Interim Guidance for Products Including or Adding Efficacy Claims for Use on Porous Materials in Non-Residential Settings

Background

EPA received requests to develop test methods for and guidance on EPA's review of applications for the registration of products intended to control public health pathogens on the surface of porous materials ("porous surfaces" or "porous materials") in clinical and institutional (non-residential) settings. In this document, EPA is providing interim guidance on test methods for efficacy claims for products (including fabrics, textiles, and upholstered items) intended for use on porous materials in clinical and institutional (non-residential) settings and on how to prepare an application for registration for such products.

Introduction

Currently, most EPA-registered liquid-based antimicrobial products, including those on EPA's list of disinfectants effective against SARS-CoV-2 (List N) are registered for use on hard, non-porous surfaces (e.g., stainless steel, porcelain, glass). This interim guidance document describes how porous surface bactericidal claims may be added to products that demonstrate efficacy against base vegetative bacteria on hard non-porous surfaces. This document also describes how porous surface virucidal claims may be added to products that demonstrate efficacy against (1) base vegetative bacteria, (2) all viruses for which claims are desired on hard non-porous surfaces, and (3) base vegetative bacteria on porous surfaces. Claims for viruses should only be added as described in this interim guidance document if the product has also met the performance standards for base bacteria on both hard, non-porous and porous surfaces.

In addition to this interim guidance, EPA is providing recommended standardized quantitative efficacy test methods for both bacteria and viruses for registrants wishing to add claims for certain porous surfaces. This interim guidance and associated test methods address only products with both porous disinfectant claims and hard, non-porous surface disinfectant claims (i.e., not products that have only porous claims).

Based on the porous materials selected in the recommended efficacy test methods, this guidance is intended to be representative of clinical and/or institutional environments (non-residential) and to address efficacy of products against public health pathogens when used on porous materials in these settings, such as non-clothing fabrics and textiles/upholstery that may be laundered on an infrequent (non-routine) basis where spot treatment is the primary means of cleaning and/or disinfection. Examples of clinical and institutional (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. This guidance is not intended to apply to claims on products for use on porous materials such as clothing, frequently laundered porous items, untreated wood, concrete and other hard porous materials, carpet or rugs, or the backing material/stuffing under the porous surface (e.g., beyond what can be visibly observed). Guidance for claims for carpet, rugs, frequently laundered textiles, mattresses, pillows, and upholstered furniture is found in 810.2400 Disinfectants and Sanitizers for Use on Fabrics and Textiles. Note the current guidance is not intended to apply to limited spectrum claims and does not address claims against

mycobacterium, fungi, yeasts, or bacterial endospores. Further, the guidance is not intended to address claims for residual efficacy on porous materials. Note that depending on their intended use, some antimicrobial products may be subject to both EPA and FDA[1] jurisdiction. See Table 1 for a summary of relevant guidance to support different claim and material types.

Table 1: Summary of Testing to Support Efficacy Claims for Use on Porous Materials

Porous Site	Claim	Materials	Guidance
Clinical and institutional (non-residential) settings	Disinfectant	Non-clothing fabrics and textiles/upholstery that may be laundered on an infrequent (non-routine) basis where spot treatment is the primary means of cleaning and/or disinfection	Interim Guidance: Review of Products Including or Adding Efficacy Claims for Use on Porous Materials In Non-Residential Settings
Laundry	Disinfectant	Clothing, outerwear, linens	810.2400 Disinfectants and Sanitizers for Use on Fabrics and Textiles
Mattress, pillow, and upholstered furniture	Sterilant, disinfectant, sanitizer (For gases and vapors)	Upholstered furniture, pillows, mattresses, and similar objects	810.2400 Disinfectants and Sanitizers for Use on Fabrics and Textiles
Carpet	Sanitizer	Carpets, rugs	810.2400 Disinfectants and Sanitizers for Use on Fabrics and Textiles
Hard porous materials	Disinfectant	Untreated wood, concrete, unglazed tile, rubber	Guidance not currently available*; consult with EPA prior to submitting methods or studies.
Residential sites	Disinfectant	Upholstered furniture including backing material/stuffing under the porous surface, carpets, rugs, draperies	Guidance not currently available*; consult with EPA prior to submitting methods or studies.

*EPA anticipates addressing these claims in future guidance.

A full description of the efficacy testing expected to support claims against both bacteria and viruses is included below. Note that EPA may consider other methods or studies to support porous surface efficacy claims provided they are scientifically sound with data to inform method variability and reproducibility. Applicants are highly encouraged to consult with EPA prior to submitting other methods or studies.

[1] Liquid chemical disinfectants and devices used to disinfect health care facilities and non-critical medical devices may require separate FDA review. Other products (e.g., liquid chemical disinfectants and devices used against microorganisms in or on humans or other animals, liquid chemical sterilants for use on critical or semi-critical medical devices) may be subject to FDA's exclusive jurisdiction and are outside the scope of this guidance.

Efficacy Testing to Support Disinfectant Claims on Products for Use on the Surfaces of Certain Porous Materials in Clinical and Institutional (Non-Residential) Settings

I. Liquid formulations or spray products should satisfy all efficacy requirements for standard disinfectant claims (hard, non-porous surface) and should have undergone testing to support standard disinfectant claims to be eligible for porous surface disinfectant claims as described in this guidance.[2]

a. Eligible product types include those applied as liquids, sprays (including trigger sprays and aerosols), and foams. For efficacy testing purposes, all products will be applied to the test material as a liquid. The wet contact time should be readily observable on all test materials for the duration of the contact time.

i. Conduct a wetness test consistent with that outlined in Methods and Guidance for Testing the Efficacy of Antimicrobial Products Against Spores of *Clostridioides difficile* on Hard Non-Porous Surfaces (September 2022) and provide evidence (such as a photo) to demonstrate that the surface remains wet for the duration of the contact time.

ii. For products using methods of application beyond those listed here including towelettes, fogging, misting, and electrostatic spray, please consult with the Agency.

II. Bactericidal claims for use on the surface of porous materials (see Table 2)

a. Utilize EPA's proposed method (see Antimicrobial Testing Methods & Procedures Developed by EPA's Microbiology Laboratory) for the Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria) to support bactericidal claims for products intended for use on the surface of porous materials ("porous surfaces" or "porous materials").

b. Base Bacteria—Consistent with EPA Guideline 810.2200 for a hospital disinfectant claim, *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) should be used to support a claim as a disinfectant for use on the surfaces of porous materials.

i. For *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442), the target control range is a mean 4.0-5.5 log CFU/carrier. Each control carrier should have a minimum 4.0 log CFU/carrier of the test microbe.

[2] This disinfectant testing should be conducted in accordance with the OCSPP 810.2200 Product Performance Test Guideline for each organism (vegetative bacterium and virus) for which porous surface claims are being requested. Per the 810.2200 Test Guideline, testing to support a base disinfectant (hard, non-porous surface) claim should utilize the AOAC Use Dilution Method or Germicidal Spray Test as appropriate. Testing should be conducted against the base bacteria *Staphylococcus aureus* (*S. aureus*) and *Pseudomonas aeruginosa* (*P. aeruginosa*). Testing to support a virucidal (hard, non-porous surface) claim should utilize ASTM E1053. The performance standards for each organism and product type are specified in the test guideline. Data to support both porous surface and hard, non-porous surface disinfectant claims can be submitted and reviewed concurrently. The agency expects that products adding porous surface disinfectant claims as described in this guidance will also have hard, non-porous surface disinfectant claims (i.e., products will not have only porous surface claims). In addition, data for porous surface bactericidal disinfectant claims should be submitted prior to or concurrently with data for porous surface virucidal claims.

c. Conduct the bacterial efficacy testing with the three representative porous materials specified in the method: vinyl seating fabric (VF-01, representative of seating fabrics found in clinical settings and laboratories), privacy curtain fabric (PCF-03), and non-PVC fabric (NVF-01, mattress cover fabrics and seating materials). To support a bactericidal efficacy claim for porous surfaces, the product should achieve the performance standard on all three material types with each base bacterium.
d. Additional porous surface materials (carriers) may be chosen by the applicant. The additional materials chosen should be able to be cut into one centimeter diameter discs (two millimeter maximum thickness), withstand physical screening, cleaning and sterilization, drying under desiccation, as well as the vortex steps outlined in the method. The inoculated material should provide the necessary recovery level of each test organism to measure acceptable performance for the claim. Applicants are encouraged to consult with EPA prior to initiating testing with additional porous surfaces.
e. For all porous surfaces tested, the applicant should document compatibility of the product with the porous material per the proposed label prior to use. Data and observations pertaining to physical degradation, pitting, fraying, cracking, delamination, bleaching of dyes, etc., may indicate incompatibility of the product with the porous surface. These data and observations should be submitted in the final report to the Agency.
f. For each lot (or batch) of product, evaluate the following for each type of porous carrier: five carriers against the product and three untreated control carriers. Test each lot on separate days; however, multiple test microbes and/or surface types may be tested on the same day.
g. Use the three-part soil load identified in the method.
h. Conduct testing on three product lots at the lower certified limit (LCL) for each bacterium. In accordance with the OCSPP 810.2000 Test Guideline, certificates of analysis should be submitted to substantiate the tested concentration.
i. To support claims for additional bacteria, testing should be conducted according to the Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria, but with a reduced number of product lots (two) as specified in the OCSPP 810.2000 Test Guideline. The same control carrier count and performance standard levels identified in Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria apply to additional microbes.
j. Each lot of the product should achieve a minimum mean 4.0-log reduction in ≤ 10 minutes ± 5 seconds for qualifying bacteria when compared to the controls to support porous surface disinfectant claims for the three representative porous surfaces and any additional fabrics/materials for which claims are made. Each of the five treated carriers for each material type should have a minimum 4.0-log reduction.
k. The contact time for disinfectants for use on porous surfaces is consistent with the contact time for disinfectants for use on hard, non-porous surfaces, as described in OCSPP 810.2200 Test Guideline.

Table 2: Summary of Testing for Adding Bactericidal Efficacy Claims to Products for Use on Porous Materials Including Fabrics, Textiles, and Upholstered Items for Clinical and Institutional (Non-Residential) Settings

Claim	Test Method	Test Organisms	Carrier Types	No. of Lots
Base Bacteria	Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria	*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442)	VF-01, PCF-03, and NVF-01	3 lots per organism at the LCL for each carrier type
Additional Vegetative Bacteria	Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria	All vegetative bacteria claimed on the label	VF-01, PCF-03, and NVF-01	2 lots per organism at the LCL for each carrier type

III. This guidance addresses only the addition of porous surface claims for viruses to products that have also met the performance standard for bacteria on porous surfaces (see Table 3).

a. Utilize EPA's proposed method (see Antimicrobial Testing Methods & Procedures Developed by EPA's Microbiology Laboratory for the Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Viruses) to support virucidal claims on products intended for use on the surface of porous materials.

b. All viruses for which claims are desired should be tested.
   i. Two lots of product at the LCL should be tested for the hardest to kill virus. For additional information on selecting the most difficult to kill virus, see EPA's Emerging Viral Pathogens Guidance. Test each lot on separate test days; however, multiple viruses and/or surface types may be tested on the same day.
   ii. Two lots of product at the nominal concentration should be tested for additional viruses. Test each lot on separate test days; however, multiple viruses and/or surface types may be tested on the same day.

c. Utilize the same porous surfaces used to conduct the bacterial testing.

d. Untreated control carriers should yield 4.0-5.5 log viable virus particles/carrier. Each control carrier should exhibit a minimum 4.0 logs of viable virus particles.

e. Use the three-part soil load identified in the method.

f. Each lot of the product should achieve a minimum mean 3.0-log reduction in ≤ 10 minutes ± 5 seconds for qualifying viruses when compared to the controls, consistent with the OCSPP 810.2200 Product Performance Test Guideline, to support porous surface disinfectant claims for the three representative porous surfaces and any additional fabrics/materials for which claims are made. Each of the five treated carriers for each material type should have a minimum 3.0-log reduction.

g. The contact time for disinfectants for use on porous surfaces is consistent with the contact time for disinfectants for use on hard, non-porous surfaces, as described in OCSPP 810.2200 Test Guideline.

Table 3: Summary of Testing for Adding Virucidal Efficacy Claims to Products for Use on Porous Materials Including Fabrics, Textiles, and Upholstered Items for Clinical and Institutional (Non-Residential) Settings

Claim	Test Method	Test Organisms	Carrier Types	No. of Lots
Base Bacteria	Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Bacteria	*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442)	VF-01, PCF-03, and NVF-01	3 lots per organism at the LCL for each carrier type
Virucidal	Interim Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces Against Viruses	Hardest to kill virus	VF-01, PCF-03, and NVF-01	2 lots at the LCL for each carrier type
		All viruses claimed on the label	VF-01, PCF-03, and NVF-01	2 lots at the nominal concentration for each carrier type

IV. Disinfectant Claims for Products for Use on Surfaces of Certain Porous Materials: Labeling and Additional Information

a. Products are eligible for inclusion on List N if they meet the criteria in the Emerging Viral Pathogens guidance or are supported by appropriate testing for a qualifying virus (e.g., SARS-CoV-2 or human coronavirus strain 229E).
b. A claim for additional microorganisms not under the scope of this guidance (e.g., mycobacterium, fungi, yeasts, or bacterial endospores) may be proposed by the registrant upon consultation with EPA prior to submission and will require a protocol submission and/or Agency protocol review separate from the current method for *S. aureus* and *P. aeruginosa*, the subject of this guidance.
c. Sample directions for use:
    i. Apply in a limited area (spot treatment), monitor treated area for wetness for duration of the contact time, and allow to dry.
    ii. Apply to surfaces only. Do not use on surfaces that routinely contact skin (i.e., clothing, sheets, towels).
    iii. Only for use on non-launderable surfaces or those that may be laundered on an infrequent (non-routine) basis.
d. Sample marketing claims
    i. An effective disinfectant for the surface of porous materials*
    *Non-clothing fabrics, textiles, and upholstery that may be laundered on an infrequent (non-routine) basis where spot treatment is the primary means of cleaning and/or disinfection such as waiting room chairs, privacy curtains, safety belts, laboratory chairs, vehicle interiors (e.g., public transit, medical transportation), seat coverings, mattress covers not intended to be laundered, and mattress covers fixed to mattresses.

V. How to Prepare an Application for Registration

a. **Requests to Amend Currently Registered Products That Require the Review of Data Under PRIA:**
    i. Submission of new efficacy data to add porous surface disinfectant claims to an already EPA-registered product can be submitted as a PRIA A570 action.
    ii. If the currently registered product labeling is approved only for sanitizer claims or the labeling is approved with no public health claims, the following data should be submitted for EPA to consider approving porous surface disinfectant and virucidal claims under this guidance:
        1. Efficacy data to support a base (hard, non-porous surface) disinfection claim (*Staphylococcus aureus* and *Pseudomonas aeruginosa*), see OCSPP 810.2200 for details, and hard, non-porous surface virus data for all viruses for which porous surface claims for viruses are made.
        2. Porous surface disinfection efficacy data (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and porous surface virucidal efficacy data for the hardest to kill virus as described above.
    iii. If the currently registered product labeling is approved for broad spectrum or hospital hard, non-porous surface disinfection and virucidal claims, the following data should be submitted for EPA to consider approving porous surface disinfectant and virucidal claims under this guidance:
        1. Porous surface disinfection efficacy data (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and porous surface virucidal efficacy data for the hardest to kill virus as described above.
    iv. If the currently registered product labeling is approved for broad spectrum or hospital hard, non-porous surface disinfection claims with no virucidal claims, the following data should be submitted for EPA to consider approving porous surface disinfectant and virucidal claims under this guidance:
        1. Hard, non-porous surface virus data for all viruses for which porous surface claims for viruses are being requested.
        2. Porous surface disinfection (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) efficacy data and porous surface virucidal efficacy data for the hardest to kill virus as described above.
    v. To ensure the efficient processing of your PRIA submission, please include the following in a cover letter to EPA:
        1. A subject line that clearly indicates "Existing Product Submission of Efficacy Data for Porous Disinfectant";
        2. A list of the submitted efficacy data;
        3. The identification of all the organism(s) and respective study ID number(s) (MRID/s) for which review is being requested.
    vi. The following should also be included with your PRIA submission:
        1. An up-to-date Certification with Respect to Data Citation Form (Form 8570-34) and Data Matrix (Form 8570-35);
        2. CSF(s) (Form 8570-4);

3. An 8570-1 application form;
4. A revised master label, both a highlighted version and a clean version, with the updated directions for use for porous surface disinfection, contact time, and emergent pathogen claims if applicable; and
5. If a request to add an emerging viral pathogen claim is being made, please refer to the instructions for adding these claims
6. A PRIA fee payment, in the amount of $4,023, or small business fee waiver request with the appropriate fee for a PRIA A570 action

vii. Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_XXXX_XXXXXXX).

viii. For questions about what is needed as part of your submission, please contact the Product Manager for your product.

b. Requests for A New Product That Requires the Review of Data Under PRIA

i. New Product Formulated with A Registered Source of Active Ingredient(s)

1. For an application for registration of a new pesticide product for porous surface disinfection intended to be formulated from a registered technical or manufacturing use product, follow the instructions in EPA's previously announced review of certain PRIA submissions for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19. Specifically, follow the directions for "Submission of an application for a new pesticide product that requires EPA to review newly submitted efficacy data to support virucidal claims where the product is formulated with a registered source of active ingredient(s)" and include the additional information specified above for porous surface disinfectants. As specified in the PRIA guidance, this is a PRIA A540 action, and the submission should include a PRIA fee payment in the amount of $5,363, or small business fee waiver request with appropriate fee for a PRIA A540 action.
2. Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_XXXX_XXXXXXX).

ii. New Product Formulated with An Unregistered Source of Active Ingredient(s)

1. For an application for registration of a new pesticide product for porous surface disinfection intended to be formulated from an unregistered technical or manufacturing use product, follow the instructions in EPA's previously announced review of certain PRIA submissions for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19.

Specifically, follow the directions for "Submission of an application for a new pesticide product that requires EPA to review newly submitted efficacy data to support virucidal claims where the product is formulated with an unregistered source of active ingredient(s)" and include the additional information specified above for porous surface disinfectants. As specified in the PRIA guidance, this may be either a PRIA A540 action or a PRIA A572 action. The submission should include a PRIA fee payment in the amount of $5,363, or small business fee waiver request with appropriate fee for a PRIA A540 action or $13,888 for an A572 action, or small business fee waiver request with the appropriate fee for a PRIA A572 action.

2. Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.govwith your CDX tracking number (CDX_XXXX_XXXXXXX).