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 Biocidal Product Family

Product type 21

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

Case Number in R4BP 3: BC-DT036545-23

Evaluating Competent Authority: Norway

Date: 07/June/2023

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# CONCLUSION

The Dicopper Oxide Biocidal Product Family (BPF) consists of products containing the active substance dicopper oxide. The products are suspension concentrates (= flowable concentrates) and suspension concentrates for direct application. The BPF is used for treatment of fish nets 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 falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The applicant originally applied for four meta SPCs with the products indicated below:

meta SPC 1 (Netpolish NI Low), meta SPC2 (Netpolish NI active), meta SPC 3 (Netrex AF) and meta SPC 4 (Netwax NI 3, Netwax NI 4, Netwax NI 5, Netwax NI 6, Netrex E4 Greenline/Netwax E4 Greenline, Netwax E5 Greenline, Netwax E6 Greenline, Netwax E7, Greenline, Netwax E8 Greenline, Netwax A5 Microfino, Netwax A7 Microfino, Netwax Gold T50 Sens/Netwax NI Gold XL, Netwax Gold T60 Sens and Netwax T4 Anti-bite).

However, in the risk assessment, sufficient efficacy was not demonstrated for the Netpolish products. Netwax T4 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 (for further information, see the confidential annex section 1.3). Furthermore, a risk was identified in the human health risk assessment for several products in meta SPC 4.

The modified BPF consists of 4 meta-SPCs. The structure of the biocidal product family into meta-SPCs is based on difference in classification, the need for separating different formulation types (concentrates versus RTU products) and difference in the risk assessment.

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 17.20-35.0% w/w dicopper oxide. The products are red or brown-red liquids with a pH range of 6.82-7.34 and a relative density of 1.19-1.3372 at ambient temperatures. The products have a shelf life of 9 months when stored at temperatures above 4oC and below 30oC.

The efficacy of the products proposed authorised has been demonstrated through field trials, assessing the efficacy of the net treatment under realistic conditions. The products are deemed to be sufficiently efficacious. There was not sufficient efficacy data to conclude on the efficacy for the two products with the lowest dicopper oxide content (Netpolish NI Low, 0.24 % w/w Cu2O and Netpolish NI Active, 2.4 % w/w Cu2O), and, hence, it is proposed not authorising these products.

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

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 for most products in the applied biocidal product family (Netrex AF, Netwax NI 3, Netwax NI 4, Netwax NI 5, Netwax NI 6, Netrex E4 Greenline/Netwax E4 Greenline, Netwax E8 Greenline and Netwax Gold T60 Sens), provided the workers wear double coverall (1% clothing penetration) and chemical resistant gloves. A borderline risk was identified for the products Netwax E5 Greenline and Netwax A5 Microfino (containing approximately 26% dicopper oxide).

Safe use could not be demonstrated even with use of double coveralls and gloves for four of the products included in the applied biocidal product family; Netwax E6 Greenline, Netwax E7 Greenline, Netwax A7 Microfino, Netwax Gold T50 Sens/Netwax NI Gold XL.

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. Safe use was demonstrated, assuming use of gloves only, for all products with acceptable risk for net treatment activities (the indicative hand exposure value in the exposure model was actual measured values inside gloves). For the two products for which a borderline risk was demonstrated for net treatment activities, an uncoated cotton coverall was additionally needed.

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

As a result of the risk assessment, the meta SPC structure was changed, and the range of active substance per meta SPC adjusted.

Risk to the environment from the use of the Dicopper oxide BPF has been assessed in two tiers. For the effects assessment, values agreed at EU level have been used. For the exposure assessment, the EU fish farm scenario was used as a first tier.  A second 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. A higher tier assessment based on field data has also been conducted.

In the tier 1 calculations, PECdissolved/PNECwater ratios based on PEC values calculated with the EU fish farm scenario were slightly above the trigger value for some products. However, the refined calculations with PEC values calculated from field data resulted in PEC/PNEC ratios ≤ 1 for Meta SPC 1, 2, and 4. In the refined calculations for the EU fish farm scenario, there were exceedances of PECdissolved/PNECwater>1 for the product in Meta SPC 3. Therefore, only the products in **meta**-**SPC 1, meta-SPC 2 and meta-SPC 4** showed an acceptable environmental risk in the EU scenario.

The products in all meta-**SPCs** showed acceptable environmental risk in the Norwegian fish farm scenario.

PEC/PNEC ratios were ≤ 1 for all products in the Norwegian fish farm scenario, indicating acceptable environmental risk.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identity of the product family

| **Dicopper Oxide Biocidal Product Family** | | |
| --- | --- | --- |
| **Identifier** | **Trade Name** | **cMS for the evaluation** |
| **Product family:** |  | Norway  Ireland  Spain  Denmark Iceland  Finland  Italy  Portugal  Greece  Croatia |
| **Meta SPC 1** | Netrex AF  Netwax NI 3  Netwax NI 4  Netrex E4 Greenline/  Netwax E4 Greenline\* |  |
| **Meta SPC 2** | Netwax E5 Greenline  Netwax A5 Microfino |
| **Meta SPC 3** | Netwax E8 Greenline  Netwax Gold T60 Sens |
| **Meta SPC 4** | Netwax NI 5  Netwax NI 6 |

\*tradenames for the same product

#### 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** |  | |

#### Manufacturer(s) 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 |

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

|  |  |
| --- | --- |
| **Active substance** | Dicopper Oxide |
| **Name of manufacturer** | Nordox AS |
| **Address of manufacturer** | Østensjøveien 13  N-0661 Oslo Norway |
| **Location of manufacturing sites** | Østensjøveien 13  N-0661 Oslo Norway |

### 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 substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **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** | 942g/ kg as cuprous oxide  837g/ kg as cooper (I) |
| **Structural formula** |  |

#### Candidate(s) for substitution

Dicopper oxide is not a candidate for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Dicopper Oxide  (in NORDOX CUPROUS OXIDE, RED, PAINT GRADE, >97 % Cu2O / NORDOX CUPROUS OXIDE, XLT-G, >94.0 % Cu2O / NORDOX CUPROUS OXIDE, AGRO GRADE >97 % Cu2O / NORDOX Microfino Grade Dicopper Oxide, >97 % Cu2O  \*see details below) | Copper (I) oxide | Active substance | 1317-39-1 | 215-270-7 | 17.20 | 35.0 |
| co-formulants | - | Non-active substance | - | - | See Confidential Annex | |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Concentration range of the BPF (% w/w)** | | | | |
| **meta-SPC number** | **1** | **2** | **3** | **4** |
| **Product name(s)** | Netrex AF  Netwax NI 3  Netwax NI 4  Netrex E4 Greenline/  Netwax E4 Greenline1 | Netwax E5 Greenline  Netwax A5 Microfino | Netwax E8 Greenline  Netwax Gold T60 Sens | Netwax NI 5  Netwax NI 6 |
| **Dicopper oxide (Cu2O)**  **Content (% w/w)** | 17.2 – 23.5 | 26.0 - 26.3 | 34.9 – 35.0 | 26.3 – 29.9 |
| **In-use concentration (Cu2O, % w/w)** | As above | As above | As above | 18.8 -21.4 |
| **Formulation type** | SD – Suspension concentrate for direct application | SD – Suspension concentrate for direct application | SD – Suspension concentrate for direct application | SC – Suspension concentrate to be diluted with water |

1 tradenames for the same product

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

\*Information on Grades of Dicopper Oxide Used in the Biocidal Product Family

All products contain Nordox AS dicopper oxide as described above. There are four different grade qualities of dicopper oxide used in the products, as detailed in the table below. Nordox Paint Grade is the standard version. During the production the particles are milled to smaller particle sizes to produce Nordox Agro Grade and Nordox Microfino Grade, for improved dispersibility. The Nordox­­ XLT‑G grade is a more granulated version of the Nordox Paint Grade.

More details on the different grade qualities can be found in the confidential Annex for competent authorities only.

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta** | **Trade Name** | **Description of Dicopper Oxide Used in the Products** | |
| **Meta SPC 1** | Netrex AF | Nordox Paint Grade (>97% Cu2O) | |
| Netwax NI 3 |
| Netwax NI 4 |
| **Meta SPC 4** | Netwax NI 5 |
| Netwax NI 6 |
| **Meta SPC 1** | Netrex E4 Greenline/ Netwax E4 Greenline | Nordox Agro Grade (>97% Cu2O) | |
| **Meta SPC 2** | Netwax E5 Greenline |
| **Meta SPC 3** | Netwax E8 Greenline |
| **Meta SPC 2** | Netwax A5 Microfino | Nordox Microfino Grade (>97% Cu2O) | |
| **Meta SPC 3** | Netwax Gold T60 Sens | Netwax Gold T60 Sens contains three different grades of dicopper oxide, at the concentrations shown in the table below. | |
| Nordox Dicopper Oxide | Composition (% w/w) |
| Nordox Paint Grade (>97% Cu2O) | 74 |
| Nordox Agro Grade (>97% Cu2O) | 20 |
| Nordox XLT-G (>94.2% Cu2O) | 6 |

#### 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.

#### 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

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

### Hazard and precautionary statements

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

**Meta SPC 1**

Netrex AF, Netwax NI 3, Netwax NI 4 and Netrex E4 Greenline/Netwax E4 Greenline

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Met. Corr. 1  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H290: May be corrosive to metals  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | |
| **Labelling** | | |
| Hazard Pictogram | pollut1 |  |
| GHS09 | GHS05 |
| Signal words | Warning | |
| Hazard statements | H290: May be corrosive to metals  H410: Very toxic to aquatic life with long-lasting effects | |
| Precautionary statements | P273: Avoid release to the environment  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 E5 Greenline and Netwax A5 Microfino

| **Classification** | | | |
| --- | --- | --- | --- |
| Hazard category | Met. Corr. 1  Acute Tox 4 (oral)  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H290: May be corrosive to metals  H302: Harmful if swallowed  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | | |
| **Labelling** | | | |
| Hazard pictograms |  | pollut1 |  |
|  | GHS07 | GHS09 | GHS05 |
| Signal words | Warning | | |
| Hazard statements | H290: May be corrosive to metals  H302: Harmful if swallowed  H410: Very toxic to aquatic life with long-lasting effects | | |
| Precautionary statements | P264: Wash hands thoroughly after handling.  P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell  P330: Rinse mouth  P273: Avoid release to the environment  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 3**

Netwax E8 Greenline and Netwax Gold T60 Sens

| **Classification** | | | |
| --- | --- | --- | --- |
| Hazard category | Met. Corr. 1  Acute Tox 4 (oral)  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H290: May be corrosive to metals  H302: Harmful if swallowed  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | | |
| **Labelling** | | | |
| Hazard pictograms |  | pollut1 |  |
|  | GHS07 | GHS09 | GHS05 |
| Signal words | Warning | | |
| Hazard statements | H290: May be corrosive to metals  H302: Harmful if swallowed  H410: Very toxic to aquatic life with long-lasting effects | | |
| Precautionary statements | P264: Wash hands thoroughly after handling.  P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell  P330: Rinse mouth  P273: Avoid release to the environment  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 4**

Netwax NI 5 and Netwax NI 6

| **Classification** | | | |
| --- | --- | --- | --- |
| Hazard category | Met. Corr. 1  Acute Tox 4 (oral)  Aquatic Acute 1  Aquatic Chronic 1 | | |
| Hazard statement | H290: May be corrosive to metals  H302: Harmful if swallowed  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects | | |
| **Labelling** | | | |
| Hazard pictograms |  | pollut1 |  |
|  | GHS07 | GHS09 | GHS05 |
| Signal words | Warning | | |
| Hazard statements | H290: May be corrosive to metals  H302: Harmful if swallowed  H410: Very toxic to aquatic life with long-lasting effects | | |
| Precautionary statements | P264: Wash hands thoroughly after handling.  P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell  P330: Rinse mouth  P273: Avoid release to the environment  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. | | |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Treatment of Aquaculture Nets – Meta SPC1

Netrex AF, Netwax NI 3, Netwax NI 4 and Netrex E4 Greenline/Netwax E4 Greenline

|  |  |
| --- | --- |
| **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(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Application rate: 0.8 - 1.2 kg of RTU product per 1 kg of dry net. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 2. Use # 2 – Treatment of Aquaculture Nets – Meta SPC2

Netwax E5 Greenline and Netwax A5 Microfino

|  |  |
| --- | --- |
| **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(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Application rate: 0.8 - 1.2 kg of RTU product per 1 kg of dry net. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 3. Use # 3 – Treatment of Aquaculture Nets – Meta SPC3

Netwax E8 Greenline and Netwax Gold T60 Sens

|  |  |
| --- | --- |
| **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(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Application rate: 0.8 - 1.2 kg of RTU product per 1 kg of dry net. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 4. Use # 4 – Treatment of Aquaculture Nets – Meta SPC4

Netwax NI 5 and Netwax NI 6

|  |  |
| --- | --- |
| **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(s)** | The products are intended to be applied by dipping or by vacuum treatment. |
| **Application rate(s) and frequency** | Application rate: 0.8 - 1.2 kg of diluted product (Netwax NI 5 and 6) per 1 kg of dry net. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

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| Meta-specific use instructions:  **Meta SPC 1**  *Netrex AF, Netwax NI 3, Netwax NI 4 and Netrex E4 Greenline/Netwax E4 Greenline*  • Stir vigorously for 5 minutes with an appropriate stirring mechanism before use to ensure a homogenous solution.  • Ready to use. To be used undiluted.  • 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.  • For vacuum impregnation, apply according to the machine manufacturer's instructions, and/or guidance from NetKem AS. Adjust pressure and number of cycles, if necessary, to achieve the desired pickup on the net.  • IMPORTANT! Nets must be completely dry before they are put into the sea.  • The container should be tilted a little for complete emptying. The product may be diluted with approx. 5 % of water to facilitate emptying.  **Meta SPC 2**  *Netwax E5 Greenline and Netwax A5 Microfino*  • Stir vigorously for 5 minutes with an appropriate stirring mechanism before use to ensure a homogenous solution.  • Ready to use. To be used undiluted.  • 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.   * For vacuum impregnation, apply according to the machine manufacturer's instructions, and/or guidance from NetKem AS. Adjust pressure and number of cycles, if necessary, to achieve the desired pickup on the net.   • IMPORTANT! Nets must be completely dry before they are put into the sea.  • The container should be tilted a little for complete emptying. The product may be diluted with approx. 5 % of water to facilitate emptying.  **Meta SPC 3**  *Netwax E8 Greenline and Netwax Gold T60 Sens*  • Stir vigorously for 5 minutes with an appropriate stirring mechanism before use to achieve a homogenous solution.  • Ready to use. To be used undiluted.  • 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.   * For vacuum impregnation, apply according to the machine manufacturer's instructions, and/or guidance from NetKem AS. Adjust pressure and number of cycles, if necessary, to achieve the desired pickup on the net.   • IMPORTANT! Nets must be completely dry before they are put into the sea.  • The container should be tilted a little for complete emptying. The product may be diluted with approx. 5 % of water to facilitate emptying.  **Meta SPC 4**  *Netwax NI 5 and Netwax NI 6*  • Stir vigorously for 5 minutes with an appropriate stirring mechanism before use to ensure a homogenous solution.  • Concentrate to be diluted with water:   * Use 1 part water and 2 parts Netwax NI 5 (1/3 water to 2/3 Netwax NI 5) * Use 1 part water and 2 parts Netwax NI 6 (1/3 water to 2/3 Netwax NI 6)   Always pour water into the product (product should NOT be added to the water). Stir until the water is mixed into the product and a homogeneous solution is obtained. Use the prescribed volume of water for dilution to rinse the IBC. The container should be tilted a little for complete emptying.  • Let the net soak in the product for a minimum of 20 minutes to ensure that 0.8 - 1.2 kg of diluted product is applied per 1 kg of dry net. Then let the net hang to dry.  • For vacuum impregnation, apply according to the machine manufacturer's instructions, and/or guidance from NetKem AS. Adjust pressure and number of cycles, if necessary, to achieve the desired pickup on the net.  • IMPORTANT! Nets must be completely dry before they are put into the sea.  • The container should be tilted a little for complete emptying.   * When the container is empty, the rinse-water can be added to the product.   See also Section 2.1.5 |
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#### Use-specific risk mitigation measures

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| See Section 2.1.5.2 |

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

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| **Meta SPC 1**  *Netrex AF, Netwax NI 3, Netwax NI 4 and Netrex E4 Greenline/Netwax E4 Greenline*  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  **Meta SPC 2 - Meta SPC 4**  *Netwax E5 Greenline and Netwax A5 Microfino*  *Netwax E8 Greenline and Netwax Gold T60 Sens*  *Netwax NI 5 and Netwax NI 6*  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.  Information to Healthcare personnel/doctor: Initiate life support measures if needed,  thereafter call a POISON CENTRE.  IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  See also Section 2.1.5.3 |

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

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| See Section 2.1.5 |

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

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| See Section 2.1.5 |

### General directions for use

#### Instructions for use

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| Ready for use-products must be stirred well for 5 minutes with an appropriate stirring mechanism until a homogenous solution is obtained before use.  Concentrates must be diluted with the correct amount of water, as specified on the label. The products must be stirred well for 5 minutes with an appropriate stirring mechanism after addition of water until a homogenous solution is obtained before use.  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. |

#### Risk mitigation measures

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| 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:   * Wear suitable gloves, i.e. Neoprene, nitrile rubber gloves or butylrubber protective gloves (EN 374). * A double coverall, a chemically resistant (at least type 3, EN-14605) coverall which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information) shall be worn with at least a long-sleeve, long-leg cotton coverall underneath. * 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

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| First aid instructions: Meta specific advice is provided under 2.1.4.4.  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

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

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| **Meta SPC 1 - Meta SPC 4**  Conditions of Storage:  PROTECT FROM FROST.  Handle and store above +4°C and below +30°C  Protect from sunlight.  Shelf Life: 9 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 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 3:  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) 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 submitted in addition to the dicopper oxide assessment report.

#### Access to documentation

Letter of Access to the active substance data and product data is contained within 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.

The applicant originally applied for four meta SPCs with the products indicated below:

meta SPC 1; Netpolish NI Low

meta SPC 2: Netpolish NI active

meta SPC 3: Netrex AF

meta SPC 4: Netwax NI 3, Netwax NI 4, Netwax NI 5, Netwax NI 6, Netrex E4 Greenline/Netwax E4 Greenline, Netwax E5 Greenline, Netwax E6 Greenline, Netwax E7 Greenline, Netwax E8 Greenline, Netwax A5 Microfino, Netwax A7 Microfino, Netwax Gold T50 Sens/Netwax NI Gold XL, Netwax Gold T60 Sens, Netwax T4 Anti-bite.

The meta structure was updated during the evaluation process, considering the change in classification, the need for separating different formulation types (concentrate and dilution) and the result of the assessment (see section 2.1.2.3).

Sufficient efficacy was not demonstrated for the Netpolish products. Netwax T4 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 (for further information, see section 1.3 in the confidential annex). Furthermore, a risk was identified in the human health risk assessment for several products in meta SPC 4.

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

### Physical, chemical and technical properties

For the physical-chemical and technical properties physical state, odour, relative density and viscosity, the following products were tested; Netwax NI 3old[[1]](#footnote-2), Netwax NI 4 and Netwax E4 Greenline in meta SPC 1; Netwax E5 Greenline and Netwax A5 Microfino in meta SPC 2; Netwax E8 Greenline in meta SPC 3; Netwax NI 6 in meta SPC 4. Furthermore, the test results for Netwax NI 3old are read-acrossed to Netrex AF, the test results for Netwax E8 Greenline are read-acrossed to Netwax Gold T60 Sens and the test results for Netwax NI 6 are read-acrossed to Netwax NI 5.

For the long-term storage stability test, Netwax NI 4 was tested. For the wet sieve analysis and test for persistent foaming, Netwax NI 3 and Netwax NI 5 were tested. For the pourability testing, Netwax E8 Greenline was tested in addition to Netwax NI 3 and Netwax NI 5. Test for surface tension was performed on the product Netwax E8 Greenline. All tested formulations are considered representative for the product family for the relevant end point.

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

**Meta SPC 1**

Netrex AF

| **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 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old.  Liquid | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |
| Colour at 20 °C and 101.3 kPa | Visual Assessment | Netwax NI 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old.  Red | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax NI 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old.  Faint | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |
| Acidity / alkalinity | CIPAC MT191 | Netwax NI 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old  pH = 7.04 at 25°C  Therefore, the test item can be regarded as having negligible acidity/alkalinity. | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |
| Relative density / bulk density | EC Method A3 | Netwax NI 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old  1.19 at 20.0 ± 0.5°C. | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3. | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 monts, 40 ± 5 °C  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 monts, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use and are not to be stored at temperatures above 30 °C, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **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 3.  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline  The surface tension determined at 20°C was 68.60 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 | Equivalent to OECD Guideline 114 (rotational viscometer) | Netwax NI 3old (17.89% w/w dicopper oxide) | Read across to Netwax NI 3old  20 °C:  0.102 sec-1:  10798–13897 mPa.s  0.238 sec-1:  6556–8098 mPa.s  0.510 sec-1:  4259–5079 mPa.s  1.02 sec-1:  2999–3449 mPa.s  40 °C  0.102 sec-1:  11298–14397 mPa.s  0.238 sec-1:  7070–8227 mPa.s  0.510 sec-1:  4639–4959 mPa.s  1.02 sec-1:  2959–3279 mPa.s | Atwal, S.S. and White, D.F (2011) Netwax NI 3: Determination of Physico-Chemical Properties; Harlan; Project Number 41004093. |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netrex AF is a red liquid with a faint odour, a pH of 7.04 at 25°C and relative density of 1.19 at 20.0 ± 0.5°C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 1**

Netwax NI 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 4 (23.5 % w/w dicopper oxide) | Liquid | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Colour at 20 °C and 101.3 kPa | Visual Assessment | Netwax NI 4 (23.5 % w/w dicopper oxide). | Red | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax NI 4 (23.5 % w/w dicopper oxide). | Not discernible | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | 6.88 at 19.6°C | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax NI 4 (23.5 % w/w dicopper oxide). | 1.1957 at 20°C | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T = 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use and are not to be stored at temperatures above 30 °C, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability/  Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **Flowability/ dustability:**  Not relevant.  The biocidal products are not powders or granules; therefore, the determination of flowability or dustability is not applicable.  **Pourability**  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 E8 Greenline (35% w/w dicopper oxide) | Read-across to Netwax E8 Greenline.  The surface tension determined at 20°C was 68.60 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, with a rotational viscometer | Netwax NI 4 (23.5 w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  211 mPas  Viscosity at 200 s-1 (40°C): 148 mPas  Netwax NI 4 is a non-newtonian liquid with thixotropic tendencies | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI 3 is a red liquid with no discernible odour, a pH of 6.88 at 19.6°C and relative density of 1.1957 at 20.0 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 1**

Netwax NI 4

| **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 4 (23.5 % w/w dicopper oxide) | Liquid | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Colour at 20°C and 101.3 kPa | Visual assessment | Netwax NI 4 (23.5 % w/w dicopper oxide). | Red | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Odour at 20°C and 101.3 kPa | Olfactory  assessment | Netwax NI 4 (23.5 % w/w dicopper oxide). | Not discernible | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | 6.88 at 19.6°C | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax NI 4 (23.5 % w/w dicopper oxide). | 1.1957 at 20°C | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |
| Storage stability test – **accelerated storage** | - | - | Not performed.  The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | **Temperature:**  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. However, since the products are stirred well prior to use and are not to be stored at temperatures above 30 °C, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (23.5 % w/w dicopper oxide). | No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **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 3.  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 marketed and used neat and water is only added to rinse out the packaging material, 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline  The surface tension determined at 20°C was 68.60 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, with a rotational viscometer | Netwax NI 4 (23.5 w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  211 mPas  Viscosity at 200 s-1 (40°C): 148 mPas  Netwax NI 4 is a non-newtonian liquid with thixotropic tendencies | Harding, L (2018a) Physical and Chemical Testing of Netwax NI 4; CEMAS; Project Number CEMR-8347 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI 4 is a red liquid with no discernible odour, a pH of 6.88 at 19.6°C and relative density of 1.1957 at 20°C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 1**

Netwax E4 Greenline/Netrex E4 Greenline

| **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 E4 Greenline (23.5 % w/w dicopper oxide) | Liquid | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; CEMR-8348 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax E4 Greenline (23.5 % w/w dicopper oxide) | Brown-red | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; CEMR-8348 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax E4 Greenline (23.5 % w/w dicopper oxide) | Not discernible | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; CEMR-8348 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax E4 Greenline (23.5 % w/w dicopper oxide) | 7.04 at 19.7°C | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; CEMR-8348 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax E4 Greenline (23.5 % w/w dicopper oxide) | 1.2139 at 20°C | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; Project Number CEMR-8348 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Storage stability test – **low temperature stability test for liquids** | - | - | 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:** Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. However, since the products are stirred well prior to use and are not to be stored at temperatures above 30 °C, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed. In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/SD | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| Disintegration time | - | - | Not applicable.  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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability/  Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **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 3.  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 or 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 E8 Greenline (35% w/w dicopper oxide) | Read-across to Netwax E8 Greenline.  The surface tension determined at 20°C was 68.60 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 E4 Greenline (23.5 % w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  239 mPas  Viscosity at 200 s-1 (40°C): 170 mPas.  Netwax E4 Greenline is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018b) Physical and Chemical Testing of Netwax E4 Greenline; CEMAS; CEMR-8348 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax E4 Greenline is a brown-red liquid with no discernible odour, a pH of 7.04 at 19.7 °C and relative density of 1.2139 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 E5 Greenline

| **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 E5 Greenline (26.3 % w/w dicopper oxide) | Liquid | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax E5 Greenline (26.3 % w/w dicopper oxide) | brown-red | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax E5 Greenline (26.3 % w/w dicopper oxide) | Not discernible | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax E5 Greenline (26.3 % w/w dicopper oxide) | 6.95 at 19.8°C | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax E5 Greenline (26.3 % w/w dicopper oxide) | 1.2472 at 20°C | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Storage stability test – **low temperature stability test for liquids** | - | - | It is considered to be scientifically justified to omit this study on the basis that the product labels state: *Protect from frost.* | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide).. | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability/  Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **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 3.  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 or 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline.  The surface tension determined at 20°C was 68.60 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 guideline 114 (rotational viscometer) | Netwax E5 Greenline (26.3 % w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  251 mPas  Viscosity at 200 s-1 (40°C): 177mPas  Netwax E5 Greenline is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018c) Physical and Chemical Testing of Netwax E5 Greenline; CEMAS; CEMR-8353 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax E5 Greenline is a brown-red liquid with no discernible odour, a pH of 6.95 at 19.8 °C and relative density of 1.2472 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 A5 Microfino

| **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 A5 Microfino (26.0 % w/w dicopper oxide) | Liquid | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax A5 Microfino (26.0 % w/w dicopper oxide) | Brown-red | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax A5 Microfino (26.0 % w/w dicopper oxide) | Not discernible | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax A5 Microfino (26.0 % w/w dicopper oxide) | 6.82 at 19.8°C | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax A5 Microfino (26.0 % w/w dicopper oxide) | 1.3204 at 20°C | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 0 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Storage stability test – **low temperature stability test for liquids** | - | - | 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax NI 3 (20.2 % w/w dicopper oxide) | **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 3.  Pourability: 97.6%  Residue: 2.4%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022b); Netwax NI 3: Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493339 |
| 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 or 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline  The surface tension determined at 20°C was 68.60 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 A5 Microfino (26.0 % w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  175 mPas  Viscosity at 200 s-1 (40°C): 124 mPas  Netwax A5 Microfino is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018d) Physical and Chemical Testing of Netwax A5 Microfino; CEMAS; CEMR-8356 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax A5 Microfino is a brown-red liquid with no discernible odour, a pH of 6.82 at 19.8 °C and relative density of 1.3204 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 3**

Netwax E8 Greenline

| **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 E8 Greenline (35 % w/w dicopper oxide) | Liquid | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax E8 Greenline (35 % w/w dicopper oxide) | Brown-red | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax E8 Greenline (35 % w/w dicopper oxide) | Not discernible | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax E8 Greenline (35 % w/w dicopper oxide) | 7.34 at 19.6°C | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax E8 Greenline (35 % w/w dicopper oxide) | 1.3372 at 20°C | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3. | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide.) | 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 5 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, 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. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax E8 Greenline (35% w/w dicopper oxide) | **Flowability/ dustability:**  Not relevant.  The biocidal products are not powders or granules; therefore, the determination of flowability or dustability is not applicable.  **Pourability**  Pourability: 95.7%  Residue: 4.3%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022c); Netwax E8 Greenline:  Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493364 |
| 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 E8 Greenline (35% w/w dicopper oxide) | Read-across to Netwax E8 Greenline.  The surface tension determined at 20°C was 68.60 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 E8 Greenline (35% w/w dicopper oxide) | Viscosity at 200 s-1 (20°C): 287 mPas  Viscosity at 200 s-1 (40°C): 204 mPas  Netwax E8 Greenline is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax E8 Greenline is a brown-red liquid with no discernible odour, a pH of 7.34 at 19.6 °C and relative density of 1.3372 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 3**

Netwax Gold T60 Sens

| **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 E8 Greenline (35 % w/w dicopper oxide) | Read across to Netwax E8 Greenline.  Liquid | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax E8 Greenline (35 % w/w dicopper oxide) | Read across to Netwax E8 Greenline.  Brown-red | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax E8 Greenline (35 % w/w dicopper oxide) | Read across to Netwax E8 Greenline.  Not discernible | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Acidity / alkalinity | - | Netwax E8 Greenline (35 % w/w dicopper oxide) | Read across to Netwax E8 Greenline.  7.34 at 19.6°C | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Relative density / bulk density | - | Netwax E8 Greenline (35 % w/w dicopper oxide) | Read across to Netwax E8 Greenline.  1.3372 at 20°C | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C:  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C:  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C:  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. Read across to Netwax NI 4. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3  Residue retained on a 75 μm sieve was 0.043 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022a) Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 3 (20.2 % w/w dicopper oxide) | Read across to Netwax NI 3.  5.4 mL (2.7%) foam was produced. A few bubbles remained around the periphery at the 10 second timepoint up until 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022a); Netwax NI 3: Determination of Wet Sieve and Persistent Foam; Labcorp Early Development Laboratories Ltd.; 8506628 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax E8 Greenline (35% w/w dicopper oxide) | **Flowability/ dustability:**  Not relevant.  The biocidal products are not powders or granules; therefore, the determination of flowability or dustability is not applicable.  **Pourability**  Pourability: 95.7%  Residue: 4.3%  The test results meet the acceptance criteria of the CIPAC MT 148.1 (residue does not exceed 5%). | Walker, J. (2022c); Netwax E8 Greenline:  Determination of Pourability; Labcorp Early Development Laboratories Ltd.; 8493364 |
| 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline.  The surface tension determined at 20°C was 68.60 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 E8 Greenline (35% w/w dicopper oxide) | Read-across to Netwax E8 Greenline.  Viscosity at 200 s-1 (20°C): 287 mPas Viscosity at 200 s-1 (40°C): 204 mPas.  Netwax E8 Greenline is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018e) Physical and Chemical Testing of Netwax E8 Greenline; CEMAS; CEMR-8333 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax Gold T60 Sens is a brown-red liquid with no discernible odour, a pH of 7.34 at 19.6 °C and relative density of 1.3372 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 4**

Netwax NI 5

| **Property** | **Guideline and MethodA** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual assessment | Netwax NI 6 (29.9 % w/w dicopper oxide) | Read across to Netwax NI 6.  Liquid. | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax NI 6 (29.9 % w/w dicopper oxide) | Read across to Netwax NI 6.  Red | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax NI 6 (29.9 % w/w dicopper oxide) | Read across to Netwax NI 6.  Not discernible | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI 6 (29.9 % w/w dicopper oxide) | Read across to Netwax NI 6.  6.96 at 19.9°C | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax NI 6 (29.9 % w/w dicopper oxide) | Read across to Netwax NI 6.  1.2635 at 20°C | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C:  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C:  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C:  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/SD formulations | - |
| Suspensibility, spontaneity and dispersion stability | **Suspensibility:**  CIPAC MT 184.1  **Spontaneity of dispersion:**  CIPAC MT 160 | Netwax NI 5 (26.3 % w/w dicopper oxide) | **Suspensibility:**  The suspensibility of dried solids in the test item was determined to be 100.9% which is within the acceptable range of 60 %-110 %.  **Spontanity of dispersion:**  The spontaneity of dispersion of dried solids in the test item was determined to be 104.9% which is within the acceptable range of 60%-105%. | Walker, J. (2023) Netwax NI 5: Determination of Suspensibility and Spontaneity of Dispersion; Labcorp Early Development Laboratories Ltd.; 8499162 |
| Wet sieve analysis and dry sieve test | CIPAC MT 185 | Netwax NI 5 (26.3 % w/w dicopper oxide) | Residue retained on a 75 μm sieve was 0.012 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 marketed and used neat and water is only added to rinse out the packaging material, therefore the determination of particle size distribution, content of dust/ fines, attrition, friability is not applicable. | - |
| Persistent foaming | CIPAC MT 47.3 | Netwax NI 5 (26.3 % w/w dicopper oxide) | 22 mL (11 %) foam was produced initially. After 1 minute, the amount of foam had reduced to 12 mL (6%) and then 5.5 mL (2.7%) after 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax NI 5 (26.3 % w/w dicopper oxide) | **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. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| 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 or 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 and 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline  The surface tension determined at 20°C was 68.60 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 with rotational viscometer | Netwax NI 6 (26.3 % w/w dicopper oxide) | Read-across to Netwax NI 6    Viscosity at 200 s-1 (20°C):  218 mPas  Viscosity at 200 s-1 (40°C): 153 mPas.  Netwax NI 6 is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI 5 is a red liquid with no discernible odour, a pH of 6.96 at 19.9 °C and relative density of 1.2635 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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 4**

Netwax NI 6

| **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 6 (29.9 % w/w dicopper oxide) | Liquid | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Netwax NI 6 (29.9 % w/w dicopper oxide) | Red | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Netwax NI 6 (26.9 % w/w dicopper oxide) | Not discernible | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350f) |
| Acidity / alkalinity | CIPAC MT 75.3 | Netwax NI 6 (26.9 % w/w dicopper oxide) | 6.96 at 19.9°C | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Relative density / bulk density | OECD Guideline 109 (Density of Liquids and Solids) | Netwax NI 6 (26.9 % w/w dicopper oxide) | 1.2635 at 20°C | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |
| Storage stability test – **accelerated storage** | - | - | Not performed. The products shall not be stored at temperatures above 30 °C. This will be clearly stated on the label. | - |
| Storage stability test – **long term storage at ambient temperature** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  The storage stability tests were performed at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  The packaging of the test material was white plastic (PE) bottles of 500 mL.  The following physico-chemcial properties were determined initially and after 6 and 9 months at ambient temperatures (20 ± 2°C).  **Active substance content:**  T=0: 22.8 % w/w Cu2O.  T=6 months: 22.8 % w/w Cu2O [0 % change in Cu2O content].  T=9 months: 22.9 % w/w Cu2O [0.1 % change in Cu2O content].  **Relative density:**  T=0: 1.22  T=6 months: 1.21  T=9 months: 1.21  **Viscosity**  T= 0, 20 ± 5 °C  0.102 sec-1:  13197-17129 mPa.s  0.238 sec-1:  7884-9298 mPa.s  0.510 sec-1:  5099-5779 mPa.s  1.02 sec-1:  3579-3889 mPa.s  T = 0, 40 ± 5 °C  0.102 sec-1:  15497-19396 mPa.s  0.238 sec-1:  9384-10541 mPa.s  0.510 sec-1:  5959-6364 mPa.s  1.02 sec-1:  3959-4089 mPa.s  T = 6 months, 20 ± 5 °C  0.102 sec-1:  11797-13598 mPa.s  0.238 sec-1:  7113-7713 mPa.s  0.510 sec-1:  4679-4959 mPa.s  1.02 sec-1:  3289-3389 mPa.s  T = 6 months, 40 ± 5 °C  0.102 sec-1:  10398-14097 mPa.s  0.238 sec-1:  6384-8089 mPa.s  0.510 sec-1:  4219-5079 mPa.s  1.02 sec-1:  2959-3389 mPa.s  T = 9 months, 20 ± 5 °C  0.102 sec-1:  11498-13897 mPa.s  0.238 sec-1:  7198-8141 mPa.s  0.510 sec-1:  4839-5219 mPa.s  1.02 sec-1:  3489-3589 mPa.s  T = 9 months, 40 ± 5 °C  0.102 sec-1:  9598-12197 mPa.s  0.238 sec-1:  5913-7070 mPa.s  0.510 sec-1:  3959-4379 mPa.s  1.02 sec-1:  2829-2929 mPa.s  No significant change in appearance or odour.  There was no significant change in the active substance concentration (dicopper oxide), appearance, odour, relative density, or viscosity of the test item after storage at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. The study data therefore demonstrates the stability of dicopper oxide in Netwax Nl4 (21.74% w/w dicopper oxide) over a period of 9 months when stored 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Storage stability test – **low temperature stability test for liquids** | - | - | 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** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | 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 5 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, 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. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | **Temperature:**  Read-across to Netwax NI 4.  The storage stability test was conducted at 4 ± 2°C, 20 ± 2°C and 30 ± 2°C for 9 months.  In general, no significant physical or chemical change to the test item or the container was observed. The exception is a thin white film covering approx. 30 % of the surface with no visual separation of the formulation was reported after 9 months of storage at 30 ± 2°C. According to the applicant, this could be wax components on the surface. However, since the products are stirred well prior to use, this is not considered a concern.  No significant change in active substance content was reported.  **Humidity:**  Not performed.  In addition, the products are aqueous wax products and are not hygroscopic, therefore, the effects of humidity do not require investigated. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Equivalent to CIPAC MT 46.3 | Netwax NI 4 (21.74% w/w dicopper oxide). | Read across to Netwax NI 4.  No significant change in the appearance of the test item or the container after 6 and 9 months of storage at ambient temperatures. No signs of seepage, corrosion or degradation. | Atwal, S.S. and White, D.F. (2012a) Netwax NI 4: Determination of Storage Stability at 4°C; Harlan; Project Number 41004098.  Atwal, S.S. and White, D.F. (2012b) Netwax NI 4: Determination of Storage Stability at 20°C; Harlan; Project Number 41004096.  Atwal, S.S. and White, D.F. (2012c) Netwax NI 4: Determination of Storage of Storage Stability at 30°C; Harlan; Project Number 41004097. |
| Wettability | - | - | Not relevant for SC/SD formulations. | - |
| Suspensibility, spontaneity and dispersion stability | **Suspensibility:**  CIPAC MT 184.1  **Spontaneity of dispersion:**  CIPAC MT 160 | Netwax NI 5 (26.3 % w/w dicopper oxide) | **Suspensibility:**  Read-across to Netwax NI 5.  The suspensibility of dried solids in the test item was determined to be 100.9% which is within the acceptable range of 60 %-110 %.  **Spontanity of dispersion:**  Read-across to Netwax NI 5.  The spontaneity of dispersion of dried solids in the test item was determined to be 104.9% which is within the acceptable range of 60%-105%. | Walker, J. (2023) Netwax NI 5: Determination of Suspensibility and Spontaneity of Dispersion; Labcorp Early Development Laboratories Ltd.; 8499162 |
| Wet sieve analysis and dry sieve test | CIPAC MT 185 | Netwax NI 5 (26.3 % w/w dicopper oxide) | Residue retained on a 75 μm sieve was 0.012 %. Result is below 2% threshold. No further assessment required. | Walker, J. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant.  The products are not emulsifiable concentrates or ready-to-use aqueous emulsions. | - |
| 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 5 (26.3 % w/w dicopper oxide) | 22 mL (11 %) foam was produced initially. After 1 minute, the amount of foam had reduced to 12 mL (6%) and then 5.5 mL (2.7%) after 12 minutes at the end of the study. Result is below the 60mL foam after 1 minute threshold. No further assessment required. | Walker, J. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| Flowability/  Pourability  /Dustability | CIPAC MT 148.1 | Netwax NI 5 (26.3 % w/w dicopper oxide) | **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. (2022d) Netwax NI 5: Determination of Physico-Chemical Properties; Labcorp Early Development Laboratories Ltd.; 8506626 |
| 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 or 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 E8 Greenline (35% w/w dicopper oxide) | Read across to Netwax E8 Greenline  The surface tension determined at 20°C was 68.60 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 with a rotational viscometer | Netwax NI 6 (26.9 % w/w dicopper oxide) | Viscosity at 200 s-1 (20°C):  218 mPas  Viscosity at 200 s-1 (40°C): 153 mPas  Netwax NI 6 is a non-newtonian liquid with thixotropic tendencies. | Harding, L (2018f) Physical and Chemical Testing of Netwax NI 6; CEMAS; CEMR-8350 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Netwax NI 6 is a red liquid with no discernible odour, a pH of 6.96 at 19.9 °C and relative density of 1.2635 at 20 °C. Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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. |

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| **Overall conclusion of the product family** |
| The product family formulation is a liquid with red/brown-red colour and faint or not discernible odour. pH is between 6.82-7.34 measured at 19.6 to 25 °C and relative density is between 1.19-1.3372 at 20.0 ± 0.5°C. Surface tension is determined to 68.60 mN/m at 20°C.  Based on the long-term storage stability data, the product is stable for 9 months when stored at 4°C, 20°C and 30°C. 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

Most of the physical hazard testing was conducted on the RTU Netwax NI 3. For the corrosive to metal test, two products were tested, Netwax NI 3 and Netwax E8 Greenline.

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 3 (20.2 % w/w dicopper oxide) | 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 76.4 J.g-1 which is < 500 J.g-1. Therefore, Netwax NI 3 is not a candidate for classification as a UN Class 1 explosive substance.  The test data can be read across to all of the products in the BPF since all of the products contain the same components. Justification for read-across is stated in the confidential PAR.  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; Explosive and Self-reactive Properties Testing on a Test Item of Netwax NI3; GLP3016010435CR1/2022 |
| 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 3 (20.2 % w/w dicopper oxide) | 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.; 2022b; Flash Point Testing on a Test Item of Netwax NI3; GLP3016010435AR1/2022 |
| 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 3 (20.2 % w/w dicopper oxide) | 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 76.4 J.g-1 which is < 300 J.g-1. Therefore, Netwax NI3 is not a candidate for classification as a UN Class 4, Division 4.1 self-reactive substance.  The test data can be read across to all of the products in the BPF since all of the products contain the same components.  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; Explosive and Self-reactive Properties Testing on a Test Item of Netwax NI3; GLP3016010435CR1/2022 |
| 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 | - | - | Not applicable to a liquid. | - |
| 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 | Evaluation on a theoretical basis | - | None of the components, or mixtures, in the biocidal product is classified as oxidising. The active substance contains oxygen but is harmonized classified as not oxidising. 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) | 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. Netwax NI 3 is therefore a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations | Siusiene, E.; 2022c; Corrosivity to Metals Testing on a Test Item of Netwax NI3; DEKRA UK Ltd; GLP3016010435DR1/2022 |
| UN Manual of tests and Criteria: Part III, 37.4: Test Methods for corrosion to metals (UN Test C.1). | Netwax E8 Greenline (35% w/w dicopper oxide) | 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. Netwax E8 Greenline is therefore a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations. | Siusiene, E.; 2022d; Corrosivity to Metals Testing on a Test Item of Netwax E8 Greenline; DEKRA UK Ltd; GLP3016010435ER |
| It can be concluded from the test data which covers the concentration range of the BPF that all products should be classified as corrosive to metal. | | | |
| Auto-ignition temperatures of products (liquids and gases) | EC A.15 | Netwax NI 3 (20.2 % w/w dicopper oxide) | The auto-ignition temperature of Netwax NI 3 was determined to be 434 °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 data can be read across to all of the products in the BPF since all of the products contain the same components. | Siusiene, E.; 2022e; Auto Ignition Temperature of Liquids Testing on a Test Item of Netwax NI3; DEKRA UK Ltd; GLP3016010435AR1/2022 |
| 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 434 °C.  The products are determined 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 dicopper oxide 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. Since there is no other source to copper in the product family, the total copper content detected can be expressed as dicopper oxide.

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 it is proposed to not authorise Netpolish NI Low due to non-conclusion for the efficacy evaluation, 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 copper and dicopper oxide in Netwax NI 4 (21.7 % w/w dicopper oxide) | 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 copper 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; 28 November 2018 |
| Dicopper Oxide (CAS No. 1317-39-1) | ICP-MS  Determination of total copper 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 |

\* Recovery was assessed by analysis of replicate determination of samples prepared by the fortification of Netrex blank formulations with 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). 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).

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 is currently no techniques available to determine the copper sources. However, methods for analysing total content of copper compounds are widely available and are reliable in identifying and quantifying such compounds. Based on the product composition, the only source of copper in the product is dicopper oxide and the interference of the co-formulants has been addressed. Hence, the total copper content detected can be expressed as dicopper oxide.  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 dicopper oxide 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 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.

#### 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 cuprous 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 organism by inactivating enzymes;

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

#### 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 3, Netwax E5 Greenline, Netwax A5 Microfino, Netwax Microfino A7[[2]](#footnote-3) and Netwax NI 5 was 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.

One efficacy trial was also performed on the product Netpolish NI Low which initially was the product with the lowest dicopper oxide content in the product family. However, the efficacy data from this trial was not sufficient to conclude on the efficacy of the product. The trial was conducted on only one replicate and without any reference to test panels with similar formulations. This is not in compliance with the Efficacy Guidance, Section 5.7.1.1.8.4 (Guidance on the BPR, Volume II, Part B+C). Hence, the Netpolish NI Low and Netpolish NI Active is not proposed for authorisation.

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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 | Netpolish NI Low (0.24% w/w Cu2O) | Typical fouling on the sites are filamentous algae (brown, red and green algae), molluscs (blue/common mussel), sea cucumbers, hydroids, and tunicates | Field trial at one location in the North of Norway | Location: At the LetSea research facility (located near the island of Dønna in Nordland County in the North of Norway.  Material and Method:  Test panels were spread out on a steel frame and held in the ocean at 3m depth close to active pens (containing fish) from Week 19 – Week 49 in 2019. The progression of biofouling was followed visually almost every week and documented by taking pictures of both the entire frames and each individual net. The type of growth identified on the nets was categorized: Algae/slime, macroalgae, hydroids, blue mussels (Mytilus edulis), crustaceans, skeleton shrimps, sea cucumbers, tunicates and others.  If uncoated nets (control samples) 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.  Replicates: 1 replicate of the relevant product.  Assessment: Biofouling was ranked and evaluated in the field in accordance to SINTEF guidelines. Biofouling was ranked on a scale from 0 to 5. | Minor biofouling growth was observed on both the treated and untreated net panel at the start of the trial. This indicates that the test location has lower degree of biofouling pressure.  In the test report, less fouling is observed on the treated panels compared to the untreaded panels. However, due to the lack of replicates, there is not sufficient data to conclude on the efficacy of Netpolish NI Low. Hence, efficacy for Netpolish NI Low is not demonstrated and is not proposed for authorisation by the rMS. | Hanssen, H. & Føsker, L. (2020) |
| PT 21 Antifouling | Netwax NI 3 (20.2 % w/w Cu2O)  Netwax E5 Greenline (26.30 % w/w Cu2O)  Netwax A5 Microfino (26.00 % w/w Cu2O)  Netwax Microfino A7 (32.0 % w/w Cu2O)  Netwax NI 5 (26.3 % w/w Cu2O, in-use concentration 18.8 % w/w Cu2O) | 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.  Among the products containing only dicopper oxide as active substance, there seems to be a correlation between concentration of dicopper oxide and biofouling reduction rank, in terms of higher reduction the higher dicopper oxide concentration.  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 3 (20.2 % w/w Cu2O)  Netwax E5 Greenline (26.30 % w/w Cu2O)  Netwax A5 Microfino (26.00 % w/w Cu2O)  Netwax Microfino A7 (32.0 % w/w Cu2O)  Netwax NI 5 (26.3 % w/w Cu2O, in-use concentration 18.8 % w/w Cu2O) | 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 Mediterranean 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 3 (20.2 % w/w Cu2O)  Netwax E5 Greenline (26.30 % w/w Cu2O)  Netwax A5 Microfino (26.00 % w/w Cu2O)  Netwax Microfino A7 (32.0 % w/w Cu2O) | 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 3 (20.2 % w/w Cu2O)  Netwax E5 Greenline (26.30 % w/w Cu2O)  Netwax A5 Microfino (26.00 % w/w Cu2O)  Netwax Microfino A7 (32.0 % w/w Cu2O) | 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** |
| **LetSea research facility, Dønna (North of Norway)**   * Hanssen, H. & Føsker, L. (2020): For the tested product Netpolish NI Low, less fouling is observed on the treated panels compared to the untreaded panels. However, due to the lack of replicates, there is not sufficient data to conclude on the efficacy of Netpolish NI Low. Hence, Netpolish NI Low (and Nepolish NI Active) is proposed not authorised.   **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 3, Netwax E5 Greenline, Netwax A5 Microfino, Netwax A7 Microfino\* and Netwax NI 5 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 3, Netwax E5 Greenline, Netwax A5 Microfino, Netwax A7 Microfino\* and Netwax NI 5 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.   **LetSea research facility, Dønna (North of Norway)**   * Hanssen, H. (2018): According to the applicant, the antifouling paint products Netwax NI 3, Netwax E5 Greenline, Netwax A5 Microfino and Netwax A7 Microfino\* have 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 3, Netwax E5 Greenline, Netwax A5 Microfino and Netwax A7 Microfino\* 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 rMS considers that there is not sufficient data to conclude on the efficacy of the two products with the lowest dicopper oxide content in the product family. Read across to the tested product with higher dicopper oxide was not considered acceptable. Hence, Netpolish NI Low (0.24 % w/w Cu2O) and Netpolish NI Active (2.4 % w/w Cu2O) cannot be authorised and are removed from the product family. * The tested product Netwax NI 3 (20.2 % w/w Cu2O), Netwax E5 Greenline (26.30 % w/w Cu2O), Netwax A5 Microfino (26.00 % w/w Cu2O), Netwax Microfino A7\* (32.0 % w/w Cu2O) and Netwax NI 5 (26.3 % w/w Cu2O, in-use concentration 18.8 % w/w dicopper oxide) are considered representative for the efficacy of the product with higher content of dicopper oxide and for Netwax AF (17.2 % w/w Cu2O) Detailed justification for read-across can be found in the confidential PAR. * 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.   \* Netwax Microfino A7 is proposed to not authorise due to unacceptable risk in the human health assessment. However, due to its relevance for the environmental assessment, the efficacy results for this product are included in the efficacy assessment as supportive information. |

#### Occurrence of resistance and resistance management

To date there have not been any recorded cases in the literature of resistance in populations of fouling organisms through the use of copper based antifouling 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.

#### 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

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

The harmonised classification for human health hazards according to the CLP Regulation (17 ATP, Regulation (EC) No 1272/2008) is: Acute Tox 4; H332 (inhalation), Acute Tox 4; H302 (oral) and Eye Dam. 1; H318 (ECHA, 2014).

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

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

The key health effects, which were used for deriving the reference values for dicopper oxide, are the kidney and forestomachdamages observed in a 90-day rat study (on copper sulphate pentahydrate, via diet; ECHA, 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.

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

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

#### Assessment of effects on Human Health

Toxicological testing of the biocidal product family has been performed for eye damage/irritation. As for orther toxicological properties, the products are classified based on information on the ingredients in the products using the conventional calculation method in Regulation 1272/2008.

The toxicological data on all co-formulants have been compiled and assessed by the applicant and is presented in the confidential annex together with the composition of the family members (section 1.1 and 1.2 of the confidential annex). Most of the co-formulants in the Dicopper oxide biocidal product family are not classified under CLP, and those that trigger classification for human health hazards, are of low toxicity.

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

The products in the meta SPCs 2, 3 and 4 are classified for acute oral toxicity (Acute Tox 4; H302) based on the classification of the ingredients.

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | No classification for Meta SPCs 1 to 4 |
| Justification for the value/conclusion | |  | | --- | | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin irritation/corrosion hazards based on the classification of the ingredient substances. The additivity principle of the CLP Regulation applies to the hazard class skin corrosion/irritation.  In accordance with Annex I section 3.2.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture, i.e. those ingredients which should be taken into account when classifying a mixture, are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for skin irritation/corrosion (see also 1.1.2.2.2 Cut off values in Annex I).  Table 3.2.3 of the regulation contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin.  Details of the product compositions are presented in the Confidential Annex (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***

| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Species,**  **Strain,**  **Sex,**  **No/group** | **Test substance, Dose levels, Duration of exposure** | **Results**  *Average score (24, 48, 72h)/*  *observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 405; GLP; Reliability:1 | Rabbit, New Zealand White; 3 Female | Netrex AF (10-20% active ingredient, Lot/batch number: CRU #99254)\*; 0.1 ml; no post-dose wash; observation period of 72 hours.  Observations at 60 min, 24, 48 and 72 hours.  Attempts made to remove residual test substance from the eye at the time the fluorescein dye was rinsed from the eyes (during the 24-hour examination). | Mild transient ocular irritation: (Slight to moderate conjunctival redness and chemosis and severe discharge in all animals at 1 hour post dose. No iridial or corneal changes. All animals were free of positive scores and all ocular irritation within 24 hours.  Overall (as well as individual) mean scores (at 24, 48 and 72 hours) for opacity, iritis, conjunctival redness, and conjunctival swelling were 0.0, 0.0, 0.0, and 0.0, respectively.  No classification warranted. | None (only a minor discrepancy related to the relative humidity, which is not considered to have affected the integrity of the study) | Blaszcak, D. L. (2000); Netrex AF: Primary Eye Irritation Study in Rabbits. Huntingdon Life Sciences; Study No. 99-0548; Un-published. |

*\* A written statement from NetKem AS of 17 August 2022 confirms that the composition of the test substance is the same as the product Netrex AF which is included in the current biocidal product family (17.2% dicopper oxide)*

| **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 E8 Greenline  (35% w/w dicopper oxide) | Ocular irritation potential of Netwax E8 Greenline 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 9.38. For IVIS > 3 or ≤ 55, no prediction can 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. Unpublished |
| OECD Guideline 492, GLP  Reliability: 1 | Netwax E8 Greenline (35% w/w dicopper oxide) and Netwax E5 Greenline  (26.3% w/w dicopper oxide) | Ocular irritation potential of Netwax E8 Greenline and Netwax E5 Greenline was evaluated using the In-vitro MatTek EpiOcular (OECD 492) test | The mean percentage viabilities of the EpiOcular™ tissues treated with Netwax E8 Greenline and Netwax E5 Greenline were 63.02% and 91.18%, respectively, compared to the negative control.  In accordance with the OECD guideline, the test items are categorised as ‘No Category’ (non-irritant) when the mean tissue viability > 60% in The EpiOcular™ EIT test system. | None | 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 Report No. 39671. Unpublished |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | No classification for Meta SPCs 1-4 |
| 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.  For the biocidal product family, studies are available for three products, i.e., an old *in vivo* 405 test on a product with 17.2% dicopper oxide, an *in vitro* OECD 437 (BCOP) test and an *in vitro* OECD 492 (Reconstructed human Cornea-like Epithelium) test on products with 26.3% and/or 35% dicopper oxide. The *in vitro* tests were performed in a top-down approach.  The same aqueous dispersion of hydrocarbon waxes (Netrex) forms the basis of all the family members, and it seems reasonable to use test results of products with the highest active substance concentrations to characterize the hazard of the family.  Study results (OECD Guideline 405 (Acute Eye Irritation / Corrosion in the New Zealand Rabbit) 2000) demonstrate that Netrex AF (17.2% w/w dicopper oxide) does not warrant classification for eye irritation/damage.  In an OECD Guideline 437 study (Bovine Corneal Opacity and Permeability Assay (BCOP) 2018) no prediction could be made for Netwax E8 Greenline (35% w/w dicopper oxide).  However, in an OECD Guideline 492 study (EpiOcular™ EIT; 2018) 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 test results and the similarity of the products in the biocidal family, no classification for serious eye damage or eye irritation according to Regulation (EC) No. 1272/2008 is proposed for the family members (which contain 17.2-35% w/w dicopper oxide). |
| Classification of the product according to CLP | Not classified. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory Track Irritation** | |
| Value/conclusion | No classification for Meta SPCs 1 to 4 |
| 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 Regulation (EC) No 1272/2008, where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances.  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 compositions are presented in the Confidential Annex (section 1.1 and 1.2).  One ingredient of the products is classified for transient target organ effects (STOT SE 3); respiratory tract irritation (H335). However, it is present in a concentration below the level which should be taken into account when classifying the products for this effect.  The products do 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 all Meta SPCs 1 to 4 |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for skin sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient which has been classified as a skin sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limits presented in Table 3.4.6 of the regulation.  Details of the product compositions are presented in the Confidential Annex (section 1.1 and 1.2).  There is one ingredient which is present in all products (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.” |
| 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 to 4 |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for respiratory sensitisation based on the classification of the ingredient substances. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a respiratory sensitiser and is present at or above the appropriate generic concentration limit shown in Table 3.4.5. Additional labelling for already sensitised individuals applies if the ingredient is present at or above the concentration limit presented in Table 3.4.6 of the regulation.  Details of the product compositions are presented in the Confidential Annex (section 1.1 and 1.2). There are no ingredients of the products classified for respiratory sensitisation. The products do not, therefore, require classification for respiratory sensitisation 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. |

***Acute toxicity***

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | No classification for products in Meta SPC 1.  Classification for products containing ≥25% w/w dicopper oxide (Meta SPC 2-4). |
| Justification for the selected values | |  | | --- | | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute oral toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredient should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  Details of the product compositions are presented in the Confidential Annex (section 1.1).  The active substance dicopper oxide is present at a range of 0.24 to 35% 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 (17ATP).  Two other ingredients in the products are classified for acute oral toxicity, but they have no specific concentration limits for acute toxicity and are present in very low concentrations (< 0.01%). Hence, the ingredients should not be taken into account (not relevant).  Classification with Acute Tox 4; H302: Harmful if swallowed is warranted for products with ≥25% of dicopper oxide based on the calculation of the ATE of the mixtures.  The calculations can be found in the Confidential Annex.  It is, considered that a study is not required, nor an appropriate use of animals. | |
| Classification of the product according to CLP | Products in the biocidal product family in the concentration range of 25% to 35% are classified as Acute Tox 4; H302: Harmful if swallowed. |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | No classification for Meta SPCs 1 to 4 |
| Justification for the selected values | |  | | --- | | 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 17.2 to 35% 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).  Classification for acute inhalational toxicity is not warranted for products in the biocidal product family based on the calculation of the ATE of the mixtures.  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 to 4 |
| Justification for the selected value | |  | | --- | | Under Regulation (EC) No 1272/2008, in the absence of data, mixtures may be classified for acute dermal toxicity based on the classification of the ingredient substances.  The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the ingredients should be taken into account of 0.1% for Acute Tox 1-3 and 1% for Acute Tox 4 (Table 1.1, in Annex I to Reg. no 1272/2008).  Details of the product compositions are presented in the Confidential Annex (section 1.1 and 1.2). There are two ingredients of the products 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). A classification for acute dermal toxicity according to Regulation (EC) No 1272/2008 is not warranted.  A study is not required, nor considered an appropriate use of animals. | |
| Classification of the product according to CLP | Not classified |

***Other effects***

None of the co-formulants has been identified as being CMR substances (see the Confidential Annex for further information of the classification of the coformulants).

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Dicopper oxide |
| Value(s)\* | Products with 17-35% (w/w) dicopper oxide: 0.98%  Products with approximately 35%(w/w) dicopper oxide: 0.67% |
| Justification for the selected value(s) | 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 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 described 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 photographic 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 values were 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.  The biocidal product family contains family members with a large variation in the active substance content (17.2% - 35.0). The formulations are all based on the same aqueous dispersion of hydrocarbon waxes, However, the variation in active substance concentration is necessarily also reflected in the content of the coformulants (including, but not restricted to water and binders). The products are provided as ready to use (RTU) products or concentrates to be diluted with water.  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). Of that reason, the value used in the risk assessment is 0.98% for 17% and higher concentrations and 0.67% for the highest concentrations (ca. 35% dicopper oxide) only.  Products with low concentration of dicopper oxide (polish products) are no longer a part of the product family which is proposed to be authorised. However, a 5 % default value referred in the assessment report for dicopper oxide (ECHA, 2016a) should be used in the exposure calculations of products with low concentrations of dicopper oxide due to the uncertainties in the results for the test material with the lowest concentration of active substance.  Analytical method validation study (Falconer, 2019): See test report in IUCLID.  (Note: No annotations are provided by refMS in the IUCLID endpoint study record). |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **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[[3]](#footnote-4) | 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 amend-ment 1, 2022)  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

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

The products do not contain any non-active substances of concern (SoC) that result in classification of the products according to Regulation (EC) No 1272/2008 (CLP).

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 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 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 |
|  | Application:  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 packaging of treated nets for shipment to the customer.  (It is assumed that the Dipping model 4 covers treatment of nets using vacuum treatment). | 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 exposure) and washing used nets (secondary exposure) | 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 to copper from dicopper oxide with the relevant toxicological reference value for the active substance. As the products are not classified for local effects, a local risk assessment has not been performed.

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 264, 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 AEL long term is applied in the risk characterisation of net treatment, and AEL medium 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. The family comprises members with an active substance content of 17.2 % - 35.0 % w/w dicopper oxide, of which most products are ready to use (RTU) products. The exposure to the undiluted concentrates will be related to the transfer of the product from the IPC to the dipping vat and is likely to be low. Thus, the exposure to the operator using these products will mainly be to the in-use concentration of the products.

The results of the exposure calculations for the products which are proposed included in the biocidal product family are presented in tables below. The calculations can be found in the attached Excel spread sheets (see 3.2.2).

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Product1** | **Formulation type** | **Cu2O**  **(% w/w)** | **Cu2O**  **in use conc2**  **(% w/w)** | **Cu equivalents (%)3** | **Dermal abs (%)** |
|  | | | | | | |
| 1 | Netrex AF | RTU | 17.2 | 17.2 | 15.27 | 0.98 |
| 1 | Netwax NI 3 | RTU | 20.2 | 20.2 | 17.94 | 0.98 |
| 1 | Netwax NI 4/  Netwax E4 Greenline/  Netrex E4 Greenline | RTU | 23.5 | 23.5 | 20.87 | 0.98 |
|  | | | | | | |
| 2 | Netwax A5 Microfino | RTU | 26 | 26 | 23.09 | 0.98 |
| 2 | Netwax E5 Greenline | RTU | 26.3 | 26.3 | 23.35 | 0.98 |
|  | Netwax E6 Greenline | RTU | 29.9 | 29.9 | 26.55 | 0.98 |
|  | Netwax E7 Greenline | RTU | 32 | 32 | 28.42 | 0.98 |
|  | Netwax A7 Microfino | RTU | 32 | 32 | 28.42 | 0.98 |
|  | Netwax Gold T50 Sens/  Netwax NI Gold XL | RTU | 32.5 | 32.5 | 28.86 | 0.98 |
|  | | | | | | |
| 3 | Netwax Gold T60 Sens | RTU | 34.9 | 34.9 | 30,99 | 0.67 |
| 3 | Netwax E8 Greenline | RTU | 35 | 35 | 31.08 | 0.67 |
|  | | | | | | |
| 4 | Netwax NI 5 (diluted 2:1 w/water) | Concentrate | 26.3 | 18.8 | 16.69 | 0.98 |
| 4 | Netwax NI 6 (diluted 2:1 w/water) | Concentrate | 29.9 | 21.4 | 19.00 | 0.98 |

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

Due to the identified risk in scenario 2 (net treatment, assuming use of double coverall and gloves) for Netwax E6 Greenline, Netwax E7 Greenline Netwax A7 Microfino Netwax Gold T50 Sens/Netwax NI Gold XL, these products have not been included in the product family which is proposed authorised by the RefMS.

(Please refer also to the Excel spread sheets (see 3.2.2).

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

Netwax NI 5: (26.3%\*1.2635)/(1.2635+0.5) = 18.8% by weight

Netwax NI6: (29.9%\*1.2635)/(1.2635+0.5)= 21.4% by weight

3 Cu equivalents are calculated using a relevant conversion factor: [Cu2O]\*0.888

RTU = ready to use product

***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 product** | | |
| 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 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 |
| Tier 1 | Actual hand exposure (*inside protective gloves*)1 | 16.7 mg/min (max value) |
| Potential body exposure1 | 221 mg/min (max value) |
| Potential inhalation exposure1 | 0.2 mg/m3 (max value) |
| Dermal absorption3 | 0.98% (products with 17-35% w/w dicopper oxide)  0.67% (products with approximately 35% w/w dicopper oxide) |
| Inhalation absorption | 100% |
| Inhalation rate2 | 1.25 m3/hr |
| Duration of exposure5 | 60 minutes |
| Body weight2 | 60 kg |
| Tier 2a | Gloves1 | Actual measurements inside gloves. No further refinement. |
| PPE (Coated coveralls)4 | 10% penetration |
| Tier 2b | Gloves1 | Actual measurements inside gloves. |
| PPE (Impermeable coveralls)4 | 5% penetration |
| Tier 2c | Gloves1 | Actual measurements inside gloves. |
| PPE (Double coveralls)4 | 1% penetration |

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

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

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

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculations – Application:** **Treatment of nets with antifouling paint**  **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)** |
| **Netrex AF** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 6.4E-04 | 3.6E-01 | - | **0.356** |
| Tier 2a/PPE  (gloves & coated coveralls) | 6.4E-04 | 5.9E-02 | - | **0.059** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 6.4E-04 | 4.2E-02 | - | **0.042** |
| Tier 2c/PPE  (gloves & double coveralls) | 6.4E-04 | 2.9E-02 | - | 0.029 |
| **Netwax NI3** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 7.5E-04 | 4.2E-01 | - | **0.419** |
| Tier 2a/PPE  (gloves & coated coveralls) | 7.5E-04 | 6.9E-02 | - | **0.069** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 7.5E-04 | 5.0E-02 | - | **0.050** |
| Tier 2c/PPE  (gloves & double coveralls) | 7.5E-04 | 3.4E-o2 | - | 0.034 |
| **Netwax NI 4/Netwax E4 Greenline/Netrex E4 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 8.8E-04 | 4.9E-01 | - | **0.487** |
| Tier 2a/PPE  (gloves & coated coveralls) | 8.8E-04 | 8.0E-02 | - | **0.080** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 8.8E-04 | 5.8E-02 | - | **0.058** |
| Tier 2c/PPE  (gloves & double coveralls) | 8.8E-04 | 4.0E-02 | - | 0.040 |
| **Netwax A5 Microfino** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 9.7E-04 | 5.4E-01 | - | **0.539** |
| Tier 2a/PPE  (gloves & coated coveralls) | 9.7E-04 | 8.9E-02 | - | **0.089** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 9.7E-04 | 6.4E-02 | - | **0.064** |
| Tier 2c/PPE  (gloves & double coveralls) | 9.7E-04 | 4.4E-02 | - | 0.044 |
| **Netwax E5 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 9.8E-04 | 5.4E-01 | - | **0.545** |
| Tier 2a/PPE  (gloves & coated coveralls) | 9.8E-04 | 9.0E-02 | - | **0.090** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 9.8E-04 | 6.4E-02 | - | **0.064** |
| Tier 2c/PPE  (gloves & double coveralls) | 9.8E-04 | 4.4E-02 | - | **0.044** |
| **Netwax Gold T60 Sens** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 1.3E-03 | 4.9E-1 | - | **0.495** |
| Tier 2a/PPE  (gloves & coated coveralls) | 1.3E-03 | 8.2E-02 | - | **0.082** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 1.3E-03 | 5.9E-02 | - | **0.059** |
| Tier 2c/PPE  (gloves & double coveralls) | 1.3E-03 | 4.1E-02 | - | 0.041 |
| **Netwax E8 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 1.3E-03 | 5.0E-01 | - | **0.496** |
| Tier 2a/PPE  (gloves & coated coveralls) | 1.3E-03 | 8.2E-02 | - | **0.082** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 1.3E-03 | 5.9E-02 | - | **0.059** |
| Tier 2c/PPE  (gloves & double coveralls) | 1.3E-03 | 4.1E-02 | - | 0.041 |
| **Netwax NI 5 (diluted 2:1 w/water)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 7.0E-04 | 3.9E-01 | - | **0.390** |
| Tier 2a/PPE  (gloves & coated coveralls) | 7.0E-04 | 6.4E-02 | - | **0.064** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 7.0E-04 | 4.6E-02 | - | **0.046** |
| Tier 1/PPE (gloves) | 7.0E-04 | 3.2E-02 | - | 0.032 |
| **Netwax NI 6 (diluted 2:1 w/water)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 8.0E-04 | 4.4E-01 | - | **0.443** |
| Tier 2a/PPE  (gloves & coated coveralls) | 8.0E-04 | 7.3E-02 | - | **0.073** |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 8.0E-04 | 5.2E-02 | - | **0.052** |
| Tier 2c/PPE  (gloves & double coveralls) | 8.0E-04 | 3.6E-02 | - | 0.036 |

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

***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 scenario is titled "installing fish cages using lifting equipment and handling nets damp with sticky product". The situation is similar as for the exposure scenario for deployment of a treated net. The original surveys are rather 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 calculations can be found in a separate annex, see section 3.2.2. | | |
| Tier | Parameters | Value |
| Tier 1 | Actual hand exposure (inside protective gloves)1 | 0.21 mg/min (75 percentile) |
| Potential body exposure1 | 7.55 mg/min (75 percentile) |
| Dermal absorption3 | 0.98% (products with 17-35% w/w dicopper oxide)  0.67% (products with approximately 35% w/w dicopper oxide) |
| Duration of exposure5 | 300 minutes (worst-case) |
| Body weight2 | 60 kg |
| Tier 2 | Gloves | Actual measurements inside gloves. No further refinement. |
| PPE (uncoated coverall)4 | 25% penetration from dry substances  *(Note: According to the applicant the product is a wax coating that is not expected to completely dry, flake or produce dusty/powdery residues).* |

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculations –Installing and handling treated nets at fish farms  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)** |
| **Netrex AF** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.058 | - | 0.058 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.016 | - | 0.016 |
| **Netwax NI3** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.068 | - | 0.068 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.018 | - | 0.018 |
| **Netwax NI 4/Netwax E4 Greenline/Netrex E4 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.079 | - | 0.079 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.021 | - | 0.021 |
| **Netwax A5 Microfino** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.088 | - | **0.088** |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.024 | - | 0.024 |
| **Netwax E5 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.089 | - | **0.089** |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.024 | - | 0.024 |
| **Netwax T60 Seens** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.081 | - | 0.081 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.022 | - | 0.022 |
| **Netwax E8 Greenline** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.081 | - | 0.081 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.022 | - | 0.022 |
| **Netwax NI 5 (diluted 2:1 w/water)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.063 | - | 0.063 |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | - | 0.017 | - | 0.017 |
| **Netwax NI 6 (diluted 2:1 w/water)** | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | - | 0.072 | - | 0.072 |
| Tier 2a/PPE  (gloves & uncoated coveralls) | - | 0.020 | - | 0.020 |

*\** 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

***Scenario 4: Washing used nets and cleaning of equipment***:

|  |
| --- |
| **Description of Scenario 4 – Post-Application – Washing used nets and cleaning equipment** |
| Cleaning/washing nets after a period of use in the sea  Et bilde som inneholder transport, heisekran  Automatisk generert beskrivelse  After a period of use in the sea, some of the dicopper oxide 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.  1.The used net arrives at the service station, typically in a large bag or in a container.  2.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.  3.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, 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). |

*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).

***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***

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 Lundebye 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.

#### Risk characterisation for human health

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

1 The assessment factors were discussed during the TM IV08 and TMI09 for PT 8 copper substances.

**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 (EU) No. 37/2010).

**Specific reference value for groundwater**

Not relevant.

***Risk for industrial users***

Production and formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation (EU) No. 528/2012. (This principle was agreed at Biocides Technical Meeting TMI06).

***Risk for industrial users due to application of the antifouling product***

***Systemic effects***

**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)** |
| **Netrex AF** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.356 | 8,7 | Yes |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.059 | 1.43 | Yes |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.042 | 1.03 | Borderline |
| Tier 2c/PPE  (gloves & double coveralls) | 0.029 | 0.71 | Yes |
| **Netwax NI3** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.419 | 10.2 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.069 | 1.68 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.050 | 1.21 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.034 | 0.83 | Yes |
| **Netwax NI 4/Netwax E4 Greenline/Netrex E4 Greenline** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.487 | 11.9 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.080 | 1.96 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.058 | 1.41 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.040 | 0.96 | Yes |
| **Netwax A5 Microfino** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.539 | 13.1 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.089 | 2.16 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.064 | 1.56 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.044 | 1.07 | Borderline |
| **Netwax E5 Greenline** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.545 | 13.3 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.090 | 2.19 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.064 | 1.57 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.044 | 1.08 | Borderline |
| **Netwax Gold T60 Sens** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.495 | 12.1 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.082 | 2.00 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.059 | 1.44 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.041 | 0.99 | Yes |
| **Netwax E8 Greenline** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.496 | 12.1 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.082 | 2.00 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.059 | 1.44 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.041 | 0.99 | Yes |
| **Netwax NI 5 (diluted 2:1 w/water)** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.390 | 9.5 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.064 | 1.57 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.046 | 1.12 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.032 | 0.77 | Yes |
| **Netwax NI 6 (diluted 2:1 w/water)** | | | | | | |
| Scenario 2 | Tier 1/PPE (gloves) | 16.3 | 0.041 | 0.443 | 10.8 | No |
| Tier 2a/PPE  (gloves & coated coveralls) | 0.073 | 1.78 | No |
| Tier 2b/PPE  (gloves & impermeable coveralls) | 0.052 | 1.28 | No |
| Tier 2c/PPE  (gloves & double coveralls) | 0.036 | 0.88 | Yes |

**Conclusion:**

Acceptable risk is demonstrated in the systemic risk assessment for industrial workers performing net treatment activities in tier 2 assuming gloves and double coverall (1% clothing penetration) for products in Meta SPC 1, 3 and 4. A borderline risk was estimated for products in meta SPC2 (in use concentration of approximately 26%) in tier 2.

No acceptable risk was demonstrated for the rest of the products in the application (Netwax E6 Greenline, Netwax E7 Greenline, Netwax A7 Microfino and Netwax Gold T50 Sens/Netwax NI Gold XL).

***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)** |
| **Netrex AF** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.058 | 0.71 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.016 | 0.19 | Yes |
| **Netwax NI3** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.068 | 0.83 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.018 | 0.22 | Yes |
| **Netwax NI 4/Netwax E4 Greenline/Netrex E4 Greenline** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.079 | 0.97 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.021 | 0.26 | Yes |
| **Netwax A5 Microfino** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.088 | 1.07 | Borderline |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.024 | 0.29 | Yes |
| **Netwax E5 Greenline** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.089 | 1.08 | Borderline |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.024 | 0.29 | Yes |
| **Netwax T60 Seens** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.081 | 0.98 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.022 | 0.27 | Yes |
| **Netwax E8 Greenline** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.081 | 0.99 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.022 | 0.27 | Yes |
| **Netwax NI 5 (diluted 2:1 w/water)** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.063 | 0.77 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.017 | 0.21 | Yes |
| **Netwax NI 6 (diluted 2:1 w/water)** | | | | | | |
| Scenario 3 | Tier 1/PPE (gloves) | 16.3 | 0.082 | 0.072 | 0.88 | Yes |
| Tier 2a/PPE  (gloves & uncoated cotton coveralls) | 0.020 | 0.24 | Yes |

**Conclusion:**

Acceptable risk is demonstrated in the systemic risk assessment of professional workers performing net deployment in tier I (use of gloves only) for all products in meta SPC 1 (Netrex AF, Netwax NI 3 and Netwax NI 4/Netrex E4 Greenline/Netwax E4 Greenline), meta 3 (Netwax T60 Seens and Netwax 8 Greenline) and meta SPC 4 (Netwax NI 5 and 6).

As for the products in Meta SPC 2 (Netwax E5 Greenline or Netwax A5 Microfino), acceptable risk is demonstrated when use of a coverall is assumed (the exposure values given in the table are for uncoated cotton coverall which is relevant when exposed to dry substances).

**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.

**Local effects**

As the products are not classified for local effects, a local risk assessment has not been performed.

**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.

An acceptable risk was demonstrated in the systemic risk assessment for industrial workers performing net treatment activities for most products in the applied biocidal product family (Netrex AF, Netwax NI 3, Netwax NI 4, Netwax NI 5, Netwax NI 6, Netrex E4 Greenline/Netwax E4 Greenline, Netwax E8 Greenline and Netwax Gold T60 Sens), provided the workers wear double coverall (1% clothing penetration) and chemical resistant gloves. A borderline risk was identified for the products containing approximately 26% dicopper oxide (Netwax E5 Greenline and Netwax A5 Microfino).

Safe use could not be demonstrated even with use of double coveralls and gloves for four of the products included in the applied biocidal product family; Netwax E6 Greenline, Netwax E7 Greenline, Netwax A7 Microfino, Netwax Gold T50 Sens/Netwax NI Gold XL.

***Professional*** ***exposure***

*Net deployment activities:*

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

An acceptable risk was demonstrated in the systemic risk assessment of professional workers performing net deployment for all products. Safe use was demonstrated, assuming use of chemical resistant gloves only, for all products with acceptable risk for net treatment activities (note that the indicative hand exposure value in the exposure model was actual measured values inside gloves). For the two products for which a borderline risk was demonstrated for net treatment activities, an uncoated cotton coverall was additionally needed.

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

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

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

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

Please refer to the dietary exposure assessment in section 2.2.6.2.

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

Not applicable

***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 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 active substance dicopper oxide (Cu2O). The Dicopper Oxide Biocidal 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 Biocidal Product Family, the harmonised scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms (ECHA, 2015b), hereafter referred to as the EU fish farm scenario, has been used for the assessment at the EU level. In addition, an exposure assessment for Norwegian fish farms has been carried out, following the Norwegian environmental emission scenario for nets used in fish farms (NO, 2019), hereafter referred to as the Norwegian fish farm scenario. The latter represents an adjustment of the EU scenario to better reflect Norwegian fish farm conditions.

#### Effects assessment on the environment

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

The relevant ecotoxicological data and the calculated PNECs are summarised in the table 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 PNEC derivation. NOEC values were related to the dissolved 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)

***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***

Details of the product composition are presented in confidential annex.

***Further Ecotoxicological studies***

All information on the ecotoxicology of the products can be extrapolated from the information on the active substance. Ecotoxicity data for the active substance are summarised in the Competent Authority Report (Dicopper Oxide, Product-type 21, France, January 2016).

No further ecotoxicological studies on the Dicopper Oxide BPFproducts are available.

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

There are no indications of risk to other specific (flora and fauna) non-target organisms.

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

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

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

No studies to assess the avoidance or palatability of the biocidal products have been conducted.

***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). It is not foreseen that a large proportion of a specific habitat is treated.

***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 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.

***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.

***Testing for distribution and dissipation in air (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.

**Aquatic bioconcentration**

Dicopper oxide

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

***If the biocidal product is to be sprayed 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.

#### Environmental exposure assessment and risk characterisation

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

1. The first tier assessment is based on the EU fish farm scenario document agreed at EU level.
2. A second 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 farm 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. |
| ESD(s) used | For the assessment covering use in the EU, the EU fish farm scenario was used:  *Scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms. Norwegian Environmental Agency, 2015.*  For the assessment representative for Norway, the Norwegian fish farm scenario was used:  *A Norwegian environmental emission scenario for fish farms - Adjustment of the EU scenario (2015) to better represent national conditions. Norwegian Environmental Agency, 2019* |
| Approach | MAMPEC v.3.1 was used for the modelling.  For the active substance, agreed values from the CAR was used as input. For other environmental parameters, default values for the environmental parameters given in the above-mentioned scenario documents were used, in addition to product-specific values where applicable |
| Distribution in the environment | The PEC values in water and sediment were calculated with MAMPEC v.3.1 based on the input described above |
| Life cycle steps assessed | |  |  | | --- | --- | | Production/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 the confidential annex. All calculations of Elocal are available upon request, see section 3.2.1.

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

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

1 Please see the [Emission scenario for nets used in fish farms (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 substance input parameters**

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

**Concentration of active ingredient (Cu) in the Dicopper Oxide products (use solutions)**

|  |  |  |
| --- | --- | --- |
| **Product** | **Concentration of Cu2O in product (g/L)** | **Concentration of Cu1 in product (g/L)** |
| **Meta 1:**  Netrex AF  Netwax NI 3  Netwax NI4  Netwax E4 Greenline/Netrex E4 Greenline | 204.7  241.5  281.0  285.3 | 180.1  212.5  247.3  251.0 |
| **Meta 2:**  Netwax E5 Greenline  Netwax A5 Microfino | 328.0  343.3 | 288.7  302.1 |
| **Meta 3:** |  |  |
| Netwax E8 Greenline  Netwax Gold T60 Sens | 468.0  466.7 | 411.9  410.7 |
| **Meta 4:**  Netwax NI 5  Netwax NI 6 | 238.1  270.7 | 209.5  238.2 |

1 Copper equivalent from dicopper oxide = 88.8%

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 Cu emission outputs (Elocal)**

|  |  |  |
| --- | --- | --- |
| **Product** | **EU fish farm scenario** | **Norwegian fish farm scenario** |
| **Meta 1:**  Netrex AF  Netwax NI 3  Netwax NI4  Netwax E4 Greenline/Netrex E4 Greenline | 14706 g/d  17354 g/d  20189 g/d  23294 g/d | 22390 g/d  26418 g/d  30744 g/d  31204 g/d |
| **Meta 2:**  Netwax E5 Greenline  Netwax A5 Microfino | 23572 g/d  24666 g/d | 35891 g/d  37557 g/d |
| **Meta 3:** |  |  |
| Netwax E8 Greenline  Netwax Gold T60 Sens | 33627 g/d  33531 g/d | 51207 g/d  51058 g/d |
| **Meta 4:**  Netwax NI 5  Netwax NI 6 | 15917 g/d  18096 g/d | 24230 g/d  27554 g/d |

#### 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***

**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***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EU fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Meta SPC 1** | | | | |
| Netrex AF | 1.29 | **1.12** | 41.63 | 0.42 |
| Netwax NI 3 | 1.33 | **1.15** | 46.23 | 0.47 |
| Netwax NI 4 | 1.37 | **1.19** | 51.15 | 0.52 |
| Netwax E4 Greenline/Netrex E4 Greenline | 1.41 | **1.22** | 56.54 | 0.57 |
| **Meta SPC 2** | | | | |
| Netwax E5 Greenline | 1.41 | **1.23** | 57.02 | 0.58 |
| Netwax A5 Microfino | 1.42 | **1.24** | 58.92 | 0.60 |
| **Meta SPC 3** | | | | |
| Netwax E8 Greenline | 1.54 | **1.34** | 74,48 | 0.75 |
| Netwax Gold T60 Sens | 1.54 | **1.34** | 74.31 | 0.75 |
| **Meta SPC 4** | | | | |
| Netwax NI 5 | 1.31 | **1.14** | 43.73 | 0.44 |
| Netwax NI 6 | 1.34 | **1.16** | 47.51 | 0.48 |

In tier 1 calculations with the EU fish farm scenario, the PEC/PNEC ratios for PECdissolved/PNECwater were above the trigger value for all products.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Norwegian fish farm scenario**  **Average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Meta SPC 1** | | | | |
| Netrex AF | 1.17 | 1.0 | 25.52 | 0.26 |
| Netwax NI 3 | 1.18 | 1.0 | 27.22 | 0.28 |
| Netwax NI 4 | 1.20 | 1.0 | 29.04 | 0.29 |
| E4 Greenline/Netrex E4 Greenline | 1.20 | 1.0 | 29.23 | 0.30 |
| **Meta SPC 2** | | | | |
| Netwax E5 Greenline | 1.21 | **1.1** | 31.20 | 0.32 |
| Netwax A5 Microfino | 1.22 | **1.1** | 31.90 | 0.32 |
| **Meta SPC 3** | | | | |
| Netwax E8 Greenline | 1.26 | **1.1** | 37.65 | 0.38 |
| Netwax Gold T60 Sens | 1.26 | **1.1** | 37.58 | 0.38 |
| **Meta SPC 4** | | | | |
| Netwax NI 5 | 1.18 | 1.0 | 26.29 | 0.27 |
| Netwax NI 6 | 1.19 | 1.0 | 27.69 | 0.28 |

In the Norwegian fish farm scenario calculations, the resulting PEC/PNEC ratios were below the trigger value for all product in Meta SPC 1 and Meta SPC 4, but above the trigger for Meta SPC-2 and Meta SPC 3.

***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 a further 6 sampling intervals over 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. Salinities 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 behaviour 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 Oslo Fjord. Antonsen (2020b) was conducted on a fish farm at Hindholmen, which is located further north on the Norwegian coast. 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 within Norway is considered justified and to other areas with similar environmental conditions.  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.  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 3. Three of the efficacy trials were conducted in Norway (duration from 260-339 days) and in Spain (duration 243 days). The trial in Spain was terminated at 243 days. Whilst this is a slightly shorter duration than the 270-day period which is proposed for the deployment time of the product, there was, according to the applicant, only moderate fouling at 243 days. In addition, the trial in Spain was terminated in January since the trial had already covered the peak biofouling season. It is, according to the applicant, unlikely that there would have been a noticeable difference between the fouling at 270 days and 243 days.

It can, therefore, be concluded that the deployment time of 270 days is appropriate for the Mediterranean regions as well as Norwegian regions.

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. Note that the Relative density values are from study data, please see Section 2.2.2.

**Coverage of product (amount of product used per kg net) calculated as L/kg**

|  |  |  |
| --- | --- | --- |
| **Products** | **1Relative density** | **2Coverage (L/kg)** |
| **Meta SPC 1** | | |
| **Netrex AF** | 1.19 | 1.0084 |
| **Netwax NI 3** | 1.1957 | 1.0036 |
| **Netwax NI 4** | 1.1957 | 1.0036 |
| **Netwax E4 Greenline / Netrex E4 Greenline** | 1.2139 | 0.9885 |
| **Meta SPC 2** | | |
| **Netwax E5 Greenline** | 1.2472 | 0.9622 |
| **Netwax A5 Microfino** | 1.3204 | 0.9088 |
| **Meta SPC 3** | | |
| **Netwax E8 Greenline** | 1.3372 | 0.8974 |
| **Netwax Gold T60 Sens** | 1.3372 | 0.8974 |
| **Meta SPC 4** | | |
| **Netwax NI 5** | 1.2635 | 0.9497 |
| **Netwax NI 6** | 1.2635 | 0.9497 |

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

2Application rate: 0.8 - 1.2 kg of RTU product or diluted product per 1 kg of dry net [Note: For use in the risk assessment calculation, the application rate expressed as L/kg is used. For conversion to volume of product (,i.e., L), the highest amount expressed in kilogram (i.e., 1.2 kg) is divided by product relative density.

**Refined daily emission outputs (Elocal)**

|  |  |  |
| --- | --- | --- |
| **Product** | **EU fish farm scenario** | **Norwegian fish farm scenario** |
| **Meta 1:**  Netrex AF  Netwax NI 3  Netwax NI4  Netwax E4 Greenline/Netrex E4 Greenline | 5067 g/d  5951 g/d  6923 g/d  7867 g/d | 7714 g/d  9059 g/d  10542 g/d  10539 g/d |
| **Meta 2:**  Netwax E5 Greenline  Netwax A5 Microfino | 7749 g/d  7659 g/d | 11799 g/d  11662 g/d |
| **Meta 3:** |  |  |
| Netwax E8 Greenline  Netwax Gold T60 Sens | 10311 g/d  10281 g/d | 15701 g/d  15655 g/d |
| **Meta 4:**  Netwax NI 5  Netwax NI 6 | 5550 g/d  6311 g/d | 8451 g/d  9609 g/d |

**Risk characterisation for the EU fish farm scenario (refined)**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EU fish farm scenario**  **Refined average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Meta SPC 1** | | | | |
| Netrex AF | 1.17 | 1.0 | 24.9 | 0.3 |
| Netwax NI 3 | 1.18 | 1.0 | 26.4 | 0.3 |
| Netwax NI 4 | 1.19 | 1.0 | 28.1 | 0.3 |
| Netrex E4 Greenline/ Netwax E4 Greenline | 1.20 | 1.0 | 29.8 | 0.3 |
| **Meta SPC 2** | | | | |
| Netwax E5 Greenline | 1.20 | 1.0 | 29.6 | 0.3 |
| Netwax A5 Microfino | 1.20 | 1.0 | 29.4 | 0.3 |
| **Meta SPC 3** | | | | |
| Netwax E8 Greenline | 1.24 | **1.1** | 34.0 | 0.3 |
| Netwax Gold T60 Sens | 1.24 | **1.1** | 34.0 | 0.3 |
| **Meta SPC 4** | | | | |
| Netwax NI 5 | 1.17 | 1.0 | 25.7 | 0.3 |
| Netwax NI 6 | 1.18 | 1.0 | 27.1 | 0.3 |

In the refined calculations for the EU fish farm scenario, there were exceedances of PECdissolved/PNECwater>1 for the product in Meta SPC-3. For Meta SPC 1, 2, and 4, PEC/PNEC ratios were ≤ 1.

According to the applicant, the minor exceedances of PEC/PNEC could be considered further in the context of the protection goals of the risk assessment:

* 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Norwegian fish farm scenario**  **Refined average PEC values calculated by MAMPEC v3.1**  **(with background concentration for Cu)** | | | | |
| **Copper**  PNECsurrounding waters = 1.15 µg/L  PNECsed = 98.8 µg/g dw | **PECdissolved**  [µg/L] | **PECdissolved / PNECwater 1** | **PECsuspended sediment**  [µg/g dw] | **PECsuspended sediment / PNECsediment 1** |
| **Meta SPC 1** | | | | |
| Netrex AF | 1.12 | 1.0 | 19.35 | 0.2 |
| Netwax NI 3 | 1.13 | 1.0 | 19.91 | 0.2 |
| Netwax NI 4 | 1.13 | 1.0 | 20.54 | 0.2 |
| Netrex E4 Greenline/ Netwax E4 Greenline | 1.13 | 1.0 | 20.53 | 0.2 |
| **Meta SPC 2** | | | | |
| Netwax E5 Greenline | 1.14 | 1.0 | 21.06 | 0.2 |
| Netwax A5 Microfino | 1.14 | 1.0 | 21.01 | 0.2 |
| **Meta SPC 3** | | | | |
| Netwax E8 Greenline | 1.15 | 1.0 | 22.7 | 0.2 |
| Netwax Gold T60 Sens | 1.15 | 1.0 | 22.7 | 0.2 |
| **Meta SPC 4** | | | | |
| Netwax NI 5 | 1.13 | 1.0 | 19.66 | 0.2 |
| Netwax NI 6 | 1.13 | 1.0 | 20.14 | 0.2 |

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

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

***Overall Conclusion***

In summary, only the product in meta-**SPC 1, meta-SPC-2, and meta-SPC 4** showed an acceptable environmental risk in the EU scenario.

The products in all meta-**SPCs** showed acceptable environmental risk in the Norwegian fish farm scenario.

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

Please refer to summary of the product assessment (section 2.1) and to the relevant sections of the assessment report.

**Recommended methods and precautions concerning transport**

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

ADR

UN number: 1760

UN proper shipping name:

CORROSIVE LIQUID, N.O.S. (dicopper oxide, copper (I) oxide)

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

Environmental hazards: Dangerous for the environment : Yes

IMDG

UN number: 1760

UN proper shipping name:

CORROSIVE LIQUID, N.O.S. (dicopper oxide, copper (I) oxide)

Transport document description: UN 1760 CORROSIVE LIQUID, n.o.s. (dicopper oxide, copper (I) oxide), 8, III, (E) MARINE POLLUTANT

Transport hazard class(es):8

Packing group: III

Environmental hazards: Dangerous for the environment : Yes; Marine pollutant : Yes

IATA

UN number: 1760

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

Transport hazard class(es):8

Packing group: III

Environmental hazards: Dangerous for the environment : Yes

RID

UN number: 1760

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

Transport hazard class(es):8

Packing group: III

Environmental hazards: Dangerous for the environment : Yes

|  |
| --- |
|  |

### Assessment of a combination of biocidal products

Not applicable.

### Comparative assessment

Not Relevant.

# 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 |
| Atwal, S.S. and White, D.F | 2011 | Netwax NI 3: Determination of Physico-Chemical Properties | Harlan Laboratories Ltd Shardlow Business Park  Shard low  Derbyshire  DE72 2GD UK | 41004093 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2011-07-19 | Unpublished | Yes |
| Atwal, S.S. and White, D.F | 2012a | Netwax NI 4: Determination of Storage Stability at 4°C | Harlan Laboratories Ltd Shardlow Business Park  Shard low  Derbyshire  DE72 2GD UK | 41004098 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2012-10-08 | Unpublished | Yes |
| Atwal, S.S. and White, D.F | 2012b | Netwax NI 4: Determination of Storage Stability at 20°C | Harlan Laboratories Ltd Shardlow Business Park  Shard low  Derbyshire  DE72 2GD UK | 41004096 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2012-10-08 | Unpublished | Yes |
| Atwal, S.S. and White, D.F | 2012c | Netwax NI 4: Determination of Storage Stability at 30°C | Harlan Laboratories Ltd Shardlow Business Park  Shard low  Derbyshire  DE72 2GD UK | 41004097 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2012-10-08 | Unpublished | Yes |
| Harding, L | 2018a | Physical and Chemical testing of Netwax NI 4 | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8347 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2018b | Physical and Chemical testing of Netwax E4 Greenline | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8348 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2018c | Physical and Chemical testing of Netwax E5 Greenline | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8353 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2018d | Physical and Chemical testing of Netwax A5 Microfino | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8356 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2018e | Physical and Chemical testing of Netwax E8 Greenline | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8333 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Harding, L | 2018f | Physical and Chemical testing of Netwax NI 6 | CEM Analytical Services Limited (CEMAS)  Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire,  RG41 2FD, UK | CEMR-8350 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2018-01-08 | Unpublished | Yes |
| Siusiene, E. | 2022a | Explosive and Self-reactive Properties Testing on a Test Item of Netwax NI3 | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016010435CR1/2022 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-11-07 | Unpublished | Yes |
| Siusiene, E. | 2022b | Flash Point Testing on a Test Item of Netwax NI3 | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016010435AR1/2022 | 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 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. | 2022d | 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 |
| Siusiene, E. | 2022e | Auto Ignition Temperature of Liquids Testing on a  Test Item of Netwax NI3 | DEKRA UK Ltd  Phi House  Southampton Science Park  Southampton  SO16 7NS  United Kingdom | GLP3016010435AR1/2022 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-11-03 | Unpublished | Yes |
| Walker, J. | 2022a | Netwax NI 3: Determination of Wet Sieve and Persistent Foam | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road, Shardlow Derbyshire DE72 2GD UK | 8506628 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-20 | Unpublished | Yes |
| Walker, J. | 2022b | Netwax NI 3: Determination of Pourability | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road, Shardlow Derbyshire DE72 2GD UK | 8493339 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-19 | Unpublished | Yes |
| Walker, J. | 2022c | Netwax E8 Greenline:  Determination of Pourability | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road Shardlow Derbyshire DE72 2GD UK | 8493364 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-19 | Unpublished | Yes |
| Walker, J. | 2022d | Netwax NI 5: Determination of Physico-Chemical Properties | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road Shardlow Derbyshire DE72 2GD UK | 8506626 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2022-12-20 | Unpublished | Yes |
| Walker, J. | 2023 | Netwax NI 5: Determination of Suspensibility and Spontaneity of Dispersion | Labcorp Early Development Laboratories Ltd. Shardlow Business Park London Road Shardlow Derbyshire DE72 2GD UK | 8499162 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2023-02-28 | 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 |
| Atwal, S.S. and Wooley, A.J. | 2011 | Netwax NI 4: Analytical method validation | Harlan Laboratories Ltd Shardlow Business Park  Shard low  Derbyshire  DE72 2GD UK | 41004094 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2011-07-21 | 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 |
| Hansen, H. & Føsker, L. | 2020 | Comparative Study of Fish Net Coatings | LetSea AS, Torolv Kveldulvsons gate 29, 8800 Sandnessjøen, Norway | Project 1905 | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-01-28 | Unpublished | Yes |
| Skjaervik, 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 | 2020-04-23  2020-06-24 (revised report) | Unpublished | Yes |
| Skjaervik, 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 leakage of copper oxide in AF | | NetKem AS | Not applicable | NetKem AS Slalåmveien 1 N0-1410 Kolbotn Norway | 2020-03-02  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** |
| Blaszcak, D. L. | 2000 | Netrex AF: Primary Eye Irritation Study in Rabbits | Huntingdon Life Sciences | Study No. 99-0548 | NetKem AS Slalamveien 1 N0-1410 Kolbotn Norway | 2000-01-14 | 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 two 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\_CuO\_EUscenario.xlsx

Netkem\_CuO\_EUscenario\_refined.xlsx

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

The following excel-files are available upon request:

Netkem\_CuO\_NOscenario.xlsx

Netkem\_CuO\_NOscenario\_refined.xlsx

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 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.

# REFERENCES

* Bernhard et al., 2020; Monitoring Program for Pharmaceuticals, illegal substances and contaminants in farmed fish – Annual Report for 2019.
* Bloecher, N, Floerl, O (2018) Guidelines for efficacy testing of antifouling coatings for nets in field tests. Technical paper, Norwegian Environment Agency, Oslo. <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2XMKICN7YW4LNG2PMFDDGEPXCOB>
* European Chemicals Agency (ECHA), 2014. Committee for Risk Assessment; RAC opinion proposing harmonised classification and labelling at EU level of Dicopper oxide. Adopted 4 December 2014
* European Chemicals Agency (ECHA), 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, 2017c). Guidance on the Application of the CLP Criteria, Version 5.0.

* European Chemicals Agency (ECHA), 2019. Draft proposal: "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA".
* European Commission (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L 353, 1-1355
* European Food Safety Authority (EFSA); Buist, H. et al. 2017: Guidance on dermal absorption. EFSA Journal, Volume 15, Issue 6, June 2017.
* Human Exposure Expert Group (HEEG) 2010. Opinion 9. Default protection factors for protective clothing and gloves. Ispra, 27.01.2010.
* Lundebye, A-K, et al (2017). Lower levels of Persistent Organic Pollutants, metals and the marine omega 3-fatty acid DHA in farmed compared to wild Atlantic salmon (Salmo salar), Environmental Research 155 (2017) 49–59.
* NO, 2019. A Norwegian environmental emission scenario for nets used in fish farms – Adjustment of the EU scenario (2015) to better reflect national conditions (Norwegian Environment Agency, 2019) <https://www.miljodirektoratet.no/sharepoint/downloaditem?id=01FM3LD2R5JRIODQDGLRGYVLQ536GBGTVY>
* OECD Guideline for Testing of Chemicals, Guideline 428: Skin Absorption: In Vitro Method (2004a)
* OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 28; Guidance Document for the Conduct of Skin Absorption Studies (2004b)
* Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment (CA-March21-Doc.4.3\_Final "Bridging Biocides with REACH) (available from: <https://circabc.europa.eu/sd/a/987cb9c0-2c8e-45d6-b431-aa456d0584ea/CA-March21-Doc.4.3_Final_Bridging%20Biocides%20with%20REACH.docx>)
* 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. At the time the study was performed (2011, prior to BPR dossier submission) the product Netwax NI 3 existed in a version that contained 17.89% w/w dicopper oxide. This version of the product is hereby named "Netwax NI 3old". Full composition can be found in the confidential PAR. [↑](#footnote-ref-2)
2. Netwax Microfino A7 is proposed to not authorise due to unacceptable risk in the human health assessment. However, due to its relevance for the environmental assessment, the efficacy results for this product are included in the efficacy assessment as supportive information. [↑](#footnote-ref-3)
3. OECD, 2004a; OECD, 2004b; EFSA, 2017; ECHA, 2016b; ECHA, 2016c [↑](#footnote-ref-4)