

# Best Practices for Reporting Antimicrobial Content

Version: 2023-07-20

## BACKGROUND

HPD users have requested a more uniform and complete reporting method for substances added to building products to act as antimicrobial pesticides. This policy outlines the essential features of an optional reporting module to fulfill that intent.

Antimicrobial pesticides (often shortened as “antimicrobials”) are required to be reported as added ingredients on HPDs, using “typical” HPD reporting methodology based on the disclosure thresholds chosen. This module fulfills the following added functions:

- More detailed information on products with added antimicrobial pesticides, including regulatory registration numbers for those substances, and the status of the product with regard to health claims.
- More explicit information on whether antimicrobial pesticides are added. If antimicrobials do not appear on an HPD, HPD users may have additional questions about why they do not appear. Is it because they are added, but below the selected reporting threshold? Are they not added in any amount? This module provides a more complete report with regard to these substances, which are often added in low concentrations.

## USE OF THIS GUIDANCE IS OPTIONAL

This module is optional for manufacturers who want to publish a complete HPD. However, it is anticipated that HPD users with an interest in this topic may request it, and therefore manufacturers would have an incentive to use it.

## GLOSSARY

Antimicrobial pesticide<sup>1</sup>: Intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime. Synonyms: antibacterial, antiviral, antifouling, biocide, disinfectant, pesticide, antifungal, preservative

Public health claims: According to the U.S. EPA<sup>2</sup>, a product makes a public health claim if one or more of the following apply:

1. A claim is made for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals).

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<sup>1</sup> Aligned with U.S. Environmental Protection Agency (EPA) definition: <https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-registration>.

<sup>2</sup> <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>

2. A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.
3. A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against non-public health fungi.
4. A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.
5. A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which applied, and:
  - The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or
  - The pesticide product is similar in composition to a registered pesticide product that makes explicit antimicrobial public health claims.

### SCOPE

The scope of this module consistent with the scope of any HPD report (Supplier HPD or Product HPD): reporting of intentionally added substances above the selected threshold, whether added by the manufacturer completing the report, or by a supplier. In addition, this module provides guidance for reporting data on antimicrobials that may be present below the reporting threshold.

Reference the [current version of the HPD Open Standard](#) for complete guidance on the scope of an HPD.

### REPORTING THRESHOLDS

As a practical constraint, this policy sets 100 ppm as the recommended threshold for reporting on added antimicrobials.

At levels lower than 100 ppm, it becomes less likely that a manufacturer would have information on an added antimicrobial substance in their product, and/or that it would be intentionally added. However, thresholds above 100 ppm are expected to offer a less complete report on possible antimicrobials.

Manufacturers may also be aware of the use of antimicrobials below the reporting threshold, and they are encouraged to report those antimicrobials using this module. Specific prompts are included to facilitate this reporting.

### REQUIRED DATA and REPORTING OF DATA

*The following questions are used to gather the required data. Notes in this section also detail how this data will be reported on an HPD in Section 1: Inventory and Screening Notes, Section 2: Content in Descending Order of Quantity – Substance Notes, and Section 5: General Notes.*

### Question 1.

Does the product (or component/mixture from a supplier) contain substance(s) that are intentionally added above the selected \_\_\_\_\_ [100 ppm/1,000 pm/SDS/Other] threshold to act as antimicrobials?

**Yes,** to offer a public health benefit. The product is registered with public health claims.

**Resulting Display in Inventory and Screening Notes:** *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 pm/SDS/Other] threshold to act as antimicrobials to offer a public health benefit.*

**Informational Note:** This is uncommon. In this situation, the product itself is registered with the regulatory agency for its activity as a pesticide, and a public health claim can be made, e.g., a wallcovering containing an added antimicrobial that deactivates viruses, with a claim that there is a benefit to occupants.

If “Yes,” also answer the following **Question 1a.**

**What is the relevant registration number(s) for the product? Select and complete as many of the following as are applicable. If multiple numbers are relevant within the same registration scheme, list one, and then also select “Other” to add additional numbers:**

EPA Reg. No. \_\_\_\_\_

Health Canada PMRA Reg. No. \_\_\_\_\_

EU BPR Authorisation No. \_\_\_\_\_

Other (see Substance Notes)

**Resulting additional statement for Inventory and Screening Notes:** *The Product is registered as follows: [include all relevant registration numbers].*

**Informational Note:** It is recommended to add to the Product Notes any claims that are required under the relevant regulation, as well as information and/or links to efficacy testing, recommended applications, etc.

**Question 1.** responses cont. on next page

Question 1. responses cont.

**Yes, to protect the product or a component of the product. The antimicrobial substance is registered, and the product has a treated article exemption.**

**Resulting Display in Inventory and Screening Notes:** *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 pm/SDS/Other] threshold to protect the product or a component of the product. The antimicrobial substance is registered, and the product has a treated article exemption.*

**Informational Note:** This is common. A registered biocide is added to a product to protect the product from degradation, e.g., an antimicrobial is added to water-based paint to prevent it from fouling in the can prior to application. The U.S. EPA refers to this as a “treated article exemption,” as the product (the treated article) is exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). No claim of public health benefit can be made, although sometimes such claims are incorrectly made or implied.

**Yes, but the above options do not fit this situation. More information will be provided in the Substance Notes.**

**Resulting Display in Inventory and Screening Notes:** *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 pm/SDS/Other] threshold to act as antimicrobials. See Substance Notes and General Notes for more information.*

**Informational Note:** This choice may be appropriate in different regulatory environments than those anticipated by these questions, or other situations.

**No, antimicrobials are not added above the [100 ppm /1,000 ppm /SDS/ Other] threshold to act as such.**

**Resulting Display in Inventory and Screening Notes:** *Antimicrobial Pesticides Reporting: This product does not contain substance(s) that are intentionally added above the [100 ppm/1,000 pm/SDS/Other] threshold to act as antimicrobials.*

**Informational Note:** Thresholds above 100 ppm are considered less definitive. See further questions.

## Question 2.

Does the product (or component/mixture from a supplier) contain substance(s) that are intentionally added *below* the selected threshold to act as antimicrobials?

Yes, antimicrobials are known to be intentionally added below the reporting threshold and *are not reported* on this HPD.

Resulting additional statement for Inventory and Screening Notes: *Substance(s) are intentionally added below the selected threshold in this role and are not reported on this HPD.*

If answer to **Question 1** was "No," the reporting module is complete (skip remaining questions).

Yes, antimicrobials are known to be intentionally added below the reporting threshold and *are reported* on this HPD.

Resulting additional statement for Inventory and Screening Notes: *Substance(s) are intentionally added below the selected threshold in this role and are reported in Section 2 of this HPD.*

**Informational Note:** If selecting this option, please report those substance(s) in the HPD content inventory, even if they are below the reporting threshold.

No further information is known or available.

Resulting additional statement for Inventory and Screening Notes: *Information is not available as to whether the product contains substance(s) that are intentionally added below the selected threshold to act as antimicrobials.*

**Informational Note:** Select this option if you decline to give further information, or if you do not have information on below-threshold contents.

If answer to **Question 1** was "No," the reporting module is complete (skip remaining questions).

### Question 3.

What is the relevant registration number(s) for the material, and/or substance? Select and complete as many of the following as are applicable. If multiple numbers are relevant within the same registration scheme, list one, and then also select “Other” to add additional numbers:

EPA Reg. No. \_\_\_\_\_

Health Canada PMRA Reg. No. \_\_\_\_\_

EU BPR Authorisation No. \_\_\_\_\_

Other (see Substance Notes)

The question is not applicable based on my previous responses.

*Informational Note:* The summary of numbers will be noted to the manufacturer completing the HPD. They will be notified to add this information to the relevant Substance Note(s).

### Question 4.

Include any Substance Notes explaining and/or linking to more information on use of antimicrobials.

If under question 1 you selected “Yes, but the above options do not fit this situation,” then provide that information in the relevant Substance Note(s), i.e., what is the regulatory framework you are operating under and how are the antimicrobial substances addressed?

If you use antimicrobial pesticides, report any required regulatory claims or other information in the relevant Substance Note(s), and/or in General Notes for this HPD report.

*Example: Under U.S. EPA FIFRA regulation, a product using the treated article exemption must display appropriate clarifying statements, for example, “Antimicrobial properties are built in to inhibit the growth of bacteria that may affect this product. The antimicrobial properties do not protect users or others against bacteria, viruses, germs, or other disease organisms. Always clean and wash this product thoroughly before and after each use.”*

Consider adding to General Note any additional information on claims, efficacy testing, recommended applications, etc.

## Antimicrobial Reporting Test without Mockups

### Question 1.

Does the product (or component/mixture from a supplier) contain substance(s) that are intentionally added above the selected [100 ppm/1,000 pm/SDS/Other] threshold to act as antimicrobials?

Options for Question 1:

- Yes, to offer a public health benefit. The product is registered with public health claims.
  - If answered go to Question 1a.
  - Resulting Display in Inventory and Screening Notes: *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 ppm/SDS Other] threshold to act as antimicrobials to offer a public health benefit.*
- Yes, to protect the product or a component of the product. The antimicrobial substance is registered, and the product has a treated article exemption.
  - If answered, go to Question 2.
  - Resulting Display in Inventory and Screening Notes: *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 ppm/SDS Other] threshold to protect the product or a component of the product. The antimicrobial substance is registered, and the product has a treated article of exemption.*
- Yes, but the above options do not fir this situation. More information will be provided in the Substance Notes.
  - If answered, go to Question 2.
  - Resulting Display in Inventory and Screening Notes: *Antimicrobial Pesticides Reporting: This product contains substance(s) that are intentionally added above the [100 ppm/1,000 ppm/SDS Other] threshold to act as antimicrobials. See Substance Notes and General Notes for more information.*
- No, antimicrobials are not added above the [100 ppm/1,000 ppm/SDS Other] threshold to act as such.
  - If answered, go to Question 2.
  - Resulting Display in Inventory and Screening Notes: *Antimicrobial Pesticides Reporting: This product does not contain substance(s) that are intentionally added above the [100 ppm/1,000 ppm/SDS Other] threshold to act as antimicrobials.*

**Question 1a.**

What is the relevant registration number(s) for the product? Select and complete as many of the following as are applicable. If multiple numbers are relevant within the same registration scheme, list one, and then also select “Other” to add additional numbers:

Options for Question 1a:

- EPA Reg. No. \_\_\_\_\_
- Health Canada PMRA Reg. No. \_\_\_\_\_
- EU BPR Authorisation No. \_\_\_\_\_
- Other (see Substance Notes)

**After an answer, go to Question 2.**

Resulting additional statement for Inventory and Screening Notes: *This Product is registered as follows: [include all relevant registration numbers].*

**Question 2.**

Does the product (or component/mixture from a supplier) contain substance(s) that are intentionally added below the selected threshold to act as antimicrobials?

Options for Question 2:

- Yes, antimicrobials are known to be intentionally added below the reporting threshold and *are not reported* in this HPD.
  - End Antimicrobials Questionnaire.
  - Resulting Display in Inventory and Screening Notes: *Substance(s) are intentionally added below the selected threshold in this role and are not reported on this HPD.*
- Yes, antimicrobials are known to be intentionally added below the reporting threshold and *are reported* in this HPD.
  - If answered, go to Question 3
  - Resulting Display in Inventory and Screening Notes: *Substance(s) are intentionally added below the selected threshold in this role and are reported in section 2 of this HPD.*
- No further information is known or available.
  - End Antimicrobials Questionnaire.
  - Resulting Display in Inventory and Screening Notes: *Information is not available as to whether the product contains substance(s) that are intentionally added below the selected threshold to act as antimicrobials.*



**Question 3**

What is the relevant registration number(s) for the material, and/or substance? Select and complete as many of the following as are applicable. If multiple numbers are relevant within the same registration scheme, list one, and then also select “Other” to add additional numbers:

- EPA Reg. No. \_\_\_\_\_
- Health Canada PMRA Reg. No. \_\_\_\_\_
- EU BPR Authorisation No. \_\_\_\_\_
- Other (see Substance Notes)
- The question is not applicable based on my previous responses.

**After an answer, go to Question 4.**

The manufacturer is notified to add this information to the relevant Substance Note(s).

**Question 4**

Include any Substance Notes explaining and/or linking to more information on use of antimicrobials.

Reference the following for this question (these are not options for answering the question, just reference material):

- If under question 1 you selected, “Yes, but the above options do not fit this situation,” then provide that information in the relevant Substance Notes(s), i.e., what is the regulatory framework you are operating under and how are the antimicrobial substances addressed?
- If you use antimicrobial pesticides, report any required regulatory claims or other information in the relevant Substance Note(s), and/or in General Notes for this HPD report.
- Consider adding to General Notes any additional information on claims, efficacy testing, recommended applications, etc.

**Version Control**

DATE	CHANGE
7/11/22	Initial upload for HPD v2.3
7/20/23	Reflects the updates for the HPD Open Standard v2.3 update. New revision log added.