

ACA REVISED GUIDANCE

December 2020

Evaluation of Biocides, Treated Articles and Canada's Restricted Use of OIT for Use as a Material Preservative in Paint

(Initial Publication - May 2019)

BACKGROUND: ACA is publishing a second revision of prior guidance regarding OIT for use in Canada as a material preservative in paint. This revision is due to Canada's decision to overturn its prior decision to ban OIT. The initial guidance published in May 2019 addressed issues specific to Canada's ban of OIT. ACA then reissued the guidance in January 2020 to address subsequent questions regarding general compliance with requirements of the Canadian Pest Management Regulatory Agency (PMRA) for biocides and for treated article labeling. This reissue addressed broader member interests, referencing requirements in the U.S., E.U. and Canada. Now, with this second reissue, ACA maintains information addressing broader member interests in biocide registration requirements while providing new use limits for OIT and updates regarding ongoing biocide evaluations in Canada.

DISCLAIMER

This guidance document is intended to assist members in understanding PMRA's Treated Article's Policy. This information is not intended to represent an interpretation of PMRA rules, regulations and policy, nor does it constitute compliance or legal advice. The information contained in this document has been compiled from sources believed to be reliable and represent the best information on the subject as of **December 1, 2020**. The American Coatings Association, Inc., makes no warranty, guarantee, or representation as to the completeness, accuracy or sufficiency of any information herein, and the Association assumes no responsibility in connection therewith; nor can it be assumed that all necessary measures are contained in these documents, or that other or additional information or measures may not be required or desirable because of particular or exceptional conditions or circumstances, or because of applicable federal, state, or local law.

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GUIDANCE

I. OIT Use Limit and Relationship to the Treated Article Requirements in Canada

a. Current OIT Use Limit

In October 2020, the Canadian Paint and Coatings Association (CPCA) announced that Canada's Pest Management Regulatory Agency (PMRA) has restored the use of commonly-used preservative OIT (octhilinone) in paint and coatings and related products sold in Canada. OIT is a critical ingredient used for the preservation of paint and stains sold in Canada. Until October, OIT had been banned for use in these products by PMRA since May 2019.

PMRA's decision to reinstate use will ensure paint products access to a critical biocide preservative, but at a slightly lower limit, noted as follows:

- **For use as a mildewcide in coatings such as latex and solvent-based paints, semi-transparent stains and solid stains. Use 1.2 to 1.8 Kg/1000 L of this product in coating formulations. The active ingredient in the above label is 45% OIT.**
- **For use as a mildewcide in building materials such as elastomeric roof and wall coatings and mastics, caulks, sealants, joint cements, spackling, stucco and grouting, use 1.2 to 2.3 Kg/1000 L at 45% active ingredient.**
- **In wallpaper pastes and adhesives, use as a mildewcidal preservative to protect materials such as polyvinyl acetate starch and dextrin based pastes from fungal attack after they are applied. Use 0.8 to 1.2 Kg/1000 L at 45% active ingredient.**

- **In aqueous adhesive and tackifier preservation, use as a mildewcidal preservative in water soluble and water dispersed adhesives such as animal glues, vegetable glues, natural rubber latices, polyvinyl acetate, styrene butadiene, polyurethane, epoxy, acrylic latices, and tackifiers derived from rosin and hydrocarbon resins, use 1.2 to 2.3 Kg/1000 L at 45% active ingredient**

PMRA has communicated directly with biocide manufacturers as a result of a submission on OIT. As such, PMRA does not have to provide official notification of its decision, allowing biocide manufacturers to convey information to downstream users. Paint formulators must comply with restrictions on use conveyed by its biocide supplier.

b. Background on Prior OIT Decision

PMRA's current use limit for OIT revokes its prior ban that went into effect in May 2019. **That ban applied to sales of all finished paints and coatings that contained OIT for a preservative effect.** Registrants could not sell OIT for use as a material preservative in the manufacture and/or sale of finished paints and coatings products in Canada. Agency inspectors reserved the right to request additional information from suppliers to confirm that OIT use rates do not exceed those noted above. PMRA allowed an unlimited sell-through of existing paint and coating stocks with OIT, if the paint or coating was manufactured in or imported to Canada prior to May 31, 2019. With the use limits of October 2020, these requirements are no longer in effect.

c. PCPA vs. FIFRA

The Canadian Pest Control Products Act (PCPA) requires that all antimicrobial preservatives be registered with PMRA.¹ Similar to U.S. requirements, Canada implements a treated article exemption. Under the exemption, paints treated with antimicrobial preservatives require registration of the pesticide but not the article itself, if:

- 1) the antimicrobial preservative used to treat the article is registered under the Pest Control Products Act;
- 2) the article is treated according to the antimicrobial preservative's approved uses; and
- 3) the use is limited in preventing degradation or damage to the product from organisms.²

In the United States, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), requires registration of all pesticides with the U.S. Environmental Protection Agency (EPA) prior to their introduction into interstate commerce. Like Canada, the EPA exempts from registration the

¹ Section 6, Pest Control Products Act

² Health Canada, *Information Note – Treated Articles*, 17 Dec. 2018, available at: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html>

article itself, if it contains a registered pesticide which is intended to protect the article. This includes paints or coatings treated with a pesticide to protect the product.

In order to comply with the OIT use limit and similar restrictions on other antimicrobial agents in Canada, companies should be aware of PMRA registration requirements. Companies are required to register any pest control product, defined as a product used for *directly or indirectly controlling, destroying, attracting or repelling a pest*.³

d. Treated Article Requirements in Canada

In its *Information Note – Treated Articles*, published December 17, 2018, PMRA sets forth guidance regarding the use of **registered pesticides for paints**:

- A **pesticide** that has been **intentionally incorporated** into or applied to an article during manufacture (i.e. making paint) for import, sale or use in Canada **must be registered under the Pest Control Products Act**.
- If a pesticide has been incorporated into or applied to an article **in order to provide a benefit to the product itself** (in other words, preservation) **the pesticide** (in other words, the antimicrobial preservative) **must be registered** under the *Pest Control Products Act* for that specific use.
- Both the U.S. and Canada require the manufacturers of treated articles to use a registered antimicrobial active ingredient and end-use product, according to approved use patterns. For imported treated articles, both require that the active ingredient used be registered in their jurisdiction for such use.

PMRA does not require registration *for use in paint* of raw materials used in the manufacture of paint outside of Canada for import to Canada when the raw material is not intentionally added for the purpose of controlling pests. Such antimicrobial is not subject to registration under the PCPA when a foreign manufacturer uses a raw material containing a residual amount of antimicrobial. Conversely, any antimicrobials in raw materials intentionally added to a paint product for a preservative effect on the paint product must be registered for that use or Canada will not allow import.

³ Section 2(1), Pest Control Products Act, defines a “pest control product” as:

- (a) a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;
- (b) an active ingredient that is used to manufacture anything described in paragraph (a); or
- (c) any other thing that is prescribed to be a pest control product. (*produit antiparasitaire*)

II. Antimicrobial Agent Checklist

When manufacturing paints outside of Canada for import into Canada, three common situations regarding the use of antimicrobial agents should be considered.

a. Situation 1: The Antimicrobial is Intentionally Added to the Paint for a Preservative Effect.

- A. An antimicrobial which is intentionally added for a preservative effect must be registered with PMRA for the manufacturer's use (in paint, coatings, etc.).
- B. The antimicrobial must be used according to all conditions and restrictions issued by PMRA.
- C. If the antimicrobial is not registered with PMRA for use in paint, it may not be used.

b. Situation 2: The Antimicrobial is in a Raw Material and the Antimicrobial is Registered with PMRA for use in the Raw Material

- A. If the antimicrobial is in residual amounts such that it is not intentionally added for a preservative effect on the final paint product, the manufacturer may use the raw material in paint. NOTE: In some cases, PMRA may prescribe a residual threshold for raw materials, above which the antimicrobial cannot be found in the finished paint.
- B. If the antimicrobial in the raw material is added for a preservative effect on the final paint product it must be registered with PMRA for that paint use or it is not permitted and may not be used in paint for sale in Canada.

c. Situation 3: The Antimicrobial is in a Raw Material and the Antimicrobial is not Registered with PMRA for use in the Raw Material

- A. Although not explicitly referenced in the regulatory guidance published by PMRA, it is ACA's understanding that if the antimicrobial is present in residual amounts such that it is not intentionally added for a preservative effect on the final paint product, the raw material may be present in paint for sale in Canada provided the antimicrobial is listed on Canada's DSL (Domestic Substances List). For further information, PMRA encourages companies to contact the agency directly, as PMRA may need to review the specific biocide and use in question.
- B. If the antimicrobial is in residual amounts and is intentionally added for a preservative effect on the final paint product, the raw material may not be used in paint for sale in Canada, unless registered with PMRA and approved for that use.

III. General Guidance

ACA recommends that its members contact their biocide/pesticide/preservative suppliers to discuss the use of their compounds in paints destined for export to Canada. Recent Canadian

revised use limits on OIT (as well as an ongoing effort to clarify the registrations for zinc pyrrithione and dimethyloxazoladine) require close cooperation by manufacturers with their suppliers. **Note:** Zinc pyrrithione is among the list of zinc compounds that are listed on the DSL (Domestic Substances List).⁴ In June 2019, it was proposed for listing in Schedule 1 of CEPA (“Toxic Substances List”) as a toxic substance. The final report confirming this listing remains to be published.

Companies importing products into Canada must also comply with general chemical control requirements administered by Environment and Climate Change Canada under authority of CEPA (Canadian Environmental Protection Act). Any formulated chemical products imported into Canada must consist of chemicals listed on Canada’s DSL (Domestic Substances List⁴).

Chemicals not listed are considered “new” in Canada and are subject to extensive notification and evaluation requirements prior to allowing entry into Canada. Finally, another relevant list is the NDSL (Non-Domestic Substances List). Chemicals listed on the NDSL are considered “new chemicals” when importing into Canada. The NDSL list is based on the U.S. TSCA Inventory, without chemicals listed on the DSL. Companies planning to import NDSL-listed chemicals will have less data submission requirements than required for “new chemicals” not on the NDSL.⁵

IV. Evaluation of Biocides in Articles in the US and EU

Canada’s PMRA states that its approach to treated articles is aligned with the United States and the European Union.⁶ Companies evaluating registration requirements for biocides in paints, coatings and similar products should take note of considerations in the U.S. and E.U. While these considerations are not determinative of an evaluation by PMRA in Canada, they are illustrative of analogous agency decision making and can assist companies to make a more informed review and evaluation of biocide use.

Canada, the EU and US require biocide registration for a specific use to treat an article domestically. For imports of treated articles, all three countries require registration of the biocide for use in the article within the importing country accepting the treated article.⁷

⁴ The DSL consists of about 26,000 chemicals, and includes many antimicrobials that are also subject to controls and/or restriction under the PCPA.

⁵ See New Substance Notification Regulations (Chemicals and Polymers), SOR/2005-247, available online at: <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/page-2.html#docCont>

⁶ Pest Management Regulatory Agency, *Information Note – Treated Articles* (Dec. 17, 2019), p. 4, available at: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html>

⁷ Pest Management Regulatory Agency, *Information Note – Treated Articles* (Dec. 17, 2019), p. 4, available at: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html>

a. Regulation of Treated Articles in the US

In the U.S., the EPA regulates antimicrobial pesticides under FIFRA (the Federal Insecticide, Fungicide and Rodenticide Act). The general rule regarding residual amounts of antimicrobials from raw materials is similar to the Canadian requirement.

In the U.S., a manufacturer cannot add an antimicrobial to treat paint or alter the paint such that it provides a public health benefit, unless the antimicrobial is registered under FIFRA for that purpose in paint. A manufacturer may add a raw material containing an antimicrobial to a paint, provided the raw material / antimicrobial combination is not added to treat the paint or provide a public health benefit, and in such instance the antimicrobial is not required to be registered for that purpose in the final paint product. However, the antimicrobial must be registered with EPA for use in the raw material.

EPA requires manufacturers register articles, such as paints, containing an antimicrobial pesticide when a label statement claims an antimicrobial effect from use of the paint, such as, “prevents bacterial growth.” In this case, the manufacturer must register the paint as required in FIFRA and apply an EPA-approved label as required for pesticide products.⁸

The “treated article exemption” exempts paints and other articles from FIFRA registration and labelling when the pesticide is added to preserve the article and the manufacturer does not claim a public health benefit or other benefit on the article’s label, provided the antimicrobial agent is registered for use in the article. The exact language of the exemption is at 40 CFR 152.25(a):

“(a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.”

This requirement applies to raw materials as it does to paints. A raw material with antimicrobials is not subject to FIFRA registration and labelling, if the antimicrobial is registered for use in the raw material. Further, a formulator can add that raw material to a paint provided the raw material is not added “to protect the treated article or substance itself.”

b. Regulation of Treated Articles in the EU

EU has a similar approach to the U.S. and Canada in evaluating antimicrobials (called biocides under the EU regulations) used in treated articles as specified in the Biocidal Products Regulation (BPR, EU Regulation 528/2012). The BPR emphasizes manufacturers’ intentional use

⁸ At 40 CFR 152.15 EPA requires any registration of any product, “intended for a pesticidal purpose, *i.e.*, use for the purpose of preventing, destroying, repelling, or mitigating any pest . . .” EPA provides explanation regarding scope, application and acceptable label statements for treated articles in a “Pesticide Registration Notice,” dated March, 2000, with the subject, *Applicability of the Treated Articles Exemption to Antimicrobial Pesticides*, available online at: <https://www.epa.gov/sites/production/files/2014-04/documents/pr2000-1.pdf>

of biocidal additives. Article 3(1)(1) of the BPR defines a treated article as “. . . any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products.” Manufacturers must use registered biocides when treating an article or intentionally adding it to the article. (BPR Art. 58). In this case, the manufacturer must also label the treated article with information about the biocide specified in Art. 58 of the BPR.

The EU Directorate-General of the Environment (hereinafter “DG Environment”) provides detailed guidance to manufacturers to determine when an article “has been treated with, or intentionally incorporates” a biocide. (Art. 3(1)(1) BPR). This guidance is particularly illustrative of the agency’s evaluation of whether a biocide in a raw material must be registered for use in a paint product and if a paint product containing such raw materials must be labelled according to Art. 58 of the BPR.

DG Environment explains:

The notion of “intentionally incorporating” in the context of Article 58 seems to imply that the incorporation of a biocidal product is made with the intention to confer a biocidal property (or even a biocidal function) to the treated article. Such an intentional incorporation would thus lead to a beneficial and desired effect in the finished good (e.g. protecting it from bio-degradation during storage or use). Following this notion of “intentionally incorporating,” it is appropriate to exclude biocidal treatments or incorporation of biocides in a substance, mixture or article, or individual constituents thereof, which were made in the course of manufacturing merely in order to perform a specific biocidal function at that stage of the process, but which will not have an intended function in the finished good as placed on the EU market.

(CA-Sept14-Doc.6.2, European Commission, Directorate-General Environment)

DG Environment also suggests three considerations in evaluating when registration and labelling of a biocide in a treated article is necessary:

- 1) Consider claims made on the label concerning biocidal properties or related functions of the article. Claims of biocidal function of the article or a biocidal property, such as the article is “protected against bio-degradation” indicate intentional presence of the biocide. The absence of such claims does not necessarily indicate unintentional presence. The manufacturer must consider other factors such as knowledge of the biocides use during manufacturing and any active concentrations in the final product, as noted below.
- 2) Consider information about the biocide, its typical use in treatment and purpose. DG Environment emphasizes that manufacturers must consider a biocide’s Product Type (PT) listed in Annex V of the BPR. Annex V includes a listing of general use designations, known as the PT, for all registered biocides. Examples include human hygiene

disinfectants (PT1), film preservatives (PT7), construction material preservatives (PT10), etc.

- 3) Consider the concentration of the biocide in the final article. Presence of low, non-effective concentrations of biocides is an indication that the product is not a treated article, absent any other indicators of intentional use of the biocide.

(CA-Sept14-Doc.6.2, European Commission, Directorate-General Environment)

Again, while the U.S. and E.U. guidance is not determinative of Canadian PMRA regulation, they are illustrative of the factors used in decision making.

V. Canada's Re-evaluation of Preservatives Used in Paints, Coating and Related Uses

On July 9, 2020 Canada's PMRA published proposed re-evaluation decisions for the biocides diodofon, sodium omadine, chlorothalonil, dazomet, folpet and ziram, as part of a "cluster-analysis" of uses in paints, coatings, sealants and adhesives. Of these, PMRA is proposing canceling registrations for use in paint for diodofon, folpet and ziram. PMRA is proposing risk mitigation measures for others. PMRA accepted comment through December 6, 2020 and is expected to publish final evaluations in 2021.

PMRA's [Re-evaluation Decisions are Available Online](#).

In 2018, PMRA initiated reviews of two additional biocides used in paints, coatings and their raw materials:

- hydroxymethyl-5,5-dimethylhydantoin (MMY) CAS 27636-82-4 and
- 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (DMY) CAS 6440-58-0

PMRA's has not yet published its final decisions of these. Decisions are expected in 2021.

[PMRA's Re-Evaluation Note for Pesticides Used as Preservatives in Paints, Coatings and Related Uses](#) is available online.

[PMRA's Re-Evaluation Note for MMY and DMY](#) is available online.

[PMRA's Special Review Workplan, including Diodofon](#) is also available online.

For More Information

Contact ACA's [Riaz Zaman](#)

Background Links

[Canadian Pest Control Act](#)

[Information Note – Treated Articles, Health Canada \(17 Dec. 2018\)](#)

[ACA News Brief regarding Canadian Revised Use Limit for OIT \(November 2, 2020\)](#)