

Guidance for Products Including or Adding Disinfectant Efficacy Claims for Use on Soft Surface Textiles in Non-Residential Settings

Background

EPA received requests to develop test methods and guidance for registering products intended to control public health pathogens on soft surface textiles (including fabrics, textiles, and upholstered items) in clinical and institutional (non-residential) settings. In this document, EPA is providing guidance on test methods to support disinfectant efficacy claims for products intended for use on soft surface textiles in clinical and institutional (non-residential) settings and on how to prepare a registration application for such products. Throughout this guidance, the term “soft surface textile” refers to a soft, porous, or non-porous surface that includes the *outer surface of non-clothing fabrics/textiles in clinical and institutional (non-residential) environments where spot treatment is the primary means of disinfection.*

In December 2022, EPA issued interim guidance and test methods for public comment as a pathway for companies to add soft surface textile claims to their products’ labels. Revisions to the guidance document and the associated methods were made based on information submitted through public comments. The revised test methods, guidance, and response to comments document are available at docket EPA-HQ-OPP-2022-0337 at [regulations.gov](https://www.regulations.gov). The revised test methods and guidance are also available on EPA's Microbiology Laboratory [Antimicrobial Testing Methods and Procedures webpage](#). EPA plans to incorporate this guidance into the relevant Series 810 Product Performance Test Guideline in a future update.

Introduction

Currently, most EPA-registered liquid-based antimicrobial products are registered for use on hard, non-porous surfaces (e.g., stainless steel, glazed porcelain, glass). This guidance document describes how soft surface textile bactericidal disinfectant claims may be added to products that demonstrate efficacy against base vegetative bacteria on hard, non-porous surfaces. This document also describes how soft surface textile virucidal disinfectant claims may be added to products that demonstrate efficacy against (1) base vegetative bacteria on hard, non-porous surfaces, (2) viruses on hard, non-porous surfaces, and (3) base vegetative bacteria on soft surface textiles. This guidance document is intended to address the addition of claims for viruses on soft surface textiles to a product only if the product has also met the performance standards for (1) base bacteria on hard, non-porous surfaces, (2) base bacteria on soft surface textiles, and (3) viruses on hard, non-porous surfaces.

In addition to this guidance, EPA is providing recommended standardized quantitative efficacy test methods for both bacteria and viruses for registrants wishing to add disinfectant claims for soft surface textiles pursuant to this guidance. This guidance and associated test methods address only products with both soft surface textile disinfectant claims and hard, non-porous surface disinfectant claims (i.e., products that have only soft surface textile claims are not within the scope of this guidance).

Based on the soft surface textiles 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 the efficacy of products against public health pathogens when used on soft surface textiles.

- Example surfaces in clinical and/or institutional environments (non-residential) that are within the scope of this guidance include 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 that are within the scope of this guidance include waiting rooms and offices in clinical settings, hospitals, and long-term care facilities; schools and daycares; interiors of medical and public transportation; hotels; movie theaters; gyms; 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:

- Clothing, frequently laundered items, untreated wood, concrete and other hard porous materials, carpet or rugs, or the backing material/stuffing under the soft surface textile (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](#).

This guidance is not intended to address claims against mycobacterium, fungi, yeasts, or bacterial endospores, nor to address claims of residual efficacy on soft surface textiles.

Note that depending on their intended use, some antimicrobial products may be subject to both EPA and FDA¹ 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 Soft Surface Textiles

Use 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	Guidance for Products Including or Adding Disinfectant Efficacy Claims for Use on Soft Surface Textiles 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

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.

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 disinfectant claims against both bacteria and viruses pursuant to this guidance is included below. Note that EPA may consider other methods or studies to support soft surface textile efficacy claims provided they are scientifically sound with data to inform method variability and reproducibility. Applicants are highly encouraged to consult with EPA (AD_Efficacy@epa.gov) prior to submitting other methods or studies or to support other soft surface textile claims not addressed in this guidance.

This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance within where circumstances warrant and without prior notice. Registrants and applicants may propose and submit modifications to the recommended test methodology to the Agency for assessment. Please contact the [PM Team](#) for your product or proposed product to facilitate discussion of modifications to the test methodology or to discuss test methodologies for soft-surface claims not addressed by this guidance. This guidance may be updated in the future.

Efficacy Testing to Support Disinfectant Claims on Products for Use on Certain Soft Surface Textiles in Clinical and Institutional (Non-Residential) Settings

I. Formulation types eligible for soft surface textile claims

- 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.
 - i. For products using methods of application beyond those listed here including towelettes, fogging, misting, and electrostatic spray, please consult with the Agency.
 - ii. Liquid formulations or spray products should satisfy all efficacy requirements for hospital or healthcare disinfectant claims (hard, non-porous surface) and should have undergone testing to support hospital or healthcare disinfectant claims (soft surface textile surfaces) to be eligible for soft surface textile bactericidal and virucidal disinfectant claims as described in this guidance.²

II. Bactericidal claims for use on the surface of soft surface textiles (see Table 2)

- a. Utilize EPA's proposed method for the Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Bacteria to support bactericidal claims for products intended for use on soft surface textiles.
- b. Base Bacteria—Consistent with EPA Guideline 810.2200 for a hospital bactericidal disinfectant claim, *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) should be used to support a claim as a bactericidal disinfectant for use on soft surface textiles.
 - i. For *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442), the target mean control carrier count level is 4.0-5.5 logs CFU/carrier. Each inoculated carrier should be within this range.
- c. Conduct the bacterial efficacy testing with the three representative soft surface textiles 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 soft surface textiles, the

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 soft surface textile claims are being requested. Per the 810.2200 Test Guideline, testing to support a base bactericidal 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 soft surface textile and hard, non-porous surface disinfectant claims can be submitted and reviewed concurrently. To add soft surface textile disinfectant claims as described in this guidance, the Agency expects that products will also have hard, non-porous surface disinfectant claims (i.e., products will not have only soft surface textile claims). In addition, data for soft surface textile bactericidal disinfectant claims should be submitted prior to or concurrently with data for soft surface textile virucidal claims.

product should achieve the performance standard on all three material types with each base bacterium.

- i. For all soft surface textiles tested, labs should document compatibility of the product with the soft surface textile material for registrant consideration for labeling. Data and observations pertaining to physical degradation, pitting, fraying, cracking, delamination, bleaching of dyes, etc., may indicate incompatibility of the product with the soft surface textile. These data and observations should be retained by the registrant in support of product labeling. The Agency reserves the right to request submission of these data if they become relevant for product efficacy concerns.
- d. For each lot (or batch) of product, evaluate the following for each type of soft surface textile 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.
- e. Use the three-part soil load identified in the method.
- f. 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.
- g. To support claims for additional bacteria, testing should be conducted according to the Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles 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 Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Bacteria apply to additional microbes.
- h. 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 soft surface textile disinfectant claims for each of the three representative soft surface textiles.
- i. The contact time for disinfectants for use on soft surface textiles 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 Soft Surface Textiles 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	Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Bacteria	<i>Staphylococcus aureus</i> (ATCC No. 6538) and <i>Pseudomonas aeruginosa</i> (ATCC No. 15442)	VF-01, PCF-03, and NVF-01	3 lots per organism at the LCL for each carrier type

Additional Vegetative Bacteria	Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Bacteria	All vegetative bacteria claimed on the label	VF-01, PCF-03, and NVF-01	2 lots per organism at the nominal concentration for each carrier type
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III. Virucidal claims for use on the surface of soft surface textiles (see Table 3)

- a. This guidance addresses only the addition of soft surface textile claims for viruses to products that have also met the performance standard for bactericidal disinfection on soft surface textiles AND virucidal disinfection for the same viruses on hard, nonporous surfaces.
- b. Utilize EPA’s method for the Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Viruses to support virucidal claims on products intended for use on soft surface textiles.
- c. All viruses for which claims are desired for soft surface textiles 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.
- d. Utilize the same soft surface textile surfaces used to conduct the bacterial testing.
- e. For viruses, the target mean control carrier count level is 4.0-5.5 logs viable virus particles/carrier. Each inoculated carrier should be within this range.
- f. Use the three-part soil load identified in the method.
- g. Each lot of the product should achieve a minimum mean 3.0-log reduction in ≤ 10 minutes ± 5 seconds for viruses when compared to the controls to support soft surface textile disinfectant claims for each of the three representative soft surface textiles.
- h. The contact time for disinfectants for use on soft surface textiles 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 Soft Surface Textiles 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	Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Bacteria	<i>Staphylococcus aureus</i> (ATCC No. 6538) and <i>Pseudomonas aeruginosa</i> (ATCC No. 15442)	VF-01, PCF-03, and NVF-01	3 lots per organism at the LCL for each carrier type

Virucidal	Quantitative Method for Evaluating the Efficacy of Antimicrobial Test Substances on Soft Surface Textiles Against Viruses	Hardest to kill virus	VF-01, PCF-03, and NVF-01	2 lots at the LCL for each carrier type
		All additional 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 Certain Soft Surface Textiles: Labeling and Additional Information

- a. Products with soft surface textile disinfectant claims added pursuant to this guidance are eligible for inclusion on relevant Agency [disinfectant lists](#). Requests for inclusion are registrant-initiated per the guidance at the link above, and dependent upon registrant submission of data determined by EPA to be acceptable to support the efficacy of a product against the organism(s) relevant to the specific disinfectant list.
- 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 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 are currently in contact with skin (i.e., clothing).
 - 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 soft surface textiles.*
*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 soft surface textile 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 soft surface textile bactericidal and virucidal disinfection claims under this guidance:

1. Disinfection efficacy data to support base (hard, non-porous surface) bactericidal claims (*Staphylococcus aureus* and *Pseudomonas aeruginosa*), see OCSPP 810.2200 for details.
 2. Disinfection efficacy data to support virucidal claims on hard, non-porous surface for all viruses for which soft surface textile claims for viruses are being requested.
 3. Soft surface textile bactericidal disinfection efficacy data (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and soft surface textile virucidal disinfection efficacy data for each virus claimed, as described above.
- iii. If the currently registered product labeling is approved for broad spectrum or hospital hard, non-porous surface bactericidal and virucidal disinfection claims, the following data should be submitted for EPA to consider approving soft surface textile bactericidal and virucidal disinfection claims under this guidance:
1. Identify MRIDs supporting disinfection efficacy claims for base (hard, non-porous surface) bactericidal claims (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and virucidal claims for which soft surface textile claims for viruses are being requested.
 2. Soft surface textile bacterial disinfection efficacy data (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and soft surface textile virucidal disinfection efficacy data for each virus claimed, as described above.
- iv. If the currently registered product labeling is approved for broad spectrum or hospital hard, non-porous surface bactericidal disinfection claims with no virucidal claims, the following data should be submitted for EPA to consider soft surface textile bactericidal and virucidal disinfection claims under this guidance:
1. Identify MRIDs supporting efficacy claims for base bactericidal claim (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) on hard, non-porous surface.
 2. Disinfection efficacy data to support virucidal claims on hard, non-porous surface for all viruses for which soft surface textile claims for viruses are being requested.
 3. Soft surface textile bactericidal disinfection (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) efficacy data and soft surface textile virucidal disinfection efficacy data for each virus claimed, 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 Soft Surface Textile Disinfectant”;
 2. A list of the submitted efficacy data;

3. The identification of all the organism(s) and respective study ID number(s) (MRIDs) 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 soft surface textile disinfection, contact time, and emerging viral 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 \$5,493, or small business fee waiver request with the appropriate fee for a PRIA A470 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 soft surface textile 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 soft surface textile disinfectants. As specified in the PRIA guidance, this is a PRIA A460 action, and the submission should include a PRIA fee payment in the amount of \$7,322, or small business fee waiver request with appropriate fee for a PRIA A460 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 soft surface textile 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 soft surface textile disinfectants. As specified in the PRIA guidance, this may be either a PRIA A460 action or a PRIA A572 action. The submission should include a PRIA fee payment in the amount of \$7,322, or small business fee waiver request with appropriate fee for a PRIA A460 action or \$18,958 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.gov with your CDX tracking number (CDX_XXXX_XXXXXXX).