



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2023-0288; FRL-11108-01-OCSP]

Draft Guidance for the Evaluation of Products for Claims Against Viruses; Notice of Availability and Request for Comments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SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on draft guidance to expand the availability of virucidal claims for antimicrobial pesticides and provide framework for registrants who seek to make such claims. This draft guidance reiterates recommended test methods and guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfections claims and the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with current test guidelines. This draft guidance specifically covers the addition of a virucidal claims to a product that has met the criteria for a bactericidal disinfectant and/or sanitizer. The methods and performance standards applicable to this expanded availability of virucidal claims are the same test methods and performance standards that are currently used to support existing virucidal claims and thus there are no expectations on reduction of product performance against viruses.

DATES: Submit your comments 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-2023-0288, 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: Luisa Samalot, Office of Chemical Safety and Pollution Prevention, Antimicrobial Division (7510M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0609; email address: samalot.luisa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This notice is directed to the general public and may be of specific interest to persons or entities that register antimicrobial pesticides. Because other entities may also be interested in this notice, the agency has not attempted to describe all the specific entities that may be interested in this subject. If you have any questions regarding the applicability of this action to a particular entity, contact 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 Tips for Effective Comments at <https://www.epa.gov/dockets>. Please note that once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket.

II. Background

Historically, EPA has approved claims for efficacy against viruses only as additional claims on certain antimicrobial products, such as those with sterilant and disinfectant claims, but not those that bear only sanitizer claims.

EPA received requests for guidance to add virucidal claims to products with sanitizing claims on hard surfaces. There is a significant interest from stakeholders and the public to add these virucidal claims to products with sanitizer label claims.

This draft guidance is intended to allow registrants to provide consumers with additional products that are effective against viruses including SARS-CoV-2. This draft guidance reiterates recommended test methods and guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfections claims in OCSPP 810.2200, Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing (EPA publication No. 712-C-17-004 (2018)).

Products should meet the test guidance requirements as described in OCSPP 810.2300 Sanitizers for Use on Hard Surfaces--Efficacy Data Recommendations (EPA publication No. 712-C-07-091 (2012)), (food or non-food contact sanitization) to treat hard, non-porous surfaces before a virucidal claim is added.

OCSPP test guidelines can be accessed online through <https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

Since there will be no changes to the test methods or performance standards recommended for virus claims, there is no concern about a reduced level of efficacy against viruses. Products that meet the basic criteria to allow for sanitizer claims and have data to support the addition of virucidal label claims, may be used only in non-healthcare use-sites in residential, commercial and institutional settings (e.g., cafeterias, waiting rooms) specifically on hard non-porous surfaces.

Additional anticipated benefits include the availability of more products with reduced contact times (time the surface must remain wet) and/or more products on EPA's Design for the

Environment list that are also effective against viruses. The expansion of the availability of virucidal claims under this draft guidance will facilitate the addition of virus claims to products bearing only sanitizer claims.

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.*

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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