

TO: J. Tavano

11/9/77

FROM: D. J. Jenkins

SUBJECT:

Comments regarding Dow Corning letter of 10/25/77 and Meeting of 10/13/77
Dow Corning 5700 Antimicrobial Agent, EPA No. 34292-1

I. Regarding letter 10/25/77: Paragraph entitled Bacteriostatic Claim:

EEEB only agrees that there is sufficient intrinsic value data in the file to support a bacteriostatic preservative claim for unfinished textile materials. This was indicated in EEEB review of 5-14-76 and in meeting of 10/13/77.

II Regarding letter of 10/25/77: Paragraph entitled Inhibition of Odor-Causing Bacteria Claim:

No agreements were made by EEEB regarding definitions of pathogenic, non-pathogenic, odor-causing, and non-odor causing bacteria. AMPAC deliberations were not discussed in detail nor agreed upon. No agreements were made by EEEB regarding odor-causing fungi.

Required testing was discussed in the 10/13/77 meeting and, in general, a laboratory study and a wear study were agreed upon. However, details of such testing were not discussed and were not agreed upon. Such details constitute the critical factors in acceptance or rejection of data.

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The following represent the testing and the details of test parameters that are required by EEEB:

- (a) Dow Corning indicated (in meeting of 10/13/77) that they have already performed studies to isolate and identify odor-causing bacteria from socks. (This information was requested in EEEB reviews of 5/14/76 and 6/2/77.) Dow Corning desires to employ these bacteria as test organisms in the simulated-use laboratory tests. Therefore, these studies, in which the odor-causing bacteria in socks were isolated and identified must be submitted as documentation of target pests. Complete details of how these studies were conducted and the results obtained must be provided.
- (b) Controlled simulated-use laboratory testing to quantitatively demonstrate the inhibition of growth of test bacteria on finished socks is required, as agreed upon in meeting of 10/13/77. The following test and control factors must be incorporated into study:

Simple demonstration of bacteriostatic activity, via zones of inhibition or other qualitative procedures, on bacterial media by impregnated materials is not sufficient to document

in-use efficacy or practical value associated with the proposed use pattern. It must be demonstrated that the expected activity occurs in/on the impregnated material itself. Since the expected activity, inhibition of growth of odor-causing bacteria on socks, is to be an extended, prolonged, or residual type of activity in-use (during 12-18 hours socks are being worn) and is to persist through multiple uses (after multiple cleaning cycles), data are required to document this expected retention of chemical treatment and residual antimicrobial activity. Therefore, a simulated-use type lab study must be designed which will establish initial bacteriostatic activity on impregnated socks; if and how long such activity can be expected to persist in actual use; and through how many cleaning cycles and multiple uses does the chemical treatment persist (use-life of treatment). Those factors which would be expected to adversely affect the retention and activity of the product in/on socks, in-use, should be incorporated into the study, such as abrasion, heat, repeated bacterial contamination, organic load, perspiration, etc. In addition, the effect of multiple washings with different commonly used detergents

varying water hardness, varying water temperatures, different laundry additives (softeners, bleaches), drying, etc. must be determined.

Other basic test factors to be included are:

- (1) At least three different batches/lots of subject chemical, of which at least one batch/lot is 60 days old, should be tested.
- (2) Each specific type of sock intended for impregnation should be tested using each of the above samples of subject chemical (example: wool socks, cotton socks, nylon socks, cotton/polyester socks, orlon/spandex socks, or whatever). The socks must be fabricated and treated using the product concentration, application techniques, finishes, etc that would be employed in actual commercialization process. At least five replicates of each type of sock per sample of chemical for each test performed should be used.
- (3) The test bacteria (and inoculum load) employed should be those that the registrant has already determined to be target pests (as per meeting 10/13/77).
- (4) The test method chosen for documentation (assay) of bacteriostatic efficacy must be

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quantitative and must be based on demonstration of activity on the fabric itself, not on leaching of the chemical into/onto agar substrates.

(5) Olfactory observations regarding development of odors on both test and control phases of the study should be included.

(6) Adequate controls are necessary for all phases of the study, and complete descriptions of fabric treatment procedures, test procedures, assay procedures, test bacteria inoculum levels, individual test and control results, etc, must be presented for evaluation.

(c). Organoleptic Test: As indicated in the meeting of 10/13/77, this type of "wear and smell" study will provide a general indication as to odors emanating from treated and control socks after wearing, contingent of course on such critical factors as selection of wearers, aeration, time lapses between wearing and sniffing, etc. However, this study will not indicate the site/pest relationship that is necessary for evaluation of pesticidal use patterns. Section 162.3 (ii)(A) of Section 3 Regulations excludes antimicrobial activity on/in living man or animals as a pesticidal use pattern. Therefore, the wear study Dr. Rogoff requested

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will be evaluated regarding intrinsic value as an antimicrobial agent, but cannot be evaluated and/or considered in support of a pesticidal use pattern. This was indicated in EEEB review of 6-2-77.

III Concerning the subject of "claims", specific commitments on specific terminology are contingent upon determination of the specific efficacy supported by the data to be submitted.

IV In regard to "inhibition of odor-causing bacteria" on all other articles of clothing, EEEB does not concur that the exact-same testing conducted for the use pattern involving socks can be performed to support efficacy for any and all other textiles. This type of commitment is all-inclusive and not scientifically advisable without any knowledge of anticipated use patterns.

In summary, it should again be noted that the meeting of 10/13/77 was grossly deficient in discussion and agreements as to details of testing. The registrant did not appear

to be concerned with such details. The agreement reached was very general, and the studies agreed upon had actually been designated in previous correspondence in greater detail. The agreement reached was simply that a simulated-use lab test on socks using identified odor-causing bacterial pests, and a wear/smell test on socks conducted by a professional organoleptic panel, would be performed. Since critical details of such testing were not discussed and not agreed upon, the registrant may wish to submit proposed protocols for comment prior to testing. At this time, EEEB has not made any commitments relative to acceptable test protocols.

Robert J. Jenkins
EEEB 11/9/77