EFFICACY REVIEW

RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIALS DIVISION

IN: 7/25/97 OUT: 9/29/97

EPA Reg. No. or File Symbol 70590-R
Lan Code 70590-R.107
Product Name Hype-Wipe Disinfecting Towel With Bleach
Company Name Current Technologies
Date Received 7/25/97
Type Product Saturated Towelettes
MRID No(s) 442209-01C & 442209-02
Product Manager Robert Brennis
Submission Purpose New application
Type Formulation Saturated Towel

Active Ingredient(s):

Sodium hypochlorite..... 0.550%

Recommendations:

The data submitted (MRID No. 442209-02) was developed using the AOAC Hard Surface Carrier Test. Because this product is a saturated towelette the registrant must submit efficacy data developed using the AOAC Germicidal Spray Test Method Modified for Towelettes and the AOAC Phenol Coefficient Test Method (see Attachment 1). In addition, please refer to the attached copies of DIS./TSS-1, 2 & 3 for further information and testing guidelines. The product label will be reviewed when the registrant submits new efficacy data.

Reviewed by Michael Nieves Date: September 29, 1997

ATTACHMENT 1

Pre-saturated or impregnated towelettes for hard surface disinfection:

Pre-saturated or impregnated towelettes represent a unique combination of antimicrobial chemicals and applicator pre-packaged as a unit in fixed proportions. Therefore, the complete product, as offered for sale, should be tested according to the directions for use to ensure its effectiveness in disinfecting hard surfaces.

(1) Recommended simulated-use test. (I) Single-use towelettes. This product is intended to be removed from the package, used immediately, and discarded after use.

(A) The standard test methods available for hard-surface disinfectants (AOAC Use-Dilution Method and AOAC Germicidal Spray Products Test), if followed exactly, would not closely simulate the way in which the disinfectant towelette is used. Of these methods, the AOAC Germicidal Spray Products Test appears to be the one most readily modified for this situation. Instead of spraying the inoculated surface of the glass slide, the product should be tested by wiping the surface of the glass slide with the saturated towelette, and then subculturing the slides after the specified holding time. All remaining liquid should be expressed from the used towelette and should also be subcultured.

(B) The towelette should be removed from its container and subsequently handled with sterile gloves. One towelette should be used to wipe 60 inoculated slides. The area of the towelette used for wiping should be rotated so as to expose a maximum amount of its surface in the course of wiping a set of slides. After wiping the last slide for a particular towelette, all of the liquid remaining in the material should be expressed into an empty sterile container by squeezing the towelette; after a specified holding time (equal to the contact time stated on the product label), an aliquot from this container (ca. 0.1 ml) should be subcultured in the same manner as the slides.

(C) Additional Test Modifications. Please refer to the DIS/TSS-2 enclosure for additional test modifications which may be necessary depending on the intended label claims and directions for use (e.g. exposure period, organic soil, etc.), as well as for documentation of neutralization. Also, please refer to the DIS/TSS-3 enclosure for guidance in reporting the tests.

DIS/TSS-1 Jan 22, 1982
EFFICACY DATA REQUIREMENTS

Disinfectants for Use on Hard Surfaces

(a) Limited efficacy claims. The label of a disinfectant which is effective against a specific major group of microorganisms only (e.g., Gram-positive or Gram-negative) must specify the major group against which it is effective.

(1) Test requirements. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products) is required. Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gram-negative bacteria) or Staphylococcus aureus ATCC 6538 (for effectiveness against Gram-positive bacteria). (Sixty carriers per sample; a total of 180 carriers.)

(2) Performance requirements. To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.

(b) General or broad-spectrum efficacy claims. Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.

(1) Test requirements. Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Product Test as in (a)(1). Sixty carriers must be tested against each of both S. choleraesuis and S. aureus with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)

(2) Performance requirements. Same as in (a)(2) above.

© Hospital or medical environment efficacy claims. Label claims for use of disinfectants in Hospital or medical environments are acceptable only for those products that are effective for general or broad-spectrum disinfection and additionally against the nosocomial bacterial pathogen Pseudomonas aeruginosa.

(1) Test requirements. Employ the AOAC Use-Dilution Method

or the AOAC Germicidal Spray Products Test as in (a)(1). Sixty carriers must be tested against each of S. choleraesuis, S. aureus, and Pseudomonas aeruginosa ATCC 15442 with each of 3 samples, representing, one of which is at least 60 days old. (180 carriers per sample; a total of 540 carriers.)

(2) Performance requirements. Same as in (A)(2) above.

(d) Other microorganisms. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest is likely to be present in or on the recommended use areas and surfaces and thus may present a potential problem.

(1) Test requirements. Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method (II. Confirmative In-Vitro Test), but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(1). Ten carriers must be tested against each specific microorganism with each of 2 samples, representing 2 different batches. (10 carriers per sample, a total of 20 carriers.)

(2) Performance requirements. Killing of the test microorganism on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least 10^4 microorganisms survive the carrier-drying step in order to provide meaningful results.

DIS/TSS-2 Jan 25, 1979

EFFICACY DATA REQUIREMENTS

Supplemental Recommendations

When an antimicrobial Agent is intended for a use pattern that is not reflected by the test conditions specified in the Recommended Methods, one or more test conditions specified in the method must be modified and/or supplementary data developed in order to provide meaningful results relative to the conditions of use. The following basic information is critical to the development and submission of appropriate data.

1. EXPOSURE PERIOD

All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. However, if the product is intended for use at exposure periods shorter or longer than those specified in the method, the method must be modified, in a manner acceptable to the Agency, to reflect the deviation in exposure intended. A modification to provide a shorter exposure period is restricted by the manipulative limitations inherent in the method, while a modification to provide a longer exposure period is restricted by the conditions applicable to the use pattern. If a ten-minute exposure period is necessary for the antimicrobial agent to be effective against the test microorganism the product cannot be represented as an "instantly active" product, or cannot be represented as being "effective in 30 seconds, "one minute," or at any time period shorter than 10 minutes. Also, the product cannot be recommended for use in a manner which is inconsistent with the exposure period necessary for effectiveness (as, for example, "Spray on surface, and immediately wipe with clean cloth") unless the standard method has been modified and reflects efficacy under such conditions of use. In any case, the exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label.

2. TYPE OF SURFACE

When an antimicrobial agent is intended to be effective in treating a hard porous surface, some of the Recommended Methods may be modified to simulate this more stringent condition by substitution of a porous surface carrier (such as a porcelain penicylinder or unglazed ceramic tile) for the non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. In addition, control data, described below in Supplemental Recommendation No. 6, must be developed to assure the validity of the test results when this modification of the method is employed. In no case may a surface carrier which represents a less stringent

condition be substituted for a surface carrier which is specified in the Recommended Method.

3. HARD WATER

The Recommended Methods may be modified to demonstrate the effectiveness of an antimicrobial agent in hard water. The hard water tolerance level may differ with level of antimicrobial activity claimed. To establish disinfectant efficacy in hard water, all microorganisms (bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

4. ORGANIC SOIL

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy by the appropriate method(s) which have been modified to include a representative organic soil such as 5% blood serum. A suggested procedure to simulate in-use conditions where the antimicrobial agent is intended to treat dry inanimate surfaces with an organic soil load involves contamination of the appropriate carrier surface with each test microorganism culture containing 5% v/v blood serum (e.g., 19 ml test microorganism culture $ 1 ml blood serum) prior to the specified carrier-drying step in the method. Control data, described below in Supplemental Recommendation No. 6, must also be developed to assure the validity of the test results when this modification is incorporated into the method. The organic soil level suggested 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 recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 106 /ml) of conidia.

5. RE-USE

The Recommended Methods are designed to demonstrate efficacy of a freshly prepared antimicrobial solution intended for a single application. When the same use solution is intended for repeated applications, testing must be conducted in accordance with a test protocol specially designed to demonstrate retention of the claimed level(s) of antimicrobial activity in the use solution after repeated microbial and other appropriate challenges (such as supplemental recommendations indicated above) and stress conditions (such as an inadvertent or incidental dilution inherent in the use pattern) over the period of time or number of times specified in the directions for use.

6. MICROORGANISM SURVIVAL AFTER DRYING ON A HARD SURFACE

Quantitative determinations of the viable microbial concentration on the untreated control carrier after drying are required in order to determine the validity of the test results obtained with treated carriers when the Recommended Methods are modified to include such elements as (I) test microorganisms not specified in the method, (ii) substitution of a porous surface (e.g., porcelain penicylinder, unglazed ceramic tile) for the specified nonporous surface (stainless steel cylinder, glass slide), and/or (iii) an organic soil load. The detailed protocol for this testing must include: (I) preparation of inoculum, (ii) application of inoculum to the carrier, (iii) the time/temperature and relative humidity conditions for drying the microorganisms on the carrier, (iv) the technique for removal of the microorganisms from the carrier, and (v) the specific assay procedure indicating such details as replication, subculture media/diluents, and the incubation time/temperature conditions for the enumeration procedure employed. The test results must include the individual counts obtained by the method.

7. NEUTRALIZATION

For each antimicrobial product, procedures must be employed that will preclude residual effects of the active ingredient(s) in the subculture medium. A specific medium capable of neutralizing the antimicrobial effects of a product (whenever one is known) should be employed prior to the microbiological assay. Some of the Recommended Methods rely solely upon the selection of an appropriate subculture medium to neutralize the antimicrobial effects of certain general types of chemical compounds (active ingredients). However, to document absence of residual effects of

the active ingredient(s) in the subculture medium, the following testing is necessary: (I) secondary subcultures must be performed to demonstrate that antimicrobial effects were overcome, or (ii) at the conclusion of the incubation period specified or employed in the method, the primary culture medium with test carrier must be inoculated with approximately 10 microorganisms/ml of the specific culture under test (documented by actual plate counts) and reincubated for the specified period to demonstrate that the subculture medium was capable of supporting bacterial growth.

8. BATCH REPLICATION FOR MODIFIED TESTS

Where the required batch replication has already been performed and accepted for a product registration with unmodified tests by the Recommended Methods, additional testing at the same use concentration under modified conditions (e.g., different exposure period, presence of organic soil or hard water, porous surface carrier, etc.) may be conducted with reduced batch replication, as follows: (I) for basic efficacy claims (e.g., sterilizers, disinfectants, or sanitizers), 2 samples, representing 2 different batches, instead of 3, and (ii) for supplemental efficacy claims (e.g., fungicides, virucides, or tuberculocides), one sample instead of 2.

EFFICACY DATA REQUIREMENTS

Reporting of Data

Systematic and complete descriptions of the tests employed and 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 the conduct of the tests.

(1) Recommended Methods. When the Recommended Methods (such as standard AOAC tests) are employed to develop efficacy data, certain minimal information must be provided in the test report. The report must include, but is not limited to, the following:

(a) Test employed, and any modifications thereto;
(b) Test microorganisms employed, including identification of the specific strain (ATCC or other);
(c) Concentration or dilution of product tested and how prepared;
(d) Number of samples, batches, and replicates tested;
(e) Preparation date of each product batch (individually formulated preparation of the product;
(f) Phenol resistance of test microorganisms (actual test results);
(g) Identification of all material or procedural options employed, where such choice is permitted or recommended in the test method selected (for example, growth media, drying time for inoculated carriers, neutralizer and/or subculture media, secondary subculturing);
(h) Complete report of results obtained for each individual replication;
(I) Any control data essential to establish the validity of the test.

(2) Modification of Recommended Methods. Where Recommended Methods are significantly modified to support specific claims and/or use patterns for a product, the protocol employed for modifying the test must be provided in specific detail with the test report. The applicant may submit the proposed modification for review and evaluation prior to initiation of the test.

(3) Other Methods. When Recommended Methods, or modification thereto, are not employed to develop efficacy data (such as actual in-use or many kinds of simulated-use testing), complete testing protocols must be submitted with the test reports. All materials and procedures employed in testing must be described in a manner consistent with original research reports published in technical or scientific journals. Where references to published reports or papers are made, copies or reprints of such references should be provided with the test reports. Proposed testing protocols for in-use or simulated-use studies of this kind may be submitted for review and evaluation by the Agency prior to initiation of the tests.