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

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



Dicopper Oxide/Copper Pyrithione Biocidal Product Family

Product type 21

Dicopper Oxide and Copper Pyrithione as included in the Union list of approved active substances

Case Number in R4BP: BC-QQ036558-09

Evaluating Competent Authority: Norway

Date:02/June/2023

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# CONCLUSION

The Dicopper Oxide/Copper Pyrithione Biocidal Product Family (BPF) consists of products containing the active substances dicopper oxide and copper pyrithione. The products are suspension concentrates for direct application. The product family is used for treatment of nets used for offshore fish farming to prevent fouling of the nets during use (by slime, weed (macro algae) and animals). The treatment of the net is performed in specialised facilities, and the user categories are industrial users.

The BPF consists of 2 meta-SPCs.

The applicant originally applied for the following products in the biocidal product family:

* Meta SPC 1: Netwax NI Gold (Light)
* Meta SPC2: Netwax NI Goldold, Netwax Gold Anti-bite and Netwax NI Gold Plus

The biocidal product family falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The overall conclusion of the evaluation is that the BPF (when modified) meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the treatment of nets used for offshore fish farming for industrial workers, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

The BPF is not considered to have endocrine-disrupting properties.

The intended use(s) as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

The identity, physico-chemical properties and analytical methods are adequately addressed. The proposed authorised biocidal product family contains 18.0-21.5 % w/w dicopper oxide and 0.2400-0.7500 % w/w copper pyrithione. The products are red liquids with a pH range of 6.86-7.38 and a relative density of 1.1830-1.2260 at ambient temperatures. The products have a shelf life of 6 months when stored at temperatures above 4oC and below 30 oC.

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

Since no substance of concern has been identified, the human health and environmental risk assessment is based on the active substances, dicopper oxide and copper pyrithione.

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

The risk to industrial workers involved in net impregnation activities was assessed using the Dipping model 4 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net dipping tasks. An acceptable risk was demonstrated in the systemic risk assessment for industrial workers performing net treatment activities with meta SPC 1 (Netwax NI Gold Light) and the modified product in meta SPC 2 (Netwax NI Gold) in tier 2c, assuming use of double coverall (1% clothing penetration) and chemical resistant gloves. No acceptable risk was identified for Netwax NI Goldold and Netwax NI Gold Plus.

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.

An acceptable risk was demonstrated in the systemic risk assessment of professional workers performing net deployment for all products. As for meta SPC 1 (Netwax NI Gold Light) and the modified meta SPC 2 (Netwax NI Gold) acceptable risk was demonstrated in tier I (use of gloves only). As for Netwax NI Goldold and Netwax NI Gold Plus, acceptable risk is demonstrated in tier 2a, assuming use of gloves and uncoated cotton coverall.

Gloves are always worn when performing this task, due to mechanical strain, and in the Atlantic region usually also due to low temperatures.

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

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

In the tier 1 calculations, there were exceedances of combined PECdissolved/PNECwater >1 for all products in both the EU fish farm scenario and the Norwegian fish farm scenario. In the Tier II mixtox assessment, calculations based on refined leaching rates and increased deployment times resulted in acceptable environmental risks for Meta-SPC 1 in both the EU fish farm scenario and the Norwegian scenario with RQ values ≤ 1 for the most sensitive trophic level (algae). The product in Meta-SPC 2 (Netwax NI Gold) did not show acceptable environmental risk in the EU fish farm scenario. However, PEC/PNEC ratios were ≤ 1 for all products in the Norwegian fish farm scenario, indicating acceptable environmental risk.

In summary, only the product in meta-**SPC 1** (Netwax NI Gold (Light)) showed an acceptable environmental risk in the EU scenario.

The products in both meta-**SPC 1 and 2**, Netwax NI Gold (Light) and Netwax NI Gold, showed acceptable environmental risk in the Norwegian fish farm scenario.

As a result of the risk assessment for human health and the environment, out of the 4 products originally included in the Biocidal Product Family (Meta 1: Netwax NI Gold (Light) and Meta 2: Netwax NI Goldold, Netwax Gold Anti-bite and Netwax NI Gold Plus), only the first product demonstrated an acceptable risk for both human health and environment.

Netwax NI Goldold was modified by reducing the amount of the active substances to an acceptable level. Hence, the active substance copper pyrithione was reduced from 1.4%(w/w) to 0.75%(w/w). It is specified in the text whether the new or old formulation has been used, and the postfix "old" has been added to the name of the original formulation (i.e., " Netwax NI Goldold") whereas the modified formulation is referred to as Netwax NI Gold. Please note that the studies performed on the old version of Netwax NI Gold are used for some endpoints. In those cases, read across from the old to the new formulation has been evaluated and deemed acceptable.

The composition of the products not authorised can be found in the confidential annex (section 1.3).

Netwax Gold Anti-bite could not be authorised due to the content of, what is considered by the RefMS based on the information provided, a PT19 biocidal active substance (repellent) not approved or included in the review program (See further information in the confidential annex).

The refMS therefore proposes to only include the products Netwax NI Gold (Light) and Netwax NI Gold in the biocidal product family.

When using the products according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier** | |  |
| --- | --- | --- |
| **Dicopper Oxide and Copper pyrithione Biocidal Product Family** | |  |
| **Identifier** | **Trade Name** | **cMS for the evaluation** |
| **Meta SPC 1** | Netwax NI Gold (Light) | Norway  Spain  Denmark  Iceland  Finland |
| **Meta SPC 2** | Netwax NI Gold |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | NetKem AS |
| **Address** | Slalåmveien 1  1410 Kolbotn  Norway |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturers of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | NetKem AS |
| **Address of manufacturer** | Slalåmveien 1  1410 Kolbotn  Norway |
| **Location of manufacturing sites** | NORDOX AS  Østensjøveien 13  N-0661 Oslo  Norway |

#### Manufacturers of the active substances

|  |  |
| --- | --- |
| **Active substance** | Dicopper Oxide |
| **Name of manufacturer** | Nordox AS |
| **Address of manufacturer** | Østensjøveien 13  N-0661 Oslo Norway |
| **Location of manufacturing sites** | NORDOX AS Østensjøveien 13  N-0661 Oslo Norway |
| **Active substance** | Copper Pyrithione |
| **Name of manufacturer** | YOU Solutions Germany GmbH |
| **Address of manufacturer** | Freundallee 9a  DE 30173  Hannover  Germany |
| **Location of manufacturing sites** | Arch Chemicals (China) Co., Ltd  No. 9 Quingquiu Street  Suzhou Industrial Park  CN-Jiangsu Province 215024, China |

### 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 constituents** | |
| **ISO name** | Dicopper Oxide |
| **IUPAC or EC name** | Copper (I) oxide |
| **EC number** | 215-270-7 |
| **CAS number** | 1317-39-1 |
| **Index number in Annex VI of CLP** | 029-002-00-X |
| **Minimum purity / content** | >97% |
| **Structural formula** |  |
| **ISO name** | No ISO-common name available  Synonyms:  copper pyrithione  copper pyridinethione  copper 2-pyridinethiol-1-oxide  2-pyridinethiol-1-oxide, copper salt  copper Omadine® (registered trademark of Arch Chemicals, Inc.) |
| **IUPAC or EC name** | Bis(1-hydroxy-1H-pyridine-2-thionato- O,S)copper (Copper pyrithione) |
| **EC number** | 238-984-0 |
| **CAS number** | 14915-37-8 |
| **Index number in Annex VI of CLP** | Not applicable (there is no harmonised classification for copper pyrithione) |
| **Minimum purity / content** | >97% |
| **Structural formula** | Bis(1-hydroxy-1H-pyridine-2-thionato-O,S)copper Structure |

#### Candidate(s) for substitution

Neither of the active substances are candidates for substitution.

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content of the AS** | **Content**  **(% w/w)** | |
| **Min** | **Max** |
| Dicopper Oxide  (in Nordox Cuprous oxide, red, Paint Grade, >97% Cu2O) | Copper (I) oxide | Active substance | 1317-39-1 | 215-270-7 | **Content of the AS used for the formulation of the BP**F **(%)** | 18.0 | 21.5 |
| **AS content in the BP**F **to be indicated in the SPC (%)** | 18.0 | 21.5 |
| **Minimum purity in the source of the AS (%)** | 97% | |
| **"Minimum pure" AS content (%)** | 17.46 | 20.86 |
| Copper Pyrithione  (in Copper OmadineTM Wet Cake, 65 % CuPY | Bis(1-hydroxy-1H-pyridine-2-thionato- O,S)copper (Copper pyrithione) | Active substance | 14915-37-8 | 238-984-0 | **Content in the BPF of the mixture including the AS (%)** | 0.3715 | 1.161 |
| **AS content in the mixture used for the formulation of the BPF (%)** | 64.61% | |
| **AS content in the BPF to be indicated in the SPC (%)** | 0.24 | 0.75 |
| **Minimum purity in the source of the AS (%)** | 95% | |
| **"Minimum pure" AS content (%)** | 0.2280 | 0.7126 |

**Overview table of the concentrations of active substance and formulation types in the BPF**

|  |  |  |  |
| --- | --- | --- | --- |
| **Concentration range of the BPF (%)** | | | |
| **meta-SPC number** | | **1** | **2** |
| **Dicopper oxide**  **Content (% w/w)** | **Content of the AS used for the formulation of the BPF (%)** | 18-18 | 21.5-21.5 |
| **AS content in the BPF to be indicated in the SPC (%)** | 18-18 | 21.5-21.5 |
| **Minimum purity in the source of the AS (%)** | 97% | |
| **"Minimum pure" AS content (%)** | 17.46-17.46 | 20.86-20.86 |
| **Copper pyrithione** | **Content in the BPF of the mixture including the AS (%)** | 0.3715-0.3715 | 1.161-1.161 |
| **AS content in the mixture used for the formulation of the BPF (%)** | 64.61% | |
| **AS content in the BPF to be indicated in the SPC (%)** | 0.2400-0.2400 | 0.7501-0.7501 |
| **Minimum purity in the source of the AS (%)** | 95% | |
| **"Minimum pure" AS content (%)** | 0.2280-0.2280 | 0.7126-0.7126 |
| **Formulation type** | | SD – Suspension concentrate for direct application | SD – Suspension concentrate for direct application |

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

#### Information on technical equivalence

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

YOU Solutions Germany GmbH is the approved substance supplier for copper pyrithione in accordance with Article 95 of the Biocidal Products Regulation (BPR) and participants in the Review Programme).

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

There are no substances of concern present in the biocidal product family.

(Please see the confidential annex for details).

#### Type of formulation

|  |
| --- |
| 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**

Netwax NI Gold (Light)

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Met. Corr. 1  Eye Damage 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H290: May be corrosive to metals  H318 Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | |
| **Labelling** | | |
| Hazard Pictogram |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger |  |
| Hazard statements | H290: May be corrosive to metals  H318 Causes serious eye damage  H410: Very toxic to aquatic life with long-lasting effects | |
| Precautionary statements | 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  P390: Absorb spillage to prevent material damage  P391: Collect Spillage  P406: Store in a corrosion resistant container/container with a resistant inner liner  P501: Dispose of contents/ container in accordance with local/ regional/national/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. | |

**Meta SPC 2**

Netwax NI Gold

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Met. Corr. 1  Eye Dam. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statements | H290: May be corrosive to metals  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | |
| **Labelling** | | |
|  |  | pollut1 |
| GHS05 | GHS09 |
| Signal words | Danger | |
| Hazard statements | H290: May be corrosive to metals  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long-lasting effects | |
| Precautionary statements | 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  P390: Absorb spillage to prevent material damage  P391: Collect Spillage  P406: Store in a corrosion resistant container/container with a resistant inner liner  P501: Dispose of contents/container to approved disposal plant in accordance with local regulations | |
| -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. | |

### Authorised use

#### Use description

Table 1. Use # 1 – Treatment of Aquaculture Nets (Meta SPC 1)

|  |  |
| --- | --- |
| **Product Type** | PT21: Products used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water. |
| **Where relevant, an exact description of the authorised use** | Protection against fouling of nets used in aquaculture. |
| **Target organism (including development stage)** | Slime, Weed (macro algae) and Animals |
| **Field of use** | Antifouling products for protection against marine growth on fish farming nets. |
| **Application method** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate and frequency** | Application rate: 0.8 - 1.2 kg of product per 1 kg of dry net. |
| **Category of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 2. Use # 1 – Treatment of Aquaculture Nets (Meta SPC 2)

|  |  |
| --- | --- |
| **Product Type** | PT21: Products used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water. |
| **Where relevant, an exact description of the authorised use** | Protection against fouling of nets used in aquaculture. |
| **Target organism (including development stage)** | Slime, Weed (macro algae) and Animals |
| **Field of use** | Antifouling products for protection against marine growth on fish farming nets. |
| **Application method** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate and frequency** | Application rate: 0.8 - 1.2 kg of product per 1 kg of dry net. |
| **Category of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| See Section 2.1.5 |

#### Use-specific risk mitigation measures

|  |
| --- |
| See Section 2.1.5 |

#### 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 |

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

|  |
| --- |
| See Section 2.1.5 |

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#### 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 |

### General directions for use

#### Instructions for use

|  |
| --- |
| • Stir vigorously for 20 minutes with an appropriate stirring mechanism before use to achieve a homogenous solution after storage.  • To be used undiluted.  • Density and viscosity must be measured to ensure that the product is homogeneous prior to treatment. The measurements must be within the specification of this authorisation. Please follow the manufacturer's directions for how to measure density and viscosity.  • Let the net soak in the product for a minimum of 20 minutes to ensure that 0.8 - 1.2 kg of product is applied per 1 kg of dry net. Then let the net hang to dry or use a closed drum system.  • IMPORTANT! Nets must be completely dry before they are put into the sea.  • The container should be tilted a little for complete emptying and may be rinsed with approximately 5% water. |

#### Risk mitigation measures

|  |
| --- |
| Avoid breathing dust/mist  Avoid contact with skin and eyes. Wash hands after handling and use.  Wash contaminated clothing before reuse.  Personal protective equipment to be worn:   * Hand protection: Wear protective chemical resistant gloves (neoprene, nitrile rubber or butylrubber protective gloves (EN 374)). * Eye protection: Wear chemical goggles or face shield (EN 166). * Skin and body protection: Wear a double coverall, a chemically resistant (at least type 3, EN-14605) coverall which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information) with at least a long-sleeve, long-leg cotton coverall underneath. * Respiratory protection: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.   Avoid release to the environment.  Application, maintenance and repair activities shall (1) be conducted within a contained area to prevent losses and minimize emissions to the environment, meaning (2) on an impermeable hard standing with bunding or (3) on soil covered with an impermeable material. Any losses or waste containing the antifouling active substances shall be collected for reuse or disposal. |

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

|  |
| --- |
| First aid measures:  IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.  If symptoms: Call 112/ambulance for medical assistance.  If no symptoms: Call a POISON CENTRE or a doctor.  IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.  IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.  IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  Emergency measures for the environment:  Methods and materials for containment and cleaning up: Use absorbent material and dispose of material or solid residues at an authorised 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 1760/European waste code EWC 02 01 99.  Recommended container return system: IBC containers are returned and recycled through a suitable return system. |

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

|  |
| --- |
| **Meta SPC 1 to Meta SPC 2**  Conditions of Storage:  PROTECT FROM FROST.  Handle and store above + 4 °C and below +30°C  Protect from sunlight.  Shelf Life: 6 months |

### Other information

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| The label of the biocidal product must provide advice 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 by the authorisation holder's recommendation based on the performed risk assessments.  The label of the biocidal product should also provide advice on the deployment time for treated nets i.e., that the nets should be deployed for 270 days before they are taken up to be cleaned and reimpregnated­.  The label of the biocidal product must inform that high pressure water jet cleaning of treated nets should not be performed on site.  **Cleaning impregnating machine**  The impregnating machine is drained and emptied after each impregnating cycle, with little paint residue remaining in the machine following this process. It is not necessary to clean the machine after each treatment. The machine is cleaned either if the machine is not to be used again for some days or if another type of antifouling paint, or coating, is going to be used. The machine is cleaned using small amounts of water only. The water is pumped through the machine, to remove paint residues from the machine, and from the pipes, valves and pumps. Where it is necessary to dispose of this water it should be disposed of at a hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.  **Cleaning dipping tank**  The dip tank is only cleaned periodically, typically every 4-8 months. Similar to the impregnation machine the dipping tank is hosed with water to remove sediment and dirt that may have come into the tank from the nets. This process is anticipated to remove the majority of paint residue with little paint residue left in the settlement and dirt on the bottom of the tank. Remaining dirt and sediment is manually removed at the end of the process. This last operation requires that the worker wears appropriate protective clothing.  Waste product from the impregnating machines or dip tanks used during the application phase is collected. Where it is necessary to dispose of this water it should be disposed of at a hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.  Meta SPC 2:  Do not apply the products to nets meant for use in Spain. |

### Packaging of the biocidal product

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| **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)** |
| Plastic Drum | 200 L | HDPE | Sealed lid: Fast Seal (made from nylon) | Industrial | Yes |
| Intermediate Bulk Containers (1000 L) made from High-density polyethylene and contained within a steel cage | 1000 L | HDPE and contained within a steel cage | Sealed lid: Fast Seal (made from nylon)  Outlet:  There is a plastic seal covering the outlet. | Industrial | Yes |

### Documentation

#### Data submitted in relation to product application

Product

Please refer to the reference list contained in Annex 3.1.

Active Substance

There are no active substance data in addition to the dicopper oxide and copper pyrithione assessment reports submitted.

#### Access to documentation

For the letters of access to the active substance data and product data, please refer to IUCLID Section 13.

## Assessment of the biocidal product family\*

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

Please refer to Section 2.1.4.1.

Note that the applicant originally applied for the following products in the biocidal product family:

* Meta SPC 1: Netwax NI Gold (Light)
* Meta SPC 2: Netwax NI Goldold, Netwax Gold Anti-bite and Netwax NI Gold Plus

However, in the risk assessment, only Netwax NI Gold (Light) demonstrated acceptable risk. Due to identified risk for human health and environment for all products in meta SPC 2, Netwax NI Goldold was modified. The amount of the active substances was reduced to an acceptable level; i.e. the active substance copper pyrithione was reduced from 1.4%(w/w) to 0.75%(w/w).

It is specified in the text whether the new or old formulation has been used. The postfix "old" has been added to the name of the original formulation (i.e., Netwax NI Goldold) whereas the modified formulation is referred to as Netwax NI Gold. Please note that the studies performed on the old version of Netwax NI Gold are used for some endpoints.

In those cases, read across from the old to the new formulation has been evaluated and deemed acceptable.

The composition of the products not proposed authorised can be found in the confidential annex (section 1.3).

Netwax Gold Anti-bite could not be authorised due to the content of a PT19 biocidal active substance (repellent) not approved or included in the review program (See further information in section 1.3. in the confidential annex.

### Physical, chemical and technical properties

For the physical-chemical and technical properties physical state, odour, relative density, viscosity and pourability, both products, Netwax NI Gold Light (meta SPC 1) and Netwax NI Gold (meta SPC 2), were tested.

The long-term storage stability test and the accelerated storage stability test was performed on Netwax NI Gold Light (meta SPC 1), and the test results are read-acrossed to Netwax NI Gold (meta SPC 2). This also applies for wet sieve analysis and persistent foam testing. Test for surface tension was performed on the product Netwax NI Gold Plus and read-acrossed to Netwax NI Gold Light (meta SPC 1) and Netwax NI Gold (meta SPC 2). It should be noted that Netwax NI Gold Plus is not proposed authorised due to unacceptable human health risk, but the test result for surface tension is valid for the product family.

Justification for read-across can be found in the confidential PAR.

**Meta SPC 1**

Netwax NI Gold (Light)

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual assessment | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Liquid | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025 (Version 2) |
| Colour at 20°C and 101.3 kPa | Visual assessment | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Red | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Odour at 20°C and 101.3 kPa | Olfactory assessment | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Slight indeterminate odour. | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | pH = 7.38 at 20 °C | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Relative density / bulk density | OECD 109 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | 1.1830 at 20 °C | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Storage stability test – **accelerated storage** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Stored for 2 weeks at 54 °C.  The packaging of the test was 500 mL PE bottles.  Appearance of the product and packaging, pH and relative density were measured after storage together with the active substance content.  **Active substance content:**  T= 0  Dicopper oxide: 18.69 % w/w  Copper pyrithione: 0.24 % w/w  T = 2 weeks  Dicopper oxide: 19.10 % w/w [2.18 % change in dicopper oxide content]  Copper pyrithione: 0.21 % w/w. [13.09 % change in copper pyrithione content].  **pH**  T = 0: 7.28  T = 2 weeks: 6.89  **Relative density**  T = 0: 1.1830  T = 2 weeks: 1.1821  **Appearance:**  There was a change in the appearance for the sample stored at 2 weeks at 54 °C. The test item was initially found to be a non-uniform, red opaque liquid. After storage, the test item was still non-uniform, but the colour was red with vertical pink streaks. After stirring the vertical pink streaks was no longer visible, but the sample still has a small amount of lighter coloured material floating om the surface of the sample and therefore not homogenous. A slight panelling was observed.  In conclusion, the test indicates that storage at higher temperatures (above 30 °C) is not recommended. No storage above 30 °C will be clearly stated on the label. | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Storage stability test – **long term storage at ambient temperature** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | The storage stability tests were performed at 20°C for 6 months.  Packaging of the test was 500 mL PE bottle.  Appearance of the product and packaging, pH, viscosity, and relative density were measured after storage together with the active substance content.  **Active substance content:**  T= 0  Dicopper oxide: 18.7 % w/w  Copper pyrithione: 0.24 % w/w  T = 6 months  Dicopper oxide: 20.80 % w/w [5.07 % change in dicopper oxide content]  Copper pyrithione: 0.21 % w/w. [-10.24 % change in copper pyrithione content].  **pH**  T = 0: 7.38  T = 6 months: 7.94  **Viscosity**  T = 0  213 mPa.s at 20°C  152 mPa.s at 40°C  T = 6 months  262 mPa.s at 20°C  189 mPa.s at 40°C  **Relative density**  T = 0: 1.1830  T = 6 months: 1.1806  **Appearance:**  The test item was initially found to be a non-uniform, red opaque liquid. After storage for 6 months at 20°C the test item was a non-uniform liquid with marbling of a pink colouration visible on the surface. After stirring for 20 minutes the marbling is still visible but reduced. No interaction on the packaging material was observed.  In conclusion, there is not any major changes of the test item after 6 months of storage. The decrease in the copper pyrithione content after 6 months of storage is acceptable (≤10 %), especially when considering that the sample material is difficult to handle.  A shelf life of 6 months is considered acceptable, but stirring for 20 minutes with an appropriate stirring mechanism must be included in the use instructions. In addition, viscosity and density must be measured to be within the specification of the authorisation. | Harding, L (2020) Storage Stability Study on Netwax NI Gold Light; CEMAS; Report Number CEMR-9027 |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not performed.  It is considered to be scientifically justified to omit this study on the basis that the product labels state: *Protect from frost.*  *Handle and store above +4° C.* | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Not performed.  Generally, dicopper oxide is not susceptible to degradation by UV light. In addition, the containers which the product is supplied in (200 L HDPE drums or 1000 L HDPE IBC containers) are not transparent and the dark pigment in the product itself will preclude light such that only the surface of the product in the container will be exposed to light. Given that the product instructions state “Stir vigorously for 20 minutes with an appropriate stirring mechanism before use to achieve a homogenous solution”, if exposed to light, the very surface of the product is mixed well throughout the product prior to use. Furthermore, the applicant state that based on experience in handling and use, the product has demonstrated to not be light sensitive.  However, copper pyrithione phototransform readily in sunlight. As the storage stability studies were conducted in the dark (only periodically exposed to light), the statement "protect from sunlight" should be included on the label as a precautionary measure. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | **Temperature:**  The results from the accelerated storage stability test for 2 weeks at 54 °C indicates that the product should not be stored at temperatures above 30 °C. Also, according to the applicant, the product should not be stored at temperatures below 4 °C to prevent freezing.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | No significant change in the appearance of the container after 6 months of storage at ambient temperatures. | Harding, L (2020) Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9027 |
| Wettability | - | - | Not relevant for SD formulations. | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant.  The product is not a suspension concentrate. | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 185 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Residue retained on a 75 μm sieve was 0.077%. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI Gold Light: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506627 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant for SD formulations. | - |
| Disintegration time | - | - | Not relevant.  The biocidal products are not tablets, therefore the determination of disintegration time is not applicable. | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not relevant.  The biocidal products are not powders or granules, therefore the determination of particle size distribution, content of dust/ fines, attrition, friability is not applicable. | - |
| Persistent foaming | CIPAC MT 47.3 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | 3.3 mL (1.6%) foam was produced initially. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. No further assessment required. | Walker, J. (2022a) Netwax NI Gold Light: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506627 |
| Flowability/ Pourability/ Dustability | CIPAC MT 148.1 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | **Flowability/ dustability:**  Not relevant.  The biocidal products are not powders or granules; therefore, the determination of flowability or dustability is not applicable.  **Pourability:**  Pourability: 97.8%  Residue: 2.2%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI Gold Light: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493367 |
| Burning rate — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the burning rate is not applicable. | - |
| Burning completeness — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the burning completeness is not applicable. | - |
| Composition of smoke — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the composition of smoke is not applicable. | - |
| Spraying pattern — aerosols | - | - | Not relevant.  The biocidal products are not aerosols, therefore the determination of the spraying pattern-aerosols is technically not possible. | - |
| Physical compatibility | - | - | Not performed.  The biocidal products are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of physical compatibility is not considered to be scientifically justified. | - |
| Chemical compatibility | - | - | Not performed.  The biocidal products are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of chemical compatibility is not considered to be scientifically justified. | - |
| Degree of dissolution and dilution stability | - | - | Not relevant.  The biocidal products are marketed and used neat. Water is only added to rinse out the packaging material, therefore the determination of degree of dissolution and dilution stability data is not applicable. | - |
| Surface tension | OECD 115 | Netwax NI Gold Plus (25 % w/w dicopper oxide, 2.5 % w/w copper pyrithione) | Read across to Netwax NI Gold Plus[[1]](#footnote-2)  The surface tension determined at 20°C was 66.70 mN/m. | Apps, G. (2018a, 2018b) Surface Tension testing on Netwax E8 Greenline and Netwax NI Gold Plus Biocide Formulations; CEMAS Report No. CEMR-8866; 26 November 2018 |
| Viscosity | OECD 114  (Rotational viscometer) | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Viscosity at 116 s-1 (20°C):  213 mPas  Viscosity at 116 s-1 (40°C): 152 mPas | Harding, L (2020) Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9027 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI Gold Light is a pink liquid with a slight indeterminate odour, a pH of 7.38 at 20 °C and relative density of 1.1830 at 20 °C. There are long-term storage stability data for the product which demonstrate that the product is stable for 6 months when stored at ambient temperature given that the products are stirred for 20 minutes with an appropriate stirring mechanism prior to use and viscosity and density are measured to be within the specification of the authorisation. The label shall clearly state that the product is not to be stored at temperatures below 4 °C or above 30 °C and protect from frost. |

**Meta SPC 2**

Netwax NI Gold[[2]](#footnote-3)

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual assessment | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | Liquid | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | Red | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | Not discernible | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | 6.86 at 19.9°C | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | 1.2260 at 20°C | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |
| Storage stability test – **accelerated storage** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read across to Netwax NI Gold Light.  Stored for 2 weeks at 54 °C.  The packaging of the test was 500 mL PE bottles.  Appearance of the product and packaging, pH and relative density were measured after storage together with the active substance content.  **Active substance content:**  T= 0  Dicopper oxide: 18.69 % w/w  Copper pyrithione: 0.24 % w/w  T = 2 weeks  Dicopper oxide: 19.10 % w/w [2.18 % change in dicopper oxide content]  Copper pyrithione: 0.21 % w/w. [13.09 % change in copper pyrithione content].  **pH**  T = 0: 7.28  T = 2 weeks: 6.89  **Relative density**  T = 0: 1.1830  T = 2 weeks: 1.1821  **Appearance:**  There was a change in the appearance for the sample stored at 2 weeks at 54 °C. The test item was initially found to be a non-uniform, red opaque liquid. After storage, the test item was still non-uniform, but the colour was red with vertical pink streaks. After stirring the vertical pink streaks was no longer visible, but the sample still has a small amount of lighter coloured material floating om the surface of the sample and therefore not homogenous. A slight panelling was observed.  In conclusion, the test indicates that storage at higher temperatures (above 30 °C) is not recommended. No storage above 30 °C will be clearly stated on the label. | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Storage stability test – **long term storage at ambient temperature** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read across to Netwax NI Gold Light.  The storage stability tests were performed at 20°C for 6 months.  Packaging of the test was 500 mL PE bottles.  Appearance of the product and packaging, pH, viscosity and relative density were measured after storage together with the active substance content.  **Active substance content:**  T= 0  Dicopper oxide: 18.7 % w/w  Copper pyrithione: 0.24 % w/w  T = 6 months  Dicopper oxide: 20.80 % w/w [5.07 % change in dicopper oxide content]  Copper pyrithione: 0.21 % w/w. [-10.24 % change in copper pyrithione content].  **pH**  T = 0: 7.38  T = 6 months: 7.94  **Viscosity**  T = 0  213 mPa.s at 20°C  152 mPa.s at 40°C  T = 6 months  262 mPa.s at 20°C  189 mPa.s at 40°C  **Relative density**  T = 0: 1.1830  T = 6 months: 1.1806  **Appearance:**  **Appearance:**  The test item was initially found to be a non-uniform, red opaque liquid. After storage for 6 months at 20°C the test item was a non-uniform liquid with marbling of a pink colouration visible on the surface. After stirring for 20 minutes the marbling is still visible but reduced. No interaction on the packaging material was observed.  In conclusion, there is not any major changes of the test item after 6 months of storage. The decrease in the copper pyrithione content after 6 months of storage is acceptable (≤10 %), especially when considering that the sample material is difficult to handle.  A shelf life of 6 months is considered acceptable, but stirring for 20 minutes with an appropriate stirring mechanism must be included in the use instructions. In addition, viscosity and density must be measured to be within the specification of the authorisation. | Harding, L (2020) Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9027 |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not performed.  It is considered to be scientifically justified to omit this study on the basis that the product labels state: *Protect from frost.*  *Handle and store above +4°C.* | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Not performed.  Generally, dicopper oxide is not susceptible to degradation by UV light. In addition, the containers which the product is supplied in (200 L HDPE drums or 1000 L HDPE IBC containers) are not transparent and the dark pigment in the product itself will preclude light such that only the surface of the product in the container will be exposed to light. Given that the product instructions state “Stir vigorously for 20 minutes with an appropriate stirring mechanism before use to achieve a homogenous solution”, if exposed to light, the very surface of the product is mixed well throughout the product prior to use. Furthermore, the applicant state that based on experience in handling and use, the product has demonstrated to not be light sensitive. However, copper pyrithione phototransform readily in sunlight.  As the storage stability studies were conducted in the dark (only periodically exposed to light), the statement "protect from sunlight" should be included on the label as a precautionary measure. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read across to Netwax NI Gold Light.  **Temperature:**  The results from the accelerated storage stability test for 2 weeks at 54 °C indicates that the product should not be stored at temperatures above 30 °C. Also, according to the applicant, the product should not be stored at temperatures below 4 °C to prevent freezing.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Harding, L (2019) Accelerated Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9025  (Version 2) |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read across to Netwax NI Gold (Light).  No significant change in the appearance of the container after 6 months of storage at ambient temperatures. | Harding, L (2020) Storage Stability on Netwax NI Gold Light; CEMAS; Report Number CEMR-9027) |
| Wettability | - | - | Not relevant for SD formulations | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant.  The product is not a suspension concentrate. | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 185 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read-across to Netwax NI Gold Light.  Residue retained on a 75 μm sieve was 0.077%. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI Gold Light: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506627A |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant for SD formulations. | - |
| Disintegration time | - | - | Not relevant.  The biocidal products are not tablets, therefore the determination of disintegration time is not applicable. | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not relevant.  The biocidal products are not powders or granules, therefore the determination of particle size distribution, content of dust/ fines, attrition, friability is not applicable. | - |
| Persistent foaming | CIPAC MT 47.3 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Read-across to Netwax NI Gold Light.  3.3 mL (1.6%) foam was produced initially. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. No further assessment required. | Walker, J. (2022a) Netwax NI Gold Light: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506627 |
| Flowability/ Pourability/ Dustability | CIPAC MT 148.1 | Netwax NI Goldold (21.5 % w/w dicopper oxide, 1.4 % w/w copper pyrithione) | **Flowability/ dustability:**  Not relevant.  The biocidal products are not powders or granules; therefore, the determination of flowability or dustability is not applicable.  **Pourability:**  Read across to Netwax NI Gold.  Pourability: 97.0%  Residue: 3.0%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022c); Netwax NI Gold: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8503460 |
| Burning rate — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the burning rate is not applicable. | - |
| Burning completeness — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the burning completeness is not applicable. | - |
| Composition of smoke — smoke generators | - | - | Not relevant.  The biocidal products are not smoke generators, therefore the determination of the composition of smoke is not applicable. | - |
| Spraying pattern — aerosols | - | - | Not relevant.  The biocidal products are not aerosols, therefore the determination of the spraying pattern-aerosols is technically not possible. | - |
| Physical compatibility | - | - | Not performed.  The biocidal products are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of physical compatibility is not considered to be scientifically justified. | - |
| Chemical compatibility | - | - | Not performed.  The biocidal products are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of chemical compatibility is not considered to be scientifically justified. | - |
| Degree of dissolution and dilution stability | - | - | Not relevant.  The biocidal products are marketed and used neat. Water is only added to rinse out the packaging material, therefore the determination of degree of dissolution and dilution stability data is not applicable. | - |
| Surface tension | OECD 115 | Netwax NI Gold Plus (25 % w/w dicopper oxide, 2.5 % w/w copper pyrithione) | Read across to Netwax NI Gold Plus[[3]](#footnote-4)  The surface tension determined at 20°C was 66.70 mN/m. | Apps, G. (2018a, 2018b) Surface Tension testing on Netwax E8 Greenline and Netwax NI Gold Plus Biocide Formulations; CEMAS Report No. CEMR-8866; 26 November 2018 |
| Viscosity | OECD 114 | Netwax NI Goldold (21.5% w/w dicopper oxide, 1.4% w/w copper pyrithione) | Viscosity at 200 s-1 (20°C):  163 mPas  Viscosity at 200 s-1 (40°C): 113 mPas  Netwax NI Gold is a non-Newtonian liquid with thixotropic tendencies. | Harding, L (2018) Physical and Chemical Testing of Netwax NI Gold; CEMR-8351. |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI Gold is a red liquid with no discernible odour, a pH of 6.86 at 19.9 °C and a relative density of 1.2260 at 20 °C. Based on the long-term storage stability data, the product is stable for 6 months when stored at ambient temperature given that the products are stirred for 20 minutes with an appropriate stirring mechanism prior to use and viscosity and density are measured to be within the specification of the authorisation. The label shall clearly state that the product is not to be stored at temperatures below 4 °C or above 30 °C and protect from frost. |

### Physical hazards and respective characteristics

The physical hazard testing was conducted on Netwax NI Gold Ligth (meta SPC 1), and the test results were read-acrossed to Netwax NI Gold (meta SPC 2).

The test results are considered representative for the whole product family. Justification for read-across can be found in the confidential PAR.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Evaluation on a theoretical basis and a differential scanning calorimetry (DSC scan).  UN Manual of Tests and Criteria: Part I: Classification procedures, test methods and criteria relating to explosive class 1 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Not determined.  A DSC scan was performed from -80 to 550 ˚C with a heat rate of normally 4 ˚C/min. The total heat of decomposition was detected to be 290.0 J.g-1 which is < 500 J.g-1. Therefore, Netwax NI Gold (Light) is not a candidate for classification as a UN Class 1 explosive substance.  The test results can be read-acrossed to the rest of the product family.  In addition, experience in the use and handling of the products does not indicate that the products are explosive according to the applicant. | Siusiene, E.; 2022a; Physico-Chemical Testing on a Test Item of Netwax NI Gold Light; GLP3016012492R1/2022 |
| Flammable gases | - | - | Not applicable to liquid products. | - |
| Flammable aerosols | - | - | Not applicable to liquid products. | - |
| Oxidising gases | - | - | Not applicable to liquid products. | - |
| Gases under pressure | - | - | Not applicable to liquid products. | - |
| Flammable liquids | EC A.9 (closed cup, Pensky-Martens Apparatus) | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | The test temperature range was 40 to 360°C. Due to the test item boiling, higher test temperatures could not be attained. Hence, no flash to boiling.  The test item is not classified as a flammable liquid under the CLP Regulation. | Siusiene, E.; 2022a; Physico-Chemical Testing on a Test Item of Netwax NI Gold Light; GLP3016012492R1/2022 |
| Flammable solids | - | - | Not applicable to a liquid. | - |
| Self-reactive substances and mixtures | Evaluation on a theoretical basis and a differential scanning calorimetry (DSC scan).  UN Manual of Tests and Criteria: Part II: test Series A to H | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | Not determined.  A DSC scan was performed from -80 to 550 ˚C with a heat rate of normally 4 ˚C/min. The total heat of decomposition was detected to be 290.0 J.g-1 which is < 300 J.g-1. Therefore, Netwax NI Gold (Light) is not a candidate for classification as a UN Class 4, Division 4.1 self-reactive substance.  The test results can be read-acrossed to the rest of the product family.  In addition, experience in the use of the products does not indicate that the products are self-reactive according to the applicant. | Siusiene, E.; 2022a; Physico-Chemical Testing on a Test Item of Netwax NI Gold Light; GLP3016012492R1/2022 |
| Pyrophoric liquids | - | - | None of the components of the products are classified as pyrophoric. Experience in the use of the products does not indicate that the products are pyrophoric. | - |
| Pyrophoric solids | - | - | Not applicable to a liquid. | - |
| Self-heating substances and mixtures | - | - | None of the components of the product are known to be self-heating. | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | Not applicable because the products are water based (approx. 50 % of the product is water). Furthermore, none of the components of the products are known to emit flammable gases when in contact with water. Experience in the use of the products does not indicate that the products will emit flammable gas when in contact with water. | - |
| Oxidising liquids | - | - | None of the components, or mixtures, in the biocidal product is classified as oxidising. The active substances dicopper oxide and copper pyrithione contains oxygen but are harmonized classified as not oxidising. The co-formulants in the product family do not contain oxygen-, fluorine- or chlorine atoms, or the oxygen-, fluorine- or chlorine atoms are chemically bonded only to carbon or hydrogen. Hence, this hazard class needs not to be applied according to the CLP guidance.  Furthermore, the product is an aqueous solution and according to the guidance on application of CLP-criteria (ver. 5.0, 2017) it is not necessary to test if the product contains less than 20% of an oxidising solid in aqueous solution. As none of the components are classified as oxidising, there cannot be more than 20% of an oxidising substance present.  Taking into account the arguments above, it can be concluded that the products are not oxidising. No further testing is necessary. | - |
| Oxidising solids | - | - | Not applicable to liquid products. | - |
| Organic peroxides | - | - | None of the components of the products are known to be organic peroxides. | - |
| Corrosive to metals | UN Manual of tests and Criteria: Part III, 37.4: Test Methods for corrosion to metals (UN Test C.1). | Netwax NI 3 (20.2 % w/w dicopper oxide)  Netwax E8 Greenline (35% w/w dicopper oxide) | Read-across to Netwax NI 3 and Netwax E8 Greenline of the product family Dicopper Oxide Biocidal Product Family.  Test results for corrosive to metal studies performed on two representative products of another product family from the same applicant with similar formulation are available. The similarity between the tested products in the other product family and this product family is reflected in the confidential PAR and concludes that the test results are considered representative for this product family.  The test results from the representative products Netwax NI3 and Netwax E8 Greenline in Dicopper Oxide Biocidal Product Family is presented below:  The percentage mass losses on steel (type SAE 1020) and aluminium (type 7075-T6 non-clad) were found to be < 51.5% over 28 days, however, the maximum pit depth on the aluminium coupons were > 480 μm for both products tested. The products are therefore candidates for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations).  These test results are representative for the product formulations in this product family as well and, hence, should be classified as "corrosive to metals" and be labelled as H290 - May be corrosive to metals. | Siusiene, E.; 2022b; Corrosivity to Metals Testing on a Test Item of Netwax NI3; DEKRA UK Ltd; GLP3016010435DR1/2022  Siusiene, E.; 2022c; Corrosivity to Metals Testing on a Test Item of Netwax E8 Greenline; DEKRA UK Ltd; GLP3016010435ER |
| Auto-ignition temperatures of products (liquids and gases) | EC A.15 | Netwax NI Gold Light (18.0 % w/w dicopper oxide, 0.24 % w/w copper pyrithione) | The auto-ignition temperature of Netwax NI Gold Light was determined to be 558 °C.  Based on the high auto ignition temperature, it can be concluded that auto ignition does not represent a potential hazard for the products in the product family.  The test results are representative for the whole product family. | Siusiene, E.; 2022a; Physico-Chemical Testing on a Test Item of Netwax NI Gold Light; GLP3016012492R1/2022 |
| Relative self-ignition temperature for solids | - | - | Not applicable to liquid products. | - |
| Dust explosion hazard | - | - | Not applicable to liquid products. | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| It can be concluded that the products in the product family are not explosive, flammable, self-reactive, pyrophoric or oxidising. None of the components are organic peroxides, and the products do not emit flammable gases when in contact with water. Auto-ignition temperature was determined to be 558 °C.  The products are expected to be corrosive to metals and the product family should be classified as "H290: May be corrosive to metals". |

### Methods for detection and identification

The validation of method for determination of total copper was initially based on redox titration (NORDOX Industries AS Method No. AN-10). The method is a well-known chemical reaction for copper with multiple publications demonstrating its acceptability. Furthermore, the supporting validation data proves that the products do not contain other materials capable of being reduced by the titrant and provide sufficient evidence for analyte confirmation. But, because of technical difficulties due to the high wax content in the product formulation, an ICP-MS method of analysis was validated. ICP-MS is a suitable method for detecting copper in the product formulations of the product family because it is element specific removing the impact of the matrix interference which may occur in waxy formulations. HPLC-UV was validated as an analytical method for the determination of copper pyrithione in Netrex formulations containing copper pyrithione in the range of 0.24-2.5 % w/w. Total copper content is determined and dicopper oxide concentrations are calculated by subtracting the measured copper pyrithione concentration.

The test results are considered representative for the product family, and the justification can be found in the confidential PAR. It should be noted that the test items Netpolish NI Low (not authorised), Netwax NI 4 and Netwax E8 Greenline are products in the product family Dicopper Oxide Biocidal Product family from the same applicant, but with dicopper oxide as the only active substance. In addition, it should be noted that the product Netwax NI Gold Plus is proposed not-authorised due the outcome of the risk assessment, but it is acceptable as test formulation for the validation of the analytical methods.

Dicopper oxide as manufactured contains the impurities arsenic, cadmium, nickel and lead. Since these impurities are chemical elements, they are present in constant quantities and, hence, do not need to be determined using a fully validated method of analysis.

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Dicopper oxide (CAS No. 1317-39-1) | Redox titration (NORDOX Industrier AS Method No. An-10)  Determination of Cu and Cu2O in Netwax NI 4 (21.7 % w/w Cu2O) | n = 5  1 fortification level | Copper:  Linear from 0 to 133 mg Cu; 10 calibration standards  r: 1.000; slop: 0.156; intercept: 2.64 x 10-2  Dicopper oxide:  Linear from 0 to 150 mg Cu2O; 10 calibration standards  r: 1.000; slop: 0.139; intercept 2.09x10-2 | No analyte interferences were observed | 98.5 % – 99.9 % | 99.3 % | 0.531 %  Repeatability:  Cu: RSD= 0.875 %  RSDr=1.70 %  RSD<RSDr  Cu2O:  RSD=0.874 %  RSDr=1.67 %  RSD<RSDr | n/a | Atwal, S.S. and Woolley, A. J. (2011) Netwax NI 4: Analytical Method Validation; Harlan; Project Number 41004094; 21 July 2011. |
| Dicopper Oxide (CAS No. 1317-39-1) | ICP-MS  Determination of total Cu in formulations with 0.24 % w/w Cu2O (approx. 0.21 % w/w Cu)  (identical or equivalent to Netpolish NI Low)\* | n = 6  2 fortification levels. 85.7-87.5 % w/w. | 0 to 100 ppb Cu; 7 calibration standards  Based on correlation of measured concentrations versus actual concentrations of Cu standards (isotope 63 Cu and 65 Cu).  63 Cu:  r = 0.9997; slope = 1.0029; intercept = -0.2037  65 Cu  r = 0.9997; slope = 1.0030; intercept = -0.2168 | ICP-MS is inherently specific. Confirmed by the comparison of data generated for two isotopes of copper (Cu 63 quantification ion and Cu 65 confirmation ion). | 69.5 – 135.3 | 107.9 | 21.1  Repeatabilty (precision):  RSD = 0.69  RSDr = 3.38  RSD<RSDr | n/a | Apps, G. (2018c) Validation of a method for the determination of total copper in Netpolish and Netwax formulations; CEMAS Report No. CEMR-8406; 29 November 2018 |
| Dicopper Oxide (CAS No. 1317-39-1) | ICP-MS  Determination of total Cu in formulations with 35 % w/w Cu2O (approx. 30 % w/w Cu) (equivalent to Netwax E8 Greenline)\* | 96.2 – 104.9 | 103.8 | 3.18  Repeatability (precision): No data. | n/a |
| Copper pyrithione (CAS No. 14915-37-8) | ICP-MS  Determination of total Cu in formulations with 2.5 % w/w CuPT (approx. 0.5 % w/w Cu) (equivalent to Netwax NI Goldold) for recovery and with 18.0 % w/w Cu2O and 0.24 % w/w Cu-PT (approx.16 % w/w Cu) (equivalent to Netwax NI Gold Light)\* for precision. | n = 6  1 fortification level for recovery. 100 % | 105.7 – 114.4 | 110 | 2.81  Repeatability (precision): RSD = 1.22  RSDr = 1.76  RSD<RSDr | n/a |
| Copper pyrithione (CAS No. 14915-37-8) | HPLC-UV  Determination of CuPT in formulations with 0.24% w/w CuPT | n = 6  1 fortification level. 100 % | Linear range from 0.0125 to 0.1497 ppm CuPT; 7 calibration standards.  r = 0.9999; slope = 47324.0; intercept = -22.034 | No analyte interferences were observed. | 99.5 -101.4 | 100.3 | 0.780  Repeatability (precision):  RSD = 0.78  RSDr = 3.30  RSD<RSDr |  | Wiles, J. (2018) Validation of method for the determination of copper pyrithione in Netwax formulations; CEMAS Report No. CEMR- 8407; 29 November 2018 |
| Copper pyrithione (CAS No. 14915-37-8) | HPLC-UV  Determination of CuPT in formulations with 2.5% w/w CuPT | 98.6-  99.3 | 99.0 | 0.264  Repeatability (precision):  RSD = 0.26  RSDr = 2.34  RSD<RSDr |

\* Recovery was assessed by analysis of replicate determination of samples prepared by the fortification of Netrex blank formulations with addition of copper equivalent to the copper dioxide concentration in Netpolish NI Low (0.24 % w/w Cu2O) and Netwax E8 Greenline (35.0 % w/w Cu2O) and copper pyrithione concentration in Netwax NI Gold Plus.

The Netrex blank formulation fortified with the equivalent concentrations of active substance is considered to adequately represent the products for the purpose of the method validation.

Repeatability (precision) was assessed by replicate determination of samples of the test item Netpolish NI Low (0.24 % Cu2O) and Netwax NI Gold Light (18.0 % w/w Cu2O and 0.24 % w/w CuPT).

Residues in soil, air water, human body fluids and tissues, or food and feeding stuff:

Netkem A/S has no new information beyond what was included in the active substance dossiers with respect to analytical methods for active substances or residues in soil, air water, human body fluids and tissues, or food and feeding stuff.

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| **Conclusion on the methods for detection and identification of the product** |
| Validated analytical methods for determination of the active substance in the products are available and includes the parameters specificity, linearity, recovery and precision.  The results obtained of the validations of the analytical methods are satisfactory as the requirements in the Guidance on the Biocidal Products Regulation, vol. I, Part A, version 2.0, 2018, have been met with one exception. The mean recovery obtained in the validation of the ICP-MS method are outside the confidence intervals indicated in SANCO/3030/99 revision 4. The high recoveries were accepted as a limitation of the method and were attributed to the following:   * The method required digestion of the analytes followed by reconstitution, significant serial dilution and ICP-MS analysis. All these factors would contribute to significant error. * The accuracy value determined as the recovery of spiked copper compounds where the stated % copper content was relatively low contributing to a possible systematic error. It is stated in the report that spinking small amounts of dicopper oxide proved to be difficult due to the highly static nature of the compound. Consequently, a wide range of actual amounts were added to the replicate samples. * In order to provide authentic accuracy data, the copper oxide was weighed out and added to the blank formulations individually prior to microwave digestion which contributed to additional errors.   The analytical methods are not specific for dicopper oxide as the form of the copper species added to the formulation cannot be identified, but there are currently no techniques available to determine the copper sources. As both active substances in the product family contain copper, the source of the copper should be determined to demonstrate stability and that transformation products have not been formed. Although the source of dicopper oxide in the products cannot be determined analytically, the copper pyrithione content can be measured by HPLC. In addition, methods for analysing the total content of copper compounds are widely available and are reliable in identifying and quantifying such compounds. Consequently, the content of dicopper oxide can be inferred using the following equation:  Dicopper oxide content = Total copper content – Copper pyrithione content.  In conclusion, the available methods are considered to be acceptable and fit for purpose.    Residues in soil, air water, human body fluids and tissues, or food and feeding stuff:  Methods of analysis for the determination of residues of dicopper oxide and copper pyrithione residues in soil, air, water, body fluids and tissues, and for food/feed of plant and animal origin have previously been evaluated at EU level and accepted for the approval of dicopper oxide and copper pyrithione under Regulation No 528/2012. |

### Efficacy against target organisms

#### Function and field of use

The antifouling products are intended to be used for the protection of nets used in aquaculture against fouling organisms in marine environments. The active substance contained in the products is dicopper oxide and copper pyrithione.

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

Protection against fouling of nets used in aquaculture. Target organism will be stated as "Slime, Weed (macro algae) and Animals".

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

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

#### Mode of action, including time delay

When copper from metallic copper, copper thiocyanate or dicopper oxide leaches into marine water in the presence of oxygen, the predominant form of the copper is the active substance, the cupric ion, Cu2+. The cupric ion acts to delay the settlement of the microscopic larvae of fouling organisms within the microlayer of water at the paint surface via two mechanisms:

(1) the ion impedes the vital processes of the organisms by inactivating enzymes;

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

Copper pyrithione acts as a ‘booster biocide’ in the antifouling paint. A booster biocide is not the main biocide in the paint, but is meant to be effective against soft-fouling organisms, so its function is to increase the efficacy of the product in order to remove the most problematic fouling organisms, for example the common algae e.g. *Enteromorph*a spp. and *Amphora* spp which are tolerant of copper. It is also called a “co-biocide”.

Copper pyrithione has an algaecide, bactericide and fungicide action on soft fouling aquatic organisms, primarily marine algae but also including diatoms. Slime forming bacteria involved in soft fouling are also inhibited from forming biofilms on the protected paint film.

Investigators at York University examined the mechanism of action for pyrithione, which is the active portion of zinc pyrithione. They found that pyrithione acts on microbial membranes to eliminate certain ion gradients that are used by bacteria to store energy and by fungi as the source of energy for nutrient transport.

The group at York University showed that pyrithione eliminates fungal membrane charge gradients, and that pyrithione acts directly or indirectly to inhibit the membrane-associated proton pump. Such activity would inhibit the membrane transport of nutrients, leading to starvation and eventual death.

The Department of Microbiology at Alazhr University, Cairo performed experiments to determine the mode of action of pyrithione. It was found that the substance was very effective in inhibiting the growth of bacterial and yeast isolates. The group concluded that pyrithione acts by catalysing the electro-neutral exchange of H+ and other ions with K+ across cell membranes, resulting in the collapse of H+ gradients, K+ gradients and other cell ion gradients important to cell function, with consequences depending upon the condition and the organism. The action was explained by predicting that pyrithione is known to form stable chelation complexes with heavy metal ions, and also forms quasi-stable coordination complexes with K+ ions.

Both research groups demonstrated independently in two different species (fungi and bacteria) that pyrithione acts to disrupt the proton motive force.

#### Efficacy data

The aim 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 adequate measures can be performed.

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

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

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

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

The efficacy trials for representative products Netwax NI Goldold (21.5 % w/w Cu2O, 1.4 % w/w CuPT)[[4]](#footnote-5) in meta SPC 2 and Netwax Gold Light (18.0 % w/w Cu2O, 0.24 % w/w CuPT) in meta SPC 1 were conducted in the time period from May 2019 to February 2020 in the field at three locations in Ireland, Mid-Norway and the south-west of Norway. The trials were carried out at fish farming locations with the water environment the products are intended for. The locations represent different environments: Northerly and southerly locations, and fjord and coastal locations.

The test surface was pieces of net attached to a frame (size: 22 cm x 28 cm). The antifouling paints in the trials were diluted with approximately 5 % water before application to stimulate the real conditions achieved by impregnation during servicing and to ensure correct absorption 0.8–1.1 L antifouling paint per kg net). Eight such net panels were placed in a frame of untreated aluminium (120 cm × 60 cm) and attached with the help of tie wraps. Panels with either a product, untreated control or positive control were placed in randomly selected positions on the frames. There were three replicates of each product at each location, and thus three frames per location. The frames were placed such that the test panels had a vertical orientation and at a depth of 3 m calculated from the frames’ upper edge. The frames were inspected approximately every 3-4 week. At each date of inspection, the frames were surfaced, and pictures were taken of each sample of net on the three frames at the respective location.

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

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

Other efficacy trials were conducted, and study reports were submitted for the antifouling products. However, they are only considered as supplemental information in this evaluation as the picture quality was too poor to be assessed by the rMS.

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT 21 Antifouling | Netwax NI Goldold (21.5 % w/w Cu2O, 1.4 % w/w CuPT)  Netwax Gold Light (18.0 % w/w Cu2O, 0.24 % w/w CuPT) | Typical fouling on the sites are filamentous algae (brown, red and green algae), molluscs (blue/common mussel), other vivalves, hydroids, acidians, sponges and nudibranchs | Field trial at 3 European locations: Ireland, mid-Norway and south-west of Norway. | Location: Hindholmen in mid-Norway, Ljøsøy-N in the south-west of Norway and Bertraghboy Bay on the west coast of Ireland.  The trials were carried out at farming locations that have the water environment the products are intended for.  The deployment times of the frames varied somewhat between locations (22-40 weeks).  Material and method  Panels with either a product, untreated control or positive control were placed in randomly selected positions on the frames.  Panels: standard nylon net (22 cm × 28 cm, i.e. 616 cm²).  Frames: an aluminium frame (120 cm × 60 cm) and attached with the help of tie wraps.  Application: The antifouling paint in the trials were diluted with ca. 5% water before application to simulate the real conditions achieved by impregnation during servicing and to ensure correct absorption (0.8–1.1 L antifouling paint per kg net). Application was done by lowering the panel into the antifouling paint for 10 minutes before drying.    The frames were placed such that the test panels had a vertical orientation and at a depth of 3 m calculated from the frames’ upper edge.  Replicates: 3 of each product at each location, and thus three frames per location.  Assessment: Biofouling was ranked and evaluated in the field in accordance to SINTEF guidelines. Biofouling was ranked on a scale from 0 to 5 | SINTEF Ocean (2019) states that it is difficult to compare biofouling results directly between different locations. This has been confirmed in the trials, with variation between the locations both in how the biofouling developed and in the type of dominant biofouling organism.  In terms of ranking of biofouling, all the treated panels at Hindholmen performed better than the best products in the tests at Ljøsøy-N and in Bertraghboy Bay. From the biofouling ranking of the negative references, it can also appear that the biofouling pressure in general is somewhat lower at Hindholmen than at the other locations.  In general, tested antifouling product demonstrate sufficient efficacy when the difference in the biofouling ranking score between the treated and untreated net is 2 ranks or more. In the independent assessment of the efficacy studies by the rMS, Hindholmen showed sufficient efficacy throughout the test period (36 weeks), while Ljøsøy-N og Bertraghboy showed sufficient efficacy for at least 12-16 weeks and 20 weeks respectively. Note that the products may still be efficacious after this time period depending on the biofouling pressure and sea conditions.  In general, all treated panels showed considerably less biofouling than the untreated panels, except for the last assessments at Bertraghboy Bay (October – February).  According to NetKem’s past experiences, different products have different effects at different locations. This is probably due to the product’s characteristics and variations in biofouling pressure. | Skjaervik, M. G. & Mortensen, H. (2020a) |
| PT 21 Antifouling | Netwax NI Goldold (21.5 % w/w Cu2O, 1.4 % w/w CuPT)  Netwax Gold Light (18.0 % w/w Cu2O, 0.24 % w/w CuPT) | Typical fouling on the sites were basically filamentous algae (brown, red and green algae) | Field trial in Spain (Alicante) | Location: Andromeda Group Niordseas S.L. location in Spain in the Mediterraniean nearby Alicante.  The frames were placed such that the test panels had a vertical orientation and at a depth of 3 m calculated from the frames’ upper edge.  Material and Method:  Panels with either a product, untreated control or positive control were placed in randomly selected positions on the frames.  Panels: standard nylon net (22 cm × 28 cm, i.e. 616 cm²)  Frames: an aluminium frame (120 cm × 60 cm) and attached with the help of tie wraps.  Application: The antifouling paint in the trials were diluted with ca. 5% water before application to simulate the real conditions achieved by impregnation during servicing and to ensure correct absorption (0.8–1.1 L antifouling paint per kg net). Application was done by lowering the panel into the antifouling paint for 10 minutes before drying.  The frames were deployed on 9 May 2019. The first evaluation of biofouling was done on 19 of June. This evaluation is not included in the material because the pictures were too unclear to interpret. The first evaluation that is included in the report is therefore from 12 July 2019 and the last evaluation was done on 7 January 2020.  Time: 35 weeks  Intervals of examination: Nets were visually inspected periodically. Evaluation of biofouling and photographic documentation was carried out approximately once a month.  Biofouling was ranked and evaluated in the field in accordance with SINTEF guidelines,  Biofouling was ranked on a scale from 0 to 5. | According to the applicant, the treated panels have less biofouling than the untreated panels, but also treated panels show a considerable amount of fouling in October – November.  The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information. | Skjaervik, M. G. & Mortensen, H. (2020b) |
| PT 21 Antifouling | Netwax NI Goldold (21.5 % w/w Cu2O, 1.4 % w/w CuPT) | General antifouling  The type of growth identified on the nets was categorized: Algae/slime, Macroalgae, Hydroids, Mussels (Mytilus edulis), Crustaceans and others. | Field trial at one location (Dønna) in the North of Norway | Location:  Operative Fish farm/research facility, Bollhaugen (Solfjellsjøen), Dønna, the North of Norway. The test panels were placed at the research facility of Letsea AS, alongside active nets.  Placement: South-Southwest direction  Depth: Approximately 3 metres  Material and Method of application:  - Metal rings with nylon net were dipped in paint.  - The paints were diluted with approximately 5% water to try to simulate real conditions, and to achieve the correct pick-up (0.8-1.1 litre/ kg net).  -Eight pieces of net were spread out on a steel frame and held in the ocean at 3metre depth close to active pens (containing fish) from 5 June 2018 to 15 November 2018.  -Assessment: The progression of biofouling was followed visually every week and documented by taking photographs of both the entire frame and each individual net.  If uncoated nets were completely grown over, these were cleaned completely and put back in the water with a special notification of cleaning to allow for comparison between the remaining treatments. | Minor biofouling growth was observed on both the treated and untreated net panels at the start of the trial. This indicates that the test location has lower degree of biofouling pressure. According to the applicant, the efficacy of the tested products was demonstrated. It can be observed large differences between the treated net panels and the untreated reference net panel at the end of the trial.  The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information. | Hanssen, H. (2018) |
| PT 21 Antifouling | Netwax NI Goldold (21.5 % w/w Cu2O, 1.4 % w/w CuPT) | General antifouling.  The type of growth identified on the nets was categorized: Algae/slime, Macroalgae, Hydroids, Mussels (Mytilus edulis), Crustaceans and others. | Field trial | Location:  Two equal frames have been placed on two different locations close to Haugesund on the west coast of Norway: Klungervik north of Haugesund, and Dale to the south of Haugesund.  The test panels were placed alongside an empty pen, with active nets on both sides.  Placement: South-east direction, in order of sample number.  Depth: Approximately 3 metres.  Material and Method of application:  - The test frames (frame #1 and frame #3) were prepared by NetKem AS. Nylon nets were dipped in paint, and then fastened to a frame of stainless steel. Each frame consists of 8 nets, including one untreated reference and one positive reference.  - The paints were diluted with approximately 5% water to best simulate real conditions, and to achieve the correct pick-up (0.8-1.1 litre pr kg net).  - The frames were put into the sea on the locations on May 3rd 2018.  Assessment: Visual inspection and rating on the % of fouling attached to the nets. The performance of the paint was ranked on a scale from 0 to 6. Pictures were taken of the full frame and of each individual sample (pictures from August were lost). If possible, showing the frame plate and/or the tag for the sample  - Intervals of examination: Nets were checked by visual inspection on 8 June 2018, 19 July 2018, 7 August 2018, 11 September 2018 and 16 October 2018. | It is stated that the test locations normally have a high amount of fouling. However, in 2018 the growth antifouling growth has been lower than normal at both sites. This can be observed through minor biofouling growth on both the treated and untreated net panels at the start of the trial. According to the applicant, the efficacy of the products was demonstrated.  The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information. | Antonsen, R. (2018) |

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| **Conclusion on the efficacy of the product** |
| **Hindholmen (Mid-Norway), Ljøsøy-N (south-west of Norway) and Bertraghboy Bay (west-coast of Ireland)**   * Skjaervik, M. G. & Mortensen, H. (2020a): The antifouling paint products Netwax NI Goldog Netwax Gold Light demonstrated sufficient efficacy throughout the test period (36 weeks) at Hindholmen, while Ljøsøy-N og Bertraghboy showed sufficient efficacy for at least 12-16 weeks and 20 weeks respectively according to the independent assessment done by the rMS. * The rMS concludes that sufficient efficacy for the tested products is demonstrated for approx. 12-16 weeks at least. Note that the products may still be efficacious after this time period depending on the biofouling pressure and sea conditions.   **Andromeda Group Niordseas (Mediterranean, Spain)**   * Skjaervik, M. G. & Mortensen, H. (2020b): According to the applicant, the treated panels with the antifouling paint products Netwax NI Gold og Netwax Gold Light has less biofouling than the untreated panels, but also treated panels show a considerable amount of fouling in October – November. * The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information.   **LetSea research facility, Dønna (North of Norway)**   * Hanssen, H. (2018): According to the applicant, the antifouling paint products Netwax NI Gold og Netwax Gold Light has less biofouling that the untreated panels, and there are no significant differences in the final growth of organisms between the treated samples. * The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information.   **Klungervik and Dale (south-west of Norway)**   * Antonsen, R. (2018): According to the applicant, Netwax NI Gold og Netwax Gold Light performed significantly better than the untreated reference, and there is little difference in performance between the treated net samples. * The pictures submitted for this efficacy study are unfortunately of too poor quality for an independent assessment to be performed by the rMS. The study and the applicant's assessment are included to provide supplemental information.   **Overall conclusion**   * The tested products Netwax NI Gold (21.5 % w/w Cu2O, 1.4 % w/w CuPT) in meta SPC 2 and Netwax Gold Light (18.0 % w/w Cu2O, 0.24 % w/w CuPT) in meta SPC 2are considered representative for the efficacy of the product with higher content of the active substances in the product family. * Based on the results of the conducted efficacy trials, the rMS concludes that all the products of the biocidal product family have demonstrated sufficient efficacy for at least 12-16 weeks. It should, however, be noted that the products may be efficacious longer depending on the degree of biofouling pressure. * Both products in the product family was tested for the efficacy and, hence, no read-across is necessary. |

#### Occurrence of resistance and resistance management

There have not been any recorded cases in the literature of resistance populations of fouling organisms through the use of copper based anti-fouling paints.

However, some studies, in the literature, showed some impacts of copper pollution on marine life and indicate that some hull-fouling species have copper tolerance (ECHA, 2016a).

The mode of action of pyrithione described in section 2.2.5.4 suggests that modification of a singular cellular component is unlikely to result in appreciable stable resistance. No anecdotal instances of pyrithione resistance have been reported.

#### Known limitations

No efficacy limitations have been found if the products are used following the use instructions.

#### Evaluation of the label claims

According to the applicant a protection time will not be stated on the label for the products. Marine biofouling pressure is extremely variable with regards to location, season, temperature, sunlight, water nutrient level etc. so a specific claims regarding protection time is difficult to make, except for reduced growth relative to an untreated net.

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

Not applicable.

### Risk assessment for human health

The toxicological properties of the two active substances in the biocidal product family are summarised in:

* Assessment report on Dicopper oxide (CAS-no: 1317-39-1) in PT21(ECHA, 2016a)
* Assessment report on Copper Pyrithione (CAS-no: 14915-37-8) in PT21 (ECHA, 2014a)

Dicopper oxide is approved for use in product-type PT21 in the context of Regulation (EU) No.528/2012. The hazard assessment of dicopper oxide was conducted in line with the assessment of other copper compounds dossiers for PT21.

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

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).

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

The key health effects, which were used for deriving the reference values for dicopper oxide, were the kidney and forestomachdamages observed in a 90-day rat study (on copper sulphate pentahydrate, via diet; ECHA, 2016a). A NOAEL of 1000 ppm (16.3 and 17.3 mg Cu/kg bw/day in male and female rats respectively) was established based on the kidney effects. The lowest of these NOAEL values was used when the short-term and long term AEL values were derived. The reference values are given in section 2.2.6.3.

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

The toxicity studies included in the CAR have been conducted with copper pyrithione, zinc pyrithione and sodium pyrithione. Read across between these substances was considered acceptable by the RefMS based on the mode of action, the toxicokinetic and the similarities in toxic effects observed in the studies performed.

Typical pyrithione effects observed in repeated dose studies in rats were mortality (sudden death), hind limb weakness/paralysis, reduced body weight and gastric irritation. Pyrithione seemed to be more toxic by the inhalation compared to the oral route (ECHA, 2014a).

No harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) of the active substance is available. The proposed human health classification presented in the assessment report is: Acute Tox 2; H330. Fatal if inhaled, Acute Tox 3; H301. Toxic if swallowed, Acute Tox 3; H 311; Toxic in contact with skin; Eye Dam. 1; H 318; Causes serious eye damage, STOT SE3; H335; May cause respiratory irritation; Repr. Cat 2; H 361 Suspected of damaging the unborn child, STOT RE1; H372; Causes damage to the nervous system through prolonged or repeated exposure (ECHA, 2014a).

The neurotoxic effect is considered to be general for pyrithiones (ECHA; 2014a).

A classification with STOT RE1; H372 has been agreed by RAC for two other pyrithiones; i.e. zinc pyrithione (CAS.no: 13463-41-7; 15 ATP, ECHA, 2018) and sodium pyrithione (CAS.no: 3811-73-2, draft 18 ATP, ECHA, 2020).

Acute Reference Dose (ARfD) and Acceptable daily intake (ADI) have been established. The ARfD is 0.02 mg/kg bw/day, based on early effects (2.5 hours) observed in a 90 day oral rat study with sodium pyrithione (ataxia in hind limb and whole body tremor seen at the LOAEL) and an assessment factor of 100. The ADI is 0.0025 mg/kg bw/day based on two chronic oral rat studies with sodium pyrithione. A LOAEL of 0.5 mg/kg bw/day was set based on nerve degeneration and muscle atrophy. An assessment factor of 200 (standard factor of 100 and an additional factor of two to extrapolate from LOAEL to NOAEL) were used.

Route-specific AELs were derived. As it was impossible to estimate a dermal AEL due to lack of dermal absorption data, it was decided that the dermal exposure should be covered by the oral AEL. The dermal short and medium term AEL is 0.005 mg/kg bw/day based on an overall NOAEL from all available oral copper pyrithione, zinc pyrithione and sodium pyrithione subacute, subchronic, teratogenicity and 2-generation studies using an assessment factor of 100. The long term dermal AEL is 0.0025 mg/kg bw/day based on the same studies used for setting ADI values.

The short and medium term inhalation AEL is 0.002 mg/kg bw/day. The AEL is based on the NOAEL in a 28 day rat inhalation study, where death of unexplained cause was seen at the LOAEL. An assessment factor of 200 was used. The extra assessment factor of 2 was used due to the severity of the effect (unexplained mortality).

The inhalation long term AEL of 0.001 mg/kg bw/day is based on the same study as the short and medium term AELs. An extra assessment factor of 4 has been used to extrapolate from short to long time exposure.

An external reference value (AEC) of 0.00002 mg/L (0.02 mg/m3) was derived from the local NOAEC (0.0005 mg/L) in the 28 day rat inhalation study, using an assessment factor of 25 (10 for intra species variation and 2.5 for interspecies variation in toxicodynamics).

The reference values are given in section 2.2.6.3

#### Assessment of effects on Human Health

Toxicological testing has been performed for eye damage/irritation. For other end points, 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).

The composition of the products and the CLP classification for human health hazards of the co-formulants are presented in detail in the confidential annex (See section 1.1).

A more elaborate explanation of the proposed classification is provided in the confidential annex of the PAR.

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | No classification for Meta SPC 1 or Meta SPC 2 |
| Justification for the value/conclusion | |  | | --- | | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin irritation/corrosion hazards based on the classification of the ingredient substances. The additivity principle of the CLP Regulation applies to the hazard class skin corrosion/irritation.    In accordance with Annex I, section 3.2.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for skin irritation/corrosion. Table 3.2.3 of the regulation contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin (see also 1.1.2.2.2 Cut off values in Annex I).  Details of the product ingredients composition are presented in the confidential annex (section 1.1 and 1.2).  Two substances are classified for skin irritation and corrosion (H315 and H314) respectively); however, these ingredients are present at concentrations below the level of when they should be taken into account (generic cut off or specific concentration limit).  The products do not, therefore, require classification for skin irritation/corrosion according to Regulation (EC) No 1272/2008.  A study is not required, nor considered an appropriate use of animals. | |
| Classification of the product according to CLP | Not classified. |

***Eye irritation***

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| **Summary table of in vitro studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g., major deviations)* | **Reference** |
| OECD Guideline 437, GLP  Reliability: 1 | Netwax NI Goldold\* (21.5% w/w dicopper oxide and 1.4% copper pyrithione) | Ocular irritation potential of Netwax NI Gold was evaluated using the Bovine Corneal Opacity and Permeability (BCOP) in vitro assay.  Post exposure rinsing (MEM with phenol red) and removing of residues with a cotton bud. | The mean in vitro irritancy score (IVIS) was 6.51.  For IVIS > 3 or ≤ 55, no prediction could be made on the eye damaging/eye irritation potential of the tested formulation in accordance with the OECD guideline.  Thus, further testing was required. | None | Vinall, J. (2018a) Netwax NI Gold and Netwax E8 Greenline: Assessment of Ocular Irritation In Vitro Using the Bovine Corneal Opacity and Permeability Assay, Charles River Laboratories Report No. 39477. |
| OECD Guideline 492, GLP  Reliability: 1 | Netwax NI Goldold\* (21.5% w/w dicopper oxide and 1.4% copper pyrithione) | Ocular irritation potential of Netwax NI Gold was evaluated using the In-vitro MatTek EpiOcular (OECD 492) test | Mean percentage viabilities of treated EpiOcular™ tissues  compared to negative control:  89.62% (SD: 25.40%)  Variability between highest and lowest treated replicate was almost 50%  In accordance with OECD 492 TGL, the test item is categorised as ‘No Category’ (non-irritant) when mean tissue viability > 60% in the EpiOcular™ EIT test system.  However, the accceptance criteria of the study was not fulfilled. Hence, no conclusion could be made on the eye damaging potential of the product. | The SD and variability were outside the acceptance criteria  (i.e., <18% SD of the final viability between the three replicates and <20% variability in the % viability of the three tissues).  In accordance with the guideline, if the variability between tissue replicates of a test chemical is outside of the accepted range, the test must be considered "non-qualified", and the test chemical should  be re-tested. | Vinall, J (2018b)  Netwax E8 Greenline, Netwax E5 Greenline, and Netwax NI Gold\*\*: MatTek EpiOcular™ Eye Irritation Test (EIT) for Assessment of the Ocular Irritation Potential of Test Items In Vitro; Charles River Laboratories Report No. 39671. |

*\*Toward the end of the evaluation phase, a risk for human health was identified for the product referred to in the PAR as Netwax NI Goldold. The product was modified, reducing the active substance content to an acceptable level. The active substance dicopper oxide was kept unchanged (21.5%) whereas the copper pyrithione content was reduced from 1.4% to 0.75%. The postfix "old" has been added to the name of the original product (i.e., Netwax Goldold) whereas the reformulated product is referred to as Netwax NI Gold. The full composition of both formulations can be found in the confidential annex.*

*\*\* The product referred to in the PAR as Netwax NI Goldold was one of three products tested with the EpiOcular™ Eye Irritation Test (EIT). The EIT test performed with Netwax NI Goldold was considered "non-qualified".*

(Note: No annotations provided by refMS in the IUCLID endpoint study records).

**Meta SPC 1 and 2**

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Meta SPC 1 and 2 are classified for eye damage |
| Justification for the value/conclusion | In accordance with the CLP guidance (3.3.3. Classification of mixtures for serious eye damage/eye irritation), the procedure for classifying mixtures is a stepwise approach based on a hierarchy principle and depending on the type and amount of available data/information. Valid test data for the whole mixture have precedence. If no such data exist, the CLP bridging principles could be applied (if possible), or an assessment based on data for the components of the mixture.  For the biocidal product family, two *in vitro* tests were performed on Netwax NI Goldold in a top-down approach.  In an OECD Guideline 492 study (EpiOcular™ EIT, 2000) Netwax NI Goldold (21.5% w/w dicopper oxide and 1.4% copper pyrithione) was categorised as ‘No Category’ for eye irritation/serious eye damage. However, the acceptance criteria of the study were not fulfilled.  Based on a supporting study (OECD Guideline 437 (Bovine Corneal Opacity and Permeability Assay (BCOP)), no prediction could be made for Netwax NI Gold.  Based on the test results from the BCOP and EIT studies, no conclusion could be made on the eye damaging potential of the products in the biocidal product family.    Bridging/read across from tested formulations of a related biocidal product family of antifouling products from the same Applicant containing only dicopper oxide as active substance (Dicopper Oxide Biocidal Product Family) were suggested by the Applicant based on a weight of evidence argumentation[[5]](#footnote-6).  The applicability of the bridging criteria for substantial similar formulations (section 1.1.3.5 in Annex I to CLP Regulation) were considered by the eCA based on the provided information.  Besides the additional active substance copper pyrithione, the two biocidal product families contain the same coformulants in a comparable range of concentrations (the compositions of the tested formulations are included in section 4.1 in the confidential annex).  From the Dicopper Oxide Biocidal Product Family, the following test results were provided: An OECD Guideline 405 study in the New Zealand Rabbit (2000) demonstrated that Netrex AF (17.2% w/w dicopper oxide) does not warrant classification for eye irritation/damage. No prediction could be made in an OECD Guideline 437 study for Netwax E8 Greenline (35% w/w dicopper oxide). However, in an OECD Guideline 492 study, Netwax E8 Greenline (35% w/w dicopper oxide) and Netwax E5 Greenline (26.3% w/w dicopper oxide) were categorised both as ‘No Category’ for eye irritation/serious eye damage. Based on the studies, no classification for eye damage/eye irritation was warranted for the representatives of the Dicopper Oxide biocidal product family. However, as the tested products contain dicopper oxide only, there is an uncertainty related to whether copper pyrithione could add to the effects on eyes and thus warrant a classification for eye damage/eye irritation.  It was proposed by the Applicant that copper pyrithione should be considered in isolation as the sole contributor to eye irritation in the Dicopper Oxide/Copper Pyrithione biocidal product family when calculating the classification in accordance with CLP, resulting in no classification for eye damage or eye irritation for formulations with ≤ 1% copper pyrithione.    Although the compositions of the biocidal products in the two different BPFs are similar, the bridging criteria for similar formulations as described in Regulation (EC) No 1272/2008 is not fulfilled as the Dicopper Oxide/Copper Pyrithione biocidal product family contains an additional substance with H318 classification (copper pyrithione).  Furthermore, it should be noted that both active substances in the biocidal product are classified with H318 based on effects observed in *in vivo* rabbit studies. However, the observed effects in the studies on copper pyrithione (OECD 405/EPA 81-4) were of a more serious nature as reflected in the higher Draize scores and lack of reversibility (ECHA, 2014a - as described in more details in the final CAR of September 2014).  As for dicopper oxide (ECHA, 2014b), effects were observed in most of the studies which fulfilled classification for reversible eye irritation. However, irreversible effects (corneal opacity; up to 21 days postexposure) were also observed. Therefore, RAC considered that at least some of the effects were irreversible and concluded that dicopper oxide should be classified for eye damage (H318).  The contribution of copper pyrithione to the effects on eyes of the biocidal product family is uncertain, and bridging is not supported.  Hence, all products would have to be classified based on the classification of the ingredient substances. The additivity principle of the CLP Regulation applies to the hazard class eye damage/irritation.  In accordance with Annex I, section 3.3.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture; i.e. those ingredients  which should be taken into account when classifying a mixture, are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for eye irritation/corrosion (see also 1.1.2.2 Cut off values in  Annex I). Table 3.3.3 of the regulation contains the generic concentration limits to be used to determine if a mixture is considered to cause irreversible or reversible eye effects.  Details of the product composition and the resulting classifications are presented in the confidential annex.  Dicopper oxide is classified as Eye Dam. 1; H318: Causes serious eye damage.  All products in the metas contain >3% (concentration triggering classification of a mixture with Eye Damage 1) of dicopper oxide and are therefore classified as “Causes serious eye damage” based on this ingredient alone.  Copper pyrithione is also proposed classified as Eye Dam. 1; H318: Causes serious eye damage (ECHA, 2014a), however, consideration of the concentrations present in the products is not necessary since the products are already classified for eye damage due to the presence of dicopper oxide.  Neither will two substances in a coformulant which both are classified with Eye Dam.1; H 318 contribute as they are below the concentration that will be taken into account when classifying for Eye Damage. |
| Classification of the product according to CLP | Classification for serious eye damage is warranted, i.e., Eye Dam. 1; H318: Causes serious eye damage. |

***Respiratory tract irritation***

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| **Conclusion used in Risk Assessment – Respiratory Track Irritation** | |
| Value/conclusion | No classification for Meta SPCs 1 or 2 |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for respiratory tract irritation based on the classification of the ingredient substances.  In accordance with Annex I, Section 3.8.3.4.1 of the regulation, where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances.  According to 3.8.3.4.5 of the regulation a generic concentration limit of 20 % applies for STOT SE 3 (respiratory tract irritation). However, expert judgement shall be exercised. The additivity applies unless there is evidence that the effects are not additive.  The generic cut off of for when ingredients shall be taken into account is 1% for STOT SE 3 (Table 1.1, Annex I)  Details of the product composition are presented in the confidential annex (section 1.1 and 1.2).  Copper pyrithione is proposed classified for transient target organ effects (STOT SE 3); respiratory tract irritation with H335 (ECHA, 2014a). The substance is well below the concentration limit of 20%, that would trigger a classification for this effect (as well as below the generic cut off for when it should be taken into account).  There is another ingredient which is classified with H335. However, it is present at <0.01% in all products; thus, should not be taken into account when classifying the product for this effect.  There are no other ingredients of the product classified for respiratory irritation or as a specific target organ toxicant according to Regulation (EC) No 1272/2008.  The product does not, therefore, require classification for respiratory tract irritation.  A study is not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | No classification for Meta SPCs 1 or 2 |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a skin sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 of the regulation. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limits presented in Table 3.4.6 of the regulation.  Details of the product composition are presented in the confidential annex (section 1.1 and 1.2).  There is one ingredient which is present in the products in Meta SPC 1 and Meta SPC 2 (mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one, CAS No. 55965-84-9) which is classified for skin sensitisation. This ingredient is not present at a concentration greater than the specific concentration limit; however, the ingredient is present in all products at a concentration which exceeds one tenth of the specific concentration limit (please refer to the confidential annex) and, therefore, in accordance with Table 3.4.6 of the regulation, all products should be labelled with:    "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".  A study is not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | No classification for Meta SPCs 1 or 2. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for respiratory sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a respiratory sensitiser and is present at or above the appropriate generic concentration limit shown in Table 3.4.5 of the regulation. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limits presented in Table 3.4.6 of the regulation.  There are no substances in the products that are classified for respiratory sensitisation. Details of the product composition are presented in the confidential annex (section 1.1 and 1.2).  A study is not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

***Acute toxicity***

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | No classification for Meta SPC 1 or SPC 2. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute oral toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredient should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  Details of the product composition are presented in the confidential annex (section 1.1 and 1.2).  The active substance dicopper oxide is present at a range of 18 to 21.5% w/w and is classified as Acute Tox 4: H302: Harmful if swallowed. An ATE of 500 is used in the calculation based on the revised harmonised classification for dicopper oxide (17 ATP).  The active substance copper pyrithione is present at a range of 0.24 to 0.75% w/w and is proposed classified as Acute Tox 3: H301: Toxic if swallowed in the assessment report of copper pyrithione, with a rat LD50 oral of 200-500 mg/kg (ECHA, 2014a).  Two other ingredients are classified for acute oral toxicity, but they are present in concentrations that are below the generic cut off limit for when the ingredients should be taken into account  Based on calculations of the ATE for the mixtures, Netwax NI Gold (Light) (Meta SPC 1) and Netwax NI Gold (Meta SPC 2) are not classified for acute oral toxicity according to Regulation (EC) No 1272/2008.  The calculations can be found in the confidential annex.  It is, therefore, considered that a study is not required, nor an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | No classification for Meta SPCs 1 or SPC 2. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute inhalational toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredients should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  The active substance dicopper oxide is present at a range of 18 to 21.5% w/w and is classified as Acute Tox 4; H332.  An ATE of 3.34 mg/l (dust or mists) is used in the calculation based on the revised harmonised classification for dicopper oxide (17 ATP).  The active substance copper pyrithione is present at a range of 0.24 to 0.75% w/w and is proposed classified as Acute Tox 2: H330: Fatal if inhaled in the assessment report of copper pyrithione, with a rat LC50 inhalation of 0.07 mg/L (4-hour, nose only) (ECHA, 2014a).  Classification for acute inhalational toxicity is not warranted for neither Netwax Ni Gold (light) (Meta SPC 1) nor Netwax NI Gold (Meta SPC 2) based on the calculation of the ATE of the mixtures.  The calculations can be found in the confidential annex.  It is, therefore, considered that a study is not required, nor an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No classification for Meta SPCs 1 or 2. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute dermal toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredients should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  The acute toxicity estimate (ATE) of ingredients is calculated and compared to Table 3.1.1 of the regulation to derive the category of toxicity.  Details of the product composition are presented in confidential annex section 1.1 and 1.2.  The active substance copper pyrithione is present at a range of 0.24 to 0.75% w/w and is proposed classified as Acute Tox 3: H311: Toxic in contact with skin in the assessment report of copper pyrithione, with a rat LD50 of 400-2000 mg/kg (ECHA, 2014a).  There are two ingredients of the product which are classified for dermal toxicity (Acute Tox 2; H310: Fatal in contact with skin and Acute Tox 4; H312: Harmful in contact with skin, respectively). However, the concentrations are low (<0.01%) and the ingredients have no specific concentration limit for acute toxicity. Hence, they should not be taken into account (not relevant).  Classification for acute dermal toxicity is not warranted for products in the biocidal product family based on the calculation of the ATE of the mixtures.  The calculations can be found in the confidential annex.  A study is not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified. |

***Other effects***

The active substance copper pyrithione is present at a range of 0.24 to 0.75% w/w and is proposed classified as STOT RE1; H372. Causes damage to the nervous system through prolonged or repeated exposure in the assessment report of copper pyrithione, (ECHA, 2014a). The substance is also proposed classified with Repr. Cat 2; H361. Suspected of damaging the unborn child.

Products containing 1% ≤ concentration < 10% copper pyrithione will be classified with STOT RE 2; H 373. May cause damage to the nervous system through prolonged or repeated exposure). The general cut off for classification of products containing Category 2 reproductive toxicants is 3%.

Thus, classification is not warranted for the biocidal product family for neither specific target organ toxicity after repeated exposure (STOT RE) nor reprotoxicity.

See section 4.1 in the confidential annex for further information of the classification of the coformulants.

***Information on dermal absorption***

***Dicopper oxide***

An *in vitro* dermal absorption study through human skin (Toner, 2019, report amendment 1) has been conducted on three net coating formulations from NetKem containing 0.24%, 17.2% and 35% w/w dicopper oxide respectively. The formulations do not contain copper pyrithione. However, reading-across from the single active products to the dual active products with regards to dicopper oxide was considered acceptable as the formulations are based on the same aqueous dispersion of hydrocarbon waxes as the members of this biocidal product family; being comparable to products with intermediate concentrations of dicopper oxide (see section 4.2 in the confidential annex for a comparison between the tested products and the members of the Dicopper Oxide-Copper Pyrithione Biocidal Product Family). It is not considered likely that the much lower concentration of copper pyrithione significantly influences the dermal absorption of dicopper oxide. Copper Pyrithione is not classified for skin irritation or sensitisation.

The study was performed according to the OECD 428 test guideline, using flow-through diffusion cells. The total amount of copper (non-radiolabelled) absorbed through split thickness human skin samples was measured using ICP-MS. This procedure is necessary as it is not technically feasible for copper to be radiolabelled.

Absorption of the test item was assessed by collecting receptor fluid in four hourly fractions from 0 to 24 h post dose. The exposure was terminated at 8 h post dose by applying a concentrated commercial hand wash soap followed by rinsing with a dilute soap solution (2%, v/v) and drying the surface with tissue paper swabs. The soap (skin wash) and tissue swabs were retained for analysis. The exposure was followed by a 16 h post exposure monitoring period.

At 24 h post dose, the underside of the skin was rinsed with receptor fluid. The cell was dismantled, and the donor chamber and receptor chamber were retained separately for analysis. The skin was then removed from the flow-through cells and the underside dried. The *stratum corneum* was removed with 20 successive tape strips. The tape strips were pooled in groups of 1-2, 3-5, 6-10, 11-15 and 16-20.

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 (blank control) was set up, washed, terminated and analysed using the same methods as for those exposed to the test preparation.

In addition, copper is naturally present in human skin, as well as in the solutions and equipment used on the study. Therefore, higher variability in the mass balance data was observed and accepted.

Since almost all measurements in the receptor fluid for skin samples with applied test material were below the LLOQ, it was not possible to determine the extent of absorption as defined in the EFSA guidance (EFSA, 2017). Hence, it could not be concluded that the absorption was essentially complete at half of the study duration. Furthermore, no photografic evidence was presented (although widely supported at the PT21 workshop, ECHA, 2016c) which might have been used to evaluate the amount of antifouling paint remaining on each tape strip. Consequently, a potential absorbable dose was calculated including tape strips 3+, in agreement with the EFSA guidance.

Where values measured were below the lower limit of quantification LLOQ, the appropriate LLOQ value was used in calculations as worst-case predictions.

For each sample, the mean copper value detected in the corresponding blank samples was subtracted prior to calculation (corrected values). For the receptor fluid samples, the corresponding pre-dose value was subtracted, where applicable. The argumentation for the latter, was that any background copper detected in the receptor fluid prior to application of the formulation would be the intrinsic copper level. Both corrected and uncorrected values were presented in the test report.

For samples where both the test material and blank control were below LLOQ, subtraction of control values represents the very best case for absorption. In reality, in these cases, the real amount of absorbed copper is likely to be somewhere in between the two sets of calculated values (corrected and uncorrected values).

It was noted that the receptor wash values for Cell 16 (test material 2) and Cell 21 (test material 3) were greater than the mean plus two standard deviations.

However, these samples were not rejected as outliers by the test house in the original report as it was considered a conservative approach to include these values.

However, in a report amendment from 2022, exclusion of receptor wash values from all dermal absorption values was proposed when reevaluating the figures. It was noted that copper was present in all receptor wash samples including the four undosed skin samples (detectable, but low levels of copper, 3 of 4 values above LLOQ). It was stated by the study director that copper present in the receptor wash samples arose from the intrinsic copper associated with the apparatus as opposed to absorbed copper from the formulation. 

In the exposure calculations, uncorrected values have been used as a basis, excluding receptor wash values from all cells. See the tables with revised values below.

***Copper pyrithione***

An *in vitro* dermal absorption study through human skin (Blackstock, 2019) has been conducted on two of the family members of this biocidal product family, containing 0.24% and 2.5% w/w [14C]-Copper Pyrithione respectively. The latter products are not proposed authorised.

The study was performed according to the OECD 428 test guideline, using flow-through diffusion cells. The amount of radiolabelled pyrithione absorbed through split thickness human skin samples were analysed by liquid scintillation counting.

Absorption of the test item was assessed by collecting receptor fluid in hourly fractions from 0-8 h post dose and then 2 hourly fractions from 8 to 24-hour post dose. The exposure was terminated at 8 h post dose by applying a concentrated commercial hand wash soap followed by rinsing with a dilute soap solution (2%, v/v) and drying the surface with tissue paper swabs. The soap (skin wash) and tissue swabs were retained for analysis.

Photo evidence was taken prior and after wash to demonstrate the efficacy of the washing.

The exposure was followed by a 16 h post exposure monitoring period. At 24 h post dose, the underside of the skin was rinsed with receptor fluid, the cell was dismantled, and the donor chamber and receptor chamber were retained separately for analysis~~.~~

The *stratum corneum* was removed with 20 successive tape strips, and the tape strips were pooled (1-2, 3-5, 6-10, 11-15 and 16-20). A potential absorbable dose was calculated including tape strips 3-20. as less than 75% of the absorption occurred within the first half of the experiment. Thus, according to the EFSA guidance the absorption was deemed to be incomplete (EFSA 2017).

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). Thus, the value used in the risk assessment for dicopper oxide is 0.98% for all products and 1.7% for products with 0.24% - <2.5% copper pyrithione and 0.53 % for products with ≥2.5% copper pyrithione.

(Note: No annotations provided by refMS in the IUCLID endpoint study records).

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Dicopper oxide (copper) | Copper pyrithione (pyrithione) |
| Value(s)\* | 0.98% | 1.7% for products with 0.24-<2.5% copper pyrithione  *(Netwax NI Gold (Light), Netwax NI Gold and Netwax NI Goldold\*)*  0.53% for products with ≥ 2.5% copper pyrithione\*  *(Netwax NI Gold Plus)* |
| Justification for the selected value(s) | A dermal absorption study (Toner, 2019, report amendment 1). The *In Vitro* Percutaneous Absorption of Dicopper Oxide in Three Formulations Through Human Skin; Charles River Report No. 782093) has been performed.  Analytical method validity study (Falconer, 2019): See test reports in IUCLID. | A dermal absorption study (Blackstock, 2019) The *In Vitro* Percutaneous Absorption of [14C]-Copper Pyrithione in Two Formulations Through Human Split-Thickness Skin; Charles River Report No. 784231) has been performed. |

\*No longer a part of the biocidal product family

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **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 1**  **(values presented as % applied dose)** | | | **Remarks** *(e.g. major deviations)* | **Reference** |
| GLP Study performed in accordance with the guidance and guidelines detailed below[[6]](#footnote-7)  Reliability: 1 | Eight samples of human split thickness membranes (400 µm depth) from four female donors (abdominal skin) per test preparation.  Additional 4 samples from four donors acted as blank controls to account for intrinsic copper levels in the matrices.  Flow through diffusion cell  8 hours exposure  (terminated by applying a conc. commercial hand wash soap, rinsing with a dilute soap solution (2%, v/v) and drying with tissue paper swabs).  16 hours post exposure monitoring period. | Netpolish NI Low (0.24% w/w dicopper oxide) Netrex AF (17.2% w/w dicopper oxide)  Netwax E8 Greenline (35% w/w dicopper oxide) | Test Preparation 1 (Netpolish NI Low)  Corrected values:  Dislodgeable Dose: 96.4%  Stratum Corneum: <0.01%  Total Unabsorbed Dose: 107.6%  Total Absorbed Dose: <0.01%  Dermal Delivery: <0.01%  Potentially Absorbable Dose: <0.01%  Mass Balance: 107.6%    Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  0.01 + (1 x 0.01) = 0.02% (n=6) | Test Preparation 2 (Netwax E8 Greenline)  Corrected values:  Dislodgeable Dose: 113.6%  Stratum Corneum: 0.09%  Total Unabsorbed Dose: 113.6%  Total Absorbed Dose: 0.18%  Dermal Delivery: 0.35%  Potentially Absorbable Dose: 0.4%  Mass Balance: 114.0%  Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation: 0.40% + (0.92 x 0.50)  0.40 + 0.46 =  0.86% (n=7)  Uncorrected values  (excluding receptor chamber wash values):  0.42% + (0.92 x0.27) =**0.67** (n=7) | Test Preparation 3 (Netrex AF)  Corrected values:  Dislodgeable Dose: 109.9%  Stratum Corneum: 0.16%  Total Unabsorbed Dose: 110.0%  Total Absorbed Dose: 0.26%  Dermal Delivery: 0.53%  Potentially Absorbable Dose: 0.57%  Mass Balance: 110.6%  Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  0.57 % + (0.92 x 0.65) = 0.57 + 0.598 = 1.2% (n=7)  Uncorrected values  (excluding receptor chamber wash values)  0.67% + (0.92 x 0.34) = **0.98** (n=7) | No deviations which impact upon the data. | Toner, F. (2019, report amendment 1) The *In Vitro* Percutaneous Absorption of Dicopper Oxide in Three Formulations Through Human Skin; Charles River Laboratories Edinburgh Ltd, Report No. 40889 |

1 Samples were analysed for their elemental copper content by ICP-MS and copper data was then converted to dicopper oxide, using a conversion factor of 1.13.

Dislodgeable Dose = 8h Skin wash + 8h Tissue Swabs + Donor Wash

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

Absorbed Dose: Cumulative Receptor Fluid + Receptor wash

Dermal Delivery: Absorbed Dose + Exposed Skin

Mass balance = Unabsorbed Dose + Dermal delivery

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

In the tables below revised values for the potentially absorbable dose are calculated based on uncorrected values from the test reports (Toner, F. 2019, amendment 1). Results are presented for the potential absorbable dose with subtracted receptor chamber wash values.

TEST PREPARATION 2, **without controls subtracted** (APPENDIX 10 in the test report, page 97)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | cell | cell | cell | cell | cell | cell | Cell | cell | Mean value | SD | Multiplying factor | Dermal abs |
|  | **9** | **10** | **11** | **12** | **13** | ***14\**** | **15** | **16** |  | | | |
| strateum corneum 3+ | 0.28 | 0.16 | 0.12 | 0.12 | 0.28 |  | 0.15 | 0.12 |
| exposed skin | 0.26 | 0.73 | 0.04 | 0.04 | 0.19 | 0.04 | 0.14 |
| receptor fluid | 0.04 | 0.04 | 0.04 | 0.04 | 0.04 | 0.04 | 0.04 |
| receptor wash | 0.06 | 0.04 | 0.04 | 0.10 | 0.04 | 0.04 | 1.35 |
| **potential absorption (- receptor wash)** | 0.58 | 0.93 | 0.20 | 0.20 | 0.51 | 0.23 | 0.30 | 0.42 | 0.27 | 0.92 | **0.67** |

\*excluded

|  |
| --- |
| TEST PREPARATION 3, **without controls subtracted** (APPENDIX 10 in the test report, Page 101) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | cell | cell | cell | cell | cell | cell | cell | cell | Mean value | SD | Multiplying factor | Dermal abs |
|  | **17** | **18** | **19** | **20** | **21** | **22** | ***23\**** | **24** |  | | | |
| strateum corneum 3+ | 0.23 | 0.34 | 0.22 | 0.22 | 0.34 | 0.23 |  | 0.33 |
| exposed skin | 0.66 | 0.89 | 0.08 | 0.16 | 0.16 | 0.22 | 0.20 |
| receptor fluid | 0.07 | 0.07 | 0.07 | 0.07 | 0.00 | 0.07 | 0.07 |
| receptor wash | 0.33 | 0.12 | 0.17 | 0.12 | 1.76 | 0.10 | 0.08 |
| **potential absorption (- receptor wash)** | 0.96 | 1.30 | 0.37 | 0.45 | 0.50 | 0.52 | 0.60 | 0.67 | 0.34 | 0.92 | **0.98** |

\*excluded

Absorbed Dose: Cumulative Receptor Fluid + Receptor wash

Dermal Delivery: Absorbed Dose + Exposed Skin

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Summary table of in vitro studies on dermal absorption** | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value**  **(values presented as % applied dose)** | | **Remarks** *(e.g. major deviations)* | **Reference** |
| GLP Study performed in accordance with the guidance and guidelines detailed below[[7]](#footnote-8)  Reliability: 1 | Eight samples of human split thickness membranes (approximately 400 µm depth) from four male and female donors (abdominal skin) per test preparation.  Flow through diffusion cell  8 hours exposure  (terminated by applying a conc. commercial hand wash soap, rinsing with a dilute soap solution (2%, v/v) and drying with tissue paper swabs).  16 hours post exposure monitoring period.  Photo evidence to demonstrate the efficacy of the washing. | Netwax NI Gold (Light) (0.24% w/w [14C]-Copper Pyrithione)  Netwax NI Gold  Plus (2.5% w/w [14C]-Copper Pyrithione) | 0.24% w/w copper [14C]-Copper Pyrithione  Total Dislodgeable Dose: 117.1%  Stratum Corneum: 0.68%  Total Unabsorbed Dose: 117.8%  Exposed skin: 0.20  Total Absorbed Dose: 0.62%  Dermal Delivery: 0.82%  Potentially Absorbable Dose: 1.15%  Mass Balance: 118.6%  Dermal absorption in accordance with EFSA 2017:  Absorption (mean value) + ks, where s is the standard deviation:  1.15 + 0.84 x 0.69= **1.7 %** | 2.5% w/w copper [14C]-Copper Pyrithione  Total Dislodgeable Dose: 101.3%  Stratum Corneum: 0.57%  Total Unabsorbed Dose: 101.8%  Exposed skin: 0.12  Total Absorbed Dose: 0.04%  Dermal Delivery: 0.16%  Potentially Absorbable Dose: 0.34%  Mass Balance: 101.9%  Dermal absorption in accordance with EFSA 2017  Absorption (mean value) + ks, where s is the standard deviation:  0.34% + 0.84 x 0.23=  **0.53** | No deviations which impact upon the data. | Blackstock, C. (2019) The *In Vitro* Percutaneous Absorption of [14C]-Copper Pyrithione in Two Formulations Through Human Split-Thickness Skin; Charles River Laboratories Edinburgh Ltd, Study No. 784321 |

Dislodgeable dose 8 h = skin wash 8 h + tissue swab 8 h + pipette tip 8 h.

Total dislodgeable dose = dislodgeable dose 8 h + donor wash + tissue swab 24 h.

*Stratum corneum* = tape strips 1 to 20.

Total unabsorbed dose = total dislodgeable dose + *stratum corneum* + unexposed skin.

Total absorbed dose = cumulative receptor fluid + receptor chamber wash + receptor rinse.

Dermal delivery = absorbed dose + exposed skin.

Potentially absorbable dose = tape strips 3-20 + dermal delivery.

Mass balance = unabsorbed dose + dermal delivery.

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

There are no substances of concern contained in the products to be considered.

For further information, see the SoC assessment provided in the Confidential Annex.

#### Exposure assessment

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

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

Production and formulation of the antifouling products is addressed under other EU legislation (e.g., Directive 98/24/EC) and not repeated under Regulation EU 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).

Treatment of nets with antifouling products is undertaken industrially by specialised service companies. This report assesses the risks to the operators involved in the treatment of nets with the Dicopper oxide/Copper pyrithione biocidal product family as well as to the workers involved in deployment of these treated nets. The relevant work tasks for industrial and professional workers dealing with antifouling coating nets are described below.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
|  | Mixing / loading (covered by scenario 2) | Primary – Mixing and loading antifouling paint | Industrial workers |
|  | Net treatment (including M&L) | Primary – Dipping model 4: Aquaculture – net dipping, dispensing to a pit from IBC, stirring and crane-assisted dipping, solvent-based and water-based products.  Describes the process of mixing/loading of antifouling product into reservoirs for net dipping, crane assisted net dipping and the packing of treated nets for shipment to the customer.  (It is assumed that the Dipping model 4 covers treatment of nets using vacuum method). | Industrial workers |
|  | Net deployment (contact with treated articles) | Secondary – Handling model 2; installing fish cages using lifting equipment and handling, nets damp with sticky product.  Describes the process where a treated net is hoisted by a crane from a service boat and deployed in the sea at an aquaculture farm (or where a net is removed). Covers also the process of changing a net which is in service in an active fish farm.  The task requires handling of treated nets; thus some physical dermal contact is expected. | Professionals |
|  | Post-application | Primary and secondary – Cleaning equipment (primary) and washing used nets (secondary) | Industrial workers |
|  | Dietary | Secondary – Dietary exposure | General public |

**General assumptions:**

The systemic exposure to the active substance is estimated using generic exposure data, i.e., exposure surveys from similar operations, and default physiological values. Generic exposure data from the simple database models presented in the Biocides Human Health Exposure Methodology (ECHA, 2015a) are used as a basis for the exposure calculations, considering also the information provided in the surveys behind these models.

The occupational risk is estimated by comparing the level of systemic exposure with the relevant toxicological reference value for the active substance. A qualitative local risk assessment is additionally performed due to the classification of the products with Eye Dam 1; H318; Causes serious eye damage. A semi quantitative risk assessment is performed due to the derived AEC value for copper pyrithione (See 2.2.6.3. Risk characterisation for human health

It was agreed among member states (Technical Meeting III, 2011), that the medium-term AEL should be used for risk characterization of professional workers applying or removing antifouling products, given the expected periodic use of the antifouling agents (ref. Biocides Human Health Exposure Methodology, page 265, ECHA, 2015a). The basis for the decision was considerations related to antifouling products on boats.

Net coating is undertaken industrially by specialised service companies employing professional operators. Treatment of nets takes place year-round, according to our information 2-3 days/week whereas deployment of treated nets is most intensive during springtime (ref. also Biocides Human health Exposure Methodology, page 86-89, ECHA, 2015a). Hence, the AELlong term is applied in the risk characterisation of net treatment, and AELmedium term in the risk characterisation of net deployment. The reference values can be found in section 2.2.6.3 (Risk characterisation for human health).

An initial screening assessment using default assumptions and only minimal clothing is performed (Tier 1). Since the products are for industrial use only, this is unlikely to be representative of the normal workplace and is considered the “extreme” worst-case. A tier-2 assessment is performed applying different types of PPE for the estimation of a more realistic systemic exposure.

An overview of the different family members in the biocidal product family are listed below. All products are ready to use products. The contribution of copper from copper pyrithione to the total amount of copper equivalence is very limited and has not been reported in the tables below but are included in the attached excel spreadsheet with exposure calculations for information. (See also 2.2.6.3. *Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product*).

Exposure calculations have been made for all products included in the original biocidal product family as well as for the modified Netwax NI Gold (named Netwax NI Gold) and are presented below.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Meta | **Product** | **Cu2O** | **CuPT** | **Cu from Cu201** | **Total Cu eq.1** | **Dermal abs**  **(copper - pyriythione)** |
| 1 | Netwax NI Gold (Light) | 18 | 0.24 | 16.0 | 16.0 | 0.98% - 1.7% |
| 2 | Netwax NI Gold | 21.5 | 0.75 | 19.1 | 19.2 | 0.98% - 1.7% |
| 2 | Netwax NI Goldold2 | 21.5 | 1.4 | 19.1 | 19.4 | 0.98% - 1.7% |
| 2 | Netwax NI Gold Plus2 | 25 | 2.5 | 22.2 | 22.7 | 0.98%- 0.53% |

*1* *Cu equivalents are calculated using relevant conversion factors: [Cu2O]\*0.888 and [CuPT]\*0.201*

*2 Due to an identified risk for all products in meta SPC2, the product was modified by reducing the amount of copper pyrithione from 1.4%(w/w) to 0.75%(w/w). Netwax NI Gold refers to the reformulated Netwax NI Gold product while Netwax NI Goldold refers to the product originally included in the BPF. The composition of products not proposed authorised can be found in the confidential annex (section 1.3).*

***Industrial exposure***

***Scenario 1* –** ***Mixing/loading***

|  |
| --- |
| **Description of Scenario 1 – Application – Mixing/loading of concentrate** |
| Normally, the product is pumped directly from the IBC container/drum into larger storage tanks and into the treatment unit (application device) using integrated systems. The unused product is pumped back to the storage tank after treatment (for re-use). Internal circulation pumps are also common in storage tanks.  To facilitate emptying the IBC/drum, small amounts of water (approx. 5 % of the product amount) might be used. The rinsing solution is emptied into the storage tank/treatment unit. Homogenisation of the preparation is ascertained by stirring.  Minimal risk of exposure is expected as the mixing and loading process is automated and occurs in a closed system. Exposure would then be accidental and mainly associated to incidental exposure in connecting and disconnecting of transfer lines. Mixing and loading is included in Dipping model 4 and is not assessed separately. |

***Scenario 2* – *Net treatment with* *antifouling paint***

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario 2 – Application –** **Treatment of nets with antifouling paint** | | | |
| Aquaculture nets are treated with the antifoulant when new and during their service life.  The predominant method for treating nets is through the use of a specially designed impregnating machine or in a dip tank at a service station. Most European based service stations now use an impregnating machine, that is typically based on a vacuum system or a drum (see pictures below). The advantage of these machines is that they are closed systems.  Crane assisted dipping is performed by lowering the net into a tank/vat containing the treatment solution. The net is left submerged in the product, held down by a weight. After treatment, the weight is removed. The net is lifted by the crane or rolled back onto the roller. Unattached product is allowed to drain off the net.  During vacuum treatment, the net is placed inside a bag. The bag is sealed and filled with product. Repeated vacuum cycles are then applied to treat the nets and 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/winch.  It is assumed that 1-2 nets are treated per day during a working day, and that this task is performed some days a week (ECHA, 2015a).  After the treatment process the net is dried, typically using a drum system (according to the applicant, normally a dedicated room/space where the door/gate is closed during the drying process) or free hanging system (with or without hot air). Once dry the nets are packed and transported to the point of installation.  Due to the large size, the transfer of the treated net is performed using winches or cranes.  There is a potential for exposure to the body and hands through direct contact with the treated nets when manually connecting/disconnecting the nets to the hoist/crane/drying drum after impregnation. Furthermore, there is a potential for dermal exposure through contact with contaminated surfaces and equipment.  Illustrations:   1. Vacuum treatment of nets. 2. Lifting of nets using a winch. 3. Drying drums for treated nets     Et bilde som inneholder innendørs  Automatisk generert beskrivelse    Et bilde som inneholder innendørs, metall, t-bane, flere  Automatisk generert beskrivelse  Further information can be found in the confidential annex.  **Description of model:**  The dipping models 1-4 in the Biocides Human Health Exposure Methodology (ECHA, 2015a, page 199) describes professionals carrying out a range of dipping activities involving a variety of articles (including mixing/diluting formulations, handling wet articles, machine minding and loading/unloading). The models are reflective of conditions where operators may contact treatment fluids and wet objects.  Dipping model 4 describes semi-automatic dipping of aquaculture nets in open vats (page 311, ECHA, 2015a). The scenario includes dispensing product from IBC, stirring and crane assisted dipping of both solvent-based and water-based products.  The scenario is based on an HSE sponsored survey from 1999 from the four major treaters of net in UK at the time. The results reflect, according to the guidance, the true nature of the net dipping activity, an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated immersion of the nets in large vats of fluid and retrieval of the nets at the end of the process. The work is followed by the preparation of the nets and wrapping prior to transportation to the customer.  The indicative values (expressed as in-use product) for this scenario are the maximum values of the data set due to the high uncertainty in the figures (low number of measurements and variability of the data) (ECHA, 2015a, page 199).  Indicative hands value (actual exposure inside protective gloves) = 16.7 mg/min  Indicative body values = 221 mg/min  Indicative inhalation value = 0.2 mg/m3  *(The indicative inhalation value is used in accordance with ad hoc recommendation 6 of the BPC Ad hoc Working Group on Human Exposure (page 11), following evaluation of dipping Model No.4 for the purposes of dipping of equipment for PT 2,3 and 4).*  The model is based on a rather old survey (from 1999) with a low number of measurements (n=9). Large tanks (2000-7000 litres) were filled with antifoulant from intermediate bulk containers (IBC). The dipping and drying techniques differed between the sites with different degrees of automatization and hence potential for dermal exposure. Dermal exposure resulted from filling of the tanks, manually connecting/disconnecting of treated nets to hoists/  forklifts/drying drums, manually immersion of buoyant nets using sticks (where relevant), contact with contaminated surfaces and physical contact when transferring the nets to the drying station. The work during the survey was considered typical for all sites. The workers wore coveralls, impervious/chemical resistant gloves and wellingtons and goggles/face protection was available.  Some of the measurements are from dipping and packing of nets treated with solvent based products (n=5). Nets treated with solvent based products need to be packed and deployed in a damp state. Thus, a higher exposure to the involved personnel might therefore result. According to our information, solvent based net impregnation products are no longer on the market in Europe. Nets treated with water-based products must be completely dry before they can be packed.  The process and procedures have developed since the performance of the study as both the aquaculture business and its service providers has grown significantly and professionalised in this period. To our knowledge, the service stations use treatment processes which involve little degree of physical contact with the nets during the treatment process. The exposure calculations must therefore be regarded as conservative.  A new exposure survey from service stations in Scotland and Norway was submitted in 2020 (Fraser, G and Cloke, D, 2020). The survey includes both semi-automated net dipping and automated vacuum impregnation processes. At most locations, the process from dipping/vacuum impregnation until packaging included partly automated processes. The conclusion was that the longest duration for physical contact with the nets during the dipping process was 15 minutes whereas the longest duration for the operators being in close proximity to the nets was 30 minutes. In addition, physical contact with the treated nets took place when drying (60 minutes daily, as a worst case) and packaging of the nets (120 minutes daily, to what we assume is touch dry nets).  A large variation in the reported contact time with nets at different service stations were noted (which might partly be related to differences in reporting). Contact time per task was requested rather than daily contact time.  The survey demonstrates that dermal contact is expected for only a minor part of the total time duration for the relevant processes. The model data (Dipping 4 model) contains exposure data from processes with infrequent handling of treated nets, with the exposure averaged over time (application/(drying)). Thus, the reported contact time in the exposure survey cannot be easily used to refine the time duration which is used as the input parameter in the exposure assessment for both dermal and inhalation exposure.  The resulting exposure values are reported below. Full details of the exposure assessment calculations can be found in a separate annex, see section 3.2.2.  **Note on vacuum treatment of nets:**  No exposure model/data exists for the assessment of exposure from vacuum treatment of nets. However, many of the tasks with potential for exposure are identical as for dipping, such as connecting/disconnecting nets to cranes/winches, exposure to contaminated equipment and transferring of nets to the drying station. Thus, it is assumed that the Dipping model 4 also covers treatment using the vacuum method. | | | |
| Tier | Parameters | Value | |
|  | Actual hand exposure *(inside protective gloves)1* | 16.7 mg/min (max values) | |
| Potential body exposure1 | 221 mg/min (max values) | |
| Potential inhalation exposure1 | 0.2 mg/m3 (max value) | |
| Dermal absorption | Dicopper oxide3: | 0.98% |
| Copper pyrithione4: | 0.53% (Netwax NI Gold Plus)  1.7% (Netwax NI Gold (Light), Netwax NI Gold and Netwax Goldold) |
| Inhalation absorption | 100% | |
| Inhalation rate2 | 1.25 m3/hr | |
| Duration of exposure6 | 60 minutes | |
| Body weight2 | 60 kg | |
| Tier 2a | Gloves1 | Actual measurements inside gloves.  No further refinement | |
|  | PPE (Coated coveralls)5 | 10% penetration | |
| Tier 2b | Gloves1 | Actual measurements inside gloves.  No further refinement | |
|  | PPE (Impermeable coveralls)5 | 5% penetration | |
| Tier 2c | Gloves1 | Actual measurements inside gloves.  No further refinement | |
|  | PPE (Double coveralls)5 | 1% penetration | |

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

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

3 Toner, F. (2019). The in vitro percutaneous Absorption of Dicopper oxide in two formulations through human skin.

4 Blackstone, (2019). The In Vitro Percutaneous Absorption of [14C]-Copper Pyrithione in Two Formulations Through Human Split-Thickness Skin

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

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

***Calculations– Application – Treatment of nets with antifouling paint – dicopper oxide***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Netwax NI Gold (Light)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 6.71E-04 | 0.372 |  | **0.373** |
| Tier 2a/PPE  (gloves & coated coveralls) | 6.71E-04 | 0.061 |  | **0.061** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 6.71E-04 | 0.043 |  | **0.044** |
| Tier 2c/PPE  (gloves & double coveralls) | 6.71E-04 | 0.030 |  | 0.030 |
| **Netwax NI Gold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 8.02E-04 | 0.445 |  | **0.446** |
| Tier 2a/PPE  (gloves & coated coveralls) | 8.02E-04 | 0.073 |  | **0.073** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 8.02E-04 | 0.052 |  | **0.053** |
| Tier 2c/PPE  (gloves & double coveralls) | 8.02E-04 | 0.035 |  | 0.036 |
| **Netwax NI Goldold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 8.02E-04 | 0.445 |  | **0.446** |
| Tier 2a/PPE  (gloves & coated coveralls) | 8.02E-04 | 0.073 |  | **0.073** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 8.02E-04 | 0.052 |  | **0.053** |
| Tier 2c/PPE  (gloves & double coveralls) | 8.02E-04 | 0.035 |  | 0.036 |
| **Netwax NI Gold Plus** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 9.32E-04 | 0.517 |  | **0.518** |
| Tier 2a/PPE  (gloves & coated coveralls) | 9.32E-04 | 0.084 |  | **0.085** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 9.32E-04 | 0.060 |  | **0.061** |
|  | Tier 2c/PPE  (gloves & double coveralls) | 9.32E-04 | 0.041 |  | **0.042** |

*\** Since the NOAEL is expressed in terms of mg Cu/kg and has been used to derive the systemic value in terms of mg Cu/kg bw/day, the exposure to dicopper oxide has been recalculated to represent the exposure to copper by applying a correction factor of 0.888 (Cu2O has a molecular weight of 143.09 g/mol, Cu of 63.546 g/mol. The portion of Cu in Cu2O is therefore 127.092/143.09=0.888).

Figures in bold: Exposure/AEL>1

***Calculations– Application – Treatment of nets with antifouling paint – copper pyrithione***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Netwax NI Gold (Light)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 1.01E-05 | 0.010 | - | **0.010** |
| Tier 2a/PPE  (gloves & coated coveralls) | 1.01E-05 | 1.6E-03 | - | 1.6E-03 |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 1.01E-05 | 1.1E-03 | - | 1.1E-03 |
| Tier 2c/PPE  (gloves & double coveralls) | 1.01E-05 | 7.7E-04 | - | 7.8E-04 |
| **Netwax NI Gold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 3.15E-05 | 0.030 |  | **0.030** |
| Tier 2a/PPE  (gloves & coated coveralls) | 3.15E-05 | 4.9E-03 |  | **5.0E-03** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 3.15E-05 | 3.5E-03 |  | **3.6E-03** |
| Tier 2c/PPE  (gloves & double coveralls) | 3.15E-05 | 2.4E-03 |  | 2.4E-03 |
| **Netwax NI Goldold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 5.88E-05 | 0.057 | - | **0.057** |
| Tier 2a/PPE  (gloves & coated coveralls) | 5.88E-05 | 9.2E-03 | - | **9.3E-03** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 5.88E-05 | 6.6E-03 | - | **6.7E-03** |
| Tier 2c/PPE  (gloves & double coveralls) | 5.88E-05 | 4.5E-03 | - | **4.6E-03** |
| **Netwax NI Gold Plus** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 1.05E-04 | 0.031 | - | **0.032** |
| Tier 2a/PPE  (gloves & coated coveralls) | 1.05E-04 | 5.1E-03 | - | **5.2E-03** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 1.05E-04 | 3.7E-03 | - | **3.8E-03** |
| Tier 2c/PPE  (gloves & double coveralls) | 1.05E-04 | 2.5E-03 | - | **2.6E-03** |

***Further information and considerations on scenario 2 - Application – Dipping nets in antifouling paint***

The products in the family are classified with Eye Dam. 1; H318 (Causes serious eye damage). Therefore, eye irritation during the handling of the product needs to be considered. A qualitative exposure and risk assessment is provided in chapter 2.2.6.3 “Risk characterisation for human health”

*Scenario 3* – *Installing and handling treated nets at fish farms*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario 3 – Installing and handling treated nets at fish farms** | | | |
| Following application, the treated nets are packed in waterproof bags or wrapped in plastic. The waterproof bags are used to prevent the nets from being exposed to rain/water as this can cause leakage. Treated nets are stored and later transported to the fish farmer. The nets are positioned and installed manually (see picture below) or using a service boat with crane:  W:\01_FELLES\Mine bilder\_Reklamebilder\Marine Harvest på Skottland som setter ut not\RIMG0593 (Large).JPG  According to the guidance document, 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 (ECHA, 2015a, page 86-89).  Scenario 3 is considered independent from other scenarios as the work is performed off-site, at the fish farm.  **Description of model:**  A scenario to assess exposure from deployment and installation of a net at a fish farm, Handling model 2, is found in the Biocides Human Health Exposure Methodology (page 303, ECHA, 2015a). Indicative values for this scenario are further given (page 198) and are the 75 percentile values.  The situation is similar as 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 are old, and the number of data points is very low. For several of the data points, the workers are deploying nets treated with solvent based antifouling products, requiring that the nets are still damp with product at deployment. This will necessarily 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 is therefore regarded as conservative.  The indicative values (expressed as in-use product) for this scenario are the 75 percentile values of the data set:  Indicative hands value (inside protective gloves) = 0.21 mg/min  Indicative body values = 7.55 mg/min  The resulting exposure values are reported below. Full details of the exposure assessment calculations can be found in a separate annex, see section 3.2.2 | | | |
| Tier | Parameters | Value | |
| Tier 1 | Actual hands exposure (inside protective gloves)1 | 0.21 mg/min (75 percentile) | |
| Potential body exposure1 | 7.55 mg/min (75 percentile) | |
| Dermal absorption | Dicopper oxide3: | 1.2% |
| Copper Pyrithione4: | 0.53% (Netwax NI Gold Plus)  1.7% (Netwax NI Gold (Light), Netwax NI Gold and Netwax NI Goldold) |
| Inhalation absorption | 100% | |
| Inhalation rate2 | 1.25 m3/hr | |
| Duration of exposure6 | 300 minutes (worst-case) | |
| Body weight2 | 60 kg | |
| Tier 2 | Hand exposure1 | Actual measurements inside gloves. No further refinement. | |
| PPE (uncoated cotton coverall)5 | 25% penetration from dry substances | |

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

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

3 Toner, F. (2019). The in vitro percutaneous Absorption of Dicopper oxide in two formulations through human skin.

4 Blackstone, (2019). The In Vitro Percutaneous Absorption of [14C]-Copper Pyrithione in Two Formulations Through Human Split-Thickness Skin

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

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

***Calculations– Installing and handling treated nets at fish farms – dicopper oxide***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Netwax NI Gold (light)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 6.1E-02 | - | 6.1E-02 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 1.6E-02 | - | 1.6E-02 |
| **Netwax NI Gold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.073 | - | 0.073 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.020 | - | 0.020 |
| **Netwax NI Goldold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.073 | - | 0.073 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.020 | - | 0.020 |
| **Netwax NI Gold Plus** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.084 | - | **0.084** |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.023 | - | 0.023 |

*\** Since the NOAEL is expressed in terms of mg Cu/kg and has been used to derive the systemic value in terms of mg Cu/kg bw/day, the exposure to dicopper oxide has been recalculated to represent the exposure to copper by applying a correction factor of 0.888 (Cu2O has a molecular weight of 143.09 g/mol, Cu of 63.546 g/mol. The portion of Cu in Cu2O is therefore 127.092/143.09=0.888).

Figures in bold: Exposure/AEL>1

***Calculations– Installing and handling treated nets at fish farms – copper pyrithione***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Summary table: estimated exposure from professional uses | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| **Netwax NI Gold (light)** | | | | | |
| - | Tier 1/PPE (gloves) | - | 1.6E-03 | - | 1.6E-03 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 4.3E-04 | - | 4.3E-04 |
| **Netwax NI Gold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 4.9E-03 |  | 4.9E-03 |
| Tier 2a/PPE  (gloves & coated coveralls) | - | 1.3E-03 |  | 1.3E-03 |
| **Netwax NI Goldold** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 9.2E-03 | - | **9.2E-03** |
| Tier 2a/PPE  (gloves & coated coveralls) | - | 2.5E-03 | - | 2.5E-03 |
| **Netetwax NI Gold Plus** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 5.1E-03 | - | **5.1E-03** |
| Tier 2a/PPE  (gloves & coated coveralls) | - | 1.4E-03 | - | 1.4E-03 |

***Further information and considerations on scenario 3 - Application – Installing and handling treated nets at fish farms***

The products in the biocidal product family are classified with Eye Dam. 1; H318 (Causes serious eye damage). Therefore, eye irritation during the handling of the products needs to be considered. A qualitative exposure and risk assessment is provided in chapter 2.2.6.3 “Risk characterisation for human health”.

*Scenario 4* – *Washing used nets and cleaning equipment*

|  |
| --- |
| **Description of Scenario 4 – Post-Application – Washing used nets and cleaning equipment** |
| Cleaning/washing nets after a period of use in the sea  After a period of use in the sea, some/most of the dicopper oxide and copper pyrithione will have leached from the net matrix. These nets are then returned to a service station for servicing. The nets arrive at the service stations “dirty zone”, where they are washed either in a net washer or cleaned by pressure sprayer before being transferred to the “clean zone”. The net wash may remove a significant amount of the product remaining on the net, plus fouling, dirt, fats, etc.  The procedure for washing the nets is described below.  Et bilde som inneholder transport, heisekran  Automatisk generert beskrivelse   * The used net arrives at the service station, typically in a large bag or in a container. * The net is then lifted into the net washing machine using a crane or a winch. This operation will require little or no physical contact with the net. See the picture to the left which shows an example of an outdoor operation. * Service stations that wash the net indoors will normally use a winch/power block, similar to the one that can be seen in the upper right picture in scenario 2 (application)   Inspection and repair of nets  In the “clean zone” the nets are repaired and refitted, and then retreated with antifouling paint. Physical handling of the net will take place. However, at the end of the service life most of the active substances are assumed to have leached out (in the risk assessment for the environment approximately 80% is assumed to have leached out). Furthermore, before being inspected and repaired, the nets have been thoroughly washed. 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 low exposure compared to e.g., the task of deployment of nets. This task is thus not further assessed. Appropriate PPE should be used.  Cleaning impregnating machine  The impregnating machine is drained and emptied after each impregnating cycle, with little paint residue remaining in the machine following this process. It is not necessary to clean the machine after each treatment. The machine is cleaned either if the machine is not to be used again for some days or if another type of antifouling paint, or coating, is going to be used. The machine is cleaned using small amounts of water only. The water is pumped through the machine, to remove paint residues from the machine (canvas), and from the pipes valves and pumps. Waste water is not generally disposed of but is re-used as appropriate.  Cleaning dipping tank  The dip tank is only cleaned periodically, typically every 4-8 months. Similar to the impregnation machine, the dipping tank is hosed with water to remove sediment and dirt that may have come into the tank from the nets. This process is anticipated to remove the majority of paint residue with little paint residue left in the settlement and dirt on the bottom of the tank. Remaining dirt and sediment is manually removed at the end of the process. The task can be performed by the same personnel that performs the net dipping. however, the cleaning of the vacuum impregnation machines/dipping vats is unlikely to be performed on the same day as dipping/impregnation. Some contact with wet surfaces will occur, and this last operation requires that the worker wears appropriate personal protective equipment (such as boots, gloves, coveralls and goggles).  As no appropriate exposure model or measurements exist for the process of cleaning impregnation machines/dipping vat, a description of the process and normally used PPE is included only. Cleaning of the dipping tank/vat, for which the exposure potential is largest is performed infrequent and is not assumed to take place at the same day as dipping of nets. The exposure is considered as being covered by the conservative assessment of dipping of nets (dipping 4 model). |

***Further information and considerations***

All products in the biocidal product family are classified with Eye Dam. 1; H318 (Causes serious eye damage). Therefore, eye irritation during the handling of these products needs to be considered. A qualitative exposure and risk assessment is provided in chapter 2.2.6.3 “Risk characterisation for human health”.

A semi quantitative risk assessment is performed due to the derived AEC value for inhalation for copper pyrithione.

*Combined scenarios*

There is a potential for the industrial worker to perform mixing and loading as well as application of products. The former two task are covered by scenario 2. Cleaning of equipment or dirty nets is considered as being covered by the conservative assessment of dipping of nets (dipping 4 model).

Scenario 3 is expected to be performed off-site with exposure occurring during installation of the net. Therefore, scenario 3 is considered independent from the other three scenarios.

***Non-professional exposure***

The Netkem products are not for use by non-professionals.

***Exposure of the general public***

Bystanders will not come in contact with the treated nets used for aquaculture.

***Monitoring data***

None available.

***Dietary exposure***

*Dicopper oxide*

Copper is naturally present in the environment and also essential for many metabolic functions and reactions for both plants and animals. Copper is authorised as a feed additive under EU Reg. 479/20064 for nutrition of livestock including fish and shellfish and is routinely added to fish feed in order to prevent copper deficiency. The maximum content in the complete feeding stuffs is 25 mg/kg for fish and 50 mg/kg for crustaceans. It is also present in many food supplements for human consumption, according to Directive 2002/46/EC. Acceptable risks due to potential exposure of copper via food contamination was identified in the competent authority report for dicopper oxide based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties, and regulations already in force (ECHA, 2016a). However, it was indicated that exposure via food contamination might need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

There is currently no harmonized methodology to assess the level in foodstuff of a PT21 active substance. The most relevant general approach available to estimate levels in fish and shellfish is based on a rough calculation using the highest Predicted Environmental Concentration (PEC) calculated from the marine environment with a Bio Concentration Factor (BCF). However, for copper this approach is not relevant. In the case of copper, the potential bioaccumulation cannot be established from the BCF values. This is due to copper being an essential metal for many organisms where a feedback regulation mechanism of the uptake exists. No concern is identified for copper, also due to its physico-chemical properties (high solubility/dilution in sea water, low bioaccumulation). See the Risk Assessment for the Environment section 2.2.8.1 for further information.

The levels of copper (Cu), as well as other metals and environmental pollutants, were analysed in a standardised muscle sample from both farmed (n=100) and wild (n=87) Atlantic salmon caught or produced in Norway in 2012 (Lundebye *et al*., 2017). The farmed Atlantic salmon were sampled at fish farms by inspectors from the Norwegian Food Safety Authority (NFSA) in 2012 (for the annual monitoring programme laid down in Directive 96/23 EC). Sampling locations represent regions with aquaculture activity along the Norwegian Coast accounting for at least 10 % of the total number of farm sites each year. The Wild Atlantic salmon were caught by nets in Norwegian northern coastal waters by commercial fishermen in 2012. Filets from the farmed salmon contained less copper than wild salmon. The mean copper value ± SD from the farmed salmon was 0.38 ± 0.09 (with a min- max range of 0.27 - 0.95) and the mean value for the wild salmon was 0.57 ± 0.15 (with a min - max range of 0.4 - 1.8). The findings in Lundeby et al. (2017) gives no indication of elevated copper levels in farmed fish compared to wild caught fish.

Copper levels in farmed Atlantic salmon filets were also given in an annual report for 2019 provided by the Norwegian Institute of Marine Research. This report is part of the monitoring program for pharmaceuticals, illegal substances and contaminants in farmed fish (Bernhard *et. al*., 2020). Samples were taken from fish farms or slaughterhouses in all fish-producing regions in Norway by official inspectors from the NFSA. The sampling plan was randomised according to season and region. When analysing the Atlantic salmon filets from the fish included in this report (n = 52), the median value was 0.4 mg/kg w.w. and the max vale was 0.7 mg/kg w.w. copper.

No information was given regarding the biocide(s) used for net treatment. However, given that the samples were taken from different farms, and considering that copper containing antifoulants is the most frequently used antifoulant in Norway, it is reasonable to believe that nets treated with such products were used in a number of the selected farms. The results from both 2012 and 2019 seem to be in the same range with the mean of 0.38 vs a median of 0.4 mg/kg w.w.

If the maximum copper value in filets of 0.95 mg/kg w.w. given in the Lundebye study is used in a reverse reference exposure calculation, a 15-kilo child would have to consume approximately 2.4 kilos of salmon per day to exceed the ADI of 0.15 mg Cu/kg bw/day. The corresponding amount for an adult of 60 kg using the same maximum value, is 9.5 kilo salmon per day.

(0.15 mg/kg bw/day X 15 kg bw) / 0.95 mg /kg w.w. = 2.4 kg w.w./day  
(0.15 mg/kg bw/day X 60 kg bw) / 0.95 mg /kg w.w. = 9.5 kg w.w./day

Based on the information above, no concern in regard to exposure via food is identified. However, when a uniform methodology to assess dietary exposure induced by an antifouling application is available, this assessment may need to be updated.

*Copper pyrithione*

In the Competent authority report on copper pyrithione, it was concluded that the evaluation of aquatic food chain accumulation that takes into account the ratio of concentration in predator relative to that of prey is not possible for copper pyrithione. The reason is that studies on pyrithione accumulation in fish indicate that pyrithione is not measurable due to the rapid metabolism. None the less, a rough calculation was presented in the CAR for a dummy product intended for treatment of aquaculture nets demonstrating that the possible exposure from eating fish or oysters was well below the ADI for copper pyrithione (ECHA, 2014a).

In the assessment of a dummy product intended for aquaculture use containing 2 % copper pyrithione, a maximum value of 3.5 mg copper pyrithione/kg ww fish was calculated based on the highest Predicted Environmental Concentration (PECfreely dissolved) in water (0.45 mg/L). However, this PEC was calculated for another intended use, i.e. antifouling paint on boats. Based on the maximum calculated fish value, a child with a body weight of 23.9 kg (6 < 11 years, HEEG opinion 17) would have to ingest more than 17 kg of fish/day to exceed the ADI (0.0025 mg/kg bw/day).

As for the use of the Dicopper Oxide-Copper Pyrithione Biocidal products family for treatment of aquaculture nets, a maximum PECdissolved of 0.0163 mg/L and 0.05 mg/L was determined for the EU fish farm scenario for Netwax NI Gold (the product with the highest concentration of copper pyrithion in the biocidal product family proposed authorized) and Netwax NI Gold Plus, respectively (section 2.2.8.2). The PEC calculations in the fish farm scenarios includes the area directly underneath the fish farm. Based on the at least 9 times lower PEC(dissolved) value compared to the value established for antifouling paint on boats, even a larger safety margin is foreseen.

The low pyrithione BCF (fish = 0.88 log l/kgwwt; invertebrates = 0.91 log l/kgwwt) combined with the relatively rapid degradation of pyrithione in natural aquatic systems, and in vertebrates tested, indicate that the inherent properties of pyrithione makes it unlikely to reach high concentrations in aquatic species, either directly or through the food webs (secondary poisoning). This is further supported by the fact that in monitoring studies, so far it has not been possible to detect pyrithione in aquatic biota, in spite of the long historical use of pyrithiones (ECHA, 2014a). Based on the information provided in the active substance evaluation, no concern in regard to exposure via food is identified.

*Conclusion*

An acceptable risk is identified for potential exposure via food contamination. This is based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force.

As for pyrithione, an acceptable risk is identified for potential exposure via food contamination based on a rough calculation. It should be noted that the inherent properties of pyrithione combined with the relatively rapid degradation of pyrithione in natural aquatic systems, make it unlikely to reach high concentrations in aquatic species.

Exposure via food contamination may need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

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

Production and formulation are addressed under other EU legislation (e.g., Directive 98/24/EC) and not repeated under Regulation EU 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation – Dicopper oxide**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| 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) | n.a. | | | 0.15 mg Cu/kg bw/day |

**Reference values to be used in Risk Characterisation - Copper pyrithione**

**(ref: Assessment report for copper pyrithione (ECHA, 2014a)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)**  **(mg/kg bw/day)** | **AF1** | **Correction for oral/dermal/ inhalation absorption** | **Value**  **(mg/kg bw/day or**  **mg/m3 (AEC))** |
| Inhalation AELshort/medium-term | 28-day rat inhalation study | 0.38 | 200a | 100% | 0.002 |
| Dermal AELshort/medium-term | Based on all available oral copper, zinc and sodium pyrithione subacute, subchronic, teratogenicity and 2-generation studies | 0.5 | 100 | 100% | 0.005 |
| Inhalation AELlong-term | 28-day rat inhalation study | 0.38 | 400b | 100% | 0.001 |
| Dermal AELlong-term | Two chronic studies with sodium pyrithione | 0.5 (LOAEL) | 200c | 100% | 0.0025 |
| ARfD | Effects seen after 2.5 hr in a 90  day study with  sodium  pyrithione | 2.0 | 100 | n.a. | 0.02 |
| ADI | Two chronic  studies with  sodium  pyrithione | 0.5 (LOAEL) | 200c | n.a. | 0.0025 |
| AEC | 28 day rat inhalation study | 0.0005 mg/L  (local NOAEC) | 25 (10 for intra species variation + 2.5 for interspecies variation in toxicodynamics | n.a. | * 1. mg/m3 |

At TM I 2012 it was decided that route-specific AELs should be set for copper pyrithione,

i.e. one inhalation and one dermal AEL for short-term, medium-term and long-term exposure respectively.

a Extra AF 2 for severe effects at LOAEL (unexplained mortality)  
b Extra AF 4 for extrapolation from short-term to long-term exposure

c Extra AF 2 for using a LOAEL and not a NOAEL

**Maximum residue limits or equivalent**

Dicopper oxide is authorised as a pharmacologically active substance and classified regarding MRLs in foodstuffs of animal origin as ‘Allowed substances, no MRL required’ (Regulation 37/2010).

Establishment of a MRL for copper pyrithione in fish (or shellfish) is not considered necessary due to this biocidal use.

**Specific reference value for groundwater**

Not applicable.

***Risk for industrial users***

Production and formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).

***Risk for industrial users***

**Systemic effects – Dicopper Oxide**

**Scenario 2 – Application – Treatment of nets with antifouling product**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg Cu/kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **Mg Cu/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **DICOPPER OXIDE (COPPER)** | | | | | | |
| **Netwax NI Gold Light** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.373 | 9.10 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.061 | 1.50 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.044 | 1.08 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.030 | 0.74 | Yes |
| **Netwax NI Gold** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.446 | 10.9 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.073 | 1.79 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.053 | 1.29 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.036 | 0.88 | Yes |
| **Netwax NI Goldold** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.446 | 10.9 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.073 | 1.79 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.053 | 1.29 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.036 | 0.88 | Yes |
| **Netwax NI Gold Plus** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.518 | 12.6 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.085 | 2.08 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.061 | 1.50 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.042 | 1.03 | Borderline |

**Systemic effects – Copper Pyrithione**

**Scenario 2 – Application – Treatment of nets with antifouling product**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg /kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **COPPER PYRITHIONE** | | | | | | |
| **Netwax NI Gold Light** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | Inhalation 0.38  Dermal 0.5 (LOAEL) | Inhalation: 0.001  Dermal 0.0025 | Inh.: 1.01E-05  Dermal:0.010  Total: 0.010 | 3.89 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | Inh.: 1.01E-05  Dermal: 1.6E-03  Total: 1.6E-03 | 0.64 | Yes |
| Tier 2b/PPE  (gloves & impermeable coveralls) | Inh.: 1.01E-05  Dermal: 1.01E-03  Total: 1.01E-03 | 0.46 | Yes |
| Tier 2c/PPE  (gloves & double coveralls) | Inh.: 1.01E-05  Dermal: 7.7E-04  Total: 7.8E-04 | 0.32 | Yes |
| **Netwax NI Gold** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | Inhalation 0.38  Dermal 0.5 (LOAEL) | Inhalation: 0.001  Dermal 0.0025 | Inh.: 3.15E-05  Dermal:0.030  Total: 0.030 | 12.2 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | Inh.: 3.15E-05  Dermal: 4.9E-03  Total: 5.0E-03 | 2.01 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | Inh.: 3.15E-05  Dermal: 3.5E-03  Total: 3.6E-03 | 1.45 | No |
| Tier 2c/PPE  (gloves & double coveralls) | Inh.: 3.15E-05  Dermal: 2.4E-03  Total: 2.4E-03 | 1.00 | Yes |
| **Netwax NI Goldold** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | Inhalation 0.38  Dermal 0.5 (LOAEL) | Inhalation: 0.001  Dermal 0.0025 | Inh.: 5.88E-05  Dermal: 0.057  Total: 0.057 | 22.7 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | Inh.: 5.88E-05  Dermal: 9.2E-03  Total: 9.3E-03 | 3.75 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | Inh.: 5.88E-05  Dermal: 6.6E-03  Total: 6.7E-03 | 2.70 | No |
| Tier 2c/PPE  (gloves & double coveralls) | Inh.: 5.88E-05  Dermal: 4.5E-03  Total: 4.6E-03 | 1.86 | No |
| **Netwax NI Gold Plus** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | Inhalation 0.38  Dermal 0.5 (LOAEL) | Inhalation: 0.001  Dermal 0.0025 | Inh.:1.05E-04  Dermal:0.031  Total: 0.032 | 12.7 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | Inh.:1.05E-04  Dermal:5.1E-03  Total: 5.2E-03 | 2.16 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | Inh.:1.05E-04  Dermal:3.7E-03  Total: 3.8E-03 | 1.58 | No |
| Tier 2c/PPE  (gloves & double coveralls) | Inh.:1.05E-04  Dermal: 2.5E-03  Total: 2.6E-03 | 1.11 | No |

**Conclusion:** The risk from systemic exposure to copper (from dicopper oxide) and copper pyrithione to industrial workers performing net treatment using Netwax NI Gold light (Meta SPC 1) and Netwax NI Gold is acceptable in tier 2c. Safe use requires the use of double coveralls and gloves.

No acceptable risk was demonstrated for industrial workers performing net treatment using

Netwax NI Goldold and Netwax NI Gold Plus.

***Risk of professional users***

**Systemic effects – Dicopper Oxide**

***Scenario 3: Installing and handling treated nets at fish farms***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg Cu/kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **Mg Cu/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **DICOPPER OXIDE (COPPER)** | | | | | | |
| **Netwax NI Gold Light** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 6.1E-02 | 0.74 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 1.6E-02 | 020 | Yes |
| **Netwax NI Gold** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.073 | 0.89 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.020 | 0.24 | Yes |
| **Netwax NI Goldold** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.073 | 0.89 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.020 | 0.24 | Yes |
| **Netwax NI Gold Plus** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.084 | 1.03 | Borderline |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.023 | 0.28 | Yes |

**Systemic effects – Copper pyrithione**

***Scenario 3: Installing and handling treated nets at fish farms***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg /kg bw/day** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **COPPER PYRITHIONE** | | | | | | |
| **Netwax NI Gold Light** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | Dermal:  0.5 | Dermal 0.005 | 1.6E-03 | 0.32 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 4.3E-04 | 0.09 | Yes |
| **Netwax NI Gold** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | Dermal:  0.5 | Dermal 0.005 | 4.9E-03 | 0.99 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 1.3E-03 | 0.27 | Yes |
| **Netwax NI Goldold** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | Dermal: 0.5 | Dermal 0.005 | 9.2E-03 | 1.85 | No |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 2.5E-03 | 0.50 | Yes |
| **Netwax NI Gold Plus** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | Dermal: 0.5 | Dermal 0.005 | 5.1E-03 | 1.03 | Borderline |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 1.4E-03 | 0.28 | Yes |

**Conclusion:**

Acceptable risk is demonstrated (all four products) when calculating the systemic exposure to copper pyrithione and copper (from dicopper oxide) for professional workers performing deployment of nets. As for Netwax NI Gold Light (Meta 1) and Netwax NI Gold, acceptable risk is demonstrated assuming chemical protective gloves only.

As for Netwax NI Goldold and Netwax NI Gold Plus, acceptable risk is demonstrated in tier 2a, assuming use of gloves and uncoated cotton coverall.

**Local effects**

A classification for Eye damage 1 (H318) is proposed for all products in the biocidal product family, necessitating a local risk assessment. A qualitative risk assessment is performed in accordance with the BPR Guidance (Chapter 4.3, ECHA, 2017a).

The products in the biocidal product family are allocated to the hazard category "High" based on this guidance.

Most of the net treatment process is operated remotely and does not involve contact with the treated nets or the dipping vat/vacuum impregnation bag. Thus, the potential for eye exposure is restricted to a limited part of the treatment process. The risk of serous eye damage will be minimal if protective goggles/eye protection is used during the performance of these tasks.

An AECinhalation value of 0.02 mg/m3 has been derived for copper pyrithione.

The indicative inhalation exposure value in the dipping model 4 is 0.2 mg/m3 product. This equals 0.0015 mg/m3 for the product with the highest concentration of copper pyrithione which is proposed to be authorised (Netwax NI Gold) and 0.005 mg/m3 for the applied product with the highest concentration of copper pyrithione in the applied family (Nerwax NI Gold Plus).

**Primary Professional Exposure**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | **Risk** |
| **Hazard Cate-gory** | **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&PPE** | **Conclusion on risk** |
| High | Eye Dam 1 (H318) | Industrial users | Net treatment (incl. Mixing and loading of antifouling paint,  washing used nets and cleaning equipment) | Skin  Eyes (splash, hand to eye tranfer) | 2-3 days per weeks  Only few minutes potential exposure due to automated processes.  Intermittent handling of treated nets.  Incidental contact with contaminated surfaces | - | Minimisation of manual phases (automatization)  Avoidance of contact with contaminated tools and objects  Regular cleaning of equipment and work areas  Training for staff on good practise; instructions for use  Personal protective equipment (coveralls, gloves, eye protection)  Organisation  General safety and hygiene measures  Good standard of personal hygiene.  (Labelling according to CLP) | Acceptable:   * Automated processes; (minimal potential for exposure) * Trained workes following instructions for use; * Use of appropriate PPE * Good standard of personal hygiene. |
| Professional users | Net deployment (Installing and handling treated nets at fish farms) | Skin  Eyes (dust, hand to eye transfer) | Infrequent task (seasonal)  Dermal contact with dry treated nets  Practically no exposure to eyes as the nets are touch dry at deployment and goggles are used | - | Training for staff on good practise; instructions for use  Personal protective equipment (coveralls, gloves, eye protection)  Good standard of personal hygiene. | Acceptable  +Exposure to dry nets  +trained workers following instructions for use  +use of appropriate PPE |

**Conclusion**

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

***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 systemic risk assessment for Meta SPC 1 (Netwax NI Gold Light) and the modified product in meta SPC 2 (Netwax NI Gold), provided that the workers wear double coveralls and chemical protective gloves. No acceptable risk was identified for Netwax NI Goldold and Netwax NI Gold Plus.

An acceptable risk was demonstrated in the semiquantitative risk assessment of local effects of copper pyrithione by inhalation.

Due to the classification of the products for Eye damage 1 (H318), protective goggles or similar eye protection should be used for tasks where workers are 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 Meta 1 (Netwax NI Gold Light) and the modified product in Meta SPC 2 (Netwax NI Gold), assuming use of chemical protective gloves only (the indicative hand exposure values in the handling model 2 is actual measured values inside gloves).

As for Netwax NI Goldold and Netwax NI Gold Plus, acceptable risk is demonstrated, assuming use of gloves and uncoated cotton coverall.

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

The use of gloves when performing this task should be required.

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

The Netkem products are not for use by non-professionals.

***Risk for the general public***

Bystanders will not come in contact with the treated nets used for aquaculture.

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

An acceptable risk is identified for potential exposure via food contamination. This is based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force.

As for pyrithione, an acceptable risk is identified for potential exposure via food contamination based on a rough calculation. It should be noted that the inherent properties of pyrithione combined with the relatively rapid degradation of pyrithione in natural aquatic systems, make it unlikely to reach high concentrations in aquatic species.

Exposure via food contamination may need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

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

There are no substances of concern in the products to be considered.

Exposure calculations have been made for the two substances separately and presented in the report. A traditional combined exposure assessment to multiple active substances within the biocidal product in accordance with the BPR Guidance; i.e. summing up the hazard quotients (HQ) for the two substances (ECHA, 2017 a, chapter 4.4.1.) has not been done. However, as both substances are copper compounds, exposure calculations have been made also for the total copper content (i.e. [Cu2O]\*0,888 and [CuPT]\*0.201). The exposure calculations are included in the attached excel spread sheet

(HH\_Exposure\_NetKem\_Dicopper Oxide\_Copper Pyrithione BPF.xlsx).

The contribution of copper from copper pyrithion is minor compared to the contribution of copper from dicopper oxide. As for the scenario with the highest risk, treatment of nets with antifouling product, the outcome of the risk assessment would be the same if total copper equivalents are used rather than copper equivalents from dicopper oxide.

***Endocrine disrupting potential***

According to the assessment performed according to the CA-March21-Doc.4.3\_Final "Bridging Biocides with REACH", none of the formulants contained in the Dicopper Oxide/Copper Pyrithione Biocidal Product Family are identified as endocrine disruptors.

The complete assessment is available in the confidential annex section 3.

### 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 pyrithione (CuPT). The Dicopper Oxide/Copper Pyrithione BPF does not contain any substances of concern that contribute to the risk to the environment. See the confidential annex for more information on the substances of concern assessment.

Regarding the exposure to the environment from the use of the Dicopper Oxide/Copper Pyrithione BPF, the harmonised scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms (ECHA, 2015b), 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). The latter represents an adjustment of the EU scenario to better reflect Norwegian fish farm conditions.

#### Effects assessment on the environment

Dicopper oxide

An evaluation of the effect data for the active substance with relevance to the aquatic compartment can be found in the 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, 2019) 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. Of the PNECs presented in the CAR, the PNECsurrounding water of 1.15 µg/L was chosen for the risk assessment based on an assessment of the DOC levels and the fact that the area relevant for PEC calculation in the fish farm scenarios includes both the area directly underneath the fish farm and transitional zones / surrounding waters.

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 pyrithione

An evaluation of the effect data for the active substance with relevance to the aquatic compartment can be found in the CAR for copper pyrithione (PT21, 2014). Effect data are available for copper-, zinc-, and sodium pyrithione, and read across from the zinc- and sodium pyrithione studies are motivated by the behaviour of these substances in dilutions where the pyrithiones transchelate and form a pattern of mainly the free pyrithione species. EU agreed PNECs are presented in the table below.

|  |  |  |
| --- | --- | --- |
| **PNEC** | **Result** | **Reference** |
| PNECsea | 17.6 ng/L | CAR copper pyrithione PT21, 2014 |
| PNECsediment | 0.0085 mg pyrithione/kg dw | CAR copper pyrithione PT21, 2014 |

The PNECsea derived for pyrithione is based on laboratory acute and chronic studies using (sodium-, copper-, or zinc) pyrithione. The base set (fish, invertebrate, algae) is complete for long-term toxicity to marine species. In addition, short-term ecotoxicity data from species representing additional marine taxonomic groups (echinoderms, mollusc, tunicate) are available. The most sensitive species was the algae *Skeletonema costatum,* and the PNEC was derived by calculating the time weighted average (TWA) of the geometric mean of four tests with this species. The geometric mean TWA was 0.176 µg/L and an assessment factor of 10 gives a PNECsea of 0.0176 µg/L.

The PNECsediment for pyrithion is based on four different tests performed for sediment dwelling organisms with zinc- or copper pyrithione. Of the three long-term NOECs from the sediment tests, the fresh water *Hyallela azteca* was considered the most reliable. The test was considered an acute test and the EC50 of 8.5 mg/kg dw and an assessment factor of 1000 gives a PNECsediment of 8.5 µg pyrithione/kg sediment dry weight (dw).

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

It is considered that the ecotoxicological information on the active substances, dicopper oxide and copper pyrithione (presented in detail in the active substance dossiers Doc. IIIA, section 7), and the data provided on the components of the product are sufficient to enable a decision concerning the classification of the products. A study using the formulated products are, therefore, not considered necessary.

***Further Ecotoxicological studies***

All information on the ecotoxicology of the products can be extrapolated from the information on the active substances and co-formulants. Ecotoxicity data for the active substances are summarised in the Competent Authority Reports (Dicopper Oxide, Product-type 21, France, 2016 and Copper Pyrithione, Product-type 21, Sweden, 2014). No additional testing with the product is, therefore, considered necessary

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

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

The products are not in the form of bait or granules and therefore this endpoint does not apply.

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

The products are not in the form of bait or granules and therefore this endpoint does not apply.

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

The products are applied to nets used in fish farms which are situated at sea (off-shore). Since the fish farms cover a small area of the vast ocean there is no exposure to a large proportion of a specific habitat, therefore, data are not required.

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

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

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

Fate and behaviour of 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 pyrithione

The fate and behaviour of copper pyrithine is described in the CAR for the active substance copper pyrithione (PT21, 2014). Metalorganic compounds such as copper pyrithione, zinc pyrithione, sodium pyrihione form ions when dissolved in water and has the potential to appear as many different species of metal chalates. It is reasonable to assume that these ions (e.g. CuPT+, PT–) due to their electrical charge have different physical-chemical properties compared to the dissolved neutral salt molecule (hydrated CuPT2, ZnPT2, NaPT). The species pattern (of ions and neutral molecules) in a water solution is a function of water composition with respect to pH, DOC, trace metal concentration, and the total pyrithione concentration. In waters where the total pyrithione concentration is low, for instance in seawater, the pattern of pyrithione ions is likely dominated by the free pyrithione ion, PT–. This is predicted from speciation calculations and is also supported by experimental observations. In some systems, such as the soil/porewater, more ions and complexes are probably formed, otherwise it is difficult to explain the experimental observations (positive and negative pH dependency).

The pyrithione moiety is readily biodegradable. The relevant metabolite 2-pyridine sulphonic acid (PSA), was also readily biodegradable in the OECD test, with 73% mineralised after 28 days.

Biodegradation rates were experimentally estimated for aerobic and anerobic conditions in water only, and water/sediment combined. Biodegradation was also demonstrated to occur in soil and in sewage treatment plants. The degradation profile is well identified, passing through several transient degradants to a final somewhat more persistent degradant PSA. It is obvious that also the copper ion is a metabolite from copper pyrithione.

Pyrithione degraded very quickly in the aerobic and anaerobic aquatic environment. In the studies conducted according to U.S. EPA guidelines, degradation was biphasic, with a fast initial rate followed by a slower rate in aerobic and anaerobic marine and freshwater sediment systems in the dark. In the studies conducted at ~50 ng/g, the initial rapid degradation in the water phase proceeded with a half-life of about 1 hour or less under both aerobic and anaerobic conditions. During the slower second degradation phase the aerobic degradation half-life was about 4 days and the anaerobic degradation half-life was about 19 hours

Pyrithione can under certain conditions degrade hydrolytically and the rate seem to be faster at lower concentration.

Photolysis is very rapid in the laboratory, and probably also in the field, again leading to the final somewhat persistent degradant PSA.

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

Information on the active substance is considered sufficient. No further testing is required.

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

Information on the active substance is considered sufficient. No further testing is required.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not relevant. The products will not be sprayed outdoors.

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

Not relevant. The products will not be sprayed outdoors and large scale dust formation is unlikely

#### Environmental exposure assessment and risk characterisation

Exposure to the environment from the use of the Dicopper Oxide/Copper Pyrithione BPF has been assessed as follows:

1. An assessment is based on the EU fish farm scenario document agreed at EU level.
2. An assessment with special regard to Norwegian fish farms has been conducted based on the Norwegian fish farm scenario document. This represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway. The most notable adjustments made in the Norwegian fish scenario as compared to the EU fish farm scenario, are that the net size (area) and sea depth is increased, the flow velocity is very slightly increased, and the parameters related to (suspended) organic matter have been adjusted. All the adjustments have been done following an investigation of information for 232 fish farm facilities which were considered relevant, i.e. they are marine salmon, trout and rainbow trout farms, and they have a moderate to high production capacity (in order to capture the trend towards larger fish farms). 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. |
| Emission Scenario Document | For the assessment covering use in the EU, the EU fish farm scenario was used:  *Scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms. Norwegian Environmental Agency, 2015.*  For the assessment representative for Norway, the Norwegian fish farm scenario was used:  *A Norwegian environmental emission scenario for fish farms - Adjustment of the EU scenario (2015) to better represent national conditions. Norwegian Environmental Agency, 2019.* |
| Approach | MAMPEC v.3.1 was used for the modelling.  For the active substances, agreed values from the CARs were used as input. For other environmental parameters, default values for the environmental parameters given in the above-mentioned scenario documents were used, in addition to product-specific values where applicable. |
| Distribution in the environment | The PEC values in water and sediment were calculated with MAMPEC v.3.1 based on the input described above. |
| Life cycle steps assessed | |  |  | | --- | --- | | Production/formulation | N | | Application | N | | Service life | Y | |

***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.

Screenshot of the MAMPEC environment for both EU and NO scenarios and compounds input parameters are presented in confidential annex. All calculations of Elocal are available upon request.

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

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

1 Please see the [Emission scenario for nets used in fish farms (ECHA, 2015b)](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** | **Value** | **Unit** | **Reference** |
| **Copper (total)** | Molecular mass | 63.5 | g/mol | PT 21 ESD excel copper |
| Saturized vapour pressure at 20°C | 0 | Pa |
| Solubility at 20°C | 0.001 | g/m3 |
| Kd | 132 | m3/kg |
| **Copper Pyrithione** | Molecular mass | 315.85 | g/mol | PT 21 ESD excel pyrithione |
| Saturized vapour pressure at 20°C | 5 x 10-7 | Pa |
| Solubility at 20°C | 0.06 | g/m3 |
| Partition coefficient (Koc)  DT50 for biodegradation in water | 4.00  21 | 10 log Koc  days |

**Concentration of active ingredients in products**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Product** | **Density1 (g/cm3)** | **Concentration of a.i. in product (%)** | | **Concentration of a.i. in product (g/L)** | | |
| **Dicopper oxide** | **Pyrithione** | | **Copper2** | **Pyrithione** |
| Meta SPC 1 | Netwax NI Gold (Light) | 1.1830 | 18 | 0.24 | | 187.39 | 2.84 |
| Meta SPC 2 | Netwax NI Goldold3  Netwax NI Gold  Netwax NI Gold Plus | 1.226  1.226  1.226 | 21.5  21.5  25 | 1.4  0.75  2.5 | | 231.96  231.96  268.31 | 17.16  9.195  30.49 |

1 Relative density values are from study data, please see Section 2.2.2.

2 Copper equivalent: dicopper oxide (88.8%)

3 "Netwax NI Gold" refers to the reformulated Netwax NI Gold product with a reduced pyrithione content (0.75%) while "Netwax NI Goldold" refers to the product originally included in the BPF

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 and the Norwegian fish farm scenario.

**Daily emission outputs (Elocal)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **EU fish farm scenario** | | **Norwegian fish farm scenario** | |
| **Copper**  **g/d** | **Pyrithione**  **g/d** | **Copper**  **g/d** | **Pyrithione**  **g/d** |
| Netwax NI Gold (Light) | 15300 | 232 | 23296 | 353 |
| Netwax NI Goldold | 18939 | 1401 | 28837 | 2133 |
| Netwax NI Gold | 18939 | 751 | 28837 | 1143 |
| Netwax NI Gold Plus | 21907 | 2489 | 33356 | 3791 |

**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 with default values***

***Meta-SPC 1***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EU fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| Netwax NI Gold (Light) | **Copper** | 1.30 | **1.13** | **1.42** | 42.66 | 0.43 | 0.79 |
| **Pyrithione** | 0.01 | 0.29 | 0.003 | 0.36 |

***Meta-SPC 2***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EU fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| Netwax NI Goldold | **Copper** | 1.35 | **1.17** | **2.91** | 48.98 | 0.50 | **2.65** |
| **Pyrithione** | 0.03 | **1.73** | 0.02 | **2.15** |
| Netwax NI Gold | **Copper** | 1.35 | **1.17** | **2.10** | 48.98 | 0.50 | **1.65** |
| **Pyrithione** | 0.0163 | 0.93 | 0.0098 | **1.15** |
| Netwax NI Gold Plus | **Copper** | 1.39 | **1.21** | **4.28** | 54.13 | 0.55 | **4.37** |
| **Pyrithione** | 0.05 | **3.08** | 0.03 | **3.82** |

In the tier 1 calculations, the combined PEC/PNEC ratios for PECdissolved/PNECwater were above the trigger value for all products. The combined PEC/PNEC ratios for PECsuspended matter/PNECsediment were above the trigger value the products in Meta-SPC 2.

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

**Meta-SPC 1**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Norwegian fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| Netwax NI Gold (Light) | **Copper** | 1.17 | 1.02 | **1.10** | 25.90 | 0.26 | 0.47 |
| **Pyrithione** | 0.001 | 0.08 | 0.002 | 0.21 |

**Meta-SPC 2**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Norwegian fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| Netwax NI Goldold | **Copper** | 1.19 | 1.04 | **1.50** | 28.23 | 0.29 | **1.56** |
| **Pyrithione** | 0.008 | 0.46 | 0.011 | **1.27** |
| Netwax NI Gold | **Copper** | 1.19 | 1.04 | **1.28** | 28.23 | 0.29 | 0.97 |
| **Pyrithione** | 0.004 | 0.25 | 0.006 | 0.68 |
| Netwax NI Gold Plus | **Copper** | 1.21 | **1.05** | **1.87** | 30.13 | 0.31 | **2.57** |
| **Pyrithione** | 0.01 | 0.82 | 0.02 | **2.26** |

In calculations with the Norwegian fish farm scenario, the combined PEC/PNEC ratios for PECdissolved/PNECwater were above the trigger value for all products. The combined PEC/PNEC ratios for PECsuspended matter/PNECsediment were above the trigger value for all products except Netwax NI Gold (Light) and Netwax NI Gold.

#### Risk characterisation

***Atmosphere***

Dicopper oxide and copper pyrithione are not volatile therefore, emissions to the atmosphere are not expected.

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

Emissions to the STP are not anticipated for the intended use.

***Aquatic compartment***

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

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values\*, EU fish farm scenario** | | |
|  | **PECdissolved/PNECwater** | **PECsuspended matter/PNECsed** |
| **SPC 1** | | |
| **Netwax NI Gold (Light)** | | |
| Copper | **1.13** | 0.43 |
| Pyrithione | 0.29 | 0.36 |
| Combined | **1.42** | 0.79 |
| **SPC 2** | | |
| **Netwax NI Goldold** | | |
| Copper | **1.17** | 0.50 |
| Pyrithione | **1.73** | **2.15** |
| *Combined* | **2.91** | **2.65** |
| **Netwax NI Gold** | | |
| Copper | **1.17** | 0.50 |
| Pyrithione | 0.93 | **1.15** |
| Combined | **2.10** | **1.65** |
| **Netwax NI Gold Plus** | | |
| Copper | **1.21** | 0.55 |
| Pyrithione | **3.08** | **3.82** |
| *Combined* | **4.28** | **4.37** |

\*with background concentrations of copper

In the tier 1 calculations, there were exceedances of combined PEC/PNEC >1 for all products.

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

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values\*, Norwegian fish farm scenario** | | |
|  | **PECdissolved/PNECwater** | **PECsuspended matter/PNECsed** |
| **SPC 1** | | |
| **Netwax NI Gold (Light)** | | |
| Copper | 1.02 | 0.26 |
| Pyrithione | 0.08 | 0.21 |
| Combined | **1.10** | 0.47 |
| **SPC 2** | | |
| **Netwax NI Goldold** | | |
| Copper | 1.04 | 0.29 |
| Pyrithione | 0.46 | **1.27** |
| *Combined* | **1.50** | **1.56** |
| **Netwax NI Gold** | | |
| Copper | 1.04 | 0.29 |
| Pyrithione | 0.25 | 0.68 |
| *Combined* | **1.28** | 0.97 |
| **Netwax NI Gold Plus** | | |
| Copper | **1.05** | 0.31 |
| Pyrithione | 0.82 | **2.26** |
| *Combined* | **1.87** | **2.57** |

\*with background concentrations of copper

For the Norwegian fish farm scenario, there were exceedances of combined PECdissolved/PNECwater >1 for all products.

***Leaching behaviour (ADS)***

A field leaching trial has been submitted by the applicant (Antonsen, 2020a) in which the leaching of copper from net panels deployed in the sea in Norway (DrØbak, Oslo Fjord) was investigated over a 7.5-month period.

Net panels were treated with Netwax NI5 at a rate of 1.04 L product/kg net, dried and fastened to frames for deployment at sea. A reference sample was taken from the net at the start of the trial to determine the initial mass of copper on the net sample. Further samples were cut from the net and analysed at 6 sampling intervals over a period of 223 days. Before each sampling, the panel was washed with low pressure to remove any fouling from the net.

At each sampling interval, the amount of copper remaining on the net was determined and the percentage reduction compared to time 0 was calculated and is summarised in the table below.

|  |  |
| --- | --- |
| **Time (days)** | **Percentage change in Cu2O** |
| 0 | 0 |
| 6 | 2.3 |
| 26 | -7 |
| 69 | -12.9 |
| 128 | -12.5 |
| 168 | -23.5 |
| 223 | -36.3 |
| 223 | -32.8 |

The field leaching trial was conducted near Drøbak in the Oslo Fjord, Norway. During the trial, sea temperatures ranged from 7.8 to 18.6oC and salinities of between 2.4 and 3.0% were measured (24.0-30.0 ‰).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **Date (2019)** | | | | | | |
| **09 Apr.** | **15 Apr.** | **05 May** | **17 Jun.** | **15 Aug.** | **24 Sept.** | **18 Nov.** |
| Temperature (°C) | 7.8 | 9.1 | 8.9 | 16.3 | 18.6 | 14.6 | 8.5 |
| Salinity (%) | 2.8 | 2.7 | 3.0 | 2.4 | 2.8 | 2.9 | 2.8 |
| Oxygen (ml/l) | Range = 6.5 to 9.5 (average = 7.5) | | | | | | |

Additional data is available which supports the results of the field leaching study (Antonsen, 2020b). Following the deployment of treated nets for 260 days in an efficacy trial (Skjærvik, M.G. and Mortensen, H.; 2020a) on a fish farm at Hindholmen, Norway, nets treated with Netwax E5 Greenline (26.3 % Cu2O) and Netwax A7 Microfino (32.0 % Cu2O) were sampled and analysed to determine the amount of copper remaining on the nets. For both products, at the start of the efficacy trial, the nets had been treated at a rate of 1.04 L product/kg net, dried and fastened to frames for deployment at sea.

For each product formulation, the nets were washed on-shore after the efficacy trial was completed. Samples from three different net panels were analysed and compared to the amount of copper present on treated nets of the same type which had not been put out to sea to determine the percentage that had been leached during the trial period.

|  |  |  |
| --- | --- | --- |
| **Formulation** | **Replicate** | **% change in Cu2O after 260 days†** |
| Netwax E5 Greenline | 1 | 39.68 |
| 2 | 40.53 |
| 3 | 39.18 |
| Netwax A7 Microfino | 1 | 40.30 |
| 2 | 59.30 |
| 3 | 40.60 |

**†**Nets were deployed from 27.05.19 to 11.02.2020

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Site** | **Coordinates** | **Trial period** | | **Farmed fish at site** | **Temperature (°C)\*** | | **Salinity (‰)\*** | |
| **From** | **To** | **Min.** | **Max.** | **Min.** | **Max.** |
| Hindholmen | 64 46.4360  11 6.4522 | 27.05.19 | 11.02.20 | From 28.08.19 to end of trial period | 4.2 | 16.0 | 24.7 | 30.6 |

\*Measured at 3 m depth.

Over the 260 day trial period, leaching from the treated nets was consistent between the two formulations used in the efficacy trial.

In addition, following the deployment of treated nets for 243 days in an efficacy trial (Skjærvik, M.G. and Mortensen, H.; 2020b) carried out at an Andromeda Group Niordseas S.L. location in Spain (nearby Alicante) in the Mediterranean Sea. Nets treated with Netwax NI 5 (2 nets treated with 26.3% Cu2O), Netwax E5 Greenline (26.3% Cu2O) and Netwax A5 Microfino (26.0% Cu2O) were sampled and analysed to determine the amount of dicopper oxide remaining on the nets.

The average temperature for the deployment period if the nets was 24.6°C (the minimum was 19.7°C and maximum was 28.0°C). The samples were deployed at sea for 243 days and then returned to Norway for analysis. The analysis was performed by Nordox AS, Norway using their standard procedures for the determination of total copper in the NetKem AS products (the methods used by Nordox AS are Nordox AN-10 (based on ASTM D283-84 (1999)) and Nordox AN-52 (Atomic Absorption Spectroscopy (AAS)).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Label** | **Dicopper Oxide Concentration (%)** | **Date** | **Days** | **Weight (g)** | **Measured amount in paint**  **Total Cu, %** | **Converted amount in paint Cu2O, gr** | **Total reduction of Cu2O,**  **%** |
| Net 0, reference, Sample taken at day 0 | - | 09.04.2019 | - | 1.19 | 45.3 | 0.213 | - |
| Net A, Untreated net |  | 09.04.2019 | - | 0.78 | N/A | - | - |
| Netwax NI5, Frame 1  Spania, (15) | 26.3% | 19.10.2020 | 243 | 1.09 | 38.6 | 0.136 | -36.1 % |
| Netwax NI5, Frame 3  Spania, (17) | 26.3% | 19.10.2020 | 243 | 1.08 | 38.3 | 0.131 | -38.6 % |
| Netwax A5 MF, Frame 1  Spania, (15) | 26.0% | 19.10.2020 | 243 | 1.08 | 40.4 | 0.138 | -35.3 % |
| Netwax E5 GL, Frame 1  Spania, (15) | 26.3% | 19.10.2020 | 243 | 1.06 | 43.0 | 0.137 | -35.7 % |

†Nets were deployed from 09.05.19 to 07.01.2020

After deployment for 243 days at sea the average reduction of dicopper oxide during this period was 36.4%.

|  |  |
| --- | --- |
| **Conclusion** | |
| Justification for the value/conclusion | In a field trial (Antonsen 2020a), conducted under best case environmental conditions for 233 days, an average of approximately 35% Cu2O was shown to leach from treated nets.  The leaching behavior determined in Antonsen (2020a) is supported by additional data obtained following deployment of treated nets in an efficacy trial (Antonsen, 2020b). Approximately 40 % losses were estimated based on the quantity of copper remaining on the nets at the end of the trail period. These leaching rates are estimated based on copper measurements from a single time point only and are based on few replicates but are consistent with the results observed over the field leaching trial of Antonsen (2020a).  Antonsen (2020a) was conducted using the Netwax NI5 formulation (26.3 % dicopper oxide). Antonsen (2020b) was conducted using the formulations Netwax E5 Greenline (26.3 % Cu2O) and Netwax A7 Microfino (32.0 % Cu2O). All the formulations in the product family consist of the same paint matrix with different active substance contents. The results of Antonsen (2020a) and Antonsen (2020b) show that leaching from the treated nets is consistent between the formulations, therefore extrapolation of the leaching data obtained using Netwax NI5 to other products within the product family may be considered justified.  Antonsen (2020a) was conducted near Drøbak in the narrow part of the Oslo Fjord. Antonsen (2020b) was conducted on a fish farm at Hindholmen, which is located on the Norwegian coast (open sea). Similar leaching rates were observed at both locations despite different environmental conditions. Therefore, extrapolation of the field leaching data from Antonsen (2020a) to other locations is considered justified.  The average of the Day 223 samples from Antonsen (2020a) and the 6 replicates from Antonsen (2020b) gives a refined Fa.i. of 0.41 for copper.  In addition, leaching data were obtained from an efficacy trial (Skjærvik, M.G. and Mortensen, H.; 2020b) near Alicante, Spain. The results show that after deployment for 243 days in the Mediterranean Sea, the average reduction of dicopper oxide was 36.4% which is comparable to the reduction in dicopper oxide observed at both sites in Norway.  We therefore consider that the refined Fa.i. of 0.41 for copper can be used also for Spain. |

According to the applicant, the deployment time for the Dicopper Oxide/Copper Pyrithione BPF is 270 days. As a refinement, the deployment time has been increased from 180 days to 270 days which is supported for all products in the BPF by the efficacy data for Netwax NI Gold Light (this product has the lowest active substance concentration (18.0% Dicopper Oxide, 0.24% copper pyrithione)). Three of the efficacy trials were conducted in Norway (duration from 260-339 days) and in Spain (duration 243 days).

The Norwegian Environment Agency has re-calculated PEC values for the EU fish farm scenario and Norwegian fish farm scenario using refined copper fraction of release a.i. per deployment time of nets (F a.i.), and using refined deployment times of 270 days. Finally, as the application rate for the products in the biocidal products family were expressed as kg per kg of dry net, the highest amount expressed in kilogram (i.e., 1.2 kg) was divided by product relative density the values in order to obtain the coverage values (1.0144 for SPC 1 (Netwax NI Gold (Light)) and 0.9788 for the products in SPC 2. Note that the Relative density values are from study data, please see Section 2.2.2.

**Refined daily emission outputs (Elocal)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **EU fish farm scenario** | | **Norwegian fish farm scenario** | |
| **Copper**  **g/d** | **Pyrithione**  **g/d** | **Copper**  **g/d** | **Pyrithione**  **g/d** |
| Netwax NI Gold (Light) | 5303 | 157 | 8074 | 239 |
| Netwax NI Goldold | 6334 | 914 | 9644 | 1392 |
| Netwax NI Gold | 6334 | 490 | 9644 | 746 |
| Netwax NI Gold Plus | 7326 | 1624 | 11155 | 2473 |

In addition to the refined PEC values based on the refined copper fraction of release a.i per deployment time of nets (F a.i.), and refined deployment times, the PECsediment was refined according to the consolidated list of PT21 technical agreements (TM II 2013 – Env- Item 3a – Consolidated PT21 Technical Agreements, Version 1.2 September 2013) by using the PECsediment at 3 cm depth instead of the PECsuspended matter. The output value for PECsediment after 20 years was calculated for pyrithione and copper.

Use of PECsediment as a refinement to PECsuspended matter for pyrithione can be justified as pyrithione has been shown to (bio)degrade in both water and sediment. However, only degradation in the water phase is included in the input parameters for pyrithione in the PEC modelling in mampec. Degradation of pyrithione would thus be expected to occur in the water phase, on suspended sediment and in the settled sediment, resulting in lower concentration in the settled sediment than in the suspended matter. As such, the PECsediment might be a better reflection of the exposure to sediment dwelling organisms.

Use of PECsediment as a refinement to PECsuspended matter for copper can be justified as the background copper concentration used in the risk characterisation is based on the copper already accumulated in the sediment. Using the 20 year PECsediment in the risk assessment would encompass both the accumulated background and the continuous addition of copper from sedimentation of suspended matter. As such, the PECsediment might be a better reflection of the exposure to sediment dwelling organisms.

***Refined PEC values and risk characterisation: the EU fish farm scenario***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EU fish farm scenario**  **Refined PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| **Meta SPC 1** | | | | | | | |
| Netwax NI Gold (Light) | **Copper** | 1.17 | 1.02 | **1.21** | 42.66 | 0.43 | 0.79 |
| **Pyrithione** | 0.003 | 0.19 | 0.003 | 0.36 |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PEC sediment**  [µg/g dw] | **PEC sediment / PNECsediment** | **Combined PEC sediment / PNECsediment** |
| **Meta-SPC 2** | | | | | | | |
| Netwax NI Goldold | **Copper** | 1.18 | 1.03 | **2.16** | 17.36 | 0.18 | 0.34 |
| **Pyrithione** | 0.02 | **1.13** | 0.0014 | 0.16 |
| Netwax NI Gold | **Copper** | 1.18 | 1.03 | **1.64** | 17.36 | 0.18 | 0.26 |
| **Pyrithione** | 0.01 | 0.61 | 0.0007 | 0.09 |
| Netwax NI Gold Plus | **Copper** | 1.20 | 1.04 | **3.05** | 17.56 | 0.18 | 0.46 |
| **Pyrithione** | 0.04 | **2.01** | 0.0024 | 0.29 |

*.*

All products have an unacceptable environmental risk based on the combined refined PECdissolved/PNECwater calculations which are all above the threshold of 1.

***Refined PEC values and risk characterisation: Norwegian fish farm scenario***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Norwegian fish farm scenario**  **Refined PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | | | | |
|  | | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater** | **Combined PECdissolved / PNECwater** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment** | **Combined PECsuspended sediment / PNECsediment** |
| **Meta-SPC 1** | | | | | | | |
| Netwax NI Gold (Light) | **Copper** | 1.13 | 0.98 | 1.0 | 19.5 | 0.2 | 0.34 |
| **Pyrithione** | 0.001 | 0.05 | 0.001 | 0.14 |
| **Meta-SPC 2** | | | | | | | |
| Netwax NI Goldold | **Copper** | 1.13 | 0.98 | **1.28** | 20.16 | 0.2 | 1.0 |
| **Pyrithione** | 0.005 | 0.30 | 0.007 | 0.83 |
| Netwax NI Gold | **Copper** | 1.13 | 0.98 | **1.14** | 20.16 | 0.2 | 0.65 |
| **Pyrithione** | 0.003 | 0.16 | 0.004 | 0.45 |
| Netwax NI Gold Plus | **Copper** | 1.14 | 0.99 | **1.52** | 20.8 | 0.21 | **1.69** |
| **Pyrithione** | 0.01 | 0.53 | 0.01 | **1.48** |

All products in Meta-SPC 2 have an unacceptable environmental risk based on the combined refined PECdissolved/PNECwater calculations which are all above the threshold of 1 under Norwegian conditions.

**Aquatic bioconcentration**

Dicopper oxide

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

Copper pyrithione

The CAR of the active substance copper pyrithione (PT21, 2014) states that the observed bioconcentration factor (BCF) for aquatic species from marine experimental studies with oyster range from 8.3 to 64, whereas the QSAR estimated BCF predicted from KOW for the same experiments ranged from 1.4 to 52. The typevalue for BCF in fish is 7.7 l/kg ww or log BCF = 0.88 log (l/kg ww). For BCF in invertebrates the typevalue is 8.0 l/kg ww or log BCF = 0.91 log (l/kg ww). These type values are one to two orders of magnitude lower than log BCF value of 3.0, above which bioconcentration is generally considered to be of concern. It is also acceptable judged by the criteria of BCF> 2000 in the TnsG of Annex 1 inclusion. The low BCF values for pyrithione are not indicative of potential bioaccumulation. The low BCF, combined with the relatively rapid degradation of pyrithione in natural aquatic systems (leading to lower exposure), and in vertebrates tested in the human toxicology data set indicates that the inherent properties of pyrithione makes it unlikely to reach high concentrations in aquatic species, either directly or through the food webs (secondary poisoning). This is further supported by the fact that in monitoring studies, so far it has not been possible to detect pyrithione in aquatic biota, in spite of the long historical use of pyrithiones.

***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, 2014c[[8]](#footnote-9)), 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.

Mixture toxicity tier II

Endpoints used for tier II mixture toxicity assessment for the aquatic compartment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 |
| Pyrithione | Fish | *Pimephales promelas* | NOEC (TWA) | 0.98 | 10 |
| Algae marine | *Skeletonema costatum* | NOEC (TWA) | 0.176 | 10 |
| Invertebrate | *Arabica punctulata* | NOEC (TWA) | 1.0 | 10 |
| **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.  **Pyrithione** assessment factor (AF) of 10. For the mixture toxicity assessment, the TWA NOECs from chronic/sub lethal key studies were selected from the assessment report for copper pyrithione. This includes the geometric mean of the four tests on *S. costatum* that was also used for the PNECsea calculation. | | | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Mixtox EU scenario – PEC refined by using leaching rate of 0.41 for Cu and deployment time of 270 days** | | | | | | | | |
| **Product** | **Trophic level** | **Substance** | **NOEC (µg/L)** | **Assessment factor (AF)** | **NOEC/AF** | **PEC** | **PEC/** | **RQProduct** |
| **(µg/L)** | **(NOEC/AF)** |
| **Meta-SPC 1** | | | | | | | | |
| **Netwax Gold Light** | Fish | Copper | 55 | 2 | 27.50 | 1.17 | 0.04 | 0.08 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.003 | 0.03 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.17 | 0.58 | 0.62 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.003 | 0.03 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.17 | 0.81 | 1.00 |
| Pyrithione | 0.18 | 10 | 0.02 | 0.003 | 0.19 |
| **Meta-SPC 2** | | | | | | | | |
| **Netwax NI Goldold** | Fish | Copper | 55 | 2 | 27.50 | 1.18 | 0.04 | 0.25 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.02 | 0.20 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.18 | 0.59 | 0.79 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.02 | 0.20 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.18 | 0.82 | **1.95** |
| Pyrithione | 0.18 | 10 | 0.02 | 0.02 | 1.13 |
| **Netwax Gold** | Fish | Copper | 55 | 2 | 27.50 | 1.18 | 0.04 | 0.15 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.01 | 0.11 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.18 | 0.59 | 0.70 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.01 | 0.11 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.18 | 0.82 | **1.42** |
| Pyrithione | 0.18 | 10 | 0.02 | 0.01 | 0.61 |
| **Netwax NI Gold Plus** | Fish | Copper | 55 | 2 | 27.50 | 1.20 | 0.04 | 0.40 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.04 | 0.36 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.20 | 0.60 | 0.95 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.04 | 0.35 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.20 | 0.83 | **2.83** |
| Pyrithione | 0.18 | 10 | 0.02 | 0.04 | 2.01 |

Based on the Tier II mixtox assessment, only one product, Netwax NI Gold (Light) in Meta-SPC 1 showed an acceptable environmental risk for the EU scenario. The RQ values were above the threshold of 1 for at least one throphic group for the remaining products, even when using refined PEC values.

According to the applicant, when concluding on the risk assessment, the minor exceedance of PEC/PNEC could be considered further in the context of the protection goals of the risk assessment for the different MS:

* The product family is intended to target diatoms, aquatic plants and aquatic animals (barnacles, mussels) that foul fish nets.
* Dilution and dissipation in the areas outside the fish farm might reduce the concentrations further, and the risk to algae and invertebrates in the wider environment might be lower.
* As stated in the Emission scenario for nets used in fish farms (ECHA, 2015b), this scenario is mainly meant as a first-tier approach for use during the product authorisation stage. For some of the parameters, values might vary between the countries. Therefore, the default/standard parameter values are used as a first-tier exposure assessment of products where there is a lack of better suited regional values. If there is knowledge within a specific country that the standard values do not represent the local conditions, the values could be changed.

For the Norwegian fish farm scenario, Meta SPC 1 (Netwax NI Gold Light) shows acceptable risk at the mix tox tier 1 (simple summation of individual PEC/PNEC ratios) and is therefore not included in the tier II for mixtox.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Mixtox NO scenario - CU PEC refined by using leaching rate of 0.41 and deployment time of 270 days** | | | | | | | | |
| **Product** | **Trophic level** | **Substance** | **NOEC (µg/L)** | **Assessment factor (AF)** | **NOEC/AF** | **PEC** | **PEC/** | **RQProduct** |
| **(µg/L)** | **(NOEC/AF)** |
| **Meta-SPC 2** | | | | | | | | |
| **Netwax NI Gold** | Fish | Copper | 55 | 2 | 27.50 | 1.13 | 0.04 | 0.07 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.003 | 0.03 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.13 | 0.57 | 0.59 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.003 | 0.03 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.13 | 0.78 | 0.94 |
| Pyrithione | 0.18 | 10 | 0.02 | 0.003 | 0.16 |
| **Netwax NI Gold old** | Fish | Copper | 55 | 2 | 27.50 | 1.13 | 0.04 | 0.10 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.005 | 0.05 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.13 | 0.57 | 0.62 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.005 | 0.05 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.13 | 0.78 | **1.08** |
| Pyrithione | 0.18 | 10 | 0.02 | 0.005 | 0.30 |
| **Netwax NI Gold Plus** | Fish | Copper | 55 | 2 | 27.50 | 1.14 | 0.04 | 0.14 |
| Pyrithione | 0.98 | 10 | 0.10 | 0.009 | 0.10 |
| Invertebrate | Copper | 4.00 | 2 | 2.00 | 1.14 | 0.57 | 0.66 |
| Pyrithione | 1.00 | 10 | 0.10 | 0.009 | 0.09 |
| Algae | Copper | 2.90 | 2 | 1.45 | 1.14 | 0.78 | **1.32** |
| Pyrithione | 0.18 | 10 | 0.02 | 0.009 | 0.53 |

Based on the Tier II mixtox assessment, Netwax NI Gold showed acceptable environmental risks for the Norwegian scenario with RQ values for the most sensitive trophic level (algae) less than the trigger of 1.0.

|  |  |  |
| --- | --- | --- |
| ***Risk characterisation***  **Norwegian fish farm scenario** | | |
|  | **Water** | **Sediment** |
| **Meta-SPC 1** | | |
| **Netwax NI Gold (Light)** | | |
| *Combined copper and pyrithione* | Combined PECdissolved / PNECwater = 1.0 | Combined PECsuspended sediment / PNECsediment= 0.34 |
| **Meta-SPC 2** | | |
| **Netwax NI Gold** | | |
| *Combined copper and pyrithione* | RQproduct = 0.94 (algae) | Combined PECsuspended sediment / PNECsediment= 0.65 |
| ***Risk characterisation***  **EU fish farm scenario** | | |
| **Meta-SPC 1** | | |
| **Netwax NI Gold (Light)** | | |
| *Combined copper and pyrithione* | RQproduct = 1.0 (algae) | Combined PECsuspended sediment / PNECsediment= 0.79 |
| **Meta-SPC 2** | | |
| **Netwax NI Gold** | | |
| *Combined copper and pyrithione* | RQ product = **1.42** (algae) | Combined PEC sediment / PNECsediment= 0.26 |

***Overall Conclusion***

In summary, only the product in meta-**SPC 1** (Netwax NI Gold (Light)) showed an acceptable environmental risk in the EU scenario.

The products in both meta-**SPC 1 and 2**, Netwax NI Gold (Light) and Netwax NI Gold, showed acceptable environmental risk in the Norwegian fish farm scenario.

***Primary and secondary poisoning***

According to the ESD for PT21 (2004), primary and secondary poisoning may be of relevance for aquaculture use of antifoulants, however no exposure scenarios are available.

Primary poisoning

The product family will be applied to the surface of fish nets only. As they will not be applied indiscriminately in the environment, or in a form that is attractive as a food source (e.g. as a bait or in granular form), the risk of primary poisoning of non-target organisms is considered low.

Secondary poisoning

Dicopper oxide: An in-depth literature search showed the absence of copper bioaccumulation across the trophic chain in the aquatic and terrestrial food chains. Secondary poisoning is therefore considered unlikely.

Copper pyrithione: Copper pyrithione has a logKow value of < 3 and low BCF (fish = 0.88 log (l/kgwwt), invertebrates = 0.91 log (l/kgwwt)). Combined with the relatively rapid degradation of pyrithione in natural aquatic systems, this indicates that the inherent properties of pyrithione make it unlikely to reach high concentrations in aquatic species, either directly or through the food webs. This is further supported by the fact that in monitoring studies, pyrithione has not been detected in aquatic biota, despite the long historical use of pyrithiones.

### 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.

**Recommended methods and precautions concerning transport**

In accordance with ADR / RID / IMDG / IATA / ADN

UN number: 1760

UN proper shipping name: CORROSIVE LIQUID, N.O.S.

Transport document description: UN 1760 CORROSIVE LIQUID, N.O.S. (dicopper oxide, copper (I) oxide), 8, III, (E)

Transport hazard class(es): 8

Packing group: III

Marine pollutant: Yes

### Assessment of a combination of biocidal products

Not applicable.

### Comparative assessment

Not applicable.

# Annexes

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

**Section 3 Physical, chemical and technical properties**

**Section 4 Physical hazards and respective characteristics**

| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity Owner** | **Report date** | **Published/**  **Unpublished** | **Data Protection** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Apps, G | 2018a | Surface Tension testing on Netwax E8 Greenline and Netwax NI Gold Plus Biocide Formulations | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG412FD, UK | CEMR-8866 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-11-26 | Unpublished | Yes |
| Apps, G | 2018b | Surface Tension testing on Netwax E8 Greenline and Netwax NI Gold Plus Biocide Formulations | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG412FD, UK | CEMR-8866 (Amendment 1) | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-11-29 | Unpublished | Yes |
| Harding, L | 2018 | Physical and Chemical Testing of Netwax NI Gold. | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG412FD, UK | CEMR-8351 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2019 | Accelerated Storage Stability Study on Netwax NI Gold Light | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-9025  (Version 2) | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2019-11-06 | Unpublished | Yes |
| Harding, L | 2020 | Storage Stability Study on Netwax NI Gold Light | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-9027 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2020-04-09 | Unpublished | Yes |
| Siusiene, E. | 2022a | Physico-Chemical Testing on a Test Item of Netwax NI Gold Light | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016012492R1/2022 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-11-02 | Unpublished | Yes |
| Siusiene, E. | 2022b | Corrosivity to Metals Testing on a Test Item of Netwax NI3 | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016010435DR1/2022 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-11-07 | Unpublished | Yes |
| Siusiene, E. | 2022c | Corrosivity to Metals Testing on a Test Item of Netwax E8 Greenline | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016010435ER | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-11-07 | Unpublished | Yes |
| Walker, J. | 2022a | Netwax NI Gold Light: Determination of Wet Sieve and Persistent Foam | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road, Shardlow Derbyshire DE72 2GD UK | 8506627 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-20 | Unpublished | Yes |
| Walker, J. | 2022b | Netwax NI Gold Light: Determination of Pourability | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road, Shardlow Derbyshire DE72 2GD UK | 8493367 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-19 | Unpublished | Yes |
| Walker, J. | 2022c | Netwax NI Gold: Determination of Pourability | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road, Shardlow Derbyshire DE72 2GD UK | 8503460 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-19 | Unpublished | Yes |

**Section 5 Methods of detection and identification**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity Owner** | **Report date** | **Published/**  **Unpublished** | **Data Protection** |
| Apps, G | 2018c | Validation of method for the determination of total copper in Netpolish and Netwax formulations. | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG412FD, UK | CEMR-8406 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-11-29 | Unpublished | Yes |
| Wiles, J | 2018 | Validation of method for the determination of copper pyrithione in Netwax formulations. | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG412FD, UK | CEMR-8407 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-11-29 | Unpublished | Yes |

**Section 6 Effectiveness and target organisms**

| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity Owner** | **Report date** | **Published/**  **Unpublished** | **Data Protection** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Antonsen, R. | 2018 | TEST REPORT: Antifouling Trial 2018 – Klungervik and Dale, Haugesund | Mørenot Karmsund AS, Husøyvegen 270 4262 Avaldsnes , Norway | RA 19/11 2018 | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2018-11-27 | Unpublished | Yes |
| Hanssen, H. | 2018 | Comparative study of fish net coatings | LetSea AS, Torolv Kveldulvsons gate 29, 8800 Sandnessjøen, Norway | Project 1806 | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2018-11-06 | Unpublished | Yes |
| Skjærvik, M.G. & Mortensen, H. | 2020a | Testing of antifouling paint formulations at locations in Norway and Ireland. | Val FoU AS, Hestvikvegen 73 7970 Kolvereid, Norway | No report number | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-03-02  2020-06-24 (revised report) | Unpublished | Yes |
| Skjærvik, M.G. & Mortensen, H. | 2020b | Testing of antifouling paint formulations at a location in Spain | Val FoU AS, Hestvikvegen 73 7970 Kolvereid, Norway | No report number | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-04-23 | Unpublished | Yes |

**Section 7 Environmental fate and behaviour**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity Owner** | **Report date** | **Published/**  **Unpublished** | **Data Protection** |
| Antonsen, R | 2020a | NetKem AS – Trial report, total leaching of copper oxide in AF | NetKem AS | Not applicable | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-06-24 (revised report) | Unpublished | Yes |
| Antonsen, R | 2020b | NetKem AS – Trial report, Total leaching of dicopper oxide from nets treated with Netwax E5 Greenline and Netwax A7 Microfino | NetKem AS | Not applicable | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-06-24 | Unpublished | Yes |

**Section 8 Toxicological profile for humans and animals**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity Owner** | **Report date** | **Published/**  **Unpublished** | **Data Protection** |
| Blackstock, C. | 2019 | The *In Vitro* Percutaneous Absorption of [14C]-Copper Pyrithione in Two Formulations Through Human Split-Thickness Skin | Charles River Laboratories Edinburgh Ltd | Charles River Study No. 784321 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2019-11-21 | Unpublished | Yes |
| Fraser, G. and Cloke, D. | 2020 | Dicopper Oxide and Dicopper Oxide/Copper Pyrithione  Biocidal Product Families  Data from Operator Survey Performed for NetKem AS Products | - | 1701058.UK0-6389 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2020-04-23 | Unpublished | Yes |
| Toner, F. | 2019 | The *In Vitro* Percutaneous Absorption of Dicopper Oxide in Three Formulations through Human Skin. | Charles River Laboratories Edinburgh Ltd  Elphinstone Research Centre  Tranent  East Lothian  EH33 2NE, UK | 40889  (Report amendment 1) | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2019-11-05 | Unpublished | Yes |
| Vinall, J. | 2018a | Netwax NI Gold and Netwax E8 Greenline: Assessment of Ocular Irritation In Vitro Using the Bovine Corneal Opacity and Permeability Assay. | Charles River Laboratories Edinburgh Ltd  Elphinstone Research Centre  Tranent  East Lothian  EH33 2NE, UK | 39477 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-04-26 | Unpublished | Yes |
| Vinall, J. | 2018b | Netwax E8 Greenline, Netwax E5 Greenline, and Netwax NI Gold: MatTek EpiOcular™ Eye Irritation Test (EIT) for assessment of the Ocular Irritation potential of test items *in vitro*. | Charles River Laboratories Edinburgh Ltd  Elphinstone Research Centre  Tranent  East Lothian  EH33 2NE, UK | 39671 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-04-02 | Unpublished | Yes |

## Output tables from exposure assessment tools

### Output tables from the environment exposure assessments

**Environmental exposure assessment, EU fish farm scenario**

The following excel-files are available upon request:

Netkem CuPT\_EU scenario.xlsx

Netkem CuPT\_EU scenario refined PEC.xlsx

**Environmental exposure assessment, Norwegian fish farm scenario**

The following excel-files are available upon request:

Netkem CuPT\_NO scenario.xlsx

Netkem CuPT\_NO scenario refined PEC.xlsx

**Mixture-toxicity:**

The following excel-files are available upon request:

Netkem\_CuPT\_mixtox

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

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

### Output tables from the human exposure assessments

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

HH\_Exposure\_NetKem\_Dicopper Oxide\_Copper Pyrithione BPF.xlsx

## New information on the active substance

There are no new data to be considered.

## Residue behaviour

Not required.

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

Not required.

## Confidential annex

Please see the separate confidential annex.

**FERENCES**

* Bernhard et al., 2020; Monitoring Program for Pharmaceuticals, illegal substances and contaminants in farmed fish – Annual Report for 2019.
* Bloecher, N, Floerl, O (2018) Guidelines for efficacy testing of antifouling coatings for nets in field tests. Technical paper, Norwegian Environment Agency, Oslo. <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB>
* European Chemicals Agency (ECHA), 2014a. Assessment Report. Evaluation of the active substance Copper Pyrithione. Product type 21. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Sweden
* European Chemicals Agency (ECHA), 2014b. 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), 2014c. Transitional Guidance on mixture toxicity assessment for biocidal products for the environment.
* European Chemicals Agency (ECHA), 2015a. Biocides human health exposure methodology. Version 1. Helsinki.
* European Chemicals Agency (ECHA), 2015b. Emission scenario for nets used in fish farms.
* European Chemicals Agency (ECHA), 2016a. Assessment Report. Evaluation of the active substance Dicopper oxide. Product type 21. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. France
* European Chemicals Agency (ECHA), 2016b ECHA Report of Dermal Absorption of PT 21 Active Substances. Agreed at Human Health Working Group Meeting WG-V-2016 (9 December 2016)
* European Chemicals Agency (ECHA), 2016c. “Dermal absorption from antifouling products and other matrices that form a dry film during testing” Report of workshop held in Berlin 19 May 2016. Date of report 19 August 2016.
* European Chemicals Agency (ECHA), 2017a. Guidance on the Biocidal Products Regulation. Volume III. Human Health. Assessment & Evaluation (Part B+C), version 4.0, Helsinki.
* European Chemicals Agency (ECHA, 2017b). Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure. Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017).
* European Chemicals Agency (ECHA), 2018. Committee for Risk Assessment; RAC opinion proposing harmonised classification and labelling at EU level of pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O) pyridine-2(1H)-thionato-.kappa.S]zinc. Adopted 14 September 2018
* European Chemicals Agency (ECHA), 2019. Draft proposal: "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA".
* European Chemicals Agency (ECHA), 2020. Committee for Risk Assessment; RAC opinion proposing harmonised classification and labelling at EU level of Pyridine-2-thiol 1-oxide, sodium salt. Adopted 8 October 2020.
* European Commission (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L 353, 1-1355.
* European Food Safety Authority (EFSA): Guidance on dermal absorption. Buist, H. et al. 2017. EFSA Journal, Volume 15, Issue 6, June 2017.
* Human Exposure Expert Group (HEEG). 2010. Opinion 9. Default protection factors for protective clothing and gloves. Ispra, 27.01.2010.
* Human Exposure Expert Group (HEEG) opinion 17. Default human factor values for use in exposure assessment for biocidal products. Endorsed at TM II 2013.
* Lundebye, A-K, et al (2017). Lower levels of Persistent Organic Pollutants, metals and the marine omega 3-fatty acid DHA in farmed compared to wild Atlantic salmon (Salmo salar), Environmental Research 155 (2017) 49–59.
* NO, 2019. A Norwegian environmental emission scenario for nets used in fish farms – Adjustment of the EU scenario (2015) to better reflect national conditions (Norwegian Environment Agency, 2019) <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY>
* OECD Guideline for Testing of Chemicals, Guideline 428: Skin Absorption: In Vitro Method (2004a);
* OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 28; Guidance Document for the Conduct of Skin Absorption Studies (2004b)
* Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment (CA-March21-Doc.4.3\_Final "Bridging Biocides with REACH) (available from: <https://circabc.europa.eu/sd/a/987cb9c0-2c8e-45d6-b431-aa456d0584ea/CA-March21-Doc.4.3_Final_Bridging%20Biocides%20with%20REACH.docx>)
* CA-June22-Doc.4.8 - Identification as a substance of concern of a non-active substance meeting the criteria for being endocrine disruptor (available from: https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/c0a1c400-f330-4231-988b-3e77e20c3a1f/details)

1. Netwax NI Gold Plus not authorised, but test results for surface tension acceptable. [↑](#footnote-ref-2)
2. Netwax NI Gold was re-formulated. However, even though almost all studies are performed on the old formulation of Netwax NI Gold (hereby: Netwax NI Goldold), they are deemed to be representative for the new version of Netwax NI Gold. A comparison of the old and new formulation can be found in the confidential PAR. [↑](#footnote-ref-3)
3. Netwax NI Gold Plus was not authorised due to unacceptable human health risk. However, a read-across of the results for the surface tension is considered acceptable in this case. [↑](#footnote-ref-4)
4. Netwax NI Gold was re-formulated. However, even though all studies are performed on the old formulation of Netwax NI Gold (hereafter called "Netwax NI Goldold", they are deemed to be representative for the new version of Netwax NI Gold. [↑](#footnote-ref-5)
5. Argumentation included in IUCLID (1701058.UK0 - 3258 Eye Irritation 21 April 2022.docx) [↑](#footnote-ref-6)
6. OECD, 2004a; OECD, 2004b; EFSA, 2017; ECHA, 2016b; ECHA, 2016c [↑](#footnote-ref-7)
7. OECD, 2004a; OECD, 2004b;EFSA, 2017; ECHA, 2016b; ECHA, 2016c [↑](#footnote-ref-8)
8. ECHA, (2014). Transitional Guidance on mixture toxicity assessment for biocidal products for the environment. [↑](#footnote-ref-9)