



Pesticides: Regulating Pesticides

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Guidance for the Efficacy Evaluation of Products with Sporicidal Claims against *Clostridium difficile*

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This document provides the Agency's interim guidance for the efficacy evaluation of antimicrobial pesticides sold as dilutable liquids and powders, ready-to-use formulations, spray products, and towelettes that are labeled for use to treat hard non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile* (*C. difficile*). As guidance, this document is not binding on either EPA or any outside parties, and the EPA may depart from it where circumstances warrant and without prior notice. Registrants and applicants may propose alternatives to the recommendations described in this guidance, and the Agency will assess them for appropriateness on a case-by-case basis. This guidance is considered interim in nature and may be updated in the future.

Test Methods

Efficacy procedures associated with one of the following test methods should be utilized:

1. Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants test, Method I for *Clostridium sporogenes*
2. AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface)
3. ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces, or
4. ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides.

Note

These methods are recommended to be used with products that are dilutable liquids and powders and ready-to-use formulations. Modifications to each test method will be necessary to specifically accommodate spores of *C. difficile*. Also since, *C. difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for recovery of viable spores. Before using any of these or other methods to test sprays, towelettes, or foams, protocols should be submitted to the Agency for review. Applicants should consult with the Agency for additional testing guidance before testing spray, towelette, or foam formulations.

Acceptable Test Strains

Until the Agency identifies a representative toxigenic strain or suitable surrogate(s) to be

used in testing against *C. difficile*, the following toxigenic strains should be used for testing: ATCC 700792, ATCC 43598 and ATCC 43599.

Number of Batches and Test Carriers per Batch:

For the AOAC Method 966.04, testing should be conducted with two separate batches of product, using 30 carriers per batch for testing of registered sterilants; and three separate batches of product (one of which is at least 60 days old), using 60 carriers per batch for testing of hospital disinfectants. For the quantitative tests, the carrier number specified in the test method should be used.

Organic Soil Load:

All products will carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum.

Product Performance:

1. For qualitative assessments, AOAC Method 966.04 specifies that inoculated carriers must meet an acceptable acid resistance standard; mean control carriers counts must be 1×10^5 to approx. 1×10^6 spores/carrier); no positive carriers/tubes are allowed for efficacy, or
2. for quantitative assessments, AOAC Method 2008.05, ASTM E 2414-05, and ASTM E 2197-02 specify a minimum 6 log reduction viable spores is necessary with control carriers counts $>10^6$ spores/carrier.

Contact Time

Contact time for testing should not exceed 10 minutes.

Claim

Kills and/or inactivates spores of *Clostridium difficile* on hard, non-porous surfaces.

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

All products bearing *Clostridium difficile* sporicide claims are to include these specific cleaning directions:

- **Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.
- **Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.
- **Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local

regulations for infectious materials disposal.