

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 06-20-84 OUT 07-27-84

Reviewed By Dennis G. Guse *DG 7/27/84* Date 07-27-84
EPA Reg. No. or File Symbol 34292-1
EPA Petition or EUP No. None
Date Division Received 06-08-84
Type Product Antimicrobial Textile Additive
Data Accession No(s). None
Product Manager 31 (Lee)
Product Name Dow Corning 5700 Antimicrobial Agent

Company Name Dow Corning Corporation
Submission Purpose Proposed test protocol for self-sanitizing
activity against athlete's foot fungi
Type Formulation Technical chemical for manufacturing use

Active Ingredient(s):

3-(Trimethoxysilyl)propyldimethyloctadecyl ammonium chloride

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200.0 Purpose of Protocol

The test protocol is proposed to demonstrate that treated sock fabrics are self-sanitizing against the athlete's foot fungus, Trichophyton mentagrophytes.

201.0 Description of Protocol

See attached protocol submitted by E. A. Abbott, Senior Regulatory Compliance Specialist, Dow Corning Corporation, Midland, MI 48640, dated 06-05-84.

Page _____ is not included in this copy.

Pages 3 through 6 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☒ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
 - ☐ The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 34292-1

Date Division Received 06-08-84

Data Accession No(s). None

Product Manager No. 31 (Lee)

Product Name Dow Corning 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

202.0 Evaluation of Protocol

The proposed test protocol to demonstrate self-sanitizing activity vs. Trichophyton mentagrophytes on chemically impregnated sock fabrics in the presence of moisture or wet contamination during use and storage is acceptable with the following qualifications or modifications:

- a. Three product samples, representing 3 different batches, one of which is at least 60 days old (shelf-life) should be used to treat each representative sock fabric for the intended use-life (i.e. for xxx number of launderings) of the ~~treated~~ material.
- b. A test should be conducted to confirm the absence of carry-over residual effects of the germicide in the subculture media. If this has already been done, the results should be submitted with the data.
- c. Since the 24-hour contact period represents both a use (wear) and storage (laundry hamper) period, the incubation temperature for the use period would appropriately be body temperature (37C) and for the storage period would be room temperature (20-25C), e.g. 37C for the first 12 hours and 20-25C for the second 12 hours. Alternately, some intermediate temperature, e.g. 30-32C, should be used throughout the entire contact period.
- d. The 99.9% reduction for the inoculated, treated fabric should be demonstrated over the "0-time" fabrics or the parallel inoculated, untreated control at the same contact time, whichever is less.

203.0 Claims

The claims for self-sanitizing activity against athlete's foot fungi or Trichophyton mentagrophytes must be limited to the sock material itself. Claims implying mitigation of the disease or benefits to the foot are not acceptable.