

US EPA ARCHIVE DOCUMENT

10-16-87

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 09-08-87 OUT 10/14/87

*Srinivas Gowda WEC 10-16-87*

Reviewed By Srinivas Gowda Date 10/14/87

EPA Reg. No. or File Symbol 8383-3

EPA Petition or EUP No. None

Date Division Received 07-17-87 & 08/05/87

Type Product(s): Hospital Disinfectant

Data Accession No(s) 402830-01

Product Mgr. No. 32 (Kempter)

Product Name(s) Permacide Brand Ristex Germicidal/Disinfectant

Company Name (s) Sporicidin International

Submission Purpose Amendment to add additional brand names and additional virucidal claim (Influenza A<sub>2</sub>/Japan) with data, label, and technical brochure

Chemical & Formulation Ready-to-use liquid

Active Ingredient (s): g

Phenol.....1.41

Sodium Phenate.....0.24

Sodium Borate.....0.47

200.00 Introduction

200.1 Use (s)

Proposed labels are attached.

200.2 Background Information

The submission received 07-17-87, is an amendment to add an additional virucidal claim against Influenza A<sub>2</sub>/Japan. A revised label and a technical brochure were also submitted.

The submission received 08-05-87, is an amendment to include the following additional brand names:

1. Sporicidin Brand Germicidal Towelette
2. Sporicidin Brand Disinfectant Towelette
3. Permacide Germicidal Towelette
4. Permacide Disinfectant Towelette
5. Rear Guard Germicidal Towelette
6. Rear Guard Disinfectant Towelette
7. Derma La Douche Germicidal Towelette
8. Derma La Douche Disinfectant Towelette
9. Vetricidin Germicidal Towelette
10. Vetricidin Disinfectant Towelette
11. O.R. Germicidal Towelette
12. O.R. Disinfectant Towelette

201.0 Data Summary

201.1 Brief Description of Test

Reports of Virucidal Tests by Herbert N. Prince and Daniel L. Prince, Gibraltar Biological Laboratories, Inc., 23 Just Road, Fairfield, New Jersey 07006, dated 06-25-87 (Accession Nos. 402830-01)

201.2 Test Summaries

a. Virucidal Tests:

1. Method: A.O.A.C. Germicidal Spray Products Test
2. Modifications: 100% Chorioallantoic fluid as organic soil (protein concentration equivalent at least to 5% calf serum).
3. Samples: 42478/1-2.

<u>Batch No.</u>	<u>Mfg.Date</u>	<u>Test Dates</u>
A	Not Listed	06-11-87 thru 06-25-87
B	"	"

4. Dilution: Spray over the virus film until wet.
5. Exposure: 10 minutes at 20-25°C
6. Recovery Medium/Neutralizer/Diluent:  
 Trypticase soy broth (TSB) was added to the virus-germicide mixture so as to achieve a total volume 2.0 ml and diluted in TSB to 10<sup>-5</sup>.
7. Incubation : 48 hours at 35°C
8. Test Virus Host System: 13 days old chick embryo
9. Assay System for Virus Recovery: Hemagglutination Test.
10. Drying Time and Temperature: 35°C ± 1°C for 30-45 min.
11. Method for Estimating 50 Per Cent end-point: Reed-Muench.
12. Test Virus: Influenza A<sub>2</sub> Japan/305/57
13. Test Results

ID-50 or LD-50 (-log 10)

<u>Test Virus</u>	<u>Batch No.</u>	<u>Virus Control</u>	<u>Virus + Disinf.</u>	<u>Toxicity Control</u>	<u>Virus Inacti.</u>
Influenza A <sub>2</sub> /Japan	A	6.0	0	0	6.0
	B	6.0	0	0	6.0

15. Conclusions: Satisfactory performance vs Influenza virus Type A<sub>2</sub>/Japan/305/57 as an undiluted spray in the presence of 100% CAF (equivalent to 5% calf serum) on moderately soiled, hard, non-porous surfaces for a contact time of 10 minutes at 20-25°C.

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Pages 4 through 11 are not included.

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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.

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TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 8383-3

Date Division Received 07-17-87 & 08-05-87

Data Accession No.(s). 402830-01

Product Manager No. PM-32 (Kempter)

Product Name Permacide Brand Ristex Germicidal/Disinfectant

Company Name Sporicidin International

202.0 Recommendations

202.1 Efficacy Supported by the Data

- a. The submitted virucidal data are adequate to support effectiveness of the product as a virucide against Influenza Type A<sub>2</sub>/Japan/305/57 (Asian Strain) when used as an undiluted spray to thoroughly wet moderately soiled, hard, non-porous surfaces (100% chorioallantoic fluid which is equivalent to 5% calf serum) for a contact time of 10 minutes at 20-25°C.

203.0 Labeling

a. Primary Labeling

1. On the Back Panel revise the statement "Permacide Brand (Ristex) Germicidal/Disinfectant Towelette provides.....Staphylococcus, Streptococcus, Salmonella, Pseudomonas, Escherichia coli, \*Herpes types 1 and 2, Influenza A<sub>2</sub> (Japan 305/57 Asian Strain), Polio 1, Trichophyton (Athlete's Foot Fungus), molds, and mildew and the tubercle bacillus on non-porous surfaces" to read Permacide Brand (Ristex) Germicidal/Disinfectant Towelette provides.....Staphylococcus aureus, Streptococcus salivarius, Streptococcus pyogenes, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli, \*Herpes Simplex types 1 and 2, Influenza A<sub>2</sub> (Japan 305/57 Asian Strain), Polio 1, Trichophyton mentagrophytes (Athlete's Foot Fungus), Mycobacterium tuberculosis and molds, and mildew on non-porous surfaces".
2. Under "A DEODORANT" revise the statement "It provides.....if not removed from surface" to read "It provides residual bacteriostatic and fungistatic activity against odor-causing organisms in the presence of adequate moisture if not removed from surface".

b. Brand Name Labels

Agency does not review additional brand name labels. However, the following labeling revision are required:

1. Comments listed under "Primary Labeling" also applies to "Brand Name Labelings".
2. Under the heading "Active Ingredients" delete "Essential Oils 0.25%" and include "Sodium Borate 0.47%"

c. Technical Brochure

Note to PM

The proposed brand names "Derma La Douche Germicidal Towelette", "Derma La Douche Disinfectant Towelette", Rear Guard Germicidal Towelette, and Rear Guard Disinfectant Towelette implies that the product is for human use and are misleading.



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Pages 15 through 23 are not included.

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A draft product label.

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