

US EPA ARCHIVE DOCUMENT

9-8-87

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I
Disinfectants Branch

IN 05-11-87 OUT 08-31-87

Reviewed By Emily H. Mitchell ^{DBB 9-8-87} Date 08-31-87

EPA Reg. No. or File Symbol 8383-3

EPA Petition or EUP No. None

Date Division Received 07-08-87

Type Product(s) Hospital/General Disinfectant

Data Accession No.(s) 401900-01

Product Mgr. No. PM 32 (Kempter)

Product Name(s) Permacide Brand Ristex Germicidal/Disinfectant

Company Name(s) Sporicidin International (The R. Schattner Co.)

Submission Purpose Admendment to add virucidal claim. Efficacy data and proposed label submitted

Chemical & Formulation Ready-to-use liquid pump spray

<u>Active Ingredient(s):</u>	<u>%</u>
Phenol	1.41%
Sodium Phenate	0.24%
Sodium Borate	0.47%

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200.0 Introduction

200.1 Uses:

A disinfectant for hospital and other institutional uses on pre-cleaned hard, non-porous surfaces.

200.2 Background Information:

The submission received 05-11-87, is an application to add an additional virucidal claim. The proposed product label and efficacy data were provided.

201.0 Data Summary (Accession No. 401900-01)

201.2 Brief Description of Tests:

Virucidal Reports performed by Dr. Philip R. Rhone, Integrity Bioservices Inc., 12280 Wilkins Ave., Rockville, Maryland 20852. The A.O.A.C. Methods, Paragraphs 4.007-4.014 were used to test against Herpes Simplex Types 1 & 2 and Poliovirus, Type-1 (dated 05-05-87).

201.3 Test Summaries:

a. Virucidal Tests

1. Method: Use A.O.A.C. Methods, Paragraphs 4.007 through 4.014 were used with modifications.
2. Modifications: 10% Bovine Fetal Calf Serum was incorporated into the viral suspensions.
3. Samples:

<u>Lot No.</u>	<u>Preparation Date</u>	<u>Test Date</u>
Lot A-K0253	Not Listed	11-15-85
Lot B-J1453	Not Listed	11-15-85

4. Dilution: undiluted
5. Exposure: 23°C for 2 minutes
6. Recovery Medium/Neutralizer/Diluent: Lethen Broth
7. Incubation: Not Listed
8. Test Virus Host System:
 Herpes Simplex, Type 1 (F Strain)-HEP II Cells
 Herpes Simplex, Type 2 (G Strain)-HEP II Cells
 Poliovirus, Type 1 (Brunhilde-ATCC, VR-58)-
 Baby Green Monkey Kidney (BGM) Cell Line
9. Drying Time and Temperature: Not Listed
10. Assay System for Virus Recovery:
 Herpes Simplex, Type 1-Vero Cells
 Herpes Simplex, Type 2-Vero Cells
 Poliovirus, Type 1-Baby Green Monkey Kidney (BGM)
 Cell Line
11. Method For Estimating 50 per cent end point:
 Reed Muench Method
12. Test Virus:
 Herpes Simplex, Type 1 (F Strain)
 Herpes Simplex, Type 2 (G Strain)
 Poliovirus, Type 1 (Brunhilde-ATCC, VR-58)
13. Test Results:

ID-50 (-log 10)

<u>Test Virus</u>	<u>Lot No.</u>	<u>Virus Control</u>	<u>Virus + Disinf.</u>	<u>Toxicity Control</u>	<u>Inacti- vation</u>
Herpes Simplex Type 1	K0253	6.5	1.5	1.5	5.0
	J1453	6.5	1.5	1.5	5.0
Herpes Simplex Type 2	K0253	7.0	1.5	1.5	5.5
	J1453	7.0	1.5	1.5	5.5
Poliovirus Type 1	K0253	7.5	3.5	3.5	4.0
	J1453	7.5	3.5	3.5	4.0

14. Conclusions: This product showed satisfactory performance against all test viruses when used undiluted on pre-cleaned hard, non-porous surfaces at a contact time of 10 minutes. However, the incubation time and temperature and the drying time and temperature were not specified.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 8383-3

Date Division Received 07-08-87

Data Accession No.(s) 401900-01

Product Manager No. PM 32 (Kempter)

Product Name Permacide Brand Ristex Germicidal/Disinfectant

Company Name Sporicidin International (The R. Schattner Co.)

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted virucidal data are acceptable to support effectiveness of the product against Herpes Simplex Type-1 (F Strain), Herpes Simplex Type-2 (G Strain) and Poliovirus Type-1 on hard, non-porous surfaces for a contact time of 10 minutes. However, the incubation time and temperature and the drying time and temperature were not specified. Refer to 202.2 below.

202.2 Additional Data/Information Required to Support Efficacy:

- a. Incubation time and temperature for the virucidal data must be provided.
- b. Drying time and temperature for the virucidal data must be provided.

203.0 Labeling

- a. In lieu of data, delete claims against Influenza A₂ (Japan 305/57 Asian Strain).
- b. On back panel revise "provides 100% kill of most disease and odor causing organisms such as molds, and mildew" to read "provides 100% of most disease and odor-causing organisms such as prevents molds and mildew on non-porous surfaces."

204.0 Technical Brochure

- a. Under Action revise "Kills mold and mildew on contact." to read "Controls mold and mildew."
- b. Under Action, item number 7 delete Chaetomium globosum, Aspergillus niger, and Pellicularia filimentosa and include them under the heading "Controls:"
- c. In lieu of data, delete claims against Influenza A₂ virus (Japan 305/57 Asian Strain).