EEB BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 7-3-78 OUT 7-6-78

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 34292-1

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 3-2-78

DATE OF SUBMISSION 2-23-78

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, (D), H, F, N, R, S Bacteriostatic preservative for unfinished textile fiber, fabri and threads

DATA ACCESSION NO(S). 012092

PRODUCT MGR. NO. 31 Tavano

PRODUCT NAME(S) Dow Corning Q 9-5700 Antimicrobial Agent

COMPANY NAME Dow Corning Corporation

SUBMISSION PURPOSE Amendment: Added use pattern and claims

CHEMICAL & FORMULATION

Active: 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride.....42%

Inert:58%

A. Date of Application for Amended Registration — Proposed Amendment

8-5-77	Add:	textile toweling
8-5-77	Add:	non-woven polyester
8-5-77	Add:	mattress ticking
8-5-77	Add:	outerwear apparel
8-5-77	Add:	women's hosiery
2-23-78	Add:	mattress pads
2-23-78	Add:	men's underwear
2-23-78	Add:	athletic and casual shoes
2-23-78	Add:	sheeting products

B. Proposed claims of efficacy for impregnation of finished, end articles:

1. ...to prevent deterioration and discoloration caused by...bacteria

2. to inhibit the growth of bacteria...to prolong the life of the...(article)...

3. to provide a treatment that lasts the lifetime of the...(article)...and is not destroyed by repeated washings.

4. to resist the development of bacterial... odors.

5. to retain its freshness by resisting the growth of odor-causing bacteria

6. as an exclusive protective treatment that resists...bacteria growth

200.0 Introduction

200.1 Uses:

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

200.2 Background Information:

With regard to the above registered claims for the subject product, the required demonstration of efficacy for the registration issued 8-4-75 was based on minimal data showing microbiostatic properties of treated textile fabrics and intrinsic value as a microbiostatic (including bacteriostatic) preservative agent for unfinished textile materials.

Thus, efficacy data relative to specific, finished textile products (such as shoes, socks, mattress pads, etc), the use patterns of the end articles, warranted claims, dosages, application techniques, duration of efficacy under use conditions, etc., were not provided by the registrant.

There are several current applications for amended registration to add use patterns for impregnation of numerous and various finished textile articles, and to extend the efficacy claims associated with the impregnation of such articles. The applications for amended registration listed below all reference Master File 34292-1 for supporting efficacy data.

The following lists delineate the proposed added use patterns, and the proposed extension of claims (the claims are identical for all proposed, listed amendments).

201.0 Data Summary

201.1.1 Brief description of tests submitted:

None submitted. The registrant referenced type of data submitted as follows:

"None. Refer to Master File 34292-1".

201.3 Data Summaries:

The referenced data have been previously reviewed. No summary is necessary.

202.0 Comments Regarding Proposed Efficacy

202.1 Efficacy Supported by the Referenced Data:

The referenced data are adequate only to support a claim for intrinsic value for manufacturing use as a bacteriostatic preservative for unfinished textile materials. The limitations of this data were previously indicated in the scientific review by Efficacy Section of EEEB, dated 5/14/76, again in a meeting of 10/13/77, again in the scientific review by Efficacy Section of EEEB, dated 11/11/77, and in Division correspondence of 11/22/77 to registrant.

202.2 Efficacy not supported by the referenced data:

The referenced data do not substantiate the proposed efficacy of the product to prevent bacterial-caused deterioration and discoloration; to inhibit the growth of bacteria for prolongation of use-life; to provide a lifetime treatment which is not destroyed by repeated washings; to resist the development of bacterial odors; to retain freshness by resisting the growth of odor-causing bacteria - for any of the following use patterns under any use conditions:

textile toweling
non-woven polyester
mattress ticking
outerwear apparel
women's hosiery
mattress pads
men's underwear
athletic and casual shoes
sheeting products

202.2.1 Insufficient and/or Inappropriate Efficacy Data:

Refer to 200.2 and 202.1 above.

202.3 Additional data and/or information necessary to document proposed efficacy of product in proposed use patterns:

1. Clarify what end-use articles and use patterns are represented by "non-woven polyester", "textile toweling", and "sheeting products".

2. Appropriate studies or other documentation must be provided which establishes the existence of bacterial - caused deterioration, discoloration, and odor problems, under the end-use conditions intended, in/on each of the finished, end-use articles/items proposed for impregnation. The end use conditions under which such problems occur must be delincated for each finished end-use article/item. For example, do the deterioration, discoloration, and odor problems occur during wearing, during use, in dry or wet storage prior to laundering, or what?

3. Appropriate studies or other documentation must be provided which identify the specific target bacterial pest(s) (and contaminant level) responsible for the bacterial-caused deterioration, discoloration, and odor production problems (documented in (2) above) during use (or other conditions intended) in/on each of the finished, end-use articles/items proposed for impregnation.

4. A controlled simulated-use laboratory study must be performed on each proposed, finished end use article/item proposed for treatment. Experimental data must be derived from protocols designed to represent each specific article/item under consideration and its usage. Such studies must confirm that deterioration, discoloration, and odors are bacteriologically produced in/on the articles/items per se, and that the subject product controls these problems at that site. Protocols must include the following elements:

   a. Must be based on controlled simulated-use lab studies on each article/item proposed for impregnation, employing as test bacteria those specific target bacterial pest(s) (and their numbers) that have been isolated from or documented to be encountered in/on the item and have been identified as the source of the problems (deterioration, discoloration, and odor) on/in each item proposed for impregnation.

   b. The temperature, relative humidity, and other environmental conditions employed in the studies must be reported and must be those expected to be encountered under normal conditions of use of each of the articles/items.

   c. Test and control articles/items must be initially challenged and subsequently re-challenged, at appropriate intervals for as long as the item is intended to provide a pesticidal function, with those elements that are associated with actual conditions of use--such as recontamination with bacterial target pests, recontamination with soil and perspiration, rewashing, etc. Since the treatment is intended to persist for the use life of the item through repeated wear/contamination/soil cycles, repeated soiled storage cycles, and multiple laundering cycles, the effect of repeated cycles of bacteria/

perspiration/soil challenges under laboratory simulated-use conditions, followed by aeration in storage, and then washing under various commercial/home laundering conditions must be incorporated into studies for assay and assessment of efficacy and duration of efficacy.

d. At least three different batches of the product should be tested, of which at least one batch is at least 60 days old.

e. Each specific type of each article intended to be treated should be tested with each of the above product batches. (For example, men's cotton underwear, men's cotton/polyester underwear, men's nylon underwear, etc, wool outerwear apparel, cotton outerwear apparel, cotton/polyester outerwear apparel, etc). The articles/items must be fabricated and treated using the range of product concentrations, application techniques, finishes, etc. that would be employed in actual commercial processes. Sufficient replication of each item and each concentration is necessary so that the amount of variation can be estimated.

f. Studies must be designed so as to utilize quantitative recovery techniques. That is - elute surviving bacteria into appropriate diluting fluid containing appropriate neutralizer for the active ingredient, and perform quantitative plate count enumeration procedures on appropriate agar containing same type of neutralizer. The determination and reporting of observed deteriorative changes, discoloration, and odor production must be conducted concurrently with the bacteriological counts. Assays should be incorporated into studies at appropriate intervals to allow assessment of product efficacy through the various cycles of the use pattern.

g. Data must demonstrate inhibition of bacterial growth (quantitatively) on treated articles/items over that of untreated control articles/items. Data from the untreated control must show that bacterial growth occurs and causes deterioration, discoloration, and odor production in/on the specific articles/items under consideration, when subjected to simulated conditions of use. Data from the treated articles/items must show that control of bacterial growth occurred (quantitatively) and that deterioration, discoloration, and odor production in/on the specific articles/items was prevented, for the entire intended use-life period, when subjected to simulated conditions of use.

In general, it should be noted that simulated-use laboratory studies constitute the required testing to document that deterioration, discoloration, and odor are bacteriologically produced in/on the proposed articles/items, and that the subject product treatment controls these problems in/on the proposed articles/items. What must be documented to support efficacy of the subject product in the proposed pesticidal use patterns for the proposed pesticidal functions is that:

1. each of the articles/items proposed for impregnation is the site of growth of specific bacterial target pests and that such growth results in the production of deterioration, discoloration, and odor in/on the articles/items per se and

2. The proposed treatment of such items per se controls these problems at that site. Wear studies, either alone or combined with laboratory studies, would not permit distinction between the human body and the

proposed articles/items as the site of the pest problem and site of control. To support a pesticidal use pattern and function, studies must be based on reproduction of the pest problems and control of the pest problems in/on/at sites other than the human body.

There is no recognized standard test protocol and/or procedural study for demonstrating the above efficacy. Therefore, it is suggested that any proposed studies designed to demonstrate such effectiveness be submitted to this Agency for comments prior to initiation of testing.

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7/5/78