E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2022-0337; FRL-10497-01-OCSPP]

Pesticides; Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces in Non-Residential Settings; Interim Guidance and Methods; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on interim guidance and methods for adding efficacy claims to antimicrobial products for use on porous materials, including fabrics, textiles, and upholstered items in non-residential settings. Specifically, EPA is seeking public comment on an interim guidance document that describes efficacy testing for antimicrobial products to support claims for use on surfaces of certain porous materials in clinical and institutional (non-residential) settings and how to prepare an application for registration, an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against viruses, and an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against bacteria. The interim guidance does not address residential use sites with surfaces such as upholstered furniture (including backing material/stuffing under the porous surface), carpets, rugs, draperies, etc. In addition to the feedback requested above, EPA is also seeking public comment on proposed carrier materials to represent the surfaces commonly found in residential settings.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE ***Federal Register***].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2022-0337, through the Federal eRulemaking Portal at *https://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. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marc Carpenter, Microbiology Laboratory Branch (7503M), Biological and Economic Analysis Division, Office of Pesticide Programs, Environmental Protection Agency, Environmental Science Center, 701 Mapes Road Ft. Meade, MD 20755-5350; telephone number: (410) 305-2927; email address: *carpenter.marc@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This document is directed to the public in general; although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit CBI information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be 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 preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Background

EPA received requests to develop interim test methods and an associated registration process for antimicrobial products intended to treat bacterial and viral public health pathogens on the surface of porous materials. There is significant interest from stakeholders and the public in the availability of antimicrobial products with these public health claims, particularly in institutional, clinical, and health-care settings. Currently, most EPA-registered liquid-based antimicrobial products are intended to treat hard, non-porous surfaces.

EPA is making available for comment interim quantitative efficacy test methods for both bacteria and viruses on porous surfaces, in addition to interim guidance for companies wishing to add specific claims to antimicrobial products for efficacy against public health pathogens when used on porous materials in clinical and institutional (non-residential) settings. These materials include non-clothing fabrics, textiles, and/or upholstery that may be laundered on an infrequent (non-routine) basis where surface wiping and spot treatment is the primary means of cleaning and or disinfection. Examples of non-residential sites include waiting rooms and offices in clinical settings, hospitals and long-term care facilities, schools, hotels, movie theaters, office buildings, and retail establishments, with a focus on high traffic areas and frequently used surfaces. The guidance does not address claims for porous materials such as clothing, untreated wood, concrete and other hard porous materials, carpet or rugs, and the backing material/stuffing under the porous surface (e.g., beyond what can be visibly observed). The guidance does not address claims for residual antimicrobial product efficacy when used on porous materials.

III. Do guidance documents contain binding requirements?

As guidance, these documents are not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the

obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance documents and any statute, regulation, or other legally binding document, the guidance documents will not be controlling.

Authority: 7 U.S.C. 136 et seq.

Dated: December 15, 2022.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

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