HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 17 januari 2014 is van

International Paint (Nederland) B.V.
Postbus 856
3160 AB RHOON
Nederland

een aanvraag tot toelating van de biocide op basis van niet geplaatste stof(fen) (overgangsrecht) ontvangen voor het middel

Micron LZ

op basis van de werkzame stof koper(I)oxide.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage III bij dit besluit is voorgeschreven.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder "verpakkingsinformatie" in bijlage I.
- Het toelatingsnummer.
- De etikettering zoals opgenomen in bijlage II bij dit besluit, deze moet volgens de voorschriften op de verpakking worden vermeld.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III, onder A.
- De gebruiksaanwijzing, hetzij letterlijk, hetzij naar zakelijke inhoud, zoals opgenomen in bijlage III, onder B. De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

2 WETTELIJKE GRONDSLAG

Besluit	art 89, tweede lid van EU 528/2012 jo art 130a, vierde lid Wet gewasbeschermingsmiddelen en biociden (Wgb) jo art 4, tweede lid Wgb (oud) jo art 121 Wgb (oud) jo art 44 Wgb (oud) .
Classificatie en etikettering	artikel 89, tweede lid, Verordening 528/2012, jo. artikel 130a, vierde lid, WBB, jo. artikel 50 WGB oud
Gebruikt toetsingskader	RGB (Hoofdstuk 10)

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 7 juli 2017

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20140120 TB
Type aanvraag:	aanvraag tot toelating van de biocide op basis van niet geplaatste stof(fen) (overgangsrecht)
Middelnaam:	Micron LZ
Verzenddatum aanvraag:	16 januari 2014
Formele registratiedatum: *	29 januari 2014
Datum in behandeling name:	16 april 2014

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
koper(I)oxide	8,0%

De werkzame stof koper(I)oxide is opgenomen in het reviewprogramma en zal worden geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012 per 1 januari 2018.

3 Toelatingsinformatie

Toelatingsnummer:	15401 N
Expiratiedatum:	1 augustus 2021
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Zowel niet-professioneel als professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Andere vloeistoffen voor directe toepassing

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BIJLAGE II Etikettering van het middel Micron LZ

Professioneel en niet-professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: ethylbenzeen, nafta laag kookpunt aromatisch, pijnhars, xyleen

Pictogram	GHS02 GHS05 GHS07 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H226 Ontvlambare vloeistof en damp. H317 Kan een allergische huidreactie veroorzaken. H318 Veroorzaakt ernstig oogletsel H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P101 Bij het inwinnen van medisch advies, de verpakking of het etiket ter beschikking houden. P102 Buiten het bereik van kinderen houden. P103 Alvorens te gebruiken, het etiket lezen. P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P271 Alleen buiten of in een goed geventileerde ruimte gebruiken. P273 Voorkom lozing in het milieu. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P305 + P351 + P338 + P310 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	EUH066 Herhaalde blootstelling kan een droge of een gebarsten huid veroorzaken.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG/GA van het middel Micron LZ,

Let op! Separate WG/GA's voor professioneel en niet-professioneel gebruik

WG/GA voor professioneel gebruik

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als aangroeiwerende verf op pleziervaartuigen.

Dit middel mag uitsluitend worden aangebracht en verwijderd op daar toe aangewezen locaties in professionele scheepswerven en droogdokken met de juiste toestemmingen in het kader van de Wet milieubeheer / Omgevingswet ter voorkoming van vervuiling van bodem, grondwater , oppervlaktewater en lucht.

Onbeschermde personen dienen niet aanwezig te zijn in de ruimten waar de behandeling plaatsvindt.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Deze verf vermindert de aangroei van micro- en macro-organismen op pleziervaartuigen en is werkzaam in wateren met lage fouling druk zoals in Europese wateren. Het verkrijgen van een goed resultaat met deze aangroeiwerende verf is van vele factoren afhankelijk. Gebruikers dienen zich te houden aan de door de fabrikant geleverde informatie en/of applicatievoorschriften.

Algemene richtlijnen
Voor gebruik goed roeren.
De ondergrond moet droog zijn en vrij van aangroei en andere verontreinigingen. Alle voorbehandelingen en verfapplicaties, in het bijzonder wanneer meer dan één laag wordt aangebracht, moeten worden uitgevoerd volgens de door de fabrikant verstrekte instructies.

Aanbrengen met kwast, rolborstel of geschikte spuitapparatuur voor airless spuiten.

Toepassing met behulp van een airless sprayer:
Aanbrengen met geschikte spuitapparatuur voor airless spuiten.
Airless Spray Pressure: 176-201 bar. Tip Size: 2180 1500psi
Behandel 5 m² per liter product.
1 laag aanbrengen met 90 micron droge laagdikte.

Toepassing met behulp van een kwast of roller:
Dit wordt uitsluitend aanbevolen voor kleine oppervlakken.
Behandel 10 m² per liter product.
Breng 1 of 2 lagen aan met ieder 45 micron droge laagdikte.

Droogtijden voor de behandeling met Micron LZ

15401 N

Oppervlakte temperatuur	5ºC	15ºC	23ºC	35ºC
Kleefvrij na	1 uur	45 mins	30 mins	20 mins
Aanbrengen 2^{e} laag na	16 uur of langer	10 uur of langer	6 uur of langer	4 uur of langer
Te water laten na	24 uur	12 uur	8 uur	6 uur

Maximale tijd voor te water laten bij 5-35ºC: 6 maanden

WG/GA voor niet-professioneel gebruik

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als aangroeiwerende verf op pleziervaartuigen.

Ter voorkoming van risico's aan bodem, grondwater, oppervlaktewater en lucht mag het product enkel aangebracht en verwijderd worden op speciaal ingerichte locaties bij havens, droogdokken en scheepshellingen, welke in het bezit zijn van toestemmingen overeenkomstig met de Wet milieubeheer/ Omgevingswet.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor niet-professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Deze verf vermindert de aangroei van micro- en macro-organismen op pleziervaartuigen en is werkzaam in wateren met lage fouling druk zoals in Europese wateren. Het verkrijgen van een goed resultaat met deze aangroeiwerende verf is van vele factoren afhankelijk. Gebruikers dienen zich te houden aan de door de fabrikant geleverde informatie en/of applicatievoorschriften.

Algemene richtlijnen
Voor gebruik goed roeren.
De ondergrond moet droog zijn en vrij van aangroei en andere verontreinigingen. Alle voorbehandelingen en verfapplicaties, in het bijzonder wanneer meer dan één laag wordt aangebracht, moeten worden uitgevoerd volgens de door de fabrikant verstrekte instructies.

Aanbrengen met kwast of rolborstel.

Toepassing met behulp van een kwast of roller:
Behandel 10 m² per liter product.
Breng 1 of 2 lagen aan met ieder 45 micron droge laagdikte.

Droogtijden voor de behandeling met Micron LZ

Oppervlakte temperatuur	5ºC	15ºC	23ºC	35ºC
Kleefvrij na	1 uur	45 mins	30 mins	20 mins
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Te water laten na	24 uur	12 uur	8 uur	6 uur

Maximale tijd voor te water laten bij 5-35ºC: 6 maanden

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant
International Paint (Nederland) B.V.
Postbus 856
3160 AB RHOON
Nederland

1.2 Active substance
Copper(I)oxide

1.3 Product
Micron LZ

1.4 Function
Micron LZ is an antifouling paint (PT21)

1.5 Background to the application
This concerns an application for authorisation of a new biocidal product.

1.6 Intended uses
The proposed field of use of Micron LZ is as an antifouling paint on pleasure crafts in marine, brackish and fresh water, to prevent the settlement and growth of micro- and macro organisms. The product is a ready to use paint available in several colours, and meant for both professional and non-professional use.

1.7 Packaging details
Epoxy-phenolic resin coated tin (750mL, 2.5L, 5L)

2 Identity

H.2.1 Identity of the active substance

Common name	Cuprous oxide
Name in Dutch	Koper(I)oxide
Chemical name	Copper(I)oxide
CAS no	1317-39-1
EC no	215-270-7

The active substance cuprous oxide is not included in the Union list of approved substances of EU Regulation 528/2012. A draft CAR is available. France is the eCA of cuprous oxide.

The list of endpoints below is taken from previously submitted data. Where relevant, some additional remarks/information are given in italics.

Active substance	Cuprous oxide (non-ISO)
Chemical name (IUPAC)	Copper (I) oxide; dicopper oxide
Chemical name (CA)	Copper oxide

CIPAC No	44
CAS No	1317-39-1
EEC No (EINECS or ELINCS)	215-270-7
FAO Specification (including year of publication)	AGP: CP/251 (1991): On a found content of 820 g/kg total copper, the maximum permitted amount of metallic copper would be 50 x 820 = 41000 mg or 41 g/kg in the material. the maximum permitted amount of cupric copper would be 100 x 820 = 82000 mg or 82 g/kg in the material. the maximum permitted amount of copper soluble in water would be 25 x 820 = 20500 g/kg 20.5 g/kg in the material. the maximum permitted amount of arsenic would be 0.1 x 820 = 82 mg/kg in the material. the maximum amount of lead would be 0.5 x 820 = 410 mg/kg in the material.the maximum permitted amount of cadmium would be 0.1 x 820 = 82 mg/kg in the material
WHO Specification (including year of publication)	Not applicable
Minimum purity of the active substance as manufactured (g/kg)	960
Molecular formula	Cu_2O
Molecular mass	143.09
Structural formula	Cu-O-Cu

H.2.2 Identity of the biocidal product

Name	Micron LZ
Formulation type	AL
Content active substance	Cuprous oxide mean: 8.0%w/w Black 7.9%w/w Navy 7.9%w/w Red 8.1%w/w Off white 7.9%w/w

Packaging information:

	Material	Size / content	Other information
Professional use	epoxy-phenolic resin coated tin	750mL, 2.5L, 5L	-
Non-professional use	epoxy-phenolic resin coated tin	750mL, 2.5L, 5L	-

H.2.3 Overall conclusions identity

The identity of the active substances and the biocidal product is sufficiently described.

Data requirements
None.

3 Physical and chemical properties

H.3.1 Physical and chemical properties of the active substance

The list of endpoints below is taken from previously submitted data. Where relevant, some additional remarks/information are given in italics.

Melting point (state purity)	1232 °C
Boiling point (state purity)	1800 °C
Temperature of decomposition	Not applicable
Appearance (state purity)	Cubic crystals or microcrystalline powder. Color may be yellow, red, or brown depending on the method of preparation and the particle size
Relative density (state purity)	D_4^{20} = 5.87
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature)	Negligible
Henry's law constant (in $Pa \cdot m^3 \cdot mol^{-1}$)	Not applicable
Solubility in water (in g/l or mg/l, state temperature)	6.39 x 10^{-4} g/l at 20 °C, pH 6.5 <5.39 x 10^{-4} g/l at 20 °C, pH 9.8 > 28.6 g/l at 20 °C, pH 4.0 at lower pH the solubility is due to a reaction; the material neutralizes acid solutions
Solubility in organic solvents (in g/l or mg/l, state temperature)	Toluene <1.4 x 10^{-2} g/l at 20°C Dichloromethane <1.0 x 10^{-2} g/l at 20°C n-hexane <1.2 x 10^{-2} g/l at 20°C ethyl acetate <1.2 x 10^{-2} g/l at 20°C methanol <9.8 x 10^{-3} g/l at 20°C acetone <1.3 x 10^{-2} g/l at 20°C
Partition co-efficient (log P_{ow}) (state pH and temperature)	Not applicable
Hydrolytic stability (DT_{50}) (state pH and temperature)	Liable to oxidation to cupric oxide and to conversion to a carbonate on exposure to moist air.
Dissociation constant	Not applicable
UV/VIS absorption (max.) (if absorption >290 nm state ε at wavelength)	Not applicable
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Not applicable
Quantum yield of direct photo-transformation in water at λ > 290 nm	Not applicable
Photochemical oxidative degradation in air	Not applicable
Flammability	Not highly flammable

Auto-flammability	Not relevant
Oxidative properties	Not oxidising
Explosive properties	Not explosive

Copper(I)oxide is an inorganic copper compound. The compound is present in nature as the mineral cuprite and is also called red copper.

A full 5-batch analysis of copper(I)oxide is not available. This is acceptable taking the nature of the substance into account. The impurities lead, cadmium and arsenic have been determined in 10 batches.

H.3.2 Physical and chemical properties of the biocidal product

Appearance	Black, navy, red, off white viscous liquid paint
Explosive properties	Not explosive
Oxidative properties	Not oxidising
Autoflammability	Not self igniting (371°C)
Flashpoint	42.8°C
pH 1% solution	6.99
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	103-143 mPa.s, at 25.°C Shear rate 10 s^{-1}
Relative density	1.27-1.40 $g.cm^{-3}$ at 23°C
Storage stability/Shelf life/Packaging	Stable for 8 weeks at 40°C in epoxy-phenolic resin coated tins. Stability data were provided of the product Fabi Skeppsmask CT Kobber Antifouling Paint. The composition of this product is comparable to the composition of Micron LZ. Therefore it is acceptable to extrapolate stability data. Properties determined before and after storage: appearance, density, viscosity, pH (1%), a.s. content, packaging stability.
Technical properties	Pourability (CIPC MT148) Residue: 15.16% Rinsed residue: 8.75% Pourability is considered acceptable for a paint.
Physical and chemical compatibility	Not applicable

Based on the accelerated storage data, extrapolation to 2 years of shelf-life is considered acceptable.

H.3.3 Overall conclusions physical and chemical properties

The physical and chemical properties of the active substances and the biocidal product are sufficiently described by the available information.

Shelf-life: 2 years in epoxy-phenolic resin coated tins

Data requirements

None.

4 Analytical methods for detection and identification

H.4.1 Analytical methods for the technical active substance

The list of endpoints below is taken from previously submitted data. Where relevant, some additional remarks/information are given in italics.

Technical as (principle of method)	AAS
Impurities in technical as (principle of method)	AAS for Pb, Cd and As.

H.4.2 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	Titration

H.4.3 Residue analytical methods

The list of endpoints below is taken from previously submitted data. Where relevant, some additional remarks/information are given in italics.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable
Soil (principle of method and LOQ)	Not applicable
Water (principle of method and LOQ)	No method submitted. Publically available methods are available for analysis of copper residues in drinking, surface and sea water.
Air (principle of method and LOQ)	Not applicable
Body fluids and tissues (principle of method and LOQ)	Not required, non toxic compound

The applicant has not submitted analytical methods for the determination of copper in water. However, several analytical methods have been developed and are publicly available. These methods are capable of analysing copper in (sea)water and the determination of the MTR-value of dissolved copper.

H.4.4 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

Micron LZ is an antifouling paint based on cuprous oxide (maximum 8.1% w/w, average 8% w/w; depending on colour).

5.2 Field of use envisaged

The proposed field of use of Micron LZ is as an antifouling paint on pleasure crafts in marine, brackish and fresh water, to prevent the settlement and growth of micro- and macro organisms. The product is a ready to use paint available in several colours.

These uses are included in PT21.

The product is intended both for professional and non-professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

A study with Micron LZ was performed at three locations in Europe which provide different fouling challenges:1. Newton Ferrers, Devon, UK: temperate coastal water with seasonal fouling challenge; 2. Brattön, Sweden: in spite of the relatively low salinity, the area supports a significant fouling community with barnacles and mussels being particularly well represented in the summer months. 3. Oskarshamn, Sweden: the fouling challenge is typically brown weed, hydroids and a small number of barnacles.

Replicate marine plywood panels (3600 cm^2) were painted with strips (approx 250 cm^2) of the test article and ‘standard antifouling’ (positive control) for comparison. A section of each board was left untreated as a negative control.

Three coats of each paint were applied to a marine ply panel of 3600cm^2 giving a dry film thickness of approximately 135µm. Three strips were the revised version of Micron LZ and three standard paints (positive control: an antifouling paint with a proven track record), and a negative control (a non-antifouling epoxy paint). The panels were exposed for a period 47 weeks at Devon (UK), 22 weeks at Bratton(Sweden) and for 16 weeks at Oskarsmanm (Sweden).

The tests conducted demonstrated that Micron LZ is efficacious on both the east and west coast of Sweden. It also demonstrates adequate antifouling performance in Newton Ferrers, UK. It performed significantly better in all locations than the non-toxic control strip, that showed 40-100% coverage with hard-bodied marine animals, whereas the panels treated with Micron LZ only showed fouling by algae and weeds. Micron LZ did not perform as well, however, as the positive reference product. In conclusions Micron LZ demonstrated effective antifouling performance at all raft locations in European seas, reducing the amount of fouling adhering to the static panels.

The available information was sufficient to evaluate the efficacy of Micron LZ to prevent the growth of micro- and macro organisms on pleasure vessels, considering evaluation is done under article 121 of the WGB. The studies show that Micron LZ is effective as an antifouling paint on pleasure craft in European waters, when used in accordance with the instructions described on the WG/GA.

5.3.2 Evaluation of the label (WG/GA)

The applicant has provided a WG/GA in Dutch. This has been adapted to our standards. In the past WG/GA’s for antifouling products contained almost no information and always referred to the manual of the manufacturer. Recent insights show that basic requirements, like doses and dilution, should be provided to prevent unauthorised use. The methods of application provided by the applicant have been combined with standard set-up of the WG/GA for antifouling products.

5.4 Mode of action
When metallic copper or cuprous oxide leaches into marine water in the presence of oxygen the predominant form of the copper is the cupric ion Cu^{2+}. This ion acts to retard biofouling via two mechanisms; (1) the ion retards organism's vital processes by inactivating enzymes, and (2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates. At the hull of the vessel the cupric ion is concentrated and is bioavailable overwhelming the natural biological processes of the organisms that under normal conditions can utilize the copper as a micronutrient or expel excess copper. The cupric ion quickly complexes and becomes more dilute as is passes away from the vessel hull and therefore organisms can exist in close proximity to the ship such as on pilings of piers and docks.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
According to the applicant development of resistance is not to be expected:

- There have never been any recorded cases of resistance in populations of fouling organisms through the use of antifouling paints.
- Resistance is unlikely due to the broad spectrum of algal and animal species controlled by these products and the general nature of the mode of action of active substances used (i.e. general metabolic inhibition)
- Several other antifouling paint products with active ingredients other than Copper(I)oxide and copper pyrithione are used
- The ships covered with the antifouling paint travel over the whole world and come in contact with non-resistant populations continuously.

No management strategy is necessary.

5.6 Overall conclusions of efficacy
Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it can be concluded that Micron LZ, when used in accordance with the proposed label (WG/GA), is effective as an antifouling paint on pleasure crafts in marine, brackish and fresh water, to prevent the settlement and growth of micro- and macro organisms.

6 Human toxicology

Human health effects assessment active substances

Copper(I)Oxide
Copper(I)oxide is an existing active substance, not included in the Union list of approved substances of EU Regulation 528/2012. An application for inclusion is submitted (France is the Reporting Member State). A draft CAR is available. The toxicological data concerning copper are summarized by the RIVM in 1998 (report number 05318A00). There is also an EFSA conclusion on the evaluation of the active substance "copper(I), copper(II) variants" from 2008, which includes copper(I)oxide. The toxicological profile of copper(I) oxide is partially based on the EFSA evaluation and RIVM report and partially on the data on copper(II) oxide, for which a final CAR for PT8 is available (France is the Reporting Member State).

Copper (Cu) is an essential trace element. The daily intake for a human adult is 1.5 – 3.5 mg. *In vivo* Cu^{+} can be converted into Cu^{2+} and vice versa, therefore no distinction on either Cu^{+}/ Cu^{2+} will be made in this risk assessment. Furthermore, within this risk assessment the word copper refers to ionic copper, except when specific copper compounds are mentioned.

Toxicokinetics

Absorption including dermal absorption
After oral exposure, 25 to 70% of the available Cu is taken up by humans. In the draft CAR of copper(II) oxide a value of 36% has been set for oral absorption. As copper(I) oxide and copper(II) oxide are both insoluble in water and in most organic solvents substances, their uptake by oral route is expected to be comparable. The Dutch Health Council uses the value of 40% for oral absorption of copper.

Based on new, limited data it was concluded by TNO that a dermal absorption value of 1% is representative for water soluble copper ligands. The dissolving capacities for copper(I)oxide in water or in organic solvents are negligible. Therefore, the value of 1% for dermal absorption is likely to be too conservative for copper(I) oxide. The value of 0.1% dermal absorption was used for copper(I)oxide by US-EPA.
A dermal absorption study with two anti-fouling paints containing copper(I) oxide was submitted by the applicant, in which a maximal absorption of 0.05% was reported following 8 hours exposure duration and 16 hours post-exposure (based on the amount of copper in the receptor fluid and in the dermis). As the composition of the formulations is comparable to Interspeed 6200, this study can be used for Micron LZ. Therefore the value of 0.05% will be used for dermal absorption in the risk assessment.

There is no accurate data available in relation to the inhalatory absorption of Copper. There could be an indication that 20% of the inhaled amount is absorbed, however, for the risk assessment an inhalatory absorption value of 100% as worst-case will be used.

Metabolism, distribution and excretion
Absorbed Cu is transported to the liver and is excreted into bile (90% of the Cu is excreted via faeces) or into the blood circulation; the uptake of Cu is physiologically regulated.

Toxicodynamics
Acute toxicity
The oral LD_{50} for Cu is highly dependent on the type of chemical compound in which it is administered. In rat a great variety of copper compounds have been tested, resulting in oral LD_{50} values of 66-960 mg/kg bw; in mouse, rabbit and guinea pig respectively LD50 values of 90, 91, and 15 mg/kg bw are reported. For copper(II) oxide, oral LD50 > 2500 mg/kg bw was reported in rats. For copper(I) oxide the EFSA evaluation suggests LD50 values in the range of 300-500 mg/kg bw. Based on this classification as Acute Toxic 4, H302 for acute oral toxicity is proposed for copper(I) oxide.

For acute dermal toxicity, dermal LD50 > 2000 mg/kg bw was reported for copper(II) oxide. Based on this data, no classification for acute dermal toxicity is proposed for copper(I) oxide.

Regarding acute inhalation toxicity, the Voluntary Risk Assessment (VRA) draft on copper and copper salts recommended to classify all relatively insoluble copper salts as Xn/R20 (harmful by inhalation) according to Directive 67/548/EEC, or as Acute Toxic 4, H332 (harmful if inhaled) according to

Regulation 1272/2008/EC. The EFSA (2008) reports the LC50 of 2.92 mg/L/4 hours (nose-only exposure). Therefore the classification as Acute Toxic 4, H332 is proposed for copper(I) oxide.

Skin contact with various copper compounds mostly does not lead to irritation. However, various copper compounds do induce eye irritation upon contact. Epidemiological human data shows that in a working setting Cu has irritating properties for both eyes and airways. Furthermore, increased sensitization is reported in humans after repeated contact. However, in humans the incidence of copper-induced contact dermatitis is very low. Based on the EFSA report (2008), copper(I) oxide is slightly irritating to skin and eyes (not sufficient for classification). Copper(I) was not sensitizing in the Magnusson-Kligman assay. Therefore no classification for skin and eye irritation and skin sensitization is proposed for copper(I) oxide.

Short-term and chronic toxicity studies
Both short-term and chronic oral toxicity studies in various species show effects on liver, kidney and the haematopoietic system. The following NOAELs were derived from subchronic oral toxicity studies with various copper compounds: 13-week rat: 5-16 mg/kg bw/day; 13-week mouse: 44-97 mg/kg bw; 1-year dog: 8-15 mg/kg bw. In studies with the exposure duration varying between 14-105 days, liver damage was found in various species at an exposure level of 25 - 40 mg Cu/kg bw/day (LOAEL). The EFSA (2008) reports a NOAEL of 27 mg Cu/kg bw/day in the 2-year study in rats with potassium sodium copper chlorophyllin based on the effects in liver and kidney.

For dermal exposure, the EFSA (2008) reports the NOAEL of 500 mg Cu/kg bw/day based on weight loss and increased incidence of dermal findings in the 21-day study with rabbits exposed to copper hydroxide.

In humans, exposure by inhalation to 0.1 - 0.3 mg/m^3 Cu fumes in air can lead to “metal fume fever” (resembling an influenza induced fever), which is reversible. In copper smelters a slightly induced body temperature and a few malign (respiratory) neoplasias are reported. Since nothing is known on the possible role of confounders, e.g. arsenic, observed effects could not be attributed to only Cu exposure. However, it should be noted that these effects are observed following the exposure to copper fumes and not to copper particulates. No further inhalation toxicity data on repeated exposure to copper-containing compounds in the form of aerosols is available.

Genotoxicity
From reviews of public domain data, there is conflicting evidence regarding the activity of copper in cell-based assays for genotoxicity. In the *in vivo* studies, conducted with copper sulphate pentahydrate, neither micronuclei induction in the polychromatic erythrocytes from the bone marrow of mice nor DNA damage in a rat hepatocyte UDS assay were observed. Equivocal results are reported in additional *in vivo* genotoxicity studies from the public domain, but these studies do not meet the higher reliability criteria (1 or 2) under the BPD.

Copper is therefore considered as non-genotoxic.

Carcinogenicity
The EFSA (2008) reports the NOAEL of 27 mg Cu/kg bw/day in the 2-year study with rats, conducted with potassium sodium copper chlorophyllin. The critical effects were observed in the liver (hypertrophied hyperchromatic parenchymal cells, necrosis and marked inflammatory reaction) and kidney (changes on the proximal convoluted tubule). No neoplastic lesions were noted. The EFSA concluded that there was no evidence of carcinogenic potential of copper in humans after oral ingestion.

Reproduction and developmental toxicity

There are several studies in the public domain that investigate the reproductive toxicity potential of copper and copper compounds. In many of these studies, positive or equivocal findings have been reported. However, on investigation, it has been shown that these positive findings are the result of inappropriate routes of administration (intraperitoneal and intravenous routes). Neither of these routes of administration is representative of an exposure to copper and copper compounds through normal use. Also the IUD (intrauterine device) toxicity/exposure route used in several studies is considered to be not suitable for drawing the conclusions on the reproductive and developmental toxicity of copper. Therefore all these studies will not be used for classification and labelling purposes or risk assessment.

Copper administered by oral route as copper hydroxide or copper gluconate was not teratogenic in rats, mice and rabbits treated during the phase of organogenesis. The lowest reported NOAELs were 6 mg/kg bw/day for both maternal toxicity, based on body weight loss, inappetence, abortion and mortality, and for fetotoxicity, based on decreased mean fetal weight and slightly increased number of skeletal variations.

It is also important to consider that copper is an essential element and many countries recommend an increased dietary intake of copper during pregnancy. This increased recommendation is because a foetus requires copper levels up to 10 times adult levels. The copper is absorbed across the placenta and is required for healthy growth and development, especially in blood maturation, bone development, heart development and function, brain development and function and the activity of 20 key enzymes. Therefore it is considered inappropriate to consider copper and copper compounds as potential teratogenic compounds due to the complex role of copper in regulating normal foetus development in humans at levels considered higher than would be expected to occur through the normal production and use of any copper compound. It is proposed not to classify copper as a teratogenic compound by oral route.

In the two-generation toxicity study with rats performed with copper sulphate pentahydrate the NOAEL for reproductive toxicity was 1500 ppm (23.6-55.7 mg Cu/kg bw/day), the highest concentration tested. The NOAEL for P1 and F1 rats and F1 and F2 offspring during lactation was 1000 ppm (15.2-35.2 mg Cu/kg bw/day), based on reduced spleen weight in P1 adult females, and F1 and F2 male and female weanlings at 1500 ppm (23.6-55.7 mg Cu/kg bw/day). However the reduced spleen weights are not considered a reproductive endpoint, as it did not affect growth or fertility. Investigation of F1 and F2 litters showed no test substance related effects on the following parameters:

- pups survival, sex ratio, and survival indices during the lactation period, body weights and clinical observations during lactation,
- macroscopic examination of pups that died during the lactation period, of weanlings with external abnormalities or clinical signs and of randomly selected weanlings,
- microscopic observations of any gross findings and of liver and brain from randomly selected high-dose and control weanlings.

Some supportive studies did not indicate any effects on reproduction.

Based on these data, copper(I) oxide is not considered to be a reproductive toxicant.

Table T.1: Toxicological endpoints of copper(I)oxide based on EFSA conclusion (2008), RIVM report (1998) and draft CAR of copper(II)oxide (RMS FR)

Toxicokinetics	

Absorption	Oral absorption: 36-40% (draft CAR copper(II)oxide, EFSA evaluation) Dermal absorption: A value of 1% is representative for water-soluble copper compounds. The dissolving capacities for copper(I) thiocyanate in water or in organic solvents are negligible. Therefore, the value of 1% for dermal absorption is too worst-case and for the risk assessment a dermal absorption of 0.05% will be used based on a dermal absorption study with two anti-fouling paints containing copper(I)oxide submitted by the applicant. There is no accurate data available in relation to the respiratory absorption of copper
Distribution	Liver and brain (muscle and bone)
Excretion	Bile formation / faeces
Relevant metabolites	-
Metabolism	Uptake of copper is physiologically regulated
Toxicodynamics *Acute toxicity*	
LD_{50} oral	300-500 mg Cu/kg bw (EFSA, 2008), classification with H302 is proposed
LD_{50} dermal	> 2000 mg Cu/kg bw (EFSA, 2008)
LC_{50} inhalation	No data; classification with H332 is proposed for insoluble Cu compounds
Skin irritant	No classification
Eye irritant	No classification
Sensitisation, skin	No classification
Sensitisation, airways	No classification
Short-term toxicity	
Target / critical effect	liver- and kidney damage, haematological effects, blood biochemistry effects
Lowest relevant NOAEL	Oral: NOAEL 5 mg Cu/kg bw/day (13-week rat) Dermal : 500 mg Cu/kg bw/day (21-day rabbit) (EFSA, 2008) Inhalation: no data available
Genotoxicity	Not genotoxic
Long-term toxicity and carcinogenicity	Not carcinogenic
Reproduction en developmental toxicity	
Reproduction	Reproductive NOAEL: 23.6 mg Cu/kg bw/day (2-generation study, rat) Parental NOAEL: 15.2 mg/kg bw/day
Developmental toxicity	Developmental and maternal NOAEL: 6 mg Cu/kg bw/day (developmental toxicity study, rabbit)
Neurotoxicity / Delayed neurotoxicity	No neurological effects observed in repeated dose studies.

Local effects

Copper(I) oxide is considered to be not irritating to skin and eyes. Based on the available data, no classification for skin sensitization is warranted.

Conclusion with regard to toxicity

Generally, for the derivation of the AEL the lowest NOAEL is used; in this case the 90-day study in rat (NOAEL 5-7 mg Cu/kg bw/day) and the 1-year dog study (NOAEL 8 mg Cu/kg bw/day) would have been used. However, as copper is an essential trace element, a minimal daily intake is necessary to prevent deficiency-based illnesses.

When the before mentioned NOAELs are used and combined with assessment factors, then the resulting AEL_{dermal} and $AEL_{inhalatory}$ are within the range of the minimal daily intake. However, the basic necessities of life can differ between species, and it is not certain that in the reported toxicity studies the amounts of copper from food and drinking water were taken into account. Consequently, it is not certain whether the obtained AELs are representative for the human situation.

Therefore, in this risk assessment the risk of overexposure to copper from the use of antifouling paint will be assessed.

The Dutch Health Council advises a daily intake of copper of 1.5-3.5 mg/day. The amount of inorganic copper necessary to induce (acute) symptoms is estimated to be 10-15 mg/day (Dutch Health Council). The current daily intake for the Dutch population (age 16-65 year) is 0.9-1.3 mg/day. Based on data regarding copper levels in food and drinking water for humans a maximal tolerable daily intake (MTDI) of 0.17 mg/kg bw/day is derived (RIVM). Based on a body weight of 60 kg for a worker, this equals 10.2 mg Cu/day.

When the exposure to copper by the use of the antifouling paint used according to the WG/GA will result in exceeding the MTDI of copper, adverse health effects cannot be excluded.

The MTDI will be exceeded when the additional exposure to copper is greater than the margin of (average) copper intake via feed (see Table T.2).

This risk assessment is based on the assumption that the copper status from workers is normal. Note that any additional copper intake resulting from eating copper treated food is not taken into account.

Table T.2 Used standards for copper intake via food

	External exposure (mg Cu/day)	*Oral absorption*	*Internal exposure [1] (mg Cu/day)*	*Reference*
Average daily intake	0.9 – 1.3	40%	0.36 – 0.52	Dutch Health Council
maximal tolerable daily intake (MTDI)	10.2	40%	4.08	RIVM
Difference between average daily intake and MTDI			3.56 – 3.72	

[1] Values are calculated based on oral absorption values used by the Dutch Health Council.

An additional internal exposure of 3.56 mg Cu/day (worst-case) will lead to exceeding the MTDI. Therefore the value of 3.56 mg Cu/day will be used as the AEL for copper. Corrected to 60 kg professional user body weight, it corresponds to (3.56 / 60 =) 0.059 mg Cu/kg bw/day.

There are indications that respiratory exposure to 0.1-0.3 mg Cu/m^3 may lead to “metal fume fever”. However, this effect occurs as a result of exposure to copper fumes in metalworking industry through hot metalworking processes, such as smelting or welding. There are no indications that such symptoms may develop following an exposure to copper particles. Therefore this information is not relevant for the risk assessment of copper-containing antifouling paints.

Data requirements active substance
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 General aspects
A request for authorisation of Micron LZ is submitted. Micron LZ is intended as antifouling paint containing copper(I)oxide (maximum concentration 8.1% w/w) as an active substance. The concentration active substance varies somewhat between the colour variations: Black 7.9%w/w, Navy 7.9%w/w, Red 8.1%w/w and Off white 7.9%w/w. The proposed field of use is PT21: The formulation will be applied by airless spraying or by brushing and rolling.

The formulation Micron LZ is intended for professional use and non-professional use.

6.1.2 Identification of main paths of professional exposure towards active substance from its use in biocidal product
The group of professional users can be divided into six sub-groups, each sub-group either forming part of the team applying paint to the surface or being workers removing paint during maintenance of a previously painted surface. The potentially exposed groups are the following:

1. Sprayer; high-pressure spraying for surface coating.
2. Painter using brush and roller.
3. Potman; mixing and loading of antifoulant from supply container to high-pressure pump reservoir ensuring continuous supply to the spray gun.
4. Ancillary worker; keeping paint lines free, manoeuvring mobile spray platforms as well as other tasks intended to aid the sprayer's job.
5. Blast worker; performs a total or partial removal of the expired coating from the ship hull using abrasive or high-pressure water.
6. Grit filler; mixing and loading of grit from supply container to high-pressure pump reservoir ensuring continuous supply to the spray gun.

Considering its use as antifouling paint, oral exposure to the active substances copper(I) oxide is considered negligible. Both respiratory and dermal exposure to copper(I) oxide is possible in case of sprayers and blast workers. For painters, potmans and grit fillers only dermal exposure is expected, as inhalation exposure is likely to be negligible in view of the low vapour pressure of cuprous oxide (decomposition temperature 1800 °C). However, for the completeness the respiratory exposure is also calculated, as it is included in the used exposure estimation models.

6.1.3 Identification of main paths of non-professional exposure towards active substance from its use in biocidal product
The formulation Micron LZ is to be used by non-professionals by brushing/rolling and airless spraying. Dermal and inhalation exposure are calculated by using the exposure estimation models.

6.1.4 Indirect exposure as a result of use of the active substance in biocidal product
Food and drinks will not be present during treatment, therefore indirect exposure via consumption of food and drinks to cuprous oxide is deemed negligible.

For professional users, secondary exposure is possible for bystanders incidentally present at the workplace yet unoccupied with the application work. For non-professional users, secondary dermal exposure due to skin contact with freshly treated areas cannot be excluded.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

For acute oral, dermal and inhalation toxicity, skin and eye irritation studies were submitted on other antifouling paints, which were considered to be comparable to Micron LZ. However, the applicant still proposes to derive classification and labelling of the formulation based on the calculation rules according to Regulation 1272/2008/EC. The studies have been submitted to show that the calculation method is more conservative in comparison to the study results and therefore represents a worst-case approach.

Therefore the classification of Micron LZ will be prepared based on the calculation rules according to Regulation 1272/2008/EC.

6.2.2 Data requirements formulated product

No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 Professional users

Airless spraying

Professionals apply antifouling paint to vessels by airless spraying. Professional painters work year-round but applying antifouling is intermittent. The frequency of exposure to any particular ingredient is very important - painters rarely apply antifouling coatings with the same active ingredients at more than one or two events per year (OECD, 2004).

HSE studies have indicated paint usage to range from 25 to over 800 litres during a spray session. The vessel surface areas ranged between 600 to 4000 m^2. The duration of the work ranged from 40 to 360 minutes (median about 180 minutes).

The description of the task is airless spraying of viscous solvent-based liquids at >100 bar pressure, overhead and forwards. As a conservative approach it was agreed to use the Spraying model 3 (HSE data) for assessment of exposure to spray painters (HEEG opinion accepted at TM III 2012). In accordance with the User Guidance for the TNsG on human exposure the uncertainty is considered moderate for the data set for potential body, actual hand and inhalation exposure and the 75th percentile exposure values are used as indicative values. Exposure duration is considered to be 180 minutes. Dermal absorption is considered to be 0.05% for copper(I) oxide.

An exposure to copper from copper(I)oxide will be compared with the derived MTDI of 0.059 mg Cu/kg bw/day. The percentage of copper in copper(I)oxide is (63.5 x 2)/143 g/mol = 88.8%. Considering the maximal concentration of copper(I)oxide of 8.1%, the amount of copper present in the formulation amounts to 8.1% x 88.8% = 7.19%.

The following exposure estimates are derived:

Table T.3 Internal professional operator exposure to copper from copper(I)oxide and risk assessment for the use of Micron LZ by airless spraying

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Airless spraying (high pressure), no PPE			
Respiratory	0.078	0.059	1.32
Dermal	0.040	0.059	0.67
Total	0.118	0.059	1.99
Airless spraying (high pressure), with RPE [3]			
Respiratory	0.008	0.059	0.13
Dermal	0.040	0.059	0.67
Total	0.048	0.059	0.81

[1] Internal exposure is calculated based on 0.05% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction.

Based on this, no adverse effects are expected for protected (suitable respiratory protective equipment with a protection factor 10) professional users from exposure to copper(I)oxide as a result of application of Micron LZ by airless spraying.

Brushing and rolling
Although painting of large ships is mainly performed by means of spray equipment, situations arise where spots on the surface have been insufficiently sprayed. Hence the worker will turn to the use of brush and roller in order to recover any mistakes.

For the use of brush and roller, Consumer product painting model 4 was recommended (HEEG opinion accepted at TM I 2012, and HEEG opinion accepted at TM III 2012). However, after more thorough evaluation, HEEG considered that the Links study (Links et al., 2007)[1] could also be used to assess the exposure of the professional painter who applies paint by brush and roller (HEEG opinion accepted at TM III 2012). In this risk assessment, both models will be used.

It should be noted that in the published report from Links et al. the AM, GM and 90th percentile exposure values are given as well as the range. Access to the raw data allows for calculating of 75th percentile exposure values, which are recommended as indicative exposure values for the specific data set. However, as the 75th percentile values were not available when the example calculation was made, only calculations with the 90th percentile exposure values are performed.

The exposure duration is considered to be 90 minutes. The following exposure estimates are derived:

Table T.4 Internal professional operator exposure to copper from copper(I)oxide and risk assessment for the use of Micron LZ by brushing

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Brushing, no PPE, Consumer Product Painting Model 4			
Respiratory	0,0001	0.059	<0.01
Dermal	0.0058	0.059	0.10
Total	0.0059	0.059	0.10

[1] Links, I; Van der Jagt, K. E.; Christopher, Y.; Lurvink, M.; Schinkel, J.; Tielemans, E.; van Hemmen, J. J.: Occupational Exposure During Application and Removal of Antifouling Paints. Annals of Occupational Hygiene, 2007 51(2):207-218.

Brushing, no PPE, Links et al. (2007) study			
Respiratory	0.0006	0.059	0.01
Dermal	0.0090	0.059	0.15
Total	0.0096	0.059	0.16

[1] Internal exposure is calculated based on Consumer Product Painting Model 4 and Links et al. (2007) study by considering 0.05% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.

Based on this, no adverse effects are expected for unprotected professional users from exposure to copper(I)oxide as a result of application of Micron LZ by brushing.

Ancillary worker
For exposure to ancillary workers, working in the vicinity of the spray painter, the exposure is considered to be no higher than the exposure to the paint sprayer. Hence, it could be assumed that the exposure is covered by the exposure data for the spray painter. Therefore, based on the conclusion for the spray painter, the estimated exposure to ancillary workers is below the AEL, assuming use of suitable respiratory protective equipment (with a protection factor 10).

This assumption for the ancillary workers is in accordance with HEEG 2012 (endorsed at TMIV 2012).

Potman
The potman has the responsibility of removing antifoulant from the supply container to the high-pressure pump reservoir thereby ensuring a continuous supply of paint to the spray gun.
For potman, exposure to the antifouling by spray aerosol is intermittent and unusual. For potman, the Mixing and loading model 6 in the TNsG on human exposure is recommended (HEEG opinion accepted at TM IV2012). The exposure duration is considered to be 180 minutes.

Based on this the following exposure estimates are derived:

Table T.5 Internal professional operator exposure of potman to copper from copper(I) oxide and risk assessment for the use of Micron LZ

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Potman, no PPE			
Respiratory	0.009	0.059	0.14
Dermal	0.013	0.059	0.22
Total	0.022	0.059	0.37

[1] Internal exposure is calculated based on Mixing and Loading Model 6 by considering 0.05% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.

Based on this, no adverse effects are expected for unprotected professional users – potmen from exposure to copper(I)oxide as a result of application of Micron LZ.

Blast worker
Expired coating is removed totally or partially from the vessel using abrasive media and/ or high-pressure water washing equipment. A worst case scenario for paint removal assumes a total removal of the antifouling coating down to the bare metal of the ship.

Following the in-service period, the concentration of active ingredient within the remaining antifouling paint to be removed has decreased relative to fresh paint, i.e. the active ingredient has leached out of the paint. There will be a lower concentration of active ingredient near the paint surface compared to the paint closer to the hull of the vessel. This has been accounted for in the OECD emission scenario document (ESD) for Antifouling Products.

An outer layer, consisting of exhausted paint, can be removed by high pressure water washing. This layer will according to the ESD contain 5 % of the original concentration of a.i. (in dry paint) and constitutes 2/3 of the paint layer left when docking. The inner layer must be removed by abrasion techniques and contains 90 % of the original concentration of a.i. (assuming that 10 % of the total amount of active ingredient initially present in the paint is available for removal at the end of the lifetime of the paint), cf. agreed proposal for revision of the ESD; TMI2012-TOX-item 7e-Fai old paint and human health exposure assessment PT21.pdf.

Depending on which technique for removal of paint is assessed (high pressure water washing or abrasive blasting) the relevant fractions of a.i. should be used in the exposure calculations. Due to lack of specific information on whether the exhausted outer layer was already removed by hydroblasting before sand blasting took place (leaving only the inner layer to be removed), the removed paint layer is assumed to consist of only the inner layer containing 90% of the original concentration of active substance as a worst case assumption.

There are no models available in the TNsG on human exposure (2002 or 2007) to assess operator exposure during paint removal. Based on the HEEG opinion 2012 (endorsed at TMIV 2012), the exposure data from the Links study (Links et al., 2007) should be used in combination with estimates from the OECD ESD on remaining fractions of the active substance in removed paint layer to estimate the exposure during paint removal.

The exposure duration is considered to be 180 minutes. Both inhalation and dermal exposure are considered to be possible.

Based on this, the following exposure estimates were derived:

Table T.6 Internal professional operator exposure of blast worker to copper from copper(I)oxide and risk assessment for the use of Micron LZ

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.066	0.059	1.12
Dermal	0.004	0.059	0.07
Total	0.070	0.059	1.19
Paint stripping, with RPE[3]			
Respiratory	0.007	0.059	0.11
Dermal	0.004	0.059	0.07
Total	0.011	0.059	0.18

[1] *Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.05% dermal absorption and 100% inhalation absorption*
[2] *Risk index is derived by dividing the internal exposure by systemic AEL.*
[3] *RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction.*

Based on this, no adverse effects are expected for protected (suitable respiratory protective equipment with a protection factor 10) professional users – blast workers from exposure to copper(I) oxide as a result of application of Micron LZ.

Grit filler
Grit fillers (or assistant sand blasting) fill the sand blasting machine with a ratio of water and grit according to the directions of the sand blaster. The grit may either be new grit from paper bags or used grit (recycled during the task) which may be contaminated. It is unknown whether or not recycled grit is used for other tasks as well.
There are no models available in the TNsG on human exposure (2002 or 2007) to assess the exposure of the grit filler.
Based on the HEEG opinion 2012 (endorsed at TMIV 2012), the exposure data from the Links study (Links et al., 2007) should be used. However, the HEEG is of the opinion that since there is no other exposure information on grit fillers, the maximum exposure levels (inhalation exposure loading and dermal exposure loading) found for grit fillers may be used as a first tier approach until any further data is presented on possible correlations in combination with estimates from the OECD ESD on remaining fractions of the active substance in removed paint layer to estimate the exposure during paint removal.
The exposure duration is considered to be 8 hours.

Based on this, the following exposure estimates were derived:

Table T.7 Internal professional operator exposure of grit filler to copper from copper(I)oxide and risk assessment for the use Micron LZ

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Grit filling, no PPE			
Respiratory	0.045	0.059	0.76
Dermal	0.138	0.059	2.34
Total	0.182	0.059	3.09
Grit filling, PPE [3]			
Respiratory	0.045	0.059	0.76
Dermal	0.002	0.059	0.03
Total	0.047	0.059	0.79

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.05% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: gloves and coverall is considered to result in 90% dermal exposure reduction.

Based on this, no adverse effects are expected for protected (gloves, coveralls) professional users – grit fillers from exposure to copper(I)oxide as a result of application of Micron LZ.

6.3.2 Non-professional users, including the general public

Airless spraying
The description of the task is airless spraying of viscous solvent-based liquids at >100 bar pressure, overhead and forwards. As a conservative approach it was agreed to use the Spraying model 3 (HSE data) for assessment of exposure to spray painters (HEEG opinion accepted at TM III 2012). In accordance with the User Guidance for the TNsG on human exposure the uncertainty is considered

moderate for the data set for potential body, actual hand and inhalation exposure and the 75th percentile exposure values are used as indicative values. Exposure duration is considered to be 180 minutes. Dermal absorption is considered to be 0.05% for copper(I)oxide.

An exposure to copper from copper(I) oxide will be compared with the derived MTDI of 0.059 mg Cu/kg bw/day. The percentage of copper in copper(I)oxide is (63.5 x 2)/143 g/mol = 88.8%. Considering the maximal concentration of copper(I)oxide of 8.1%, the amount of copper present in the formulation amounts to 8.1% x 88.8% = 7.19%.

The following exposure estimates are derived:

Table T.8 Internal non-professional operator exposure to copper from copper(I)oxide and risk assessment for the use of Micron LZ by airless spraying for 180 minutes and 90 minutes airless spraying without ppe

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
airless spraying (high pressure), no PPE			
Respiratory	0.078	0.059	1.32
Dermal	0.04	0.059	0.67
Total	0.118	0.059	1.99

[1] Internal exposure is calculated based on 0.05% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.

Based on this, adverse effects are expected for non-professional users from exposure to copper(I)oxide as a result of application of Micron LZ by 180 minutes airless spraying.
In order to have a safe use the time that a non-professional user apply the paint by airless spraying may not exceed 90 minutes (RI=1.0).
Less than 90 minutes airless spraying by non-professional users is not considered a realistic scenario. Furthermore a restriction in spraying duration to mitigate the risk cannot be enforced in a non-professional setting. Therefore, no safe use can be concluded for non-professional users from exposure to copper(I)oxide as a result of application of Micron LZ by airless spraying.

Brushing and rolling
For the exposure calculations the Consumer Product Painting Model 4 was used according to the HEEG Opinion 2012 (endorsed at TM IV 2012). The study of Links *et al.* (2007) used for the exposure calculations for professional users is not considered to be suitable for non-professional users.

The following exposure estimates were derived:

Table T.9 Internal non-professional operator exposure to copper from copper(I)oxide and risk assessment for the use of Micron LZ by brushing and rolling

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Brushing, no PPE, Consumer Product Painting Model 4			
Respiratory	0.0005	0.059	0.01
Dermal	0.0232	0.059	0.39
Total	0.0236	0.059	0.40

[1] Internal exposure is calculated based on Consumer Product Painting Model 4 and Links et al. (2007) study by considering 0.05% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.

Based on this, no adverse effects from exposure to copper (I) oxide is expected for unprotected non-professional users due to the application of Micron LZ by brushing and rolling.

Paint removal by hydroblasting or grit blasting
In order to assess the exposure of non-professional users during the paint removal by hydroblasting and/or grit blasting, the same approach was used as for professional users, but considering a shorter exposure duration (90 minutes instead of 180 minutes). Based on the HEEG opinion 2012 (endorsed at TMIV 2012), the exposure data from the Links study (Links et al., 2007) should be used in combination with estimates from the OECD ESD on remaining fractions of the active substance in removed paint layer to estimate the exposure during paint removal.

The exposure duration is considered to be 90 minutes. Both inhalation and dermal exposure are considered to be possible.

Based on this, the following exposure estimates were derived:

Table T.10 Internal non-professional operator exposure to copper from copper(I)oxide during the paint removal and risk assessment for the use of Micron LZ

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.033	0.059	0.56
Dermal	0.002	0.059	0.04
Total	0.035	0.059	0.60

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.05% dermal absorption and 100% inhalation absorption

Based on this, no adverse effects are expected for unprotected non-professional users during the paint removal from exposure to copper(I)oxide as a result of application of Micron LZ.

6.3.3 Indirect exposure as a result of use
Access of unauthorised personal to professional shipyards is considered to be unlikely. At TMIII 2011 it was agreed that a specific bystander exposure scenario was not necessary to include into CA/reports on active substances in antifouling products. To keep unauthorised persons from entering the treatment area, the product label should carry the phrase "Unprotected persons should be kept out of treatment areas".

For non-professional users, secondary dermal exposure due to skin contact with freshly treated areas cannot be excluded. Considering the application rate of 10 m^2/L and the relative density of 1.39 g/ml;, the maximal concentration of the formulation on the surface is 1.39 kg/10 m^2, or 139 g/m^2, or 13.9 mg/cm^2. Considering the concentration of copper in the formulation of 7.19%, this corresponds to 1.0 mg Cu/cm^2. As a worst case, an exposure of a child of 35 kg is considered. A contamination of both hands (400 cm^2 according to TNsG 2007) is considered. According to TNsG on Human exposure, part 2, page 204, a maximal transfer coefficient for dried fluid from different types of surfaces is 18%. Based on this the resulting exposure estimates are derived:

1.0 mg/cm^2 x 18% x 400 cm^2 = 72 mg copper on hands, or, considering 0.05% dermal absorption and 35 kg child body weight, 0.001 mg/kg bw/day. Comparing this with the AEL of 0.059 mg/kg bw/day, the resulting risk index is 0.02. Based on this no adverse effects from secondary dermal exposure to copper(I)oxide due to the contact with freshly treated surfaces is expected.

6.3.4 Combined exposure
Micron LZ contains only one active substance and it is not described that it should be used in combination with other formulations.

6.3.5 Substances of concern
The formulation Micron LZ contains two co-formulants which can be considered as substances of concern. These co-formulants are referred to as SoC Human Toxicology 1 and SoC Human Toxicology 1. The risk assessment for these substances was performed using the same approach as for the active substance. Based on the risk assessment (resulting in a risk index of max 0.17 of the resulting risk indices for copper for each identified SoCs Human Toxicology), no adverse effects from exposure to these SoCs Human Toxicology are assumed for professional and non-professional users for all assessed exposure scenarios, if the same level of personal protective equipment is assumed as indicated for the active substance.

6.4 Overall conclusions for the aspect human health

For the professional user, the following conclusions can be drawn based on the risk assessment:
1. no adverse effects are expected for protected (suitable respiratory protective equipment with a protection factor 10) professional users from exposure to copper(I)oxide as a result of application of Micron LZ by airless spraying.
2. no adverse effects are expected for unprotected professional users from exposure to copper(I)oxide as a result of application of Micron LZ by brushing.
3. no adverse effects are expected for protected (suitable respiratory protective equipment with a protection factor 10) professional users from exposure to copper(I)oxide as a result of application of Micron LZ for the ancillary worker.
4. no adverse effects are expected for unprotected professional users – potmen from exposure to copper(I)oxide as a result of application of Micron LZ.
5. no adverse effects are expected for protected (suitable respiratory protective equipment with a protection factor 10) professional users – blast workers from exposure to copper(I) oxide as a result of application of Micron LZ.
6. no adverse effects are expected for protected (gloves, coveralls) professional users – grit fillers from exposure to copper(I)oxide as a result of application of Micron LZ.

To keep unauthorised persons from entering the treatment area, the product label should carry the phrase "Unprotected persons should be kept out of treatment areas".

For the non-professional user, the following conclusions can be drawn based on the risk assessment:
1. adverse effects cannot be excluded for unprotected non-professional users from exposure to copper(I)oxide as a result of application of Micron LZ by airless spraying. Therefore, the application by airless spraying for non-professionals cannot be authorised.
2. no adverse effects are expected for unprotected non-professional users from exposure to copper(I)oxide as a result of application of Micron LZ by brushing.
3. no adverse effects are expected for unprotected non-professional users – hydroblasting and grit blasting from exposure to copper(I)oxide as a result of application of Micron LZ.

Furthermore, when used according to the WG/GA, no adverse health effects are expected for the general public by indirect exposure to copper(I)oxide as a result of the application of Micron LZ.

7 Environment

7.1 Introduction

Authorisation is requested for the product Micron LZ as an antifouling paint (PT21) based on the active substance copper(I)oxide (8.1% w/w). The biocidal product concerns an antifouling paint, to control growth and settlement of fouling organisms on submerged surfaces of pleasure crafts in freshwater and marine environments. This application falls under the category PT21 (antifouling products) and is intended for professional and non- professional use. The intended use is described in table E.1.

Table E.1. Intended use of the active substance.

Intended use	Area of use	Applicators
Application of antifouling paint to pleasure crafts.	Fresh, brackish and saltwater	Professional and non-professional users

Although no active substance, one co-formulant triggered the classification of the product according to CLP Regulation EC 1272/2008. This means that this substance of concern (SoC) would classify the product, even if the active substance would not have been present in the mixture. For reasons of confidentiality of the composition of the product, the SoC will not be addressed with its common name, but it will be referred to as SE1. It is assessed in a similar way as the active substance and it is also presented in the tables as if being an active substance. The PEC and PNEC will not be shown, but the PEC/PNEC ratio will be presented in the risk characterization table.

7.2 Product related studies

The exposure assessment is based on data for the active substance. There are no fate or ecotoxicity data available for the product
Depending on several product characteristics (i.e. layer thickness; applied layers; dry weight volume) the leaching of the active substance and SoC from the paint is calculated according to the non-validated European Council of the Paint, Printing Ink and Artists Colours Industry (CEPE) model, as endorsed during the Leaching Workshop in Ispra (2006).

Leaching rate from paint layer to water according to CEPE model
On basis of calculations from the CEPE model , leaching rates are derived for the flux from paint layers. The method is a simplified generic model of biocide release, which is based on the assumption that the majority of biocide in the paint that is applied, is released at a constant rate during the specified lifetime.
The calculated release rate derives from the volume of dry paint film applied, the loading of biocide in the paint, and the specified lifetime of the product.
The model assumes that:

- the biocide release rate falls linearly for the first 14 days following immersion;
- the biocide release rate is thereafter constant from day 14 until the last day of the coating's specified life-time;

- 10% of biocide is retained in the paint film at the end of its specified lifetime (Antifouling leaching rate workshop, Ispra, 2006).

Based on these assumptions and on knowledge of the biocide content of the paint, specified dry film thickness and the paint's specified lifetime, it is possible to calculate
X: Amount of biocide released during first 14 days (µg/cm^2)
Y: Average leaching rate during the rest of the lifetime (µg/cm^2 per day)

Table E.2 Assumptions as applied in the CEPE model

Application Methods	Brush, roller (Professional users and non-professional users) Airless sprayer (Professional users)
Number of coats (N)	1-2 coats
Volume of dry paint versus volume wet paint (SVR)	45%
Specific gravity wet paint (SPG)	1.27 g/cm^3
Recommended dry film thickness (DFT)	Brush, roller: 2 x 45 microns = 90 microns Airless sprayer: 1 x 90 microns
Leaching rate	Copper: 9.42 µg a.s. cm^2/·d for the first 14 days and 4.40 µg a.s. cm^2/·d for the rest of the service life of the paint layer
	SE1: Not presented due to confidentiality

The service life of the paint is one year and during service life of the antifouling 90% of the active substance is released from the paint.
In order to calculate the leach rate of copper alone (i.e. excluding oxygen), 89% of the concentration of Cu_2O in the paint was used, based on the proportion of copper in copper oxide using molecular weights (Cu_2O = 143.1, Cu = 63.55).

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

Copper(I)oxide

It is not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation. Copper(I)oxide as an inorganic compound is not subjected to biological degradation in any environmental compartment. The substance is non-volatile, hydrolytically stable and not biodegradable. Phototransformation in water is not expected. The strong adsorbance to organic carbon, manganese and iron oxides increases in soil with increasing pH. As all metals, copper becomes complexed to organic and inorganic matter in waters, soil and sediments and this affects copper speciation, bioavailability and toxicity.

7.3.2 Distribution in the environment

Emission routes

Releases into the environment can take place at any stage of the life cycle of a product. Major emissions from the application of antifouling paint derive from the service life of the product as it functions as a protective coating to prevent unwanted growth of fouling organisms (microbes and higher forms of plant and animal species) on a ship hull.
For antifouling products, the risk assessment focuses on environmental emissions during the service life phase of the product. Emissions during the a.i. production, product formulation, and the application phase and the waste phase of the product are considered less relevant.

The product Micron LZ is intended for professional and non-professional use on pleasure crafts with ship movements in marine and freshwater environments. The foreseeable routes of entry into the environment during the application, in-service and waste phase are listed in Table E.3.

Table E.3 **Foreseeable routes of entry into the environment on the basis of the use envisaged**

		Environmental compartments and groups of organisms exposed				
Use scenario		**STP**	**Water***	**Soil****	**Air**	**Birds and mammals**
Application	New building	++	++	(+)	+ Q	(+)
	Maintenance and repair	++	++	(+)	+ Q	(+)
Service life	Marina	-	++	-	-	(+)
Removal	Maintenance and repair	++	++	(+)	+ Q	(+)

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to a.s. hazard data, legally driven risk mitigation measures and scale of exposure), - Compartment not exposed, * Including sediment, ** In the Netherlands, surplus sludge of public STPs is not applied for fertilization and soil improvement of agricultural soil. Therefore, exposure of soil and groundwater via STP surplus sludge application is not part of the risk assessment. Q: Emission to air can be relevant for professional applications of airless sprayers or removal of the paint by blasting or sanding. These types of emission is evaluated qualitatively.

7.3.3 Predicted environment concentration calculations

Service life
During its service life, the emission of the active substance and SE1will come from the antifouling paint on the submerged surfaces of pleasure crafts which dissolves into the water phase with subsequent partitioning to the sediment.
The exposure of the environmental compartments can occur through:

- *Surface waters*: aqueous solubilisation of the active substance and SE1, leaching into the water phase and sediment during sailing or while the pleasure crafts remain in the marina.
- *Soil/groundwater:* no exposure assumed
- *Air:* no exposure assumed

Application phase/removal phase
Emissions to the environment do take place during both application and removal phase. These two phases are hard to separate because they occur at the same time; the removal of the old paint layers and the application of the new paint layers are part of the same cycle with the same elimination/waste routes.

Non-professional application and removal of antifouling paints in the Netherlands mostly takes place at special locations in marinas. For non-professional use in the Netherlands normal use may include maintenance and repair at a private site (i.e drive of a home) without taking mitigation measures. To address this the EUSES private use scenario was applied in order to calculate emissions to soil, see section 7.5.2.

The application phase comprises the application of a new layer of paint on the new or existing pleasure crafts. Product authorization is requested for professional use in shipyards and docks and non-professional use in marinas.
Shipyards and docks must have the appropriate permits in accordance with the Environmental Management Act ("Wet Milieubeheer"). Due to this system of permits, work instructions and inspection, emission reduction measures are mandatory. Dry docks and slipways in the Netherlands have watertight floors and therefore the emission to water and soil by professional application of the

paint is assumed to be negligible. Emission in the application phase through paint left in the dock will be removed as chemical waste. This will partially end up in the pumping pit and partially settle on the bottom.

Other sources of emission during application phase include empty cartridges/cans, contaminated clothes etc.

The removal phase of antifouling products comprises of the removal of the old layer of paint on existing pleasure crafts. Emissions in the removal phase are therefore mostly from old paint particles. Professional removal of the layer of paint is done by scraping, blasting or sanding it off. About 80-90% of the blasting is done using abrasive blasting although (high pressure) hydro-blasting is also being used. As a result of the blasting, a mixture of blasting material and paint particles from the vessel surface is created. A part of this mixture will be emitted to the air when applied outdoors. The majority of the mixture that is created in the dock will be treated and removed as chemical waste. Only a minor amount of the mixture will end up in waste water. Professional docks and slipways in the Netherlands have a settling tank or other settling device. Through the settlement in the pump pit and in the settling tank, the majority of the paint particles/blasting material mixture will be trapped. The remaining suspended solids in the waste water is directly emitted to surface waters.
The non-professional application differs from professional application by the techniques which are used to remove the paint layers (sanding) and the scale of use of the antifouling paint. The construction to reduce emissions varies from the presence of a watertight floor in a marina or the use of a plastic groundsheet.
The exposure of the environment during application and removal of the layer of paint can occur by means of:
Surface waters: waste water from the settling tank, deposition of paint particles and blasting dust from the air, leaching of paint particles and blasting material from the floor.
Soil/groundwater: deposition of paint particles and blasting dust from the air, through spillage during application, using scraping or sand blasting of the vessel surface. The exposure is largely limited/prevented by the application of cover material, the use of roofed areas and watertight floors.
Air: no exposure assumed; it is assumed that the paint particles and the blasting dust will be deposited onto soil and surface waters.
Provided that the risk mitigation measures, enforced by the Environmental Management Act, are in place, minimal risks from the application and removal stages will occur. For risk assessments under Chapter 10 of the RGB [Transition period for EU Regulation 528/2012], therefore, no quantitative risk assessment is performed for the application and removal of antifouling paints. Available scenarios in the ESD represent worst-case scenarios for new building and maintenance & repair and do not acknowledge effective reduction of environmental emissions by risk mitigation measures in a good regulatory framework. Risk mitigation measures can be added to the label to ascertain a safe application and removal of antifouling paints by non-professionals.

Scenarios and models used for PEC calculations

Choice of model
For the derivation of the PEC_{water}, the model MAMPEC 3.0 is used. Conform the legal instructions for use, the following scenarios were taken into account in the risk assessment:

1. OECD saltwater marina;
2. Inland freshwater marina (OECD marina scenario adapted regarding freshwater environmental characteristics specific for The Netherlands, see Appendix 1).

The scenarios assume an application factor of 0.9 (market share 90%).

The temperature of the marine and freshwater scenarios was set to 9 resp. 12°C, which are defaults according to the ECHA Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015).

Service life
During its service life, the active substance copper(I)oxide will leach from the antifouling paint on the submerged surfaces of pleasure yachts to the water and the sediment.
The default settings of MAMPEC 3.0 were used regarding the dimensions of the scenarios and the environmental conditions.

PEC values were calculated for the active substance. Table E.4 shows the input variables as used in MAMPEC.

Table E.4 Input variables of MAMPEC 3.0

Variable	Copper seawater	Copper fresh water		Unit
Molar mass	63.5	63.5		g/mol
Vapour pressure	1.0×10^{-6}	1.0×10^{-6}		Pa [20°C]
Solubility	1	0.001		g/m^3 [20°C]
Octanol-water part. coeff.	-	-		10 log K_{ow}
Sediment-water part. coeff. K_d	30.246	56.234		m^3/kg
Partition coefficient K_{oc}	-	-		10 log K_{oc}
Henrys law constant	-	-		$Pa.m^3/mol$
Melting point	-	-		°C
pKa	-	-		-
Maximum % formed in marine/brackish water/sediment systems (whole system)	n.a.	n.a.		%
In water phase:				
Biodegradation (20°C)	0	0	*	1/day
Hydrolysis rate	0	0	*	1/day
Photolysis rate	0	0	**	1/day
In sediment phase:				
Biodegradation (20°C)	0	0	*	1/day
Leaching rate ****	4.40	4.40	***	$\mu g/cm^2/day$

* Hydrolysis was set to zero in the model calculations as hydrolysis is covered in the experimental determination of the $DT_{50,water}$.
** The model MAMPEC 3.0 includes a module to calculate photolysis. However, this module was not used for the derivations of the PECs. In the North sea and harbours the high turbidity and coverage of the water affect the light penetration and therefore photolysis is considered negligible in those environments. As a result, photolysis was set to 0 in the derivation of the PECwater. In sediment, the photolysis can also be assumed negligible and was also set to 0.
*** For ships moving and at berth.

The resulting concentrations of the active substance in the water and sediment phase calculated by MAMPEC are presented in Tables E.7 and E.8.

7.4 Environmental effect assessment

Risk assessment is based on Predicted No-Effect Concentrations (PNECs) for the different compartments which are derived from ecotoxicity data and applying assessment factors. The assessment factor depends on the type of test performed (acute or chronic), the toxicological endpoint (effect concentrations (ECs), no-observed effect concentrations (NOECs), etc), and the number of data and is determined according to the ECHA Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015).

For the PNEC derivation of copper a statistical extrapolation method (Species Sensitivity Distribution, SSD) was used. This method is in accordance with Directive 98/8/EC and a detailed description of the methodology can be found in the ECHA Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015).
By combining the copper data, there is sufficient data to derive the PNEC using a species sensitivity distribution for aquatic organisms, see Table E.5.

Table E.5 Predicted no-effect concentrations for copper

PNEC	Value	AF	PNEC	Data available at Ctgb
fresh water	7.8 µg Cu/L	1	7.8 µg Cu/L	SSD analysis
Marine water	5.2 µg Cu/L	2	2.6 µg Cu/L	SSD analysis
Freshwater sediment	87 mg/kg dw	1	139* mg/kg dw	SSD analysis
Marine sediment	-	-	98.8 mg/kg dw	Derived from equilibrium partitioning using the 10th percentile of the available K_d-values
soil	45.6 mg Cu/kg dry weight	1	45.6 mg Cu/kg dw	SSD analysis

* PNEC freshwater of 87 mg/kg dwt standard sediment is recalculated to the 6.6% organic carbon, being the value used in MAMPEC freshwater.

7.5 Risk characterisation for the environment

For each relevant compartment, PECs are divided by PNECs. Risks are considered unacceptable when PEC/PNEC >1.

7.5.1 Aquatic compartment (incl. sediment) and STP

Water and sediment organisms

Service life
The risk for water- and sediment organisms by the use of antifouling paint is estimated by comparing the (average) predicted concentrations of the active substances in the water phase and suspended matter (PECs) with the derived PNECs. If the PEC is lower than the PNEC, than the risk is small and the product complies with the standard for the risk assessment of chronic exposure to water- and sediment organisms. If the PEC is higher than the PNEC then a risk is indicated.

The risk assessment for the environment is based on the total risk approach for copper, taking natural background concentrations of copper into account. The Dutch RIVM presents national background concentrations of copper in freshwater, freshwater sediment and salt water on their website (https://rvs.rivm.nl/zoeksysteem/stof/detail/861). Additionally, the *European Union Risk Assessment Report: Voluntary Risk Assessment (VRAR) of copper* presents background concentrations for saltwater sediments (http://echa.europa.eu/nl/copper-voluntary-risk-assessment-reports). See table E.8 for an overview of the background concentrations.

Table E.6. Background concentrations applied for the PEC calculations.

Compartment	Concentration	Source	Remarks
Fresh surface water	0.4 µg/L	RIVM website	dissolved copper
Salt water surface water	0.3 µg/L	RIVM website	dissolved copper
Fresh water	23.85	RIVM website	Based on 36 mg/kg dw standard sediment as reported on

sediment			RIVM website, corrected for organic carbon
Salt water sediment	6.2 mg/kg dw	VRAR	Based on Ambient PEC

Local concentrations in water and especially in sediment of marinas and harbours can even be higher due to contributions from various emission sources of copper including antifoulings.
The background concentrations are added to the calculated PECs of the fresh and salt water marina scenarios.
The difference in risks between freshwater and saltwater marinas can mainly be explained by differences in hydrodynamical and water characteristics of these two types of marinas.

The suspended solids concentration is used to assess the risk to sediment organisms. MAMPEC calculates the concentration of the active substance in suspended solids using the 'equilibrium partitioning method', based on the estimated concentrations in the water phase. The exposure of the sediment organisms to the active substances depends on their life cycle and feeding traits. The suspended solids concentration is therefore most relevant to the exposure of the sediment organisms that fall into the category of suspension feeders. The concentration of active substance in the sediment can be substantially lower than on suspended solids because the concentration of the active substance may be affected by degradation, considering the retention times of suspended solids in the sediment. To use suspended matter for PECsediment calculations is an agreed approach used in the ECHA Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015), also required for calculations with MAMPEC.
In the next paragraphs the PEC to PNEC ratios will be presented to assess the risk.

Table E.7 PEC and PEC to PNEC ratio to assess the risk for water and sediment organisms during the service life of the antifouling product for application of two layers

		Water		Sediment	
Scenario	**Substance**	**PEC (µg a.s./L)**	**PEC/PNEC ratio**	**PEC (mg a.s./kg dwt)**	**PEC/PNEC ratio**
Freshwater marina	Copper**	5.05	0.647	164	**1.18**
	SE1	*	0.289	*	**5.06**
	Mixture		0.937		**6.24**
Saltwater marina	Copper**	0.30	0.117	6.38	0.065
	SE1	*	0.02	*	0.156
	Mixture		0.137		0.221

* Not presented due to confidentiality
** taking into account the background concentration of copper

The applicant submitted information that the paint can be used as a single layer antifouling. This results in the following PEC, and PEC to PNEC ratios.

Table E.8 PEC and PEC to PNEC ratio to assess the risk for water and sediment organisms during the service life of the antifouling product for application of one layer.

		Water		Sediment	
Scenario	**Substance**	**PEC (µg a.s./L)**	**PEC/PNEC ratio**	**PEC (mg a.s./kg dwt)**	**PEC/PNEC ratio**
Freshwater marina	Copper**	2.72	0.349	94	0.674
	SE1	*	0.145	*	**2.53**
	Mixture		0.494		**3.22**
Saltwater marina	Copper**	0.30	0.116	6.29	0.064
	SE1	*	0.01	*	0.078
	Mixture		0.126		0.142

* Not presented due to confidentiality

** taking into account the background concentration of copper

The PEC to PNEC ratios for water organisms for application as antifouling on pleasure crafts in freshwater and marine environments is <1.0, implying a low risk and therefore the product Micron LZ meets the standards for water organisms for application as antifouling on pleasure crafts in freshwater and marine environments.

In saltwater marinas the PEC to PNEC ratios for sediment dwelling organisms are not exceeded implying a low risk and therefore the product Micron LZ meets the standards for sediment organisms for application as antifouling on pleasure crafts in marine environments. For pleasure crafts in freshwater environments, however, the PEC to PNEC ratio is above 1 thus the standards for sediment organisms are not met. If the use of the product is restricted to one layer antifouling, still unacceptable risks are identified for sediment, but these are only caused by the substance of concern.

Application/Removal phase

Risk mitigation measures, permits, work instructions and inspection at ship yards, enforced by the Environmental Management Act, adequately reduce emissions from the application and removal stages. In view of this, a low risk for aquatic and sediment organisms is expected. Emissions to water from the application and removal stages are considered acceptable and do not require examination against the standards for aquatic and sediment organisms.

Micro-organisms in the STP

Risk mitigation measures, permits, work instructions and inspection at ship yards, enforced by the Environmental Management Act, adequately reduce emissions from the application and removal stages. The toxicity data for microbial endpoints in sewage treatment plants show that both active substances are not very toxic to bacteria. In view of this, a low risk for micro-organisms in the STP is expected. Emissions to the STP are considered acceptable and do not require examination against the standards for micro-organisms in the STP.

Monitoring data (surface water)

Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters for which the results are publicly available on-line (www. pesticidesatlas.nl). Here, monitoring data are processed in a graphic format aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards. The Pesticide Atlas was used to evaluate measured concentrations of pesticides in Dutch surface water, but no data are available regarding the presence of the copper and co-formulant SE1 in Dutch surface water.

Surface water intended for the abstraction of drinking water

Biocidal products with the active substance copper have been on the market for more than three years. Neither copper nor the co-formulant SE1 are included in the list of substances of concern due to their presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb (2015). In addition, the active substance is not included on the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). The RIVM has not taken copper into consideration for monitoring in surface water intended for the abstraction of drinking water, as the substance is naturally occurring and is also emitted by other sources than biocides.
Considering this, the Ctgb concludes that there are in this case insufficient indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water is met for this product.

7.5.2 Terrestrial compartment

Soil organisms and non target arthropods (including bees)
For professionals risk mitigation measures, permits, work instructions and inspection at ship yards enforced by the Environmental Management Act, adequately reduce emissions from the application and removal stages.

For non-professional use in the Netherlands normal use may include maintenance and repair at a private site (i.e drive of a home) without taking mitigation measures. To address this, the EUSES private use scenario was applied assuming maintenance and repair of 1 ship 1 time per year. The following parameters were used:

Table E.8 Parameters applied for terrestrial PEC calculation

Case type used for antifouling	Typical case/realistic worst-case
Number of boats/ships treated per period	1
Painting period	1 day
Removal period	1 day
Painting frequency per year	1
Application interval	365 days
Number of days of application	1-11* days
Removal interval	365 days
Number of days of removal	1-11* days
Concentration of active ingredient in the paint	81.0 g Cu/L
Theoretical amount of paint applied per ship	2.5 L

* 11 represents 10 years of application and removal of paint

The risk assessment for the environment is based on the total risk approach for copper, taking natural background concentrations of copper into account. The Dutch RIVM reports national background concentrations of 36 mg copper (total)/kg dwt for a standard soil (https://rvs.rivm.nl/zoeksysteem/stof/detail/861). The background concentration added to the peak concentration in soil after 10 years of application of 103 mg/kg dwt which is the highest concentration soil for the ''realistic worst-case scenario'' gives a total concentration of 139 mg/kg dwt. This PEC_{soil} is much higher than the lowest $PNEC_{soil}$ of 45.6 mg/kg dwt.
Adding SE1 to the risk assessment will even result in higher PEC to PNEC ratios above 1. The proposed application of the product does not meet the standards for soil organisms and non-target arthropods (including bees).

There is no concrete indication for concern for emission to soil if the product is used conform its instructions restricting application and removal of the product to specified locations at marinas, dry docks and slipways with appropriate permits in accordance with the Environmental Management Act ("Wet Milieubeheer") to prevent pollution of soil, groundwater, surface water and air.

Groundwater
The restriction that is presented in chapter 7.5.2.1. prevents use on pleasure crafts and the use of this product by non-professionals during application and removal phase, thereby preventing emission to the groundwater.
For professionals, risk mitigation measures, permits, work instructions and inspection at ship yards, enforced by the Environmental Management Act, adequately reduce emissions from the application and removal stages. There is no concrete indication for concern for emission to groundwater if the product is used conform its instructions restricting application and removal of the product to specified locations at dry docks and slipways with appropriate permits in accordance with the

Environmental Management Act ("Wet Milieubeheer") to prevent pollution of soil, groundwater, surface water and air.
In view of this, a low risk for groundwater is expected. Emissions to soil are considered negligible. Therefore the proposed application of the product meets the standards for the production of drinking water from groundwater.

Persistence in soil
Being an inorganic compound, the persistence criteria of DT90, field < 1 year and DT50 at 20°C < 6 months are not applicable to copper(I)oxide. Copper(I)oxide does not meet the criteria for persistence in soil. SE1 does not meet the criteria for persistence in soil either.

7.5.3 Non compartment specific effects relevant to the food chain

Bioconcentration

Uptake, distribution and bioconcentration of metal ions in organisms is fundamentally different from the bioaccumulation of lipophilic organic compounds which occurs in biota. In the food chain in fish and mussels, etc., bioavailability of metals is often limited. For a risk for secondary poisoning of birds and mammals can be excluded (see above). The risk for bioconcentration of copper is considered acceptable. Therefore, the proposed application of Micron LZ meets the standards for bioconcentration.

SE1 shows similar bioconcentration behaviour in organisms when compared to copper. Therefore the product Micron LZ meets the standards for sediment organisms for application as antifouling on pleasure crafts in marine environments.

Primary and secondary poisoning of birds and mammals
The assessment of environmental fate of the active ingredients showed that direct exposure to these substances are negligible for birds and mammals. During the service life of the antifouling paint, the most relevant route of exposure to birds and mammals is secondary poisoning through the aquatic food web (water phase → fish → bird/mammal).
The Voluntary RAR (environmental effects part 3) extensively describe sthe role of copper as an essential nutrient and regulatory mechanisms to retain homeostasis in the internal copper concentrations under conditions of high or low environmental concentrations. This mechanism is known for all species, from micro-organism and plants to invertebrates and vertebrates including fish, birds and mammals. Difference in copper uptake rates are related to essential needs, varying with species, size, life stage, seasons etc. Thus, unlike for organic substances, the BCF/BAF is not dependent on exposure concentrations.
It has also been demonstrated that copper concentrations do not biomagnify across the trophic food chain, neither in aquatic nor in terrestrial chains. For aquatic organisms it was shown that waterborne copper and not dietary exposure has been related to copper effects, with gills and gill-like surfaces as key target organs for acute as well as chronic toxicity in fish and invertebrates. The regulatory capacity of fish and invertebrates explains the observed absence of copper toxicity induced by accumulation of copper from dietary exposure.
The VRAR and AR show that there is little concern related to food chain transfer and secondary poisoning within the pelagic food chain as well as towards birds and mammals.

The co-formulant SE1 demonstrates a comparative toxicity to birds and mammals when exposed via the aquatic food chain when compared to copper. Therefore, it is considered that the risk assessment for copper covers the co-formulant as well.

7.5.4 Atmosphere

Copper(I)oxide is poorly volatile. Significant exposure of the environment via air is thus not expected. Criteria for the examination of environmental risks to air are not specified by a numerical standard. Therefore, effects on air quality are only taken into account when adverse effects are foreseen. Currently, the assessment of potential impacts on air quality is aimed to minimise the risk for stratospheric ozone depletion.

Since copper(I)oxide is poorly volatile and there are no indications that copper(I)oxide contributes to depletion of the ozone layer (no classification H420: Harms public health and the environment by destroying ozone in the upper atmosphere), the environmental risk to air is considered acceptable. As SE1 has similar physico-chemical properties as copper(I)oxide, also for this substance the environmental risk to air is considered acceptable. The proposed application of the product meets the standards for air.

7.6 Measures to protect the environment (risk mitigation measures)

Due to risks to the terrestrial compartments after non-professional application of the product, the following risk mitigation measure is included in the WG/GA:

EN: Application and removal of this product is restricted to specified locations at saltwater dry docks and slipways with appropriate permits in accordance with the Environmental Management Act (“Wet Milieubeheer”) to prevent pollution of soil, groundwater, surface water and air.
NL: Dit middel mag uitsluitend worden aangebracht en verwijderd op daar toe aangewezen locaties in jachthavens, professionele scheepswerven en droogdokken met de juiste toestemmingen in het kader van de Wet Milieubeheer / Omgevingswet ter voorkoming van vervuiling van bodem, grondwater, oppervlakte water en lucht.
The risks to the aquatic freshwater organisms are discussed in the next chapter.

7.7 Overall conclusion for the aspect Environment

A risk has been identified for aquatic and sediment organisms for the freshwater environment, also when refining the maximum number layers of paint of 45 micron dry film thickness to 1. For the marine water environment, no risk was identified, but pleasure crafts can navigate freely between the freshwater and marine environment. Based on the available data, it can be concluded that Micron LZ, when used in accordance with the proposed label (WG/GA) does not comply with the environmental standards and will cause unacceptable effects on the environment. Underlying product, however, contains lower concentrations active substance and substance of concern compared to authorised antifouling products . Therefore the risk is considered acceptable for limited authorisation over a restricted period. During this period the industry is encouraged to develop antifouling products safe for the environment, with lower concentrations of active substances and substances of concern.

8 Conclusion

The applicant has proven that Micron LZ under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment (Art. 121 jo art. 49 first paragraph Dutch 2007 Plant Protection Products and Biocides Act).

9 Classification and labelling

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

Professional user:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Gum Rosin, xylene, ethylbenzene, solvent nafta			
Pictogram:	GHS02 GHS05 GHS07 GHS09	Signal word:	Danger
H-statements:	H226	Flammable liquid and vapour	
	H317	May cause an allergic skin reaction	
	H318	Causes serious eye damage.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P101	If medical advice is needed, have product container or label at hand.	
	P102	Keep out of reach of children.	
	P103	Read label before use.	
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	
	P271	Use only outdoors or in a well-ventilated area.	
	P273	Avoid release to the environment.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].	
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
	P305 + P351 + P338+ P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/…	
	P501	Dispose of contents/container to hazardous or special waste collection point.	
Supplemental Hazard information:	EUH066	Repeated exposure may cause skin dryness or cracking.	
Child-resistant fastening obligatory?			**Not applicable**
Tactile warning of danger obligatory?			**Not applicable**

Explanation:	
Pictogram:	-
H-statements:	Based on the calculation performed by the Ctgb H312, H15, H319 and H332 are not considered necessary. H318 is applicable due to the classification according to the 9th ATP entry of copper(1)oxide
P-statements:	P235 is proposed by the applicant. P235 is considered

	redundant for category 3 flammable liquids.P280 is highly recommended with the assigned H-statement and based on the risk assessment P280(gloves/coverall) for the professional user P305+P351+P338 in combination with H310 is highly recommended when H318 is assigned. The other (highly recommended) P-statements are adopted from proposal applicant
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

10 References

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Appendix 1 MAMPEC inland freshwater marina scenario

IVM and Deltares have reviewed the dimensions, hydrodynamics and physico-chemistry of Dutch inland marinas and draft a MAMPEC definition for a typical inland water marina in the Netherlands. The objective of the work was to review existing inland marinas and to propose representative settings for the environmental and emission definitions in MAMPEC to allow an exposure assessment for small freshwater marinas in the Netherlands.
Based on a short inventory of the most relevant input parameters in MAMPEC for the OECD-EU marina scenario for which new values have been proposed additional data were derived for a selection of 50 inland freshwater marinas. Data on dimensions, orientation, number of berths, depth, etc. were obtained from public data available on the internet (Google Earth, portals and homepages of Dutch inland marinas) and completed with data from technical reports of various Dutch organisations. Using local hydrodynamic and meteorological information, estimates were made for horizontal exchange due to currents and parameters for wind exchange. Water quality information was obtained from regional water authorities and dedicated databases. The proposed new settings are summarized below and used in the risk assessment of antifoulings on pleasure crafts in freshwater environments.

Settings in MAMPEC for the different characteristics in an inland freshwater marina.

Category	Parameter	Value in OECD-EU marina scenario	Proposed value in small freshwater marina scenario
Hydrodynamics	Tidal period Tidal difference Max. density difference tide Non tidal water level change Flow velocity	12.41 h 1.5 m 0.1 kg/m^3 0 m 1 m/s	12.41h 0 m 0 kg/m^3 0 m 0.2 m/s
Water characteristics	SPM concentration POC concentration DOC concentration Chlorophyll Salinity Temperature pH	35 mg/L 1 mg/L 2 mg/L 3 µg/L 34 psu 20 °C 8	8 mg/L 0.53 mg/L 5.6 mg/L 5 µg/L 0.2 psu 12 °C 8
Layout	Length x1 x2 Width y1 y2 Depth Mouthwidth x3	141.5 m 141.5 m 141.5 m 141.5 m 4 m 100 m	125 m 125 m 131 m 131 m 2.2 m 26 m
General	Latitude	<u>50</u>° <u>(dec) NH</u>	<u>50</u>° <u>(dec) NH</u>
Sediment	Depth mixed sediment layer Sediment density Degr. Organic carbon in sediment Nett sedimentation velocity	0.1 m 1000 kg/m^3 0 d-1 0.5 m/d	0.03 m 1000 kg/m^3 0 d-1 0.5 m/d
Wind	Average wind speed Fraction of time wind perpendicular	0 m/s 0	3.3 m/s 0.1
Flush	Flush (f) Max. density difference flush	0 m^3/s 0 kg/m^3	0 m^3/s 0 kg/m^3
Harbour lay-out data, used for density flow exchange	Height of submerged dam Width of submerged dam Depth-MSL in harbour entrance h0	0 m 0 m 4 m	0 m 0 m 2.2 m

Category	Parameter	Value in OECD-EU marina scenario	Proposed value in small freshwater marina scenario
Calculate emission – Service life	Length class	1-50 m	8.9 m
	Surface area	30.7 m^2	17.8 m^2
	No. ships at berth	500 -> 276	218
	No. ships moving	0	0
	Application factor	90% *	90% *
Calculate emission - Application / removal	Extensive list of parameters for application and removal of antifouling paints	All parameters set to zero, i.e. application and removal assumed negligible	All parameters set to zero, i.e. application and removal assumed negligible

** It should be noted that these values should be amended to reflect the specific parameters most relevant for the biocide or product being risk assessed*