EEE BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 11-9 OUT 11-11-77

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 34292-1

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 3-9-77

DATE OF SUBMISSION 3-3-77

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): I, (D,)(H,)(F,) N, R, S Antimicrobial Textile Additive

DATA ACCESSION NO(S). _____

PRODUCT MGR. NO. 31

PRODUCT NAME(S) Dow Corning Q9-5700 Antimicrobial Agent

COMPANY NAME Dow Corning Corporation

SUBMISSION PURPOSE Amendment with data

CHEMICAL & FORMULATION Concentrate for manufacturing use only

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

200.0 Introduction

200.1 Use(s):

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

A label claim has also been accepted for its use in a finished article--socks--to prevent deterioration and discoloration cause by fungi.

The purpose of the current submission is to extend the claims to include prevention of deterioration and discoloration caused by bacteria in finished socks during use.

200.2 Background Information:

With regard to 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.

Thus, efficacy data relative to specific finished textile products (such as socks), the use pattern of the end article, warranted claims, dosage, application techniques, duration of efficacy under use conditions, etc., were not provided by the registrant.

201.0 Data Summary

201.1.1 Brief Description of Tests:

The applicant referenced efficacy data as follows:

"The data to support this revised claim is in our Master File #34292-1, Section IV pages 15-17, Section V pages 31-32 and in our accepted 'Collateral Label' Bulletin 19-015 page 5. For your convenience I am submitting copies of the data referred to in the master file and in the collateral label."

201.1.2 Data Summaries:

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

202.0 Recommendations

202.1 Claims Supported by the Data:

The referenced data are adequate only to support a claim for intrinsic value for manufacturing use as a bacteriostatic preservative for unfinished textile material.

The limitations of this data were previously indicated in the review by Efficacy Section, EEE Branch, dated 5-14-76, and again in a meeting of 10-13-77.

202.2 Claims Not Supported by the Data:

The referenced data do not support a claim for the product in prevention of deterioration and/or discoloration caused by bacteria in finished socks during use.

In addition, no information is available to indicate that bacteria cause a problem relative to deterioration or discoloration of socks.

202.3 Additional Data Required to Support Claims:

To support the proposed claims:

(A) A study must be designed and performed to establish:

(1) The existence of a bacterial deterioration problem with socks under conditions of use;

(2) The identity and contaminant levels of bacterial flora responsible for the observed deterioration;

(3) The conditions necessary to reproduce/simulate the in-use situation in controlled experimental tests.

(B) Based on the information obtained in (A), a controlled simulated-use study must be designed and performed to demonstrate efficacy of the product, as follows:

(1) Quantitative measurement of bacteriostatic activity of the product in treated socks compared to untreated control socks. The test organisms and inoculum load should be representative of that determined in (A)(2) above, and the experimental conditions representative of that determined in (A)(3) above;

(2) Demonstration of prevention in treated socks of the deteriorative changes observed in untreated control socks;

(3) The duration of effectiveness of the treatment through repeated cycles of wear/soiled storage/laundering.

(C) There is no recognized standard protocol or procedure for the testing indicated above. Therefore, it is recommended that any proposed test design be submitted for review and comment prior to the initiation of the tests. For general guidance, the following basic elements should be incorporated into the proposed tests:

(1) At least 3 different batches of the product should be tested, of which at least one batch is 60 days old.

(2) Each specific type of sock intended to be treated should be tested with each of the above product batches (examples: cotton socks, wool socks, various types of synthetic socks, cotton/synthetic socks, etc.). The socks must be fabricated and treated using a range of product concentrations, application techniques, finishes, etc., that would be employed in actual commercial processes. Sufficient replicates of each type of sock should be included so that the amount of variation can be estimated.

(3) Those in-use conditions which would be expected to affect performance and/or retention of the chemical in/on the treated socks should be incorporated into the study (examples: perspiration, soil, abrasion, etc.).

(4) Since the treatment is intended to persist for an extended period of time through repeated wear cycles (ca. 12-18 hours), repeated soiled storage cycles (ca. 1-7 days), and multiple cleaning cycles, the effect of repeated bacterial/perspiration/soil challenge under simulated wear conditions, followed by aeration and storage, and then washing under various commercial/home laundering conditions, must be assessed.

(5) The test method chosen for assay of bacteriostatic efficacy should be based on quantitative (colony forming units) demonstration of activity on the fabric itself and not on leaching of the active ingredient into

agar substrates. You may wish to modify any of several existing test procedures suitable for the purpose such as the AATCC Method 100-1974 or similar methods.

(6) Adequate controls must be included for all phases of the study. The controls must show not only survival, but significant bacterial growth and resultant deteriorative changes in untreated socks. The type of deterioration that occurs in the untreated socks must be described and documented.

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