

Clarifying the Different Health and Safety Information Appearing on Antimicrobial Pesticide Labels and Safety Data Sheets for Disinfectants

Introduction

Products used to kill or reduce microbes are actually antimicrobial “pesticides”. Antimicrobial pesticides are categorized based on the type of microbial “pest” they are formulated and tested to be effective against¹. Some products control the growth of pests (e.g., algae) that do not pose a threat to human health, while others such as sanitizers and disinfectants, kill, reduce or mitigate growth of “pathogenic” microbes that are potentially harmful and can cause disease. They are commonly called germs.



Antimicrobial products are categorized as both a pesticide and a hazardous product, and are regulated under two different laws by two different federal agencies. Both of the following agencies govern the requirements for the content of a pesticide’s product health and safety information:

1. The Occupational Safety and Health Administration (OSHA) specifies content requirements for product hazards, precautions and safety and health information in the Safety Data Sheets (SDS) format under the Global Harmonized System (GHS) portion of the Hazard Communication Standard (HCS) (29 CFR 1910.1200).
2. The United States Environmental Protection Agency (EPA) specifies content requirements for antimicrobial pesticide labels under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

EPA requires a pesticide label to be the user’s guide to applying pesticides to minimize risk and maximize efficacy. The label provides information about how to safely and legally handle and use pesticide products. Pesticide labels are legally enforceable, and all of them carry the statement: “It is a violation of federal law to use this product in a manner inconsistent with its labeling.”²

What are the challenges to interpreting an antimicrobial product’s health information?

The health and safety information on an antimicrobial pesticide product’s label and an SDS can be different from each other, and at times, appear to be, or are actually conflicting. The inconsistencies in this information can cause confusion under the following circumstances:

1. It can be confusing to the end user if they are trying to use the information to make a product selection (e.g., trying to find the least toxic product).
2. The “workplace labels” used on secondary containers (e.g., spray bottles) of diluted product, may actually be hazard information about the concentrate, not the hazards of the diluted product. Please see the section in this document, *Labels on Secondary Containers of Antimicrobial Products*, for more information.

¹ National Pesticide Information Center, <http://npic.orst.edu/ingred/ptype/amicrob/index.html>

² Note that EPA does not recommend that other elements of the FIFRA label, such as directions for use, should be included.

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What are some of the differences between health information on the SDS and the pesticide information referenced on the same SDS?

Some differences are illustrated below for Purtabs,
a disinfectant tab, that is made into a solution:

Information SDS for the diluted product:	Pesticide Label Information in the SDS for the concentrate in tab form:
Section 2: Hazards Identification Section 9: Physical/Chemical Properties Section 11: Toxicological Information Section 16: Other Information	Section 16: Other information
Signal Word: WARNING	Signal Word: DANGER
pH 5.5 - 6.5 (not corrosive) <ul style="list-style-type: none"> • Causes serious eye irritation. • Harmful in contact with skin. • Harmful if swallowed. • Prolonged inhalation may be harmful. May cause irritation to the respiratory system. 	CORROSIVE <ul style="list-style-type: none"> • Causes irreversible eye damage and skin burns. • Harmful if swallowed, inhaled or absorbed through the skin.
Pictogram	N/A
Exclamation Mark  <ul style="list-style-type: none"> ▪ Irritant (skin and eye) ▪ Skin Sensitizer ▪ Acute Toxicity ▪ Narcotic Effects ▪ Respiratory Tract Irritant 	
Hazardous Materials Information Systems (HMIS) Hazard Ratings Health: 1 (note a corrosive is typically a 3 rating) Flammability: 0 Physical Hazard: 0	N/A
National Fire Protection Association (NFPA) Hazard Ratings Health: 1 Flammability: 0 Instability: 0	N/A

Why the Confusion?

The confusion is due to the fact that EPA has not adopted OSHA’s HCS GHS criteria; there are differences between EPA’s requirements and OSHA’s related to: classification criteria, hazard statements, pictograms, and signal words.

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How did EPA seek to reconcile these potential problems?

In order to avoid potential inconsistencies between EPA-approved labels for pesticides regulated under FIFRA, and the SDSs that OSHA requires under the HCS, EPA issued a clarification³ of its policy. EPA's recommended guidance⁴ is designed to prevent this problem as noted below:

“Generally, every pesticide sold or distributed in the United States must be registered by EPA (FIFRA § 12(a)(1)(A)). In granting a registration, EPA must determine that the pesticide's “labeling” complies with the requirements of FIFRA (FIFRA § 3(c)(5)(B)). In Section 2(p)(2)(A), FIFRA defines “labeling” to include all written, printed, or graphic matter accompanying the pesticide at any time. One of FIFRA's requirements for labeling is that it not be false or misleading in any particular.”

EPA's policy allows SDSs to accompany pesticides so long as they do not obscure or conflict with the labeling approved by EPA.

To provide an adequate explanation in the SDS so the pesticide labeling is not misleading, EPA recommends manufacturers include the following information in the product's SDS:

- FIFRA label information in their SDSs in Section 15, “Regulatory Information”.

The recommended information would provide a brief explanation for any differences between the pesticide label information and the SDS information, as well as FIFRA hazard statements (e.g., “fatal if swallowed”), signal word, and symbol (if required).

- EPA also recommends that the following general statement be included in the SDS Section 15:

“This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use. [Insert FIFRA label hazard information]

³ EPA, Pesticide Registration (PR) Notice 2012-1, April 20, 2012

⁴ FIFRA 2(p)(2)(A) EPA, Label Review Manual (for Pesticides), Revised July 2011

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What are other important points of note?

- OSHA does not require manufactures to complete SDS sections 12 (Ecological Information), 13 (Disposal Considerations), 14 (Transport Information), and 15 (Regulatory Information) of the SDS format specified by the HCS GHS.

EPA recommends that any information from the FIFRA label on hazards included in the SDS be located in SDS Section 15, or, for ecological hazards, in SDS Section 12.

- EPA does not recommend that other elements of the FIFRA label should be included, such as directions for use.
- FIFRA labels approved by EPA pre-empt OSHA’s label requirements.
- WPA only uses one symbol, the skull and crossbones, for severe acute toxicity and products containing methanol at concentrations above 4%. The GHS uses symbols for all hazard classes (but not all categories)⁵.
- EPA’s signal words on labels are different from OSHA’s signal words on labels:

Signal words indicate a product’s potential for making you sick. Regardless of how many hazards a chemical may have, there will only be one signal word on the label. The signal word for the highest hazard will appear on the label.

EPA prohibits the use of signal words for environmental or physical hazards⁶; the GHS mandates their use for some categories (e.g. extremely flammable liquids). Other differences are illustrated below:

EPA’s Signal Words	OSHA’s Signal Words⁷
“Caution” appears on products that are the least harmful to you.	
“Warning” means a product is more harmful than one with a “Caution” label.	“Warning” is used for the less severe hazards
“Danger” means a product is poisonous or corrosive and should be used with extreme care. GHS uses the “danger” signal word and skull and cross bones symbol for chemicals in Categories 1-3 (e.g., oral LD50 of up to 300 mg/kg) and introduces the exclamation point symbol for Category 4.	“Danger” is used for the more severe hazards. EPA uses the “danger” signal word and skull and crossbones symbol for chemicals in Categories I and II (e.g. oral LD50 of up to 50 mg/kg).

⁵ EPA, Chemical Hazard Classification and Labeling: Comparison of OPP Requirements and the GHS

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⁷ OSHA Brief: Hazard Communication Standard: Labels and Pictograms

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Conclusion

Although EPA has sought to minimize inconsistencies between the two sets of requirements for health information, it is obvious from the sample provided above that either there are significant inconsistencies between the information provided for many of the antimicrobial products that are considered to be safer, or the information is too technical for the layperson to interpret. If there are questions based on what appear to be inconsistencies or conflicting or confusing information, contact the manufacturer directly to clarify any concerns. Also, you can consult the EPA publication, *Chemical Hazard Classification and Labeling: Comparison of OPP Requirements and the GHS*, for a detailed comparison.

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Sample Pesticide Label with GHS Modifications for Illustration Purposes

Note: Although EPA developed the label comparison below, a statement on their webpage notes that; “EPA has not adopted GHS for pesticide product classification and labeling. In most cases, GHS hazard statements and pictograms should not appear on pesticide product labels sold and distributed in the United States.”

The following label is for an insecticide pesticide, not an antimicrobial pesticide.

Pesticide Label



Home and Garden
DUST

Contains XXX Biological Insecticide
Active ingredient:
XXX.....0.5%
INERT INGREDIENTS.....99.5%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

FIRST AID
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Have product container or label with you when calling a poison control center or doctor or going for treatment. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.
PESTICIDE STORAGE: Pesticide should be stored in the original container in a locked storage area.
PESTICIDE DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Arlington Agricultural Insecticides, Inc.
Arlington, VA 22202
EPA REG. No. XXX-XXX EPA EST. No. XXX-VA-1 Net Weight 2 lbs (.905 kg)

Pesticide Label with GHS Elements



Home and Garden
DUST

Contains XXX Biological Insecticide
Active ingredient:
XXX.....0.5%
INERT INGREDIENTS.....99.5%
TOTAL.....100.0%

 **KEEP OUT OF REACH OF CHILDREN**
WARNING

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
Harmful if inhaled. Avoid breathing dust. **Causes eye irritation.** **Causes mild skin irritation.** Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
Harmful to aquatic life. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

FIRST AID
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Have product container or label with you when calling a poison control center or doctor or going for treatment. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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Assigning the appropriate hazard communication elements to pesticide products requires knowledge of the product’s toxicity categories. The assumptions for the toxicity categories of the sample product are as follows:

Under Current OPP Requirements:

- Acute Inhalation Toxicity: Category III
- Acute Dermal Toxicity: Category IV
- Acute Oral Toxicity: Category IV
- Skin Corrosion/Irritation: Category III
- Eye Damage/Irritation: Category III
- Acute Hazard to the Aquatic Environment: N/A

Under GHS:

- Acute Inhalation Toxicity: Category 4
- Acute Dermal Toxicity: Unclassified
- Acute Oral Toxicity: Unclassified
- Skin Corrosion/Irritation: Category 3
- Eye Damage/Irritation: Category 2 B
- Acute Hazard to the Aquatic Environment: Category 3

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Illustration and Explanation of How to Read an Antimicrobial Label

Only products with EPA registration numbers should be used. This number indicates the product has been reviewed by the EPA and poses minimal risk to animals, people and the environment when used in accordance with the label.

Products must be used according to label directions. Disinfectants (i.e., antimicrobial pesticides) are regulated under the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act.

EPA Reg. No.
1638-XX

EPA Est. No.
163X-MD-1



Product-X

Disinfect-Cleaner-Sanitizer-Fungicide-Mildewicide* -
Deodorizer for Hospitals, Institutional and Industrial Use
Effective in hard water up to 400 ppm hardness (calculated as
CaCO₃) in the presence of 5% serum contamination

ACTIVE INGREDIENTS:	
Octyl decyl dimethyl ammonium chloride	1.650%
Dioctyl dimethyl ammonium chloride	0.825%
Didecyl dimethyl ammonium chloride	0.825%
Allyl dimethyl benzyl ammonium chloride	2.200%
INERT INGREDIENTS:	94.500%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

HAZARD TO HUMANS AND DOMESTIC ANIMALS

PRECAUTIONARY STATEMENTS

CORROSIVE: Causes severe eye and skin damage. Do not get into eyes, on skin, or clothing. Wear goggles or face shield and rubber gloves when handling Product X. Harmful or fatal if swallowed. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS: Do not use or store near heat or open flame.

STATEMENT OF PRACTICAL TREATMENT: In case of contact, immediately flush eyes or skin with plenty of water for at least 20 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If ingested call a physician immediately.

NOTE TO PHYSICIAN: Probable maximal damage may contraindicate the use of gastric lavage.

Manufactured by Y Chemical Company, Somerton, Illinois 62240

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DIRECTIONS FOR USE

Product X is a germicide, soapless cleaner and deodorant which is effective in water up to 400 ppm hardness in the presence of organic soil (5% serum). When used as directed, will not harm tile, terrazzo, resilient flooring, concrete, painted or varnished wood, glass or metals.

FOR USE IN VETERINARY CLINICS, ANIMAL CARE FACILITIES, LIVESTOCK FACILITIES AND ANIMAL QUARANTINE AREAS

Apply Product X to walls, floors and other hard (inanimate) non-porous surfaces with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. Prepare a fresh solution daily or when use solution becomes visibly dirty.

DISINFECTION: To disinfect hard surfaces, use 1 fluid ounce of Product X per gallon of water. Apply by immersion, flushing solution over treated surfaces with a mop, sponge or cloth to thoroughly wet surfaces. Allow treated surfaces to remain moist for at least 15 minutes before wiping or rinsing. Product X will disinfect hard, non-porous surfaces in veterinary clinics, animal care facilities, livestock facilities and animal quarantine areas.

For heavily soiled areas, a preliminary cleaning is required.

2 oz. gallon use-level. The activity of Product X has been evaluated in the presence of 5% serum and 400 ppm hard-water by the AGAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

<i>Pseudomonas aeruginosa</i>	<i>Enterobacter aerogenes</i>
<i>Staphylococcus aureus</i>	<i>Streptococcus faecalis</i>
<i>Salmonella choleraesuis</i>	<i>Shigella dysenteriae</i>
<i>Escherichia coli</i>	<i>Divulobacterium ammontagenes</i>
<i>Streptococcus pyogenes</i>	<i>Salmonella typhi</i>
<i>Klebsiella pneumoniae</i>	<i>Serratia marcescens</i>

Boot bath: Use 1.5 fluid ounces per gallon in boot baths. Change solution daily and anytime it becomes visibly soiled. Use a bristle brush to clear soil from boots before disinfecting with Product X.

Disinfecting trucks and farm vehicles: Clean and rinse vehicles and disinfect with 1 fluid ounce per gallon of Product X. If desired, rinse after 12 minutes contact or leave untreated. Do not use Product X on vaccination equipment, needles, or diluent bottles as the residual germicide may render the vaccines ineffective.

Sanitizing non-food contact surfaces (such as floors, walls, tables, etc.) A 1 ounce per 2 oz. gallon use-level, Product X is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

This section will describe the hazards related to humans and animals when using this product. It recommends personal protective gear that should be worn, what effects it will have on the environment and treatment information should it be splashed into the eyes or ingested.

Some products may have multiple uses (i.e., cleaning versus disinfection) and require different dilutions and contact times for such actions.

This section describes what disease organism the product works against and under what conditions it was tested.

This section describes what dilutions should be used for different applications. Specialty applications (e.g., boot baths) will also be listed.

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Overview - Labels on Secondary Containers of Antimicrobial Products

The following information is provided to help explain another related, but separate issue that is potentially misleading. This issue is also a consequence of the label being governed by two different agencies.

A primary container is the original container a product comes in with the manufacturer's label. A secondary container is any container holding a product which is not the original container supplied by the manufacturer. It is most often used in schools for diluting and applying a product.

EPA does not require labels on secondary containers. OSHA does have requirements that apply for "workplace" labels under the HCS GHS. Please see the OSHA sample workplace label with requirements highlighted at the end of this document.

EPA

- **What are EPA's recommendations⁸ for information to be included in OSHA workplace labels on secondary containers?**

EPA recommends that the applicator identify the material in the secondary container in the event of a spill to ensure that adequate information can be obtained in case of medical or environmental emergency. EPA recommends that such labels include the following information:

- The name, address and telephone number of the applicator/pest control firm [if applicable].
- Product name.
- EPA registration number.
- Name and percentage of active ingredient.
- If the product in the container is diluted, it should be followed by the phrase:
"The product in this container is diluted as directed on the pesticide product label."
- **Signal word and precautionary statements (including First Aid statements) from the registered label unless the registrant has acute toxicity data supporting lesser precautionary statements for the diluted product and alternate directions for the diluted product are indicated on the product label. The secondary container may have reduced precautionary language (if supported by dilution-specific acute toxicity data) but not a reduced signal word.**
- The statement:
"Follow the directions for use on the pesticide label when applying this product."

⁸ EPA, <https://www.epa.gov/pesticide-labels/secondary-containers-and-service-containers-pesticides>

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Note: Information provided in a pesticide label is considered a regulatory requirement governing use of an antimicrobial product. If someone does not follow these directions, it is considered a violation of the law. Thus, EPA's recommendation to include this statement on the label reinforces this requirement.

- **What is EPA's position on manufacturers providing ready-made labels on secondary containers?**

- EPA also allows manufacturers to provide labels to users for secondary containers that are used to apply or temporarily store end-use pesticides, as long as the labels are not inconsistent (e.g., have no other statements that conflict), with the EPA approved pesticide label.

- **What is EPA's position on ingredient information on the workplace label?**

The percentage of active ingredient listed on the secondary container may reflect the concentrated product, or if known, the percentage of active ingredient in the end-use dilution. Listing the percentage of active ingredient as reflected on the product label and indicating the product has been diluted as directed relieves the user from having to calculate the percentage of active in the dilute formulation.

Such a calculation can be difficult for the average user when the directions for use call for a ratio of product to diluent, (e.g. 1-part product to 64 parts diluent or 5 ounces of product to 128 ounces of water), and the directions do not list the percentage of active ingredient in the finished dilution.

- **Why is the ingredient information a concern?**

Some diluted products in secondary containers have manufacturer's labels with information from the concentrate. Cross check with the concentrate's label with the label on the "ready to use" product because the manufacturer may have provided the same label for both the concentration and the dilute. This is important information to distribute with the product for end users to understand the hazard level and precautions for the product.

