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Information Note – Treated Articles

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Introduction

This information note provides guidance to manufacturers, distributors and importers of pesticide treated articles that are sold and used in Canada. Its **primary purpose** is to clarify existing Canadian regulatory requirements for articles that have been treated with antimicrobial preservatives (in other words, pesticides). It also provides a link to the list of registered antimicrobial preservatives in Canada and a link to a guidance document on acceptable label claims for treated articles. Both of these documents will be useful to manufacturers and registrants when determining if current products meet Canadian regulatory requirements.

Until now, Health Canada's Pest Management Regulatory Agency (PMRA) has been responding to questions regarding Canadian regulatory requirements for treated articles on a case by case basis. This information note serves as a means to educate and communicate Health Canada's approach for treated articles to all relevant stakeholders.

Treated Articles

In Canada, the *Pest Control Products Act* defines a pest control product¹ as a product, an organism or a substance that is used directly or indirectly to control, destroy, attract or repel a pest, or mitigating or preventing its injurious, noxious or troublesome effects. The term 'pesticide', while not defined in the *Pest Control Products Act*, is often used to describe a pest control product and covers a broad range of substances that are commonly known as 'herbicides', 'insecticides', 'rodenticides', 'fungicides', 'antimicrobials', etc. Many everyday items (for example, household products, clothing, and toys) that are currently available on the Canadian market have been treated with a pesticide during the manufacturing stage, in order to protect the product and to extend its shelf-life. Treatment with a preservative allows the manufacturer to produce a longer lasting product, which is a quality many consumers are looking for when making a purchase. Registered pesticides used to treat these products have undergone a rigorous scientific assessment by the PMRA to determine if the risks associated with the use of the pesticide are acceptable.

The term "treated article" is generally used to refer to any product that has been intentionally treated with a pesticide. Articles can be treated with pesticides such as antimicrobials (for example, textile treated with a preservative), insecticides (for example, insecticide-treated clothing), and herbicides (for example, herbicide-treated landscape fabric). A **pesticide** that has been intentionally incorporated into or applied to an article during manufacture for import, sale or use in Canada **must be registered** under the *Pest Control Products Act*.

Examples of products that may contain antimicrobial preservatives include: water-based paints; certain plastic products, such as shower curtains; and wood and construction/masonry materials. The range of products that could be treated with an antimicrobial preservative is quite broad. In most cases, there is no requirement for the label of an article treated with an antimicrobial preservative to include a statement indicating it has been treated. Therefore, knowing which articles have been treated is not always obvious.

¹ For full definition of Pest Control Product, see section 2 of the *Pest Control Products Act*.



Table 1 Some examples of articles treated with antimicrobial preservatives

Examples of Uses for the Antimicrobial Preservative	Preservation Type	Purpose
Paints, fabric softener, laundry detergent, inks, joint compounds, adhesives, caulking, sealants	In-Can Preservation	To prevent or control microbial growth in aqueous-based solutions, which may cause deterioration prior to use. Helps to ensure product integrity during normal shelf life.
Paints, plastics, sealants, caulking, adhesives, grout, stucco	Dry-Film Preservation	To prevent or control microbial growth on films or coatings, which may cause aesthetic disfigurement. Also helps to maintain film integrity.
Awnings and tents, sails and ropes, clothing, footwear, PVC shower curtains	Fibre/Textile, Leather, Rubber and Polymerized Material Preservation	To prevent or control microbial growth in or on the material, which may cause deterioration or embrittlement, discolouration, fungal decay, aesthetic disfigurement, or odour.
Utility poles, lumber, joinery/millwork	Wood Preservation	To prevent or control microbial growth in wood to increase the service life of wood products, which are susceptible to premature failure from decay and insect damage.

What are the regulatory requirements for treated articles?

Treated articles are defined as a pest control product under the *Pest Control Products Act*. The antimicrobial preservative used to treat the article, is **always** required to be registered under the *Pest Control Products Act*; however, the PMRA will **not require** the registration of **some articles** treated with an antimicrobial preservative, if they meet certain criteria. Even though some articles may be exempt from registration (including documentation and renewals), they are still subject to regulatory oversight.

Treated articles that require registration

If a pesticide has been incorporated into or applied to an article **in order for the article to act as a delivery mechanism for the pesticide, the pesticide** (for example, insecticide) **and the treated article** (for example, clothing) **must each be registered** as a pest control product under the *Pest Control Products Act*. In this example, the clothing acts as a delivery mechanism for the pesticide when it is treated with an insecticide to repel mosquitoes or ticks.

Treated articles that require registration of the pesticide only

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. In this case, the PMRA will not typically require the registration of the treated article itself.



Thus, for articles treated with antimicrobial preservatives, the PMRA will generally exempt the article itself from registration, as long as the following conditions are met:

- 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 (in other words, the same use specified on the label of the registered end-use product²); and
- 3) the use is limited to preventing degradation or damage to the product from microorganisms.

Examples of Treated Articles regulated under the *Pest Control Products Act*

Table 2 provides some examples of treated articles that typically require or do not require registration under the *Pest Control Products Act*. In the table, all examples require the pesticide used to treat the articles to be registered. In the first five treated articles examples, the antimicrobial preservative is used to extend the life of the product itself and therefore the article itself **does not require** registration. However, in the case of packaging materials (for example, sheets, stickers) the antimicrobial preservative is protecting an external product and the treated article is considered a delivery mechanism and therefore the article **does require** registration.

Table 2 Some examples of treated articles regulated under the *Pest Control Products Act*

Treated Article	Registration of the Pesticide	Registration of the Article
Article is being preserved		
Paints treated with antimicrobial ³ preservative	Required	Not Required
Shower curtain treated with antimicrobial preservative	Required	Not Required
Lumber treated with antimicrobial preservative	Required	Not Required
Caulking treated with antimicrobial preservative	Required	Not Required
Clothing treated with antimicrobial preservative	Required	Not Required
Article acts as the delivery mechanism		
Packaging materials treated with antimicrobial pesticide to protect packaged products during transport	Required	Required
Mosquito repelling clothing treated with an insecticide	Required	Required
Herbicide-treated landscaping fabric	Required	Required

² Generally understood to be a pest control product consisting of its active ingredient and formulant(s).

³ The example of paints treated with antimicrobial does not include antifouling paint.



What does this mean for manufacturers and importers?

Manufacturers treating articles with antimicrobial preservatives in Canada are required to use an active ingredient and an end-use product that are registered under the *Pest Control Products Act* for that use.

For treated articles that have been imported, the end-use product used to treat the article (in the foreign jurisdiction) must contain an active ingredient that is also registered under the *Pest Control Products Act* in Canada for that same use.

This requirement applies to treated articles whether label claims are being made or not.

Is Canada's approach to Treated Articles similar to other Countries?

In practice, Canada's approach to articles treated with antimicrobial preservatives is aligned with similar jurisdictions such as the United States and the European Union. Alignment of regulatory approaches helps facilitate global markets. For domestically treated articles, each of these jurisdictions requires 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, all three jurisdictions require that the active ingredient used be registered in their jurisdiction for such use. The majority of antimicrobial preservatives used in manufacturing are currently registered in all three jurisdictions. Each country also has restrictions around label claims (for example, claims cannot be misleading).

Which antimicrobial preservatives are registered in Canada?

Canada has close to 50 antimicrobial active ingredients and approximately 500 antimicrobial preservatives registered currently that manufacturers can consider using when treating an article. You can confirm if an antimicrobial preservative is registered for use in Canada and for what specific use(s) it is registered (both active ingredient and end-use product) by:

- 1) checking the list of approved antimicrobial preservatives in Canada available through Health Canada's Pesticides and Pest Management web page;
- 2) searching the PMRA's pesticide label database; or
- 3) contacting the PMRA's Information Service (1-800-267-6315; hc.pmra.info-arla.sc@canada.ca).

If an antimicrobial preservative to be used for treatment of an article for use, import or sale in Canada is not yet registered in Canada (or not registered for that use), an application should be made by the registrant to register the active and/or the use.

How do I register my antimicrobial preservative in Canada?

Before a pesticide can be registered so it can be manufactured, imported, sold or used in Canada, the PMRA conducts a pre-market assessment to review scientific information to assess the acceptability of the health or environmental risk and to determine whether there is value in using



that product in Canada. The pre-market assessment (or registration) process requires the submission of a complete application for registration, which includes all required forms, fees and scientific data to support the product. Additional information on the registration process can be found in the Registrants and Applicants section or by consulting our various policy and guideline documents.

You may also contact the PMRA for a pre-submission consultation. This is a no-cost service offered by the PMRA that provides prospective applicants written guidance to help them generate and submit a complete, high quality application package to register a new pesticide or to amend the registration of an approved pesticide. For more information regarding pre-submission consultations, please refer to the frequently asked questions page on the PMRA website.

If the antimicrobial preservative is currently registered in another jurisdiction, such as the United States, can I use the same data package for registration in Canada?

Yes, you can submit a modern data package that was submitted for registration in other jurisdictions, along with all applicable Canadian forms required for registration. The PMRA encourages registrants to submit recent foreign reviews (for example, United States Environmental Protection Agency or European Union) with their data package, which can be taken into consideration during the PMRA's evaluation, and may represent sufficient evidence to support decision making in Canada.

While the Canadian and American regulatory approaches are closely aligned, we continue to explore opportunities to bridge regulatory differences. For example, the PMRA recently published new "Value Guidelines for New Antimicrobial Pest Control Products and Label Amendments", which provide a weight of evidence approach for value, from both efficacy and benefits information.

Are there restrictions on what claims can be made on the label?

Yes, the claims on articles treated with an antimicrobial preservative are limited to the effect of the antimicrobial preservative used to treat the articles. As per section 6 of the *Pest Control Products Act*, any misleading marketing claims that do not accurately reflect the purpose of the antimicrobial treatment are not permitted. You can refer to the *Acceptable Claims for Articles Treated with Antimicrobial Preservatives* document for general guidance on acceptable label claims. In addition, it is the responsibility of manufacturers, importers, retailers and distributors of articles treated with antimicrobial preservatives to follow Regulatory Directive DIR2016-01, *Guidelines for the Advertising of Pest Control Products*.

Does my registered treated article (for example, insecticide treated clothing that acts as a delivery mechanism for the insecticide) require a Pest Control Product number on the product?

Yes, all treated articles that require registration must include the Pest Control Product number assigned to that product on the product.



What does Health Canada do for the safety of consumer products?

Health Canada gathers information, both domestically and internationally, about injuries, emerging issues and new science related to consumer product safety and conducts routine sampling and testing of products in the marketplace. Health Canada works closely with the Canada Border Services Agency, and other domestic and international regulators, to verify the compliance of products being imported into Canada.

Health Canada takes a risk-based approach to identify health or safety issues for follow-up compliance and enforcement activity. For pesticides, Health Canada follows Regulatory Directive DIR2007-02, *Compliance Policy*, targeting regulated activities where actual/known or suspected non-compliance would result in an unacceptable risk or harm to Canadians or the environment. If an incident were to occur, Health Canada would take an immediate action. In circumstances where a significant risk to human health or the environment is identified, compliance measures are taken commensurate with the risk.

Under the *Canada Consumer Product Safety Act*, it is also mandatory for companies to report to Health Canada any health or safety incidents involving their consumer products. Consumers are also encouraged to report health or safety concerns to Health Canada, as well as to the company from which they purchased the products.

What's next?

Health Canada continues to work closely with stakeholders to increase awareness of the regulatory requirements for treated articles in Canada. If you have any comments or questions, contact the PMRA's Information Service at:

Toll-free	1-800-267-6315
Email	hc.pmra.info-arla.sc@canada.ca