TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07-03-78 OUT 05-11-79

Reviewed by Dennis G. Guse DMP Date 05-11-79

EPA Reg. No. or File Symbol 34292-1

EPA Petition or EUP No. None

Date Division Received 07-11-77

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

Data Accession No(s). 232335

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 for treatment on bed sheets)

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 fungi and to inhibit odor causing bacteria.

The purpose of the current submission is to add the use for treatment of bed sheets. No proposed claims or labeling were included with the submission.

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 Bed Sheets Treated with Dow Corning 5700 Antimicrobial Agent". Report pp. 15d (dated 08-06-75), 15e (dated 08-05-75), and 15f (dated 03-13-75).

(B) "Antibacterial Finishes on Fabrics, Evaluation of", CTM-0829, dated 11-17-75, pp. 1-4.

(C) "Antibacterial Finishes on Fabrics, Evaluation of", AATCC Test Method 100-1974, pp. 272-73.

The above tests were apparently conducted by Dow Corning Corporation, Midland, MI, although the identity of the investigator(s) was not provided. The data are contained in Accession No. 232336.

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201.1.2 Data Summaries:

The methodology [201.1.1 (B) and (C)] was previously furnished and is included with the review by Technical Support Section (Efficacy), Disinfectants Branch, RD, dated 08-11-78, for the application for amended registration of EPA Registration No. 34292-1 for use on carpets received 05-05-77.

Treated cotton/polyester sheeting and untreated control fabric were tested according to a modified AATCC Method 100-1974 (CTM-0829) against Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352. Raw data (bacterial counts) were not included, only "% Reduction" values. The reported results are shown in the following tables, in their entirety:

ANTIMICROBIAL ACTIVITY OF BED SHEETS
TREATED WITH DOW CORNING® 5700 ANTIMICROBIAL AGENT

BACTERIOSTATIC ACTIVITY

Staphylococcus aureus ATCC 6538	Cotton/Polyester Sheeting	CTM-0829 (Modified 4 Hours)
Sample	Treatment	% Reduction
Cotton/Polyester Sheeting	None	0
Cotton/Polyester Sheeting	0.75%	99.8
Cotton/Polyester Sheeting	0.75%	99.6
Cotton/Polyester Sheeting	0.75%	99.6

		CTM-0829 (Modified 24 Hours)
Sample	Treatment	% Reduction
Cotton/Polyester Sheeting	None	0
Cotton/Polyester Sheeting	0.75%	100
Cotton/Polyester Sheeting	0.75%	100
Cotton/Polyester Sheeting	0.75%	100

BACTERIOSTATIC ACTIVITY

Klebsiella pneumoniae ATCC 4352	Cotton/Polyester Sheeting	CTM-0829 (Modified 4 Hours)
Sample	**Treatment**	**% Reduction**
Cotton/Polyester Sheeting	None	0
Cotton/Polyester Sheeting	0.75%	87.0
Cotton/Polyester Sheeting	0.75%	99.3
Cotton/Polyester Sheeting	0.75%	94.2

CTM-0829
(Modified 24 Hours)

Sample	Treatment	% Reduction
Cotton/Polyester Sheeting	None	0
Cotton/Polyester Sheeting	0.75%	100
Cotton/Polyester Sheeting	0.75%	100
Cotton/Polyester Sheeting	0.75%	100

WASH DURABILITY OF TREATED COTTON/POLYESTER SHEETING

Treatment 0.75% Dow Corning® 5700 Antimicrobial Agent

Klebsiella pneumoniae ATCC 4352 — CTM-0829

Treatment	No. of Machine Washing Cycles	% Bacterial Reduction
5700	0	99.5
5700	25	98.7
5700	50	94.1
5700	75	85.0

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 tests (Aspergillus niger) should be referred to Fungicides for efficacy review.

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TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 07-03-78 OUT 05-11-79

EPA Reg. No. or File Symbol 34292-1

Date Division Received 07-11-77

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 raw data (including bacterial plate counts) for the submitted studies were provided, the data would be adequate only to support intrinsic value of the product as a bacteriostatic treatment for manufacturing use in the impregnation of cotton/polyester sheeting. The test did not address the criteria necessary to evaluate claims for specific end uses of the product in finished bed sheets. No attempt was made to demonstrate any microbiological problem in untreated bed sheets. No proposed labeling was submitted to delineate the intended claims and pattern(s) of use in finished bed sheets.

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 bed sheets, the claim must so specify and supporting efficacy data will not be required. However, the pesticidal problem which is the basis for the claim and treatment must be known or documented to exist for the intended pattern of use. Sufficient information as to the specific pattern of use must be provided, as well as adequate and complete directions for the end-use.

(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 of target pathogens. When such claims involve highly critical patient care environments (operating suites, intensive care wards) only elimination of target infectious organisms, on/in the treated items (i.e., sterilization, disinfection) can be considered. A level of effectiveness providing only inhibition of bacterial growth (bacteriostasis) cannot be considered in situations where a human health hazard may exist.

(C) Clarification, as indicated above, is required for any proposed additional claims for the product in the treatment of end-use articles or items.