

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I
Disinfectants Branch

IN 07-10-87

OUT 08/24/87

Reviewed By Srinivas Gowda <sup>REC
8-25-87</sup> Date 08/24/87

EPA Reg. No. or File Symbol 10466-28

EPA Petition or EUP No. None

Date Division Received 06/30/87

Type Product(s): Bacteriostatic/Fungistatic Industrial Preservative

Data Accession No(s) 402499-00

Product Mgr. No. 32 (Kempter)

Product Name(s) Ultra-Fresh® DM-50

Company Name (s) Thomson Research Associates, Ltd.

Submission Purpose Amendment (to include an additional fungistatic activity against Trichophyton mentagrophytes in collateral labelings) with efficacy data, revised technical data sheets, product information sheets, and labels.

Chemical & Formulation Liquid concentrate for manufacturing use only

Active Ingredient (s): 8

Tributyltin maleate.....25.0

200.0 Introduction

200.1 Use (s)

The product is presently registered as a bacteriostatic and fungistatic industrial preservative. The product is for manufacturing use only.

200.2 Background Information

The submission received 06-30-87 is an application for amendment to include an additional fungistatic activity against Trichophyton mentagrophytes in collateral labeling. Efficacy data, revised Technical Data Sheets, Product Information Sheets, and labels accompanied the application.

201.0 Data Summary

201.1 Brief Description of Test

"The Control of Athlete's Foot Fungus Trichophyton mentagrophytes By Ultra-Fresh® DM-50" by Laval Yau and G. Runciman, Thompson Research Associates, 223 Adelaide street West, Toronto, Ontario, M5H 1X4, dated 06-30-87 (Accession No. 402499-00).

201.2 Test Results

The submitted data was not reviewed because, the data was intended only to indicate the broad-spectrum activity of the product in collateral labeling and was not intended as a claim for recommended use concentrations under practical conditions against Trichophyton mentagrophytes.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 10466-28
Date Division Received 06-30-87
Data Accession No.(s). None
Product Manager No. PM-32 (Kempter)
Product Name Ultra-Fresh® DM-50
Company Name Thomson Research Associates, Ltd.

202.0 Recommendations

The amendment to include fungistatic activity against Trichophyton mentagrophytes in collateral labelings are acceptable only to indicate the broad-spectrum activity of the product and not as a claim against T. mentagrophytes.

202.1 Labeling:

N A C

202.2 PRODUCT INFORMATION SHEET:

Under "Primary Use" the statement " aids in reducing Athlete Foot fungi on....." implies effectiveness against microorganisms infectious for man. Such claims must be deleted in order to remove implications of human health significance. Bacteriostatic / Fungistatic claims will only be permitted for products expressly recommended for control of microorganisms of economic or esthetic significance (e.g. odor-causing bacteria).

202.3 TECHNICAL DATA SHEET:

N A C