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Antimicrobial Pesticide Registration 101

A step-by-step resource to help individuals navigate the antimicrobial pesticide registration process

Disclaimer

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The following information is intended to be a high-level guide to preparing and submitting a basic antimicrobial pesticide application. This guide should not be relied upon exclusively. First time applicants should still consult EPA and consider engaging with experienced personnel (e.g., third party consultants).

Objectives

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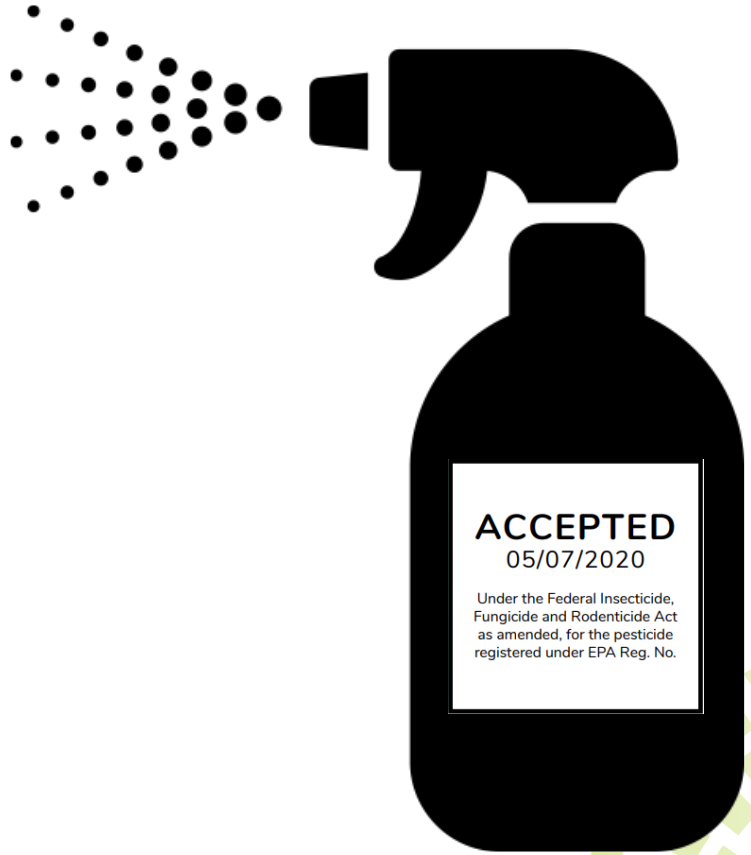
- General overview for preparing and submitting a basic antimicrobial pesticide application

- Provide a "toolbox" of important resources



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Introduction

Registration is Required by Law

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Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Federal statute that governs the registration, distribution, sale, and use of pesticides in the United States.
- With certain exceptions, a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, or any nitrogen stabilizer. (40 CFR § 152.3)
  - An antimicrobial is a pesticide

Registration Required to go to Market

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Requires data to demonstrate the products do not have "unreasonable adverse effects" on man or the environment (7 U.S. Code § 136)

Pesticides must be registered by EPA before they can be marketed.

EPA's acceptance takes the form of a stamped, accepted label, called a "registration."

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Office of Pesticide Programs Organizational Chart

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Registering Antimicrobial Pesticides

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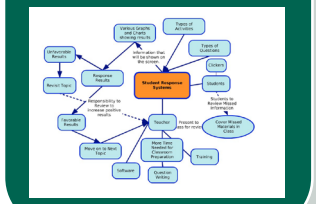
Information Collection



Pre-Application Meeting

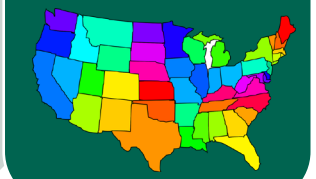
Pre-Submission

Application Submission

Post Submission

EPA Decision

State Registration



[Key Resource: EPA Pesticide Registration Manual]

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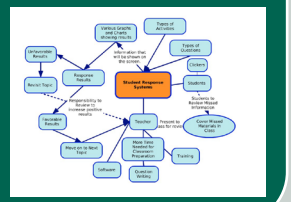
Step 1: Information Collection

Information Collection



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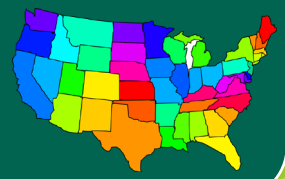

Information Collection "Checklist"

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- ❑Type of Registration
- ❑Active & Inert/Other Ingredients
- ❑Options to Fulfill Data Requirements
- ❑Draft Label
- ❑PRIA Code

Types of Registrations

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Manufacturing Use Product (MUP): These products are used to formulate other EPA-registered pesticides.

- Example: an 80% concentrate of DDAC used to formulate a 3% ready-to-use product

End Use Products (EPs): These products generally are applied by users as antimicrobial pesticides

- Examples: hard surface disinfectant or material preservative used in household paint manufacturing

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Ingredients

Actives: Does your product include active ingredients that are already approved for the proposed use(s) by EPA?

- If yes, data citation may be possible, reducing time and testing but imposing compensation obligation
- If no, all applicable data requirements must be met

Active Ingredient Chemical Search

Pesticide Product Label System (PPLS)

National Pesticide Information Retrieval System (NPIRS)

Inerts/Other: Does your product include inert ingredients already approved for the proposed use(s)?

InertFinder (for single ingredient)

Trade Name Database

Commodity Inert Ingredients

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Commonly used inert ingredients that **do not** require the applicant to provide specific information on the supplier.

Tip: use CAS # to identify inerts to avoid name confusion.

https://www.epa.gov/pesticide-registration/commodity-inert-ingredients

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Determining How to Fulfill Data Requirements

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What are the relevant data requirements?

How do you plan to meet applicable data requirements?

Are there any data compensation obligations associated with data already submitted to EPA that you plan to rely upon?

<u>Tip:</u> consider using outside experts or consultants

Pesticide Data Requirements: 40 CFR Part 158

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Division	Type of Pesticide	Applicable Data Requirement
RD	Conventionals	Subpart D – Product Chemistry Subpart E – Product Performance Subpart F – Toxicology Subpart G – Ecological Effects Subpart K – Human Exposure Subpart L – Spray Drift Subpart N – Environmental Fate Subpart O – Residue Chemistry
BPPD	Biochemicals	Subpart U – Biochemical Pesticides
BPPD	Microbial	Subpart V – Microbial Pesticides
AD	**Antimicrobials**	**Subpart W – Antimicrobial Pesticides**

Antimicrobial Data Requirements: 40 C.F.R. Subpart 158W

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40 CFR §	Description
158.2210	Product Chemistry
158.2220	Product Performance – data must be submitted to support any public health claim
158.2230	Toxicology
158.2240	Nontarget Organisms
158.2250	Nonplant Protection
158.2260	Applicator Exposure
158.2270	Post-application Exposure
158.2280	Environmental Fate
158.2290	Residue Chemistry
**** Pay particular attention to the associated footnotes ****	

Options for Fulfilling Data Requirements

Supply the data

- Provide requested study report
  - Formatting Requirements: PR Notice 2011-3 "Standard format for Data submitted Under FIFRA and Certain Provisions of FFDAC"
- Cite to data already in EPA's database
- Bridge to existing data

OR

Request a waiver based on a scientific rationale

OR

Indicate the data is "Not Applicable" and provide the rationale

Data Citation and Compensation

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Rely upon data for registered actives if you make an effort to reasonably compensate the original data submitter for any data submitted to EPA within the last 15 years. (FIFRA Section 3(c)(1)(F)(iii))

Identify data owners from EPA's most recent data submitters list

Good faith offer-to-pay letter

Failure to provide may result in costly disputes

- binding arbitration or
- a petition EPA by data submitter to deny, cancel or suspend registration where an OTP is not received or is invalid/inadequate

Resources on Data Requirements

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- Test Guidelines for performing the required studies
- EPA Cost Estimates for Studies Required for Pesticide Registration
- Data Submitter's List (for citing to data)
- Third Party Consultants
- GLP Certified Laboratories

Information Collection "Checklist"

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- ✓Type of Registration
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- ❑Draft Label
- ❑PRIA Code

"The Label is the Law"

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- Regulated federally under 40 CFR 156
- Includes certain marketing materials, websites, etc.
- Establishes product claims
- Products must be sold with language required by EPA-accepted labels.
- Master Label vs. Product label

Drafting a Label

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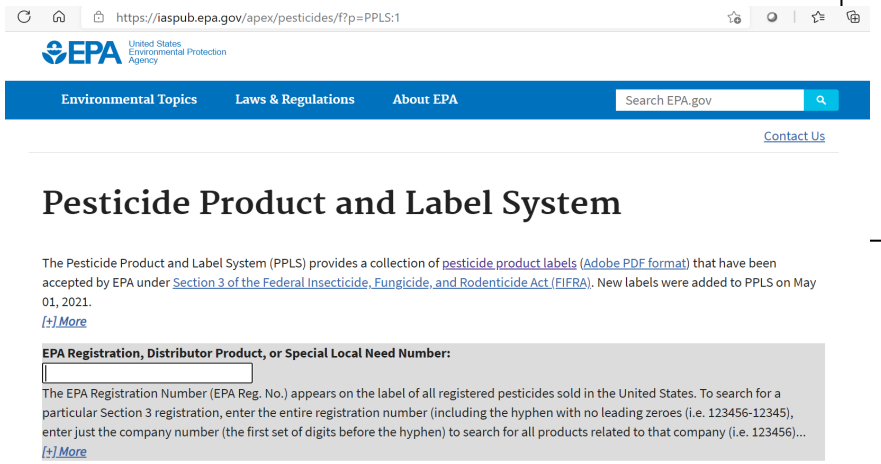
Resources:

- Label Review Manual
- Pesticide Product Label System (PPLS)
- PR Notices



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What is a PRIA Code?

- Pesticide Registration Improvement Extension Act of 2018 (PRIA 4)
  - Registration service fee system for applications for specific pesticide registration actions.
  - Fee waivers of 50-75% possible for small businesses

- Decision Tree for Antimicrobial PRIA Fee Determinations

- Antimicrobial Ombudsman: pesticidequestions@epa.gov

PRIA Code Example

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Table 9 - New Registration, Substantially Similar End Use Product

Antimicrobial Active Ingredient Registration for End Use Product

Below is the fee for your selected Fee Category for Fiscal Years 2020–2021

Action Code	Description	FY'20-FY'21 Fee	Decision Time (months)
A530	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2) (3)	$1,342	4

Note: 21-day "front end" screen added to all PRIA timelines for EPA completeness check

Information Collection "Checklist"

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- ✓Type of Registration
- ✓Active & Inert/Other Ingredients
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Step 2: Pre-Application Meeting

Information Collection

Pre-Application Meeting

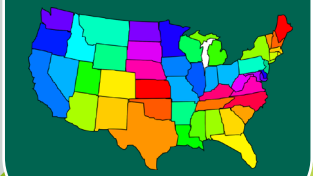
Pre-Submission

Application Submission

Post Submission

EPA Decision

State Registration



Required Materials

- AD-specific meeting request form
- Proposed label
- Proposed agenda and topics for discussion

Tip: Provide a detailed slide presentation summarizing more detailed information on your application and available data.

Pre-Application Meeting Resources

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Resources:

- Antimicrobials Division Contacts
- EPA Pre-Application Meeting Guidance

TIP: take notes during the meeting to include in your application package

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Step 3: Pre-Submission

Information Collection

Pre-Application Meeting

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Pre-Application Meeting Output

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Were any changes to the proposed label suggested by EPA?

Were there any changes to your proposed use patterns, or specific pests proposed for public health products?

Were there any changes to the proposed plan to fulfill data requirements?

Did you agree on the appropriate PRIA code?

Data Generation

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Estimated Timelines

- Acute toxicity data ~ 3-6 months
- Efficacy data ~ 3-4 months
- Product chemistry data ~ 2-3 months
- Generic data requirements can take anywhere from 3 months to 2 years to complete

Other Pre-Submission Steps

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- Paying PRIA Fees
  - Pay.gov
  - Proof of payment must be included with application

- Send out any required "Offer to Pay" Letters

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Step 4: Application Submission

Information Collection

Pre-Application Meeting

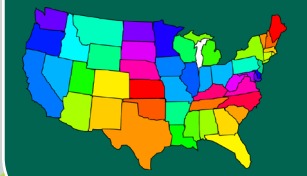
Pre-Submission

Application Submission

Post Submission

EPA Decision

State Registration



How to Submit Your Application

Create a CDX account (provides access to the Pesticide Submission Portal)

- https://cdx.epa.gov/
- New Registrants must request a company # to include in the unique registration number assigned to your approved products.
- On Site formulations require an establishment #

Create a "shell" of your submission in the Pesticide Submission Portal (PSP)

- Create a unique password – DO NOT LOSE THIS!
- Define the name/nature of the package
- Note if package needs to be expedited

Upload Required Items to "shell"

Tip: create a checklist of required forms and reports

Required Items for Submission

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Administrative-Level Items

- Cover letter
- Transmittal Document
- Proof of PRIA Payment
- Small business waiver (if applicable)

Package-Level Items

- Label
- Required forms (See Reference Materials)
- Formatted Data and Data Summaries

Forms:

★ 8570-1	Application for Pesticide Registration/Amendment (Note: Do not be concerned that the Internet copy of this form may not have a red number in the upper right-hand corner. EPA will fill in this number upon receipt.)
★ 8570-4	Confidential Statement of Formula (CSF)
8570-5	Notice of Supplemental Distribution of a Registered Pesticide Product
8570-27	Formulator's Exemption Statement
8570-28	Certification of Compliance with Data Gap Procedures
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data
8570-34	Certification with Respect to Citations of Data (as referenced in PR Notice 98-5)
★ 8570-35	Data Matrix (as referenced in PR Notice 98-5)
★ 8570-36	Summary of the Physical/Chemical Properties (as referenced in PR Notice 98-1)
8570-37	Self-Certification Statement for the Physical/Chemical Properties (as referenced in PR Notice 98-1)

★ Required for most basic packages.

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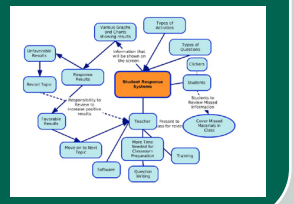
Step 5: Post-Submission

Information Collection



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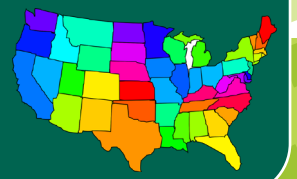

EPA Review Milestones (PRIA Actions only)

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Applicant receives emails for the following milestones

1. Application received
2. PRIA Category assigned
3. Data sent to review
4. 45/90 day Technical Screen ended (automatic)
5. Actual last science review completed
6. Pre-decisional determination date reached (automatic)
7. Regulatory decision completed

NOTE: Some of these are automatically generated emails.

Confirmation of Receipt from EPA

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From: PRIARegistrationTracking@epa.gov
Sent: Thursday, October 12, 2017 9:51 AM
To: [redacted]
Cc:
Subject: [redacted] PRIA TRACKING MILESTONE # 1

Email: [redacted]

Your application dated 10/09/2017 for a New Registration, [redacted] has been received by EPA's Office of Pesticide Programs.

Receipt number assigned: [redacted]
EPA receipt date: 10/10/2017

If this submission is not subject to PRIA, this will be your last automated notification related to this submission.

MILESTONE 1 IS COMPLETED

Application Follow-up

Track for EPA review milestones

Monitor progress via EPA Reviewer

Promptly address concerns with application or labeling raised by EPA during review

- Acute tox review
- Efficacy review
- Risk assessment team

Elevate issues to Team Leader when necessary

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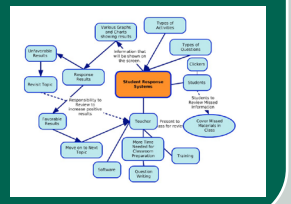
Step 6: EPA Decision

Information Collection



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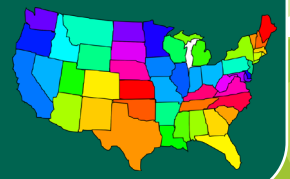

EPA Decision Documents – What to Expect

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Initial Decision

- Notice of Registrations – if a Conditional Registration was granted, document sets out timeline for submitting required information
- EPA stamped label
- Data Evaluation Records (DERs) on the studies reviewed*

Acceptance of Amendment

- EPA stamped label
- Data Evaluation Records (DERs) on the studies reviewed*

*If not provided, these will need to be requested from the EPA Product Manager

After you get the registration…

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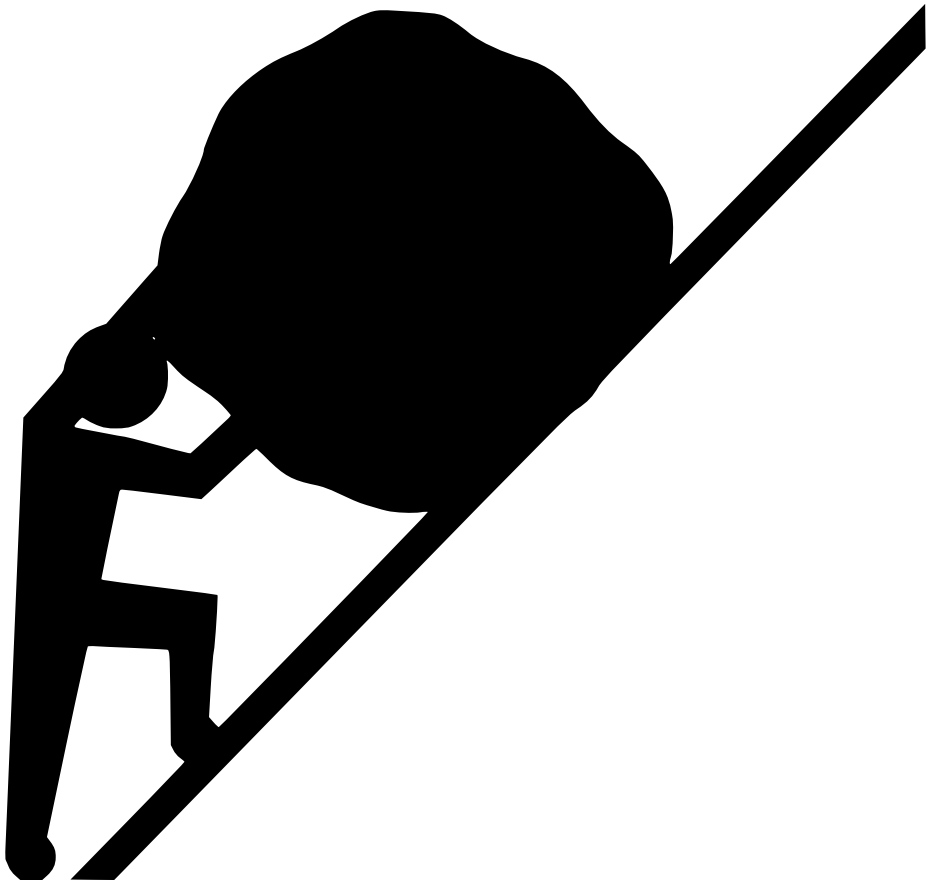
It’s not over!



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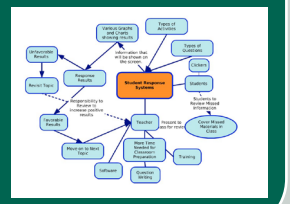
Step 7: State Registration

Information Collection



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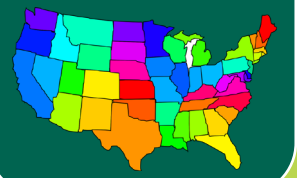

State Resources

ALSTAR – State Registration Portal for ~40 states

Note: Only register in states/territories where you intend to sell the product.

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Resources

Resources

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- EPA Pesticide Registration Manual: https://www.epa.gov/pesticide-registration/pesticide-registration-manual
- Antimicrobials Division Contacts: https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division
- Active Ingredient Chemical Search: https://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1
- National Pesticide Information Retrieval System: http://npirspublic.ceris.purdue.edu/ppis/
- InertFinder: https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:1::::1::
- Commodity Inert Ingredients: https://www.epa.gov/pesticide-registration/commodity-inert-ingredients
- Trade Name Database: https://iaspub.epa.gov/apex/pesticides/f?p=inertfinder:mixtures

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- Test Guidelines for performing the required studies: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances
- EPA Cost Estimates for Studies Required for Pesticide Registration: https://www.epa.gov/pesticide-registration/cost-estimates-studies-required-pesticide-registration
- Pests of Public Health Significance: https://www.epa.gov/pesticide-registration/prn-2002-1-lists-pests-significant-public-health-importance
- Data Submitter's List (for citing to data): https://www.epa.gov/pesticide-registration/files-listing-pesticide-data-submitters
- EPA Label Review Manual: https://www.epa.gov/pesticide-registration/label-review-manual
- Pesticide Product Label System: https://protect-us.mimecast.com/s/jf56C2k1Q7TkzK6Gt1slrN?domain=urldefense.com

Resources

- PRIA Decision Tree (to determine applicable code): https://www.epa.gov/pria-fees/pria-3-fee-determination-decision-tree
- Antimicrobial Ombudsman: pesticidequestions@epa.gov
- Pre-Application Meeting Guidance: https://www.epa.gov/pesticide-registration/guidance-pre-application-meetings-new-active-ingredients-major-new-uses-and/
- Small Business Waivers: https://www.epa.gov/pria-fees/pria-fee-waivers-small-businesses
- Paying PRIA Fees: Pay.gov
- CDX: https://cdx.epa.gov/
- EPA Forms: https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms

Need More Information?

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CBC & Steptoe are here to help!

Visit our website at
https://biocides.americanchemistry.com/
&
https://www.steptoe.com/en/