EEE BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 4-6-77 and 5-19-77 OUT 6-2-77

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 34292-1

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 4-6-77 and 3-9-77, 5-9-77

DATE OF SUBMISSION 4-6-77 and 3-3-77,5-9-77,5-5-77

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, (D) H, F, N, R, S Bacteriostatic, fungistatic, algistatic preservative for unfinished textiles

PRODUCT MGR. NO. 31 Tavano

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

COMPANY NAME Dow Corning Corporation

SUBMISSION PURPOSE Submission of proposed test protocol for comments.

CHEMICAL & FORMULATION

Active: 3-(Trimethoxysilyl)-propyldimethyloctadecyl ammoni ammonium chloride - - - - - - - - - - - 42%

Inert: 58%

200.0 Introduction:

200.1 Use(s):

The pattern of use discussed in this report is the treatment of finished socks with Dow Corning Q9-5700 Antimicrobial Agent to inhibit the growth of odor-causing microorganisms on finished socks during use (wearing by purchaser), and thus inhibit, reduce, and/or control sock odor.

202.2 Background information:

The purpose of this submission is to obtain comments relative to the proposed test protocol, submitted on April 6, 1977 by the registrant, to develop data to demonstrate the efficacy of Dow Corning Q9-5700 Antimicrobial Agent in the above described pattern of use.

This submission consists of the following:

1. "Protocol for Efficacy Evaluation of Dow Corning Q9-5700 Treatment on Socks." (In-Use Wear Tests).

2. Scientific literature intended as documentation of the relationship of bacterial numbers in/on socks to odor production in/on socks, to validate the appropriateness of the design of the proposed efficacy testing protocol.

204.0 Proposed Protocol

204.1 Test protocol and scientific literature:

See registration file of subject product for details of proposed efficacy testing protocol. The following scientific literature was submitted in support of the proposed protocol:

1. Abramson, C. and Terleckyj, B. Foot Odor.

2. Abel, R. B., Becker, J. S., Green, R. and Hodge, W. R. 1976. The Incidence of Isolation of Candida Species from the Human Foot. JAPA. 66:237-41.

3. Cunliffe, W. J. and Tan, S. G. 1976. Hyperhidrosis and Hypohidrosis. The Practioner. 216:149-53.

4. Davis, J. A. 1975. A Study to Determine the Relative Absorbability and Wicking Effect of Certain Major Sock Materials on Perspiration of the Human Foot. J. Am. Pod. Assoc. 65:11:1051-57.

5. Ellis, H. 1975. Hyperhidrosis and Its Surgical Management. Postgraduate Medicine. 58:3:191-96.

6. Hole, L. G. 1973. Sweat Disposal from Footwear and Health and Hygiene of Foot Skin. J. Soc. Cosmet. Chem. 24:43-63.

7. Kligman, A. M., Leyden, J.J., and McGinley, K. J. 1976. Bacteriology J. Invest. Dermatol. 67:160-68.

8. Leyden, J. J. and Kligman, A. M. 1975. Aluminum Chloride in the Treatment of Symptomatic Athlete's Foot. Arch. Dermatol. 111: 1004-10.

9. Marples, M. J. 1974. The Normal Microbial Flora of the Skin. Soc. Appl. Bacteriol. Symp. Ser. 3:13-34.

10. McBride, M., Duncan, W., Knox, J. 1977. The Environment and the Microbial Ecology of Human Skin. Appl. and Envr. Micro. 33:3: 603-608.

11. Rubinlicht, J. R. 1976. Bacterial infections of the Foot. JAPA. 66:397-407.

12. Shelley, W. B., Hurley, H. J. and Nichols, A. C. 1953. Axillary Odor. Arch. Dermatol. Syphilol. 68:430-46.

13. Stewart, R. C. 1973. The Regrowth of the Cutaneous Flora of the Foot Following Antisepsis. JAPA. 63:639-646.

14. Tachibana, D. K. 1976. Microbiology of the Foot. Ann. Rev. Microbiol. 30:351-75.

15. Woodroffe, R.C.S. and Shaw, D.A. Natural Control and Ecology of Microbial Populations on Skin and Hair. Unilever Research. Isleworth Laboratory, Middlesex, England.

204.2 Comments:

The scientific literature submitted to document the relationship of bacterial numbers in/on socks to odor production in/on socks, in order to validate the appropriateness of design of the efficacy testing protocols proposed for the subject product, Q9-5700, has been reviewed.

The literature submitted fails to provide information relating the numbers of different types of microorganisms on feet (or socks) to the production of offensive odors on feet (or socks). Therefore, there is no basis for employing reduction of bacterial numbers or inhibition of bacterial growth on socks as an indicator to the control of sock odor.

The literature indicates that very little is known relative to the microbiology or the biochemistry of foot odor. There are indications that apocrine sweat and the activity of microorganisms can be associated with the production of foul or offensive odors on those body areas where apocrine glands exist. However, the role of eccrine sweat in foul or offensive odor production by microbial activity is not established, especially in regard to feet. The role of apocrine sweat and microbial activity in axillary odor cannot be correlated with eccrine sweat and microbial activity in foot odor.

The "concept" or "notion" (as it is referred to in the literature) that foot odor is associated with hyperhidrosis of the feet and that microbial metabolism on the skin may be associated with the production of volatile, foul, foot odor is not challenged, as a concept, by the Agency. However, what must be documented in order to support registration of the subject product in the proposed use pattern is that socks are the site of microbial growth and offensive odor production rather than the feet, and that the treatment of such socks per se, controls sock odor. If in fact, the feet are the site of microbial activity and odor production, and the socks are merely absorbents or adsorbents of volatile, offensively aromatic, metabolic by-

products from the feet, then the site of antimicrobial activity for control of odor production obviously must be the feet. If antimicrobial activity is directed to the feet, whether by direct application of the chemical agent or by indirect application of chemically treated fabrics to the feet, then the pattern of use is not pesticidal.

Therefore, the following types of studies are needed to support the pattern of use for the subject product:

1. Controlled in-use wear studies of untreated socks to establish the identity and concentration of the microbial flora that contaminate socks and are associated with the production of offensive odors in/on socks. (Identify and quantify the odor-causing target pest(s) in/on socks).

2. Simulated-use laboratory studies which confirm that offensive sock odor is microbiologically produced in/on socks, and that Q9-5700 treatment controls the problem. It must be documented that the specific types of bacteria and their numbers that were found to contaminate socks in the controlled in-use wear studies are in fact responsible for the production of offensive sock odor and that the site of production of such odor by these bacteria is in/on socks. Reproduction of offensive odor in/on socks must be performed under simulated use conditions in the laboratory using the identified odor-causing target bacterial pest(s). Control studies should demonstrate microbial growth (quantitatively) and offensive odor production in/on untreated socks. Test studies should demonstrate control of microbial growth (quantitatively) and control of odor production in/on Q9-5700 treated socks.

   Demonstration of duration of activity through multiple launderings and multiple bacterial challenges should be included, using both treated and untreated socks, and determining both microbial control and odor control.

If it is deemed necessary to employ perspiration in the simulated use laboratory studies, only eccrine or simulated eccrine sweat, will be acceptable. The type and amount of replication for laboratory testing have been previously indicated.

The proposed "Protocol for Efficacy Evaluation of Dow Cornings Q9-5700 Treatment on Socks" submitted for comment is (a) not directed to the types of studies indicated in I and 2 above, and (b) the assumption that measurement of inhibition of bacterial growth can be interpreted as demonstration of odor reduction is not validated by the literature submitted. Additionally, based upon further consideration and the information provided in the literature submitted, it is our opinion that the proposed in-use wear tests of treated socks would not permit distinction between the feet and socks as the site of the problem and site of control. Therefore, information derived from such studies could not be interpreted as to pesticidal efficacy. For the above reasons, the proposed protocol is unacceptable and it is not considered meaningful to provide an in-depth critique of the protocol.

Protocols developed in accordance with the objectives delineated in the studies designated as I and 2 above can be submitted for comment. Note that such protocols must provide full details of all aspects of the anticipated studies.

Doris Jean Jenkins

Doris Jean Jenkins
Efficacy Section
Efficacy and Ecological Effects Branch
June 2, 1977

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