TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 08-04-78 OUT 05-14-79

Reviewed by Dennis G. Guse Date 05-14-79

EPA Reg. No. or File Symbol 34292-1

EPA Petition or EUP No. None

Date Division Received 08-04-78

Type Product(s): I, (D), H, (F), N, R, S Industrial Antimicrobial

Data Accession No(s). None

Product Mgr. No. 31 (Lee)

Product Name(s) DC 5700 Antimicrobial Agent

Company Name(s) Dow Corning Corporation

Submission Purpose Amendment with data (added use to treat disposable polyurethane foam cushions for Lapidus Airfloat System)

Chemical & Formulation Technical chemical for manufacturing use

Active Ingredient(s): %

3-(Trimethoxysilyl)-propyldimethyl-octadecyl ammonium chloride ..... 42

200.0 Introduction

200.1 Use(s):

The product is registered as a bacteriostat, algistat, and fungistat for manufacturing use as a preservative for unfinished textile fibers, fabrics, and threads.

Claims have also been accepted for its use in a finished article, socks, to prevent deterioration and discoloration caused by fungiand to inhibit odor causing bacteria.

The purpose of the current submission is to add the use to treat disposable polyurethane foam cushions for Lapidus Airfloat Systems for the following claim:

> Polyurethane foam treated with Dow Corning 5700 Antimicrobial Agent exhibits broad spectrum anti-microbial activity against both Gram-negative and Gram-positive bacteria and fungi.

No proposed labeling was submitted.

200.2 Background Information:

It should be noted that this review addresses only the specific data which are the subject of this proposed amendment. No attempt has been made in this review to reevaluate previously submitted data or previously accepted claims or other proposed amendments for added uses which are also under consideration for this product.

201.0 Data Summary

201.1.1 Brief Description of Tests:

(A) "Antimicrobial Activity of Polyurethane Foam Treated with Dow Corning 5700 Antimicrobial Agent". Reference E-2069-8, dated 06-06-78 (Accession No. unassigned).

The above tests were apparently conducted by Dow Corning Corporation, Midland, MI, although the identity of the investigators was not provided.

201.1.2 Data Summaries:

Purpose: The study was intended to support the claim "Polyurethane foam treated with Dow Corning 5700 Antimicrobial Agent exhibits broad spectrum activity against both Gram-negative and Gram-positive bacteria and fungi."

Test Material:

Closed-cell polyurethane foam from Hamilton Industries was treated with Dow Corning 5700 antimicrobial agent at 0.4% wt./wt. pickup of active ingredient.

MICROBIOLOGICAL METHODS:

The untreated and treated polyurethane foam were tested according to a previously described modified AATCC Test Method 100-1974 (CTM-0829) against each of the following bacteria:

1. Klebsiella pneumoniae ATCC 4352
2. Staphylococcus aureus ATCC 6538
3. Pseudomonas aeruginosa ATCC 15442
4. Escherichia coli ATCC 23226
5. Staphyloccus epidermidis (isolated from skin)

Results: See Table I.

TABLE I

ANTIBACTERIAL ACTIVITY OF DOW CORNING 5700 ANTIMICROBIAL AGENT TREATED POLYURETHANE FOAM

| Sample | Organism | Number of Bacteria Remaining At: 0 Time | 4 Hours | % Reduction |
|---|---|---|---|---|
| Untreated Control | Klebsiella pneumoniae | 200,500 | 1,840,000 | 0 (Increase) |
| Treated | | 191,000 | 4,300 | 97.8 |
| Untreated Control | Staphylococcus aureus | 144,000 | 24,000 | 83.3 |
| Treated | | 142,000 | 800 | 99.4 |
| Untreated Control | Pseudomonas aeruginosa | 204,000 | 33,000 | 83.8 |
| Treated | | 227,000 | 350 | 99.8 |
| Untreated Control | Escherichia coli | 260,000 | 26,000 | 90.0 |
| Treated | | 235,000 | 750 | 99.7 |
| Untreated Control | Staphyloccus epidermidis | 10,500 | 9,500 | 9.5 |
| Treated | | 11,000 | 250 | 97.7 |

Conclusions:

Procedural detail was lacking with respect to the following:

1. The method of treatment of the foam samples with the product was not described;

2. The relationship between the foam samples tested and the finished item for which claims are intended (e.g. Lapidus Intensive Care Foam Pad, Lapidus Incontinent Pad, Lapidus Foam Mattress) was not delineated.

3. The number of samples inoculated and the volume of inoculum per sample were not indicated.

4. Raw data were not included. The results appear to be either from a single replication or averages from an unknown number of replications.

Assuming that the above-mentioned information could be provided, the test results indicate that substantial reduction of numbers of K.pneumoniae and S. epidermidis was observed when liquid inocula were placed on treated (0.4% a.i.) polyurethane foam samples for 4 hours at 37°C in screw-capped bottles with the caps screwed on tight to prevent ventilation or evaporation. Under these conditions, populations of the same organisms increased or remained relatively constant on untreated controls samples. However, under the same conditions, the remaining test bacteria (S. aureus, P. aeruginosa, E. coli) decreased in numbers (83-90%) on the untreated control samples, thereby reducing the significance of any effect of the treatment. No attempt was made to simulate conditions anticipated in Lapidus Airfloat Systems. The results cannot be related to any specific claim for effectiveness of the treatment in the end-use system.

Note to PM-31: It should be pointed out that the above summary concerns only that portion of the test report involving bacteriological testing. The remainder of the report concerning fungistatic testing (non-pathogen Aspergillus niger) should be referred to Fungicides for efficacy review.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 08-04-78 OUT 05-14-79

EPA Reg. No. or File Symbol 34292-1

Date Division Received 08-04-78

Product Manager No. 31 (Lee)

Product Name DC 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

202.0 Recommendations

202.1 Efficacy Supported by the Data Submitted:

None.
If complete procedural details and raw data for the submitted study were provided, the data would appear adequate only to support limited intrinsic value of the product as a bacteriostatic treatment for manufacturing use in the impregnation of polyurethane foam. The tests did not address the criteria necessary to evaluate the product purpose, function, or performance for use in Lapidus Airfloat Systems. No attempt was made to establish the microbiological problem or simulate use conditions in the finished items. No proposed labeling was submitted to specify the purpose, claims, and pattern(s) of use for the treatment in the finished items.

202.3 Additional Information/Data Required to Support Efficacy:

(A) If the treatment is intended to control microorganisms not related to human health (e.g. odor-causing bacteria in/on polyurethane foam intended for use in the Lapidus Incontinent Pad in the presence of urine or wet fecal material during use and/or subsequent disposal), the claim must so specify and supporting efficacy will not be required. However, the microbiological problem which is the basis for the claim and treatment must be known or shown to exist for the intended pattern of use (such as the example given above), as well as adequate and complete directions for use in treating the finished item.

(B) If the treatment is intended to control infectious microorganisms related to human health, the claim must so specify and supporting efficacy data for the specific end-uses will be required. For claims against infectious disease organisms, the treatment must provide elimination or significant reduction in numbers (i.e. 99.9%) of target pathogens. When such claims involve highly critical patient care environments (such as the Lapidus Intensive Care Foam Pad used with decubitus ulcers), only elimination of target infectious organisms, on/in treated items (i.e., sterilization, disinfection) can be considered. A level of effectiveness providing only inhibition of growth (bacteriostasis) cannot be considered in situations where a human health hazard may exist.

(C) Claims such as "exhibits broad-spectrum antimicrobial activity against both Gram-negative and Gram-positive bacteria..." are too vague to be meaningful and are unacceptable.

(D) Clarification, as indicated above, is required for any proposed claims for the product in the treatment of polyurethane foam for Lapidus Airfloat Systems. In addition , the specific end-use item(s) intended to be treated (e.g. Lapidus Intensive Care Pad, Lapidus Incontinent Pad, Lapidus Foam Mattress) must be delineated in conjunction with clarified claims. Recommendations and directions for use must be adequate and complete.