Performance Standard for the AOAC Use-dilution Methods

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February 19, 2014
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http://www.epa.gov/oppad001/regpolicy.htm

Antimicrobial Policy & Guidance Documents

The Registration Policy Documents section is organized to include relevant sections of the Code of Federal Regulations (as references), internal Guidance/Guidelines, Letters (containing guidance or relevant information), Protocols, Science Policy, and Templates for registrants’ use.

- Code Of Federal Regulations (CFR)
- Guidance / Guidelines
- Letters
- Protocols
- Science Policy
- Templates

You will need Adobe Reader to view some of the files on this page. See EPA’s PDF page.

Code Of Federal Regulations (CFR)
- 40 CFR part 150 & 40 CFR part 156 - Antimicrobial Registration Requirements
- 40 CFR part 156 - Data Requirements

Guidance / Guidelines
- Lower Certified Limit Testing Guidance (5 pp, 104 KB) (Please direct comments to Mark Perry at perry.mark@epa.gov)
- UCM Performance Standard Revision Document (3 pp, 44 KB)
- Crosswalk Table for Non-public Health Guidelines
- Fragrance Notification Pilot Program (9 pp, 47 KB)
- Guidelines for Voluntary Disclosure of Antimicrobial Ingredient Information on Company Websites and/or Labels
- Use of Disinfectants and Sanitizers in Heating, Ventilation, Air Conditioning, and Refrigeration (HVAC&R) Systems - Supplemental Guidance
- Antimicrobials Used in the Fermentation of Fuel Ethanol – Clarification of Jurisdiction
- Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine flu)
- Guidance on what the net contents statements should contain for antimicrobial wipe/toilette products
- Guidance for the Efficacy Evaluation of Products with Antimicrobial Claims against Clostridium difficile - This document provides the Agency’s guidance for efficacy testing to obtain a label claim against the spores of Clostridium difficile
- This is a response to questions concerning existing C. diff claims (vegetative form) on antimicrobial product labels.
- Barrier Products Clarification Document - Guidance on what is needed for an Agency barrier determination.
- Use of the Term “Shock” on Non-pesticide Labeling (PDF) (3 pp, 116 KB) - This document further clarifies what claims can be made for non-pesticide shock products.
The new performance standard criteria only apply to liquid products tested with the UDM against *S. aureus* and *P. aeruginosa*.

UDM requirements for testing *Salmonella enterica* are not impacted.

For limited and broad spectrum disinfectant claims, the new performance standard for *S. aureus* applies.

The new performance standard criteria are applicable to data used to support new registrations, label amendments, data call-ins issued by the Agency, and in post registration testing.
The current versions of AOAC Methods 955.15 and 964.02 were posted by AOAC in September, 2013 and should be used for testing.

The revised AOAC methods are posted online at: http://www.aoac.org/imis15_prod/AOAC/Default.aspx


A reassessment of the method’s performance standard was conducted utilizing the best available data and statistical methodology to analyze the UDM’s variability.

To support revisions, the EPA, in collaboration with MSU, submitted three manuscripts to the JAOAC Int. for technical review and approval. The manuscripts describe:

- the outcome of a 2009 UDM collaborative study,
- a statistical model for assessing performance standards of disinfectant test methods, and
- the use of statistical modeling to reassess the UDM performance standard.
New Performance Standard

- Each microbe should be tested three times.
- Each test should be conducted against a separate batch of product for a total of three batches.
- All three batches should be at the lower certified limit \( (LCL) \) of the active ingredient(s).
- Each of the three tests should be conducted on a different day.
- Testing at a single lab is acceptable.
- Sixty carriers are required per test, without contamination in the subculture media.
The performance standard for *S. aureus* is 0-3 positive carriers out of sixty.

The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty.

To be deemed an effective product, the product must pass all tests (6) for both microbes.

The Agency will monitor the outcome of the new performance standard criteria as data are generated, and if necessary, adjust the performance standard at a later date.
New Performance Standard

- Example: for 955.15 – September 13, 2013
  - (h) Performance standard.— 3 positive (growth) carriers out of 60 tested. Conduct three separate UDM tests, one test conducted per day. All tests must meet the performance standard. Testing at a single laboratory is acceptable.

- Note: A hospital-level disinfectant product (as defined by the U.S. EPA) must pass both *S. aureus* and *P. aeruginosa* tests to be deemed effective (a total of six tests).
References


Questions/Comments