

US EPA ARCHIVE DOCUMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 11/05/91 Review Start Date: 06/02/92

Date EPA Received: 10/16/91

Project Return Date: 01/14/92 Review Completion Date: 06/02/92

Reviewed by: Arnold E. Layne 6/2/92 Microbiologist Date: 06/02/92

EPA Reg. No. or File Symbol: 8383-3

EPA Petition or RUP No.: NONE

Product Type: Hospital Disinfectant

MRID No(s): None

Product Manager & Team No.: 32 Ruth Douglas

Product Name: Sporicidin Disinfectant Solution

Company Name: Sporicidin International

Submission Purpose: Resubmitted in response to letter dated July 22, 1991. Label Amendment.

Product Formulation: Spray

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Phenol.....	1.41%
Sodium Phenate.....	0.24%

200.0 **INTRODUCTION**

200.1 **USE(S):**

Refer to the attached labeling for specific uses.

200.2 **BACKGROUND INFORMATION**

This submission, received by RD on 11/05/91, is an amendment application to comply with the attached Agency letter of July 22, 1991.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration No.: 8383-3Date EPA Received: 10/16/91Date RD Received: 11/05/91Project Return Date: 01/14/92Review Start Date: 06/02/92Review Completion Date: 06/02/92MRID No(s): NONEProduct Manager & Team No.: 32 Ruth DouglasProduct Name: Sporicidin Disinfectant SolutionCompany Name: Sporicidin International

202.0 **RECOMMENDATIONS**

203.0 **LABELING**

The registrant has complied with most of the efficacy product labeling revisions outlined in the Agency letter dated July 22, 1991. However, listed below are Agency recommended labeling changes:

The registrant has not submitted data to verify the claim for sanitization of air ducts. Furthermore, due to the current controversy and proposed PR Notice on claims for Air duct sanitization/disinfection, the request to retain the claim is denied. Therefore, Sporocidin Bulletin No. 302 is unacceptable.

Registrant must submit Sporocidin Bulletin 301 for Agency review.

Under the heading "TO DISINFECT AND DEODORIZE" expand the wording to comply with those elements outlined in DIS/TSS-15 attached.

NOTE TO PM: Due to the current enforcement actions, this submission should be routed to Juanita Wills for review.