



**ACCURATUS**  
— LAB SERVICES —  
THE ANTIMICROBIAL AUTHORITY

# **ANTIMICROBIAL REGULATORY OVERVIEW**

**UNDERSTANDING EPA CHEMISTRY DATA  
REQUIREMENTS OF ANTIMICROBIAL PRODUCTS**

**WHITE PAPERS**

# Antimicrobial Regulatory Overview

## 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 is 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** – which 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** – which reduce the number of microorganisms (typically limited to bacteria) in the inanimate environment.

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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 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.

Table 1: Stability Study Framework

Claim	Method	Base (Specified) Test Organisms	Test Parameters (for the base organism)	Success Criteria for Efficacy	Additional Organisms	
<b>Sporicide</b>	AOAC 966.04 Sporicidal Activity of Disinfectants	<i>Clostridium sporogenes</i> , <i>Bacillus subtilis</i>	3 batches 2 carrier types 60 carriers	Kill on 720/720 carriers	Not Applicable	
<b>Disinfectant</b>	Soak/Mop	AOAC 955.14, 955.15, 964.02 Use Dilution	<i>Staphylococcus aureus</i> , <i>Salmonella enterica</i> , <i>Pseudomonas aeruginosa</i>	SA: 57/60  SE: 59/60  PA: 54/60	Fungi, TB, antibiotic-resistant organisms, pathogens of environmental or clinical relevance, viruses	
	Spray	AOAC 961.02 Germicidal Spray Products as Disinfectants	<i>Staphylococcus aureus</i> , <i>Salmonella enterica</i> , <i>Pseudomonas aeruginosa</i>	3 batches 60 carriers ≤10 minute exposure time		
	Wipe	AOAC 961.02 Germicidal Spray Products as Disinfectants (modified)				
<b>Sanitizer</b>	For Food-Contact Surfaces	AOAC 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants	<i>Staphylococcus aureus</i> , <i>Escherichia coli</i>	3 batches 30 second exposure time	99.999% (5 log <sub>10</sub> ) reduction over the control	Relevant food-borne pathogens (e.g. E. coli O157:H7)
	For Non-Food Contact Surfaces	ASTM E1153 Efficacy of Sanitizers	<i>Staphylococcus aureus</i> , <i>Klebsiella pneumoniae</i> or <i>Enterobacter aerogenes</i>	3 batches 5 carriers ≤5 minute exposure time	99.9% reduction over the control	Bacterial pathogens of environmental or clinical relevance

# Antimicrobial Regulatory Overview

## What to Consider When Developing An Antimicrobial Pesticide?

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.

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.

## How We Can Help

## About Accuratus Lab Services

Accuratus Lab Services is the trusted partner and industry leader to the developers, manufacturers, and the users of antimicrobials and has been for over 25 years. We provide our clients with the most comprehensive range of microbiology, virology, and product chemistry services to support product development, claims, regulatory registration, and end-use validations of antimicrobial products used in most industries. Accuratus Labs is continuously expanding capabilities to serve the antimicrobial, medical device, pharmaceutical, paints and coatings, treated fabrics, cosmetic and personal care industries and more.

Our client-focused scientific, quality assurance, technical staff has built an unparalleled reputation for technical expertise, regulatory compliance knowledge, and superior client service. Our scientific data is of the highest quality and our reports have earned distinguished record of acceptance with regulatory agencies in the United States, Canada, and abroad.

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