TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 11-02-78 OUT 03-21-79 WEC 3/30/79

Reviewed by Dennis G. Guse Date 03-21-79

EPA Reg. No. or File Symbol 34292-1

Date Division Received 09-21-78

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

Date Accession No(s). _____

Product Manager No. 31 (Lee)

Product Name DC 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

Submission Purpose Testing Protocol (control of odor-causing bacteria on outerwear)

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 "outerwear" to: (a) inhibit the growth of odor-causing bacteria on outerwear apparel for (specify duration of activity); (b) inhibit the growth of bacteria on outerwear 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 Secton 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 outerwear 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 warrented, will also be provided.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 11-02-78 OUT 03-21-79

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 outerwear 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 outerwear 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 phenonmenon 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 ot 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 undesirable 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 clothing 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 treatment of "outerwear" and/or "to inhibit the growth of bacteria" are unacceptable.

The labeling for this pattern of use should provide guidance as to the specific types of clothing 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. dry cleaning, water proofing, etc.) 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 clothing 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 conditons 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, wool, nylon) after 0, 25, and 50 launderings.

The test is not designed to assess the actual need for the treatment, or lack thereof, on clothing 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.

textiles may result in odor problems, discoloration, or deterioration" should be modified to indicate that these problems will only occur during storage under moist/humid conditions.

3) Statements such as "for lasting freshness", "to prolong the life of the (article/garment) ","to provide a durable, non-leachable antimicrobial treatment", and "to provide a treatment that lasts the lifetime of the (article/garment) "and is not destroyed by repeated (washing/shampooing/dry cleaning)"are considered long term (residual) fungal control claims, unless properly qualified to exclude this claim.

4) Labeling for "nonwoven polyster," "outerwear apparel," "sheeting products," and "polyurethane foam" end-use items must be modified to specifically identify the intended end-use articles/garments to be treated.

5) Since the use concentration needed to effectively treat any article/garment will vary with the method of application, the dosage should be expressed as the final concentration attained on the treated fabric (specify whether wet or dry weight basis).

6) Some of the technical bulletins submitted only contained the front page, while no labeling was submitted with the polyurethane foam application. Any additional page(s) must be submitted (or when appropriate, properly referenced) in order for the bulletins to be accepted. We would suggest that you consider numbering and/or dating all of your technical bulletins so as to facilitate recordkeeping and reference to said documents.

7) If residual efficacy claims for the life of the article/garment cannot be supported by the test results, we could consider accepting claims which relate the length of residual effectiveness to a specific number of launderings, shampooings, or drycleanings supported by the data.

202.3 Comments on the List of Fourteen Proposed Claims

1) If the proposed claims appear on the "Dow Corning 5700" product label, or associated technical bulletins, they would be considered fungicide claims.

2) If these claims appear on the labeling of treated end-use articles/garments they would not be considered fungicide claims for these treated items. However, it is possible that these labels would be considered supplemental labeling for "Dow Corning 5700," when the product name is associated with these claims.

3) Based on the data submitted thus far, none of the proposed fungicide pest claims are acceptable for any of the proposed end-use textile items. Similarly, without additional data we cannot determine what lesser claims would be acceptable with respect to protection of these end-use items.

4) Based on the current accepted "fungistatic" claim for Dow Corning 5700 the only claim which can be permitted on end-use article/garment labeling is: "The material from which this (garment/article) is made has been treated with Dow Corning 5700 Antimicrobial Agent, to reduce the likelihood of fungal deterioration of the material during storage under (moist/humid) conditions, solely for the protection of the material prior to the manufacture of this (garment/article)."

NOTE: Any alternate wording that is desired must be formally submitted for approval.

Richard E. Michell
Fungicide Evaluation Staff
FHB

Richard E Michell
9-27-78

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200.0 Introduction

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TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

IN 11-02-78 OUT 03-21-79

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EFFICACY REVIEW -- Fungicides

200.0 Introduction - The purpose of these submissions is to: (1) amend the registered label by adding a list of specific end-use garments/articles to labeling (separate technical bulletins for each category of garments/articles); and (2) to determine the acceptability of fourteen claims (submitted with letter of 8-21-78) intended to be used in conjunction with treated textile items.

200.1 Uses The proposed list of specific end-wise garments/articles that were reviewed are:

a) Carpeting/Throw rugs (5-5-78 application)
b) Women's Hosiery (8-5-77 application)
c) Mattress Pads (2-23-78 application)
d) Mattress Ticking (8-5-77 application)
e) Outerwear Apparel (8-5-77 application)
f) Non-woven Polyester (8-5-77 application)
g) Polyurthane Foam (6-12-78 application)
h) Sheeting Products (2-23-78) application)
i) Athletic and Casual Shoes (2-23-78 application)
j) Toweling (8-5-77 application)
k) Men's Underwear (2-23-78 application)

The expressed and implied fungicide claims associated with all the specific end-use garments/articles involve control of fungal rot (decay)and mildew (mold, fungal discoloration, fungal odor). Statements such as, "for lasting freshness", "to prolong the life of the (article/garment)", "to provide a durable, non-leachable antimicrobial treatment", "and to provide a treatment that lasts the lifetime of the (article/garment) and is not destroyed by repeated (washing/shampooing/cleaning)" are also considered long term (residual) fungal control claims, unless properly qualified to exclude this claim.

For complete information on the list of fourteen claims (submitted with letter of 8-21-78) proposed to be used interchangeably for each of the specific end-use articles/garments see attached copy of said claims.

200.2 Background Information The subject product was originally registered on 8-4-75 for use on textiles with a general "fungistatic" claim, based on a short-term soil burial test and a short term agar plate test. This was accepted only with the understanding that the textile manufacturer would be instructed to conduct his own tests to determine the actual concentration necessary for a particular textile, prior to commercialization of the treated textile. It was also understood that use on "textiles" did not include treatment of end-use articles or garments.

Subsequently, a label amendment was accepted on 7-2-76 allowing the product to be used on socks for the purpose of providing lasting freshness and to prevent discoloration (mildew) and deterioration (rot) caused by fungi. We are not aware of any additional efficacy data being submitted to support these claims, nor of any fungicide evaluation staff being involved in the acceptance of these additional claims. Consequently, the existing data in the subject product files are inadequate to support any of the more recent proposed amendments (additional end-use garments/articles) that have been submitted between 8-5-77 and 6-12-78. Our involvement in the end-use article/garment amendments was initiated on 9-6-78 when we received a memo dated 8-29-78 from Mr. J.M. Tavano (Acting Branch Chief, Disinfectants Branch) requesting our review of the recent amendments and the separate list of fourteen claims to be used in conjunction with the amendments.

In the process of trying to locate all the relevant fungicide efficacy data in the files which could be used to support the amendments very little data was found. Since the product file was somewhat fragmented (as a result of numerous pieces of correspondence, data submissions, technical bulletins, and incomplete documentation of meetings) the registrant was contacted to identify all relevant data in the files and to submit any additional data which was available. The registrant responded (letter of 9-5-78, handcarried 9-7-78) by identifying the fungicide data in the product files which had been submitted.

201.0 Data Summary See attached sheets containing the seven fungicide test reports that were reviewed.

202.0 Conclusions and Recommendations The data in the files are not adequate to support the proposed fungicide

rot (deterioration) and mildew (mold, fungal odors, fungal discoloration) claims on the following end-use textile items: carpeting/throw rugs, women's hosiery, mattress pads, mattress ticking, outerwear apparel, non-woven polyester, polyurethane foam, sheeting products, athletic and casual shoes, toweling, and men's underwear.

These data were indequate for one or more of the following reasons:

1) The individual test periods were too short to determine efficacy for the life of the article/garments;

2) The tests were primarily limited to control of mildew growth rather than rot;

3) The experimental design did not include a relevant number of launderings, dry cleanings, or shampooings to evaluate what effect on efficacy they might have over the service life of the articles/garments. (Note: several tests indicated that control of bacteria and fungi decreased significantly with only a few launderings);

4) Many of the treated fabrics supported mildew growth within a 14 to 28 day period; and

5) The test procedures and results were incompletely reported because some of the pertinent information was omitted (e.g., dates, method of application, wet pickup dosage, evaluation criteria, genera of fungi involved, type(s) of finishes on test fabrics, and specific test procedures and conditions).

202.1 Additional Data Needed to Support Claims The following methods contain acceptable procedures for developing data to support fungal rot and mildew claims:

1) "Method of Test for Control of Fabric Mildew by Fungistats" - [mildew claims (copy attached), suggest using a 12-week incubation period with weekly ratings on mildew growth];

2) Federal Test Method Standard. October 5, 1972. "Mildew resistance of textile materials; soil burial method". Method 5762.1 in Textile test methods No. 191 General Services Administration, Washington, D.C. 20407 -- [rot claims for soil or nonsoil contact fabric uses]; and

3) Federal Test Method Standard. December 31, 1968 "Mildew resistance of textile materials; mixed culture method". Method 5760 in Textile test methods No.191, General Services Administration, Washington, D.C. 20407 - [rot claims for non-soil contact fabric uses].

In order to obtain the appropriate fungicide efficacy data to support registration for the various types of end-use articles/garments the above methods must be modified so as to at least evaluate representative types of fabric (chemical composition, thickness, density, etc.), methods of application (padding, dipping), ranges of wet pickup, and a sufficient range of launderings, dry cleanings, or shampooings (to include the maximum number of such exposures that would be anticipated over the service life of the respective articles/garments. Since August 4, 1975 accepted labeling on Technical Bulletin 19-015 states that the chemical can be inactivated (neutralized in treatment baths by adding a nonionic detergent, studies should be submitted to demonstrate that this does not occur with detergents of this type that are likely to be used in laundering or shampooing treatments. We recommend that you evaluate the possible neutralization effects of anionic, cationic, and nonionic detergents to determine their potential impact on the residual effectiveness of the treated fabrics. Additionally, some observations should be made to assess whether or not the treatment has any adverse effect on the aesthetic or functional qualities of treated items (e.g., discoloration, colorfastness, water repellancy, and softness).

It would be adviseable to submit a detailed outline of your proposed test program, accompanied by a list of your proposed end-use items and pest claims, prior to initiating studies. It is recommended that you also include the necessary background information to support the rationale for test method modifications and the selection of treatments to be evaluated[e.g. expected service life of end-use items, maximum number of launderings, dry cleanings, or shampooings likely to occur over the service life of end-use items, types of fabric from which end-use items are made (nylon, rayon, cotton, wool etc.) and choice of detergents used in laundering and shampooing evaluations].

202.2 General Labeling Comments

1) Efficacy data summary tables listed in your technical bulletins should either be deleted or properly qualified so as not to imply that the data presented would preclude the need for efficacy testing by the user before commercialization of the treated textile items.

2) Statements, such as "microbial contamination of

PROPOSED CLAIMS

1. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent for lasting freshness and to prevent deterioration and discoloration due to bacteria and fungi, hence prolonging the life of the material while in storage.

2. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent for lasting freshness and to prevent deterioration and discoloration due to bacteria and fungi, hence extending the life of the material while in storage.

3. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent for lasting freshness and to prevent deterioration and discoloration due to bacteria and fungi, while in storage between laundering.

4. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent for lasting freshness and to prevent deterioration and discoloration due to bacteria and fungi, thereby extending the overall life of the article/garment/material.

5. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria and fungi for the life of the material.

6. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria and fungi while in storage.

7. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria and fungi. This treatment also imparts durable protection against mold and mildew while in storage between laundering.

PROPOSED CLAIMS

8. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria and fungi. This treatment also imparts durable protection against mold and mildew while in storage.

9. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria and fungi. This treatment also imparts durable protection while in storage between laundering.

10. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria, mold and mildew. This treatment also imparts durable protection while in storage between laundering.

11. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria, mold and mildew for the life of the material.

12. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria, mold and mildew while in storage.

13. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria, mold and mildew. This treatment also imparts durable protection against mold and mildew while in storage between laundering.

PROPOSED CLAIMS

14. The material from which this garment/article is made has been treated with DOW CORNING® 5700 Antimicrobial Agent. This treatment imparts lasting freshness and prevents discoloration and deterioration due to bacteria, mold and mildew. This treatment also imparts durable protection against mold and mildew while in storage.