

US EPA ARCHIVE DOCUMENT

Dow Corning Corporation
Attention: Mr. Gordon Needleman
South Saginaw Road
Midland, Michigan 48640

DEC 31 1974

Gentlemen:

Subject: X9-5700-ANTIMICROBIAL AGENT
EPA File Symbol No. 34292-R
Application of March 27, 1974

The application for registration of the subject product is not acceptable for the reasons given below. When the requested information is submitted, along with five copies of revised labeling, further consideration will be given to this application.

1. The following additional toxicity data are required prior to registration of this product:

- a. Acute rat inhalation LC₅₀ on the formulation
- b. Acute rat inhalation LC₅₀ on the active ingredient.
- c. Acute rat oral LD₅₀ on the active ingredient.
- d. Acute rabbit dermal LD₅₀ on the active ingredient.
- e. 21-day rat inhalation at 1 and 5 times the expected air concentration in the treatment area of the factory.

2. The efficacy data submitted relative to bacteriostatic activity and the data represented in Tables II and III of the Bulletin are considered inappropriate to support registration. Tables II and III should be deleted from the Bulletin.

It appears, from the literature submitted, that one of the unique features of the product is that antimicrobial activity is not dependent on solubility or release of chemical from the surface. It would appear that the unique feature intended is that moisture is not required for antimicrobial activity and this is a dry contact phenomena. If this is not your intent, clarification is required. The efficacy data submitted are all based on wet-inoculum procedures, and, therefore, do not simulate the use pattern intended. They cannot be correlated with the proposed claims for the product.

3. Efficacy data must be developed relative to each type of textile claimed, employing bacterial test organisms representative of those responsible for

textile deterioration and/or discoloration. The test procedure must be based on contamination of dry textile substrates with dry test inoculums.

- a. The test protocol should be based on one chemical treatment of each textile claimed, but must incorporate multiple wash challenges and multiple bacterial contamination challenges for each fabric.
- b. Adequate and appropriate controls must be employed.
- c. Measurements of the physical parameters of deterioration and/or discoloration by bacteria should also be incorporated into the test procedure.
- d. Studies should include data relative to use with anionic and non-ionic detergents, protein, varying pH, under simulated use conditions (not serial dilution).
- e. All data must include the dosage range recommended (0.1-1.0%).
- f. If it is intended to recommend organic solvents as diluents, parallel data should be developed accordingly.

Since no standard test protocols exist for development of data to support the type of claims you propose, you may wish to develop and submit a test protocol for comments prior to initiation of testing.

4. Further testing of this product as a fungistat should be conducted or the claims modified. The agar plate method for testing fungi indicated poor control of 0.1% and in some cases probably only fair control at 0.5%. The soil burial test was run only at 1%. Test the product by soil burial at lower concentrations or indicate that claims relative to deterioration refer only to the 1% rate.

For claims to control Aspergillus niger or mold and mildew fungi, the product should be tested in a manner such as in the Fabric Mildew Fungistatic Test Method (enclosed). The test should be modified to treat the cloth in the same manner as recommended on the label. We would accept a rate of 1% for mold and mildew, based on the data presented, but lower dosage rates should be supported by tests using the Fabric Mildew Test and should pass the test for a minimum of four weeks.

5. For guidance for mold and mildew labeling and testing, refer to the enclosed copy of "A Guide to Testing and Claims for Mildewcides Under the Federal Insecticide, Fungicide, and Rodenticide Act."

6. Submit small samples of the technical product and the analytical standard. Please refer to the above file symbol on the sample. These samples should be addressed to:

Supervisory Chemist
Chemistry Laboratory
Technical Service Division, EPA
Room 101, South Laboratory Building, ARC
Beltsville, Maryland 20705

7. Submit storage stability data based on chemical analyses before and after storage.

8. Bird toxicity data will not be required prior to registration of the uses proposed in the present application; however, these data will be required before additional uses may be accepted. This was brought to your attention during our meeting on November 14, 1973, and the appropriate protocol was provided for conducting such tests.

9. The label must be revised as follows:

a. The label statement "For Use as a Coating in Industrial Processes" should be relocated and combined with the claim "Bacteriostat, Fungistat, and Algistat" so as to read, "For Industrial Use only, as a Final Bacteriostatic, Fungistatic, Algistatic Preservative Finish for Textiles" or "For Industrial Use only, as a Final Bacteriostatic, Fungistatic, Algistatic Preservative Coating for Textiles."

b. Wherever it appears in the bulletin, change "Protection" to "Preservation."

c. Change ". . . wide variety of substrates . . ." to ". . . wide variety of textiles . . ."

d. Delete references to dilution with organic solvents. Data of this type has not been provided.

e. Under "Typical Benefits" and throughout the bulletin, either delete references to ". . . bacteriostatic activity . . . on surfaces" or qualify as ". . . bacteriostatic activity . . . on textile surfaces . . ." Unqualified reference to surfaces implies hard inanimate surfaces other than textiles.

f. Change ". . . all types of fibers . . ." to "many types of fibers . . ."

g. The following textiles were not evaluated for bacteriostatic activity: cellulose acetate, rayon, acetate, vinyl, wool, linen and felt. Table 1 of the bulletin must be revised to accurately reflect which textiles were tested for what type of activity.

h. Delete the entire list of pathogenic bacteria and T. interdigitale which appear in Table V. The sole purpose of the product is claimed to be the preservation of textiles from deterioration and discoloration. We have no evidence that the bacteria listed or T. interdigitale have any significance in discoloration and/or deterioration of fabrics. Therefore, the list is not relevant to the proposed use pattern for the product.

i. The directions for use specify use concentrations of 0.1% to 1.0% depending on the textile being treated. This should be clarified in the directions. If different types of textiles require different concentrations for efficacy, or have different retention, this must be delineated.

j. Replace the reference to activity at "0.5% or below" with a specific range of concentrations.

k. If "wash resistance" is intended as a claim, the directions should specify the number of washes recommended before activity is significantly reduced.

l. Under "Storage and Shelf Life" replace the claim "no known limits on useful life" with the limits tested.

m. On the product label, reference to "Dow Corning's Technical Bulletin" must be changed to "Dow Corning's Technical Bulletin 19-015."

n. On the first page of the Technical Bulletin, under Description, change "non-leaching" to a more accurate phraseology, such as "leach resistant". Again, on the third page, change "surface treatment is non-leachable" to wording such as "surface treatment is leach-resistant."

o. If the use directions in the Technical Bulletin, state the method of application. Is the product applied by padding, soaking, or other method?

p. Delete or modify the first sentence of the warranty statement. Statements which negate or detract from labeling information required under the Act and Regulations are not acceptable on products proposed for registration. Refer to the "Notice to Registrants" dated November 16, 1966 (copy enclosed).

Sincerely,

Douglas D. Campt
Pesticide Registration Officer
Registration Division (WH-567)

Enclosures

EPA:PR:SX:PCCritchlow:lms 12/26/78

cc: Coord. Br.
CB
TB
Chron

[Handwritten signature]
12/26/74

Etk
12/24/74

[Handwritten initials]
12-27-74

OK. WSW

Int. RDC 12/27/74