Australian Government

Australian Pesticides and Veterinary Medicines Authority

APVMA anti-fouling paint guidance for use on boat hulls

Consultation draft

MARCH 2019

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This publication is available from the APVMA website.

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1 PURPOSE

Consultation period: Friday 15 March 2019 to Friday 12 April 2019

Submissions are invited from interested stakeholders on the proposed guidance for registration of specific anti-fouling products for use on vessels.

1.1 Background

The purpose of this APVMA guidance is to establish criteria for registration of specific anti-fouling products for use on vessels, streamlining the application process. The anti-fouling products covered in this guidance are those listed in this guidance which release substances, chemicals or biocides. This guidance does not refer to non-biocide-release anti-fouling coatings (foul-release coatings).

This guidance sets parameters regarding the permissible constituents, use patterns, chemistry and manufacture and efficacy and safety criteria in order to satisfy the APVMA legislative requirements for specific anti-fouling products. In addition, applicants should be mindful of requirements of other regulatory bodies and legislation that may apply (see Section 6 of this guidance).

If the product contains an active constituent not already approved by the APVMA, makes any claims other than those specified here, or does not otherwise comply with the criteria of this guidance, a conventional application to the APVMA will be required.

The consultation period is open until close of business on 12 April 2019. Following consideration of comments received during the consultation period, the guidance will be finalised and made available on the APVMA website.

Please send your written submission by email to enquiries@apvma.gov.au.

2 DEFINITIONS

For the purpose of this guidance, the following definitions apply:

- active constituents (also referred to as ‘actives’) are biocides, that is, chemicals used to destroy, deter or otherwise control harmful organisms. Actives are incorporated into product formulations, and, in the case of anti-foulings, interact with aquatic organisms such as barnacles, tubeworms, weed and microalgae (slime), to prevent their adhesion to a surface. Actives must be approved for use with the APVMA prior to their use in anti-fouling paints in Australia
- an anti-fouling paint is any film-forming coating that allows the controlled release of biocides contained within the coating. Anti-foulings prevent the settlement and growth of fouling marine organisms, including algae, on the hulls of boats. Anti-foulings are considered agricultural products that require registration with the APVMA
- a surface coating, or paint, is a substance composed of pigment, binder, additives and solvent suspended or dissolved in a liquid medium which is applied to a surface. Upon drying (usually by evaporation of solvent) the substance forms an adhering film for protection, decoration or other purpose
- efficacy is a measure of how well a formulation meets its statement of claim. An anti-fouling product which meets the criteria as outlined in this guidance is deemed to also to meet the required efficacy
- fouling, or biofouling, is the term used for the growth of organisms such as barnacles, tubeworms, weed and microalgae (slime) on immersed surfaces including the outside of vessels. This growth causes a loss of speed, and manoeuvrability as the resistance of the water is increased by the irregular shape and increased weight of the vessel and loss of efficiency. Fouling may enable the transfer of invasive aquatic species to new environments
- foul-release coatings don’t contain an active constituent. They rely on their physical characteristics to repel or minimise the strength of attachment of aquatic organisms and are not required to be registered with the APVMA
- invasive aquatic species are organisms which establish in new environments in numbers that pose threats to existing ecosystems, human health, property or resources
- substrate is the term for the surface on which a paint is applied
- a vessel refers to any structure designed to float on water.

3 PRODUCT CLAIMS

The statement of claim made pursuant to this guidance should confirm the products' only use is the control of marine growth below the waterline on vessels.

4 SITUATIONS OF USE

An anti-fouling product conforming to this guidance should only be for the application to the hulls and/or the undersides of vessels, including inside niche areas such as sea chests.

5 APPLICATION METHODS

5.1 Application

The application of anti-fouling products can be undertaken using a variety of methods. These may include the use of spray systems, paint brushes and rollers.

5.2 Directions of use

Application instructions that should be included in a label include:

- substrate preparation (specified in accordance with vessel substrate—steel, aluminium, wood, fibreglass etc): washing, sanding or blasting instructions; suitable paint products which can be painted over or any tie coat necessary, “refer to tech data sheet”
- paint preparation (thoroughly mix before use)
- approximate number of coats to achieve required thickness. Differentiate between spray application and brush or roller application
- expected film thickness per coat
- specification of the thinner to use and whether this is also suitable for cleaning of equipment.

Further instructions may be included in a technical data sheet or a specification written for a particular vessel or installation. Where a technical data sheet is available it should be referenced in the label instruction.

6 COMPLIANCE WITH A PUBLISHED GUIDANCE

Anti-fouling products are subject to other regulatory requirements that APVMA does not regulate or authorise (eg the Globally Harmonised System of Classification and Labelling). It is the applicant's responsibility to ensure they comply with all other requirements.

The guidance for the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) contains specific instructions for the labelling of paint products. Substances (active constituents and non-active constituents) that are scheduled in the SUSMP and are in the product formulation, must be included on the product label. It may also be necessary to declare the concentration of non-active constituents (excipients) on the label if they appear in the SUSMP. Some first aid instructions and safety directions will also be dependent on the SUSMP.

7 PARAMETERS FOR CHEMISTRY AND MANUFACTURING

7.1 Active constituents and formulations

To obtain registration of an anti-fouling product by reference to this guidance, the product can only contain those active constituents (or combinations thereof) listed in Table 1, and in concentrations within that range. These amounts have already been determined by the APVMA to meet the necessary efficacy and safety criteria.

Table 1: Active constituents and combinations of actives and their regulatory acceptable concentrations

Category	Actives	CAS number	Minimum g/L	Maximum g/L
1	Cuprous oxide (alone)	1317-39-1	624	1030
2	Cuprous oxide AND	1317-39-1	332	900
	Diuron OR	330-54-1	45	120
	Copper pyrithione OR	14915-37-8	49	90
	Zinc pyrithione OR	13463-41-7	43	172
	Dichlofluanid	1085-98-9	13	45
3	Cuprous oxide AND	1317-39-1	332	900
	Zinc oxide	1314-13-2	185	244
4	Cuprous thiocyanate AND	1111-67-7	125	251
	Diuron OR	330-54-1	45	120
	Zineb OR	12122-67-7	50	115
	Copper pyrithione OR	14915-37-8	49	90
	Zinc pyrithione OR	13463-41-7	43	172

As anti-fouling paints are often produced in a range of colours, there may be small variations in the concentration of active ingredient between different colours of the same product. If the variation in concentration is less than 5 per cent, the concentration may be expressed as a range in a single active constituent statement, however, if the concentration varies more than 5 per cent, separate active constituent statements will be required for the label for each colour.

7.2 Non-active constituents

Products containing any of the following types of non-active constituents may be hazardous to human health and safety (see Table 2). If your product contains non-active constituents outside of the typical concentration range, it is recommended that you discuss your application with the APVMA to ascertain if additional toxicological information is required. APVMA's approach to treating health and safety concerns within the guidance is to require labelling consistent with high-risk scenarios. For specific label instructions refer to Appendix A: Label particulars.

Table 2: Excipient types and typical concentration ranges

Non-active constituent type	Example	Typical concentration range
Binder	Acrylic polymer—'soft' film	10–20%
Binder	Rosin—'hard' film	10–20%
Pigment	Zinc oxide; iron oxide; titanium dioxide	10–30%
Extender	Bentonite; talc	5–10%
Solvent	Hydrocarbon mixture; xylene; alcohols	10–25%
Additive	Polymer with active functional groups	<10%

7.3 Quality

The source of the active constituents must be approved by the APVMA, unless the active constituent is exempt from approval. Where these are established, active constituents must comply with the relevant APVMA Standard. Please note that a number of active constituents exempt from approval also have standards and may still require an assessment for safety. All ingredients used in the manufacture of anti-foulings must meet the quality specifications as designated by the manufacturer.

Manufacture of anti-foulings must be sufficiently controlled so that batch variation is within specification limits. Typical specifications for an anti-fouling are: active content; viscosity; specific gravity; fineness of grind; dry thickness; colour and drying time.

7.4 Shelf life

All agricultural chemical products must include a batch number and date of manufacture on the product label.

Under the registration requirements for agricultural chemical products an applicant is required to demonstrate that the product will be stable for two years when stored under normal conditions (considered to be below 30 °C (room temperature)). If the product meets those requirements (with the exception of products which are 'date controlled' agricultural chemical products) there is no specific requirement from the APVMA to include an expiry date. In some situations where a product is closely similar to a reference product, data may not be required.

Products where two years of stability have not been demonstrated and products containing the active constituent zineb (which is a date controlled agricultural chemical product) must include an expiry date on the product label. The requirement for an expiry date is included as a condition of label approval and the shelf life will be determined based on the data submitted for consideration with the application.

7.5 Maximum pack size

The maximum allowable pack size for a product registered according to this guidance is 20 L.

8 SAFETY

8.1 Work Health and Safety (WH&S)

Based on the assessment of the active constituents, the APVMA has previously determined the hazards associated with the individual active constituents and these have been used to establish standard first aid instructions and hazard statements (see columns 3 and 4 in Table 3 below). Consideration of the formulation excipients, likely exposure routes and level of exposure of workers have been used to establish appropriate safety directions which are included on the product label to mitigate the risk posed by exposure to these products. Each of these need to be included as appropriate on the product label.

Table 3: Active constituents, first aid instructions and safety directions from Schedule E, Poisons Standards

Category	Actives	(3) first aid instruction standard statements	(4) safety directions opening statement	(5) detailed safety directions
1	Copper oxide (alone)	a	Harmful if swallowed. May irritate the eyes and skin.	Avoid contact with the eyes and skin. Open container in the open air. Ensure adequate ventilation during use. When opening the container and preparing the paint wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves and eye protection. If applying by brush or roller wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, protective gloves and eye protection. If spray painting wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), a full face piece respirator and protective gloves. Wash hands after use. After each day's use wash contaminated clothing.
2	Copper oxide AND	a		
	Diuron OR	a		
	Copper pyrithione OR	a, s	Harmful if swallowed. Will damage eyes. May irritate the skin.	
	Zinc pyrithione OR	a, s		
	Dichlofluanid	a	Harmful if swallowed. May irritate the eyes and skin.	
3	Copper oxide AND	a		
	Zinc oxide	a		
4	Copper thiocyanate AND	a		
	Diuron OR	a		
	Zineb OR	a		
	Copper pyrithione OR	a, s	Harmful if swallowed. Will damage eyes. May irritate the skin.	
	Zinc pyrithione OR	a, s		

Category	Actives	(3) first aid instruction standard statements	(4) safety directions opening statement	(5) detailed safety directions
2 & 3 combined	IMPORTANT: Where category 2 and 3 actives are combined in the one product, APVMA has assumed the highest risk exposure scenario.		Harmful if swallowed. Will damage eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. May irritate the skin.	

8.2 Environmental safety

To satisfy environment criteria with respect to safety, the applicant will need to confirm that each active constituent's leaching rate from the treated surface is predicted to result in an environmental concentration (PEC) that is below the regulatory acceptable concentration (RAC) in Table 4. For full details on how APVMA arrived at the values table and methodology refer to Appendix A.

Table 4: Active constituents and their regulatory acceptable concentrations and maximum leaching rates

Active constituent	Regulatory acceptable concentration (RAC)	Maximum leaching rate allowable to achieve RAC (R)
Copper present as cuprous oxide	5.2 µg Cu/L	30 µg Cu/cm^2/day
Copper pyrithione	0.18 µg ac/L	1.0 µg Cu/cm^2/day
Copper thiocyanate	2.0 µg ac/L	5 µg Cu/cm^2/day
Dichlofluanid	0.64 µg ac/L	29 µg Cu/cm^2/day
Diuron	1.6 µg ac/L	8.9 µg Cu/cm^2/day
Mancozeb	2.2 µg ac/L	21 µg Cu/cm^2/day
Zinc pyrithione	1.2 µg ac/L	145 µg Cu/cm^2/day
Zineb	2.2 µg ac/L	12 µg Cu/cm^2/day

9 LABELLING GUIDANCE

9.1 Label requirements

Labels prepared according to this guidance must contain all the relevant information, presented in the manner and format consistent with labelling standards. The label information is summarised below:

Table 5: Label particulars

Main panel parts	Details
1. Signal heading	CAUTION/POISON (as appropriate for the active and excipients present—refer to SUSMP or CAUTION for schedule 5 and POISON for schedule 6) KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
2. Product name	(To be proposed by applicant)
3. Active constituent statement/colour (Section 7.1 of this guidance)	ACTIVE CONSTITUENT (insert active, concentration, and approved common name for the product/pigment. If multiple actives, list each active beginning with the active which has the highest concentration)
4. Solvent statement (Section 7.2 of this guidance)	SOLVENT (insert solvent, concentration, and approved common name for the product if of a type required to be declared in the SUSMP) *Example*: Blue: Active constituent: 123 g/L copper present as cuprous thiocyanate, 45 g/L diuron Black: Active constituent: 124.5 copper present as cuprous thiocyanate, 42 g/L diuron
5. Statement of claims for use (Section 3 and 4 of this guidance)	For control of marine growth beneath the water line on vessels (Applicant may provide more detail here)
6. Net contents statement	(To be proposed by applicant but no more than 20 L)
7. Name and address of manufacturer/importer	(To be proposed by applicant)

Ancillary panel parts	Details
1. Directions for use (Section 5 of this guidance)	(To be proposed by applicant) *Example:* THIS ANTI-FOULING is suitable for most vessel types/aluminium hulls only. To be applied over an anti-corrosive coating (such as THIS PRODUCT) or existing ANTI-FOULING provided it is in sound condition which has been high pressure water washed and allowed to dry thoroughly

Ancillary panel parts	Details
	MIXING: Thoroughly power mix before use THINNING: Thin up to X% with THIS THINNER APPLICATION METHOD: Spray is preferred, brush/roller is acceptable but extra coats may be required to achieve the correct thickness. Apply 2 coats per season on the hull and 3 on leading and trailing edges, rudder, keel and skeg COVERAGE: Theoretical coverage is X m2/L per coat DRY FILM THICKNESS: Recommend at X µm per coat. For further information refer to 'technical data sheet' DRYING TIMES: @ 20–25°C. Allow minimum of X hours between coats TIME BEFORE LAUNCHING: @20–25°c. Allow minimum X hours and max Y hours
2. Limitation on use statement	NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION
3. Other limitations and prohibitions	(To be proposed by applicant—may include surface to which the product is not to be applied) Example: NOT TO BE USED ON ALUMINIUM HULLS
4. General instructions	(To be proposed by applicant—may include detail on surface preparation and in season maintenance)
5. Precautionary statements	(To be proposed by applicant, noting precaution statements will be determined by the active ingredient and the solvents present in the formulation) Example: PROTECTION OF WILDLIFE, FISH, CRUSTACEA AND ENVIRONMENT Very toxic to aquatic life. DO NOT contaminate soil or waterways with paint dust and scrapings or with used containers
6. Storage and disposal statements	Store in the closed original container, in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Do not re-use any empty containers. Dispose of containers by crushing and disposing in an industrial waste bin or at a municipal refuse disposal site. Do not pour leftover paint down drains. Keep unwanted paint in sealed containers for disposal via special chemical waste collections.
7. First aid instructions (Section 8.1 of this guidance)	(Applicant to refer to Table 3 column (3) to determine if any of the statements a, c, f and s (below) should be deleted) a. If poisoning occurs, contact a doctor or Poisons Information Centre (Phone 131126) New Zealand 0800 764 766 c. If swallowed, do NOT induce vomiting f. If skin contact occurs, remove contaminated clothing and wash skin thoroughly

Ancillary panel parts	Details
	s. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor
8. Safety directions (Section 8.1 of this guidance)	(Applicant to refer to Table 3 column (4) to determine which opening statement needs to be inserted (below) before the paragraph) Avoid contact with the eyes and skin. Open container in the open air. Ensure adequate ventilation during use. When opening the container and preparing the paint wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves and eye protection. If applying by brush or roller wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, protective gloves and eye protection. If spray painting wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), a full face piece respirator and protective gloves. Wash hands after use. After each day's use wash contaminated clothing.
9. Batch number (Section 7.4 of this guidance)	(To be added by applicant)
10. Date of manufacture and / or expiry date (Section 7.4 of this guidance)	(To be added by applicant)
11. APVMA label approval number	(To be added by APVMA)
12. Dangerous goods and worker safety legislative requirements	(To be added by applicant. Refer to guidance from Safe Work Australia or the relevant state workplace authority)

Additional APVMA guidance can be found under:

- Labelling of anti-fouling paints
- Label Presentation and layout
- Label content

Appendix

APPENDIX A: TECHNICAL NOTE ON ENVIRONMENTAL REQUIREMENTS

The Regulatory Acceptable Concentration (RAC) is determined from the active constituent's toxicity to aquatic and sediment dwelling species. For the determination of the Predicted Environmental Concentration (PEC), the guidance needs to be based on the release rate of active constituent form the painted surface (µg/cm^2/day). The guidance could then established based on product-specific parameters. However, a guidance for each of these parameters cannot be established as they are inter-related in the determination of the outcome release rate. The guidance is presented in presented Table 3, the model in Tables 5 and 6, and the methodology is described below.

Methodology

The worst-case was determined to involve an Australian large marina, with application of the anti-foulings to all types of craft including pleasure craft.

The average PEC was modelled using MAMPEC 3.1 (van Huttum et al, 2017), which includes an updated hydrodynamic harbour exchange module (Deltares 2017). This leads to a slightly lower (~6 per cent) predictions compared to previous MAMPEC versions for the default OECD marina. The average PEC value was considered appropriate as several input parameters are conservative.

The MAMPEC inputs require:

- the environment (eg a marina of specific dimensions)
- the chemical properties
- the release of the active constituent from the anti-fouling paint to determine the PEC.

Until more recent data was available from the NZ EPA (Gadd et al 2011) and from a survey of the Australian Marina Industry (RMRC, 2013) the default OECD marina (van Huttum et al, 2017) has been used in the determinations of the PEC. The determination of settings for an Australian marina for the MAMPEC model are detailed below.

Settings for the environment

RMRC (2013) in its survey of marinas, classified them in three categories small, (< 100 spaces), medium 100–250, large >250. Queensland had the largest marinas and had an average of 270 berths/pens and moorings, for all categories. Based on this data a worst-case Australia Marina was determined to have 500 berths/pens and moorings. The size of the marina was then determined by comparing the ratio of the hull surface area (15 350 m^2) to marina area (22 000 m^2) for the OECD default marina. A factor of 1.43 was determined and this was applied to Australian marinas.

The hull surface area for Australian marinas was determined by using the methodology described by Gadd et al, (2011), where the surface area of the hull may be estimated from the from the length and type (motor boat, sail boat, sail boat deep keel) of vessel. The vessels were combined into four categories (5–11, 12–20, 21–30 and 31–40 m) and the average length (rounded up to the nearest metre) for each category was used to calculate the

surface areas. As the each type of boat has a different length to surface ratio a weighted average was used. No information is available for the proportion of sail boats which are deep keel, so a 50:50 split was assumed. However, according to RMRC (2013) the proportion of power boats to sail boats is approximately 70:30. The weighted average surface area based on each class length was calculated from the analysis by Gadd et al (2011) on surface area for power boats and sail boats as follows.

The percentage of berths/pens and moorings by length class was determined by RMRC (2013) and this was applied to the Australian worst-case marina with 500 berth/pens or moorings.

The marina surface area is estimated as 47300 m^2 (33077 m^2 × 1.43) which was modelled assuming square dimensions of 217 m (x2) × 217 m (y1).

Table 6: Boat hull surface area based on categories proposed by Gadd et al, (2011)

Marina length class (m)	Surface area (m^2)
5–10	25
11–20	78
21–30	152
31–40	276

Table 7: Australian large marina settings

Length	5–10 m	11–20 m	21–30 m	31–40 m	Total
Number	157	316	26	2	501*
Surface area (m^2)	3925	24648	3952	552	33077

** Rounded*

Settings for the chemical properties

Settings for the chemical properties are obtained from the public domain including APVMA (2001, 2011), MAMPEC 3.1 model (van Hattum et al, 2017) and (Hellio and Yebra, 2009), EC (2009), ECHA (2015, 2016b), and Madesen et al (2000).

Settings for the release of the active constituent

The settings for the release of the active constituent are based on the surface area described above (Table 6). In addition to account for vessels not using the active or vacant moorings an application factor of 90 per cent was used. This is the current OECD (2005) default level but also reflects high occupancy rates in Australian marinas, with half reporting greater than 90 per cent (RMRC 2013). The input parameters for the model assumes that all vessels are moored (the number moving through the marina at any one time is negligible). However, the release of active constituent in µg/cm2/day as a required input of the model is calculated by the CEPE (2003) method, which is for moving vessels. Finnie (2006) recommends a correction factor of 2.9 extrapolated from available laboratory

and field data. Accordingly the guidance will be established on the release of active constituent in µg/cm2/day for moored vessels as modelled by MAMPEC with the above settings, multiplied by 2.9.

Determination of release rate of active constituent from product-specific parameters

The release rate of the active constituent can be calculated from product-specific parameters using the CEPE (2003) methodology and considering that the fraction of solids is in w/w%.

Equation 1: Worst case calculation of release of active constituent from product- specific parameters

$$\overline{R} = \frac{0.9 \times a \times w_a \times N \times 3.29}{C \times 12}$$

Where:

- *a* is the mass fraction of biocide in the biocidal ingredient; (in general a is equal to 1 for most active constituents)
- *wa* is the content of biocidal ingredient in the paint formulation as manufactured, in g/L
- *C* is the theoretical coverage in m^2 for each litre of paint (single coat)
- *N* is the maximum number of coats
- 3.29 is the conversation factor for calculating months/day and cm^3/dm^3 and g/L to %
- 12 is the number of months per year (worst case service life).

Regulatory acceptable concentrations

Terrestrial vertebrates

Exposure of terrestrial vertebrates to the active constituents of anti-foulings is considered to be negligible. Risks of anti-fouling to terrestrial vertebrates are considered to be acceptable.

Non-target aquatic organisms

There are three potential exposure routes of the active constituents into the aquatic environment:

- during application via spray drift
- during service by continuous direct release from the coated surface immersed in water
- during removal of paint close to the water.

Exposure during application and paint removal are mitigated by the following label restraint:

DO NOT contaminate soil or waterways with paint, dust and scrapings, or with used containers.

Maximum leaching rates for each active constituent have been established to address the risks to non-target aquatic organisms during service life time.

Copper present as cuprous oxide

The key regulatory endpoint was obtained from ECHA (2016a) which is based on 56 high-quality chronic No Observable Effect Concentration (NOEC) or EC_{10} values resulting in 24 different species-specific NOEC values covering different trophic levels (fish, invertebrates, algae). The NOEC values were related to the dissolved oxygen concentrations (DOC) of the marine test media. Species-specific NOEC values were therefore calculated after DOC-normalising the NOEC values. These species-specific NOEC values were used for the derivation of a species sensitivity distribution (SSD) and $HC_{5\text{-}50}$[1] values. For the marina scenario, the typical DOC level is 2 mg/l resulting in an $HC_{5\text{-}50}$ value of 5.2 µg Cu/L. The resulting RAC is 5.2 µg Cu/L (no assessment factor is applied to the $HC_{5\text{-}50}$). None of the underlying studies cited by ECHA (2016a) are protected in Australia.

Copper pyrithione

The key regulatory endpoint is based on inhibition of the growth rate of the marine diatom *Skeletonema costatum* following static exposure (NOEC 0.18 µg ac/L, geomean based on time-weight average concentrations from four studies). The resulting RAC is 0.18 µg ac/L (no assessment factor is applied to the NOEC). The underlying studies are ABC Laboratories (2010), Mayer et al (2002), Minderhout et al (2008), and TR Wilbury Laboratories (2004), which were cited by ECHA (2015). The underlying studies are not protected in Australia.

Copper thiocyanate

The key regulatory endpoint is based on acute immobilisation of the water flea *Daphnia magna* based on measured concentrations following 48 hours of static exposure (EC_{50} 20 µg ac/L). The resulting RAC is 2.0 µg ac/L (EC_{50} divided by assessment factor of 10). The underlying study is Cameron et al (1989) which was cited by ECHA (2016b). The underlying study is not protected in Australia.

Dichlofluanid

The key regulatory endpoint is based on inhibition of the growth rate of the marine diatom *Skeletonema costatum* following 72 hours of static exposure (NOEC 0.64 µg ac/L). The resulting RAC is 0.64 µg ac/L (no assessment factor is applied to the NOEC). The underlying study is Scheerbaum (2004) which was cited by ECHA (2016c). The underlying study is not protected in Australia.

Diuron

The key regulatory endpoint was obtained from APVMA (2011) which is based on 28 chronic values for primary producers (algae and aquatic plants). These NOEC values were used for the derivation of a SSD and HC_5 value (1.6 µg ac/L). The resulting RAC is 1.6 µg ac/L (no assessment factor is applied to the HC_5). The underlying studies are listed in Appendix E of APVMA (2011) and are not protected.

[1] $HC_{5\text{-}50}$ is the median fifth percentile of the SSD

Mancozeb

The key regulatory endpoint is based on reduced survival and growth in the early life stage of the fathead minnow *Pimephales promelas* following long-term exposure to 4.6 µg ac/L (NOEC 2.2 µg ac/L). The resulting RAC is 2.2 µg ac/L (no assessment factor is applied to the NOEC). The underlying study is Rhodes et al (1994) which was cited by EC (2009), PMRA (2013) and USEPA (2005). The underlying study is not protected in Australia.

Zinc pyrithione

The key regulatory endpoint is based on reduced survival and growth and increased incidence of bent spinal columns in the early life stage of the fathead minnow *Pimephales promelas* following long-term exposure to 2.8 µg ac/L (NOEC 1.2 µg ac/L). The resulting RAC is 1.2 µg ac/L (no assessment factor is applied to the NOEC). The underlying study is Boeri et al (1999) which was cited by APVMA (2001) and USEPA (2004b). The underlying study is not protected in Australia.

Zineb

The key regulatory endpoint is based on reduced survival and growth in the early life stage of the fathead minnow *Pimephales promelas* following long-term exposure to 4.6 µg ac/L of mancozeb (NOEC 2.2 mg ac/L). Mancozeb is used as a surrogate for zineb because both are structurally similar as ethylenebisdithiocarbamate (EBDC) polymers and only the EBDC anion is considered to be of ecotoxicological significance. The resulting RAC is 2.2 µg ac/L (no assessment factor is applied to the NOEC). The mancozeb endpoint was utilised by ECHA (2013) in its assessment of zineb as an anti-fouling paint.

Bees and other non-target arthropods

Exposure of bees and other non-target arthropods to the active constituents of anti-foulings is considered to be negligible. Risks of anti-foulings to bees and other non-target arthropods are considered to be acceptable.

Soil organisms and non-target terrestrial plants

Direct exposure is possible during application or removal of paint from pleasure craft. Exposure to soil is not considered a typical case scenario but depends on the control measures of the boat yard. Exposure of soil is mitigated by the following label restraint:

DO NOT contaminate soil or waterways with paint, dust and scrapings, or with used containers.

REFERENCE

ABC Laboratories 2010, *Static growth inhibition test with the marine diatom, Skeletonema costatum*, study no. 66218, unpublished.

APVMA 2001, *Public release summary on evaluation of the new active zinc pyrithione in the product International Intersmooth 360 Ecoloflex Anti-fouling.*

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