Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes

April 12, 2001

SUBJECT: Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes

This document addresses the Agency's recommendations for evaluating the non-residual sanitizing efficacy of antimicrobial products (specifically pre-saturated towelettes) after application to hard, inanimate surfaces with which food may come in contact.

Specifically, the guidance provides details on the following:

1. purpose and scope of the guidance document,
2. test substance,
3. test methods,
4. reporting of data,
5. test standard, (which includes discussion of the test organisms, procedure, organic soil load, single pack towelettes versus roll of towelettes, towelette size and treatment surface area, and data generation),and
6. performance standard.

This draft, interim guidance should be followed when evaluating efficacy protocols for products of this type. This document may be released to the public when requested. If you have any questions, please contact your branch chief, team leader, or Laura Morris-Bailey.

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Draft Interim Guidance for AD Staff

Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes

1. Purpose and Scope

Testing is to be based upon an adequately controlled in-use study or simulated in-use study. At a minimum, the microorganisms that must be tested are Staphylococcus aureus (ATCC 6538) and Escherichia coli (ATCC 11229). Testing also must be undertaken for any additional microorganisms that are claimed on the label. The starting inocula of the test microorganisms must be of sufficient concentration to provide between 75 - 125 x 106 cfu/ml on the parallel control surface.

2. Test Substance

Unless otherwise specified, antimicrobial pesticides are to be tested with the formulation to be offered for sale using the product packaged in the same packaging intended to be marketed. Towelettes are a unique combination of antimicrobial chemical products pre-packaged as a unit in fixed proportions for application. Therefore, the complete products, as packaged in the manner to be offered for sale, must be tested according to the directions for use to insure efficacy as a hard surface sanitizer. The product tested must be from three batches as referenced in Section 5.6. Simulated re-use is not required since the product is intended to be removed from the package, used immediately, and discarded after use.

3. Test Methods

Test antimicrobial products in accordance with the proposed directions for use. Depending upon the type of antimicrobial agent, target microorganisms, and the site to be treated, all tests are to address those factors that would normally be expected to be encountered in the use pattern intended for the product, including, but not limited to, the method of application; the nature of the surface (i.e., hard non-porous surface), item surface to be treated; the presence or absence of soil or other interfering conditions; ambient temperature and exposure period of 30 seconds.

Modification of the standard AOAC Germicidal Spray Products Test, official final method, (Official Methods of Analysis of the AOAC International. Chapter 6, Disinfectants, Official Method 961.02 Germicidal Spray Products as Disinfectants, Seventeenth edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417) is appropriate for this scenario. Instead of spraying the inoculated surface of the glass slide (as noted in the AOAC Germicidal Spray Products Test method), the towelette product is tested by wiping the surface of the glass slide with the saturated towelette, and then subculturing the slides after a 30 second exposure time. Liquid expressed from the used towelette needs to be subcultured separately. Subcultures of the liquid expressed from the used towelettes are expected to be negative for growth.

4. Reporting of Data

Systematic and complete descriptions of the tests employed and (see item #3 above) the results obtained are essential for proper review and evaluation of product performance by the Agency. All test reports must include identification of the testing laboratory or organization, when and where the tests were conducted and the name of the person(s) responsible for conducting the tests and those who prepared the study report.

5. Test Standard

The following parameters need to be taken into account when developing efficacy data for sanitizing activity of towelettes used on hard inanimate surfaces:

1. Test Organisms

Testing is to be based upon an adequately controlled in-use study or simulated in-use study. At a minimum, the microorganisms that must be tested are Staphylococcus aureus (ATCC 6538) and Escherichia coli (ATCC 11229). Testing also must be undertaken for any additional microorganisms that are claimed on the label. The starting inocula of the test microorganisms must be of sufficient concentration to provide between 75 - 125 x 106 cfu/ml on the parallel control surface.

2. Procedure

Based on the claims, a variety of surfaces may be treated with the product. Each of the different types of test surfaces claimed may be used in the efficacy testing of the product (i.e., glass, stainless steel, plastic, and ceramic). At a minimum, the applicant must test:1) a stainless steel or glass surface, and 2) a plastic with a rough surface (i.e., plastic cutting boards). Inoculate the test surface with the challenge microorganisms. After inoculation, the test surface is dried for 40 minutes in an incubator at 30 - 37EC. A "zero-time" bacterial numbers recovery test must be performed to demonstrate the efficiency of the recovery process, and must be reported.

The towelette is removed from its container and handled with sterile gloves. The inoculated surfaces are to be tested by wiping the surfaces with the saturated towelette. The area of the towelette used for wiping is rotated so as to expose a maximum amount of its surface in the course of wiping the contaminated test surface. After wiping the contaminated surface with the towelette, all remaining liquid is to be expressed from the used towelette into an empty sterile container and subcultured separately. Run parallel tests on towelette (as well as expressed liquid from the used towelette) with the active ingredients omitted in an identical manner to serve as the control.

After the 30 second contact time, recover the test microorganisms by washing the treated surfaces with adequate agitation in an appropriate media or dilution fluid containing appropriate neutralizers. Enumerate microorganisms on appropriate nutrient agar, containing the same neutralizers, by the pour or spread plate technique.

The environmental conditions, such as relative humidity and temperature, employed in the test must also be reported. These conditions must be the same as those likely to be encountered under normal conditions of use.

3. Organic Soil Load

For products making one-step sanitization claims, the test surface must have an organic soil load applied to the surface prior to the initial treatment and challenge (at a minimum 5% bovine serum). The organic soil level indicated is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be required on the label prior to the application of the antimicrobial agent. In the absence of testing with an organic soil load, a one-step claim cannot be made and a pre-cleaning step is required and must be noted on the label.

4. Single Pack towelettes Versus Roll of Toweletts

There may be more moisture retained in a towelette from single pack towelettes than in a towelette from a roll of towelettes. If the towelette roll container does not remain closed, there is a possibility that the towelettes at the end of the roll may not contain as much moisture as those towelettes at the start of the roll. Therefore, to ensure continued efficacy, the label needs to state that the towelette must be visibly wet (saturated) before use, and that the surface treated must be visibly wet after use.

5. Towelette Size and Surface Area

At this time, there are no limitations/restrictions regarding the size of the towelette. The Agency's suggested minimum surface area to be treated per towelette is 2' x 2'. However, the size of the surface area treated must be representative of the area that the towelette will treat effectively and reflective of the surface area to be tested in the study. The size of the surface area to be treated, as demonstrated by the data, must also be stated on the label as the recommended maximum surface area to be treated.

6. Data Generation

Three samples, representing three different batches, one of which is at least 60 days old, must be evaluated for efficacy against Escherichia coli (ATCC 11229) and Staphylococcus aureus (ATCC 6538). Testing for additional microorganisms claimed on the label is to be conducted on two batches of product. Tests are to be conducted in triplicate.

6. Performance Standard

The product must demonstrate at least a 99.999% reduction in the number of test microorganisms (bacteria) within 30 seconds. The result must be reported according to the actual count and percentage reduction over the control.

Guidance approved as Agency standard April 12, 2001 by the Office of Pesticide Programs/Antimicrobials Division.