

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
ANTIMICROBIAL PROGRAM BRANCH
EFFICACY REVIEW - FORM 1

Date RD Received: 07/17/92 Review Start Date: 09/09/92

Date EPA Received: 06/17/92

Project Return Date: 09/15/92 Review Completion Date: 09/09/92

Reviewed by: Arnold E. Layne, Microbiologist Date: 09/09/92
Arnold E. Layne 9/9/92

EPA Reg. No. or File Symbol: 8383-7

EPA Petition or EUP No.: NONE

Product Type: Disinfectant Towelette

MRID No(s): NONE

Product Manager & Team No.: PM-32 Douglas

Product Name: Sporicidin Brand Disinfectant Towlette (formerly
Permacide Brand RISTEX Germicidal Disinf. Towelette

Company Name: Sporicidin International

Submission Purpose: Add HIV-1 claim; change basic product name;
label review; review of FDA/EPA PACKAGE
INSERT.

Product Formulation: Towelette

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Phenol.....	1.56%
Sodium Phenate.....	0.06%



200.0 **INTRODUCTION**

200.1 **USE(S):**

Refer to the attached labeling for specific uses.

200.2 **BACKGROUND INFORMATION**

This submission, received 06/17/92, is an amendment to

- Change the basic product name
- Add the claim for effectiveness against HIV-1
- Review proposed new product labeling
- Seek approval of the EPA/FDA PACKAGE INSERT

201.0 **DATA SUMMARY**

NO DATA SUBMITTED WITH THIS SUBMISSION.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
ANTIMICROBIAL PROGRAM BRANCH
EFFICACY REVIEW - FORM 2

EPA Registration No.: 8383-7

Date EPA Received: 06/17/92

Date RD Received: 07/17/92

Project Return Date: 09/15/92

Review Start Date: 09/09/92

Review Completion Date: 09/09/92

MRID No(s): NONE

Product Manager & Team No.: PM-32 Douglas

Product Name: Sporicidin Brand Disinfectant Towelette

Company Name: Sporicidin International

202.0 RECOMMENDATIONS

The proposed new basic product name is acceptable.

202.2 EFFICACY NOT SUPPORTED BY THE DATA

The registrant must reference (submit) the appropriate MRID numbers corresponding to the HIV-1 efficacy data generated for EPA Reg. No. 8383-3. Until such time, the claim for effectiveness against HIV-1 must be deleted from the labeling and PACKAGE INSERT.

NOTE TO PM: The CSF should reflect the change in percentages of active ingredients as stated on the labeling. Furthermore, this application **MUST BE SUBMITTED TO J. WILLS FOR CONCURRENCE.**

203.0 LABELING**FRONT PANEL**

No adverse comments.

BACK PANEL

Delete claim for effectiveness against HIV-1 (AIDS virus) on environmental surfaces.

Delete "NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions."

PACKAGE INSERT

Change "Noncritical devices...cleaned and intermediate... cross contamination." to read "Noncritical devices... must be precleaned with soap and water followed by intermediate level disinfection to reduce risk of cross-contamination."

Delete all claims regarding HIV-1 effectiveness.