ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 VERLENGING TOELATING

Gelet op de aanvraag d.d. 15 juli 2013 (20131067 TVB) van

Chugoku Paints B.V.
Sluisweg 12
4794 SW HEIJNINGEN

tot verlenging van de toelating als bedoeld in artikel 49, eerste lid, Wet gewasbeschermingsmiddelen en biociden, voor de biocide, op basis van de werkzame stof koper(I)oxide

SEA TENDER 10

gelet op artikel 66, eerste lid, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Verlenging toelating

1. De toelating van het middel SEA TENDER 10, welke expireert op 1 november 2014 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 12029. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 1 mei 2024.

1.2 Samenstelling, vorm en verpakking

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

1.3 Gebruik

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

1.4 Classificatie en etikettering

Gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Andere vloeistoffen voor directe toepassing

werkzame stof:	*gehalte:*
koper(I)oxide	45 %

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
butylglycol, pijnhars

PICTOGRAM(MEN)

pictogram:
GHS02-ontvlambaar
GHS07-schadelijk
GHS09-milieu

SIGNAALWOORD

Waarschuwing

Gevarenaanduidingen

H226	Ontvlambare vloeistof en damp.
H302	Schadelijk bij inslikken.
H315	Veroorzaakt huidirritatie.
H317	Kan een allergische huidreactie veroorzaken.
H410	Zeer giftig voor in het water levende organismen, met langdurige gevolgen.

Voorzorgsmaatregelen

P210	Verwijderd houden van warmte/vonken/open vuur/hete oppervlakken. — Niet roken.
P273	Voorkom lozing in het milieu.
P280	Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen.
P284	Adembescherming dragen.
P303 + P361 + P353	BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken – huid met water afspoelen/afdouchen.
P312	Bij onwel voelen een ANTIGIFCENTRUM of een arts raadplegen.

Aanvullende etiketelementen

EUH205	Bevat epoxyverbindingen. Kan een allergische reactie veroorzaken.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

b. hetzij letterlijk, hetzij naar zakelijke inhoud:
de gebruiksaanwijzing
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

2 DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraag
De toelating van het middel SEA TENDER 10 is laatstelijk bij besluit d.d. 8 oktober 2004 verlengd tot 1 november 2014. Het betreft een aanvraag tot verlenging van de toelating van het middel SEA TENDER 10 (12029 N), een middel op basis van de werkzame stof koper(I)oxide. De verlenging wordt aangevraagd voor de toelating als aangroeiwerende verf (PT21)

2.2 Informatie met betrekking tot de stof
De werkzame stof koper(I)oxide is nog niet geplaatst op de Unielijst van goedgekeurde werkzame stoffen van EU-verordening 528/2012.

2.3 Karakterisering van het middel
SEA TENDER 10 is een middel op basis van koper(I)oxide. Aangenomen wordt dat de biocide werking afhankelijk is van de affiniteit van het koper-ion voor verscheidene chemische groepen, waaronder thiol groepen Dit resulteert in niet-specifieke denaturatie van eiwitten en enzymen. Daarnaast kan het koper-ion mogelijk interfereren met de activiteit van het pyruvaat dehydrogenase systeem.

2.4 Voorgeschiedenis
De aanvraag is op 15 juli 2013 ontvangen; op 16 juli 2013 zijn de verschuldigde aanvraagkosten ontvangen. Bij brief d.d. 26 juli 2013 is de aanvraag in behandeling genomen.

2.5 Eindconclusie
Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel SEA TENDER 10 op basis van de werkzame stof koper(I)oxide voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

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 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 2 mei 2014

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 bij het besluit d.d. 2 mei 2014 tot verlenging van de toelating van het middel SEA TENDER 10, toelatingnummer 12029 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als aangroeiwerende verf echter uitsluitend voor zeegaande schepen die worden gebruikt voor beroep of bedrijf alsmede oorlogsschepen, marine- hulpschepen of andere schepen die in gebruik zijn voor de militaire taak.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

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 en/of geschikte spuitapparatuur. Op de werkplek mogen geen onbevoegde personen aanwezig zijn.

Draag adembescherming met een beschermingsfactor 40 bij de toepassing middels airless spuiten. Gebruik adembescherming met een beschermingsfactor 10 bij overige toepassingen, met uitzondering van de toepassing middels kwasten, waarvoor geen adembescherming nodig is.

Wanneer de verf in meerdere lagen wordt aangebracht dienen de aanwijzingen van de fabrikant met betrekking tot de minimaal en/of maximaal aan te houden droogtijden in acht te worden genomen. Dit geldt ook voor de periode tussen het schilderen en het te water laten.

Dosering:
Gebruik 1 liter verf op 4 m².
Droge laagdikte: 150µm.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 2 mei 2014 tot verlenging van de toelating van het middel SEA TENDER 10, toelatingnummer 12029 N

RISKMANAGEMENT

Contents **Page**

H.1	**Introduction**	**3**
H.2	**Identity**	**3**
H.3	**Physical and chemical properties**	**3**
H.4	**Analytical methods for detection and identification**	**3**
H.5	**Efficacy**	**3**
H.6	**Human toxicology**	**3**
H.7	**Environment**	**15**
H.8	**Conclusion**	**27**
H.9	**Classification and labelling**	**27**

H.1. *Introduction*

H.1.1 Applicant
Chugoku Paints B.V.

H.1.2 Active substance
Copper(I) oxide

H.1.3 Product
SEA TENDER 10

H.1.4 Function
SEA TENDER 10 is commercialized as an anti-fouling paint (PT21).

H.1.5 Background to the application
Application for re-authorisation of an existing authorisation of a biocidal product

H.1.6 Intended uses
SEA TENDER 10 is commercialized as an anti-fouling paint (PT21).

H.2. *Identity*

Since this concerns a renewal of the authorization, an assessment of the identity has not been performed.

H.3. *Physical and chemical properties*

Since this concerns a renewal of the authorization, an assessment of the physical and chemical properties have not been performed.

H.4. *Analytical methods for detection and identification*

Since this concerns a renewal of the authorization, an assessment of the analytical methods for detection and identification have not been performed.

H.5. *Efficacy*
Since this concerns a renewal of the authorization, an assessment of the efficacy has not been performed.

H.6. *Human toxicology*

Copper(I) oxide
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 draft CAR 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. The same value is set for copper in humans on a copper adequate diet by the EFSA (2008). 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 compounds. 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. The same value will be used in the present risk assessment.

There is no accurate data available in relation to the respiratory absorption of copper. There is an indication that 20% of the inhaled amount is absorbed, however, for the risk assessment an respiratory 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(I) oxide by the EFSA. 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 BPR.

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	36-40% (draft CAR copper(II) oxide, EFSA evaluation) 0.14% uptake of dermal dose (data provided by the applicant on a comparable paint formulation)
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	Dermal : 500 mg Cu/kg bw/day (21-day rabbit) (EFSA, 2008) Inhalation: no data available Oral: NOAEL 5 mg Cu/kg bw/day (13-week rat)
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)

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.1).

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.1 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

6.1 Human exposure assessment active substance

6.1.1 General aspects

SEA TENDER 10 is a ready-to-use antifouling paint (relative density 1.91) containing 45% copper(I) oxide as an active substance. The proposed field of use of SEA TENDER 10 is PT21: application against marine growth on seagoing vessels that are used for commercial or military purposes. The formulation will be applied by airless spraying or by brushing with a spreading rate of 4 m^2/L, considering a thickness per dry layer of 150 µm.

The formulation SEA TENDER 10 is intended for professional use only.

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.

As the formulation SEA TENDER 10 is intended for professional use only, oral exposure to the active substance 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, potmen and grit fillers only dermal exposure is expected, as inhalation exposure is likely to be negligible in view of the low vapour pressure of copper(I) oxide (decomposition temperature 1800 °C). However, for completeness respiratory exposure for these groups was still calculated, as it is included in the used exposure models.

6.1.3 Identification of main paths of non-professional exposure towards active substance from its use in biocidal product

The formulation SEA TENDER 10 is intended for professional use only.

6.1.4 Indirect exposure as a result of use of the active substance in biocidal product

Access of unauthorised personal to professional shipyards is considered to be unlikely. However, secondary exposure is possible for bystanders incidentally present at the workplace yet unoccupied with the application work.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No studies with SEA TENDER 10 have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex I of 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 0.1% 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 45%, the amount of copper present in the formulation amounts to 45% x 88.8% = 39.96%.

The following exposure estimates are derived:

Table T.2 Internal professional operator exposure to copper from copper(I) oxide and risk assessment for the use of SEA TENDER 10 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	0.4321	0.059	7.32
Dermal	0.4424	0.059	7.50
Total	0.8744	0.059	14.82
Airless spraying (high pressure), with PPE [3] and RPE [4]			
Respiratory	0.0108	0.059	0.18
Dermal	0.0324	0.059	0.55
Total	0.0432	0.059	0.73

[1] Internal exposure is calculated based on 0.1% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: coated coveralls and gloves. For dermal exposure of the body, the use of coveralls (90% exposure reduction) is considered. For the dermal exposure on hands, the indicative values from Spraying Model 3 inside protective gloves are used to calculate the exposure reduction by the use of protective gloves.
4 RPE (respiratory protective equipment) is considered to result in 97.5% respiratory exposure reduction.

Based on this, no adverse effects are expected for protected (gloves, coated coveralls, suitable respiratory protective equipment with a protection factor 40) professional users from exposure to copper(I) oxide as a result of application of SEA TENDER 10 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.

[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.

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

Table T.3 Internal professional operator exposure to copper from copper(I) oxide and and risk assessment for the use of SEA TENDER 10 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	0.0006	0.059	0.01
Dermal	0.0644	0.059	1.09
Total	0.0650	0.059	1.10
Brushing, with PPE[3], Consumer Product Painting Model 4			
Respiratory	0.0006	0.059	0.01
Dermal	0.0130	0.059	0.22
Total	0.0136	0.059	0.23
Brushing, no PPE, Links et al. (2007) study			
Respiratory	0.0035	0.059	0.06
Dermal	0.0996	0.059	1.69
Total	0.1031	0.059	1.75
Brushing, with PPE[4], Links et al. (2007) study			
Respiratory	0.0035	0.059	0.06
Dermal	0.0003	0.059	<0.01
Total	0.0038	0.059	0.06

[1] Internal exposure is calculated based on Consumer Product Painting Model 4 and Links et al. (2007) study by considering 0.1% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: gloves and coverall. For dermal exposure of the body, the use of coated coveralls (90% exposure reduction) is considered. For the dermal exposure on hands, the indicative values from Consumer Product Painting Model 4 inside protective gloves are used to calculate the exposure reduction by the use of protective gloves.
[4] The exposure with PPE is calculated considering indicative exposure values from the Links et al., 2007 study

Based on this, no adverse effects are expected for protected (gloves, coated coveralls) professional users from exposure to copper(I) oxide as a result of application of SEA TENDER 10 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 gloves, coated coveralls, and suitable respiratory protective equipment (with a protection factor 40).

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.4 Internal professional operator exposure of potman to copper from copper(I) oxide and risk assessment for the use of SEA TENDER 10

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Potman, no PPE			
Respiratory	0.0475	0.059	0.80
Dermal	0.1463	0.059	2.48
Total	0.1937	0.059	3.28
Potman, PPE[3] and RPE[4]			
Respiratory	0.0047	0.059	0.08
Dermal	0.0209	0.059	0.35
Total	0.0256	0.059	0.43

[1] Internal exposure is calculated based on Mixing and Loading Model 6 by considering 0.1% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: gloves and coverall. For dermal exposure of the body, the use of coveralls (90% exposure reduction) is considered. For the dermal exposure on hands, the indicative values from Mixing and Loading Model 6 inside protective gloves are used to calculate the exposure reduction by the use of protective gloves
[4] RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction (TNsG, 2007).

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

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.5 Internal professional operator exposure of blast worker to copper from copper(I) oxide risk assessment for the use of SEA TENDER 10

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.3482	0.059	5.90
Dermal	0.0437	0.059	0.74
Total	0.3919	0.059	6.64
Paint stripping, with PPE[3] and RPE[4]			
Respiratory	0.0402	0.059	0.59
Dermaal	0.0054	0.059	0.09
Total	0.0402	0.059	0.68

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.1% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: gloves and coverall. The exposure with PPE is calculated considering indicative exposure values from the Links et al., 2007 study
[4] RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction.

Based on this, no adverse effects are expected for protected (gloves, coveralls, 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 SEA TENDER 10.

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.6 Internal professional operator exposure of grit filler to total copper from copper(I) oxide and copper pyrithione and risk assessment for the use of Hempel's antifouling Globic 9000 78950

Route	Internal exposure	Systemic AEL	Risk-index[2]

	(mg/kg bw/day) [1]	(mg/kg bw/day)	
Grit filling, no PPE			
Respiratory	0.2349	0.059	3.98
Dermal	1.4504	0.059	24.58
Total	1.6853	0.059	28.56
Grit filling, PPE [3] and RPE [4]			
Respiratory	0.0235	0.059	0.40
Dermal	0.0192	0.059	0.32
Total	0.0427	0.059	0.72

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.1% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: gloves and coverall. For dermal exposure of the body, the use of coated coveralls (90% exposure reduction) is considered. For the dermal exposure on hands, the exposure using PPE (gloves) is calculated based on the indicative values for actual hand exposure inside gloves from the study of Links et al. (2007).
4 RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction.

Based on this, no adverse effects are expected for protected (gloves, coveralls, suitable respiratory protective equipment with a protection factor 10) professional users – grit fillers from exposure to copper(I) oxide as a result of application of SEA TENDER 10.

6.3.2 Non-professional users, including the general public

SEA TENDER 10 is intended for professional use only.

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".

6.3.4 Combined exposure

SEA TENDER 10 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 contains three substances for which Community Exposure Limits (SCOELs) have been set. These substances are referred to as Human Health SoC 1, 2 and 3. 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 indices of <0.01 for all substances), no adverse effects from exposure to these substances are assumed for 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

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, coated coveralls, respiratory protective equipment with protection factor 40) professional users after dermal and respiratory exposure to copper(I) oxide as a result of the application of SEA TENDER 10 by airless spraying when used in accordance to the WG/GA. Furthermore, no adverse effects are expected for the protected (gloves, coated coveralls, respiratory protective equipment with protection factor 40) ancillary worker after dermal and respiratory exposure to copper(I) oxide as a result of the application of SEA TENDER 10.

It was concluded that no adverse health effects are expected for the protected (gloves, coveralls) professional user after dermal and respiratory exposure to copper(I) oxide as a result of the application of SEA TENDER by brushing and rolling when used in accordance to the WG/GA.

It was concluded that no adverse health effects are expected for the protected (gloves, coveralls and respiratory protection with a protection factor 10) professional user after dermal and respiratory exposure to copper(I) oxide as a result of performing potman tasks and grit filling during the application of SEA TENDER 10, and as a result of sand blast removal of antifouling paint containing SEA TENDER 10 when used in accordance to the WG/GA.

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 SEA TENDER 10.
However, based on the risk assessment, the following text should be included in the WG/GA: "Unprotected persons should be kept out of treatment areas".

H.7. *Environment*

7.1 Introduction

Authorisation is requested for the biocidal product SEA TENDER 10 containing as active substance copper(I)oxide (maximum pure concentration 45% w/w). In addition, two co-formulants are considered Substances of Concern (SoCs) because they contribute to the classification of the product. These SoCs are qualitatively assessed in the risk assessment, according to expert judgement.

The biocidal product concerns an antifouling paint, to control and avoid growth of fouling organisms on submerged surfaces of commercial, navy and government ships in marine environments, see also Table E.1.This application falls under the product type category PT21 (antifouling products). The product is for professional use only.

Tabel E.1 Intended use

Antifouling paint applied to hulls of ships in marine environments (application: airless spray, brush and roller)	Outdoor	Prof

7.2. Product related studies

Leaching rate from paint layer to water
On basis of calculations from a non-validated model (CEPE), 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 applied paint is released at a constant rate during the specified lifetime of the paint.
The release rate is determined using the volume of dry paint film applied (53%), the loading of biocide in the paint (45% w/w), and the specified lifetime of the paint (worst case/minimal of 3 year). 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 paint's specified life-time;

- the ratio of the cumulative amount of biocide released during the first 14 days following immersion to the average release rate during the remainder of the paint's specified lifetime is 30;
- 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 knowledge about the biocide content of the paint, specified dry film thickness and its 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 of the paint (µg/cm^2 per day)

The following assumptions are applied: one paint layer having a dry film thickness of 150 µm is applied to the ships hull. The service life of the paint is minimal three years 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).

The calculated leaching rate of copper(I)oxide is 38.13 µg·a.s. cm^{-2}·d^{-1} for the first 14 days and 17.79 µg·a.s. cm^{-2}·d^{-1} for the rest of the service life of the paint layer.

According to the PT21 workshop on harmonisation of leaching rates (Van de Plassche, 2006) this method overestimates the leaching rate. Therefore an additional reduction with a factor of 2.9 may be applied to the calculated leaching rates. The leach rate correction factor should only be applied to vessels at berth if data (e.g. leaching rate studies) supporting this reduction factor is provided (source: final minutes of TM IV 2011 and TM II 2010).
The environmental exposure assessment will be carried out using the leaching rate calculated with the CEPE mass-balance method. If at this tier the PEC/PNEC for the saltwater scenarios is higher than one, a correction factor of 2.9 can be applied in a second tier. However, a justification for the use of this correction factor for this type of formulation is not available and a weight of evidence approach should be investigated at TM level which is supported by the Commission. SE pointed to a recent paper on ASTM leaching rate studies with a period of 120 instead of 42 days. In that case there would be no need for an extra correction factor according to SE as steady-state is reached. SE will make the paper on longer term ASTM leaching studies available to the TM. UK will, based on these data, present a revised proposal on the use and justification of the Finnie leaching rate correction factor.
For the time being we stick to the CEPE mass balance value and do not use the 2.9 factor.

7.3. Environmental exposure assessment product

7.3.1 Chemistry and/or metabolism

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 result 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. Emissions during the production of the active substance, product formulation, and the application and waste phase of the product are considered less relevant.

The product SEA TENDER 10 is intended for professional use on commercial, navy and government vessels with ship movements in marine environments. The foreseeable routes of entry into the environment during the application, in-service and waste phase are listed in Table E.2.

Table E.2 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	++	++	(+)	-	(+)
	Maintenance and repair	++	++	(+)	-	(+)
Service life	Shipping lane	-	++	-	-	+
	Open sea	-	++	-	-	+
Removal	Maintenance and repair	++	++	(+)	-	(+)

++ 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.

Service life
During its service life, the emission of the active substances will come from the antifouling paint on the submerged surfaces of the commercial, navy and government ships, 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 substances, leaching into the water phase and sediment during sailing or while the commercial, navy and government ships remain in the harbour.
- *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.

The application phase comprises the application of a new layer of paint on the new or existing commercial, navy and government ships. Product authorization is requested for professional use in shipyards and docks.
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 consists of the removal of the old layer of paint on existing commercial, navy and government ships. 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 devices. 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 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 is assumed; it is presumed 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. Therefore, no quantitative risk assessment is performed for the application and removal of antifouling paints for risk assessments under Chapter 10 of the RGB [Transition period for EU Regulation 528/2012]. Available scenarios in the ESD represent worst-case scenarios for newly built vessels, and maintenance and repair, and do not acknowledge effective reduction of environmental emissions by risk mitigation measures in a good regulatory framework.

Scenarios and models used for PEC calculations

Choice of model
Predicted Environmental Concentrations (PEC) for outdoor applications were calculated in accordance with the scenarios from OECD Emissions Scenario Documents (ESDs). 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 shipping lane
2. ‘’OECD” open sea (OECD shipping lane scenario with number of ships moving conform default open sea scenario with MAMPEC)

These scenarios employ a few assumptions. Firstly, an application factor of 0.9 (market share 90%) is assumed. Secondly, in accordance with the direction of the minister of Housing and Spatial Planning (VROM) of June 30th 2004, the commercial harbour scenario will not be assessed. As the antifouling paint is used for marine vessels, fresh water habitats are not taken into account. And thirdly, the temperature of the marine scenario was set to 9 °C, which is a default for marine systems according to the TGD.

Service life
During its service life, the active substance copper(I)oxide will leach from the antifouling paint on the submerged surfaces of ships 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.

Table E.3 shows the input variables as used in MAMPEC.

Table E.3 Input variables of MAMPEC 3.0

Variable	Copper	Unit
Molar mass	63.5	g/mol
Vapour pressure	1.0×10^{-6}	Pa [25°C] [20°C]
Solubility	1	g/m^3 [20°C]
Octanol-water part. coeff.	-	(10) log K_{ow}
Sediment-water part. coeff. K_d	30	m^3/kg
Partition coefficient K_{oc}	-	10 log K_{oc}
Henrys law constant	-	$Pa.m^3/mol$
Melting point	-	°C
pKa	-	-
In water phase:		
Biodegradation (20°C)	0*	1/day
Hydrolysis rate	0*	1/day
Photolysis rate	0**	1/day
In sediment phase:		
Biodegradation (20°C)	0*	1/day
Leaching rate	17.79***	$\mu g/cm^2/day$

* 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 phase and in the suspended matter calculated by MAMPEC are presented in Table E.4.

Table E.4 Predicted concentrations of copper in water (PEC, µg/L) and in suspended matter using MAMPEC 3.0

Copper concentrations	Water phase (µg/L)	Suspended matter (mg/kg dwt)
Shipping lane	1.5×10^{-4}	4.4×10^{-3}
Open sea	3.4×10^{-6}	1.0×10^{-4}

7.4 PNEC derivation

The risk assessment will be based on available toxicity data of copper. For the derivation of the predicted no effect levels (PNECs) for the water compartment, a statistical extrapolation method (Species Sensitivity Distribution, SSD) was used, as shown in Table E.6. This method is in accordance with Directive 93/67/EC and a detailed description of the methodology can be found in the TGD ("Technical Guidance Document in support of commission directive 93/67/EC on risk assessment for new notified substances, commission regulation (EC) no. 1488/94 on risk assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the Market (2003)).
As other compartments (freshwater and soil) are not expected to be exposed, these risk assessment are qualitatively and the PNECs are not discussed.

Table E.6 Toxicity data for copper

Compartment	Organisms	Lowest endpoint [µg a.s./L]	Safety factor	PNEC

Compartment	Organisms	Lowest endpoint [µg a.s./L]	Safety factor	PNEC
Seawater	Multiple chronic studies, sufficient taxa for SSD*	HC_5=5.2 µg/L **	2	2.6 µg/L **
Marine sediment	-	-	-	87 mg/kg dwt ***

* The PNECs for copper are based on the Species Sensitivity Distribution (SSD), a statistical extrapolation model

** Based on total (background concentration in most sensitive eco-region+added) concentrations in the water compartment

*** The lowest PNEC was selected from the PNEC freshwater sediment (87 mg/kg dwt), and the PNECs calculated for the estuarine (144 mg/kg dwt) and the marine environment (338 mg/kg dwt), using the equilibrium partitioning method and the PNEC aquatic marine of 2.6 µg/L

7.5 Risk characterisation for the environment

Aquatic compartment (incl. Sediment) and STP

7.5.1 Water and sediment organisms

The risk for water- and sediment organisms by the use of antifouling paint is estimated by comparing the (average) PECs in the water phase and suspended matter 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. In the next paragraphs the PEC to PNEC ratios will be presented to assess the risk.
The risk assessment for the environment is based on the total risk approach for copper. It was not considered necessary to take background concentrations of copper in the marine environment into account in the risk calculations.

Service life
The PEC to PNEC ratios for water organisms for application as antifouling on commercial, navy and government ships in marine environments are < 0.01, implying a very low risk (Table E.8) and therefore the product SEA TENDER 10 meets the standards for water organisms for application as antifouling on ships in marine environments.

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

	PEC (µg Cu/L)	PNEC (µg Cu/L)	PEC/PNEC ratio
Shipping lane	1.5×10^{-4}	2.6	5.8×10^{-5}
Open sea	3.4×10^{-6}	2.6	1.3×10^{-6}

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 substance depends on the life cycle and feeding traits of these organisms. The concentration of active substance in the sediment can be substantially lower than on suspended solids, because the concentration of the active substances may be affected by degradation, considering the retention times of suspended solids in the sediment. The suspended solids concentration is therefore most relevant to the exposure of the sediment organisms that fall into the category of suspension feeders.

The PEC/PNEC ratio for sediment dwelling organisms does not exceed the trigger value 1 for seagoing ships in marine environments implying a low risk (Table E.9) and therefore the product SEA TENDER 10 meets the standards for sediment organisms for application as antifouling on seagoing ships in marine environments.

Table E.9 PEC, PNEC and PEC to PNEC ratio to assess the risk for sediment organisms during the service life of the antifouling product.

	PEC (mg Cu/kg dwt)	PNEC (mg Cu/kg dwt)	PEC/PNEC ratio
Shipping lane	4.4×10^{-3}	87	5.1×10^{-5}
Open sea	1.0×10^{-4}	87	1.2×10^{-6}

The product contains two co-formulants which trigger classification of the product. As these compounds are present in the product at much lower concentrations and demonstrate less sensitive ecotoxicity endpoints for aquatic organisms, when compared with copper, it is considered that the risk assessment for copper covers the co-formulants as well.

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.

7.5.2 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 (PNECstp = 0.23 mg Cu/L) show that the active substance is 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.

7.5.3 Surface water intended for the abstraction of drinking water

From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete 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.
Copper(I)oxide is not on the list of substances of concern for surface water at drinking water abstraction points as established by VEWIN/Ctgb. The active substance is also not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010), because the substance is naturally occurring and is also emitted by other sources than biocides. The Ctgb does under this approach does not expect an exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

7.5.4 Air

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 H420 classification: Harms public health and the environment by destroying ozone in the upper atmosphere), the environmental risk to air is considered acceptable and the proposed application of the product meets the standards for air.

7.5.5 Terrestrial compartment

Soil organisms and non target arthropods (including bees)
For professionals, 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. Hence, the proposed applications of the product meet the standards for soil organisms and non-target arthropods (including bees).

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. However, 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"). Therefore, copper(I)oxide meets the criteria for persistence in soil.

Groundwater
Risk mitigation measures, permits, work instructions and inspection at ship yards, enforced by the Environmental Management Act ("Wet Milieubeheer"), adequately reduce emissions to groundwater from the application and removal stages. In view of this, a low risk for groundwater is expected. Therefore the proposed application of the product meets the standards for the production of drinking water from groundwater.

7.5.7 Non compartment specific effects relevant to the food chain

Primary and secondary poisoning of birds and mammals
The assessment of environmental fate of the active ingredients showed that direct exposure to the active substance is 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 vRAR of copper (2008; environmental effects part 3) extensively describes the role of copper as an essential nutrient and for 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-organisms and plants to invertebrates and vertebrates. Difference in copper uptake rates are related to essential needs, varying with species, size, life stage, seasons etc. Thus, unlike for organic substances, bioconcentration 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 shows 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.

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 bioavailability of metals is often limited. For copper 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 applications of SEA TENDER 10 meet the standards for bioconcentration.

7.6 Measures to protect the environment (risk mitigation measures)
No additional measures to protect the environment (risk mitigation measures) are required.

7.7 Overall conclusion for the aspect environment
Based on the available data, it can be concluded that SEA TENDER 10, when used in accordance with the proposed label (WG/GA), complies with the environmental standards and will not cause unacceptable effects on the environment.

7.8 Data requirements
There are no additional data required.

7.9References

Consolidated list of PT21 technical agreements included in MOTA v.6
Harmonisation of Environmental Emission Scenarios: An Emission Scenario Document for Antifouling Products in OECD countries. European Commission Directorate-General Environment. 23 September 2004. Final Report 9M2892.01
MAMPEC Version 3.0
http://www.rivm.nl/rvs/Normen/Eindresultaat?groep=normen&waarde=koper&lijst=milieukwaliteit&veld=substancename_tagged
Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances; Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, Ispra, Italy, 2003.
Van de Plassche, 2006. PT21 workshop on harmonisation of leaching rates, Ispra.

H.8. *Conclusion*
The applicant has proven that SEA TENDER 10, 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).

H.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:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Butylglycol, mixture of various rosin acids, xylene			
Pictogram:	GHS02 GHS07 GHS09	Signal word:	Warning
H-statements:	H226	Flammable liquid and vapour	
	H302	Harmful if swallowed	
	H315	Causes skin irritation	
	H317	May cause an allergic skin reaction	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	
	P273	Avoid release to the environment	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	

	P284	Wear respiratory protection
	P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
	P312	Call a POISON CENTER/doctor/... if you feel unwell.
Supplemental Hazard information:	EUH205	Contains epoxy constituents. May produce an allergic reaction.
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

Explanation:	
Pictogram:	-
H-statements:	H312 and H332 are not assigned based on the calculation rules according to Regulation 1272/2008/EC.
P-statements:	P284 is assigned based on the risk assessment. P261 is not assigned, as it is considered to be covered by P284. P501 is not assigned, as this would lead to > 6 P-statements. Other P-statements are assigned as proposed by the applicant.
Other:	Butylglycol and mixture of various rosin acids are included on the label, as they contribute to the classification of the product as acute toxic Cat. 4 and sensitizing.

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