Regulatory Directive

Dir94-03

Registration of Antifouling Coatings

This document provides an update to the paint and coatings industry on the regulatory requirements for the registration of antifouling coatings in accordance with Section 4 of the Pest Control Products Act (PCP Act).

These requirements are similar to those of the United States with respect to tin-based products. However, Canadian requirements for copper-based products differ as release rate data is required.

Model labels for antifouling coatings are provided in this document. Experience to date has shown that the use of model labels has led to an increase in operating efficiency for both the government and industry, while ensuring consistent information to users of these products.

This Regulatory Directive replaces Trade Memorandum T-1-254 (February 12, 1987) and the following Notes to CAPCO: C87-16, C89-02 and C90-08.

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1.0 Background

Antifouling coatings are used to control aquatic fouling pest organisms (algae, barnacles, mussels, and other molluscs,) on ships, small boats and other surfaces found in freshwater and marine environments. The requirements for the registration of antifouling coatings for ship hulls were developed primarily to address an absence of information on the environmental effects of currently registered active ingredients when used in this new area. The release of active ingredients from antifouling coatings has been shown to have some potentially adverse effects on non-target aquatic organisms.

Wax materials and other non-biocidal coatings (i.e, teflon) provide a physical barrier to the growth of unwanted organisms on nets, hulls, and other marine surfaces. As a result, they are not subject to the *PCP Act*. These products may be used as alternatives to conventional antifouling coatings.

Organotin and copper-based products have traditionally been the antifouling coatings of choice. The active ingredients (cuprous oxide, elemental copper, copper flakes, and tributyltin oxide) contained in these products were available in other registered products prior to their registration as antifouling coatings. Products containing these actives are acceptable for use in antifouling coating formulations provided the criteria outlined below are followed. This document will be restricted mainly to organotin and copper products, although some other chemicals will be briefly discussed.

2.0 Toxicological Requirements

Over the past five years, labelling requirements for both tin and copper-based antifouling coatings have been upgraded to contribute to the safe and proper use of these paints. Antifouling coatings represent only a small segment of the paint and coating industry. Other paints and coatings are regulated by different legislation e.g., the *Hazardous Products Act*. Because antifouling paints have many of the same chemical components found in coatings used in other areas, any safety considerations with respect to formulants would be similar to those for products not regulated by the *PCP Act*. Any safety assessment of coatings regulated under the *PCP Act* would have to take into consideration both operational resources and coordination with other Departments involved in regulation of non-pesticide coatings.

In the meantime, registrations pursuant to the *PCP Act* will require labels reflecting the current knowledge of individual ingredients contained in the formulation. Material Safety Data Sheets (MSDS's) are the primary source of information for the development of appropriate labelling statements.

If registrants/applicants have or are going to develop a toxicological data base for their products, all data to be submitted must be organized according to Regulatory Directive Dir93-03, *Organization of Data for End-Use Products*.

Please consult the following pages for specific requirements on the environmental assessment of tin or copper-based products.

3.0 Registration Requirements

Registrants/applicants wishing to obtain registrations for copper-based or organo-tin based antifouling coatings will be required to provide the following:

- an application for new or amended registration (AGR1170).
- a completed Product Specification form (AGR1168) for each paint color, indicating all sources of active ingredients and their registration numbers, as well as the remainder of the individual formulants (multi-color lines may use the same registration number if the guarantee of active ingredient remains the same and the variation in inert formulant(s) is considered to be minor).

Also, indicate in the covering letter for your submission and on your Product Specification Form (Form AGR1168 Section 7) if the formulation is:

- Copolymer paint (biocidal material chemically bound to the paint and released on reaction with water);
- Free association paint (biocidal material is dissolved or dispersed in the matrix of the paint).
- an MSDS and Chemical Abstract Service Number (CAS) for each formulant listed on the Product Specification Form.
- updated letters of confirmation of source of supply for each source of active ingredient.
- five (5) copies of a proposed label which incorporates the antifouling coating labelling requirements (model label see Apppendix II, although these labels are for copper-based coatings, they may be adapted to other active ingredients).
- registration fee of \$300 per product if release rate data is required (see below) or \$100 if release rate data is not required, payable to the Receiver General of Canada.
- release Rate data of the active ingredient as per Appendix I (two copies, indexed as per Dir93-03, Appendix I, parts 6 and 7) or a scientific rationale for waiver of such data. In cases of similar formulations, i.e., only minor variation in "inert ingredients" such as pigments, release rate data will only be required for a representative formulation.
- efficacy data may be required, on a case by case basis, as per part 8, Appendix I, of Dir93-03.

4.0 Copper-Based Antifouling Coatings

Because copper ions are persistent and accumulate in the environment, the long-term use of copper in antifouling coatings presents some potential concern for the environment. Anthropogenic sources of copper may account for concentrations of the element to rise above the natural background levels in high risk areas of the environment.

Registrants/applicants wishing to obtain registrations for copper-based antifouling coatings will be required to provide the following:

Relevant studies on the environmental chemistry, fate (part 6 of Dir93-03), and on the environmental toxicology (part 7 of Dir93-03) of copper-based products. This data is probably available in open literature. Registrants/applicants may consider the option of producing individual data bases or forming a task force to coordinate their efforts.

Data on the release/leaching Cu^{2+} rate, comprised of repeated triplicate experiments, using an appropriate test method (see Appendix I) for each product submission. Justifiable exemptions submitted by the applicant will be considered on the basis of a written scientific rationale (e.g., pigment/color difference). The maximum daily release rate mean, from experiments, should not exceed $40~\mu g/cm^2/day$.

Insoluble film formers (relying on high concentrations of Cu^{2+} which dissolve in an exponential manner from the fixed matrix resulting in an irregular release of the active ingredient) are unacceptable, unless it can be shown that the release/leaching rate of Cu^{2+} does not exceed 40 μ g/cm²/day at any time during the life of the paint. Because insoluble film formers generally leach higher amounts of Cu^{2+} early in their leaching profile, a minimum two week testing period is required with the appropriate test method.

Copper-based antifouling coatings that meet the maximum daily release rate criteria will be accepted for registration providing:

- they contain a registered technical active ingredient;
- data indicates that they meet the release rates requirements; and
- the products are labelled according to standard model labels (use Appendix II as a guide).

5.0 Tin-Based Antifouling Coatings

Canada and other National regulatory agencies (e.g. USA, Sweden) have been working towards a common objective: to minimize the environmental impact of organotins. The following registration standards for organotin coatings were established in 1989:

- A maximum daily release rate of four micrograms per day of organotin per square centimetre of hull surface (calculated as tributyltin cation);
- Organotins products are prohibited from use on vessels that are less than 25 meters, unless the
 vessels are aluminum. Outboard motors and lower drive units are also exempt from the
 prohibition.

Tin-based antifouling coatings that meet the maximum daily release rate criteria will be accepted for registration providing:

- they contain a registered technical active ingredient;
- data indicates that they meet the release rates requirements; and
- the products are labelled according to standard model labels (use Appendix II as a guide).

6.0 Combination Tin/Copper Products

Combination tin/copper/organotin products must meet both release/leaching rates for copper (40 $\mu g/cm^2/day$) and organotin (4 $\mu g/cm^2/day$).

Combination copper/organotin-based antifouling coatings that meet the maximum daily release rate criteria will be accepted for registration providing:

- they contain registered technical active ingredients;
- data indicates that they meet the release rates requirements; and
- the products are labelled according to standard model labels (use Appendix II as a guide).

7.0 Net Antifouling Coatings

These products are generally used to control molluscs and algae on nets, principally in aquaculture. Nets are usually dipped in a solution of the product or it is sprayed on the net. A product using cuprous oxide as the active ingredient has recently been registered for antifouling purposes on nets.

The use of antifouling coatings on fish nets and other aquatic surfaces will be considered for registration if:

- the product contains a registered technical active ingredient; and
- data is provided to allow a health, safety and environmental assessment to be conducted.

Release rate data will be an important element in conducting an assessment of environmental hazards.

Additional information on this document may be obtained from:

Information Service
Pest Management Regulatory Agency
2250 Riverside Drive
Ottawa, Ontario
K1A 0K9

Telephone: 1-800-267-6315

Testing Protocol for Release Rate

The method of testing suggested is the American Society for Testing and Materials (ASTM) Standard Test Method for Organotin Release Rates of Antifouling Coating Systems in Sea Water (dry film thickness, ASTM D 4138; substitute ocean water, ASTM D 1141), adapted/modified for the determination of copper (standard specification for cuprous oxide for use in antifouling paints/coatings, ASTM D 912-81; methods of chemical analysis of cuprous oxide and copper pigments, ASTM D 283).

This does not exclude the use of other appropriate analytical methodologies for the extraction and detection and/or determination of trace levels of copper in sea water.

Model Labels Appendix II

PRINCIPAL DISPLAY PANEL

YOUR BRAND NAME

ANTIFOULING PAINT [colour]

DOMESTIC

READ THE LABEL BEFORE USING

REG. NO. 00000 P.C.P. ACT

DANGER



FLAMMABLE EYE IRRITANT SKIN IRRITANT

POISON

NOT FOR SPRAY USE - ONLY BRUSH OR ROLLER APPLICATION

NET CONTENTS

Your company, Your Street Address (or P.O. Box no.)
Your City, Your Province,
Postal Code

Appendix II Model Labels

SECONDARY DISPLAY PANEL

PRECAUTIONS:

 Wear chemical resistant gloves, goggles and footwear, and chemical resistant clothing including hood or hat at all times during handling and applying.

- Keep out of reach of children.
- Handle with care and mix only in a closed container.
- Use only in well ventilated areas.
- When using do not eat, drink or smoke.
- Take a shower immediately after work.
- Wear freshly laundered clothes daily.
- Wash hands and face before eating, drinking, smoking and using the toilet.
- Store and wash all protective clothing separately from household laundry.
- Wash protective clothing in detergent and hot water before reuse.

FIRST AID:

If splashed in eyes or on skin, flush thoroughly with water for 15 minutes. For eye contact, get medical attention. If swallowed, drink 2 or 3 glasses of milk or water. Do not induce vomiting. Call a physician immediately.

TOXICOLOGICAL INFORMATION:

Contains petroleum distillates. Do not induce vomiting.

Add information as per section V of the Material Safety Data Sheet.

ENVIRONMENTAL HAZARDS:

Toxic to aquatic organisms. Do not contaminate water. Do not apply directly to water by cleaning of equipment or disposal of wastes. Do not allow chips or dust generated during paint removal to enter water.

DISPOSAL:

Dispose of empty containers and paint debris in accordance with provincial requirements. For information on the disposal of unused or unwanted product and the cleanup of spills, contact the regional office of Environment Canada.

Model Labels Appendix II

DIRECTIONS FOR USE:

Refer to product data sheet [add READ THE LABEL AND PRODUCT DATA SHEET to primary panel]

or

product specific directions

Reference must be made to time allotted for drying (curing) of the product prior to introduction into water.

Appendix II Model Labels

PRINCIPAL DISPLAY PANEL

YOUR BRAND NAME

ANTIFOULING PAINT [colour]

COMMERCIAL

READ THE LABEL BEFORE USING

REGISTRATION NO. 00000 PEST CONTROL PRODUCTS ACT

DANGER



FLAMMABLE EYE IRRITANT SKIN IRRITANT

POISON

NET CONTENTS

Your company, Your Street Address (or P.O. Box no.)
Your City, Your Province,
Postal Code

Model Labels Appendix II

SECONDARY DISPLAY PANEL

PRECAUTIONS:

 Wear an air-fed respirator with a full face mask during handling and applying. Wear chemical resistant gloves, and footwear, and chemical resistant clothing with head covering at all times during handling and applying.

- Keep out of reach of children.
- Handle with care and mix only in a closed container.
- Use only in well ventilated areas.
- When using do not eat, drink or smoke.
- Take a shower immediately after work.
- Wear freshly laundered clothes daily.
- Wash hands and face before eating, drinking, smoking and using the toilet.
- Store and wash all protective clothing separately from household laundry.
- Wash protective clothing in detergent and hot water before reuse.

FIRST AID:

If splashed in eyes or on skin, flush thoroughly with water for 15 minutes. For eye contact, get medical attention. If swallowed, drink 2 or 3 glasses of milk or water. Do not induce vomiting. Call a physician immediately.

TOXICOLOGICAL INFORMATION:

Contains petroleum distillates. Do not induce vomiting.

Add information as per Section V of the Material Safety Data Sheet.

NOTICE TO USER:

This control product is to be used only in accordance with the directions on this label. It is an offense under the *Pest Control Products Act* to use a control product under unsafe conditions.

ENVIRONMENTAL HAZARDS:

Toxic to aquatic organisms. Do not contaminate water. Do not apply directly to water by cleaning of equipment or disposal of wastes. Do not allow chips or dust generated during paint removal to enter water.

Appendix II Model Labels

DISPOSAL:

Dispose of empty containers and paint debris in accordance with provincial requirements. For information on the disposal of unused or unwanted product and the cleanup of spills, contact the regional office of Environment Canada.

DIRECTIONS FOR USE:

Refer to product data sheet.
[add READ THE LABEL AND PRODUCT DATA SHEET to primary panel]

or

product specific directions

Reference must be made to time allotted for drying (curing) of the product prior to introduction into water.

Large vessels, i.e., over 25m; must be treated by trained applicators.