TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectant Branch

IN 06/17/87 OUT 09/01/87

Reviewed By Srinivas Gowda Srinivas Gowda Date 09/01/87

EPA Reg. No. or File Symbol 8383-5

EPA Petition or EUP NO. NONE

Data Division Received 06-17-87

Type Product Hospital Disinfectant/Sterilant

Date Accession No.(s) 402354-01 & 402354-02

Product Manager PM 31 (Lee)

Product Name Sporicidin

Company Name Sporicidin International

Submission Purpose Amended application to include 14-day, and 30-day reuse sterilizing claims efficacy data & proposed label provided.

Type Formulation Two-component liquid to be combined and used undiluted or diluted with water

Active Ingredient(s):	%
Phenol	7.05
Glutaraldehyde	2.00
Sodium phenate	1.20

200.0 Introduction

200.1 Use(s)

A sterilizing and disinfecting solution for use in hospitals, medical, dental and veterinary clinics/ offices, nursing homes and ambulances on medical and dental instruments, equipments and fiberoptics in endoscopy, surgery anesthesiology, respiratory therapy and dentistry. Label bears sporicidal, virucidal, bactericidal, tuberculocidal, pseudomonacidal, and fungicidal claims. Label also bears 30 and 14 days repeated reuse claims as a sterilant (1:8 dilution) and 30 days repeated re-use claim as a disinfectant (1:16 dilution) in manual systems.

200.2 Background Information

The submission received 06-17-87 is an amended application to include 14, and 30 day reuse sporicidal claims. Efficacy data developed in accordance with an EPA approved reuse protocol and proposed labeling accompanied the application.

201.0 Data Summary

201.1 Brief Description of Test

"Reuse efficacy tests using four lots of Sporicidin disinfectant diluted 1:8, stressed in a manual reuse system and tested in the A.O.A.C. Sterilant Test" by Kyle Sibinovic, Shaldra Biotest, Inc., P.O. Box 34317 W. Bethesda, MD. 20817, dated 04-30-87 (Accession No. 402354-01).

"Report for Confirmatory Sporicidal Tests on Sporicidin Cold Sterilizing Solution at 1:8 Dilution After Stress in Manual Reuse Protocol" by Richard Gammon, Presque Isle Cultures, P.O. Box 8191, Presque Isle, PA 16505, dated May 1987 (Accession No. 402354-02).

201.2 Test Summaries

Simulated Reuse testing

a. Re-Use Protocol:

1. Type and Duration: Manual reuse for up to 30 days as a sterilant and/or disinfectant in a bucket system.

2. Test samples: "Sporicidin", activated solution from 3 different batches, Lots F0563, B1063, and G076, manufactured 06-86, 02-86, and 07-86, respectively. Activator Lot Numbers A1763, E2063, and E263, manufactured 01-86, 05-86, and 05-86 respectively. Solution volume = 5 gallons/batch (18925 ml).

3. Use Cycles & Equipment: 3 simulated use cycles/ day, each cycle consisting of a wash step w/soap or detergent, a water rinse and a soaking step in the test solution. Equipment consisted of 2 anesthesia sets/5 gallons, each set containing 2 sections corrugated rubber tubing (each 3-4 feet long), 1 rebreathing bag (2-3 liter capacity), 1 endotracheal tube, 1 "Y" connector, and 1 face mask.

4. Microbiological Bioburden: Stainless steel cyliders containing Staphylococcus aureus ATCC6538, Salmonella choleraesuis ATCC 10708, and Pseudomonas aeruginosa ATCC 15442; and porcelain cylinders containing spores of Bacillus subtilis ATCC 19659 and Clostridium sporogenes ATCC 3584. A set of 60 carriers with one of each of the above organisms were added to 1 liter of the solution removed from the ducket after the third cycle each day and soaked for 1 hour (vegetative bacteria) or overnight (spores). The carriers were then removed and the sample returned to the bucket, except when retained for testing. The addition schedule was as follows (Option II):

Daily: 60 carriers/liter (1000 ml)/day, except on test days.

Test Days: 180 carriers/liter on day 14
270 carriers/liter on day 21
390 carriers/liter on day 30

Then samples are retained and not returned to the bucket.

Quantitative Bioburden (Option II):

For 14 days:

$$K = \frac{13 \times 60}{13 \times 18925} + \frac{1 \times 180}{14 \times 1000} = 0.0032 + 0.0129 = 0.016 \text{ carriers/ml}$$

For 21 days:

$$K = \frac{20 \times 60}{20 \times 18925} + \frac{1 \times 270}{21 \times 1000} = 0.0032 + 0.0129 = 0.016 \text{ carriers/ml}$$

For 30 days:

$$K = \frac{29 \times 60}{29 \times 18925} + \frac{1 \times 390}{30 \times 1000} = 0.0032 + 0.0129 = 0.016 \text{ carriers/ml}$$

5. Conclusions: The reuse protocol meets the required specifications.

b. Sporicidal Test

1. Method: A.O.A.C. Sporicidal Test Method

2. Modifications: None reported

3. Samples:

Batch No.	Manfg.Dates	Test Dates
Sporicidin S10U #F0563	06-86	08-12-86
Activator Lot # A1763	01-86	"
Sporicidin S10V #B1063	02-86	08-12-86
Activator Lot # E2063	05-86	"
Sporicidin S10W(1)#G076	07-86	08-14-86
Activator Lot # E263	05-86	"

4. Dilution: 1:8

5.

Reuse Test	Exposure
14 days reuse	8 hours at 20°C
21 "	10 "
30 "	10 "

6. Subculture Medium: Fluid Thioglycolate Medium USP XX
Neutralizer: Letheen Broth with Tween-80
Neutralization Time: 10 minutes at 20°C

7. Incubation of Subcultures: 21 days at 37°C;
Heat Shock 20 min at 80°C; reincubation 3 days at 37°C.

8.

Test Bacteria	ATCC No.	HCl Res.
Clostridium sporogenes	3584	>2 min
Bacillus subtilis	19659	>2 min

9. Carriers Tested:

Porcelain Penicylinders and Surgical Silk Suture Loops

10. Test Results:

Test Organisms	Batch No.	Reuse (Days)	Carriers Tested	# Carriers Tested	# Positives/ Total Carriers
C. sporogenes	F0563	14	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
B. subtilis	F0563	"	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
C. sporogenes	F0563	21	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
B. subtilis	F0563	"	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
C. sporogenes	F0563	30	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
B. subtilis	F0563	"	Cylinders	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60
	F0563	"	Loops	60	0/60
	B1063	"	"	60	0/60
	G076	"	"	60	0/60

11. Conclusions: The reuse protocol meets the required specifications. The Sporicidin cold sterilizing solution when tested at a 1:8 dilution in a manual reuse test for up to 30 days was an effective sterilant at the following exposure times when tested by the A.O.A.C. Sporicidal Test at 20°C:

Tested at 14 Days Reuse	8 Hours Exposure Time
Tested at 21 Days Reuse	10 Hours Exposure Time
Tested at 30 Days Reuse	10 Hours Exposure Time

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 8383-5

Date Division Received 06-17-87

Data Accession No.(s). 402354-01 & 402354-02

Product Manager No. PM-31 (Lee)

Product Name Sporicidin

Company Name Sporicidin International

202.0 Recommendations

202.1 Efficacy Supported by the Data

a. The submitted sporicidal data support efficacy of of this product as a sterilant after reuse of the activated, 1:8 solution for 14 days in manual (bucket) systems at a contact time of 8 hours at 20°C when tested by the A.O.A.C. Sporicidal Test with 3 different batches.

b. The submitted sporicidal data also support efficacy of of this product as a sterilant after reuse of the activated, 1:8 solution for 21 days in manual (bucket) systems at a contact time of 10 hours at 20°C when tested by the A.O.A.C. Sporicidal Test with 3 different batches.

c. The submitted sporicidal data also support efficacy of of this product as a sterilant after reuse of the activated, 1:8 solution for 30 days in manual (bucket) systems at a contact time of 10 hours at 20°C when tested by the A.O.A.C. Sporicidal Test with 3 different batches.

203.0 Labeling (Dated: 06-17-87)

a. On the "Left Panel" delete the following statements

"No gloves required"
"Won't smart eyes or nostrils"

b. On the "Front Panel" revise the statement "WILL NOT YELLOW NOR IRRITATE HANDS When Diluted for Disinfection" to read "WILL NOT YELLOW HANDS When Diluted for Disinfection"

c. On the "Back Panel" provide instructions for the preparation of 1:8 dilution.

Labeling (Dated: 07-16-87)

N A C

204.0 Collateral Labeling

a. Under "Notes", delete the entire paragraph and footnote in (2) concerning inactivation of Hepatitis B virus by Sporicidin. The current Agency policy toward claims of effectiveness for antimicrobial pesticides against human pathogens, such as Hepatitis B virus (HBV), was published in 51 FR, No. 102, dated 05-28-86, pp. 19174-19175. Unwarranted claims of this kind are deemed unacceptable.