



Protéger la santé humaine et l'environnement

Pest Management Regulatory Agency Questions and Answers – Treated Articles

General Questions:

01 What is a treated article? What types of products meet this definition?

The term "treated article" refers to a product or article that has been **intentionally** treated with a pest control product (commonly referred to as a pesticide), subject to the exception noted in question 2 (Q2). For example, fabric or plastic treated with pesticides that kill microbes (antimicrobials), clothing treated with pesticides that prevent insect bites to the person wearing the clothing (insecticides), and landscape fabric or roof shingles treated with pesticides that prevent plant growth (herbicides), are all considered to be treated articles.

Under the Pest Control Products Regulations (3) Subsection 1(1), the term "treated article": means an inanimate product or substance, but does not include a "food" as defined in section 2 of the Food and Drugs Act,

- a) that, during the manufacturing process, is treated with a pest control product either by intentionally:
 - i. incorporating the product into the article; or
 - applying it to the article, and ii.
- b) whose primary purpose, prior to that treatment, is not, directly or indirectly, to control, destroy, attract or repel a pest or to mitigate or prevent the injurious, noxious or troublesome effects of a pest.

Treated articles can be grouped into:

- 1. articles whose purpose is to deliver a pesticide;
- articles that are treated for the preservation of the article itself. 2.

Many different kinds of common household products can be treated with antimicrobials, including: paints; clothing and footwear; detergents; fabric softeners; plastic products, such as shower curtains; and wood and construction/masonry materials.

Q2 What types of products fall outside the scope of the treated articles definition?

If a treated article is itself a pest control product (including a pest control product device) prior to any treatment, then it is not a treated article. For example, a liquid herbicide or a rodenticide (both pest control products) might be treated with an antimicrobial preservative(s) to extend the life of the product. The product, in this case the herbicide or rodenticide, was a pest control product prior to being treated with a preservative and therefore would not be considered a treated article. The antimicrobial preservative used in these formulations would still require registration under the Pest Control Products Regulations.

Treated food likewise falls outside the treated articles definition.

Q3 What is meant by "antimicrobial" and "antimicrobial preservative"?

For treated articles, the term "antimicrobial" refers to pesticides used for the control of microorganisms (for example, bacteria, fungi, algae) on non-living items (in other words, articles/products).

An "antimicrobial preservative" is a chemical substance or a mixture of chemical substances, that is intentionally incorporated into, or applied to, an article for the purpose of preserving it from deterioration or degradation by preventing the growth of micro-organisms.

Q4 What does "intentionally treated with a pesticide" mean?

When a pesticide has been applied to an item, or is mixed in with an item, to control a pest, it is considered intentionally treated.

Q5 What are the regulatory requirements for treated articles?

Treated articles are pest control products under the *Pest Control Products Act*. The antimicrobial preservative used to treat the article is always required to be registered or otherwise authorized under the *Pest Control Products Act*; however, the Pest Control Products Regulations authorize (meaning registration is not required for them to be used and sold in Canada) some articles treated with an antimicrobial preservative if they meet certain criteria. Even though registration is not required for these authorized treated articles, they are subject to regulatory oversight under the *Pest Control Product Act*.

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 must each be registered under the *Pest Control Products Act*. Clothing treated with a pesticide that protects the wearer from mosquitoes or ticks is an example of a treated article that would have to be registered or otherwise authorized¹ under the *Pest Control Products Act*. This is because the pesticide is not used to protect the clothing, rather the clothing itself is used to deliver the pesticide to where it is needed. In this case, both the pesticide and the clothing treated with the pesticide must be registered or otherwise authorized as pest control products *Act*.

If the registration of this type of treated article was cancelled, the treated article could remain authorized for a period of time under subsection 21(5) of the *Pest Control Products Act* in accordance with the cancellation decision relevant to that treated article.

Treated articles that only require registration of the pesticide used to treat the article:

Both the antimicrobial preservative and the treated article are pest control products. Articles that have been treated with a pesticide to preserve the article itself usually do not themselves have to be registered under the *Pest Control Products Act*. Rather, the pesticide that is used to preserve that article must be registered or otherwise authorized under the *Pest Control Products Act* for that purpose (for example, to prevent damage to fabric or mould buildup in water-based paint).

Articles that have been treated with an antimicrobial preservative to protect them from microbial damage are authorized (meaning registration is not required) under the *Pest Control Products Act* as long as:

- 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 pesticide's approved uses under the *Pest Control Products Act* (in other words, the pesticide label says that it can be used on this type of article, and the article has been treated with approved rates)
- 3. the use is limited to preventing degradation or damage to the product from microorganisms.

Q6 Does the concentration of the pesticide in the finished article influence whether the product is a treated article?

No, as long as the pesticide was intentionally added to the article to control a pest, and the article does not fall outside the scope of the treated articles definition (see question 2 (Q2), then the finished article is considered to be a treated article. As noted in the answer to Q2, food treated with a pest control product falls outside the definition of a treated article. The concentration of the pesticide added to the finished treated article must be efficacious at controlling the pest (for example, microorganisms) and could require a different concentration for different materials. The article must be treated in accordance with the approved range of application rates, which is set out in the approved end-use product labels associated with the active ingredient.

Q7 Is Canada's approach to treated articles similar to that of other countries?

Canada's approach to regulating treated articles is very similar to those of our major trading partners such as the United States and the European Union. Having similar regulations makes it easier to trade with other countries. All three jurisdictions require the pesticide(s) used to treat an article be approved for that use.

There are also restrictions in each country about what claims can be put on the article label (for example, claims cannot be misleading).

Q8 What does Health Canada do for the safety of consumer products and pesticides?

Health Canada gathers information, both domestically and internationally, about injuries, emerging issues and new science related to consumer product safety and conducts inspections 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 followup compliance and enforcement activity. For pesticides, Health Canada follows Regulatory Directive <u>DIR2021-01</u>, *Compliance and enforcement policy for pesticides*, focusing its compliance verification activities to address the highest risks to human health and the environment. In circumstances where a significant risk to human health or the environment is identified, Health Canada will follow up and take enforcement actions commensurate with the risk when required. Under the <u>Canada Consumer Product Safety Act</u>, it is 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. Similarly, under the *Pest Control Products Act*, the PMRA's Pesticide Incident Reporting Program collects incident reports, which can help detect adverse effects that are not evident during the initial registration of a pesticide. In accordance with the *Pest Control Products Incident Reporting Regulations*, pesticide registrants and applicants are required to report to the Pest Management Regulatory Agency (PMRA) all incidents associated with their products. Other people in Canada are encouraged to submit <u>voluntary reports</u> of pesticide incidents. The PMRA uses incident reports to identify and characterize potential risk to humans, domestic animals or the environment from the use of pesticides. If a potential risk is identified, protective action may be taken, such as changes to how a pesticide may be manufactured, packaged, labelled, or used.

Articles that have been treated with an antimicrobial preservative for protection of the article itself:

Q9 Which antimicrobial preservatives are registered in Canada?

Canada has close to 50 antimicrobial active ingredients and approximately 500 antimicrobial preservatives (end-use products) currently registered that manufacturers may use when treating an article. You can confirm if an antimicrobial preservative is registered for use (and the approved rates) in Canada by:

- searching the PMRA's <u>Pesticide Product Information Database</u>; or
- searching the PMRA's <u>Pesticide Label Database</u>; or
- contacting the <u>PMRA's Information Service</u> (1-800-267-6315; pmra.info-arla@hc-sc.gc.ca).

If a manufacturer wishes to use an antimicrobial preservative to treat an article that is for use, import or sale in Canada and the preservative is not yet registered in Canada (or not registered for that use), an <u>application</u> should be made to register the antimicrobial preservative and/or the use.

Q10 How can I search the databases to find which antimicrobial preservatives are registered in Canada?

The <u>pesticide product information database</u> contains a listing of active ingredients and end-use products that are registered in Canada. In the Product search, antimicrobial preservatives fall under use-site category 18 – MATERIAL. This use-site category can be used to filter the search results.

To create a list of <u>registered products</u> under use-site category 18 - MATERIAL, you can enter the following information, using the drop-down lists:

- Search Rule 1: Filter = Use-Site Category; Operator = contains; and Value = 18 MATERIAL
- Add a second rule (+ Add rule button)
- Search Rule 2: Filter = Current/Historical; Operator = equal; and Value = Current
- Select "Search" to populate the results.

To verify the use patterns (in other words, use and approved rates) for an active ingredient, you can review end-use product labels via the <u>label search tool</u>.

- Search Field = Product Name; Operator = contains; Criteria = "insert product name"
- Select "Submit Search Requirements" to populate the product label
- Select "Registration Number" to view product label

Note: The label search engine has options in the search field that may be easier to find more similar products: The CAS# or active ingredient name option can pull up more hits than searching with a product name which can be case sensitive. Using wildcard "%" can be helpful when unsure of spelling.

Q11 How do I register my antimicrobial preservative in Canada?

Before a pesticide is registered in Canada, the PMRA conducts a scientific assessment of any potential health or environmental risks, and determines whether there is value in using that product in Canada. The premarket assessment (or registration) process requires the submission of a complete application for registration, which includes all required forms, fees and information, including scientific data, in support of the product application. Additional information on the registration process can be found in the <u>Registrants and Applicants</u> page on the <u>Pesticides</u> section of the Canada.ca website or by consulting our various <u>policy and guideline</u> documents.

You may also contact the PMRA for a pre-submission consultation. This is a no-cost service offered by the PMRA that provides written guidance to prospective applicants 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 <u>Registrants and</u> <u>Applicants page for Pre-submission Consultations</u> or the <u>frequently asked questions</u> page on the Pesticides section of Canada.ca.

Q12 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 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, from the United States Environmental Protection Agency or the 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.

The Canadian and American regulatory approaches are closely aligned,. 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, taking into account both efficacy and benefits information.

Q13 Can I request an expedited registration timeline?

Under the current <u>Management of Submissions Policy</u> (<u>4 May 2021</u>), an applicant may request an expedited timeline based upon a critical need. The intent of expedited reviews is to meet the urgent needs of users of pest control products, to facilitate risk reduction or to address a public health or environmental concern. For example, a formulation amendment to replace a formulant of concern, or products needed to mitigate a public health or environmental risk may be expedited.

The request to expedite the review of an application may only be considered after the preliminary science review stage is completed and PMRA has determined that all the information required to proceed with the evaluation has been submitted.

Q14 Do articles treated with antimicrobial preservatives require label claims on the packaging?

Authorized treated articles do not require label claims; but, label claims are permitted with restrictions. See question 15 (Q15) for more information on label claims.

If the antimicrobial has been incorporated into or applied to an article in order for the article to act as a delivery mechanism for the pesticide, then registration and labelling are needed.

Q15 Are there restrictions on what claims can be made on the label?

Claims on articles treated with an antimicrobial preservative must be consistent with the approved label for that antimicrobial. As per section 6(7) of the *Pest Control Products* <u>*Act*</u>, any misleading marketing claims that do not accurately reflect the purpose, registration status, etc., of the antimicrobial treatment are not permitted. You can refer to the <u>Acceptable Claims for Articles Treated with Antimicrobial Preservatives</u> 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*.

Q16 What is required of manufacturers and importers of articles treated with an antimicrobial preservative?

Manufacturers treating articles with antimicrobial preservatives in Canada are required to use an active ingredient(s) and an end-use product(s) that are registered or otherwise authorized under the *Pest Control Products Act* for that use and within the range of approved rates.

For imported articles treated with antimicrobial preservative(s), the end-use product used to treat the article (in the foreign jurisdiction) does not require registration in Canada, but that end-use product must contain an active ingredient(s) that is (are) registered under the *Pest Control Products Act* for that same use and the articles must be treated within the range of rates approved in Canada.

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

Q17 A container of pigment is treated with an antimicrobial preservative (A) for preservation of the pigment itself. Some of the pigment is later added to a can of paint for the purpose of colouring the paint. The paint is treated with an antimicrobial preservative (B) (in-can preservative) in order to protect the paint from deterioration. If this paint is then imported into Canada, does the antimicrobial preservative used in the pigment (A) need to be registered in Canada for that use?

In this example, the pigment is treated outside of Canada. As noted above, for imports it is only the active ingredient that needs to be registered in Canada (for that use), not the end-use product used to treat the article outside of Canada.

Antimicrobial preservative (A) used in the pigment would not require registration in Canada, as it was not intentionally added to the paint (the finished product for use, sale and distribution in Canada) to control a pest. The pigment was added for colouring the

paint, not preservation of the paint. Antimicrobial preservative (B), the in-can preservative, would require registration in Canada, as it was added for protection of the paint (the finished product).

If a container of the pigment was imported into Canada (as a finished product) then antimicrobial preservative (A) would require registration in Canada, as it was intentionally added to preserve the pigment.

Generally speaking, for imported products, only the antimicrobial preservative used to protect the finished product that is being imported into Canada requires registration.

Q18 A sofa has been treated in Canada with a material preservative to prevent growth of mould during shipping. Does the sofa require registration under the *Pest Control Products Act*?

The material preservative that is used to treat the sofa is required to be registered for the specific use in Canada to prevent the growth of microorganisms. However, the sofa itself is not required to be registered.

The article acts as a delivery mechanism to deliver the pesticide.

Q19 A piece of clothing has been treated with an insecticide to repel mosquitoes and ticks. Is the clothing required to be registered?

The clothing has been treated with an insecticide to protect the person wearing the garment from mosquitoes and ticks. This is an example where the clothing is acting as a delivery mechanism for the insecticide and is providing protection to the person wearing the clothing. The insecticide and the article would each require registration under the *Pest Control Products Act*.

Q20 Does my registered treated article (for example, insecticide treated clothing) require a registration number on the product?

Yes, all treated articles that require registration of the product must include the registration number assigned to that product, on, attached to or accompanying the product. In this example, the insecticide treated clothing would be required to display the registration number (for example, on a hangtag).

Q21 Do antimicrobial treated stickers or sheets used to protect products from microbes during shipping or storage require registration?

Yes, sheets or stickers that are treated with an antimicrobial preservative and placed with goods (for example, clothing, footwear, luggage) for the purpose of controlling odour-causing bacteria, mould and mildew require registration of the antimicrobial preservative and the sheet or sticker itself. In this case, the sheet or sticker acts as a delivery mechanism for the antimicrobial preservative, which is providing an external benefit to the goods, and not to the sheet or sticker itself.

Q22 Does landscape fabric treated with a herbicide require registration?

The landscape fabric has been treated with a herbicide to prevent weeds from growing. The fabric acts as a delivery mechanism for the herbicide. The fabric and the herbicide would both require registration under the *Pest Control Products Act*.

