 with an ATE of 500 mg/kg bw (17 ATP to CLP).

Two co-formulants are also classified for acute oral toxicity (Acute Tox 4; H302) but should not be taken into account in the calculation of ATE value for acute oral toxicity as they are present in concentrations below the generic cut of value of 1% for Acute Tox 4 classified substances (Table 1.1, in Annex I to Reg. no 1272/2008).

Due to the contribution of dicopper oxide in the family member AquaNet North Sea CCT 100 plus, a classification for this endpoint is required according to the ATE calculation method (see the confidential annex for details). The three other family members, AquaNet North Sea Standard, AquaNet North Sea Ultra and AquaNet North Sea C50 are not classified for acute oral toxicity.

According to Annex III, point 8.5.1, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the acute toxic effects of AquaNet North Sea BPF is not considered necessary.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Acute oral toxicity Cat. 4 (AquaNet North Sea CCT 100 plus) |
| Justification for the selected value | The product is classified for acute oral toxicity based on the classification of the active substance dicopper oxide. |
| Classification of the product according to CLP | Acute Tox. 4 (H302, oral) |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity |
| Justification | Waiving according to Annex III, point No. 8.5.1, Column 3 of the BPR:  There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected. |

*Acute toxicity by inhalation*

No studies for the assessment of acute inhalation toxicity of AquaNet North Sea BPF are available. This is not considered a data gap since the information on the ingredients is sufficient to generate the product classification for this endpoint.

A harmonised classification exists for the active substance dicopper oxide, which is classified with Acute Tox 4, H332 with an ATE of 3.34 mg/l (dusts or mists, 17 ATP to CLP). None of the co-formulants are classified for this endpoint. Dicopper oxide is, however, present in the products at subthreshold levels according to the ATE calculation method, and no classification for this endpoint is required for the AquaNet North Sea product family members.

According to Annex III, point 8.5.2, Column 3 of the BPR, as sufficient information is available for the active substances and the co-formulants, a study investigating the acute toxic effects after inhalation of the AquaNet North Seaproducts is not considered necessary.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | No acute inhalation toxicity |
| Justification for the selected value | Dicopper oxide is classified for acute inhalational toxicity. However, the substance is present in the products at subthreshold levels according to the ATE calculation method. |
| Classification of the product according to CLP | Not classified for acute inhalation toxicity |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity |
| Justification | Waiving according to Annex III, point 8.5.2, Column 3 of the BPR:  There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected. |

*Acute toxicity by dermal route*

No studies for the assessment of acute dermal toxicity of AquaNet North Seaproducts are available. Dicopper oxide and the co-formulants are not classified for this endpoint. Therefore, no acute dermal toxicity effects are expected, and no classification is required according to Regulation (EC) No 1272/2008.

According to Annex III, point 8.5.3, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, and the co-formulants are available in the product at low concentrations (<1%) only, a study investigating the acute dermal toxicity of AquaNet North Sea Products is not considered necessary.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No acute dermal toxicity |
| Justification for the selected value | No substances present in the Product Family are classified for acute dermal toxicity |
| Classification of the product according to CLP | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute dermal toxicity |
| Justification | Waiving according to Annex III, point No. 8.5.3, Column 3 of the BPR:  There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected. |

*Respiratory tract irritation*

No studies for the assessment of respiratory tract irritation of AquaNet North Seaproducts are available. None of the ingredients of the product mixture including the co-formulants in AquaNet North Seaproducts are classified for respiratory tract irritation.

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Not irritating to the respiratory tract |
| Justification for the value/conclusion | No substance present in the North Sea Product Family is classified for respiratory irritation (STOT SE 3; H335). Therefore, this BPF is not classified for this endpoint. |
| Classification of the product according to CLP | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | No study required for this endpoint according to Annex III to BPR. |

##### Information on dermal absorption

The AquaNet North Sea product family consists of two ready-for-use products and two concentrates which must be diluted with water before use.

No dermal absorption studies have been performed on the members of the AquaNet North Sea product family. The applicant has, however, performed *in vitro* dermal absorption studies, in accordance with the OECD 428 test guideline, on two closely related PT 21 products belonging to other product families; AquaNet Premium (AquaNet Premium BPF), a ready-to-use formulation containing approximately 10% dicopper oxide (Cu2O) and 2% Tralopyril (Bernal, J. 2018b), and on AquaNet LG 360 (AquaNet 360 BPF), a concentrate containing 13.8% dicopper oxide (Cu2O) and 3.9% copper thiocyanate (CuSCN) (Bernal, J. 2018a). The latter was tested both in its concentrated form and in the diluted in-use concentration (7.56% Cu2O and 2.14% CuSCN). Owing to deficiencies identified in the study on AquaNet Premium (analytical problems resulting in a lack of exposed skin samples), the study was considered invalid and was repeated.

The total amount of copper (non-radiolabelled) absorbed through split thickness human skin samples was measured using ICP-MS in both studies. The procedure is necessary as it is not technically feasible for copper to be radiolabelled.

As is the situation for other PT 21 paints, the applied paint dries on the skin samples and is difficult to wash off without damaging the skin sample. Hence, in the study on AquaNet LG 360 the paint was left on the skin for the full sample period of 24 hours, as recommended by the PT21 dermal absorption guidance (ECHA, 2016b). The *stratum corneum* was removed with up to 15 successive tape strips. All tape strips were photographed and analysed separately. Based on the photos taken, almost all paint was removed at the first two tape strips. Some splinters were however observed in some of the following strips for the diluted product (indicating that the paint was not fully removed), with concurrent higher measured values of test material. The test material in the paint layer should be considered as non-absorbed.

In the study, the receptor fluid was sampled six times at 1h, 2h, 4h, 8h, 12h and 24h from the commencement of the application. More than 75% of the total absorption was according to the study report recovered at half of the study duration (i.e., 12 hours), thus the material present in all tape strips was considered as non-absorbed (EFSA, 2017). There were quantifiable low levels of copper in the receptor fluid at the first sampling time only, whereas all other measurements were below the limit of quantification. Hence, the relative amount of copper in the receptor fluid at half the study duration could not be convincingly demonstrated due to uncertainties in the figures(measurements below the limit of quantification, LOQ were set as zero in the calculation of mean relative permeation in the receptor fluid at t0.5). Nevertheless, considering also the conservative exposure duration and the referred photo evidence, the exclusion of the tape strips was considered acceptable.

A second dermal absorption study was conducted on AquaNet Premium (Wallace, J., 2020). In the study, the paint was removed after 8-hours. To demonstrate the extent of paint removal, one photograph of each skin sample was taken before and one after the washing procedure was complete. After a 16-hour post-dose monitoring period. the stratum corneum was removed with 20 successive tape strips. Photographs were taken after each tape strip of the skin and tape strips (unless no paint was present on pre‑tape stripping image) until all the paint formulation had been removed from the skin surface.

Four‑hourly fractions of the receptor fluid from 0 to 24h post dose were collected. The test system, especially the cell apparatus, can contain levels of endogenous copper that must be accounted for to ensure reliable data. Hence, a second undosed group of skin samples from the same donors was set up, washed, terminated and analysed using the same methods described for those exposed to the test preparation. Based on the undosed group results (and the results of blank sample analysis), it was not considered necessary to adjustthe data to account for intrinsic copper content since low background levels of Cu were measured.

An adjustment was nevertheless made for the receptor wash samples. Small, but measurable levels of copper (all values above LOQ) were found for the undosed group at around the same levels as the ones in the test material treated group. It was concluded that the copper present in the receptor wash sample is very unlikely to come from the test material and should not contribute to the risk assessment figures. Hence, the mean receptor wash value from the undosed group (0.11%) was subtracted from each individual cells in the test material treated group. The impact on the dermal absorption value of this adjustment was minor.

Since all measurements in the receptor fluid for skin samples with applied test material were below the LOQ, it was not possible to determine the extent of absorption as defined in the EFSA guidance. Hence, it could not be concluded that the absorption was essentially complete at half of the study duration. Furthermore, based on the available photo evidence of the tape strips, there was no convincing evidence for disregarding tape strips 3+. Consequently, a potential absorbable dose was calculated including tape strips 3+, in agreement with the EFSA guidance.

Where values measured were below LOQ, this value was used in calculations. An additional set of results were generated on the request of the applicant (report amendment 1) for which all values for the test material treated group were corrected for the background/LOQ values seen in the undosed group. However, it was stressed in the report that these values represent the very best case for absorption. The real amount of absorbed copper is likely to be somewhere in between the two sets of calculated values. Keeping in mind the uncertainties in the figures and the aim of the risk assessment, i.e. to ascertain safe use of the workers, the rMS is of the opinion that the calculated best-case values would not be sufficiently protective.

It's a general principle that the relative dermal absorption from a formulation is inversely related to the concentration of the substance in question (EFSA, 2017). The concentration of dicopper oxide in the tested formulations are all lower than the concentration in the AquaNet North Sea family members and are thus suitable to be used for read across to this product family. Furthermore, the rMS has evaluated the compositions of these 3 product families to be similar enough for such a read across to be valid (please see more details on this in the confidential annex to this PAR).

More specifically, there is a high level of similarity in the composition among the ready-for-use formulations and among the concentrates, also across the product families. The rMS consider that the results of the dermal absorption study on Aquanet Premium (10% Cu2O and 2% Tralopyril) can be used also for the Aquanet North Sea Standard and Aquanet North Sea Ultra products. Hence a dermal absorption value of 1.1% has been used in the risk assessment of these two family members (see summary table below).

The rMS also consider that the results of the dermal absorption study on Aquanet LG 360 (in-use dilution of the formulation containing 7.56% Cu2O and 2.14% CuSCN) can be used for the Aquanet North Sea CCT 100 plus and Aquanet North Sea C50 products. Hence a dermal absorption value of 0.4% has been used in the risk assessment of in-use dilutions of these two family members (see summary table below). For the concentrated products, a dermal absorption value of 0.1% can be used for risk assessment purposes in line with the result of the dermal absorption study on concentrated Aquanet LG 360. However, the exposure to the operator using these products will mainly be to the in-use dilutions of the products. The exposure to the undiluted products can only happen during the transfer of the product from the IPC to the dipping vat and is likely to be very low/negligible.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AquaNet North Sea BPF (RTU-formulations)** | | | | | | | **Tested formulation** | |
|  | **AquaNet North Sea Standard**  **% (w/w)** | | **AquaNet North Sea Ultra**  **% (w/w)** | | **AquaNet North Sea Ultra old**  **% (w/w)** | | **AquaNet Premium (Aquanet Premium BPF)**  **% (w/w)** | |
| Dicopper oxide | 17.46 | | 21.8 | | 29.5 | | 9.99 | |
| Copper2 | 15.5 | | 19.4 | | 26.2 | | 8.87 | |
|  | | | | | | | | |
| **AquaNet North Sea BPF (concentrated formulations)** | | | | | | **Tested formulation** | | |
|  | **AquaNet North Sea CCT 100 plus**  **% (w/w)** | | | **AquaNet North Sea C50**  **% (w/w)** | | **AquaNet LG 360 (Aquanet 360 BPF)**  **% (w/w)** | | |
|  | Conc. | In-use1 | | Conc. | In-use1 | Conc. | | In-use1 |
| Dicopper oxide | 26.42 | 15.23 | | 19.83 | 14.23 | 13.8 | | 7.56 |
| Copper thiocyanate | - | - | | - | - | 3.91 | | 2.14 |
| Copper2 | 23.46 | 13.52 | | 17.6 | 12.63 | 14.3 | | 7.83 |

1 Density has been taken into account when calculating the concentration of the active substances in the in-use dilutions of the products.

2 Conversion factors: ([Cu2O]\*0.888) and ([CuSCN]\*0.522

| **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** | **Remarks** *(e.g. major deviations)* |
| In-vitro human skin pene-tration of total copper in AquaNet LG 360 PT21 Biocide product  OECD TG 428 (2004)  GLP  Reliability 1  Bernal, J. (2018a) | *In vitro*, split thickness human skin, abdomen, 4 donors, 2 samples per dose  Static diffusion cells, 24h exposure  Receptor fluid sampled at 1h, 2h, 4h, 8h, 12h and 24h  Tape stripping (max 15)  Photo-evidence of tape strips | | AquaNet LG360  Concentrate: dicopper oxide 13.8% and copper thiocyanate  3.9%  Dilution: concentrate diluted 1:1 with water | |  |  |  | | --- | --- | --- | | Compart-ment | Concentrate | Dilution | | Tape strips  1 & 2 | 108.88±  13.87 | 96.52±  4.46 | | Tape-strips 3+ | 0.44±  0.40 | 3.07±  3.54 | | Skin  (exposed + surrounding skin) | 0.05±  0.05 | 0.28±  0.11 | | Receptor Fluid  (incl. receptor compartment rinsing) | 0.01±  0.001 | 0.01±  0.02 | | Potentially absorbable dose\* | 0.06±  0.05 | 0.29±  0.12 | | Total absorption (mean + 0.84\*SD) | 0.109 | 0.400\*\* | | Total recovery | 109.39±  13.8 | 98.9±  5.06 | | \* Skin + receptor fluid - all tape-strips (absorption complete)  \*\*Excludes one cell owing to poor recovery (therefore n=7; mean + 0.92\*SD) | | |   Final dermal absorption value correcting for variability according to EFSA, 2017:  0.1% (concentrate) and 0.4% (dilution) | Non-radio-labelled (copper cannot be radio-labelled)  absorption of total copper measured  Values below LOQ set as zero in the calcu-lations;  thus underestimating somewhat the dermal absorption |
| The In Vitro Percutaneous Absorption of Dicopper Oxide in AquaNet Premium antifouling paint formulation through Human Split-Thickness Skin  OECD TG 428 (2004)  GLP  Reliability 1  Wallace, J (2020) | | *In vitro, split thickness human skin, abdomen, 12 samples from 4 donors (8 processed)*  *Additional 8 samples from 4 donors (blank controls to account for intrinsic copper levels in the matrices).*  *Blank samples:*  *(4 receptor fluid,*  *4 skin, 4 tape strips, 4 skin washes, 4 tissue swabs, 8 donor and 8 receptor chamber washes).*  *Flow-through diffusion cells,*  *8 h exposure (paint removed with Swarfega® Paint Pro),*  *16 h post exposure monitoring.*  *Photos demonstrating extent of paint removal.*  *4h fractions of receptor fluid (0 to 24h post dose).*  *Tape stripping (20). Photo-evidence.* | AquaNet Premium  dicopper oxide 10% and tralopyril 2% | |  |  | | --- | --- | | Compartment | Concentrate | | Tape strips 1 & 2 | 1±0.73 | | Tape-strips 3+ | 0.65±0.10 | | Exposed skin | 0.23±0.05 | | Receptor fluid | 0.07±0.00 | | Receptor wash | 0.01±0.01 | | Total absorbed dose\* | 0.08±0.01 | | Dermal delivery\*\* | 0.30±0.05 | | Potential absorbable dose \*\*\* | 0.95±0.12. | | Total recovery | 104.84±  5.26 | | \*cumulative receptor fluid + receptor chamber wash (excluding mean value from the undosed group from the latter).  \*\*absorbed dose + exposed skin.  \*\*\* Dermal delivery + *stratum corneum* 3-20 | |   Final dermal absorption value correcting for variability according to EFSA, 2017  (mean value + 0.84 x standard deviation; n=8): 0.4% (excluding tape strips) – 1.1% (including tape strips 3-20) | Non-radio-labelled (copper cannot be radio-labelled)  Absorption of total copper measured  LOQ used in the calcu-lations for values below LOQ |

|  |  |  |  |
| --- | --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | | |
| Substance | Dicopper Oxide | Dicopper Oxide |
| Value(s) | 1.1% | 0.4 % |
| Justification for the selected value(s) | Read-across to an *in vitro* study through human skin conducted on a similar formulation (AquaNet premium) (Wallace, J. 2020). Valid only for the ready-for-use formulations in the family; AquaNet North Sea Standard and AquaNet North Sea Ultra (old and current version) | Read-across to an *in vitro* study through human skin conducted on a similar formulation (AquaNet LG 360) (Bernal, J. 2018a).  Valid for the in-use dilutions of the concentrated formulations in the family; AquaNet North Sea CCT 100 plus and AquaNet North Sea C50 |

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

Toxicological information on the co-formulants is summarized in a separate report (see further information in the confidential annex).

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

Not relevant

***Other***

***Endocrine disrupting potential***

According to the assessment performed according to the draft document "*Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA",* none of the formulants contained in the products of the AquaNet North Sea family are identified as endocrine disruptors.

However, there might be indications that one co-formulant shows alerts for endocrine disruption potential from in vitro assays and in silico models. An Endocrine Disruption Screening Program (EDSP) 21 search was done, and the substance tested positive in 5 of 26 estrogen receptor (ER) bioactivity assays; 8 of 16 androgen receptor (AR) bioactivity assay, 5 of 10 thyroid bioactivity assays and 2 of 2 steroidogenesis assays. According to a ToxCast model prediction for the co-formulant, it seems to be an ED alert at least for anti-androgenicity, that should be further explored. No evidence of endocrine disruption effects has been observed in standard in vivo regulatory studies or in the published literature. Based on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. The co-formulant is a biocidal active substance currently under evaluation as an active substance. If the substance is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

Another co-formulant is included in the 2022 CORAP-list with suspected reproduction toxic effects included as initial grounds for concern. ED is not among the initial grounds of concern to be clarified under substance evaluation, and the co-formulant does not have ED indications based on the available information. This situation might change however, if substance evaluation would show reprotoxic properties with a possible ED mode of action. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

The complete assessment is available in the confidential annex (1.6).

#### Exposure assessment

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

Nets used to house fish in aquaculture are coated with an antifouling product before being used on fish farms. The treatment process is undertaken industrially by specialist companies. This document assesses the risks to the operators and workers involved in the treatment and deployment of nets when using the products in the AquaNet North Sea biocidal product family, in compliance with Regulation (EU) No. 528/2012. The relevant work tasks for industrial and professional workers dealing with antifouling coating nets are described below

***Mixing and loading***

Under normal working procedures, the product is pumped directly from the 1000 litre IBC containers into larger storage tanks. From here the product is pumped to the treatment unit using integrated systems. After a treatment episode, the unused product is pumped back to the storage tank for re-use. Internal circulation pumps in holding/storage tanks are also common. Since there is no pouring or mixing by hand, no physical contact is expected. However, as a worst-case scenario, some dermal exposure may occur during the fixing/removing of the pump lines to the IBC (Figure 1).



Figure 1: Mixing and loading operations with AquaNet products (Figure: Steen-Hansen)

***Treatment of nets***

In general, there are two methods in use for the treatment of aquaculture nets; crane assisted dipping in open tanks and vacuum treatment.

**Crane assisted dipping**

Crane assisted dipping is performed by lowering the net into a vat containing the product. The net is left submerged in the product for approximately 20 minutes whilst being held down by a weight attached to a crane. After treatment, the weight is removed, and the net is either rolled back onto the roller or is gradually lifted by the crane to allow unattached product to drain off the net (Figure 2). It is assumed that no more than two nets are treated during a working day, and that this task is performed 2-3 times per week.

There is a potential for dermal exposure through contact with contaminated surfaces/equipment.



Figure 2: Net dipping procedure using dipping tanks (Figure: Steen-Hansen)

**Vacuum treatment**

Vacuum treatment is performed by placing the net inside a special bag. The bag is then sealed tight and is filled with product. Repeated vacuum cycles are then applied to "suck" the product into the net, and later to remove excess product from the net. At the end of the treatment, excess product is pumped out from the bottom of the bag. The drip-dry net is then hoisted out of the bag by crane or winch.

There is a potential for exposure to the body and hands through direct contact with the treated nets when manually reconnecting the nets from the hoist after impregnation.

The applicant Steen-Hansen recommends dip treatment with their products, as they are of the opinion that this method gives the best quality of the treatment. It can nevertheless not be excluded that some service stations, choose to apply their products using the vacuum method.

***Net drying***

After treatment, the net can be left hanging freely over the dipping tank to dry in ambient temperature. The drying may also be accelerated by exposing it to dried heated air. Net drying may also be done in a separate drying station. An alternative method in use is when the net is wound up on a net roller which is injected in the centre with dried heated air.

When the net is totally dry, it is transferred to a compression/packing unit where it is tightly packed in a sealed waterproof bag. The transfer of the treated net is performed using winches or cranes. In a worst-case scenario, the drip-free net is suspended in a drying tower or left dry freely using outside freestanding cranes (Figure 3).

Exposure may occur when the treated net is connected to the crane or drying roller in the drying station and by manual assistance when the net is wound up on the roller.



Figure 3: Net drying procedure (Figure: Steen-Hansen)

***Cleaning of dipping vats***

Cleaning of dipping vats is normally performed once pr. year. All product is pumped out of the vat and the metal inlay is hoisted out and is left to dry overnight. Residues in the bottom of the vat is removed manually and transferred to an empty IBC. The inlay is then scraped free of dry product.

The task is performed by the same personnel as performs the net dipping. Some contact with wet surfaces will occur and single-use coveralls, boots, gloves and a face shield are used when cleaning is performed.

***Inspection and repair of used nets***

Net service companies typically treat both new and used nets. Used nets are returned to the service station by boat or truck in closed containers. The nets are then cleaned and disinfected before they are thoroughly inspected and repaired if necessary.

The net is lifted using an electrically operated hoist/crane and manoeuvred into a tumble washer containing seawater. It is washed for 3 – 5 hours where the biofouling and old coating are removed primarily through mechanical action. The cleaning is conducted in a closed loop process with the wash water being reused after extraction of the solid waste. The solid waste is incinerated or is sent for recovery of the metals. The washed nets are then submerged in disinfectant fluids in an aseptic zone (Figure 4). No physical contact is expected during the net cleaning procedures.



Figure 4: Net washing and disinfection procedure (Figure: Steen-Hansen)

**Inspection/repair of cleaned nets**

The entire net is inspected for damage and the breakage strength is tested in several places, depending on the size of the net (Figure 5). Any damaged areas are repaired manually. This activity requires physical handling of the nets.

The nets will, however, at this point contain a very small amount of remaining product. Personnel involved in the inspection and repair process may thus be exposed to a very small amount of product residues by dermal contact with the net and through inhalation of formed dust.



Figure 5: Net inspection procedure (Figure: Steen-Hansen)

***Deployment/removal of nets***

The treated net is hoisted by a crane into a service boat. The net is attached to one side of a floating frame and then pulled towards the other side of the frame. Remotely controlled weights and supports are lowered into the water. The net is attached to floats and its upper part is tied to the cage fence. These activities require handling the nets and although limited, physical contact is expected, and workers would be exposed via the dermal route. Removal of the net is the opposite process of deployment. Up to 6 people are involved in the deployment of one net and the operators may deploy up to 3-7 nets in a day. As nets are normally changed with 5 – 10 months intervals, the involved personnel perform this task infrequently.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: relevant paths of human exposure** | | | | | | | |
| Exposure path | **Primary (direct) exposure** (treatment of nets) | | | **Secondary (indirect) exposure**  (deployment and washing of nets) | | | |
|  | Industrial use | Professional use | Non-professional use | Industrial use | Professional use | Non-professional use | 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 |

***List of scenarios.***

***Mixing and loading***

Minimal risk of exposure is expected as the mixing and loading process is automated and occurs in a closed system. Some accidental exposure can occur during fixing/removal of the pump lines. Mixing and loading is included in Dipping model 4 and is not assessed separately.

***Inspection and repair of used nets***

A scenario to assess exposure from the task of inspecting and repairing used nets does not exist. At the end of the service life of a net, it is in the risk assessment for the environment assumed that approx. 80% of the active substances has leached out. Before being inspected, the nets have also been thoroughly washed in a tumble washing machine with the aim to remove all remaining coating and attached debris and have been disinfected. It can thus reasonably be expected that the small amount of product residues that may still be found in the nets at this point represents a negligible exposure compared to e.g. deployment of nets. This task is thus not further assessed.

***Treatment of nets – semiautomatic dipping***

A scenario to assess exposure from dip treatment of aquaculture nets, Dipping model 4, is found in the Biocides Human Health Exposure Methodology (page 311, ECHA, 2015a). The scenario includes dispensing product from IBC (mixing and loading), stirring and crane assisted dipping of both solvent-based and water-based products. Indicative values for this scenario are further given (page 199). The indicative values are the maximum values due to the low number of measurements and the large variation.

The scenario is based on survey data from different dipping processes.

According to the guidance document, 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 similar retrieval at the conclusion of the process. This work is then followed by the drying and preparation of the nets and wrapping prior to transportation to the ultimate customer.

The survey reports it is based on are, however, rather old (from 1999), and the number of measurements is very low (n=9). The dipping techniques used differ between the sites included in the survey with different degrees of automatization and hence potential for dermal exposure. Dermal exposure resulted from manually connecting/disconnecting of treated nets to hoists/forklifts/drums, contact with contaminated surfaces, manually immersion of buoyant nets using sticks (where relevant, two sites only) and particularly from physical contact when transferring the nets to the drying stations.

Several of the measurements (n=5) are from dipping and packing of nets treated with solvent based products. Nets treated with solvent based products need to be packed and deployed in a damp state and might therefore result in a high exposure to the involved personnel. Solvent based net impregnation products are no longer on the market in Europe. Nets treated with water-based products on the contrary must be completely dry before they can be packed. The packing process does no longer involve any manual handling as the nets are transferred directly by winch into a special waterproof net bag in a compression unit for packing.

The dipping process has been developed in the last 20 years, as both the aquaculture business and its service providers has grown significantly and professionalised in this period. The service stations use, to our knowledge, treatment processes which involve very little degree of physical contact with the nets during the treatment process.

The recommendation in the Biocides Human Health Exposure Methodology for this exposure model is that the maximum value is used, due to the low number and the variability of the data. This is obviously a very conservative approach, and the exposure calculations must therefore be regarded as conservative.

***Treatment of nets – Vacuum treatment***

No scenario exists for the assessment of exposure from vacuum treatment of nets. Many of the tasks involving potential exposure to treated nets and contaminated surfaces are, however, identical as for dipping, such as connecting/disconnecting of nets to cranes/winches and transferring the nets to the drying station.

It is assumed that the Dipping model 4 also covers treatment using the vacuum method.

***Cleaning of dipping vats***

No scenario exists for the assessment of exposure from cleaning of dipping vats. Cleaning is normally performed once per year and is performed using single-use coveralls, gloves, boots and face shields. The exposure is regarded as being covered by the dipping 4 model.

***Deployment of treated nets***

A scenario to assess exposure from deployment and installation of a net at a fish farm, Handling model 2, is found in the Biocides Human Health Exposure Methodology (page 303, ECHA, 2015a). Indicative values for this scenario are further given (page 198) and are the 75th percentile values.

The situation is similar for the exposure scenario for deployment of a treated net as for treatment of nets. The scenario is titled "installing fish cages using lifting equipment and handling nets damp with sticky product". The original surveys the scenario is based upon are rather old, and the number of data is very low. For several of the data, the workers are employing nets treated with solvent based antifouling products, requiring that the nets are still damp with product at deployment. This will inevitably result in a higher risk for exposure than if the nets are treated with a water-based product which is completely dry before the net is installed. The assessment must therefore be regarded as being conservative.

| **Summary table: Scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary (direct) or secondary (indirect) exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) | |
| 1. | Dipping Model 4; Net Dipping | Describes the process of mixing and loading antifouling product into reservoirs for net dipping, crane assisted net dipping and the packing of treated nets for shipment out to the customer. The model covers the use of both water-based and solvent based products. Hand exposure is actual values inside gloves. Indicative values are maximum values. | Industrial workers | |
| 2. | Handling model 2; Net deployment/removal | Describes the process where the treated net is hoisted by a crane from a service boat and employed in the sea at an aquaculture farm. It will also cover the process of changing a net which is still in service in an active fish farm. These activities require handling the nets and although limited, physical contact is expected, and workers would be exposed via the dermal route. Removal of the net is the opposite process of deployment.  Hand exposure is actual values inside gloves. Indicative values are 75th percentile values. | Professional operators | |

| **Description of Scenario 1: Net dipping** | | |
| --- | --- | --- |
| **Dipping Model-4** | | |
|  | Parameters | Value |
| Tier 1 | Body1 | 221 mg/min |
| Hands1  (Hand exposure values are actual measurements inside gloves) | 16.7 mg/min |
| Inhalation1 | 0.20 mg/min |
| Inhalation rate2 | 1.25 m3/h |
| Duration1 | 60 min. |
| Body weight2 | 60 kg |
| Dermal absorption4  (copper) | 1.1% for AquaNet Standard and AquaNet Ultra(old).  0.4% for AquaNet CCT 100 plus and C50. |
| Tier 2a | Clothing penetration  (coated coverall)3 | 10% |
| Hand exposure1 | Hand exposure values are actual measurements inside gloves. |
| Tier 2b | Clothing penetration (Impermeable coverall)3 | 5% |
| Hand exposure1 | Hand exposure values are actual measurements inside gloves. |
| Tier 2 c | Clothing penetration  (Double coverall)3 | 1% |
| Hand exposure1 | Hand exposure values are actual measurements inside gloves. |

1) Dipping model 4; Biocides Human Health Exposure Methodology, maximum values (ECHA, 2015a).

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

3) HEEG opinion 9, Default protection factors for protective clothing and gloves

4) Dermal absorption of copper (Wallace, 2020; Bernal, 2018a)

| **Description of Scenario 2: Net deployment** | | |
| --- | --- | --- |
| **Handling model 2** | | |
|  | Parameters | Value |
| Tier 1 | Body1 | 7.55 mg/min |
| Hands1  (Hand exposure values are actual measurements inside gloves) | 0.21 mg/min |
| Duration1 | 300 min |
| Body weight2 | 60 kg |
| Dermal absorption3  (copper) | 1.1% for AquaNet Standard and AquaNet Ultra(old).  0.4% for AquaNet CCT 100 plus and C50. |
| Tier 2 | Clothing penetration  (Uncoated cotton coveralls (dry))2 | 25% penetration from dry substances |
| Hand exposure1 | Hand exposure values are actual measurements inside gloves |

1) Handling model 2; Biocides Human Health Exposure Methodology, 75 percentile values (ECHA, 2015a).

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

3 Dermal absorption of copper: (Wallace, 2020; Bernal, 2018a)

**General assumptions:**

The systemic exposure to the active substance via the dermal and inhalation routes was estimated using default physiological values (body weight, breathing rate, etc.) and either default or refined model input values for each scenario. After estimation of the systemic exposure, the occupational risks were estimated by comparing the level of systemic exposure with the relevant toxicological reference value for the active substance.

The long-term Acceptable Exposure Level value (AEL) of 0.041 mg Cu/kg bw/day was used in the assessment of net treatment based on the description of the frequency of use. Personnel involved in net treatment may perform this task 2-3 days per week the whole year. In the assessment of net deployment, the medium term AEL value of 0.082 mg Cu/kg bw/day was used since this task is performed infrequently. This value is reported in the Assessment Report for the approval of dicopper oxide as a biocidal active substance.

An initial screening assessment (Tier-1) using default assumptions and only minimal clothing as well as gloves (hand exposure being actual values inside gloves) was conducted. Since AquaNet products are for professional use only, this was considered the “extreme” worst-case scenario and is unlikely to be representative of the normal workplace. A tier-2 approach was used for the estimation of dermal exposure in the net dipping and net deployment scenarios, and different level of PPE was considered to translate more realistic scenarios.

Based on a tiered approach, the exposure assessment and risk characterisation were performed for the family members of the AquaNet North Sea BPF.

| **Active substances present in the**  **AquaNet North Sea product family members** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Representative product | **Standard** | **Ultraold1** | **Ultra** | **CCT100+** | **C50** |
| Active ingredient (% Cu2O, w/w) | 17.5 | 29.5 | 21.8 | 26.4 | 19.8 |
| Read-for-use or concentrate | Ready for use | Ready for  use | Ready for use | Concentrate (1:1 dilution with water) | Concentrate (1:0.5 dilution with water) |
| In-use concentration Cu2O (%, w/w)2 | 17.5 | 29.5 | 21.8 | 15.2 | 14.2 |
| Ionic equivalents (In-use conc. of copper; % w/w)3 | 15.5 | 26.2 | 19.4 | 13.5 | 12.6 |

1 Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

2 Density has been taken into account when calculating the in-use concentrations.

3 Conversion factors: ([Cu2O]\*0,888)

***Industrial exposure***

*Scenario [1] Industrial use: Net treatment*

The modelling input parameters of Dipping model 4 were used to calculate the exposure values for the AquaNet North Sea BPF members.

|  |  |
| --- | --- |
| **Summary table: Estimated systemic exposure from industrial use** | | | | | |
| **Exposure scenario** | Tier/PPE | Estimated inhalation uptake (mg/kg bw) | Estimated dermal intake (mg/kg bw) | Estimated oral intake (mg/kg bw) | Estimated total systemic uptake (mg/kg bw) |
|  | | | | | |
| **Scenario 1: Net dipping** | | | | | |
|  | | | | | |
| **AquaNet North Sea Standard** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Industrial dipping of aquaculture nets; Dipping model 4 | Tier 1; Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves) | 6.51e-04 | 0.41 | - | 0.41 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves | 6.51e-04 | 0.066 | - | 0.067 |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves | 6.51e-04 | 0.047 | - | 0.048 |
|  | Tier 2c; double coverall (1% penetration) and gloves | 6.51e-04 | 0.032 | - | 0.033 |
|  | | | | | |
| **AquaNet North Sea Ultraold1** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Industrial dipping of aquaculture nets; Dipping model 4 | Tier 1; Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves) | 1.1e-03 | 0.69 | - | 0.69 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves | 1.1e-03 | 0.11 | - | 0.11 |
|  | Tier 2b; impermeable coverall (5% penetration) and gloves | 1.1e-03 | 0.080 | - | 0.081 |
|  | Tier 2c; double coverall (1% penetration) and gloves | 1.1e-03 | 0.054 | - | 0.056 |
|  | | | | | |
| **AquaNet North Sea Ultra** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Industrial dipping of aquaculture nets; Dipping model 4 | Tier 1; Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves) | 8.1e-04 | 0.51 | - | 0.51 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves | 8.1e-04 | 0.083 | - | 0.083 |
|  | Tier 2b; impermeable coverall (5% penetration) and gloves | 8.1e-04 | 0.059 | - | 0.060 |
|  | Tier 2c; double coverall (1% penetration) and gloves | 8.1e-04 | 0.040 | - | 0.041 |
|  | | | | | |
| **AquaNet North Sea CCT 100 plus** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Industrial dipping of aquaculture nets; Dipping model 4 | Tier 1; Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves) | 5.7e-04 | 0.13 | - | 0.13 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves | 5.7e-04 | 0.021 | - | 0.022 |
|  | | | | | |
| **AquaNet North Sea C50** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Industrial dipping of aquaculture nets; Dipping model 4 | Tier 1; Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves) | 5.3e-04 | 0.12 | - | 0.12 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves | 5.3e-04 | 0.020 | - | 0.020 |

1.Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

***Professional exposure***

*Scenario [2] Professional use: Net deployment*

The modelling input parameters of Handling model 2 were used to calculate the exposure values for the AquaNet North Sea BPF members.

|  |  |
| --- | --- |
| **Summary table: Estimated systemic exposure from professional use** | | | | |
| **Exposure scenario** | Tier/PPE | Estimated inhalation uptake (mg/kg bw) | Estimated dermal intake (mg/kg bw) | Estimated total systemic uptake (mg/kg bw) |
|  | | | | |
| **Scenario 2: Net deployment** | | | | |
|  | | | | |
| **AquaNet North Sea Standard** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional deployment of nets | Tier 1;  Light clothing (100% penetration),  gloves (hand exposure is actual exposure inside gloves) | - | 0.066 | 0.066 |
|  | | | | |
| **AquaNet North Sea Ultraold1** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional deployment of nets | Tier 1;  Light clothing (100% penetration),  gloves (hand exposure is actual exposure inside gloves). | - | 0.11 | 0.11 |
|  | Tier 2  uncoated coveralls, gloves (hand exposure is actual exposure inside gloves) | - | 0.030 | 0.030 |
|  | | | | |
| **AquaNet North Sea Ultra** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional deployment of nets | Tier 1;  Light clothing (100% penetration),  Gloves (hand exposure is actual exposure inside gloves). | - | 0.083 | 0.083 |
|  | Tier 2  uncoated coveralls, gloves (hand exposure is actual exposure inside gloves) | - | 0.022 | 0.022 |
|  | | | | |
| **AquaNet North Sea CCT 100 plus** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional deployment of nets | Tier 1;  Light clothing (100% penetration),  gloves (hand exposure is actual exposure inside gloves) | - | 0.021 | 0.021 |
|  | | | | |
| **AquaNet North Sea C50** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional deployment of nets | Tier 1;  Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves) | - | 0.020 | 0.020 |

1.Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

#### Risk characterisation for human health

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

**(ref: Assessment report for dicopper oxide (ECHA, 2016a))**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **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 |

***Industrial exposure***

*Scenario [1] Industrial use: Net dipping*

The predicted levels of systemic exposure of operators to copper when undertaking net dipping activities of the Aquanet North Sea products are summarised and compared with the relevant AEL-value below.

|  |  |
| --- | --- |
| **Risk characterisation of industrial use** | | | | |
| **Exposure scenario** | Tier/PPE | Estimated total systemic uptake (mg/kg bw) | AELLong term (mg/kg bw/day) | **Exposure/AEL** |
|  | | | | |
| **Aquanet North Sea Standard** | | | | |
|  | | | | |
| **Copper** | | | | |
| Industrial dipping of nets; Dipping model 4 | Tier 1;  Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves)) | 0.41 | 0.041 | **9.9** |
|  | Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves). | 0.067 | 0.041 | **1.6** |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves). | 0.048 | 0.041 | **1.2** |
|  | Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves). | 0.033 | 0.041 | 0.80 |
|  | | | | |
| **Aquanet North Sea Ultraold1** | | | | |
|  | | | | |
| **Copper** | | | | |
| Industrial dipping of nets Dipping model 4 | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.69 | 0.041 | **17** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.11 | 0.041 | **2.8** |
|  | Tier 2b;  Impermeable coverall (5% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.081 | 0.041 | **2.0** |
|  | Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves). | 0.056 | 0.041 | **1.4** |
|  | | | | |
| **Aquanet North Sea Ultra** | | | | |
|  | | | | |
| **Copper** | | | | |
| Industrial dipping of nets Dipping model 4 | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.51 | 0.041 | **12** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.083 | 0.041 | **2.0** |
|  | Tier 2b; Impermeable coverall (5% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.060 | 0.041 | **1.5** |
|  | Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves). | 0.041 | 0.041 | 1.0 |
|  | | | | |
| **Aquanet CCT 100 Plus** | | | | |
|  | | | | |
| **Copper** | | | | |
| Industrial dipping of nets; Dipping model 4 | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.13 | 0.041 | **3.2** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.022 | 0.041 | 0.53 |
|  | | | | |
| **Aquanet C50** | | | | |
|  | | | | |
| **Copper** | | | | |
| Industrial dipping of nets Dipping model 4 | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.12 | 0.041 | **2.9** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.020 | 0.041 | 0.49 |

1.Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Conclusion: The risk assessment of exposure to copper to industrial workers performing net treatment activities using AquaNet North Sea Standard shows an acceptable risk, with an exposure AEL ratio of 0.80 in the tier 2c assessment. Safe use requires the use of double coveralls (1% penetration) and gloves.

The risk from systemic exposure to copper to industrial workers performing net treatment activities using AquaNet North Sea CCT 100 plus and AquaNet North Sea C50 was acceptable in the tier 2a assessment. Safe use requires the use of coated coveralls (10% penetration) and gloves.

Safe use could not be demonstrated for AquaNet North Sea Ultraold even with use of double coveralls and gloves. Consequently, the product was modified (new name: AquaNet North Sea Ultra). reducing the amount of active substance content to an acceptable level. Safe use of the modified product necessitates use of double coveralls and gloves.

*Scenario [2] Professional use: Net deployment*

The predicted levels of systemic exposure of operators to cuprous oxide when undertaking net deployment activities are summarised and compared with the relevant AEL-value below.

|  |  |
| --- | --- |
| **Risk characterisation of professional use** | | | | |
| **Exposure scenario** | Tier/PPE | Estimated total systemic uptake (mg/kg bw) | AELMedium term (mg/kg bw/day) | **Exposure/AEL** |
|  | | | | |
| **Aquanet North Sea Standard** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional aquaculture net deployment; Handling model 2. | Tier 1;  Light clothing (100% penetration) and gloves  (hand exposure is actual exposure inside gloves) | 0.066 | 0.082 | 0.81 |
|  | | | | |
| **Aquanet North Sea Ultraold1** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional aquaculture net deployment; Handling model 2. | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.11 | 0.082 | **1.4** |
| Professional aquaculture net deployment; Handling model 2. | Tier 2; Uncoated cotton coveralls, gloves (hand exposure is actual exposure inside gloves) | 0.030 | 0.082 | 0.37 |
|  | | | | |
| **Aquanet North Sea Ultra** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional aquaculture net deployment; Handling model 2. | Tier 1; Light clothing (100% penetration); gloves (hand exposure is actual exposure inside gloves) | 0.083 | 0.082 | 1.0 |
| Professional aquaculture net deployment; Handling model 2. | Tier 2; Uncoated cotton coveralls, gloves (hand exposure is actual exposure inside gloves) | 0.022 | 0.082 | 0.27 |
|  | | | | |
| **Aquanet North Sea CCT 100 plus** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional aquaculture net deployment; Handling model 2. | Tier 1; No PPE (100% penetration) gloves (hand exposure is actual exposure inside gloves) | 0.021 | 0.082 | 0.26 |
|  | | | | |
| **Aquanet North Sea C50** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional aquaculture net deployment; Handling model 2. | Tier 1; Light clothing(100% penetration) gloves (hand exposure is actual exposure inside gloves) | 0.020 | 0.082 | 0.24 |

1.Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Conclusion: The risk to professional workers involved in net deployment activities of nets treated with AquaNet North Sea Standard, AquaNet North Sea Ultra, CCT 100 plus and C50 was demonstrated to be acceptable in the tier 1 assessment.

The risk to workers involved in net deployment activities of nets treated with AquaNet North Sea Ultraold was demonstrated to be acceptable in the tier 2 assessment. Tier 2 assumes the use of uncoated coveralls (25% penetration).

Gloves are normally worn, also due to physical strain and in the North Atlantic region due to low temperatures.

***Combined scenarios***

Not applicable

***Local effects***

A classification for Eye damage 1 (H318) is proposed for all products in the AquaNet North Sea family; therefore, consideration of a local risk assessment is required. No relevant quantitative information is available in order to conduct a quantitative risk assessment, and so in this case a qualitative risk assessment is considered appropriate in accordance with the BPR Guidance (Chapter 4.3, ECHA, 2017a).

Most of the net treatment process is remotely operated and does not involve physical contact with the dipping vat/vacuum impregnation bag or the treated net. The tasks where the workers may be at risk to be exposed to splashes or dripping of product that may come into their eyes, thus constitute a limited part of the whole treatment process. By requiring that protective goggles or similar eye protection is used during the performance of these tasks, the risk of serous eye damage will be minimal.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | |  | **Risk** | |
| Hazard category | Effects in terms of c&L | 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 | Industrial workers | Net treatment | skin  Eye (splashes, hand to eye transfer) | 2-3 days per weeks  Only a few minutes potential exposure due to automated processes;  intermittent handling of treated nets at various stages of dryness,  (mainly due to connecting/ disconnecting of treated nets to hoist/drums), incidental contact with contaminated surfaces | n.r. | Minimisation of manual phases (automatization; crane assisted lifting of nets)  Avoidance of contact with contaminated tools and objects  Training for staff on good practice; instructions for use  Regular cleaning of equipment and work area  Good standard of personal hygiene  Coveralls, gloves, eye protection (goggles)  Labelling as H318 | Acceptable  +Automated processes;  Minimal potential for exposure  +Minimal aerosol formation  +trained workers  +use of appropriate PPE |
| Professionals | Net deployment | Skin  Eye (dust, hand to eye transfer) | Infrequent task  Dermal contact with dry treated nets.  Practically no exposure to eyes due to the use of goggles during net deployment. | n.r. | Training for staff on good practice; instructions for use  Good standard of personal hygiene  Coveralls, gloves, goggles\*  *\*goggles are worn during net deployment because of risk of debris from nets (e.g. dried microorganisms)* | Acceptable  +Exposure to dry nets  +trained workers  +use of appropriate PPE |

**Conclusion**

***Industrial exposure***

*Net treatment activities:*

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 products formulated as concentrates, AquaNet North Sea CCT 100 plus and AquaNet North Sea C50, show and acceptable risk in the tier 2a assessment. Safe use requires the use of coated coveralls (10% penetration) and gloves.

For the family members formulated as ready-for-use products, AquaNet North Sea Standard gives an acceptable risk in the tier 2c assessment. Safe use requires the use of double coveralls (1% penetration) and gloves.

Safe use could not be demonstrated for AquaNet North Sea Ultraold (29.5% Cu2O) even with the use of double coveralls. An acceptable risk was estimated for the modified product, AquaNet North Sea Ultra.

Due to the classification of the products for Eye damage 1 (H318), protective goggles or similar eye protection should be used for the tasks where the workers may be at risk to be exposed to the product.

***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.

The risk was demonstrated to be acceptable in the Tier 1 assessment for AquaNet North Sea Standard, AquaNet North Sea Ultra, AquaNet North Sea CCT 100 plus and AquaNet North Sea C50. Acceptable risk for AquaNet North Sea Ultraold was demonstrated in the tier 2 assessment which assumes the use of uncoated cotton coveralls (25% penetration) in addition to gloves.

The indicative hand exposure value in the exposure model is actual measured values inside gloves. Gloves are always worn when performing this task, due to mechanical strain, and in the Atlantic region usually also due to low temperatures. The use of gloves when performing this task should be required.

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

The products are not used by non-professionals.

***Risk for the general public***

The products are only for industrial use, and no exposure to the general public is possible.

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

Copper is naturally present in the environment and is an essential nutrient for plants and animals, in which levels are under homeostatic control. Copper is authorised as a feed additive (EU reg. 479/2006) in the 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 included 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.

n).

There is currently no harmonised methodology to assess the level in foodstuff of a PT21 active substance. The most relevant methodology currently available to estimate level in fish and shellfish is based on a rough calculation with the highest Predicted Environmental Concentration (PEC) calculated from the marine environment and the 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 bioaccumulation). See the Risk Assessment for the Environment section 2.2.8. 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 copper value ± SD from the farmed salmon was 0.38 ± 0.09 mg/kg w.w. (with a min- max range of 0.27 – 0.95) and the mean value for the wild salmon was 0.57 ± 0.15 mg/kg w.w (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 regarding 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.

### 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 North Sea BPF does not contain any substances of concern (SoC) that contribute to the risk to the environment.

Regarding the exposure to the environment from the use of the North Sea BPF, the harmonised scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms (NO, 2015), hereafter referred to as the EU fish farm scenario, has been used for the 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.

#### 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.

For the marine PNECsediment derivation, as no reliable toxicity data are available for the marine sediment compartment, 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. 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

Available effect data for the co-formulants are documented in the separate file “Environmental hazards of co-formulants in North Sea BPF 2017”. The available data allow the first evaluation of co-formulants and a classification of the biocidal product family.

No specific risk assessment of co-formulants has been carried out. See the Confidential annex for an evaluation of substances of concern present in the biocidal product family.

***Further Ecotoxicological studies***

No further ecotoxicological studies on North Seaproducts are available. According to Annex III, point 8.5(1), Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, further ecotoxicology studies on North Seaproducts are not considered necessary.

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

There are no indications of specific environmental risk due to specific properties of the biocidal product or information on 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 studies to assess the avoidance or palatability of the biocidal products have been conducted.

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

Biocides from antifouling paints applied on aquaculture nets enter the marine environment because of direct leaching from the paint while a treated net is in service on a fish farm. The Emission Scenario Document presents a default scenario for the calculation of environmental exposure from antifouling active substances from nets used in farms using the MAMPEC model.

***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.

Fate and behaviour of co-formulants

Biodegradability data of the co-formulants are documented in the environmental background documentation for co-formulants attached to section 13 of the IUCLID file.

***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. Dicopper oxide is an inorganic compound and as such has negligible volatility. Hence, the amount emitted to air is expected to be low and no risk assessment is carried out for the atmosphere compartment.

**Aquatic bioconcentration**

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 compounds/metals, and biomagnification in food webs.

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

The biocidal product is not sprayed outside, and no large-scale formation of dust is expected.

#### Environmental exposure assessment and risk characterisation

Exposure to the environment from the use of the North Sea BPF has been assessed using the following scenarios:

1. An assessment based on the EU fish farm scenario document agreed at the EU level.
2. An 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. 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).

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 North Sea products are envisaged and have been assessed. |
| Emission Scenario Document | For the assessment covering use in the EU, the EU fish farm scenario was used:  *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, 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. |
| 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** | **Norwegian fish farm scenario2** |
| 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 (NO, 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.

**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 North Sea products**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Product** | **Density  (g/cm3)** | **In Use Density  (g/cm3)** | **Concentration of Cu1 in product  (%, w/w)** | **Concentration of Cu1 in product  (g/L)** |
| Meta SPC 1 | AquaNet North Sea Standard | 1.17 | 1.17 | 15.50 | 181.40 |
| Meta SPC 1 | AquaNet North Sea Ultra2 | 1.333,\* | 1.33 | 22.0 | 259.83 |
| Meta SPC 2 | AquaNet North Sea CCT 100 Plus | 1.364 | 1.185 | 13.527 | 159.537 |
| Meta SPC 3 | AquaNet North Sea C50 | 1.27 | 1.186 | 12.637 | 149.097 |

1 Copper equivalent from dicopper oxide = 88.8%

2 In part 2.2.8 Risk for the environment, "Aquanet North Sea Ultra" refers to the Ultra product with a reduced active ingredient content (22%) while "Ultraold" refers to the product originally included in the BPF  
3 Density (T=0 1.33 g/cm3), see Report 7P04987-03b

4 See Report 7P04987-01b

5 AquaNet CCT 100 Plus, In-Use Density based on 1:1 dilution

6 AquaNet C50, In-Use Density based on 1:0.5 dilution

7 For the products: AquaNet CCT 100 Plus and AquaNet C50 the concentrations reflect the diluted product.

\*calculated with a density of 1.33 from the original Ultra product

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** | **Norwegian fish farm scenario** |
| AquaNet North Sea standard | 14811 g/d | 22552 g/d |
| AquaNet North Sea Ultra | 21215 g/d | 32302 g/d |
| AquaNet North Sea CCT 100 Plus | 13025 g/d | 19833 g/d |
| AquaNet North Sea C50 | 12173 g/d | 18535 g/d |

**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***

***SPC 1***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Standard**  **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 | 25.71 | 0.26 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Standard**  **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** | 1.3 | **1.1** | 41.8 | 0.4 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Ultra**  **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** | 0.28 | 0.24 | 36.83 | 0.37 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea Ultra**  **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** | 1.4 | **1.2** | 53 | 0.54 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

***SPC 2***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea CCT 100 Plus**  **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** | 0.17 | 0.15 | 22.61 | 0.23 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea CCT 100 Plus**  **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** | 1.3 | **1.1** | 38.7 | 0.4 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

***SPC 3***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea C50**  **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** | 0.16 | 0.14 | 21.13 | 0.21 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea C50**  **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** | 1.3 | **1.1** | 37.2 | 0.4 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

The resulting PEC/PNEC ratios for PECdissolved/PNECwater ratios with background concentrations of Cu were slightly above the trigger value for all North Sea products.

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

***SPC 1***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Standard**  **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** | 7.21E-02 | 6.72E-02 | 9.48 | 9.59E-02 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Standard**  **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** | 1.2 | 1.0 | 25.6 | 0.3 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Ultra**  **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** | 0.10 | 0.09 | 13.6 | 0.14 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea Ultra**  **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** | 1.2 | 1.0 | 29.7 | 0.3 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.  ***SPC 2*** | | | | |
| **AquaNet North Sea CCT 100 Plus**  **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** | 6.34E-02 | 5.51E-02 | 8.35 | 8.45E-02 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea CCT 100 Plus**  **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** | 1.2 | 1.0 | 24.5 | 0.3 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

***SPC 3***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea C50**  **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** | 5.91E-02 | 5.14E-02 | 7.79 | 7.88E-02 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet North Sea C50**  **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** | 1.2 | 1.0 | 23.9 | 0.2 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

All resulting PEC/PNEC ratios for the Norwegian fish farm scenario were found to be ≤ 1 except for the PEC/PNEC for water for AquaNet North Sea Ultraold, which is slightly above 1.

#### Risk characterisation

***Atmosphere***

No exposure to the atmosphere as the active ingredients do not volatilise.

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

The proposed uses of the North Sea products as antifouling coatings for nets used in aquaculture would not result in any direct or indirect exposure to STPs. Hence the risks to STP microorganisms are considered acceptable.

***Aquatic compartment***

**Tier 1**

**Risk characterisation for the EU fish farm scenario**

The 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** |
| ***SPC 1*** |  |  |
| AquaNet North Sea Standard | | |
| Total copper | **1.1** | < 1 |
| AquaNet North Sea Ultra | | |
| Total copper | **1.2** | < 1 |
| ***SPC 2*** |  |  |
| AquaNet North Sea CCT 100 Plus | | |
| Total copper | **1.1** | < 1 |
| ***SPC 3*** |  |  |
| AquaNet North Sea C50 |  |  |
| Total copper | **1.1** | < 1 |

\*with background concentrations of copper

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

**Risk characterisation for the Norwegian fish farm scenario**

The 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** |
| ***SPC 1*** |  |  |
| AquaNet North Sea Standard | | |
| Total copper | 1.0 | 0.3 |
| AquaNet North Sea Ultraold | | |
| Total copper | 1.0 | 0.3 |
| ***SPC 2*** |  |  |
| AquaNet North Sea CCT 100 Plus | | |
| Total copper | 1.0 | 0.3 |
| ***SPC 3*** |  |  |
| AquaNet North Sea C50 |  |  |
| Total copper | 1.0 | 0.2 |

\*with background concentrations of copper

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

***Leaching behavior***

Field and farm studies to determine the release of biocides from aquaculture nets coated with antifouling products have been submitted by the applicant. These studies aim to determine the loss of biocide during commercial conditions with and without high water jetting (in-situ cleaning).

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Overview**  Biocide release from Aquaculture nets  DOKID-794567110-370\* | | | |
| **Test matrix and test substance** | **Method** | **Compartment,**  **pH,**  **Temp [°C]** | **Reference** |
| Field Study  AquaNet North Sea Ultra(old). | Bespoke method | Norwegian Coastal Seawater (submerged at 6 metres depth),  pH not measured,  8.7 to 17.8°C | Ulriksen, U (2020) |
| Farm Study  AquaNet North Sea Ultra(old). | Bespoke method | Nets deployed in Norwegian Coastal Seawater,  pH not measured,  Temperature not measured | Ulriksen, U (2020) |

\*See IUCLID section 10.3.2 for further details of the studies

|  |
| --- |
| **Study summaries** |
| **Field Study - Ulriksen, U (2020)**  Egersund nylon net dipped in AquaNet Ultra(old) was used to determine the amount of copper released into coastal waters by comparing nets deployed with Day 0 samples.  Using a destructive analysis technique (method SP5458) the remaining copper content in the nets was determined at different time points. The change in copper content was calculated, this represents the fraction of biocide release (Fa.i.).  The lack of triplicate data points and limited duration of the trial introduces some uncertainty regarding its results. There is a relatively good correlation with findings in the Farm study (see below).  **Farm Study - Ulriksen, U (2020)**  Commercial nets treated with North Sea Ultra(old) were deployed throughout 2016 to 2019 in aquaculture farms in the West coast of Norway. Some of the nets were cleaned in-situ, some were not cleaned in-situ.  The nets have been used for regular commercial farming. The average time the nets were deployed at sea was 8 months.  Samples of net were taken before and after use, dissolved in nitric acid and analysed for copper using ICP-MS (method NS-EN ISO r7294-2).  Data for a total of 62 nets were analysed. Copper release was compared with nets cleaned in-situ and nets without cleaning at sea.  **Rationale for refining Fa.i.**  The rationale for refining Fa.i. in the environmental risk assessment with a ‘field and farm net’ study is:   * The use of field and farm data for copper is preferable to laboratory derived leaching rates * As copper is an element, destructive sample analysis is possible, therefore copper remaining in the aquaculture net can be accurately quantified over time deployed * Real life aquaculture conditions are used, representative for farmers in both Norway with an operational practice including with and without in-situ cleaning of treated nets * There is some uncertainty due to the small sample size for the nets that were not in-situ cleaned (farm study), (n = 13\* ) |

\* Samples from 7 nets, 7 samples of the net bottom, 6 samples of the net wall

The Norwegian Environment Agency has evaluated the Ulriksen, 2020 study and have re-calculated PEC values for the EU fish farm scenario using the following fraction of release a.i. per deployment time of nets (F a.i.):

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Sample set** | **Refined Fa.i** | **Number of samples (n)** |
| 1: both cleaned and not in-situ cleaned nets | "Farm study:" Average of wall and bottom samples from all nets that were deployed at sea during summer months\* | 0.44 | 113 Samples from 58 nets, 58 samples of the net bottom, 55 samples of the net wall |
| 2: not in-situ cleaned nets | "Farm study:" 90th percentile value from nets that were not in-situ cleaned | 0.28 | **13** |

\*4 nets were excluded from the data set since they were only deployed at sea during winter months and are therefore not considered to represent realistic worst case conditions in terms of fouling.

**Refined Daily Cu emission outputs (Elocal)**

|  |  |
| --- | --- |
| **Product/Scenario** | **EU fish farm scenario\*** |
| **SPC 1** |  |
| AquaNet North Sea Ultra | 7425 |
| AquaNet North Sea Standard | 5184 |
| **SPC 2** |  |
| AquaNet North Sea CCT 100 Plus | 4559 |
| **SPC 3** |  |
| AquaNet North Sea C50 | 4261 |

\*Based on sampled nets that had not been in-situ cleaned

***SPC 1***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Ultra**  **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** | 1.2 | **1.0** | 29 | 0.3 |

1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea Standard**  **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** | 1.2 | 1.0 | 25 | 0.3 |

1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

***SPC 2***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea CCT 100 Plus**  **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** | 1.2 | 1.0 | 24.0 | 0.2 |

1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

***SPC 3***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet North Sea C50**  **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** | 1.2 | 1.0 | 23.5 | 0.3 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.  **Risk characterisation for the EU fish farm scenario (refined)**  The PEC/PNEC ratios based on PEC values calculated with the EU fish farm scenario are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on calculated refined PEC/PNEC values\*, EU fish farm scenario** | | | |  | **PECdissolved/PNECwater** | **PECsuspended matter/PNECsed** | | ***SPC 1*** |  |  | | AquaNet North Sea Standard | | | | Total copper | 1.0 | < 1 | | AquaNet North Sea Ultra | | | | Total copper | 1.0 | < 1 | | ***SPC 2*** |  |  | | AquaNet North Sea CCT 100 Plus | | | | Total copper | 1.0 | < 1 | | ***SPC 3*** |  |  | | AquaNet North Sea C50 |  |  | | Total copper | 1.0 | < 1 |   \*with background concentrations of copper  In the EU scenario, refined calculations for the scenario based on nets that are not in-situ cleaned, showed PEC/PNEC ratios ≤ 1, indicating acceptable environmental risk. | | | | |
|  | | | | |

In the calculations with the Norwegian fish farm scenario, the PEC/PNEC ratio for the AquaNet North Sea products were ≤ 1, indicating acceptable environmental risk for all products in the BPF under Norwegian conditions.

The 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** |
| ***SPC 1*** |  |  |
| AquaNet North Sea Standard | | |
| Total copper | 1.0 | 0.3 |
| AquaNet North Sea Ultra | | |
| Total copper | 1.0 | 0.3 |
| ***SPC 2*** |  |  |
| AquaNet North Sea CCT 100 Plus | | |
| Total copper | 1.0 | 0.3 |
| ***SPC 3*** |  |  |
| AquaNet North Sea C50 |  |  |
| Total copper | 1.0 | 0.2 |

\*with background concentrations of copper

**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. For areas of low salinity environment, the products with lower levels of copper are preferred.

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 product 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 and 2 should not be applied to nets meant for use in the Baltic Sea.

It is noted that a harmonisation of the adaptation of the EU fish farm scenario to version 3.1 of MAMPEC is proposed for the Baltic Sea. A refinement of the EU scenario for the Baltic Sea in MAMPEC v3.1 is to add the values for Wind Speed and Fraction of Time Wind Perpendicular. One source of input values for this is Hanninen 2019[[5]](#footnote-6) where the values of 3.8 m/s (Wind Speed) and 0.5 (Fraction of Time Wind Perpendicular) are recommended. In addition, the MAMPEC layout parameters are updated according to Hanninen (2009) in order to be representative for the Baltic Sea:

x1: 75 m

x2: 300 m

y1: 150 m

y2: 150 m

Please see below calculations for AquaNet C50 (Meta SPC 3) with the above-mentioned modifications:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AquaNet North Sea C50 (SPC 3)**  **Average PEC values calculated by MAMPEC v3.1** | | | | | | | | | | | | | |
| **MAMPEC input** | **X1** | **X2** | **Y1** | **Y2** | **F. a.i** | **Deployment (days)** | **E local  (g/d)** | **PEC dissolved (μg/L)** | **Background concentration added (Cu: 1,1 µg/L)** | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **Background concentration added (Cu: 16,1 µg/g)** | **PECsuspended sediment / PNECsediment 1** |
| Baltic scenario | 75 | 300 | 150 | 150 | 0.8 | 730 | 3002 | 0.08 | 1.1 | 1.0 | 10.5 | 16.1 | 0.3 |

In the refined calculations with the EU fish farm scenario (Baltic Sea), PEC/PNEC ratios for Meta SPC 3 were found to be ≤ 1.

***Terrestrial compartment***

The proposed uses of the North Sea products as antifouling coatings for nets used in aquaculture would not result in any direct or indirect exposure of the terrestrial environment. Hence the risks to the terrestrial compart are considered acceptable.

***Groundwater***

The proposed uses of the North Sea products as antifouling coatings for nets used in aquaculture would not result in any exposure to groundwater. Hence, the risks to groundwater are considered acceptable.

***Primary and 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.

***Mixture toxicity***

The North Sea formulations contain only an active substance, dicopper dioxide. Therefore, mixture toxicity is not relevant for the North Sea Biocidal Product Family.

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

Article 19(2) and Annex VI of the Biocidal Products Regulation (EC) 528/2012 (BPR) state that the evaluation shall take into account cumulative and synergistic effects associated with the relevant individual components of the biocidal product. According to the provisions given in the BPR, aggregated risk assessments shall not be carried out routinely in the Review Programme but only where relevant.

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

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

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Not relevant.

# Annexes

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

| **Author** | **Year** | **Title**  **Report No.**  **Laboratory**  **GLP**  **Published** | **Owner** |
| --- | --- | --- | --- |
| Bernal, J. | 2018a | In-vitro human skin penetration of total copper in AquaNet LG 360 PT21 Biocide product  Report no. S17-08530  Eurofins agroscience services Chem SAS  Yes  No | Steen-Hansen |
| Bernal, J. | 2018b | In-vitro human skin penetration of total copper in AquaNet premium PT21 Biocide product  Report no. S17-08528  Eurofins agroscience services Chem SAS  Yes  No | Steen-Hansen |
| Bloecher and Floerl | 2018 | [Guidelines for efficacy testing of antifouling coatings for nets in](https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB)  [field tests](https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB) | SINTEF / Norwegian Environment Agency |
| Fagerlid, S | 2017a | AquaNet Standard Greece 2017  DOKID-1294561088-225  Steen-Hansen  No  No | Steen-Hansen |
| Fagerlid, S | 2017b | AquaNet Ultra Greece 2017  DOKID-1294561088-224  Steen-Hansen  No  No | Steen-Hansen |
| Fagerlid, S | 2017c | AquaNet CCT100 Plus Greece 2017 DOKID-1294561088-227  Steen-Hansen  No  No | Steen-Hansen |
| Fischer, A | 2018a | Interim report 6 months AquaNet CCT100 Plus  7PO4987-01  RISE, Sweden  No  No | Steen-Hansen |
| Fischer, A | 2018b | Final report 12 months AquaNet CCT100 Plus  7PO4987-01b  RISE, Sweden  No  No | Steen-Hansen |
| Fischer, A | 2018c | Interim report 6 months AquaNet North Sea Ultra  7P04987-03  RISE, Sweden  No  No | Steen-Hansen |
| Fischer, A | 2018d | Final report 12 months AquaNet North Sea Ultra  7P04987-03b  RISE, Sweden  No  No | Steen-Hansen |
| Hope, B | 2017a | AquaNet Standard Norway Trial 2 2017 DOKID-1294561088-103  Steen-Hansen  No  No | Steen-Hansen |
| Hope, B | 2017b | AquaNet Ultra Norway Trial 2 2017  DOKID-1294561088-97  Steen-Hansen  No  No | Steen-Hansen |
| Hope, B | 2017c | Aqua Net CCT100 Plus Norway Trial 2 2017  DOKID-1294561088-103  Steen-Hansen  No  No | Steen-Hansen |
| Hope, B | 2018a | AquaNet Standard Norway trial 2018  DOKID-1294561088-97  Steen-Hansen  No  No | Steen-Hansen |
| Hope, B | 2018b | AquaNet Ultra Norway trial 2018  DOKID-1294561088-97  Steen-Hansen  No  No | Steen-Hansen |
| Hope, B | 2018c | AquaNet CCT100 Plus Norway trial 2018  DOKID-1294561088-97  Steen-Hansen  No  No | Steen-Hansen |
| Sharpe, J. & Oliver, R. | 2022 | AquaNet North Sea Persistent Foaming Testing, 2022, study number RH/17/005-2022 | Steen-Hansen |
| Ulriksen, U | 2020 | Biocide release from Aquaculture nets  DOKID-794567110-370 | Steen-Hansen |
| Younis, S | 2017 | Hazardous Properties Testing on a Sample of Aqua Net CCT100 Plus  GLP3016001671CR1V1/2017  Dekra Insight, UK  Yes  No | Steen-Hansen |
| Wallace, J. | 2020 | The *In Vitro* Percutaneous Absorption of Dicopper Oxide in AquaNet Premium Paint Formulation through Human Split-Thickness Skin  Report number 786208  (Report amendment 1)  Charles River  Yes  No | Steen-Hansen |

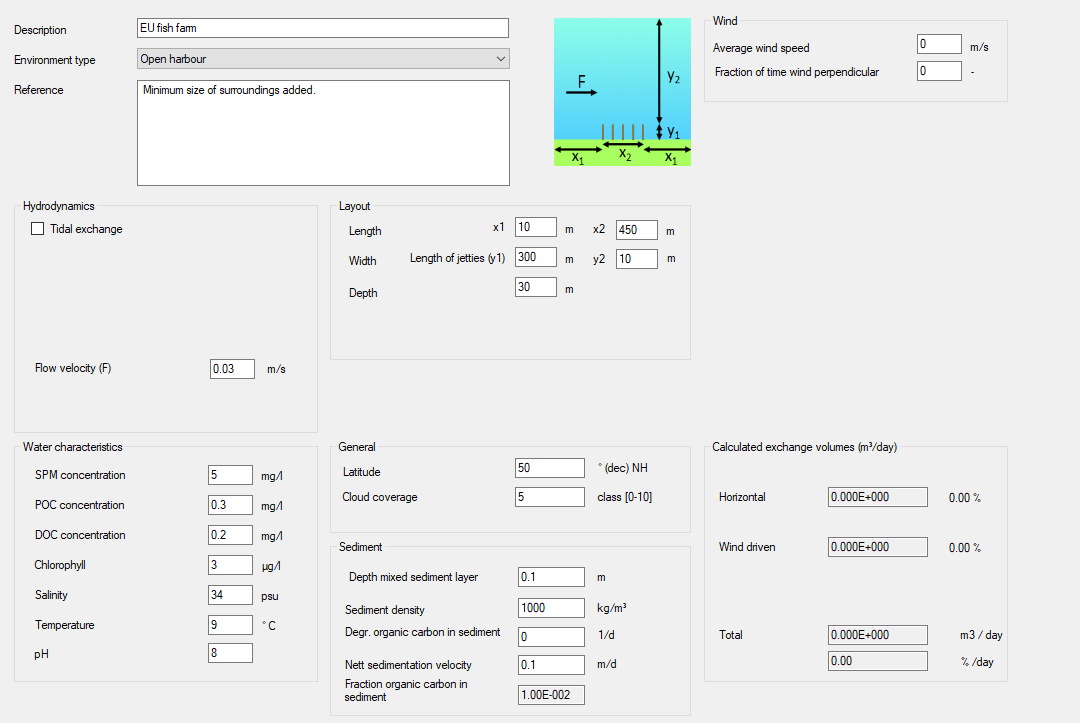
## Output tables from exposure assessment tools

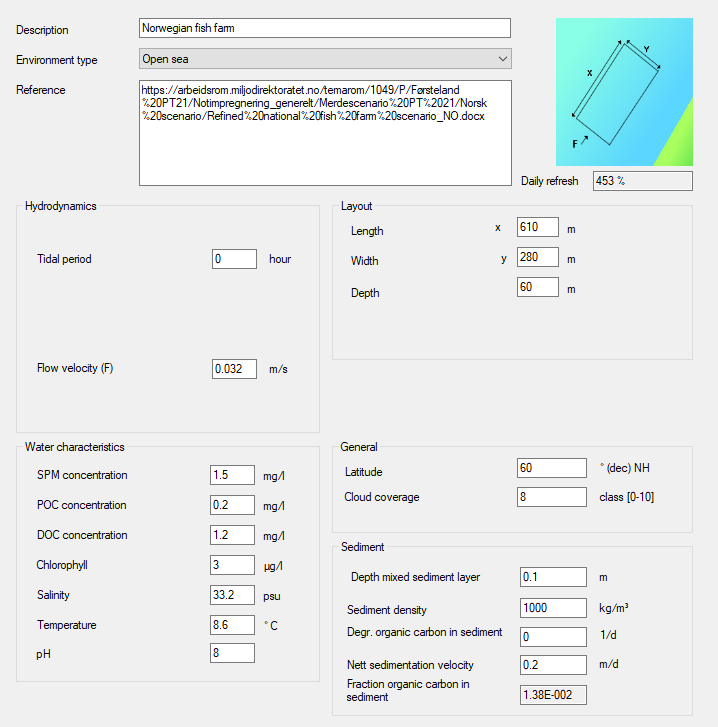
### Output tables from the environmental exposure assessments

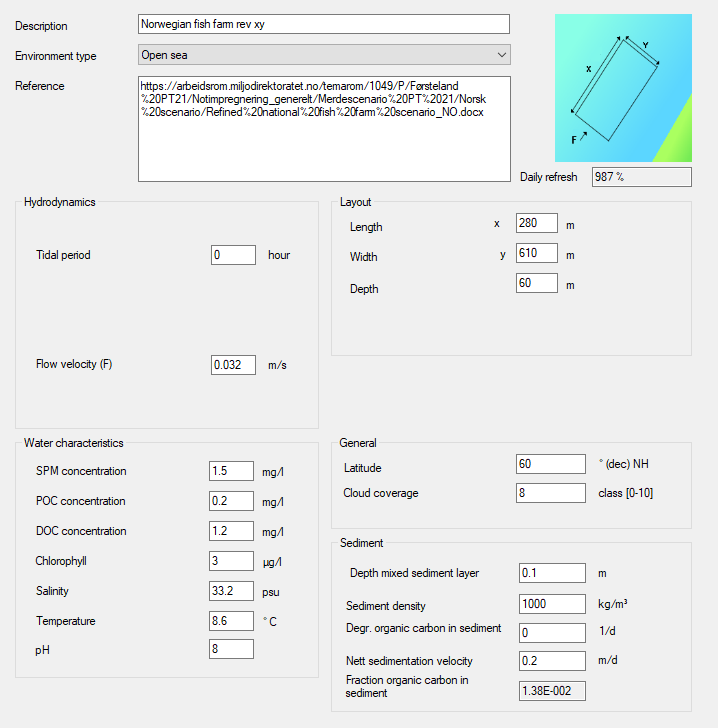
Excel-files are available upon request.

Environment parameters from MAMPEC reports for the EU fish net scenario and the NO fish net scenario.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Description | EU fish farm | No Fish farm | No fish farm reverse XY | Unit |
| Average wind speed | 0.00E+000 | 0.00E+000 | 0.00E+000 | m/s |
| Chlorophyll | 3.00E+000 | 3.00E+000 | 3.00E+000 | µg/L |
| Degr. organic carbon in sediment | 0.00E+000 | 0.00E+000 | 0.00E+000 | 1/d |
| Depth | 3.00E+001 | 6.00E+001 | 6.00E+001 | m |
| Depth mixed sediment layer | 1.00E-001 | 1.00E-001 | 1.00E-001 | m |
| Depth-MSL in harbour entrance | 3.00E+001 | 6.00E+001 | 6.00E+001 | m |
| DOC concentration | 2.00E-001 | 1.20E+000 | 1.20E+000 | mg/l |
| Exchange area harbour mouth (below mean sea level) | 0.00E+000 | 0.00E+000 | 0.00E+000 | m2 |
| Calculated exchange volumes (m³/tide) | 0.00E+000 | 0.00E+000 | 0.00E+000 | m³ / tide |
| Calculated exchange volumes (m³/tide) | 0.00E+000 | 0.00E+000 | 0.00E+000 | % /tide |
| Flow velocity (F) | 3.00E-002 | 3.20E-002 | 3.20E-002 | m/s |
| Flush (f) | 0.00E+000 | 0.00E+000 | 0.00E+000 | m³/s |
| Fraction of time wind perpendicular | 0.00E+000 | 0.00E+000 | 0.00E+000 |  |
| Fraction organic carbon in sediment | 1.00E-002 | 1.38E-002 | 1.38E-002 |  |
| Environment type | Open harbour | Open sea | Open sea |  |
| Height of submerged dam | 0.00E+000 | 0.00E+000 | 0.00E+000 | m |
| Latitude | 5.00E+001 | 6.00E+001 | 6.00E+001 | ° (dec) |
| Cloud coverage | 5.00E+000 | 8.00E+000 | 8.00E+000 |  |
| X1 | 1.00E+001 | 6.10E+002 | 2.80E+002 | m |
| X2 | 4.50E+002 | 0.00E+000 | 0.00E+000 | m |
| Max. density difference flush | 0.00E+000 | 0.00E+000 | 0.00E+000 | kg/m³ |
| Max. density difference tide | 0.00E+000 | 0.00E+000 | 0.00E+000 | kg/m³ |
| Mouth width | 0.00E+000 | 0.00E+000 | 0.00E+000 | m |
| Nett sedimentation velocity | 1.00E-001 | 2.00E-001 | 2.00E-001 | m/d |
| Non tidal daily water level change | 0.00E+000 | 0.00E+000 | 0.00E+000 | m |
| pH | 8.00E+000 | 8.00E+000 | 8.00E+000 |  |
| POC concentration | 3.00E-001 | 2.00E-001 | 2.00E-001 | mg OC/l |
| Reference | Minimum size of surroundings added |  |  |  |
| Salinity | 3.40E+001 | 3.32E+001 | 3.32E+001 | s.e. |
| Sediment density | 1.00E+003 | 1.00E+003 | 1.00E+003 | kg/m³ |
| SPM concentration | 5.00E+000 | 1.50E+000 | 1.50E+000 | mg/l |
| Temperature | 9.00E+000 | 8.60E+000 | 8.60E+000 | ° C |
| Tidal difference | 0.00E+000 | 0.00E+000 | 0.00E+000 | m |
| Tidal period | 0.00E+000 | 0.00E+000 | 0.00E+000 | Hour |
| Width of submerged dam | 0.00E+000 | 0.00E+000 | 0.00E+000 | m |
| Y1 | 3.00E+002 | 2.80E+002 | 6.10E+002 | m |
| Y2 | 1.00E+001 | 0.00E+000 | 0.00E+000 | m |
| Daily refresh | - | 453 % | 987 % | Per day |







### Output tables from the human health exposure assessments

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

HH\_Exposure\_aquanet\_North Sea.xlsx

## New information on the active substances

None.

## Residue behaviour

NorthSea BPF is only to be used as antifouling paints applied to aquaculture nets and it is not expectable residues of the active substances or its degradation products. Therefore, it is not required complying with the obligations under the Biocides Regulation (BPR).

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

Please see section 2.2.5.5 and IUCLID.

## Confidential annex

## Other

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*](https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY)

Proposed guidance document for efficacy testing of antifouling coatings for nets in field trials, developed by SINTEF ocean for the Norwegian Environment Agency.

<https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB>

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* 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) 2015a. Biocides human health exposure methodology. Version 1. Helsinki.
* European Chemicals Agency (ECHA), 2015b. Emission scenario for nets used in fish farms.
* 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. France 132p.
* European Chemicals Agency (ECHA) 2016b, “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).
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* European Chemicals Agency (ECHA). 2019. Draft proposal: "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA".
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* 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.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. The reported steel code (S275JR) differs from the preferred steel code in the CLP Regulation (S275J2G3+CR). However, the alternatively metal used was considered sufficiently comparable and, hence, acceptable. [↑](#footnote-ref-3)
3. Aquanet HG360 is a part of the Steen Hansen product family Aquanet 360 BPF but it is considered acceptable to use it as a product formulation for the validation. [↑](#footnote-ref-4)
4. These values were not reported but confirmed by the lab in a personal communication. [↑](#footnote-ref-5)
5. Oskari Hanninen (2019). NORDIC WORKING PAPERS, NORDIC ANTIFOULING PROJECT, A follow-up of the MAMPEC workshop from 2017, Adjustment of the environment input parameters for more realistic values [↑](#footnote-ref-6)