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

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



AquaNet 360 Biocidal Product Family:

Product names: AquaNet LG 360, AquaNet HG 360, AquaNet RFU 360

Product type(s) 21

Dicopper oxide and copper thiocyanate

Case Number in R4BP3: [BC-FA036514-64]

Evaluating Competent Authority: Norway

Date: [12th March/2021]

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# CONCLUSION

The biocidal product family Aquanet 360contains the active substances dicopper oxide and copper thiocyanate. 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.

The identity, physico-chemical properties and analytical methods were adequately addressed. The biocidal product family contains 12.3-24.52% dicopper oxide in combination with 1.7-8.04% copper thiocyanate. The representative products are red in colour with a pH of 8.8. The density of the concentrated products is 1.43 g/cm3 and 1.22 g/cm3 for the in-use concentrations. The products have a shelf life of 12 months when stored protected from frost.

Exposure to the environment from the use of the AquaNet 360 BPF has been assessed in a tiered approach. For the assessment covering use in the EU, the EU fish farm scenario was used. In addition, 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.

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 AquaNet 360 products. A refined risk assessment based on PEC values calculated from field data and a refinement of the mixture toxicity assessment resulted in PEC/PNEC ratios below 1, indication acceptable environmental risk for use in the EU. The PEC/PNEC ratios based on PEC values calculated with the Norwegian fish farm scenario, were found to be ≤ 1 indicating acceptable environmental risk.

Exposure to human health from the use of the AquaNet 360 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 LG 360 and AquaNet HG 360, provided that the workers wear coated coveralls and gloves and for AquaNet 360 RFU provided that the workers wear impermeable coveralls and gloves.

The risk to professional workers involved in net deployment activities was assessed using the Handling model 2 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net deployment activities. The risk was demonstrated to be acceptable in the tier 1 assessment for all family members, assuming use of gloves (the indicative hand exposure value in the exposure model was 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.

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

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| Product family: 360 products, consisting of | NO, IT, ES, UK, EL |
| AquaNet LG360 |  |
| AquaNet HG360 |  |
| RFU 360 |  |

#### 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 |
| **Location of manufacturing sites** | 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 |

|  |  |
| --- | --- |
| **Active substance** | Copper thiocyanate |
| **Name of manufacturer** | Bardyke Chemicals Limited |
| **Address of manufacturer** | Hamilton Road, Cambuslang, Scotland G72 7XJ |
| **Location of manufacturing sites** | As per the active substance data set |

### Product (family) composition and formulation

The full composition of the product family is provided in the confidential annex to this document.

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 (I) oxide |
| **EC number** | 215-270-7 |
| **CAS number** | 1317-39-1 |
| **Index number in Annex VI of CLP** | 029-002-00-X |
| **Minimum purity / content** | 94.2% |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Copper thiocyanate |
| **IUPAC or EC name** | Copper (I) thiocyanate |
| **EC number** | 214-183-1 |
| **CAS number** | 1111-67-7 |
| **Index number in Annex VI of CLP** | N/A |
| **Minimum purity / content** | 99.5% |
| **Structural formula** |  |

#### Candidate(s) for substitution

None of the active substances, dicopper oxide and copper thiocyanate, are considered as candidates for substitution.

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

|  |  |  |  |
| --- | --- | --- | --- |
| Product name | Formulation: | Copper oxide (Cu2O; % w/w) | Copper thiocyanate (CuSCN; % w/w) |
| **AquaNet 360 BPF** |  | 12.3 – 24.52 | 1.7 – 8.04 |
| **AquaNet RFU 360** | Ready for use | 12.3 | 1.72 |
| **AquaNet LG 360** | Concentrate (1:1 dilution) | 13.8 | 3.91 |
| **AquaNet HG 360** | Concentrate (1:1 dilution) | 24.52 | 8.04 |

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

#### Information on technical equivalence

Spiess-Urania Chemicals GmbH and Bardyke Chemicals Limited are listed as approved suppliers in accordance with Article 95 of the Biocidal Products Regulation (BPR).

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

There are no substances of concern present in the AquaNet 360 products.

#### 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 LG 360** | | |
| --- | --- | --- |
| **Classification** | | |
| Hazard category | Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | |
| **Labelling** | | |
| Hazard pictograms |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger | |
| Hazard statements | H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | |
| Precautionary statements | P273 - Avoid release to the environment.  P280 - Wear eye or face protection.  P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310 - Immediately call a POISON CENTER or doctor.  P391 - Collect spillage.  P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. | |
| 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 2**

| **AquaNet HG 360** | | | |
| --- | --- | --- | --- |
| **Classification** | | | |
| Hazard category | Acute Tox. 4 (Oral)  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H302: Harmful if swallowed  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects | | |
| **Labelling** | | | |
| Hazard pictograms |  |  | pollut1 |
|  | GHS07 | GHS05 | GHS09 |
| Signal words | Danger | | |
| Hazard statements | H302: Harmful if swallowed  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effects | | |
| Precautionary statements | 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 RFU 360** | | |
| --- | --- | --- |
| **Classification** | | |
| Hazard category | Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H318 - Causes serious eye damage.  H400: Very toxic to aquatic life  H410 - Very toxic to aquatic life with long lasting effects. | |
| **Labelling** | | |
| Hazard pictograms |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger | |
| Hazard statements | H318 - Causes serious eye damage.  H410 - Very toxic to aquatic life with long lasting effects. | |
| Precautionary statements | P273 - Avoid release to the environment.  P280 - Wear eye or face protection.  P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  P310– Immediately call a POISON CENTER/doctor if you feel unwell  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 | |

### Authorised use(s)

#### Use description

Table 1. Use PT 21 – Antifouling

|  |  |
| --- | --- |
| **Product Type** | 21 |
| **Where relevant, an exact description of the authorised use** | The AquaNet 360 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  The AquaNet 360 products are used in the control of fouling organisms in marine environment. |
| **Application methods** | The AquaNet 360 products are marketed in 1000 litre IBC HDPE containers as liquid formulations.  AquaNet RFU 360 is a ready to use product, while AquaNet LG 360 and AquaNet HG 360 are concentrates which should be diluted 1:1 with water before use.  The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate and frequency** | Application rates:  AquaNet RFU 360: 1 – 1.2 litre/kg net  AquaNet LG 360 and AquaNet HG 360: 1 – 1.1 litre (in-use concentration)/kg net.  1 treatment per net. |
| **Category of users** | Industrial use |
| **Pack sizes and packaging material** | 1000 L IBC HDPE containers |

#### Use-specific instructions for use

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| --- |
| See section 2.1.5.1. |

#### Use-specific risk mitigation measures

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| --- |
| Meta-specific PPE to be worn:  Meta 1:  Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves. Layer thickness: > 0.20 mm. Breakthrough time: 480 minutes. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard 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.  Meta 2:  Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves. Layer thickness: > 0.20 mm. Breakthrough time: 480 minutes. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard 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.  Meta 3:  Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves. Layer thickness: > 0.20 mm. Breakthrough time: 480 minutes. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN 374.  A protective coverall (at least type 3 or 4, EN-14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).  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.  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.  Density and viscosity must be measured to ensure that the product is homogeneous prior to treatment. Please follow the manufacturer's directions for how to measure density and viscosity.  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, 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.  Avoid release to the environment  Application, maintenance and repair activities shall be conducted within a contained area to prevent losses and minimise emissions to the environment. This means that activities must take place on impermeable hard standing with bunding or on soil covered with an impermeable material. Any losses or waste containing antifouling biocides shall be collected for reuse or disposal. |

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

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

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

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

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

|  |
| --- |
| The product must be stored at temperatures above 5oC and below 30 oC  The AquaNet 360 products are stable, when stored in the original packaging at ambient temperatures, for up to 12 months, provided that proper measures are taken to ensure that the product is homogeneous prior to application  Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. |

### Other information

|  |
| --- |
| 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. |

### 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 substances, dicopper oxide and copper thiocyanate. Letters of access are provided.

The applicant is the owner of all data submitted on the Aquanet 360 BPF.

## Assessment of the biocidal product family

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

Table 2. Intended use # 21 – Antifouling

|  |  |
| --- | --- |
| Product Type | 21 |
| Where relevant, an exact description of the authorised use | The AquaNet 360 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  The AquaNet 360 products are used in the control of fouling organisms in marine environment. |
| Application method(s) | Net dipping: The product is pumped to a dipping tank where the net is lowered into the product using remotely operated cranes.  Vacuum treatment: The product is pumped into a sealed vacuum bag containing the net. Vacuum cycles are applied in order to evenly distribute the product into the net. |
| Application rate(s) and frequency | Application rates:  AquaNet RFU 360: 1 – 1.2 litre/kg net  AquaNet LG 360 and AquaNet HG 360: 1 – 1.1 litre (in-use concentration)/kg net. |
| Category of users | Industrial use |
| Pack sizes and packaging material | 1000 L IBC HDPE containers |

### Physical, chemical and technical properties

The physical, chemical and technical properties were determined for the representative product of the 360 BPF, AquaNet HG360. All products in the family are composed of the same components, but in varying concentrations. The HG360 is the product with the highest content of active substance.

| **Property** | **Guideline and Method** | **Results** | **Reference** |
| --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | EPA OPPTS 830.6303 | Liquid aqueous suspension concentrate.  No change after 6-months storage but some clumping and phase separation were observed after 12-months storage, however this could be re-homogenised with stirring. | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Colour at 20°C and 101.3 kPa | EPA OPPTS 830.6302 | Red  No significant change after 6 or 12 months storage. | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Odour at 20°C and 101.3 kPa | EPA OPPTS 830.6304 | Odourless to slight damp odour  No significant change after 6 or 12 months storage. | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| pH | CIPAC MT 75.3  (Measured on concentrate) | T=0 months: pH 8.9  T=6 months: pH 8.8  T=12 months: pH 8.8 | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Acidity / alkalinity | Not Performed due to pH result | | |
| Relative density | ISO 2811-1  (Measured on concentrate) | T=0 months:  Density: 1.43 g/cm3  T=6 months:  Density: 1.43 g/cm3  T=12 months:  Density: 1.41 g/cm3    Calculated density for in-use concentration: 1.22g/cm3 | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Storage stability test – **accelerated storage** | Not performed | | |
| Storage stability test – **long term storage at ambient temperature** | According to requirements of regulation 528/2012 | Active substances contents at:  T=0: Cu2O 24% w/w, CuSCN 7.9% w/w  T=6 months: Cu2O 24% w/w, CuSCN 8.2% w/w  T=12 months: Cu2O 25% w/w, CuSCN 8.3% w/w | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Storage stability test – **low temperature stability test for liquids** | Not performed | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **light** | Storage condition under Artificial light 24h/day | No significant change after 6 or 12 months storage. No effect of light on active ingredient content was observed | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Not performed | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **reactivity towards container material** | No guideline followed | No significant change was observed during long term storage test. So, no reactivity towards container material is expected. | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Wettability | Not performed as not applicable to this product | | |
| Suspensibility, spontaneity and dispersion stability | CIPAC MT 184  CIPAC MT 160 | T=0 months:  Suspensibility 102% for Cu2O and 101% for CuSCN  Spontaneity of dispersion 94% for Cu2O and 91% for CuSCN  T=6 months:  Suspensibility: Cu2O = 101%, CuSCN = 103%  Spontaneity of dispersion: Cu2O = 55%\*, CuSCN = 62%  T=12 months:  Suspensibility: Cu2O = 98%, CuSCN = 100%  Spontaneity of dispersion: Cu2O = 57%\*, CuSCN = 60%  See comments in conclusion section | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Wet sieve analysis and dry sieve test | Not performed as not applicable to this product | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Not performed as not applicable to this product | | |
| Disintegration time | Not performed as not applicable to this product | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not performed as not applicable to this product | | |
| Persistent foaming | CIPAC MT 47.2 | T=0 months   |  |  |  |  |  | | --- | --- | --- | --- | --- | | T= 0s | T=10s | T= 60s | T= 180s | T= 720s | | 23 | 23 | 23 | 20 | 18 |   T=6 months:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | T=0s | T=10s | T=60s | T=180s | T=720s | | 18 | 18 | 16 | 15 | 14 |   T= 12 months:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | T=0s | T=10s | T=60s | T=180s | T=720s | | 25 | 24 | 23 | 23 | 20 | | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Flowability/Poura-bility/Dustability | CIPAC MT 148 | T=0 months:  Pourability= 4.77%  Rinsability= 3.90%\*  Results at 6 months:  Pourability= 4.61%  Rinsability= 3.63%\*  Results at 12 months:  Pourability= 5.91%\*  Rinsability= 4.29%\*  .  \*See comments in the conclusions section | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |
| Burning rate — smoke generators | Not performed as not relevant for this product | | |
| Burning completeness — smoke generators | Not performed as not relevant for this product | | |
| Composition of smoke — smoke generators | Not performed as not relevant for this product | | |
| Spraying pattern — aerosols | Not performed as not relevant for this product | | |
| Physical compatibility | AquaNet HG360 is intended to be used as dipping product. Therefore, no physical constraint is expected. This study is considered as not relevant for this product | | |
| Chemical compatibility | The product is not intended to be mixed with other chemical product. The study is therefore not considered as relevant for this product. | | |
| Degree of dissolution and dilution stability | Not performed as not relevant for this product | | |
| Surface tension | OECD 115 | 3859 mN/m (at 25oC) | Salter 2020 |
| Viscosity | ISO 2431 | T=0 months:   |  |  | | --- | --- | | 20°C Cup ISO 3 | 40°C Cup ISO 3 | | 51 | 44 |  |  |  | | --- | --- | | 20°C Cup ISO 4 | 40°C Cup ISO 4 | | 22 | 18 |   T=6 months:   |  |  | | --- | --- | | 20°C Cup ISO 3 | 40°C Cup ISO 3 | | 68 | 55 |  |  |  | | --- | --- | | 20°C Cup ISO 4 | 40°C Cup ISO 4 | | 24 | 20 |   T=12 months:   |  |  | | --- | --- | | 20°C Cup ISO 3 | 40°C Cup ISO 3 | | 56 | 52 |  |  |  | | --- | --- | | 20°C Cup ISO 4 | 40°C Cup ISO 4 | | 23 | 21 | | Interim report 6 months AquaNet HG360, 2018, report number 7P04987-02  Final report 12 months AquaNet HG360, 2018, report number 7P04987-02b |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| AquaNet HG360 is a dark red liquid aqueous suspension concentrate at room temperature with a relative density of about 1.43, a pH of 8.9 and a pourability of 4.77%. Its viscosity at 20ºC (ISO3) and at 20ºC (ISO4) is 51 s and 22 s, respectively. It is stable for storage at ambient conditions for up to 12 months (temperature 5-30oC).  Data are presented after 6 and 12 months storage. The active substances content remains stable after storage. With a few exceptions, the physicochemical properties remain stable. Some phase separation and clumping are observed at 12 months, but this can be re-homogenised. However, the spontaneity of dispersion declines to below 60% after 6 (55%) or 12 (57%) months storage. The rinsed and non-rinsed residue increases.  As the spontaneity of dispersion is outside the requirements in the guidance documents (range 60-105%) actions must be taken to ensure the product is homogeneous when applied. Therefore, 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 applicant.  As the pourability and rinsability 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 " Use-specific instructions 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 of in accordance with local regulations.  The use procedure for the RTU-product "AquaNet RFU" involves only a minor rinsing (addition of 3-5% of the volume in water), or no rinsing at all. It is therefore not possible to minimize residues in the packaging by thorough rinsing. As the product is ready to use, there is no risk of erroneous dilutions, but waste handling may med affected by this. Hence, the empety product packaging (container) must be disposed of in accordance with local regulations.  The product 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. |

### Physical hazards and respective characteristics

The physical hazards and respective characteristics were determined for the representative product of the 360 BPF, AquaNet HG360.

| **Property** | **Guideline and Method** | **Results** | **Reference** |
| --- | --- | --- | --- |
| Explosives | Differential scanning colorimetry | The total heat of decomposition was found to be < 500 Jg-1. The sample is therefore not considered to have explosive properties. | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| 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 | ASTM D93 | The closed-cup flash point temperature of Aqua Net HG360 has been determined to be ‘No Flash to Boiling’. | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Flammable solids | Not performed as not relevant for this product | | |
| Self-reactive substances and mixtures | Not performed | According to the differential scanning colorimetry performed, the total heat of decomposition was determined as 358.5 J g-1. According to CLP Classification, HG360 should be considered as a Self-reactive mixture (Type G). | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Pyrophoric liquids | Not performed | No ignition of the product by air is expected.  The product is a liquid use for net dipping. The product has already been sold previously under the old directive and no Pyrophoric property has been saw. | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Pyrophoric solids | Not performed as not relevant for this product | | |
| Self-heating substances and mixtures | Differential scanning colorimetry | A sample is a candidate for classification as a UN Class 4, Division 4.1 self-reactive substance if the heat of decomposition is > 300 Jg-1.  AquaNet HG360 has a total heat of decomposition of 358.5 Jg-1. | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Substances and mixtures which in contact with water emit flammable gases | Not performed | The product is intended to be diluted with water and/or already contains water as solvent. No flammable gases occurred after dilution. | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Oxidising liquids | Calculation based on components properties | The product is not considered as having oxidising properties | Hazardous Properties Testing on a Sample of  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| Oxidising solids | Not performed as not relevant for this product | | |
| Organic peroxides | Not performed as not relevant for this 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 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  AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| 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 HG360 Plus has been determined to be 455°C | AquaNet HG360, 2017 report number GLP3016001671BR1V1/2017 |
| 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 HG360 product is a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations) and candidate for classification as a UN Class 4, Division 4.1 self-reactive (Type G) and self-heating mixture.  It is not explosive or oxidising and has an auto ignition temperature of 455ºC. |

### Methods for detection and identification

**Analytical methods for the analysis of the product as such including the active substance, impurities and residues**

The copper(I) oxide and copper thiocyanate contents of the AquaNet 360 biocidal products are determined according to an internal method SP5458. This method is based on several well-established standard methods: EN 13656, EPA Method 3052, and EN ISO 11885 that are fully validated. Samples are dried and digested in a mixture of nitric acid and hydrogen peroxide in closed containers that are heated using microwaves. Copper (Cu) and sulphur (S) are then determined in the resulting solutions using inductively coupled plasma – optical emission spectrometry (ICP-OES). Cu and S can be recalculated to Cu2O and CuSCN by assuming that all S is present as CuSCN and all Cu is present as Cu2O and CuSCN.

*Summary of validation parameters for determination of copper and sulphur in paints.*

|  |  |
| --- | --- |
| **Precision** | Repeatability:  RSD for Cu: 1.41 % (at 26 weight-%, n=5)  RSD for S: 1.24 % (at 2.2 weight-%, n=5) |
| **Accuracy (trueness)** | Bias:  Recovery for Cu: 98.6 %  Recovery for S: 98.6 %    Selectivity/specificity/interferences:  High selectivity/specificity and no or few interferences can be expected. |
|  |  |

**Analytical methods used for monitoring:**

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Bardyke Chemicals Limited 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 Chemicals GmbH and Bardyke Chemicals Limited 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 Chemicals GmbH and Bardyke Chemicals Limited 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 Chemicals GmbH and Bardyke Chemicals Limited 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 Chemicals GmbH and Bardyke Chemicals Limited 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 Chemicals GmbH and Bardyke Chemicals Limited 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** |
| All methods are valid and acceptable. |

### Efficacy against target organisms

#### Function and field of use

**Function:** Antifoulant

**Field of use:** Aquaculture

The AquaNet 360 BPF products are 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

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

When copper from cuprous oxide and copper thiocyanate leaches into marine water in the presence of oxygen, the predominant form of the copper is the cupric ion, Cu2+. Cupric ions retard the settlement of 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 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 in 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 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.

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 SINTEF document.

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

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

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

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 differ.

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 if the net is cleaned or at incidences with heavy weather. An untreated net in a peak fouling period can become fully overgrown in only one week.

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

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.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | | | | |
| **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time**    **(Location)** | **Test results: effects** | **Reference** |
| AquaNet LG360 | *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) | Active protection time > 5 months  (the applicant's own assessment)  Reliability: 3 | Hope, B (2017) |
| AquaNet LG360 | *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 | Nets were coated as per normal commercial practices and deployed for 5 months.  (Greece) | Active protection time > 5 months  (the applicant's own assessment)  Reliability: 3 | Fagerlid, S (2017) |
| AquaNet HG360 | *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 | Nets were coated as per normal commercial practices and deployed for 5 months.  (Greece) | Active protection time > 5 months  (the applicant's own assessment)  Reliability: 3 | Fagerlid, S (2017) |
| AquaNet HG360 | *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) | Active protection time > 5 months  (the applicant's own assessment)  Reliability: 3 | Hope, B (2017) |
| AquaNet HG360 | *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 (6 replicates) or control (7 replicates) | Active protection time 14 weeks  Reliability 2 | Hope, B (2018) |
| AquaNet LG360 | *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 (6 replicates) or control (7 replicates) | Active protection time: 14 weeks  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 LG 360:**  **Norwegian south-western coast, April to November 2018**  In the efficacy test performed on AquaNet LG 360 on the Norwegian south-western coast in 2018 (Hope, B.; 2018), the product showed good protection up to, and including, the sampling date at 98 days (14 weeks) in the sea. At the next sampling point at 134 days (19 weeks), the samples had accumulated a significant amount of fouling organisms (Hydroids and skeleton shrimp were most abundant). The rMS has evaluated these samples to a rank score of 5 (equal to > 80 % biofouling cover), which is regarded as an unacceptable fouling level and a clear indication that the antifouling protection has decreased to a level where it no longer provides sufficient protection against fouling.  At sampling day 176 (25 weeks), the samples had lost much of the attached fouling organisms. No explanation to this shredding event was presented. It is noted by the applicant that new settlement of hydroids was observed and that some skeleton shrimp was seen. We can, however, not with certainty relate this observed loss of fouling to be caused by a biocidal effect and not by an external factor such as heavy weather, as also the control sample had lost much of its fouling load at this sampling time. It is, nevertheless, possible that the antifouling coat causes the fouling organisms to fall off easier than from the control samples when the net is agitated. The samples were evaluated by the rMS to a rank of 3. The active re-colonisation by hydroids at this time point, is, nevertheless, taken as evidence that the efficacy of the antifouling coat is no longer sufficiently effective.  At the last sampling day 231 (33 weeks), (Heavy fouling >80%) was observed and these samples were assigned a rank of 5.  **Horgefjorden on the Norwegian south-western coast, April to November 2017:**  In the 2017 test performed with AquaNet LG 360 in Horgefjorden on the Norwegian south-western coast (Hope, B.; 2017), the results are comparable to the 2018 test. The test sample after 104 days was given a score of 4 by the applicant, while the next sample at 127 days was given a score of 5. This is an indication that the efficacy of the coating after 104 days in the sea has decreased to a level where it no longer provides efficacious protection against fouling.  The pictures submitted with this study are of too low quality for the rMS to be able to perform an independent analysis of the observed fouling and the evaluation is by the applicant alone. The study is included to provide supplemental information.  **Galaxidi, central Greece May to November 2017:**  In the 2017 test performed on AquaNet LG 360 in Galaxidi in central Greece (Fagerlid, S.; 2017), the applicant has evaluated the samples to reach a score of 6 (>90% biofouling cover) after 125 days in the sea. The sample analysed after 111 days was given a score of 4 (35-64% biofouling cover).  The pictures submitted with this study were of too low quality for the rMS to be able to perform an independent assessment. Much of the visible fouling is described as being algae, which are not sessile organisms and are not regarded as part of the fouling community. The rMS could not evaluate the correctness of this information, nor the scores given by the applicant. The study is included to provide supportive information.  **Conclusion:**  The rMS concludes that the AquaNet LG360 product has proven an efficacy of 14 weeks in North Atlantic waters based on the submitted efficacy studies.  The rMS has not been able to perform an independent assessment of the efficacy test performed in Greek Mediterranean waters (Fagerlid, S.; 2017). According to the applicant's assessment, an efficacy of 16 weeks was demonstrated.  **AquaNet HG 360**  **Norwegian south-western coast, April to November 2018**  In the efficacy test performed on AquaNet HG 360 in 2018 on the Norwegian south-western coast (Hope, B.; 2018), the product showed good protection up to, and including the sampling date after 98 days (14 weeks) in the sea. The 98 days samples were assigned a rank of 1 (<20% biofouling cover). At the next sampling point at 134 days, the samples had accumulated a significant amount of fouling organisms (Hydroids and skeleton shrimp were most abundant). The rMS has assigned the 134-day samples to a rank 4 (60 – 80% biofouling cover). The increase in fouling observed between these two sampling points gives an indication that the coating at this point no longer was efficacious enough to withstand the fouling pressure.  At sampling day 176 (25 weeks), the samples had lost much of the attached fouling organisms. No explanation to this event was presented. It is noted by the applicant that new settlement of hydroids was observed and that some skeleton shrimp was seen. We can, however, not with certainty relate this observed loss of fouling to be caused by a biocidal effect and not by an external factor such as heavy weather, as also the control sample had lost much of its fouling load at this sampling time. It is, nevertheless, possible that the antifouling coat causes the fouling organisms to fall off easier than from the control samples when the net is agitated. The samples were evaluated by the rMS to a rank of 4 (60-80% biofouling cover). The active re-colonisation by a significant number of hydroids at this time point, is, nevertheless, taken as evidence that the efficacy of the antifouling coat is no longer sufficiently effective.  At sampling day 231, the test samples were heavily fouled, and was evaluated to a rank 5 (> 80% biofouling) by the rMS indicating that the coating no longer provides protection against biofouling.  **Horgefjorden on the Norwegian south-western coast, April to November 2017:**  In the test performed with AquaNet HG 360 in Horgefjorden on the Norwegian south-western coast in 2017 (Hope, B.; 2017), the applicant has evaluated the samples to a maximum score of 4 after 127 and 162 days in the sea (according to the applicant's own internal evaluation routine. Please see the study report for further explanation).  Due to the low quality of the pictures submitted with this study, the rMS was not able to perform an independent assessment of the fouling levels reported in this study.  **Galaxidi, central Greece May to November 2017:**  In the test performed in 2017 with AquaNet HG 360 in Galaxidi in central Greece (Fagerlid, S.; 2017), the applicant has evaluated the samples to a score of no more than 3 (10 – 34% fouling) throughout the study period of 167 days.  The pictures submitted with this study are of too low quality for the rMS to be able to perform an independent assessment. Much of the visible fouling is described as consisting of algae, which are not sessile organisms and are not regarded as part of the fouling community. The rMS could not evaluate the correctness of this information, nor the scores assigned by the applicant.  **Conclusion:**  The rMS concludes that the AquaNet HG360 product has demonstrated an efficacy of 14 weeks in North Atlantic waters based on the submitted efficacy studies.  According to the applicant, AquaNet HG 360 has been proven efficacious in Greek Mediterranean waters for 167 days, equal to approx. 6 months. The rMS has not been able to perform an independent assessment of this test.  **AquaNet 360 RFU**  No studies on AquaNet 360 RFU was submitted.  There is a high level of similarity in the composition of the AquaNet 360 family members, as well as with the AquaNet North Sea BPF. The latter contains also ready-for-use formulation for which efficacy studies have been submitted (AquaNet North Sea Standard and AquaNet North Sea Ultra).  AquaNet 360 RFU contains an intermediate concentration of active substances relative to AquaNet LG 360 and AquaNet HG 360. It contains slightly less active substance compared to the tested formulations from the AquaNet North Sea BPF.  On the basis of active substance content and similarity in product composition, the rMS concludes that read across of efficacy data from the mentioned formulation to AquaNet 360 RFU can be accepted. On the basis of the submitted efficacy studies on the related formulation, an efficacy of 14 weeks in North Atlantic waters can be expected. |

#### Occurrence of resistance and resistance management

Considering the non-selective mode of action of both active substances (dicopper oxide and copper thiocyanate), development of resistance against the AquaNet 360 products is considered unlikely.

As stated in the CAR for dicopper oxide (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. However, some literature studies demonstrate some impacts of copper pollution on marine life that indicate that some hull-fouling species have developed copper tolerance.

#### Known limitations

Not 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 season, location, temperature, sunlight, water nutrient level etc. so no specific claims are possible to make, except for reduced growth relative to an untreated net.

According to Steen-Hansen's internal procedure, nets treated with Aquanet 360 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’.

However, the environmental risk assessment has been conducted with the assumption that some in-situ water cleaning takes place as this is an assumption embedded in the exposure scenarios.

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

The AquaNet 360 products are not intended to be used in combination with other products.

### Risk assessment for human health

The toxicology of the active substances dicopper oxide (Cu2O) and copper thiocyanate (CuSCN) was examined according to standard requirements in the review programme under BPR. The toxicological properties of the active substances are summarised in the respective CA reports, as reflected in the assessment reports:

* Assessment report on Dicopper oxide (CAS-no: 1317-39-1), Product type 21, eCA FR, January 2016 (ECHA, 2016a)
* Assessment report on Copper thiocyanate (CAS-no. 1111-67-7), Product type 21, eCA FR, January 2016 (ECHA, 2016b)

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 360 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.).

Toxicological data on all co-formulants have been compiled and assessed by the applicant and is presented in a separate document (see report in “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 BPF 2017”). Sufficient information is available for the co-formulants to assess all relevant endpoints and to allow for classification of the 360 products.

The AquaNet HG 360 product is classified for acute oral toxicity (Cat 4, H302) and serious eye damage (Cat 1, H318) based on the respective classification of the ingredients. The AquaNet LG 360 and AquaNet 360 RFU products are classified for Serious eye damage (Eye Dam. Cat 1; H318) based on the respective classification of the ingredients. More information can be found in the confidential annex.

**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. 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 (ATP09). 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).

Copper thiocyanate is approved for use in product-type PT21 in the context of Regulation (EU) No.528/2012.

The harmonised classification according to Regulation (EC) No 1272/2008 is available (ATP09) for copper thiocyanate and does not include any classification for human hazards.

No repeated toxicity study by oral route was provided for dicopper oxide nor copper thiocyanate. 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 reports, as further elaborated in the competent authority reports of dicopper oxide and copper thiocyanate (ECHA, 2016a and 2016b).

It is important to note that 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 and 2016b).

Based on the CA reports on dicopper oxide and copper thiocyanate, 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.

No robust data on toxicity is available to the SCN anion (Only 90-day and 14-day studies for repeated toxicity were provided, whereas information on teratogenicity, fertility and carcinogenicity were not available). It is proposed to compare the exposure of thiocyanate via antifouling use to the daily exposure via diet in humans as proposed in the assessment report on copper thiocyanate (ECHA, 2016b).

Most of the co-formulants in the AquaNet 360 biocidal products are not classified under CLP, and those that trigger classification for human health hazards are of low toxicity. None of the co-formulants has been identified as being CMR substances (see the respective documentation in Section 13 of the IUCLID file).

The composition and CLP classification for human health hazards of the co-formulants are presented in the confidential Annex (See section 3.6).

Overall, neither the active substances (dicopper oxide or copper thiocyanate) nor the co-formulations show any sign of carcinogenic, genotoxic or reproductive/ developmental (CMR) effects (for further information please refer to the assessment report (AR) of the active substances).

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

**(ref: Assessment report for dicopper oxide and copper thiocyanate (ECHA, 2016a and ECHA, 2016b))**

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| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| **Reference value for copper (from dicopper oxide and copper thiocyanate)** | | | | | |
| 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 |
| **Reference value for thiocyanate** | | | | | |
| Minimal daily exposure via diet: 10 mg/d, corresponding to 0.17mg/kg/d considering an oral  absorption of 100% and a body weight of 60 kg | | | | | |

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No studies for the assessment of skin irritation/corrosion of AquaNet 360BPF 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 and copper thiocyanate, are 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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 BPF 2017. pdf”), a study investigating the skin irritating effects of the AquaNet 360 products is not considered necessary.

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive or irritating to skin |
| Justification for the value/conclusion | The active substances are 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 |

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| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion or skin irritation |
| Justification | Waiving according to Annex III, point No. 8.1, Column 3 of the BPR:  There are sufficient data available on each of the components in the products to allow classification of the products. 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 12.3 and 24.5% (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 one as serious eye damaging (Cat 1, H318). However, the concentration of the latter is 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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 BPF 2017.pdf”), a study investigating the eye irritating effects of the AquaNet 360 BPF is not considered necessary.

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| **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 the classification of the active ingredient dicopper oxide. |
| Classification of the product according to CLP | Eye Dam. 1, H318 |

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| **Data waiving** | |
| Information requirement | Eye irritation or damage |
| Justification | Waiving according to Annex III, point No. 8.2, 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. |

***Skin sensitisation***

No studies for the assessment of skin sensitisation of AquaNet 360BPF are available.

The active substances (dicopper oxide or copper thiocyanate) of the AquaNet formulations are not classified for skin sensitisation (ATP09 to CLP). One co-formulant does 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 a concentration which triggers labelling of the family members LG 360 and HG 360 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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 BPF 2017.pdf”), a study investigating the skin sensitizing effects of 360BPF is not considered necessary.

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| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not skin sensitising |
| Justification for the value/conclusion | The active substances present in the AquaNet AquaNet 360 Biocidal Product Family are not classified for skin sensitisation. One co-formulant does 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 a concentration which triggers labelling of the family members LG 360 and HG 360 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 LG 360 and AquaNet HG 360 family members) |

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| **Data waiving** | |
| Information requirement | Skin sensitisation |
| Justification | Waiving according to Annex III, point No. 8.3, Column 3 of the BPR:  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 360BPF are available. The active substances (dicopper oxide or copper thiocyanate) are not classified for respiratory sensitisation (ATP09 to CLP). In addition, none of the co-formulants are classified for this endpoint. A study investigating the respiratory sensitising effects of AquaNet360 BPF is not considered necessary.

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| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not a respiratory sensitiser |
| Justification for the value/conclusion | No substances present in the AquaNet 360 Product Family are classified for respiratory sensitisation. Therefore, this BPF is not classified for this endpoint. |
| Classification of the product according to CLP and DSD | Not classified |

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| **Data waiving** | |
| Information requirement | Not a core data requirement |
| Justification | No test guideline available.  The toxicity of the active substances (a.s.), and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

No studies for the assessment of acute oral toxicity of AquaNet360 BPF are available. Harmonised classification exists for both active substances. Dicopper oxide is classified with Acute Tox. 4, H302 whereas copper thiocyanate is not classified for acute toxicity (ATP09 to CLP).

One co-formulant is 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 it is present in a concentration below the generic cut of value of 1% for this end point (Table 1.1, in Annex I to Reg. no 1272/2008).

Due to the contribution of dicopper oxide in the family member AquaNet HG 360, the classification for this endpoint is required according to the ATE calculation method (see the confidential annex for details). The two other family members, AquaNet LG 360 and AquaNet 360 RFU 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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 Biocidal Product Family 2017.pdf”), a study investigating the acute toxic effects of AquaNet 360 BPF is not considered necessary.

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| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Acute oral toxicity Cat. 4 (AquaNet HG 360 only) |
| Justification for the selected value | The products are classified as 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) |

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| **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 360 BPF are available. Although this is not considered a data gap since the information on the ingredients is sufficient to generate the product classification for this endpoint.

Harmonised classification exists for both active substances. Dicopper oxide is classified with Acute Tox. 4, H332 whereas copper thiocyanate is not classified for acute inhalation toxicity (ATP09 to CLP). None of the co-formulants are classified for this endpoint.

Dicopper oxide is present in the products at subthreshold levels according to the ATE calculation method, and no classification for this endpoint is required for this AquaNet product family.

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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 Biocidal Product Family 2017.pdf”), a study investigating the acute toxic effects after inhalation of the AquaNet 360products is not considered necessary.

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| **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 |

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| **Data waiving** | |
| Information requirement | Acute inhalation toxicity |
| Justification | Waiving according to Annex III, point No. 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 the AquaNet 360 products are available. Dicopper oxide, copper thiocyanate and the co-formulants are not classified for this endpoint.

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 (see separate report “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 Biocidal Product Family 2017.pdf"), a study investigating the acute dermal toxicity of 360 products is not considered necessary.

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| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No acute dermal toxicity |
| Justification for the selected value | No substance present in the 360 Biocidal Product Family is classified for acute toxicity by dermal route. Therefore, this BPF is not classified for this endpoint. |
| Classification of the product according to CLP | Not classified |

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| **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 the AquaNet 360 products are available. None of the ingredients of the product mixture including the co-formulants in 360 products are classified for respiratory tract irritation.

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Not irritating |
| Justification for the value/conclusion | No substance present in the AquaNet 360 Biocidal Product Family is classified for respiratory tract irritation (STOT SE 3; H335). Therefore, this BPF is not classified for this endpoint. |
| Classification of the product according to CLP | Not classified |

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

##### Information on dermal absorption

An *in vitro* dermal absorption study through human skin (Bernal, J., 2018a) has been conducted on the representative family member AquaNet LG 360; testing both the concentrated product (13.8% Cu2O + 3.9% CuSCN (w/w)) and the diluted in-use concentration of the product (7.56% Cu2O + 2.14% CuSCN (w/w)). The study was performed according to the OECD 428 test guideline. The study measured the total amount of copper (non-radiolabelled) absorbed through split thickness human skin samples using ICP-MS; this procedure is necessary as it is not technically feasible for copper to be radiolabelled.

The product is a paint formulation which dries on the skin and is difficult to remove by washing without damaging the skin sample. The test formulation was therefore left on the skin samples for the whole test period of 24 hours, as recommended by the PT21 dermal absorption guidance (ECHA, 2016c). 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.

The receptor fluid was sampled six times at 1h, 2h, 4h, 8h, 12h and 24h from the commencement of the application. According to the study report, more than 75% of the total absorption was recovered at half of the study duration (i.e. 12 hours), and all tape strips were consequently considered as non-absorbed and discarded (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 (24 hours) and the referred photo evidence, the exclusion of the tape strips was considered acceptable.

The thiocyanate ion is not possible to accurately quantify in human skin, due to relatively high levels of endogenous thiocyanate. Although it is reasonable to assume that a proportional amount of thiocyanate and copper ions are released when solid copper thiocyanate dissociates, the dermal absorption value found for copper is not necessarily also valid for thiocyanate. A dermal absorption value of 5% for the thiocyanate moiety was therefore applied in accordance with the recommendation given in the copper thiocyanate CAR.

An *in vitro* dermal absorption study through human skin (Bernal, J., 2018b) was also performed on a similar PT21 product from the same applicant, belonging to a different product family, AquaNet Premium (containing 10% Cu2O and 2% Tralopyril), with a very similar formulation as the AquaNet 360 product family. The AquaNet Premium family consists only of ready-for-use formulations. This test formulation was also left on the skin samples for the whole test period of 24 hours as recommended by the PT21 dermal absorption guidance (ECHA, 2016c). All tape strips were photographed and analysed separately. Owing to deficiencies identified in the study (analytical problems resulting in a lack of exposed skin samples), this study was considered invalid.

A second dermal absorption study was therefore conducted (Wallace, J., 2020). In this 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 of the skin and tape strips were taken after each tape strips until all of the paint formulation had been removed from the skin surface, unless no paint was present on pre-tape stripping image.

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. In reality, 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 percentage dermal absorption of a substance from a formulation is inversely related to the concentration of the substance in the formulation (EFSA, 2017). The family members HG and LG are marketed as concentrates to be diluted 1:1 with water, while RFU is a ready-for-use product. The exposure to the operator using these products will mainly be to the in-use concentration 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. As the in-use concentration of AquaNet LG 360 is the formulation with the lowest content of active substance, it is the best suited candidate as a representative product for this product family.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **AquaNet 360 BPF** | | | | | | **Aquanet Premium BPF** |
|  | **AquaNet LG 360** | | **AquaNet HG 360** | | **AquaNet RFU 360** | **Aquanet Premium** |
|  | Conc. | In-use1 | Conc. | In-use1 | Ready to use | Ready to use |
| Dicopper oxide | 13.8 | 7.56 | 24.5 | 14.22 | 12.3 | 10 |
| Copper thiocyanate | 3.9 | 2.14 | 8.04 | 4.66 | 1.7 | (Tralopyril 2%) |
| Copper2 | 14.3 | 7.83 | 26.45 | 15.06 | 11.82 | 8.87 |
| Thiocyanate3 | 1.87 | 1.02 | 3.84 | 2.23 | 0.82 | (Tralopyril 2%) |

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

2 Includes contribution of copper from both active substances, using relevant conversion factors:

([Cu2O]\*0,888)+([CuSCN]\*0,522)

3 Conversion factor: [CuSCN]\*0,478

As described in more detail in the confidential annex (see confidential annex, 3.6.1.) there is a high degree of similarity in the product composition of the AquaNet LG 360 and the AquaNet HG 360 products. The dermal absorption value found for the LG 360 product can therefore be deemed valid for the HG 360 product.

The dermal absorption values applied for the LG 360 and the HG 360 products are thus:

For the undiluted product:

Copper: 0.1% dermal uptake

Thiocyanate: 5% dermal uptake

For the in-use concentration of the products

Copper: 0.4% dermal uptake

Thiocyanate: 5% dermal uptake

As for AquaNet 360 RFU, there is a higher degree of similarity with the composition of AquaNet Premium (see confidential annex, 3.6.1.) than with AquaNet LG 360. The rMS has therefore found it more appropriate to use the dermal absorption value found in the study on this product to read across to the AquaNet RFU product.

The dermal absorption values applied for AquaNet 360 RFU are:

Copper: 1.1% dermal uptake

Thiocyanate: 5% dermal uptake

| **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 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 strip, 4 skin wash, 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  (copper) | Copper thiocyanate  (copper) | Copper thiocyanate (thiocyanate) |
| Value(s) | For LG 360 and HG 360:  0.1% (concentrate) and 0.4% (In-use concentration)  For RFU 360: 1.1% | For LG 360 and HG 360:  0.1% (concentrate) and 0.4% (In-use concentration)  For RFU 360: 1.1% | 5% |
| Justification for the selected value(s) | *In vitro* study through human skin | *In vitro* study through human skin | Recommendation in the copper thiocyanate CAR |

***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 “Section 13 of the IUCLID file: “Background Document on the Human Health Hazard of Co-formulants in 360 Biocidal Product Family 2017.pdf").

***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 360 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.

The complete assessment is available in the confidential annex (3.6.5).

#### 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 specialised service companies. This document assesses the risks to the operators and workers involved in the treatment and deployment of nets when using the applicant’s Biocidal Product Family – Aquanet 360, 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** is performed by lowering the net into a vat containing the product. The net is left submerged in the product for app. 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 pr. 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** 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 per 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 must be 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 and deployment of nets) | | | **Secondary (indirect) exposure** | | | |
|  | Industrial use | Professional use | Non-professional use | Industrial use | Professional use | Non-professional use | Via food |
| Inhalation | Yes | Negligible | n.a. | n.a. | n.a. | n.a. | n.a. |
| Dermal | Yes | Yes | n.a. | n.a. | n.a. | n.a. | n.a. |
| Oral | No | No | n.a. | n.a. | n.a. | 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). 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/fork lifts/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 very 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 physical handling are, however, identical, such as connecting/disconnecting nets to cranes/winches, spills on the equipment and handling when the net is transferred 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 pr. year and is performed using single-use coveralls, gloves, boots and face shields. The exposure is considered 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). Indicative values for this scenario are further given (page 198) and are the 75 percentile values.

The situation is similar for the exposure scenario for deployment of a treated net. 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 75 percentile values. | Professional operators |

| **Description of Scenario 1** | | |
| --- | --- | --- |
| **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 | 0.4% (copper; LG and HG 360 products); 1.1% (copper; RFU 360); 5% (thiocyanate) |
| 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. |

1)Dipping model 4; Biocides Human Health Exposure Methodology, maximum values.

2)HEEG opinion 17, default human factor values for use in exposure assessment for biocidal products

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

4)Dermal absorption of copper: Studies; Dermal absorption of thiocyanate: 5% in accordance with the AR for CuSCN (See ch. 2.4.1.1.12)

| **Description of Scenario 2** | | |
| --- | --- | --- |
| **Handling model 2** | | |
|  | Parameters | Value |
| Tier 1 | Body | 7.55 mg/min1 |
| Hands (indicative hand exposure values are actual measurements inside gloves) | 0.21 mg/min1 |
| Duration1 | 300 min |
| Body weight2 | 60 kg |
| Dermal absorption3 | 0.4% (copper; LG and HG 360 products); 1.1% (copper, RFU 360); 5% (thiocyanate) |

1)Handling model 2; Biocides Human Health Exposure Methodology. 75 percentile values.

2)HEEG opinion 17, default human factor values for use in exposure assessment for biocidal products

3)Dermal absorption of copper: Studies; Dermal absorption of thiocyanate: 5% in accordance with the AR for CuSCN (See ch. 2.4.1.1.12.).

**General assumptions:**

The systemic exposure of each active substance via the dermal and inhalation routes were 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 each active substance.

The long-term Acceptable Exposure Level value (AEL) of 0.041 mg Cu/kg bw/day and the reference value of 0.17 mg SCN/kg bw/day, respectively were 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 and the reference value of 0.17 mg SCN/kg bw/day were used as this task is performed infrequently. These values are reported in the respective Assessment Reports for the approval of the use of these active substances as biocides.

An initial screening assessment (Tier-1) using default assumptions and only minimal clothing was conducted. Since the 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 assessment was used applying representative PPE for the estimation of a more realistic systemic exposure where necessary.

| **Active substances present in the AquaNet 360 Product Family members** | | | |
| --- | --- | --- | --- |
| Representative product | **LG360** | **HG360** | **RFU360** |
| Active substance (%, w/w) | 13.8% Cu2O  + 3.9% CuSCN | 24.5% Cu2O  + 8% CuSCN | 12.3% Cu2O  + 1.72% CuSCN |
| Formulation (Ready-for-use or concentrate) | Concentrate (to be diluted 1:1 with water) | Concentrate (to be diluted 1:1 with water) | Ready for use |
| In-use concentration a.s. (%, w/w)1 | 7.56% Cu2O +  2.14% CuSCN | 14.22% Cu2O +  4.66% CuSCN | 12.3% Cu2O + 1.72% CuSCN |
| Ionic equivalents (in-use conc; % w/w)2 | Total Cu: 7.83%  Total SCN: 1.0% | Total Cu: 15.06%  Total SCN: 2.23% | Total Cu: 11.82%  Total SCN: 0.82% |

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

2 Total Cu includes contribution from both active substances, using relevant conversion factors: ([Cu2O]\*0,888)+([CuSCN]\*0,522). Total SCN: Conversion factor: [CuSCN]\*0,478

***Industrial exposure***

*Scenario [1] Industriall use: Net treatment*

The modelling input parameters of Dipping model 4 were used to calculate the exposure values for the AquaNet 360 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 HG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 6.33e-04 | 0.143 | - | 0.144 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 6.33e-04 | 0.023 | - | 0.024 |
| **Thiocyanate** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 9.37e-05 | 0.265 | - | 0.265 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 9.37e-05 | 0.043 | - | 0.043 |
|  | | | | | |
| **AquaNet LG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 3.29e-04 | 0.074 | - | 0.075 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 3.29e-04 | 0.012 | - | 0.012 |
| **Thiocyanate** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 4.28e-05 | 0.12 | - | 0.12 |
|  | Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 4.28e-05 | 0.02 | - | 0.02 |
|  | | | | | |
| **AquaNet 360 RFU** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 4.96e-04 | 0.31 | - | 0.31 |
|  | Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 4.96e-04 | 0.050 | - | 0.051 |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 4.96e-04 | 0.036 | - | 0.037 |
| **Thiocyanate** | | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 3.44e-05 | 0.097 | - | 0.097 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 3.44e-05 | 0.016 | - | 0.016 |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 3.44e-05 | 0.011 | - | 0.011 |

***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 360 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 oral intake (mg/kg bw) | Estimated total systemic uptake (mg/kg bw) |
| **Scenario 2: Net deployment** | | | | | |
|  | | | | | |
| **AquaNet HG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.023 | - | 0.023 |
| **Thiocyanate** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.043 | - | 0.043 |
|  | | | | | |
| **AquaNet LG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.012 | - | 0.012 |
| **Thiocyanate** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.02 | - | 0.02 |
|  | | | | | |
| **AquaNet RFU 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.050 | - | 0.050 |
| **Thiocyanate** | | | | | |
| Professional deployment of aquaculture nets; Handling model 2 | Tier 1; Light clothing, gloves (Hand exposure is actual exposure inside gloves) | - | 0.016 | - | 0.016 |

#### Risk characterisation for human health

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

**(ref: Assessment report for dicopper oxide and copper thiocyanate)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| **Reference values for copper (from dicopper oxide and copper thiocyanate)** | | | | | |
| 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 |
| **Reference value for thiocyanate** | | | | | |
| Minimal daily exposure via diet: 10 mg/d, corresponding to 0.17mg/kg/d considering an oral  absorption of 100% and a body weight of 60 kg | | | | | |

***Industrial use***

*Scenario [1] Industrial use: Net dipping*

The predicted levels of systemic exposure of operators to copper and thiocyanate when undertaking net dipping activities are summarised and compared with the relevant AEL-values 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 HG 360** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.144 | 0.041 | **3.51** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.024 | 0.041 | 0.59 |
| **Thiocyanate** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.265 | 0.17 | **1.56** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.043 | 0.17 | 0.26 |
|  | | | | |
| **AquaNet LG 360** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.075 | 0.041 | **1.82** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.012 | 0.041 | 0.3 |
| **Thiocyanate** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.12 | 0.17 | 0.71 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.02 | 0.17 | 0.12 |
|  | | | | |
| **AquaNet 360 RFU** | | | | |
|  | | | | |
| **Copper** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.31 | 0.041 | **7.55** |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.051 | 0.041 | **1.24** |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.037 | 0.041 | 0.89 |
| **Thiocyanate** | | | | |
| Professional dipping of aquaculture nets; Dipping model 4 | Tier 1; No PPE  Gloves (hand exposure is actual exposure inside gloves) | 0.097 | 0.17 | 0.57 |
|  | Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.016 | 0.17 | 0.09 |
|  | Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves) | 0.011 | 0.17 | 0.07 |

Values in bold represents exposure/AEL values >1

Conclusion: The risk from systemic exposure to copper to industrial workers performing net treatment activities using AquaNet LG 360 and AquaNet HG 360 is acceptable in Tier 2a. Safe use requires the use of coated coveralls and gloves.

The risk from the systemic exposure to copper to industrial workers performing net treatment activities using AquaNet 360 RFU is acceptable in Tier 2b. Safe use requires the use of impermeable coveralls and gloves.

***Professional use***

Scenario 2: Net deployment

The predicted levels of systemic exposure of operators to copper and thiocyanate when performing net deployment activities are summarised and compared with the relevant AEL-values 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 HG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.023 | 0.082 | 0.29 |
| **Thiocyanate** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.043 | 0.17 | 0.25 |
|  | | | | | |
| **AquaNet LG 360** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.012 | 0.082 | 0.15 |
| **Thiocyanate** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.02 | 0.17 | 0.12 |
|  | | | | | |
| **AquaNet 360 RFU** | | | | | |
|  | | | | | |
| **Copper** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.050 | 0.082 | 0.62 |
| **Thiocyanate** | | | | | |
| Professional deployment of nets | Tier 1; No PPE (100% penetration) gloves (indicative values are actual inside gloves) | | 0.016 | 0.17 | 0.09 |

Conclusion: The risk from the systemic exposure to the AquaNet 360 biocidal product family members to professionals performing net deployment activities is acceptable in the Tier 1 assessment for all family members.

***Combined scenarios***

Not applicable

***Local effects***

A classification for Eye damage 1 (H318) is proposed for all products in the AquaNet 360 family; therefore, consideration of a local risk assessment is required. No relevant quantitative information is available in order to conduct a risk assessment and so in this case a qualitative risk assessment is considered appropriate in accordance with the BPR Guidance (Chapter 4.3, ECHA, 2017).

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  +No 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 use of goggles during deployment | n.r. | Training for staff on good practice; instructions for use  Good standard of personal hygiene  Coveralls, gloves, eye protection (goggles) | 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 risk was demonstrated to be acceptable in the Tier 2a assessment for AquaNet LG 360 and AquaNet HG 360, provided that the workers wear coated coveralls and gloves. The risk was demonstrated to be acceptable in the Tier 2b assessment for AquaNet 360 RFU, provided that the workers wear impermeable coveralls and gloves.

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.

***Profesional 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 all family members. The indicative hand exposure values 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 professional 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. It is also included in many food supplements for human consumption according to Directive 2002/46/EC. As a result, acceptable risks have been identified for potential exposure of copper via food contamination (see Dicopper oxide CAR PT 21 2016 for further information).

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). Based on the particular case of copper (ionic form), and its properties (high solubility/dilution in sea water, complexation, low bio-accumulation, natural occurrence and physiological needs), this approach is not deemed relevant in this case.

In a study by Lundebye *et al*. (2017), the levels of copper (Cu), as well as other metals and environmental pollutants, was analysed in a standardised muscle sample from both farmed (n=100) and wild (n=87) atlantic salmon, caught or produced in Norway in 2012. The results show that filet from farmed salmon contain less copper than wild salmon (0.38 versus 0.57 mg/kg wet weight). Also filet from recaptured escaped farmed salmon was analysed, showing intermediate copper levels (0.55 mg/kg wet weight). The biocide use in the farms is not specified in the study. It is reported that samples were taken from different farms, exerting approx. 10% of the farms in the area. Considering that the use of copper containing antifoulants is commonly used, it is reasonable to believe that this was indeed the case in a number of the selected farms.

The findings in Lundeby *et al. (2017)* gives no indication of elevated copper levels in farmed fish compared to wild caught fish, neither from feed consumption nor from treated nets.

In order to exceed the ADI of 0.15 mg Cu/kg bw/day, a 15-kilo child would, based on these data, have to consume approx. 6 kilos of salmon. The corresponding amount for an adult of 60 kg is 24 kilo salmon.

No further assessment of risk from dietary exposure to copper is considered necessary.

### Risk assessment for animal health

Not relevant for these products.

### Risk assessment for the environment

The environmental risk assessment covers the two active substances dicopper oxide (Cu2O) and copper thiocyanate (CuSCN). The AquaNet 360 BPF does not contain any substances of concern (SoC) for the environment.

Regarding the exposure to the environment from the use of the AquaNet 360 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 a first tier assessment at the EU level. In addition, an exposure assessment for Norwegian fish farms has been carried out, following the Norwegian environmental emission scenario for nets used in fish farms (NO, 2019), hereafter referred to as the Norwegian fish farm scenario. The latter represents an adjustment of the EU scenario to better reflect Norwegian fish farm conditions.

#### Effects assessment on the environment

According to the copper thiocyanate PT21 Competent Authority Report (CAR), copper thiocyanate exists in solution as copper and thiocyanate ions, and not as ‘molecular’ copper thiocyanate. Hence, the aquatic environment will not be exposed to copper thiocyanate (CuSCN) as such, but to the ions, Cu2+ and SCN-.

Dicopper oxide

An evaluation of the effect data for the active substance with relevance to the aquatic compartment can be found in the 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).

Copper thiocyanate compound (CuSCN)

According to Document IIA, Copper thiocyanate PT21, acute toxicity studies are available for only two trophic levels (fish and invertebrates) and no chronic studies are available. The results are based on calculated concentrations from measured concentrations and shows toxic effects on CuSCN. A comparison of the endpoints was made between fresh and saltwater species, and the difference in sensitivity are within a factor of 10 for fish but not for invertebrate. The lowest LC50 value for marine water is for fish.

Thiocyanate

The effect data for thiocyanate are taken from the Competent Authority Report for copper thiocyanate (PT 21, 2016).

**Predicted no effect concentrations for thiocyanate used for the risk characterisation**

|  |  |  |
| --- | --- | --- |
| **PNEC** | **Result** | **Reference** |
| PNECsea | 0.011 mg SCN-/L. | Fish: NOEC = 1.1 mg SCN-/L  AF = 100  (CAR PT21, 2016). |
| PNECsediment | 0.045 mg SCN-/kg sediment (dry weight) | No reliable toxicity data. PNEC calculated on the basis of the Equilibrium Partition  Method (EPM) (CAR PT21, 2016). |

The PNECs derived for the thiocyanate ion SCN- are based on laboratory acute and chronic studies using the thiocyanate salts KSCN and NH4SCN. The base set (fish, invertebrate, algae) is complete for both acute and long-term toxicity and the lowest long-term NOEC is 1.1 mg SCN-/L for fish (*Pimephales promelas)*.

Since no data are available on the toxicity of the thiocyanate ion on marine organisms, the PNEC for the marine compartment is derived from the lowest long-term NOECs of the freshwater dataset divided by an assessment factor of 100 as stated in the EU-TGD (2003). Therefore, PNECsea = 1.1/100 = 0.011 mg SCN-/L.

No data are available on the toxicity of the thiocyanate ion on marine sediment dwelling organisms. Subsequently PNEC assessment is performed on the basis of the Equilibrium Partition Method (EPM) according to the EU-TGD (2003). Hence, PNECsediment for saltwater = 0.0097 mg SCN-/kg ww sediment equivalent to 0.045 mg SCN-/kg sediment (dry weight).

Co-formulants

Available effect data for the co-formulants are documented in the separate file “Environmental hazards of co-formulants in 360 BPF 2017”. The available data allow the first evaluation of co-formulants and a classification of the biocidal product family.

None of the co-formulants are regarded as substances of concern (SoC), since they do not affect the overall classification of 360 BPF products. Thus, no specific risk assessment of co-formulants has been carried out.

***Further Ecotoxicological studies***

No further ecotoxicological studies on 360products 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 (see separate report “Section 13 of the IUCLID file: “Environmental hazards of co-formulants in 360 BPF 2017.pdf”), further ecotoxicology studies on 360 products 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 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 copper thiocyanate

The CAR for the active substance copper thiocyanate (PT21, 2016) states that copper compounds such as copper thiocyanate are often used as a biocide in antifouling paints. They are crystalline solids that have only marginal solubility in water and organic solvents. As strong electrolytes, they dissolve in aqueous media as dissociated ions, and not as ‘molecular’ copper thiocyanate. In pure water, copper thiocyanate dissolves by simple dissociation of the ionic crystal lattice to release Cu+ and SCN- ions. In natural saltwater that contain chloride ions, such as seawater and brackish waters, the products of dissolution are the cuprochloride ion, CuCl2-, and SCN-. Once released from an antifouling paint film, these copper species can undergo oxidation and participate in equilibrium processes with a range of inorganic and organic ligand donors in solution.

These processes are independent of the nature of the parent copper-containing material. Therefore, when particles of paint containing CuSCN enter aqueous media such as fresh and marine waters: CuSCN mainly dissociates into the ions, Cu2+ and SCN- and to a lesser extent as copper thiocyanate is sparingly soluble, some undissociated CuSCN may also be present but this phenomenon is likely to be limited. The sediment compartment is mainly exposed to the ions Cu2+ and SCN- after dissociation of CuSCN in the aqueous media/water phase.

When particles of CuSCN enter solid media such as the soil, CuSCN mainly remain undissociated in the solid phase of the soil. In aqueous terrestrial media pore water and groundwater, CuSCN mainly dissociates into the ions Cu2+ and SCN- and some undissociated CuSCN may also be present due to its low solubility but this phenomenon is likely to be limited.

Subsequently, the 3 compounds: Cu2+, SCN- and CuSCN - but only to a lesser extent and mainly in the terrestrial environment - can be found in the environment from the use of copper thiocyanate (CuSCN) in antifouling paints and have to be taken into account for risk assessment.

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. Copper is an inorganic compound and as such has negligible volatility. Hence, the amount emitted to air is expected to be very 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 forms of metals, and biomagnification in food webs.

Copper thiocyanate

The CAR of the active substance copper thiocyanate (PT21, 2016) states that predicted Koc value estimated with EPIWIN software gave an estimated Koc = 4.5 L/kg (LogKoc = 0.65) (PCKocWIN Program v1.66). As the applicant also provided information on the training set of EPIWIN model that includes substances with a similar structure to thiocyanate, the model can be considered valid for thiocyanate KOC values. Concerning the bioaccumulation potential, as the ammonium thiocyanate is readily biodegradable, and as the thiocyanate presents an estimated log Kow < 3 (0.58), it can be stated that accumulation potential of the thiocyanate ion is low.

***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 AquaNet 360 BPF has been assessed in two tiers:

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

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

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 21 |
| Assessed scenarios | Environmental emissions from nets used in fish farms, during the deployment time of the nets in the sea.  Only professional uses of the 360 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, as a tier 1 assessment:  *Scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms. Norwegian Environmental Agency, 2015.*  For the assessment representative for Norway (i.e. a tier 2 assessment for the use in Norway), the Norwegian fish farm scenario was used:  *A Norwegian environmental emission scenario for fish farms - Adjustment of the EU scenario (2015) to better represent national conditions. Norwegian Environmental Agency, 2018.* |
| Approach | MAMPEC v.3.1 was used for the modelling.  For the active substances, agreed values from the CARs were used as input. For other environmental parameters, efault 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 information  Formulation: No information  Use:  Service life: |

***Emission estimation***

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

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

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

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

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

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

1 Please see the [Emission scenario for nets used in fish farms (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 substances 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 |
| **Thiocyanate** | Molecular mass | g/mol | 58.1 | PT 21 ESD excel thiocyanate |
| Saturized vapour pressure at 20°C | Pa | 1E-05 |
| Solubility at 20°C | g/m3 | 2.03 |
| Kd | m3/kg | 0.00E+00 |

**Concentration of active ingredients in AquaNet 360 products**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **Concentration of a.i. in product (%, w/w)** | | **Concentration of a.i. in product (g/L)** | | |
| **Copper1** | **Thiocyanate** | | **Copper1** | **Thiocyanate** |
| AquaNet LG360 | 7.83 | 1.02 | | 86.92 | 11.37 |
| AquaNet HG360 | 15.06 | 2.23 | | 179.19 | 26.52 |
| AquaNet RFU360 | 11.82 | 0.82 | | 133.59 | 9.31 |

1 Copper equivalent: dicopper oxide = 88.8%; copper thiocyanate = 52.0%

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 emission outputs (Elocal)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **EU fish farm scenario**  **(tier 1)** | | **Norwegian fish farm scenario (tier 2)** | |
| **Copper** | **Thiocyanate** | **Copper** | **Thiocyanate** |
| AquaNet LG360 | 7097 g/d | 928 g/d | 10810 g/d | 1404 g/d |
| AquaNet HG360 | 14631 g/d | 2165 g/d | 22277 g/d | 3297 g/d |
| AquaNet RFU | 10907 g/d | 760 g/d | 16608 g/d | 1157 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***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet LG360**  **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** | 0.09 | 0.08 | 12.32 | 0,12 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.83E-03 | 5.38E-06 | 1.20E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **AquaNet LG360**  **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** | 1.19 | **1.04** | | 28.42 | | 0.29 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | | **PECsuspended sediment**  [µg/g dw] | | **PECsuspended sediment / PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.83E-03 | | 5.38E-06 | | 1.20E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | | | |
| **AquaNet HG360**  **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 | | 25.61 | | 0.26 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | | **PECsuspended sediment**  [µg/g dw] | | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.05 | 0.0043 | | 1.27E-05 | | 2.8E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | | | |
| **AquaNet HG360**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | |
|  | | | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | | **PECdissolved / PNECwater 1** | | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 1.29 | | **1.13** | | 41.17 | 0.42 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | | **PECdissolved / PNECwater 1** | | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.05 | | 0.0043 | | 1.27E-05 | 2.8E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet RFU360**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.14 | 0.125 | 18.93 | 0.19 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.50E-03 | 4.44E-06 | 9.86E05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **'AquaNet RFU360**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 1.24 | **1.08** | 35.00 | 0.35 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.50E-03 | 4.44E-06 | 9.86E05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

The resulting PEC/PNEC ratios without background concentrations were found to be below the trigger value of 1. However, in the tier 1 calculations, the PEC/PNEC ratios for PECdissolved/PNECwater ratios with background concentrations of Cu were slightly above the trigger value for all AquaNet 360 products.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet LG360**  **Average PEC values calculated by MAMPEC v3.1**  **(without bakground 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** | 0.03 | 0.03 | 4.55 | 0.05 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 5.34E-03 | 4.85E-04 | 3.18E-06 | 7.07E-05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet LG360**  **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** | 1.13 | 0.99 | 20.65 | 0.21 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Norwegian fish farm scenario** | 5.34E-03 | 4.85E-04 | 3.18E-06 | 7.07E-05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| **AquaNet HG360**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.07 | 0.06 | 9.35 | 0.09 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.01 | 1.14E-03 | 7.47E-06 | 1.66E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet HG360**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.17 | 1.02 | 25.5 | 0.26 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.01 | 1.14E-03 | 7.47E-06 | 1.66E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet RFU360**  **Average PEC values calculated by MAMPEC v3.1**  **(without background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 0.05 | 0.05 | 6.97 | 0.07 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 4.40E-03 | 4.00E-04 | 2.63E-06 | 5.83E-05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet RFU360**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 1.15 | 1.00 | 23.07 | 0.23 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **Norwegian fish farm scenario** | 4.40E-03 | 4.00E-04 | 2.63E-06 | 5.83E-05 |
| 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.

#### Risk characterisation

***Atmosphere***

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

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

The proposed uses of the 360 Biocidal Product Family 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***

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

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** |
| **AquaNet LG360** | | |
| Total copper | **1.04** | 0.29 |
| Thiocyanate | 1.83E-03 | 1.20E-04 |
| Combined | **1.04** | 0.29 |
| **AquaNet HG360** | | |
| Total copper | **1.13** | 0.42 |
| Thiocyanate | 0.0043 | 2.8E-04 |
| *Combined* | **1.13** | 0.42 |
| **AquaNet RFU360** | | |
| Total copper | **1.08** | 0.355 |
| Thiocyanate | 1.50E-03 | 9.86E-03 |
| *Combined* | **1.08** | 0.355 |

\*with background concentrations of copper

In the tier 1 calculations, there were minor exceedances of PECdissolved/PNECwater>1.

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

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** |
| **AquaNet LG360** | | |
| Total copper | 0.99 | 0.21 |
| Thiocyanate | 4.85E-04 | 7.07E-05 |
| Combined | 0.99 | 0.21 |
| **AquaNet HG360** | | |
| Total copper | 1.02 | 0.26 |
| Thiocyanate | 1.14E-03 | 1.66E-04 |
| *Combined* | 1.02 | 0.26 |
| **AquaNet RFU360** | | |
| Total copper | 1.00 | 0.23 |
| Thiocyanate | 4.00E-04 | 5.83E-05 |
| *Combined* | 1.00 | 0.23 |

\*with background concentrations of copper

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

***Leaching behavior***

The applicant has submitted field and farm studies to determine the release of dicopper oxide from aquaculture nets coated with Aquanet antifouling products. These studies aim to determine the loss of biocide during commercial conditions with or 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 | 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 | Bespoke method | Nets deployed in Norwegian Coastal Seawater,  pH not measured,  Temperature not measured | Ulriksen, U (2020) |

|  |
| --- |
| **Study summaries** |
| **Field Study - Ulriksen, U (2020)**  Egersund nylon net dipped in AquaNet Ultra 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 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. A majority of the nets have been cleaned at sea using high pressure water jetting. Time to first cleaning has been on average 3 months, with subsequent cleanings averaging every 2 weeks for the net walls. The net bottom has been cleaned less efficiently due to machine limitations when cleaning the coned floor. Seasonal variation of cleaning includes a higher frequency from June to October and lesser with low sea temperatures. This is due to the variation of fouling pressure related to sea temperatures in the Norwegian coastal areas. The dataset consists of several types of high effect cleaning equipment all operated with pressure between 100 and 300 bar. Deployment data such as time in sea, cage id and location were recorded.  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 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\*) * The farm and field studies use North Sea Ultra, this is the AquaNet product with the highest concentration of copper. It is therefore possible to use these values for Fa.i. as a surrogate in all AquaNet products as it represents a worst-case scenario and worst-case leaching into the coastal waters. |

\* 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 refined 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: not in-situ cleaned nets | "Farm study:" 90th percentile value from nets that were not in-situ cleaned | 0.28 | 13 |
| 2: 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 |

\*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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet LG360**  **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 scenario2** | 1.15 | 1.0 | 22.88 | 0.23 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.83E-03 | 5.38E-06 | 1.20E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| 2 Refined based on field study data with both cleaned and not in-situ cleaned nets (Refined Fa.i. of 0.44) | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet HG360**  **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 scenario2** | 1.21 | 1.0 | 30.07 | 0.30 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.05 | 0.0043 | 1.27E-05 | 2.8E-04 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| 2 Refined based on field study data with both cleaned and not in-situ cleaned nets (Refined Fa.i. of 0.44) | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AquaNet RFU360**  **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 scenario2** | 1.18 | 1.0 | 26.51 | 0.27 |
| **Thiocyanate**  PNEC surrounding waters = 11 µg/L  PNECsed = 0.045 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment/ PNECsediment 1** |
| **EU fish farm scenario** | 0.02 | 1.50E-03 | 4.44E-06 | 9.86E05 |
| 1 PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks. | | | | |
| 2 Refined based on field study data with both cleaned and not in-situ cleaned nets (Refined Fa.i. of 0.44) | | | | |

**Refined risk characterisation for the EU fish farm scenario (higher tier)**

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** |
| **AquaNet LG360** | | |
| Total copper | 1.0 | 0.23 |
| Thiocyanate | 1.83E-03 | 1.20E-04 |
| Combined | 1.0 | 0.23 |
| **AquaNet HG360** | | |
| Total copper | 1.0 | 0.30 |
| Thiocyanate | 0.0043 | 2.8E-04 |
| *Combined* | 1.05 | 0.30 |
| **AquaNet RFU360** | | |
| Total copper | 1.0 | 0.27 |
| Thiocyanate | 1.50E-03 | 9.86E-03 |
| *Combined* | 1.0 | 0.27 |

\*with background concentrations of copper

For the refined calculations, PEC/PNEC ratios were found to be ≤ 1, except for the Aquanet HG360 product where there is a minor exceedance of the threshold (combined PECdissolved/PNECwater). Therefore, further refinement of mixture toxicity is required. Please see mixture toxicity section below for details.

***Terrestrial compartment***

The proposed uses of the 360 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 360 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.

Copper thiocyanate:

Concerning the bioaccumulation potential, the thiocyanate presents an estimated log Kow < 3 (0.58), it can be stated that accumulation potential of the thiocyanate ion is low.

***Mixture toxicity***

According to the PT 21 Product Authorisation manual, products that contain relevant mixtures of substances (e.g. multiple active substances) an assessment of mixture toxicity is triggered. At tier 1 this requires simple summation of individual PEC/PNEC ratios. This approach has been followed, see the chapter on risk characterisation above.

At tier 2 of the mixtures risk assessment (see ECHA, 2014[[2]](#footnote-3)), the RQproduct is determined by use of a modified toxic unit approach. This approach allows for the summation of toxic units across different active substances (or substances of concern) that have differing amounts of experimental data and therefore differing assessment factors used in the determination of the PNECs for each substance. In this tier, the three trophic levels are assessed independently, using the same assessment factor used for calculating the PNEC of the respective substance at tier 1 and according to the following equation:

where:

* PEC = predicted environmental concentration
* ECx = the lowest effect concentration affecting x% (may also be a NOEC) for the trophic level and substance
* AF = Assessment factor used in the determination of the PNEC for the substance assessed individually

The RQProduct is the highest RQ of all the trophic levels.

**Lowest endpoints used in PNEC calculations**

The lowest endpoints and associated assessment factors used in the individual risk assessment for copper and thiocyanate ion are summarised in the following table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Substance** | **Taxa** | **Species** | **Chronic Endpoints** | **Value (µg/L)** | **Assessment factor\*** |
| Copper | Fish | *Atherinops affinis* | NOEC | 55 | 2 |
| Invertebrate | *Ceriodaphnia dubia* | NOEC | 4 | 2 |
| Algae | *Phaeodactylum tricornutum* | NOEC | 2.9 | 2 |
| Thiocyanate ion | Fish | *Pimephales*  *Promelas* | NOEC | 1100 | 1000 |
| Invertebrate | *Daphnia magna* | NOEC | 1250 | 1000 |
| Algae | *Selenastrum*  *capricornutum* | NOEC | 2200 | 1000 |
| \***Copper** assessment factor (AF) used based on 56 chronic NOEC/EC10 values for the marine compartment, resulting in 24 different species-specific NOEC values covering different trophic levels (fish, invertebrates, algae). 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 using an assessment factor of 2.  **Thiocyanate** ion assessment factor (AF) of 1000 comprised of an AF of 10 (based upon a full base set of freshwater data: fish, invertebrate and algae) plus an additional AF of 100 to account for freshwater/marine conversion in the absence of marine ecotoxicity data. | | | | | |

**Tier 2 calculations for EU scenario**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product** | **Trophic level** | **Substance** | **NOEC (µg/L)** | **Assessment factor (AF)** | **NOEC/AF** | **PEC**  **(µg/L)** | **PEC/**  **(NOEC/AF)** | **RQProduct** |
| HG360 | Fish | Copper | 55 | 2 | 27.5 | 1.21\* | 0.04 | 0.09 |
| Thiocyanate | 1100 | 1000 | 1.1 | 0.05000 | 0.05 |
| Invertebrate | Copper | 4 | 2 | 2 | 1.21 | 0.61 | 0.65 |
| Thiocyanate | 1250 | 1000 | 1.25 | 0.05000 | 0.04 |
| Algae | Copper | 2.9 | 2 | 1.45 | 1.21 | 0.83 | 0.86 |
| Thiocyanate | 2200 | 1000 | 2.2 | 0.05000 | 0.02 |
|  |  |  |  |  |  |  |  |  |

\***Copper refined PEC**

RQProduct calculated in the mixtures risk assessment (tier 2) falls below the trigger of 1 for the Aquanet HG360 product.

All AquaNet 360 products show acceptable risk to the aquatic environment.

***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 consider 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 |
| Fagerlid, S. | 2017a | AquaNet HG360 Greece 2017  Report No. DOKID-1294561088-222  No  No | Steen-Hansen |
| Fagerlid, S. | 2017b | AquaNet LG360 Greece 2017  Report No. DOKID-1294561088-223  No  No | Steen-Hansen |
| Fischer, A | 2017 | Interim report 3 months AquaNet HG360  7PO4987-02  RISE, Sweden  No  No | Steen-Hansen |
| Fischer, A | 2018a | Interim report 6 months AquaNet HG360  7PO4987-02  RISE, Sweden  No  No | Steen-Hansen |
| Fischer, A | 2018b | Final report 12 months AquaNet HG360  7PO4987-02b  RISE, Sweden  No  No | Steen-Hansen |
| Hope, B | 2017a | AquaNet HG360 Norway Trial 2 2017  Report No. DOKI D-1294561088-97  No  No | Steen-Hansen |
| Hope, B | 2017b | AquaNet LG360 Norway Trial 2 2017  Report No. DO Kl D-1294561088-97  No  No | Steen-Hansen |
| Hope, B | 2018a | AquaNet HG360 Norway 2018  Report number. DOKID-1294561088-97  No  No | Steen-Hansen |
| Hope, B | 2018b | AquaNet LG360 Norway 2018  Document ID. Not provided  No  No | Steen-Hansen |
| Younis S. | 2017 | Hazardous Properties Testing on a Sample of Aqua Net HG360  Report No. GLP3016001671BR1V1/2017  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

**Environmental exposure assessment, EU fish farm scenario (tier 1)**

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

MAMPEC\_aquanet\_HG360\_EU2.xlsx

MAMPEC\_aquanet\_LG360\_EU2.xlsx

MAMPEC\_aquanet\_RFU360\_EU2.xlsx

**Environmental exposure assessment, Norwegian fish farm scenario (tier 2)**

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

MAMPEC\_aquanet\_HG360\_NO2.xlsx

MAMPEC\_aquanet\_LG360\_NO.xlsx

MAMPEC\_aquanet\_RFU360\_NO2.xlsx

### Output tables from the human exposure assessments

The following excel-file has been uploaded to RBP3 separately:

HH\_Exposure\_aquanet\_360.xlsx

## New information on the active substances

None.

## Residue behaviour

AquaNet 360 BPF is only to be used as antifouling paint 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)[[3]](#footnote-4)

Please see section 2.2.5.5 and IUCLID.

## Confidential annex

Please see the separate confidential annex.

## Other

**REFERENCES**

* Bloecher N, Floerl O, Sunde LM. 2015. Amplified recruitment pressure of biofouling organisms in commercial salmon farms: potential causes and implications for farm management. Biofouling 31:163-172.
* Cherrie, J. 2017. COPD and low toxicity dust. IOM Working for a Healthier Future. Institute of Occupational Medicine. Edinburg. Available at [www.iom-world.org](http://www.iom-world.org).
* Committee on Biocidal Products (2013). Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. Assessment Report. Iodine (including PVP-iodine) Product types 1, 3, 4, 22 Finalised in the Standing Committee on Biocidal Products at its meeting on 13 December 2013, Sweden.
* Dürr S, Watson DI 2010. Biofouling and antifouling in aquaculture. In: Dürr S, Thomason JC, editors. Biofouling. West Sussex (UK): Wiley-Blackwell; p. 267-287
* European Chemicals Agency (ECHA), 2015. Biocides human health exposure methodology. Version 1. Helsinki.
* European Chemicals Agency (ECHA), 2014a. 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), 2014b. Committee for Risk Assessment, RAC Opinion proposing harmonised classification and labelling at EU level of copper thiocyanate. Adopted 4 December 2014
* 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
* European Chemicals Agency (ECHA), 2016b. Assessment Report. Evaluation of the active substance Copper Thiocyanate. Product type 21. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. France
* European Chemicals Agency (ECHA), 2016c. “Dermal absorption from antifouling products and other matrices that form a dry film during testing” Report of workshop held in Berlin 19 May 2016 Date of report 19 August 2016.
* European Chemicals Agency (ECHA), 2017. Guidance on the Biocidal Products Regulation. Volume III. Human Health. Assessment & Evaluation (Part B+C), version 4.0, Helsinki.
* European Chemicals Agency (ECHA), 2018. Guidance on the Biocidal Products Regulation. Volume III. Human Health. Information requirements (Part A), version 1.2, Helsinki.
* European Chemicals Agency (ECHA), 2019. Draft proposal: "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA".
* European Commission 2003. Technical guidance document on risk assessment. Institute of Health and Consumer Protection. European Chemicals Bureau. TGD Part1.Italy, 302p.-
* European Commission (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L 353, 1-1355
* European Commission. 2016. Proposal for a Directive of the European Parliament and of the Council. Amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Brussels 13.5.2016. COM (2016) 248 final. 2016/0130 (COD).
* European Food Safety Authority (EFSA): Guidance on dermal absorption. Harrie Buist, H. et al. 2017. EFSA Journal, Volume 15, Issue 6, June 2017.
* European Journal of the European Union. 2004. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC. L158/50-76.
* Human Exposure Expert Group (HEEG). 2010. Opinion 9. Default protection factors for protective clothing and gloves. Ispra, 27.01.2010.
* Human Exposure Expert Group (HEEG) opinion 17. Default human factor values for use in exposure assessment for biocidal products. Endorsed at TM II 2013.

Human Health Working Group meeting WG-V-2016: Dermal absorption of PT 21 active substances 9 December 2016.

* Lane A, Willemsen PR 2004. Collaborative effort looks into biofouling. Fish Farming int. 2004:34-35
* Lundebye, A-K, et al (2017). Lower levels of Persistent Organic Pollutants, metals and the marine omega 3-fatty acid DHA in farmed compared to wild Atlantic salmon (Salmo salar), Environmental Research 155 (2017) 49–59.
* NO, 2019. A Norwegian environmental emission scenario for nets used in fish farms – Adjustment of the EU scenario (2015) to better reflect national conditions (Norwegian Environment Agency, 2019) <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY>
* Official Journal of the European Communities. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC. L 131/11-23.
* Official Journal of the European Union. 2014. Commission Implementing Regulation (EU) N. 408/2014 of 23 April 2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18. L121/17.
* SINTEF. 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>

1. [↑](#footnote-ref-2)
2. ECHA, (2014). Transitional Guidance on mixture toxicity assessment for biocidal products for the environment. [↑](#footnote-ref-3)
3. [↑](#footnote-ref-4)