HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 4 juli 2013 is van

International Paint (Nederland) BV
Postbus 856
3160 AB RHOON

een aanvraag verlenging toelating biocide ontvangen voor het middel

Interspeed 340

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

HET COLLEGE BESLUIT tot verlenging van bovenstaand middel voor gebruik als aangroeiwerende verf op zeegaande schepen die worden gebruikt voor beroep of bedrijf alsmede oorlogsschepen, marine-hulpschepen of andere schepen die in gebruik zijn voor de militaire taak.

HET COLLEGE BESLUIT tot afwijzing van bovenstaand middel voor alle andere toepassingen als aangroeiwerende verf.

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.
- 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.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 122 (alleen als de aanvraag in 2007 is ingediend), artikel 121, eerste lid, de juncto artikel 66, eerste lid, Wet gewasbeschermingsmiddelen en biociden
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, 9 oktober 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

11858 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20131011 TVB
Type aanvraag:	aanvraag verlenging toelating biocide
Middelnaam:	Interspeed 340
Verzenddatum aanvraag:	2 juli 2013
Formele registratiedatum: *	4 juli 2013
Datum in behandeling name:	27 januari 2014

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

2 Stofinformatie

Werkzame stof	Gehalte
koper(I)oxide	40%
zineb	4,4%

De werkzame stof koper(I)oxide, zineb is opgenomen in het reviewprogramma maar nog niet geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	11858 N
Expiratiedatum:	1 november 2025
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel
Aflevertermijn niet-professioneel gebruik:	1 april 2016
Opgebruiktermijn niet-professioneel gebruik:	31 mei 2016

4 Verpakkingsinformatie

Aard van het preparaat:
Andere vloeistoffen voor directe toepassing

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BIJLAGE II Etikettering van het middel Interspeed 340

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
ethylbenzeen, pijnhars, xyleen, zineb

Pictogram	GHS02 GHS07 GHS08 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H226 Ontvlambare vloeistof en damp. H332 Schadelijk bij inademing. H361d Wordt ervan verdacht het ongeboren kind te schaden. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P202 Pas gebruiken nadat u alle veiligheidsvoorschriften gelezen en begrepen heeft. P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P273 Voorkom lozing in het milieu. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	EUH208 Bevat pijnhars en zineb. Kan een allergische reactie veroorzaken.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

11858 N

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BIJLAGE III WG/GA van het middel Interspeed 340

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

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

Dit middel mag uitsluitend worden aangebracht en verwijderd op daar toe aangewezen locaties in professionele scheepswerven en droogdokken met de juiste vergunningen in het kader van de Wet Milieubeheer ter voorkoming van vervuiling van bodem, grondwater en oppervlakte water en lucht.

Draag adembescherming met een beschermingsfactor 40 bij de toepassing middels airless spuiten en bij het verwijderen van oude verflagen. Met uitzondering van de toepassing door middelen van kwasten, dient voor alle overige toepassingen adembescherming met een beschermingsfactor van 10 gedragen te worden.

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

Het verkrijgen van een goed resultaat met deze aangroeiwerende verf is van vele factoren afhankelijk. Gebruikers dienen zich te houden aan de applicatievoorschriften op het label en de technische informatiebladen.

Algemene richtlijnen

Voor gebruik goed roeren.

Aanbrengen met kwast, rolborstel en/of geschikte spuitapparatuur.

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 verstrekte instructies.

Houdt de aanbevolen minimale en/of maximale droogtijden en de aanbevolen periode tussen het schilderen en het te water laten aan.
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HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

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1 Introduction

1.1 Applicant

International Paint (Nederland) BV
Postbus 856
3160 AB RHOON

1.2 Active substance

Copper(I)oxide and Zineb

1.3 Product

Interspeed 340

1.4 Function

Anti-fouling paint (PT21)

1.5 Background to the application

This concerns an application for re-registration of an existing registration of a biocidal product.

1.6 Intended uses

The intended use of the product is the use as anti-fouling paint on ships in fresh water and salt water.

2 Identity

This concerns an application for re-registration of an existing registration of a biocidal product, and therefore the identity of the product has not been re-established.

3 Physical and chemical properties

This concerns an application for re-registration of an existing registration of a biocidal product, and therefore the physical and chemical properties of the product have not been re-established.

4 Analytical methods for the technical active substances

This concerns an application for re-registration of an existing registration of a biocidal product, and therefore the analytical methods for the technical active substances of the product have not been re-established.

5 Efficacy

This concerns an application for re-registration of an existing registration of a biocidal product, and therefore the efficacy of the product has not been re-established.

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 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 therefore for the risk assessment a dermal absorption of 0.1% will be used (in accordance to the dermal absorption value of 0.1% used by

	US-EPA). 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.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
No additional data requirements are identified.

Zineb
Zineb is an existing active substance, is not included in the Union list of approved substances of EU Regulation 528/2012. A draft final CAR is available (Ireland is the

Reporting Member State). The risk assessment is based on the List of Endpoints as reported in the draft final CAR.

Absorption, Distribution, Metabolism and Excretion in Mammals

Rate and extent of oral absorption:	Rapid, 50% based on urinary and biliary excretion
Rate and extent of dermal absorption:	0.11% by 8 hrs (high level dose formulation) 0.24% by 8 hours (low level dose formulation) Based on results of the in vivo rat dermal absorption study.
Distribution:	Widely distributed, the highest residues in thyroid
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapid, > 95% within 4 days
Toxicologically significant metabolite	Ethylene thiourea (ETU)

Acute Toxicity

Rat LD_{50} oral	> 2000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5 mg/l (nose only)
Skin irritation	Non irritant
Eye irritation	Non irritant
Skin sensitization (test method used and result)	Sensitizing (M&K)

Repeated Dose Toxicity

Species/ target / critical effect	Thyroid (inhibition of thyroid peroxidase, hyperplasia/hypertrophy)
Lowest relevant oral NOAEL	7 mg/kg bw/day (overall NOAEL, 90-day rat, 90-day & 1-yr dog)
Lowest relevant dermal NOAEL	>1000 mg/kg bw/day (28-day, rat)
Lowest relevant inhalation NOAEL	36 mg/m^3 (respirable concentration) (90-day, rat)

Genotoxicity (Annex IIA, point 6.6)	The overall body of toxicological data coming from a number of in vitro and in vivo assays indicates that there is no concern.

Carcinogenicity

Species/type of tumour	Rat/ thyroid adenomas and carcinomas
lowest dose with tumours	30.9 mg/kg bw (rat, 750 ppm)

Reproductive Toxicity

Species/ Reproduction target / critical effect	Rat, decreased pup weight at parentally toxic level
Lowest relevant reproductive NOAEL	150 ppm (about 7 mg/kg bw/day) (two-generation study in rat)
Species/Developmental target / critical effect	Malformations at high doses in rats; embryo-/fetotoxicity (delayed ossification, abortions) at lower maternally toxic doses in rats and rabbits
Lowest relevant developmental NOAEL	Rat: 60 mg/kg bw/day

Neurotoxicity/Delayed Neurotoxicity

Species/ target/critical effect	There is no evidence from toxicology studies for delayed neurotoxicity. Clinical signs and histopathology.
Lowest relevant developmental NOAEL	Rat: 125 ppm (8.2 mg/kg bw/day)
	The developmental neurotoxicity NOAEL was set at 30 mg/kg bw the highest dose tested. The maternal NOAEL in the study was set at 15 mg/kg bw/day based on findings of thyroid follicular cell hypertrophy and decreased body weight gain during gestation at 30mg/kg bw/day

Other Toxicological Studies

None

Medical Data

Human studies of manufacturing workers exposed to mancozeb have detected the presence of mancozeb in urine but, with the exception of sporadic reports of sensitisation by skin contact; no evidence of thyroid effects; evidence of increased chromosomal aberrations in manufacturing workers in one report.

Summary

	Value	Study	Safety factor
ADI	0.05 mg/kg bw/day	2 year rat	100
$AEL_{MEDIUM-TERM}$	0.035 mg/kg bw/day	overall sub chronic NOAEL in rats and dogs; correction for 50 % oral absorption	100
$AEL_{LONG-TERM}$	0.024 mg/kg bw/d	2 year rat; correction for	100

		50 % oral absorption	
AEL_{ACUTE}	0.075 mg/kg bw/day	NOAEL from rat developmental neurotox study	100

Local effects
Zineb produces skin effects in a sensitisation study, but these effects are covered in the risk assessment/management by means of assignment of H- and P-statements. Zineb does not produce local effects after repeated exposure.

6.1 Human exposure assessment active substance

6.1.1 General aspects
Interspeed 340 (11858 N) is an antifouling paint containing copper(I)oxide (maximum concentration 41.55%) and zineb (maximum 4.28%) as an active substances. The concentration active substance varies somewhat between the colour variations (brown, plum, red and coastal red). The proposed field of use is PT21:
The formulation will be applied by airless spraying or by brushing and rolling.

The formulation Interspeed 340 is intended for professional 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 and zineb is considered negligible. Both respiratory and dermal exposure to copper(I) oxide and zineb 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) and zineb (<3.6 x 10^{-5} Pa at 20 °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
As Interspeed 340 is applied by brushing/rolling of the paint, the non-professional users can be dermally exposed to copper(I) oxide and zineb. As the low vapour pressure of cuprous oxide (decomposition temperature 1800 °C) and zineb (<3.6 x 10^{-5} Pa at 20 °C), respiratory exposure during brushing/rolling is expected to be negligible. However, for the completeness

the respiratory exposure is also calculated, as it is included in the used 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 and zineb 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
Studies with a comparable formulation are available. Based on these results, Interspeed 340 does not need to be classified on the basis of its acute oral (LD_{50} rat >2000 mg/kg bw) and dermal (LD_{50} rat >2000 mg/kg bw). Interspeed 340 is not a skin or eye irritant. Interspeed 340 does not have sensitising properties in a Maximisation test.

The classification for acute inhalation toxicity of Interspeed 340 will be based on the calculation method described in Annex I of Regulation 1272/2008/EC, as it was not possible to generate.

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 and 0.24% for zineb.

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 41.55%, the amount of copper present in the formulation amounts to 41.55% x 88.8% = 36.9%.

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 Interspeed 340 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	0.399	0.059	6.76
Dermal	0.408	0.059	6.92
Total	0.807	0.059	13.69
Airless spraying (high pressure), with PPE [3] and RPE [4]			
Respiratory	0.010	0.059	0.17
Dermal	0.030	0.059	0.51
Total	0.040	0.059	0.68

[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.

Table T.3 Internal professional operator exposure to zineb and risk assessment for the use of Interspeed 340 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	0.046	0.035	1.32
Dermal	0.114	0.035	3.25
Total	0.160	0.035	4.57
Airless spraying (high pressure), with PPE [3] and RPE [4]			
Respiratory	0.005	0.035	0.13
Dermal	0.008	0.035	0.24
Total	0.013	0.035	0.37

[1] Internal exposure is calculated based on 0.24% 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 90% 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 and zineb as a result of application of Interspeed 340 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 and risk assessment for the use of Interspeed 340 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	0.0595	0.059	1.01
Total	0.0600	0.059	1.02
Brushing, with PPE[3], Consumer Product Painting Model 4			
Respiratory	0.0006	0.059	0.01
Dermal	0.0273	0.059	0.46
Total	0.0279	0.059	0.47
Brushing, no PPE, Links et al. (2007) study			
Respiratory	0.0032	0.059	0.05
Dermal	0.0919	0.059	1.56
Total	0.0952	0.059	1.61
Brushing, with PPE[4], Links et al. (2007) study			
Respiratory	0.0032	0.059	0.05
Dermal	0.0466	0.059	0.79
Total	0.0498	0.059	0.84

[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. 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] PPE: gloves. The exposure with PPE is calculated considering indicative exposure values from the Links et al., 2007 study

Table T.5 Internal professional operator exposure to zineb and risk assessment for the use of Interspeed 340 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	0.035	<0.01
Dermal	0.0165	0.035	0.47

[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.

Total	0.0166	0.035	0.47
Brushing, no PPE, Links et al. (2007) study			
Respiratory	0.0004	0.035	0.01
Dermal	0.0256	0.035	0.73
Total	0.0260	0.035	0.74

[1] Internal exposure is calculated based on Consumer Product Painting Model 4 and Links et al. (2007) study by considering 0.24% 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 protected (gloves) professional users from exposure to copper(I) oxide and zineb as a result of application of Interspeed 340 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.6 Internal professional operator exposure of potman to copper from copper(I) oxide and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Potman, no PPE			
Respiratory	0.044	0.059	0.74
Dermal	0.135	0.059	2.29
Total	0.179	0.059	3.03
Potman, PPE[3] and RPE[4]			
Respiratory	0.004	0.059	0.07
Dermal	0.043	0.059	0.74
Total	0.048	0.059	0.81

[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: coverall. For dermal exposure of the body, the use of coveralls (90% exposure reduction) is considered.
[4] RPE (respiratory protective equipment) is considered to result in 90% respiratory exposure reduction (TNsG, 2007).

Table T.7 Internal professional operator exposure of potman to zineb and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Potman, no PPE			
Respiratory	0.0051	0.035	0.15
Dermal	0.0376	0.035	1.07
Total	0.0427	0.035	1.22
Potman, PPE [3]			
Respiratory	0.0051	0.035	0.15
Dermal	0.0054	0.035	0.35
Total	0.0256	0.035	0.49

[1] Internal exposure is calculated based on Mixing and Loading Model 6 by considering 0.24% dermal absorption and 100% inhalation absorption
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] PPE: coverall. For dermal exposure of the body, the use of coveralls (90% exposure reduction) is considered.

Based on this, no adverse effects are expected for protected (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 Interspeed 340.

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.8 Internal professional operator exposure of blast worker to copper from copper(I) oxide and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.322	0.059	5.46
Dermal	0.040	0.059	0.68
Total	0.362	0.059	6.14
Paint stripping, with PPE[3] and RPE[4]			
Respiratory	0.032	0.059	0.55
Dermaal	0.005	0.059	0.08
Total	0.037	0.059	0.63

[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.

Table T.9 Internal professional operator exposure of blast worker to zineb and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.0411	0.035	1.18
Dermal	0.0124	0.035	0.35
Total	0.0535	0.035	1.53
Paint stripping, with RPE[3]			
Respiratory	0.0041	0.035	0.12
Dermaal	0.0124	0.035	0.35
Total	0.0165	0.035	0.47

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.24% 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 (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 Interspeed 340.

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.10 Internal professional operator exposure of grit filler to total copper from copper(I) oxide and risk assessment for the use Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Grit filling, no PPE			
Respiratory	0.217	0.059	3.68
Dermal	1.341	0.059	22.72
Total	1.558	0.059	26.40
Grit filling, PPE [3] and RPE [4]			
Respiratory	0.022	0.059	0.37
Dermal	0.018	0.059	0.30
Total	0.039	0.059	0.67

[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.

Table T.11 Internal professional operator exposure of grit filler to zineb and risk assessment for the use Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Grit filling, no PPE			
Respiratory	0.028	0.035	0.79
Dermal	0.411	0.035	11.75
Total	0.439	0.035	12.54
Grit filling, PPE [3]			
Respiratory	0.028	0.035	0.16
Dermal	0.005	0.035	0.79
Total	0.03	0.035	0.95

[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).

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 Interspeed 340.

6.3.2 Non-professional users, including the general public

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.12 Internal non-professional operator exposure to copper from copper(I) oxide and risk assessment for the use of Interspeed 340 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	0.0006	0.059	0.01
Dermal	0.0595	0.059	1.01
Total	0.0600	0.059	1.02

[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.

Table T.13 Internal non-professional operator exposure to zineb and risk assessment for the use of Interspeed 340 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	<0.0001	0.035	<0.01
Dermal	0.0165	0.035	0.47
Total	0.0166	0.035	0.47

[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.

Based on this, no adverse effects from exposure to copper or zineb is expected for unprotected non-professional users due to the application of Interspeed 340 by brushing and rolling, although the risk index for copper is slightly exceeded (RI 1.02).

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.14 Internal non-professional operator exposure to copper from copper(I)oxide during the paint removal and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.1609	0.059	2.73
Dermal	0.0202	0.059	0.34
Total	0.1811	0.059	3.07

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.1% dermal absorption and 100% inhalation absorption

Table T.15 Internal non-professional operator exposure to zineb during the paint removal and risk assessment for the use of Interspeed 340

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Paint stripping, no PPE			
Respiratory	0.0206	0.035	0.59
Dermal	0.0062	0.035	0.18
Total	0.0268	0.035	0.76

[1] Internal exposure is calculated based on the study of Links et al. (2007) by considering 0.1% dermal absorption and 100% inhalation absorption

Based on this, adverse effects are expected for unprotected non-professional users during the paint removal from exposure to copper as a result of application of Interspeed 340. As PPE cannot be prescribed for non-professional users to reduce the risk, the application of Interspeed 340 by non-professional users cannot be authorised.

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 4.80m^2/l and the relative density of 1.988, the maximal concentration of the formulation on the surface is 1.988 kg/4.8 m^2, or 414 g/m^2, or 41.4 mg/cm^2. Considering the concentration of copper in the formulation of 36.9%, this corresponds to 15.3 mg Cu/cm^2, for zineb 4.28% this correspond to 1.77 mg zineb/ 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:

Copper from copper(I) oxide:
15.3 mg/cm^2 x 18% x 400 cm^2 = 1101.6 mg copper on hands, or, considering 0.1% dermal absorption and 35 kg child body weight, 0.031 mg/kg bw/day. Comparing this with the AEL of 0.059 mg/kg bw/day, the resulting risk index is 0.53.

Zineb:
1.77 mg/cm^2 x 18% x 400 cm^2 = 127.44 mg zineb on hands, or, considering 0.24% dermal absorption and 35 kg child body weight, 0.0087 mg/kg bw/day. Comparing this with the AEL of 0.035 mg/kg bw/day, the resulting risk index is 0.25.

Based on this no adverse effects from secondary dermal exposure to zineb due to the contact with freshly treated surfaces is expected.

6.3.4 Combined exposure

The formulation Interspeed340 is a mixture of 2 active substances. The combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity.

Based on the proposal for the assessment of combined exposure proposed by the MS France and endorsed at the TM IV, 2012, as a first tier the systemic effects of both

substances are considered to be additive by default. This implies that if the sum of risk indices per exposure scenario is below 1, no risk of adverse effects from combined exposure to both substances is expected.

The following sums of risk indices can be calculated for each exposure scenario:

Airless spraying:	0.68 + 0.37 = 1.05
Brushing and rolling:	0.47 + 0.47 = 0.94 (Consumer Exposure Model 4)
	0.84 + 0.74 = 1.58 (Links et al., 2007)
Potman:	0.81 + 0.49 = 1.3
Blast worker:	0.63 + 0.47 = 1.1
Grit filler:	0.67 + 0.95 = 1.62

Based on this, it can be seen that the sum of risk indices exceeds 1 for most of the exposure scenarios.

As a second tier, the critical effects of both substances need to be considered. The critical systemic effects from exposure to copper are effects on liver and kidney, haematological effects and effects on blood biochemistry. In case of exposure to zineb, critical effects are thyroid gland effects (inhibition of thyroid peroxidase, hyperplasia/hypertrophy). The critical effects observed above the NOAEL which was used for setting the AELmedium-term systemic, which was used in the risk assessment, are a decrease in T4 hormone and an increase in TSH in females in a 13-week rat study. It can thus be concluded with a reasonable degree of certainty that the substances do not exhibit systemic toxicity by the same mode of action and do not have the same target organs. It is therefore not expected that combined exposure to (residues of) the 2 active substances in Interspeed 340 will result in an additional risk above the estimated risks based on the individual substances.

6.3.5 Substances of concern

The formulation Interspeed 340 contains two co-formulants for which Community Exposure Limits (SCOELs) have been set. These co-formulants are referred to as SoC Human Toxicology 1 and 2. The concentration of these SoCs Human Toxicology 1 and 2 in the formulations are 25.28% and 10.18%, respectively. 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 max 0.06 of the resulting risk indices for copper for both 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 (gloves, coated coveralls, suitable respiratory protective equipment with a protection factor 40) professional users from exposure to copper(I) oxide and zineb as a result of application of Interspeed 340 by airless spraying.
2. no adverse effects are expected for protected (gloves) professional users from exposure to copper(I) oxide and zineb as a result of application of Interspeed 340 by brushing.
3. 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 and zineb as a result of application of Interspeed 340 for the ancillary worker.
4. no adverse effects are expected for protected (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 Interspeed 340.

5. 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 Interspeed 340.
6. 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 Interspeed 340.

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:

Adverse effects are expected for unprotected non-professional users during the paint removal from exposure to copper as a result of application of Interspeed 340. As PPE cannot be prescribed for non-professional users to reduce the risk, the application of Interspeed 340 by non-professional users cannot be authorised.

7 Environment

7.1 Introduction

Authorisation is requested for the product Interspeed 340 as an antifouling paint (PT21) based on the active substances copper(I)oxide (43.05% w/w) and zineb (4.56% w/w). The biocidal product concerns an antifouling paint, to control growth and settlement of fouling organisms on submerged surfaces of commercial, navy and government vessels in marine water, and pleasure craft 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 uses are described in table E.1.

Table E.1 Intended uses of Interspeed 340

Area of use envisaged	Area of use	Applicators
Antifouling paint applied to hulls of commercial, navy and government vessels.	Saltwater	Professional
Applied to pleasure craft.	Fresh and saltwater	Professional and Non-professional

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 for copper for PT5, for which NL (Ctgb) is the Rapporteur Member State and for PT21 for which FR is the Rapporteur Member State.
For zineb a draft final CAR (May 2013) exists of which Ireland is the RMS.
Although no active substances, two co-formulants triggered the classification of the product according to CLP Regulation EC 1272/2008. This means that these substances of concern (SoC) would classify the product, even if the active substances would not have been present in the mixture. For reasons of confidentiality of the composition of the product, the SoC will not be addressed in their common name, but they will be referred to as SE1 and SE2. They are assessed in a similar way as the active substances and are also presented in the tables as if being active substances. The PEC and PNEC will not be shown, but the PEC/PNEC ratio will be presented in the risk characterization.

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. The data for the active substance applied in the current risk assessment is presented in appendix I.

Depending on several product characteristics (i.e. layer thickness; applied layers; dry weight volume) the leaching of the active substance from the paint is calculated according to the unvalidated 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 spray (Professional users only)
Number of coats	Apply 1 coat (3 year) on the hull. Apply 1 coat (3 year) by airless spray
Volume of dry paint versus volume wet paint (SVR)	60%
Specific gravity wet paint (SPG)	1.978 g/cm^3
Recommended dry film thickness (DFT)	250 microns
Leaching rate *	Copper ships moving: 55.62 µg a.s. cm^{-2}·d^{-1} for the first 14 days and 25.95 µg a.s. cm^{-2}·d^{-1} for the rest of the service life of the paint layer Copper ships berth: 19.18 µg a.s. cm^{-2}·d^{-1} for the first 14 days and 8.95 µg a.s. cm^{-2}·d^{-1} for the rest of the service life of the paint layer Zineb: 6.62 µg a.s. cm^{-2}·d^{-1} for the first 14 days and 3.09 µg a.s. cm^{-2}·d^{-1} for the rest of the service life of the paint layer. SE1 and SE2: Not presented due to confidentiality

* For the calculations an extra assessment factor of 2.9 is applied to the leaching of copper from vessels at berth.

The service life of the paint is 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). In order to calculate the leach rate of copper oxide it is assumed that 100% of the concentration acts as the biocide.

7.3. Environmental exposure assessment product

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.

Zineb
Degradation in the hydrosphere (including sediment)
Zineb was shown to be hydrolytically unstable at pH 4, 7 and 9 at 20 and 40°C. The amount of zineb at time 0 ranged from 4.2 % to 24.8 %, with most of the values < 10 %. Similar rates of degradation were observed at pH 4, 7 and 9. The major products of zineb hydrolysis were identified as 5,6-dihydro-*3 H-imidazo*(2,1- C-)-1,2,3-dithiazole-3-thione (DIDT, max 36 % (0 d) pH 9, 20°C), ethylenethiourea (ETU, 15.6 % (7 d) pH 9, 20°C), and ethyleneurea or 2-imidazolidinone (EU, max 52.3 % (30 d), pH 7 marine). Relative to zineb, all metabolites degraded more slowly. The EU metabolite exhibited the slowest degradation rate of all the metabolites.

Figure 1 shows the proposed route of degradation of zineb under aqueous conditions.

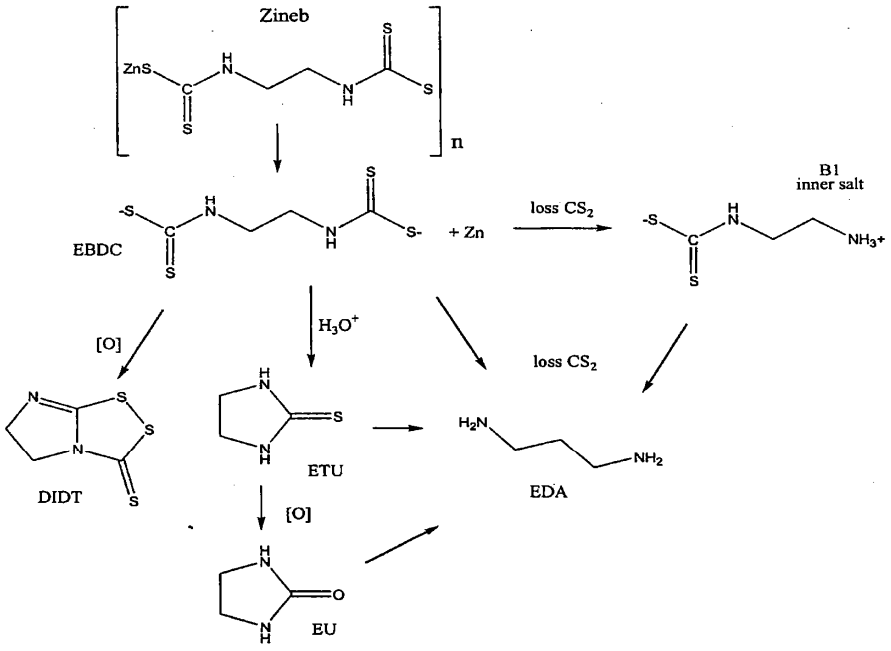

Figure 1. Zineb-route of degradation under aqueous conditions

The available photolysis study suggests this process is not relevant, because mancozeb, which is structurally similar to zineb, was decomposed within 3 hours in the presence or absence of irradiation. Consequently, the exposure assessment (MAMPEC) will assume that no degradation via photolysis occurs.

In the environment zineb is not readily biodegradable. The biodegradation of zineb in seawater was investigated using the OECD 306 closed bottle method. This assessed ultimate biodegradation or mineralisation. Zineb showed no significant (<10%) ultimate biodegradation after 28 days at any of the concentrations tested.

In marine water/sediment systems, the whole system DT50 for zineb was 0.0104 d at 10°C (0.0086 d at 12°C/0.011 d at 11°C). Degradation of zineb was accompanied by metabolite formation DIDT (max 35.8 %, 0.25 d), ETU (41.3 %, 2 d) and EU (65.2 %, 29 d) in brackish/marine water sediment systems. Bound residues reached 43.5 %AR in the brackish test system at the end of the incubation. Apart from the marine and copper systems (10°C, 48.2 %AR 7 d), lower levels of bound residues were observed in the other systems (river system, 20°C, 24.5 %AR 103 d, marine system, 10°C, 30.6 %AR 103 d). Bound residues steadily increased during the study and did not reach a plateau. The highest level of mineralisation occurred in the river system (61.7%AR $^{14}CO2$ at the end of the incubation (103 d)). Lower amounts of mineralisation were observed in the brackish (33.7 %AR), marine (5.6%) and marine and copper systems (2.1 %) respectively. EU was observed to be stable in marine systems. A slightly longer DT50 was observed in the marine system that contained copper (II) ions (DT50 0.016 hr at 10°C). In addition lower amounts of radioactivity were observed in the water phase until day 63. There was a corresponding higher amount of radioactivity found in the sediment, which was due to an increase in non-extractable radioactivity. This might be due to the formation of copper complexes with zineb metabolites. DIDT was observed in significantly lower amounts in the marine and copper system. After formation, these complexes may precipitate and contribute to the non extractable radioactivity (NER). This may be a reversible process as the amount of NER decreased after day 29. The degree of mineralisation was not equal in the test systems. Lower amounts of radioactivity were observed in the marine and copper systems. Relative to the marine system, a longer DT50 was observed for ETU in the marine system containing copper ions (22.4 d Vs. 12 d). This may be due to the bactericidal properties of copper.

Degradation in the terrestrial compartment
In view of the similar chemical structures and identical degradation pathways, it is considered that the results of studies carried out with mancozeb may be read across directly to zineb for the purposes of environmental risk assessment. Mancozeb degrades rapidly in soil (DT50 = 0.2568 d at 12°C). As in the water/sediment studies, the significant degradation products were DIDT, ETU and EU. However, the soil DT50s normalised to 12 °C are less than < 6 months. Consequently, these metabolites do not fulfil the persistence criteria in soil. The highest DT50 was observed for the EU metabolite (59.58 d at 12°C)

Soil mobility
Mancozeb and its degradates bind strongly to soil. Adsorption Ka_{oc} values ranged from 363 (silt loam) to 2,334 (sand); 1/n ranges from 0.686 to 0.777. The mean Ka_{oc} for all four soils tested was 997.5 L/kg. ETU is not strongly adsorbed by soil. An average adsorption coefficient of 70 L/kg (high mobility) was obtained. The mean Ka_{oc} for all four soils tested was 9.75 L/kg for EU. No experimentally derived data are available on the adsorption/desorption properties of the soil metabolite DIDT. This is presumably due to its fast degradation in soil. A Koc for DIDT (40.02 L/kg) using the US EPA EPIWIN v 3.12-computer program was calculated.

Degradation in the atmospheric compartment
Due to the low vapour pressure (< 3.6×10^{-5} Pa, 20°C) and the low Henry's law constant (4.6×10^{-2} Pa m^3 mol-1 at 20°C) zineb is not expected to volatilise in large quantities from soil and water to air.

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 production of the active substance and the formulation of the product are considered less relevant.

The product Interspeed 340 is intended for professional on commercial, navy and government vessels and professional and non- professional use pleasure craft in freshwater and marine 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**	**Freshwater**[2]	**Marine** [2]	**Soil** [3]	**Air**
Application	New building	++[4]	-	-	-	-
	Maintenance and repair	-	-	-	- / ++[4]	-
Service life	Marina [1]	-	++	++	++	-
	Shipping lane [5]	-	-	++		-
	Open sea	-	-	++		-
Removal	Maintenance and repair	++[4]	++	++	- / ++[4]	-

++ 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, [1] Only for pleasure crafts. [2] Including sediment, [3] Including groundwater, [4] For non-professional use, emission should be incorporated. [5] This includes salt-/brackish water only.

Service life
During its service life, the emission of the active substance will come from the antifouling paint on the submerged surfaces of ships and 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, leaching into the water phase and sediment during sailing or while the commercial vessels and pleasure crafts remain in the marina or 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.

Non-professional application and removal of antifouling paints in the Netherlands mostly takes place at special locations in marinas. This is regulated in the Decision Marinas (''Besluit Jachthavens'') of the 3rd of August 2004) with prescriptions for the protection of the environment during the maintenance and repair of pleasure yachts.
However, 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 7.5.3.

The application phase comprises the application of a new layer of paint on the new or existing professional vessels and non-professional 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 the removal of the old layer of paint on existing professional vessels and non-professional 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 up in waste water. Professional docks en slipways in the Netherlands have a settling tank or other settling device. Through the settlement in the pump pit and the settlement 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 to the use of a plastic groundsheet at a private site.
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
Predicted Environmental Concentrations (PECs) were calculated according to relevant exposure scenario documents (ESDs, release to the environment), the Technical Guidance Document (distribution in the environment), and the model SimpleTreat (concentrations for micro-organisms in a STP and the STP's effluent) by using the default values for parameters, unless otherwise noted. The applied methods are explained below.

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 shipping lane

2. ''OECD" open sea (OECD shipping lane scenario with number of ships moving conform default open sea scenario with MAMPEC)
3. OECD saltwater marina
4. Inland freshwater marina (OECD marina scenario adapted regarding freshwater environmental characteristics specific for The Netherlands, see Appendix 1)

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

No emission scenario for rivers exists and therefore the risk for rivers cannot be determined.

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.

The temperature of the marine and freshwater scenarios was set to 9 and 12°C respectively, which are defaults according to the TGD.

Service life

During its service life, the active substances copper(I)oxide, zineb and the substances of concern SE1 and SE2 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.4 shows the input variables for each active substance as used in MAMPEC. The substance of concern SE1 and SE2 are not presented due to confidentiality.

Table E.4 Input variables of MAMPEC 3.0

Variable	Copper seawater	Copper fresh water	Zineb	DIDT	ETU	EU		Unit
Molar mass	63.5	63.5	275.74	176.48	102.03	85.48		g/mol
Vapour pressure	1.0×10^{-6}	1.0×10^{-6}	$< 3.6 \times 10^{-5}$	2.6×10^{-3}	1.25×10^{-4}	0.97		Pa [20°C]
Solubility	1	0.001	0.22	2.31×10^{3}	1.96×10^{5}	2.47×10^{4}		g/m^3 [20°C]
Octanol-water part. coeff.	-	-	0.32	1.60	-0.66	-0.74		10 log K_{ow}
Sediment-water part. coeff. K_d	30	50	-	-	-	-		m^3/kg
Partition coefficient K_{oc}	-	-	3.00	1.6	1.845	0.989		10 log K_{oc}
Henrys law constant	-	-	<0.046	$1.98_4 \times 10^{-}$	6.51×10^{-8}	$3.38_3 \times 10^{-}$		$Pa.m^3/mol$
Melting point	-	-	Decomp. at ca. 165 °C	122.43	203	35.56		°C
pKa	-	-	12.2	-	-	-		-
Maximum % formed in marine/brackish water/sediment systems (whole system)	n.a.	n.a.	-	35.8	41.3	65.2		%
In water phase:								
Biodegradation (20°C)	0	0	148.43	0.481	0.1286	6.93E-4	*	1/day
Hydrolysis rate	0	0	0	0	0	0	*	1/day
Photolysis rate	0	0	0	0	0	0	**	1/day
In sediment phase:								
Biodegradation (20°C)	0	0	6.93E-4	6.93E-4	6.93E-4	6.93E-4	*	1/day
Leaching rate	25.95 / 8.95***	25.95 / 8.95***	3.09	-	-	-		$\mu g/cm^2/day$

* 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 is therefore also set to 0.

*** For the calculations an extra assessment factor of 2.9 is applied to the leaching of copper from vessels at berth.

PEC values were calculated for the active substances and the major degradation products of zineb where they occurred at concentrations greater than 10 % of the total concentration of the parent compound, in water/sediment studies. However, MAMPEC does not have the ability to simulate degradation to metabolites. To overcome this, the zineb emission loading (i.e. g/d) in MAMPEC was corrected for the maximum observed percentage of the metabolite in marine/brackish water/sediment systems and for differences in molecular mass. To prevent underestimating the concentration arising in the surface water body, the maximum observed level of the metabolite in the whole system is used as MAMPEC partitions the substance between water, suspended matter and sediment. This general approach to metabolites was endorsed at TM III (2011).

The PEC calculations are based on the total risk approach for copper, which takes both the calculated PEC and the natural background concentrations of copper into account. The Dutch RIVM reports *(http://www.rivm.nl/rvs/Normen)* national background concentrations of 1.1 µg copper (total)/L and 0.79 µg copper (dissolved)/L (corrected for particulate matter in freshwater marinas) for freshwater and 36 mg copper (total)/kg dwt for freshwater sediment. Local concentrations in water and sediment of marinas and harbours can even be higher due to contributions from various emission sources of copper including antifoulings. Correction for background concentrations in marine waters was not possible due to lack of information (reference to Crommentuijn et al. 1997 report nr 601501001).

7.4 Environmental effect assessment

7.4.1 PNEC for water organisms

For the PNEC derivation of copper a statistical extrapolation method (Species Sensitivity Distribution, SSD) was used, see Table E.7. This method is in accordance with Directive 98/8/EC and a detailed description of the methodology can be found in the TGD (“Technical Guidance Document in support of commission Directive 98/8/EC (2003).
By combining the copper data, there is sufficient data to derive the PNEC using a species sensitivity distribution for aquatic organisms, see Table E.7.

Acute and chronic long-term NOECs are available for zineb for marine/brackish and/or freshwater species from the taxonomic groups of algae, crustaceans and fish. For metabolites DIDT, ETU and EU only short-term (acute) toxicity data are available for both marine/brackish and/or freshwater species. According to the TGD, data on freshwater or marine fish, crustacea and algae can be used interchangeably for the evaluation of risks to either compartment.

Table E.5 Toxicity data for water organisms and PNEC derivation

Active Substance	Organisms	Lowest endpoint [µg a.s./L]	Safety factor	PNEC [µg a.s./L]
Copper (salt water)	Multiple chronic studies, sufficient taxa for SSD*	HC_5=5.2**	2	2.6**
Copper (fresh water)	Multiple chronic studies, sufficient taxa for SSD*	HC_5 = 7.8 µg/L	1	7.8
Zineb (salt water)	Chronic toxicity data for three separate trophic levels	NOEC=2.19	100	0.0219
Zineb (fresh water)	Chronic toxicity data for three separate trophic levels	NOEC=2.19	10	0.219
DIDT (salt water)	Acute toxicity data for three separate trophic levels	E_rC_{50}=180	10,000	0.018
DIDT (fresh water)	Acute toxicity data for three separate trophic levels	E_rC_{50}=180	1000	0.18
ETU (salt water)	Acute toxicity data for three separate trophic levels	EC_{50}=21600	10,000	2.16
ETU (fresh water)	Acute toxicity data for three separate trophic levels	EC_{50}=21600	1000	21.6
EU (salt water)	Acute toxicity data for three separate trophic levels	$NOEC_r$=119000	10,000	11.9
EU (fresh water)			1000	119
SE1	Not presented due to confidentiality			
SE2				

* The PNEC for copper is 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

7.4.2 PNEC for sediment organisms

The lowest toxicity data and the derived PNEC for sediment organisms for both active substances and zineb metabolites DIDT, ETU and EU is based on equilibrium partitioning and can be found in Table E.6.

Table E.6 Available data and derived PNECs for sediment organisms based

Active substance	Organism	Lowest value	Safety factor	PNEC [mg a.s./kg dwt]
Copper (saltwater sediment)	-	-	-	87
Copper (freshwater sediment)				87
Zineb (saltwater sediment)	-	-	-	4.550
Zineb (freshwater sediment)				45500
DIDT (saltwater sediment)	-	-	-	137
DIDT (freshwater sediment)				1370

Active substance	Organism	Lowest value	Safety factor	PNEC [mg a.s./kg dwt]
ETU (saltwater sediment)	-	-	-	22900
ETU (freshwater sediment)				229000
EU (saltwater sediment)	-	-	-	54400
EU (freshwater sediment)				544000
SE1	Not presented due to confidentiality			
SE2				

7.4.3 PNEC for soil organisms

The lowest toxicity data and the derived PNEC for soil organisms for copper and zineb can be found in Table E.9. For zineb and its metabolites DIDT, ETU and EU, the PNEC is based on equilibrium partitioning.

Table E.7 Available data and derived PNECs for soil organisms partitioning

Active Substance	Organisms	Lowest endpoint [mg a.s./ kg dwt]	Safety factor	PNEC [mg a.s./kg dwt]
Copper	Multiple chronic studies, sufficient taxa for SSD*, with normalisation but without correction for aging (use of a Leaching/Aging factor of 2)	HC_5 = 62.7 mg/kg dwt**/***	1	62.7 mg/kg dwt **/***
		HC_5 = 54.2 mg/kg dwt**/***		54.2 mg/kg dwt**/#
Zineb	-	-	-	8.83
DIDT	-	-	-	0.168
ETU	-	-	-	110
EU	-	-	-	11
SE1	Not presented due to confidentiality			
SE2				

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

** Loamy sandy soil – The Netherlands Log Pearson VI or Log-normal distribution

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

7.5 Risk characterisation for the environment

7.5.1. Aquatic compartment (incl. Sediment) and STP

7.5.1.1 Water and sediment organisms

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 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 TGD, also required for calculations with MAMPEC.
In the next paragraphs the PEC to PNEC ratios will be presented to assess the risk.

Service life

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

		Water		Sediment	
Scenario	**Substance**	**PEC (µg a.s./L)**	**PEC/PNEC ratio**	**PEC (mg a.s./kg ww)**	**PEC/PNEC ratio**
Shipping lane	Copper	6.84E-5	<0.001	2.05E-03	<0.001
	Zineb	2.98E-06	<0.001	6.33E-07	<0.001
	DIDT	6.11E-06	<0.001	3.66E-10	<0.001
	ETU	4.14E-06	<0.001	1.74E-08	<0.001
	EU	2.97E-06	<0.001	1.74E-09	<0.001
	SE1	*	<0.001	*	<0.001
	SE2	*	<0.001	*	<0.001
	Mixture		<0.001		<0.001
Open sea	Copper	1.6E-6	<0.001	5.05E-5	<0.001
	Zineb	7.18E-08	<0.001	4.31E-09	<0.001
	DIDT	1.68E-07	<0.001	1.01E-11	<0.001
	ETU	1.14E-07	<0.001	4.77E-10	<0.001
	EU	1.51E-07	<0.001	8.83E-11	<0.001
	SE1	*	<0.001	*	<0.001
	SE2	*	<0.001	*	<0.001
	Mixture		<0.001		<0.001
Freshwater marina	Copper**	8.997	**1.15**	446.36	**5.13**
	Zineb	0.035	0.158	2.30E-03	0.051
	DIDT	0.728	**4.04**	4.82E-05	0.035
	ETU	0.599	0.028	2.78E-03	0.012
	EU	0.865	0.007	5.58E-04	0.001
	SE1	*	0.598	*	**10.5**
	SE2	*	0.008	*	0.001
	Mixture		**5.99**		**15.7**
Saltwater marina	Copper	0.425	0.163	12.84	0.148
	Zineb	0.072	**3.29**	2.06E-03	0.453
	DIDT	0.124	**6.89**	3.54E-06	0.026
	ETU	0.084	0.039	1.68E-04	0.007
	EU	0.112	0.009	3.11E-05	<0.001
	SE1	*	0.042	*	0.323
	SE2	*	0.002	*	0.001
	Mixture		**10.4**		0.957

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

The PEC/PNEC ratios of copper, zineb and its metabolites, SE1 and SE2 for water organisms for application as antifouling on commercial, navy and government vessels, in marine environments are < 0.001 implying a low risk (Table E.8). However, the risk for marinas is > 1. Therefore the product Interspeed 340 does not meet the standards for water organisms for application as antifouling on pleasure crafts in freshwater and saltwater marinas.

Based on the toxicity of both active substances, the metabolites of zineb and both SoC, the combined PEC/PNEC ratio for sediment dwelling organisms is acceptable for seagoing commercial, navy and government vessels in shipping lanes, open sea and saltwater marinas.
The combined PEC/PNEC ratio for sediment dwelling organisms is exceeded for pleasure crafts in freshwater marinas (Table E.8). Therefore the product Interspeed 340 does not meet the standards for sediment organisms for application as antifouling on pleasure crafts in freshwater marinas.

Application/Removal phase
Due to the risk mitigation that prevents the use of this product on pleasure crafts by non professionals, the exposure and risk to surface water is not assessed further. See also chapter 7.5.3. for the risk exposure to soil for the application and 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 for professional use. 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.

7.5.1.2 Micro-organisms in the STP
The restriction that is presented in chapter 7.5.3. prevents use on pleasure crafts and the use of this product by non-professionals during application and removal phase, thereby preventing emission to 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 for professional use. Moreover, the toxicity data for microbial endpoints in sewage treatment plants show that the active substances and the SoC are not very toxic to bacteria. In view of this, a low risk for micro-organisms in the STP is expected.

7.5.1.3 Surface water intended for the abstraction of drinking water
From the general scientific knowledge collected by the Ctgb about the product and its active substances, 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, the SoC and zineb nor its metabolites are on the list of substances of concern for surface water at drinking water abstraction points as established by VEWIN/Ctgb. The active substances, SoC and zinebs metabolites are also not 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. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

7.5.2 Atmosphere
Copper(I)oxide, zineb and both SoCs are 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 both active substances are poorly volatile and there are no indications that copper(I)oxide and zineb contribute 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 and the proposed application of the product meets the standards for air.

7.5.3 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.9 Input parameters for EUSES non professional application and removal of anti-fouling paint

Case type used for antifouling	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	430 g Cu/L and 45.6 g zineb/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 (http://www.rivm.nl/rvs/Normen/Eindresultaat?groep=normen&waarde=koper&lijst=milieukwaliteit&veld=substancename_tagged). The background concentration added up to the peak concentration in soil after 10 years of application of 696 mg/kg dwt which is the highest concentration soil for the ''realistic worst-case scenario'' gives a total concentration of 732 mg/kg dwt. This PEC_{soil} is much higher than the $PNEC_{soil}$ of 54.2 mg/kg dwt.

For Zineb, it was assumed that the substance does not degrade in soil, in order to account for metabolite formation. The highest concentration of zineb in soil for the ''realistic worst-case scenario'' is 74.7 mg/kg dwt, which is much higher than the $PNEC_{soil}$ of 8.83 mg/kg dwt.

Adding SE1 and SE2 to the risk assessment does not influence the result of the PEC to PNEC ratios, because they remain above 1. The proposed application of the product does not meet the standards for soil organisms and non-target arthropods (including bees).

The calculation as presented above assumes no mitigation measures for non-professionals. Assuming there are preventive measures to avoid spillage to soil, there is no concern for risks to the soil compartment. The preventive measures consist of instructions that restrict 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.

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 oxide does not meet the criteria for persistence in soil.

The half live of zineb in soil is 0.26 days at 12°C, soil DT50s normalised to 12 °C are less than < 6 months for DIDT (max DT50 at 12°C is 14.67 d), ETU (max DT50 at 12°C is 9.05 d) and EU (max DT50 at 12°C is 59.58 d). Therefore zineb and its metabolites meet the criteria for persistence in soil.
SE1 and SE2 both meet the criteria for persistence in soil.

7.5.4 Groundwater

The restriction that is presented in chapter 7.5.3. 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.

7.5.5 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 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 describes the 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 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.

As the log K_{ow} of zineb (0.32) is < 3, the potential for bioaccumulation is considered low. Log Kow values of 1.5, -0.66 and -0.74 for DIDT, ETU and EU respectively similarly suggest that the significant metabolites of Zineb are unlikely to bioaccumulate. No further assessment of secondary poisoning is deemed necessary for zineb and its metabolites.

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 copper and zineb a risk for secondary poisoning of birds and mammals can be excluded (see above). The risk for bioconcentration of copper and zineb, as well as the two SoC is considered acceptable. Therefore, the proposed applications of Interspeed 340 meet the standards for bioconcentration.

7.6 Measures to protect the environment (risk mitigation measures)

Application and in service use of Interspeed 340 must be restricted to commercial, navy and government vessels remaining in marine waters.

The following risk mitigation has to be added to 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 professionele scheepswerven en droogdokken met de juiste vergunningen in het kader van de Wet Milieubeheer ter voorkoming van vervuiling van bodem, grondwater , oppervlaktewater en lucht.

7.7 Overall conclusion for the aspect environment

An authorisation of a biocide in the Netherlands is only possible when the risks related to the product application are acceptable. An overview of the risks for the product for which authorisation is requested is given in Table E.10.

Table E.10 Overall conclusions for the aspect Environment

	Aquatic organisms	Sediment organisms	Micro-organisms in STP	Air	Drinking water from surface water	Soil organisms	Non target arthropods (including bees)	Groundwater	Persistence in soil	BCF	Birds and mammals	Overall
Open sea (commercial, navy and government vessels)	√	√	√	√	√	√	√	√	√	√	√	√
Shipping lane (commercial, navy and government vessels)	√	√	√	√	√	√	√	√	√	√	√	√
Saltwater marina (pleasure crafts)	**X**	√	√	√	√	**R**	**R**	**R**	√	√	√	**X**
Freshwater marina (pleasure crafts)	**X**	**X**	√	√	√	**R**	**R**	**R**	√	√	√	**X**

X risk unacceptable, √ risk acceptable, **R** risk acceptable with proposed restriction mitigation measure

Based on the available data, it can be concluded that Interspeed 340 when used in accordance with the proposed label (WG/GA) complies with the environmental standards and will not cause unacceptable effects on the environment.

8 Conclusion

The applicant has proven that Interspeed 340 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:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Ethylbenzene, gum rosin, xylene, zineb			
Pictogram:	GHS02 GSH07 GSH08 GHS09	Signal word:	Warning
H-statements:	H226	Flammable liquid and vapour.	
	H332	Harmful if inhaled.	
	H361d	Suspected of damaging the unborn child.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P202	Do not handle until all safety precautions have been read and understood.	
	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.	
	P273	Avoid release to the environment.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P284	Wear respiratory protection.	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	EUH208	Contains gum rosin and zineb. May produce an allergic reaction.	
Child-resistant fastening obligatory?			**Not applicable**
Tactile warning of danger obligatory?			**Not applicable**

Explanation:	
Pictogram:	GHS08 is assigned based on H361d.
H-statements:	Based on its flashpoint the product is a category 3 flammable liquid and H226 is assigned. H361d is assigned, because according to the CAR zineb is classified as a developmental toxicant (read-across from Mancozeb).
P-statements:	P210 is highly recommended in combination with H226. P280 (gloves and coverall) and P284 are based on the risk assessment. The other P-statements are adopted from proposal applicant
Other:	-

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

10 References

Consolidated list of PT21 technical agreements included in MOTA v.6
European Union Risk Assessment Report. Voluntary Risk Assessment of copper, Copper II Voluntary Risk assessment of copper, copperII sulphate pentahydrate, copper(I)oxide, copper(II)oxide, dicopper chloride trihydroxide, 2008. (ECHA website)
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MAMPEC Version 3.0 and User manual-Quick guide, MAMPEC 3.0. Deltares, IVM, 2011.
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CEPE leaching workshop documentation: https://echa.europa.eu/documents/10162/16908203/pt21_leaching_workshop_en.pdf
RIVM report background concentrations metals http://www.rivm.nl/bibliotheek/rapporten/601501001.pdf

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.

Proposed 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	50° (dec) NH	50° (dec) NH
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
Calculate	Length class	1-50 m	8.9 m

Category	**Parameter**	**Value in OECD-EU marina scenario**	**Proposed value in small freshwater marina scenario**
emission – Service life			
	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*