

US EPA ARCHIVE DOCUMENT

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

Reviewed by William E. Campbell Jr. IN 08/14/79 OUT 10/09/79 Date October 9, 1979
D. Jenkins

EPA Reg. No. or File Symbol 4001-G

EPA Petition or EUP No. _____

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Type Product(s): I, (D), H, F, N, R, S Impregnated Product

Data Accession No(s). _____

Product Mgr. No. (32) Castillo

Product Name(s) Dr. Sholl's Deodorant Insoles

Company Name(s) Sholl, Inc.

Submission Purpose New Registration

Chemical & Formulation Impregnated foam latex

Active Ingredient(s): _____ 8

5-Chloro-2-(2,4-dichlorophenoxy) phenol..... 0.76
(Irgasan DP-300)

200.0 Introduction

200.1 Use

Shoe insoles with a latex foam layer containing a bacteriostat to inhibit the growth of odor-causing bacteria.

200.2 Background Information

The antimicrobial agent Irgasan DP-300, EPA Registration No. 100-502, is used to impregnate latex foam used in the insoles. The subject application is for registration of the impregnated insole.

Since a number of articles are proposed for the market place which are impregnated with or contain materials intended to give the articles pesticidal properties, the Agency has taken the position that rather than register the treated articles themselves, the antimicrobial agents used therein or thereon must be registered for each intended use. Based on this policy, the manufacturer or formulator of the antimicrobial product used for such treatment must obtain registration for each of the specific claims and patterns of use before it can be legally sold for such use, or the impregnated article or material marketed with such claims. The impregnated article or material is then exempted from the requirement for registration under the provisions of 40 CFR 162.4(c) of the Regulations for Enforcement of the FIFRA.

200.2.1 Factors Affecting Amount/Type of Data Required

Pursuant to Section 3(c)(5) of the FIFRA, as amended by the Federal Pesticide Act of 1978, and under the provision of 40 CFR 162.18-2, claims for control of microorganisms not directly related to human health do not require supporting efficacy data. On this basis, a product intended for use as a bacteriostat to inhibit the growth of odor-causing bacteria in shoe insoles would not require submission of efficacy data.

202.0 Conclusions and Recommendations

202.1 Uses Related to Human Health

None

202.2 Uses Not Related to Human Health

Since the claim for the product, to inhibit the growth of odor-causing bacteria on shoe insoles containing a treated latex foam layer, is not considered to be related to human health and specific efficacy data are not required, a finding of efficacy for the recommended use is waived.

2

Labeling

The registration of the subject product, Irgasan DP-300, must be amended to cover the use of the product in insoles. Failing this, it will be necessary for you to formally apply for a new and separate registration for the use of this pesticide product to impregnate latex foam used in shoe insoles before such insoles can be legally placed on the market.

The labeling must provide adequate information that is pertinent to the needs of the formulators. This information should include:

1. Physical and chemical properties of the product including volatility, stability in treated items, leachability, photo-degradation, etc.
2. Adequate directions for use including the purpose of the treatment, the type(s) of materials to be treated, dosage, how and when applied and the duration of effectiveness intended for the treatment.
3. Any restrictions in applying the treatment, or in the types of materials to be treated, or in subsequent handling of the treated material, so as to avoid any adverse effects.

The label claims and marketing representations for the treated (impregnated) insoles must not exceed the following:

1. "Treated to retard the growth of bacteria on the insoles that act on perspiration to cause unplesant ordors" or....
2. "Bacteriostat in the foam inhibits the growth of odor-causing bacteria on the insoles."

Claims such as "Controls foot odor", or "inhibit foot odor", will not be accepted. Such claims imply treatment of the feet and/or antimicrobial activity on the feet, and as such, would be considered within the purview of the Federal Food, Drug and Cosmetic Act and regulated by the Food and Drug Administration.

Additionally, the labeling for the treated insoles must indicate the expected life of the claimed activity.