

TECHNICAL SUPPORT EFFICACY REVIEW - I

Disinfectants Branch

IN 07-03-78 OUT 03-26-79 *REC 3/30/79*
Reviewed by Dennis G. Guse Date 03-26-79

EPA Reg. No. or File Symbol 34292-1

EPA Petition or EUP No. _____

Date Division Received 03-02-78

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

Data Accession No(s). 233247

Product Mgr. No. 31 (Lee)

Product Name(s) DC 5700 Antimicrobial Agent

Company Name(s) Dow Corning Corporation

Submission Purpose Additional data "in support of all pending
amended registrations"

Chemical & Formulation Technical chemical for
manufacturing use

Active Ingredient(s): 8

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 current submission is intended "in support of all pending amended registrations." No specific claim(s) and pattern(s) of use are proposed or described.

201.0 Data Summary

201.1.1 Brief Description of Tests:

(A) "Identification of Bacteria Isolated from the Axillary Region of the Human Body."
Reference: E-3069-D, dated 2-21-78.

(B) "Antibacterial Activity of Apparel Fabric Treated with Dow Corning 5700 Antimicrobial Agent."
E-3069-E, dated 2-21-78.

The above data are under Accession No. 233247.

201.1.2 Data Summaries:

See attached reports.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 07-03-78 OUT 03-26-79

EPA Reg. No. or File Symbol 34292-1

Date Division Received 03-02-78

Product Manager No. 31 (Lee)

Product Name DC 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

Recommendations

(A) The submitted test data are adequate only to support the intrinsic value of the product as a bacteriostatic treatment for manufacturing use in the impregnation of textile fabrics. The tests did not address the criteria necessary to evaluate claims for specific end-uses of the product in finished textile articles or items. No attempt was made to demonstrate the microbiological problem in untreated apparel fabric (e.g. production of bacterial-caused odor).

(B) If the treatment is intended to control microorganisms not related to human health (e.g. odor-causing bacteria) in wearing apparel, 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.

(C) If the treatment is intended to control infectious microorganisms related to human health, the claim must so specify and supporting efficacy 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.

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