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**Australian Pesticides and
Veterinary Medicines Authority**



Anti-fouling paint for use on boat hulls

Guidance document

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Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au

This publication is available from the [APVMA website](#).

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1 BACKGROUND

An anti-fouling paint is a film-forming coating that allows the controlled release of biocides (active constituents) contained within the coating. The biocides are intended to prevent the settlement and growth of fouling marine organisms, including algae, on the hulls of boats, fish nets used in aquaculture and other structures in the aquatic environment. It is desirable to prevent this growth (fouling) on boat hulls because it 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, resulting in loss of efficiency. Additionally, fouling may enable the transfer of invasive aquatic species to new environments. Anti-fouling paints that contain an active constituent are considered agricultural product that require registration with the APVMA.

The purpose of this APVMA guidance is to provide advice to industry on the registration and assessment requirements for anti-fouling paints, with the intention to clarify and streamline the application process. When assessing a registration application for an anti-fouling paint, the APVMA is required to consider:

- active constituent/s (including if the source of active is approved)
- chemistry and manufacture of the product (formulation specific)
- efficacy of the product (the ability of the product to perform according to label claims when used according to the label instructions)
- human safety, and
- the environment.

The APVMA also approves the product label to ensure it contains adequate information/instructions for the product to be used safely and effectively. This guidance lays out the information that is required for a registration application and describes the circumstances when particular assessments may not be needed.

The anti-fouling products covered in this guidance are those which release biocides. This guidance does not refer to non-biocide-release anti-fouling coatings, which rely on their physical characteristics (eg very low friction) to repel or minimise the strength of attachment of aquatic organisms, and are not required to be registered by the APVMA.

If your proposed product contains a new active constituent, the APVMA must approve the active constituent and register the product. This is not within the scope of this guidance.

Applicants should be mindful of requirements of other regulatory bodies and legislation that may apply (see Section 8 of this guidance).

2 REGISTRATION OF A NEW ANTI-FOULING PAINT

For registration of a new anti-fouling paint, an application must be made to the APVMA. A registered product must contain an approved active constituent.

2.1 Approval of active constituent

There are three components to the approval of an active constituent for this guidance to be relevant. The active constituent (eg diuron, cuprous oxide or thiram etc) must be already used in an existing registered anti-fouling product. If you wish to use an active constituent that has not previously been used in an antifouling paint, the APVMA will need to assess the efficacy of product and this guidance will not be relevant.

Secondly, the source (ie manufacturer) of the active constituent proposed to be used in the new anti-fouling paint must be an approved source of that particular active constituent. If you wish to use a new source (ie new manufacturer) of active constituent, you must seek approval from the APVMA and this guidance will not be relevant.

Finally, if your proposed product contains a new active constituent, the APVMA must approve the active constituent. This is not within the scope of this guidance. Please refer to the [relevant information](#) on the APVMA website.

2.2 Registration of product

This guidance is relevant for Item 10 applications where the active constituent/s is already approved and used in an existing registered anti-fouling product.

An application should be supported by information that allows the APVMA to determine whether the product meets the [statutory criteria](#) (safety, trade, efficacy and labelling criteria).

In general, this supporting information will be new product-specific data, scientific argument or reliance on an existing registered product for satisfaction of all or some of statutory criteria. In addition for anti-fouling paints, this guidance describes some circumstances when a human health, chemistry and manufacture, environment and/or efficacy assessment is not considered necessary, because the APVMA can rely on previous assessments.

However, if your proposed new product is a repack of an existing registered product (ie is the same) or is *closely similar*¹ to an existing registered product, this guidance is not necessary and you should submit an Item 7 (*closely similar*) or Item 8 (repack) application (see our website [for more information](#)).

To determine the appropriate item number for your application, you need to first establish whether your product meets the statutory definition of *similar* or *closely similar* in relation to a reference product. The following table lists the criteria to assist you through this step.

¹ An agricultural product is considered to be *closely similar* to a reference product if:

- the active constituents in the proposed chemical product are the same and at the same concentration as the approved active constituents in the reference chemical product; and
- the other ingredients in the formulations of the proposed and reference chemical products are the same or perform similar functions (for example, as emulsifiers, surfactants, dyes or solvents); and
- the formulation type of the proposed and reference chemical products are the same; and
- the label of the proposed chemical product refers to the same crops, situations and pests as the approved label of the reference chemical product (that is, the proposed chemical product must have no uses additional to those of the reference chemical product); and
- the label of the proposed chemical product includes similar instructions on how to use the product, and precautionary or safety instructions, as the approved label of the reference chemical product; and
- either:
 - the claims on the labels of the proposed and reference chemical products are the same; or
 - if the claims are different, the claims on the label of the proposed chemical product are fewer or reduced compared to the claims on the approved label of the reference chemical product.

Table 1: *Similar, closely similar or neither*

Criteria (proposed product compared to reference product)	<i>Similar</i> (Item 5)	<i>Closely similar</i> (Item 6 or 7)	Use this guidance (Item 10)
Same active/s	Y	Y	Y
Same concentration of active/s	N/A	Y	N/A
Other ingredients in the formulation are the same or perform the same function	N/A	Y	N/A
Formulation type is the same (paint)	Y	Y	Y
Label refers to same situations as the reference product label	Y	Y	Y
Label includes similar instructions for use as the reference product	Y	Y	Y
Label claims are the same, fewer or reduced	Y	Y	Y
Reference product information is not subject to limit of use of information or the applicant has obtained consent from the owner to use the data from the reference product	Y	Y	Y

The following table depicts for each relevant risk area where either a specific ‘assessment’ will apply, or where the APVMA can rely on the ‘reference product’ and previous assessments to be satisfied.

Table 2: Assessments required for a proposed new anti-fouling product

	<i>Similar</i>	<i>Closely similar</i>	<i>Neither similar nor closely similar</i>
Risk area by module type	Item 5	Item 6	Item 7
Chemistry	Assessment	Assessment	Reference product
Toxicology	Reference product*		
Toxicology—poison scheduling	Reference product*		
Work health and safety	Reference product*		
Environment	Reference product*		
Efficacy	Assessment	Reference product*	

Note that the assessment areas 'residues and trade', 'non-food trade' and 'special data' are not relevant for anti-fouling paints.

*Reference product = risk assessment can be satisfied by assessment previously undertaken on a single reference product.

2.3 How to submit an application

Detailed guidance on how to submit an application is available on the [APVMA website](#).

Detailed information on [addressing the statutory requirements and submitting an Item 10 application](#) and [data guidelines](#) can also be found on our website.

2.4 How to use this guidance

If your proposed new product contains an approved active constituent, from an approved source, that is already used in a registered anti-fouling paint product, you may be able to refer to this guidance to address one or more of the statutory criteria, reducing the number of assessments required, which in turn will reduce the cost of the application and may reduce the timeframe.

Under each section below, consider how you will provide information to satisfy the statutory criteria. You may provide data, scientific argument or rely on the information in this guidance for a particular scientific assessment area. If you wish to rely on this guidance for a particular assessment area, in your application clearly demonstrate how your proposed product meets the intent of this guidance.

See the [tailored guidance material for Item 10 applications](#) for specific information on assessment areas and modules on our website.

The use of this guidance does not mean that no assessment is required for any of the statutory criteria. For example, you may be able to rely on this guidance for efficacy but still require a chemistry and manufacture assessment and an environmental assessment. See examples below.

All applications for new anti-fouling paint require submission of a draft label (see Section 8).

If after considering this guidance and the application information on the APVMA website you still require assistance, you may request [pre-application assistance](#) to address your specific questions.

Example 1: You wish to register a new formulation of anti-fouling paint that contains existing approved active constituents

You wish to register a new anti-fouling paint which contains the actives:

- copper present as cuprous oxide 700 g/L
- copper pyrithione 100 g/L.

Both active constituents are sourced from an approved source of active. You have identified a registered reference product that contains these same actives at the same concentrations as in your proposed product, and the reference product does not have any protected data.

The paint is to be applied at 4.8 m² per litre, with one coat only being required.

Assessment areas:

Chemistry and manufacture: An assessment is required to demonstrate that the new formulation meets the technical specifications and is stable for the proposed shelf life.

Efficacy: The active constituents are present at concentrations that are expected to be efficacious according to the guidance in Section 4. As an assessment of these active constituents has already been done by the APVMA. No further assessment of efficacy is required.

Human health: The active and excipient constituents are present at concentrations expected to be safe if the appropriate first aid instructions and safety directions in Section 6.1 are included on the product label. No further assessment of human safety is required.

Environment: You have calculated the leaching rate based on the formula provided in Section 6.2.

Cuprous oxide: Based on a certificate of analysis, the cuprous oxide is 820 g/kg total copper. Using this information the worst case scenario leaching is 29.5 µg active constituent/cm²/day, which is below the regulatory acceptable concentration.

Copper pyrithione: Using the worst case scenario calculation copper pyrithione leaches at a rate of 5 µg active constituent/cm²/day, which is above the maximum leaching rate to achieve the regulatory acceptable concentration.

An environmental assessment is required. Data to satisfy the APVMA that the product will meet the environmental statutory criteria will need to be supplied by the applicant.

Labelling: A draft label must be submitted with the application.

Example 2: You wish to register a new formulation of anti-fouling paint that contains existing approved active constituents

You wish to register a new anti-fouling paint which contains the active copper present as cuprous oxide 350 g/L. It also contains xylene at 400 g/L as a solvent.

The active constituent is sourced from an approved source of active and is 820 g/kg total copper. You have identified a registered reference product that contains this active constituent at the same concentrations as in your proposed product, and the reference product does not have any protected data.

The paint is to be applied at 5 m² per litre, with two coats being required.

Assessment areas:

Chemistry and manufacture: An assessment is required to demonstrate that the new formulation meets the technical specifications and is stable for the proposed shelf life.

Efficacy: The active constituent is present at concentrations that are expected to be efficacious according to the guidance in Section 4. No further assessment of efficacy is required.

Human health: The active and excipient constituents are present at concentrations expected to be safe if the first aid instructions and safety directions in Section 6.1 are included on the product label. The formulation also contains a scheduled solvent, xylene. You will need to consult the APVMA's handbook of first aid instructions and safety directions to determine the correct first aid instructions and safety directions to include on the label.

No further assessment of human safety is required.

Environment: You have calculated the leaching rate based on the formula provided in Section 6.2 and it is below the maximum leaching rate to achieve the regulatory acceptable concentration. No further environmental assessment is required.

Labelling: A draft label must be submitted with the application.

Example 3: You wish to register a new formulation of anti-fouling paint that contains existing approved active constituents and is *closely similar* to a registered reference product

The proposed new product has the same active/s (from an approved source) at the same concentrations as the registered reference product. The other ingredients in the paint formulation are not identical but do perform similar functions. The registered reference product does not have any protected data. You wish to use the same label claims and directions for use on your proposed product as are on the label for the registered reference product.

No assessments are required. The APVMA has already done equivalent assessments and is satisfied that the product will pose no greater risk than the registered reference product.

You should make an [Item 7 application](#), and this guidance is not relevant.

Labelling: A draft label must be submitted with the application.

3 EFFICACY AND PRODUCT CLAIMS

To use this guidance to support the efficacy of a new anti-fouling paint, the proposed new product may only be applied to the hulls and/or the undersides of vessels, including inside niche areas such as sea chests. The statement of claim should indicate the product is only used for the control of marine growth below the waterline on vessels.

To make an application for registration of an anti-fouling product by reference to this guidance, an applicant must show that the proposed product contains one or more approved active constituents that are used at the same concentration and for an equivalent use in another registered product, where the other registered product is not subject to limits on use of information (restricted information). This can be done by nominating a registered reference product with the same active constituents at the same concentrations with no limits on use of information. These concentrations have already been determined by the APVMA to meet the necessary efficacy criteria.

Table 3 lists actives that have been assessed by the APVMA in anti-fouling paints. Some actives are used alone or in combination with others in order to be effective.

Table 3: Active constituents previously approved by the APVMA in anti-fouling paints

Actives	CAS number	Maximum g/L
Copper pyrithione	14915-37-8	172
Cuprous oxide	1317-39-1	1030
Cuprous thiocyanate	1111-67-7	251
Dichlofluanid	1085-98-9	45
4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one (DCOIT)	64359-81-5	38
Diuron	330-54-1	120
Thiram	137-26-8	45
Zinc oxide*	1314-13-2	244
Zinc pyrithione	13463-41-7	172
Zineb	12122-67-7	115

* Zinc oxide can be an active constituent and/or a pigment. Applicants should comment on whether zinc oxide is present as an active constituent or only functions as a pigment when making an application.

4 PARAMETERS FOR CHEMISTRY AND MANUFACTURING

To register a new anti-fouling product a chemistry assessment is required to address the safety criteria for chemistry and manufacture unless the formulation is the same as or *closely similar* to a registered reference product (see Tables 1 and 2 above). Information on [chemistry assessments and data requirements](#) is available on the APVMA website.

As anti-fouling paints may be produced in a range of colours, there may be small variations in the formulations (both active constituents and non-active constituents) between different colours of the same product. In this case, the formulation for each paint colour must be provided.

4.1 Active constituents

The source of the active constituents must be approved by the APVMA, unless the active constituent is [exempt from approval](#). Active constituents must comply with a relevant APVMA standard, where one exists. Please note that a number of active constituents exempt from approval also have standards (for example, [cuprous oxide](#)).

4.2 Non-active constituents

In addition to active constituents, anti-fouling products contain non-active constituents (excipients). These include binders, pigments, extenders, solvents and additives. The typical concentration ranges provided in Table 4 are for information only and do not impact on what assessments may be required. All constituents used in the manufacture of anti-fouling paints must meet the quality specifications as designated by the manufacturer.

Table 4: 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	10–50%
Additive	Polymer with active functional groups	<10%

* Zinc oxide can be an active constituent and/or pigment. Applicants should state whether zinc oxide is present as an active constituent or only functions as a pigment when making an application.

4.3 Quality

Manufacture of anti-fouling paints 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; colour and drying time. This must be demonstrated as part of the application.

4.4 Shelf life

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 or at room temperature). This can be demonstrated using standard accelerated methodologies. If the product meets those requirements there is no specific requirement from the APVMA to include an expiry date.

However, 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.

5 SAFETY

5.1 Human health

To register a new anti-fouling paint, the APVMA must be satisfied that the product meets the safety criteria and when used in accordance with label instructions will not pose an unacceptable risk to users. The APVMA has considered the human health aspects of the active constituents used in anti-fouling paints at the maximum concentrations listed in Table 3 above as well as commonly used excipient constituents.

Based on assessments of the active constituents and commonly used excipient constituents, the APVMA has determined the likely hazards associated with the different paint formulations. These have been used to establish standard first aid instructions (see column 3 in Table 5 below and Section 8). Prediction of the hazard of the paint formulation (including that posed by typical excipients), likely exposure routes and user exposure to anti-fouling paints have been considered to establish the safety directions. The specified safety directions are to be included on the product label to mitigate the risk posed to users of these products. If the proposed product contains different active constituents or active constituents at higher concentration to those in Table 3, a human health assessment will be required.

Table 5: First aid instructions and safety directions to be applied to anti-fouling paints based on active constituent(s)

Category	Active constituents	First aid instruction code ^{^s}	Category specific safety directions*	Safety directions common to all categories
1 (actives individually or in combinations)	Cuprous oxide	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126, New Zealand 0800 764 766	Harmful if swallowed or inhaled. May irritate the eyes and skin.	Avoid contact with the eyes and skin. Do not inhale vapour. Ensure adequate ventilation during mixing and use. When opening the container and preparing the paint wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves [applicant to nominate appropriate type of 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 [applicant to nominate appropriate type of gloves]** and eye protection. If spray painting wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves [applicant to nominate appropriate type of gloves]**, a respirator with [applicant to nominate appropriate cartridge and filter]** cartridge and filter (either a full-face piece respirator, or a half-face piece respirator with eye protection and a hat). Wash hands after use. After each day's use wash contaminated clothing, hat#, gloves, eyewear# and respirator.
	Copper thiocyanate			
	Dichlofluanid			
	Diuron			
	Thiram			
	Zinc oxide			
Zineb				
2 (actives individually or in combination with category 1 actives)	Copper pyrithione	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766. If in eyes wash out immediately with water.	Harmful if swallowed or inhaled. Will damage eyes. May irritate the skin.	
	Zinc pyrithione			

Category	Active constituents	First aid instruction code [^] \$	Category specific safety directions*	Safety directions common to all categories
3 (active individually or in combination with category 1 actives)	4,5-Dichloro-2-n-octyl-4-isothiazolin-3-one (DCOIT)	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766.</p> <p>If swallowed, do NOT induce vomiting.</p> <p>If skin contact occurs, remove contaminated clothing and wash skin thoroughly.</p> <p>If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.</p>	Harmful if swallowed or inhaled. Will irritate the eyes and skin. Repeated exposure may cause allergic disorders.	<p>Avoid contact with the eyes and skin. Do not inhale vapour. Ensure adequate ventilation during mixing and use.</p> <p>When opening the container and preparing the paint wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves [applicant to nominate appropriate type of gloves]** and eye protection.</p> <p>If applying by brush or roller wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, protective gloves [applicant to nominate appropriate type of gloves]** and eye protection.</p> <p>If spray painting wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), protective gloves [applicant to nominate appropriate type of gloves]**, a respirator with [applicant to nominate appropriate cartridge and filter]** cartridge and filter (either a full-face piece respirator, or a half-face piece respirator with eye protection and a hat).</p>
Combination of category 2 and 3 (may also include category 1 actives)		Select as appropriate from above	Harmful if swallowed. Will damage eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. May irritate the skin.	Wash hands after use. After each day's use wash contaminated clothing, hat [#] , gloves, eyewear [#] and respirator.

[^] If the first aid instructions require statement 'If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor', do not also include statement 'If in eyes wash out immediately with water' on the label.

**both the 'category specific' and 'common' safety directions should be combined and included on the label.*

***based on the constituents in the paint formulation, the applicant should nominate an appropriate material/type.*

#delete PPE as appropriate (eg, hat not required if a full face piece respirator is selected).

\$For first aid instructions (FAIs) for scheduled excipient constituents use the [First Aid Instruction and Safety Directions \(FAISD\) Handbook as a guide](#). If the required FAI is a repeat of a FAI required for an active constituent in the paint, or another excipient constituent, do not repeat the FAI. If the paint constituents result in two different FAIs related to the same hazard, only incorporate the more stringent statement into the FAIs. For example, with regards to eye irritation, if both the statements 'If in eyes wash out immediately with water' and 'If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor' are indicated for the label, only include the latter statement.

5.2 Environmental safety

The APVMA has used the following worst case scenario calculation for a number of active constituents present in anti-fouling paints. For full details on this methodology refer to [Supporting information](#).

To satisfy environmental 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 6.

This calculation is only suitable for use with the active constituents listed in Table 6. Other active constituents (for example thiram and DCOIT) will require an environmental safety assessment.

Where the concentration of active constituent results in a leaching rate that would exceed the RAC in Table 6, an environmental assessment will be required. [Data guidelines for environmental assessment](#) are available on the APVMA website.

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

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

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

Where:

- a is the mass fraction of biocide in the biocidal ingredient; (in general a is equal to 1 for most active constituents)
- w_a 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 conversion 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).

Table 6: 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 ac/cm ² /day
Copper pyrithione	0.18 µg ac/L	1.0 µg ac/cm ² /day
Copper thiocyanate	2.0 µg ac/L	5 µg ac/cm ² /day
DCOIT	Not established for this guidance and an environmental assessment will be required	
Dichlofluanid	0.64 µg ac/L	29 µg ac/cm ² /day
Diuron	1.6 µg ac/L	8.9 µg ac/cm ² /day
Thiram	Not established for this guidance and an environmental assessment will be required	
Zinc pyrithione	1.2 µg ac/L	145 µg ac/cm ² /day
Zineb	2.2 µg ac/L	12 µg ac/cm ² /day

All product labels must have the environmental protection statement 'Very toxic to aquatic life. Do not contaminate soil or waterways with paint, dust and scrapings, or with used containers.' See section 8 below on labelling.

6 APPLICATION METHODS

6.1 Application

Anti-fouling products can be applied using a variety of methods. These may include the use of spray systems, paint brushes and rollers.

6.2 Directions for use

Application instructions on the label should include:

- substrate preparation, specified in accordance with vessel substrate (eg steel, aluminium, wood, fibreglass): washing, sanding or blasting instructions; suitable paint products which can be painted over or any tie coat necessary
- paint preparation (eg thoroughly mix before use)
- 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.

7 LABELLING GUIDANCE

7.1 Label requirements

All applications for new antifouling paints must be accompanied by the proposed label, which will be assessed by the APVMA. Guidance on the information that needs to be on the label of an antifouling paint is available in the [anti-fouling paint labelling code](#).

Additional information on label requirements is available in the Ag Labelling Code:

- [label presentation and layout](#)
- [label content](#).

8 OTHER REQUIREMENTS

Anti-fouling products are subject to other regulatory requirements that APVMA does not have responsibility for (eg the Globally Harmonised System of Classification and Labelling). It is the applicant's responsibility to ensure the product complies with all other requirements.