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ANTIMICROBIAL REGULATORY OVERVIEW

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INTRODUCTION

The U.S. EPA regulates antimicrobial pesticides, which include sanitizers, disinfectants and sterilants. Testing must be performed following specific guidance and methods to be eligible for label claims. The testing required includes toxicology, analytical chemistry and product efficacy. It is important to know what is required before you begin testing your product.

ANTIMICROBIAL PESTICIDE TESTING

When are Antimicrobial Products Considered to be Public Health Pesticides?

According to FIFRA, the term "public health pesticide" applies to a registered pesticide product used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria or other microorganisms that pose a threat to public health.

What Type of Testing is Required for Antimicrobial Pesticides?

In order to register an antimicrobial pesticide, the EPA requires registrants to generate scientific data necessary to address concerns regarding product identity, composition, potential adverse effects, efficacy and the environmental fate of the product.

PRODUCT IDENTITY AND COMPOSITION-- PRODUCT CHEMISTRY TESTING

According to 40 CFR Part 158 Subpart D, manufacturers of pesticide products must provide general formulation and production information for the product as well as scientific data related to the identity and composition of the product. The testing used to generate these data follows the 830 series guidelines developed by the Office of Chemical Safety and Pollution Prevention (OCSPP). The following data are often required:

- Identity and composition of the active ingredient
- Physical chemistry data including but not limited to: color, physical state, odor, pH, viscosity, density, oxidation/reduction potential, and flammability
- Storage stability testing and corrosion assessment of the product containers

TOXICOLOGY TESTING

According to 40 CFR Part 158 Subpart F, toxicology data must also be developed for the pesticide to determine the degree to which a substance can be safely used. Typical toxicology testing includes but may not be limited to:

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Primary Eye Irritation
- Primary Dermal Irritation
- Dermal Sensitization

PRODUCT EFFICACY TESTING

Antimicrobial pesticides bearing public health claims generally fall into one of the following categories listed in order of highest potency to lowest potency:

Sterilizers, Sterilants or Sporicides: Eliminate (kill or inactivate) all microbes including spores.

Disinfectants: Either hospital type, general use or limited, which destroy or permanently inactivate bacteria, fungi, virus but not necessarily bacterial spores.

Sanitizers: Reduce the number of microorganisms (typically limited to bacteria) in the inanimate environment.

The EPA requires antimicrobial pesticides bearing public health label claims be tested according to the OCSPP 810 Product Performance Test Guidelines in accordance with Good Laboratory Practices (GLPs). The harmonized guidelines specify the methods that the EPA recommends be used to generate data to support the antimicrobial effectiveness of the product. Generally, a base claim needs to be made against standard organisms before additional organism claims can be made. In most studies, representative surfaces (carriers) are contaminated with the specified test organism and exposed to the product. After the specified exposure time, the activity of the product is halted and the survivors are evaluated to determine efficacy. Once efficacy is demonstrated using three separate batches of product, additional organism claims may be made, typically by testing two batches of product. Below is a sample of claims that can be made with EPA and the associated testing required.

Claim	Category	Test Method	Base (Specified) Test Organisms	EPA Guidance Document
Sporicide	Soak	AOAC 966.04 Sporicidal Activity of Disinfectants	Clostridium sporogenes Bacillus subtilis	810.2100 - Sterilants, Sporicides and Decontaminants https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0150-0035
Disinfectant	Soak/Mop	AOAC 955.14, 955.15, 964.02 Use Dilution	Staphyloccus aureus Salmonella enterica Pseudomonas aeruginosa	810.2200 - Disinfectants for Use on Environmental Surfaces https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0150-0036
	Spray	AOAC 961.02 Germicidal Spray Products as Disinfectants		
	Wipe	AOAC 961.02 Germicidal Spray Products as Disinfectants (Modified)		
Tuberculocidal	Soak/Mop, Spray, Wipe	AOAC Tuberculocidal Activity Method 965.12	Mycobacterium bovis - BCG	
Fungicide	Soak/Mop, Spray, Wipe	AOAC 955.14 Use Dilution; AOAC 961.02 Germicidal Spray Products as Disinfectants	Trichophyton interdigitale (formerly Trichophyton mentagrophytes)	
Viricide	Soak/Mop, Spray, Wipe	ASTM E1053: Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces	Each virus to be claimed on label must be tested	
Clostridium difficile	Liquid	EPA MLB SOP MB-31: Quantitative Method for Testing Antimicrobial Products Against Spores of Clostridium difficile (ATCC 43598) on Inanimate, Hard, Non-porous Surfaces	Clostridium difficile - spore form (ATCC 4598)	https://www.epa.gov/pesticide-analytical-methods/antimicrobial-testing-methods-procedures-mb-31
Candida auris	Liquid	EPA MLB SOP MB-35: Quantitative Method for Evaluating the Efficacy of Liquid Antimicrobials against Candida auris on Hard, Non-porous Surfaces	Candida auris	https://www.epa.gov/pesticide-analytical-methods/antimicrobial-testing-methods-procedures-mb-35-03
Biofilm	Liquid	EPA MLB SOP MB-20: Single Tube Method for Determining the Efficacy of Disinfectants against Bacterial Biofilms	Staphylococcus aureus Pseudomonas aeruginosa	https://www.epa.gov/pesticide-analytical-methods/antimicrobial-testing-methods-procedures-mb-20-03
Sanitizer	For Food Contact Surfaces	AOAC 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants	Staphylococcus aureus Escherichia coli	810.2300 - Sanitizers for Use on Hard Surfaces - Efficacy Data Recommendations https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0150-0022
	For Non-Food Contact Surfaces	ASTM E1153 Efficacy of Sanitizers	Staphylococcus aureus Klebsiella pneumoniae or Enterobacter aerogenes	

ANTIMICROBIAL PESTICIDE CONSIDERATIONS

Benjamin Franklin once said, “By failing to prepare, you are preparing to fail.” Here are some key items to prepare for when developing an antimicrobial pesticide:

1. Understand the Marketplace and Regulatory Landscape

Understanding the claims you want to make and the claims you can make with your antimicrobial product before you begin formulating and testing will save you time and money. A reputable product testing laboratory or experienced regulatory consultant can help successfully pave the way from product development to formal pesticide registration in an efficient manner.

2. Do Your Research Before Doing Your Research

There are a variety of testing labs and testing programs out there. Research a laboratory with a proven GLP-compliant testing program and successful antimicrobial registrations. As the old adage goes, you often get what you pay for. Partner with organizations that will deliver high-quality, accurate and timely results.

3. Develop an Effective Testing Plan

Time is money. Understanding the biggest challenges your product will face from a testing standpoint will allow you to develop a testing plan that is both time-effective and cost-effective. An experienced laboratory or regulatory consultant can help you develop a testing plan that suits your budget and meets your timeline.

How We Can Help

In addition to providing the highest quality antimicrobial efficacy testing services in the industry, we also offer analytical chemistry testing to provide a streamlined approach to product registration. Our experience in executing test methodologies and understanding of regulatory requirements enables us to provide clients with the guidance needed to successfully navigate product development and registration activities.

CONCLUSION

If you plan to market your sanitizer, disinfectant or sterilant, you must ensure you are following the regulatory guidance and methods required by U.S. EPA for label claims. Developing a robust testing plan that includes toxicology, analytical chemistry and product efficacy testing will set your product and your company up for success. The regulatory requirements for antimicrobial products are rigorous and are designed ensure human health and well-being, as well as ecological integrity.

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