



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0539; FRL-9362-3]

### **Pesticides; Draft Guidance for Pesticide Registrants on Antimicrobial Pesticide Products with Mold-Related Label Claims; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Agency is announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) titled “Guidance on Antimicrobial Pesticide Products with Mold-Related Label Claims.” PR Notices are issued by EPA’s Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration-related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular draft PR Notice, once final, will provide guidance to the registrant concerning product performance (efficacy) data and labeling for “mold-related” pesticide products. EPA believes that the label improvements described in this draft document, once final, will provide consumers better product information with which to make an informed choice in selecting mold-related products that best suit their needs and thereby help improve protection of public health.

**DATES:** Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0539, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Jeff Kempter, Antimicrobials Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5448; fax number: (703) 308-6467; email address: [kempter.carlton@epa.gov](mailto:kempter.carlton@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are required to submit data under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or are required to register pesticides. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Producers of pesticide products (NAICS 32532).
- Producers of antimicrobial pesticides (NAICS 32561).

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

*C. How Can I Get Copies of this Document and Other Related Information?*

A copy of the draft PR notice is available in the docket, identified by docket identification (ID) number EPA-HQ-OPP-2010-0539.

**II. What Guidance Does this PR Notice Provide?**

This draft PR Notice, once final, will provide guidance to the registrant concerning product performance (efficacy) data and labeling for “mold-related” pesticide products. Mold-related pesticides are antimicrobial pesticides that bear a label claim to inhibit or destroy mold or mildew growth on hard, nonporous and porous surfaces in indoor environments (hereinafter referred to as “mold-related pesticides”). “Fungicides” are antimicrobial pesticides that destroy fungi (including yeasts) and fungal spores pathogenic to humans. “Fungistats” are antimicrobial pesticides intended for aesthetic or cosmetic purposes and only inhibit fungal growth.

This guidance, once final, will explain when the Agency expects to require applicants or registrants to submit efficacy data in support of the registration of mold-related pesticides. In accordance with 40 CFR part 161, EPA pursuant to FIFRA requires the submission of efficacy data for fungicides. EPA also requires the submission of

efficacy data when any specific species of fungus is listed on the label of fungicides, or when “residual” or “prevention” claims are made for fungicides. For fungistats, registrants must conduct efficacy studies but are not required under 40 CFR part 161 to submit them to EPA except upon request.

This guidance, once final, will also describe appropriate label language for fungicides and fungistats, and for products used for mold remediation, on nonporous and porous surfaces, for residual activity, for mold prevention, and in heating, ventilation, air conditioning and refrigeration systems. All of these recommended label changes are designed to improve protection of public health through proper use of mold-related pesticides.

### **III. Do PR Notices Contain Binding Requirements?**

The PR Notice discussed in this notice is intended to provide guidance to EPA personnel and decisionmakers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

**Authority:** Sections 2 through 34 of FIFRA (7 U.S.C. 136-136y).

**List of Subjects**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 29, 2012.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

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