

TECHNICAL SUPPORT EFFICACY REVIEW - I

Disinfectants Branch

IN 11-02-78 OUT 04-03-79

*REC
4/4/79*

Reviewed by Dennis G. Guse Date 04-03-79

EPA Reg. No. or File Symbol 34292-1

EPA Petition or EUP No. _____

Date Division Received 09-21-78

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

Data Accession No(s). _____

Product Mgr. No. 31 (Lee)

Product Name(s) DC 5700 Antimicrobial Agent

Company Name(s) Dow Corning Corporation

Submission Purpose Test Protocol (control of odor-causing
bacteria on underwear)

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 finished socks to prevent deterioration and discoloration caused by fungi, and to inhibit odor-causing bacteria.

The current submission consists of a proposed test protocol intended to substantiate efficacy of the product in finished underwear to: (a) inhibit the growth of odor-causing bacteria on underwear apparel for (specify duration of activity); (b) inhibit the growth of bacteria on underwear apparel for (specify duration of activity).

200.2 Background Information:

Several previous efficacy reviews and meetings have addressed the impregnation of finished textile articles with this product, and have delineated the type of efficacy data required to document the pesticidal purpose (odor control, deterioration control, etc.) which is intended for the impregnated articles. In addition, the requirements for efficacy testing of impregnated fabrics and textiles are outlined in the revised proposed Product Performance Guidelines [163.91-3 (d) and 163.91-2 (e)].

200.3 Factors Affecting Amount/Type of Data Required:

Pursuant to Section 3(c)(5) of the FIFRA, as amended by the Federal Pesticide Act of 1978, and under the provisions of PR Notice 78-5, claims for control of microorganisms not directly related to human health do not require supporting efficacy data.

On this basis, the proposed claim for this product to inhibit the growth of odor-causing bacteria on underwear apparel would not require supporting efficacy data. However, the pesticidal purpose or function of the product for the proposed claim and pattern of use must be known or shown to exist, and sufficiently detailed recommendations and directions for use must be provided in labeling.

Therefore, the test protocol submitted for the proposed claim and pattern of use will be evaluated as to its conformance with the criteria of the revised proposed Product Performance Guidelines and comments will be provided for the information of the applicant, although the actual data need not be submitted. In addition, comments on the proposed claim and pattern of use, if warranted, will also be provided.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 11-02-78 OUT 04-03-79

EPA Reg. No. or File Symbol 34292-1

Date Division Received 09-21-78

Product Manager No. 31 (Lee)

Product Name DC 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

202.0 Recommendations

202.1 Claims Related to Human Health:

The proposed claim to "inhibit the growth of bacteria on underwear apparel" is too vague to be meaningful and could include or imply effectiveness against pathogenic microorganisms related to human health. Furthermore, elimination or significant reduction in numbers of microorganisms is required where claims against infectious disease organisms are made. Inhibition of growth (bacteriostasis) cannot be considered where a human health hazard may exist. On this basis, the above claim must be revised or excluded.

202.2 Claims not Related to Human Health:

The proposed claim to "inhibit the growth of odor-causing bacteria on underwear apparel" is not considered to be related to human health and supporting efficacy data are not required. However, the pesticidal purpose or function of the product for the proposed claim and pattern of use must be known or shown to exist, and sufficient information on the pattern of use must be provided in labeling.

202.4 Comments on the Claim and Pattern of Use:

It was documented that human apocrine sweat may be acted upon by resident and/or transient human skin bacteria to produce classically unpleasant axillary odor, and that this phenomenon has been reproduced in vitro. Documentation was also provided that clothing may serve as a site for axillary odor production since bacteria cling to clothing along with axillary secretion to produce decomposition and odor production. Therefore, the function or purpose of treating clothing with an antimicrobial agent to inhibit the growth of odor-causing bacteria and inhibit production of bacterial-caused odors is valid. However, the types of clothing and conditions in which undersirable odors are likely to be a problem in actual wear are not unlimited. It is assumed that clothing associated closely with the body, with physical activity, or with warm, humid conditions (underwear, sportswear, work clothes, summer and tropical wear, etc.) is more likely to be associated with sweat and odor production than other types. The recommendations for use of the product should likewise reflect the need for it.

Claims for the treatment should be restricted to inhibition of the growth of odor-causing bacteria and/or inhibition or reduction of bacterial-caused odors on underclothing fabric during wear under conditions where bacterial-caused odors are likely to be a problem or in damp storage prior to laundering. The duration of effectiveness of the fabric treatment between launderings must be specified, as well as the number of times the apparel may be laundered and retain effectiveness.

Broad and unqualified claims for the treatment "to inhibit the growth of bacteria" are unacceptable.

The labeling for this pattern of use should provide guidance as to the specific types of underwear which are recommended to be treated for odor problems.

Complete directions for use of the product must also be provided in labeling, i.e., dosage recommendations, as well as how, when and where the treatment is applied to the fabric.

Any restrictions in applying the product to fabric or in subsequent treatment or cleaning of the finished clothing (e.g. use of bleaching or bluing agents) which may inactivate or nullify the effect of the bacteriostatic agent should also be indicated in labeling.

The labeling should include a statement to indicate that the treatment is intended only for odor control on underwear fabric and is not intended to prevent or reduce bodily odors or perspiration.

202.6

Evaluation of Test Protocol:

The basic elements of the proposed test protocol are generally adequate, except as noted below.

The proposed test appears designed to assess effectiveness of the treatment for a short-time (24 hours) simulated "worst-case" situation. Fabric samples are heavily contaminated with the test bacteria and simulated human sweat under conditions of high temperature (37.5° C), high relative humidity, and absence of ventilation (closed jar) for up to 24 hours.

The protocol includes untreated control fabric samples which must support significant bacterial growth and/or odor production in order to provide a basis for a valid test. Under the above conditions, the efficacy of the proposed treatment levels to inhibit the growth of the test bacteria and to inhibit or reduce odor can be assessed on the specified fabrics (cotton, polyester) after 0, 25, and 50 launderings.

The test is not designed to assess the actual need for the treatment, or lack thereof, on underwear items under average or varied conditions of temperature and relative humidity, or lower bacterial and sweat loads, or for extended periods of time between launderings (days, weeks), or under repeated daily challenge to the fabric.