TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

08-20-86,
09-05-86,
IN 10-28-86, **OUT** 01-12-87
& 09-19-86 (labels only)

Reviewed By Dennis G. Guse **Date** 01-12-87

EPA Reg. No. or File Symbol 8383-5

EPA Petition or EUP No. None

Date Division Received 08-20-86, 09-05-86, 10-20-86, & 08-07-86 (labels only)

Type Product Hospital Sterilant/Disinfectant

Data Accession No(s). 264607 & 264608 (New Data)

Product Manager 31 (Lee)

Product Name Sporicidin

Company Name Sporicidin Company

Submission Purpose Response to Tuberculocidal Data Call-In Notice & composite labeling

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

Active Ingredient(s):	%
Phenol	7.05
Sodium tetraborate	2.35
Glutaraldehyde	2.00
Sodium phenate	1.20

200.0 Introduction

200.1 Uses

Refer to the last accepted labeling, dated 12-28-83, attached.

200.2 Background & Factors Affecting Amount/Type of Data Required

Efficacy data were previously accepted for this product to support a tuberculocidal claim under the following conditions for a single day's use:

> Effectiveness as a tuberculocide for up to a 30-day old (shelf-life) activated stock solution at a 1/16 dilution in 10 minutes at 20°C on previously cleaned, hard surfaces (Standard AOAC Tuberculocidal Activity Method).

Efficacy data were subsequently submitted and evaluated for this product in reviews by TSS (Efficacy), dated 08-12-85 and 02-14-86, to support a tuberculocidal claim for re-use in manual procedures. The data were considered acceptable, but not incorporated into labeling by the registrant, to support a tuberculocidal claim under the following conditions for re-use:

> Effectiveness as a tuberculocide after activation at a 1/16 dilution in 15 minutes at 20°C for a 14-day re-used solution, in 25 minutes at 20°C for a 21-day re-used solution, and 55 minutes at 20°C for a 30-day re-used solution (New Quantitative Tuberculocidal Activity Method).

The data submitted in response to the Tuberculocidal Data Call-In Notice consists of new efficacy data developed to support effectiveness of the product as a tuberculocide after activation at a 1/16 dilution in 10 minutes at 20°C for a 30-day re-used solution (Standard AOAC Tuberculocidal Activity Method with 2 different batches of re-used product). Validation testing with 1 of the batches by another laboratory is also included.

201.0 Data Summary (Accession Nos. 264607 & 264608)

201.1 Brief Description of Tests (New Data)

a. "AOAC Tuberculocidal Efficacy Test with 5% Added Soil Using Sporicidin Lots S100 and S10P" by Kyle H. Sibinovich (Director), Shaldra Biotest, Inc., W. Bethesda, MD 20817, dated 07-24-86, consisting of the following:

   1. General Reuse Protocol, including Schedule of Bioburden Tests for Project No. S100 & S10P, and Determination of Glutaraldehyde and Phenol on Samples S100 & S10P.

   2. Reports for AOAC Tuberculocidal Test on Samples S100 & S10P.

b. Laboratory Reports by Herbert N. Prince (Director), Gibraltar Biological Laboratories, Inc., Fairfield, NJ 07006, dated 08-11-86, 09-02-86, and 05-01-86, consisting of the following:

1. AOAC Confirmative Test for Tuberculocidal Activity (Interim Report & Final Report) on Sporicidin Lot S100.

2. Virucide Assay - EPA Method on Sporicidin Lots S100 & S10P.

201.2 Test Summaries

a. Re-Use Protocol

1. Type & Duration: Manual use for up to 30 days as a sterilant and/or disinfectant.

2. Samples: Sporicidin, activated solution from 2 different batches, Lots S100 & S10P, 5 gallons of solution for each batch, prepared (activated and diluted) on 03-18-86. Testing period from 03-18-86 to 04-17-86).

3. Use Cycles & Equipment: 3 simulated-use cycles per day, each cycle consisting of a washing step with soap/detergent, water rinse, and soaking in the test solution for 1 hour. Equipment consisted of 2 anesthesia sets per 5 gallons, each set containing of 2 sections corrugated rubber tubing, 1 rebreathing bag, 1 endotracheal tube, 1 "Y" connector, and 1 face mask, in a bucket system. Five gallons = 18925 ml.

4. Microbiological Bioburden: Stainless steel carriers containing Staphylococcus aureus ATCC 6538, Salmonella choleraesuis ATCC 10708, and Pseudomonas aeruginosa ATCC 15442; and porcelain penicylinders containing spores of Bacillus subtilis ATCC 19659 and Clostridium sporogenes ATCC 3584. A set of carriers with one of each of the above organisms are added to 1 liter of the solution removed from the bucket and soaked for 1 hour (vegetative bacteria) or overnight (spores). The carriers are 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 on day 14, 270 carriers/liter on day 21, and 390 carriers/liter on day 30; and the samples (or a portion thereof) are retained and not returned to the bucket.

The cumulative bioburden calculations (Option II) are as follows:

For 14 days, $K = \frac{13 \times 60}{13 \times 18925} + \frac{1 \times 180}{14 \times 1000} = 0.0032 + 0.0129$ carriers/ml
$= 0.0161$ " /"

For 21 days, $K = \frac{20 \times 60}{20 \times 18925} + \frac{1 \times 270}{21 \times 1000} = 0.0032 + 0.0129$ carriers/ml
$= 0.0161$ " /"

For 30 days, $K = \frac{29 \times 60}{29 \times 18925} + \frac{1 \times 390}{30 \times 1000} = 0.0032 + 0.0129$ carriers/ml
$= 0.0161$ " /"

5. Dilution: 1/16, nominally providing 0.125% glutaraldehyde and 0.515% phenol. The initial pH (as reported in previous re-use studies) is 8.0-8.

6. Significant Modifications: None reported. The use of additional stress, such as organic soil (blood serum) was not specified. However, such a modification is optional, and not required.

7. Chemical Determinations: Samples for chemical analyses were taken before, and at days 7, 15, 21, and 30 of the re-use period. The concentration of glutaraldehyde and phenol, and the pH, were determined on each of the chemical samples.

Re-Use (Days)	% Glutaraldehyde		% Phenol		pH	
	S100	S10P	S100	S10P	S100	S10P
0	0.137	0.144	0.676	0.649	7.95	8.03
7	0.126	0.136	0.551	0.596	7.95	7.94
15	0.123	0.133	0.557	0.588	7.85	7.88
21	0.128	0.138	0.563	0.592	7.90	7.90
30	0.129	0.138	0.534	0.566	7.93	7.90

8. Conclusions: The re-use protocol meets the required specifications.

b. Tuberculocidal Tests (Initial Testing with 2 Different Batches - Shaldra)

1. Method: AOAC Tuberculocidal Activity Method (II. Confirmative In Vitro Test).

2. Modifications: None reported. The use of additional stress, such as organic soil (blood serum) was not specified. However, such a modification is optional, and not required.

3. Samples: Same as specified in 201.2(a)(2) above, tested after re-use for 14, 21, and 30 days after activation.

4. Dilution: 1/16.

5. Exposure: 10 minutes at 20°C.

6. Test Organism: Mycobacterium bovis (BCG). Phenol resistance: No growth @ 1:50 in 10 minutes at 20°C; growth @ 1:70 in 10 minutes at 20°C.

7. Neutralizer/Subculture Media: Letheen broth with Tween 80 as neutralizer; modified Proskauer-Beck broth (MPB), Middlebrook 7H9 broth (7H9), and TB broth (TBB) as subculture media.

8. Incubation: 90 days at 37°C.

9. Results: See next page.

Test Organism	Test Sample	Re-Use (Days)	Use-Dilution	Positive/Total Carriers: MPB	7H9	TBB
Mycobacterium bovis	S100	14	1/16	0/10	0/10	0/10
" "	"	21	"	0/10	0/10	0/10
" "	"	30	"	0/10	0/10	0/10
" "	S10P	14	"	0/10	0/10	0/10
" "	"	21	"	0/10	0/10	0/10
" "	"	30	"	0/10	0/10	0/10

10. Conclusions: No failures reported with exposure of 10 minutes at 20°C for a 1/16 dilution on 2 batches of product re-used in a manual system for up to 30 days after activation.

11. Comments: The reference in the report title to 5% added soil was not specified or explained in either the re-use protocol or the tuberculocidal test report.

c. Tuberculocidal Tests (Validation Testing with 1 Batch - Gibraltar)

1. Method: AOAC Tuberculocidal Activity Method (II. Confirmative In Vitro Test).

2. Modifications: 5% horse serum was added to the bacterial culture as organic soil.

3. Samples: Sporicidin, Lot S100, as described in 201.2(a)(2) and tested in 201.2(b)(3) above, after re-use for 30 days after activation.

4. Dilution: 1/16.

5. Exposure: 10 minutes at 20°C.

6. Test Organism: Mycobacterium bovis (BCG). Phenol resistance: No growth @ 1:50 in 10 minutes at 20°C; growth @ 1:75 in 10 minutes at 20°C.

7. Neutralizer/Subculture Media: Horse serum as neutralizer; modified Proskauer-Beck broth (MPB), Middlebrook 7H9 broth (7H9), and Dubos broth (DUB) as subculture media.

8. Incubation: 90 days at 35°C.

9. Results:

Test Organism	Test Sample	Re-Use (Days)	Use-Dilution	Positive/Total Carriers: MPB	7H9	DUB
Mycobacterium bovis	S100	30	1/16	0/10	0/10	0/10

10. Conclusions: No failures reported with exposure of 10 minutes at 20°C for a 1/16 dilution on 1 batch of product re-used in a manual system for up to 30 days after activation. The test was performed with added organic soil (5% blood serum) in the inoculum.

11. Comments: The use of organic soil in this validation test was neither necessary or sufficient to support a claim for the product in this regard since the basic data and pattern of use is for previously cleaned surfaces.

d. Virucidal Tests (Gibraltar)

1. Procedure: Two-tenths ml of virus inoculum was spread over the bottom of glass petri dishes and allowed to dry for 30-45 minutes at 35°C. Then 2.0 ml of disinfectant was spread over the surface and allowed to remain for 10 minutes at 20-25°C. After exposure, the virus-disinfectant mixture was removed by pipette and diluted in trypticase soy broth. Serial 10-fold dilutions were made and inoculated into cell cultures. After incubation, the presence or absence of virus was determined by cytopathic effect. The virus control consisted of an inoculated surface exposed to 2.0 ml of trypticase soy broth. The cytotoxicity control consisted of the disinfectant without the virus.

2. Modifications: 5% blood serum was added to the virus inoculum as organic soil.

3. Samples: Same as specified in 201.2(a)(2) above, tested after re-use for 30 days after activation.

4. Dilution: 1/16.

5. Exposure: 10 minutes at 20-25°C.

6. Test Virus: Poliovirus Type 2, ATCC VR-1002 (Lab V-537), grown in MRC-5 cells in 95-EMEM-5CS medium.

7. Incubation: 8 days at 35°C.

8. Results:

		ID-50 or LD-50 (-Log 10)			
Test Virus	Test Sample	Virus Control	Virus-Disinfectant	Cytotox.	Reduc.
Poliovirus Type 2	S10O	5.5	2.5	2.5	3.0
" " "	S10P	5.7	2.5	2.5	3.2

9. Conclusions: Satisfactory performance with exposure of 10 minutes at 20-25°C at a 1/16 dilution on 2 batches of product re-used in a manual system for 30 days after activation.

10. Comments: The use of organic soil in this virucidal test was neither necessary or sufficient to support a claim for the product in this regard since the basic data and pattern of use is for previously cleaned surfaces

Product Name: SPORICIDIN
Registration No.: 8383-5

FRONT LABEL - BUFFER

DILUTE
FOR
DISINFECTION

ACCEPTED
with COMMENTS
In EPA Letter Dated:

DEC 23 1983

... Act
... pesticide
... under EPA Reg. No.
8383-5

(BUFFER SOLUTION)

Sporicidin®

COLD STERILIZING SOLUTION

No Heat Required

- SPORICIDAL
- BACTERICIDAL
- VIRUCIDAL
- FUNGICIDAL
- TUBERCULOCIDAL
- PSEUDOMONACIDAL

ACTIVE INGREDIENTS: (Activator plus Buffer)

Phenol	7.05%
Sodium Tetraborate	2.35%
Glutaraldehyde	2.00%
Sodium Phenate	1.20%
INERT INGREDIENTS	**87.40%**

WARNING: KEEP OUT OF REACH OF CHILDREN

(See First-aid and Other Precautions On Back Label)

EPA Reg. No. 8383-5
EPA Est. No. 37615-MD-01
U.S. Patent No. 4,103,001

THE SPORICIDIN COMPANY
CHEVY CHASE, MARYLAND
WASHINGTON, D.C. 20015

CONTENTS: 1 QUART
(ACTIVATOR PLUS BUFFER)

RECEIVED

DEC 27 1983

Registration No. 7

Product Name: SPORICIDIN
Registration No.: 8383-5

ACCEPTED
with COMMENTS
In EPA Letter Dated:

DEC 28 1983

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8383-5

BACK LABEL

SPORICIDIN STERILIZING SOLUTION
For Medical and Dental Instruments and Equipment
Respiratory Therapy, Surgery, Anesthesiology, Urology, and Dentistry

DIRECTIONS:

1. Add Activator Solution to this Buffer Solution. After mixing, the stock solution has a shelf-life of 30 days and can be used as directed for both sterilization and disinfection.

2. Thoroughly clean, rinse and rough dry objects before immersion.

3. For sterilization: Completely immerse articles for 6-3/4 hours at room temperature in stock solution.

4. For disinfection: Completely immerse articles for 10 minutes at room temperature in a 1 in 16 dilution of the stock solution.
   Note: (a) Undiluted stock solution will disinfect immersed articles in 2 minutes.
   (b) A 1 in 30 dilution of freshly activated solution will disinfect immersed articles in 10 minutes.
   (c) If tubercle bacillus, Polio I or Influenza A_2 are suspected, and for dental instruments, immerse in a 1 in 16 dilution for 10 minutes.

   To Prepare: For 1 in 16 dilution, add 1 part of activated solution to 15 parts of water; i.e., add 8 ozs. of solution to 120 ozs. of water to make 1 gallon.
   For 1 in 30 dilution, add 1 part of activated solution to 29 parts of water; i.e., add 4 ozs. of solution to 116 ozs. of water.

5. Articles: For plastics, rubber, and carbon steel, use disinfection directions. Should not be used as an overnight holding solution for carbon steel and dental burs. Should not be used for injection needles.

6. Remove instruments using aseptic technique. Rinse with sterile water.

PRECAUTIONS:

- Avoid eye contact: Causes eye irritation. In case of contact, flush with water immediately and get medical attention.
- Avoid skin contact: At full strength, possibility of sensitization exists and may cause skin irritation. Flush thoroughly with water after contact.
- Harmful if swallowed. If swallowed, drink large quantities of water and call physician immediately.
- Avoid food contamination.

RECEIVED
DEC 27 1983
Registration Division (TS-767)

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Product Name: SPORICIDIN
Registration No. 8383-5

FRONT LABEL - ACTIVATOR

(Activator Solution)

Sporicidin®

For use With Sporicidin Buffer Solution

Directions: Add these contents to the Sporicidin Buffer in the 1 quart container to make 1 quart of activated Sporicidin. Shake to mix.

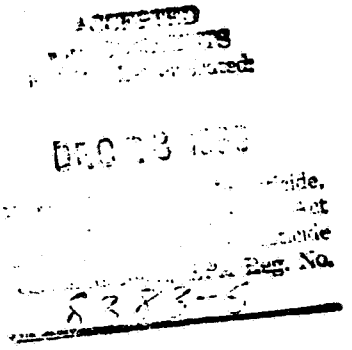
INGREDIENTS

Glutaraldehyde 25%

Contents: 2.56 fl. ozs.

WARNING: KEEP OUT OF REACH OF CHILDREN

(See Precautions on Back Label)



BACK LABEL - ACTIVATOR

PRECAUTIONS:

- Avoid eye contact: Causes eye irritation. In case of contact, flush with water immediately and get medical attention.
- Avoid skin contact: At full strength, possibility of sensitization exists and may cause skin irritation. Flush thoroughly with water after contact.
- Harmful if swallowed. If swallowed, drink large quantities of water and call physician immediately.
- Avoid food contamination.

EPA Reg. No. 8383-5

THE SPORICIDIN COMPANY
4000 Massachusetts Ave., N.W.
Washington, D.C. 20016

Product Name: SPORICIDIN
Registration No. 8383-5

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 28 1983

Under the ... ide.
... registration No.
8383-5

COLLATERAL LABELING

Hospital and Institutional Sterilizing and Disinfecting Solution

Sporicidin is a water soluble chemo-sterilizer, capable of killing all forms of micro-organisms in 6-3/4 hours at room temperature. It is especially adapte for hospital and institutional use to sterilize medical and dental instruments and equipment. It reduces the hazards of cross-infection from medical and dental instruments and equipment and environmental surfaces.

USES: Sporicidin is a "cold sterilizer", requiring no heat. It is especially suited for sterilizing or disinfecting articles including dental, medical, and surgical instruments such as mirrors, burs, diamond points, forceps, scissors, scalpels, tubing, 'scopes, catheters, syringes, and thermometers.

ACTION: In addition to the uses and directions shown on the label:

(1) Freshly activated solution disinfects immersed articles in 1 minute. If tubercle bacillus, Polio I or Influenza A_2 are suspected, and for dental instruments, follow disinfection directions on label.

(2) Water soluble.

(3) Low volatility. The vapor pressure (21-22mm.), boilding point (214°F) (101°C) and specific gravity (1.02) are practically the same as water.

(4) Non-flammable.

BEST DOCUMENT AVAILABLE

RECEIVED

DEC 2 7 1983

Reg...

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ACCEPTED
with COMMENTS
in EPA Letter dated:

DEC 23 1988

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 8-51-2

SPORICIDIN
For Dialysis

Rapid-Acting/Equipment Safe/Non-Staining
Pseudomonacidal Bactericidal
Virucidal* Fungicidal
Formulated for decontamination Hemodialysate delivery systems

Disinfecting Solution for Dialysis
Machines and Hemodialyzers
For Use in Hospitals, Dialysis Centers, and Health Care Institutions

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Note: Follow specific equipment manufacturer's recommendation for cleansing and disinfecting. Sporicidin can be used for 10 minute disinfection of hemodialysate delivery systems when diluted 1:34 with water in the system.

DIRECTIONS FOR ACTIVATION AND USE

Flush equipment thoroughly with water before introducing activated Sporicidin full strength solution. Add Activator to Special Buffer Solution. Use activated solution within 21 days of activation.

Single Patient Delivery Systems. Place 150 cc (5.08 ozs.) into the hemodialysate system. Allow the machine to run until all of the Sporicidin is drawn into the concentrate line. This will allow for automatic proportioning of solution with tap water.

Multipatient Delivery Systems. Place 1.0 liter (33.82 ozs.) into the hemodialysate delivery system. Allow the machine to run until all of the Sporicidin is drawn into the concentrate line. This will allow for automatic proportioning of solution with tap water.

Note: use of an insufficient quantity of activated Sporicidin solution will result in inadequate treatment of the hemodialysate delivery system. Some systems will require a larger quantity of solution than specified in the direction above. Additional diluted quantities are prepared by mixing 1 part of activated Sporicidin to 34 parts of water.

Hemodialyzers. When dialyzers are reused, a 1:16 dilution (1 part of activated Sporicidin to 15 parts of water) is recommended. Allow solution to remain in the dialyzer for 24 hours. Drain Sporicidin and thoroughly rinse with water. Test final rinse water for residual using the Sporicidin Residual Test Kit (P-2108) to assure complete rinsing.

DISINFECTION

It is recommended that disinfection procedures be accomplished immediately preceeding use of the hemodialysate system.

After filling the delivery system, hold Sporicidin in the system for a minimum of 10 minutes. Drain Sporicidin from the system and thoroughly rinse with water. Test final rinse water for residual using the Sporicidin Residual Test Kit (P-2108) to assure complete rinsing.

RECEIVED
DEC 27 1988

Reg. No. 8-51-2

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Sporicidin is recommended for decontaminating single patient and multipatient hemodialysate delivery systems. Sporicidin has been shown to be an effective disinfectant (virucide, fungicde, bactericide, pseudomonacide) when tested by AOAC and EPA Test Methods. Sporicidin exhibits virucidal* activity against both hydrophilic and lipophilic viruses including Polio Type I, Herpes Simplex Type 2." and Influenza A2 Japan on environmental hard surfaces at 1:34 dilution. Sporicidin may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery system.

Guidelines for hemodialysate systems are available from the Hepatitis Laboratories, Centers for Disease Control, Phoenix, Arizona 85201, (602) 241-2662.

PRECAUTIONARY STATEMENTS

Eyes. Avoid eye contact. Causes eye irritation. In case of contact, flush with water immediately and get medical attention.

Skin. Avoid skin contact. At full strength, possibility of skin sensitivity exists and may cause skin irritation. Flush thoroughly with water after contact. Harmful if swallowed. If swallowed, drink large quantities of water and call a physician immediately. Avoid food contamination.

STORAGE AND DISPOSAL

Store at room temperature. Rinse empty container thoroughly with water and discard in trash. Do not reuse solution.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

DEC 23 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. [illegible]

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 8383-5

Date Division Received 08-20-86, 09-05-86, 10-28-86, & 08-07-86 (labels only)

Data Accession No(s). 264607 & 264608 (New Data)

Product Manager No. 31 (Lee)

Product Name Sporicidin

Company Name Sporicidin Company

202.0 Recommendations

202.1 Efficacy Supported by the Data

a. Tuberculocidal Tests

The submitted data meet the requirements of the Tuberculocidal Data Call-In Notice to support effectiveness of the product as a tuberculocide for re-use in manual systems for up to 30 days after activation at a 1/16 dilution in 10 minutes at 20°C on previously cleaned surfaces when tested by the AOAC Tuberculocidal Activity Method (unmodified) with 2 different batches by the first laboratory (Shaldra) and validated with 1 batch by a second laboratory (Gibraltar).

Data were also previously submitted and accepted to support effectiveness of the product as a tuberculocide for re-use in manual systems at a 1/16 dilution in 55 minutes at 20°C for up to 30 days re-use, in 25 minutes at 20°C for up to 21 days re-use, and in 15 minutes at 20°C for up to 14 days re-use on previously cleaned surfaces when tested by the new quantitative Tuberculocidal Activity Test Method with 4 differ- batches by the first laboratory above (Shaldra).

The above data show significantly different results obtained with solutions subjected to the same manual re-use stress procedure, depending on the tuberculocidal test method employed to determine efficacy of the solutions. In view of the conflicting data submitted, the conditions recommended on the label for tuberculocidal efficacy should reflect the greatest margin of safety and degree of public health protection as determined by the tests. Therefore, the directions for use should specify the more stringent conditions represented by the results obtained by the new quantitative method, i.e., at least 55 minutes at 20°C for solutions re-used up to 30 days in manual systems. The directions may additionally include the shorter contact times determined for lesser periods of re-use, i.e., 25 minutes at 20°C for up to 21 days re-use, 15 minutes at 20°C for up to 14 days re-use, and 10 minutes at 20°C for a single day's usage.

b. Virucidal Tests

The submitted data support effectiveness of the product as a virucide for re-use in manual systems for up to 30 days after activation at a 1/16 dilution in 10 minutes at 20-25°C (room temperature), under the conditions of the accepted use pattern for this product on previously cleaned surfaces, against Poliovirus Type 2.

202.2 Additional Information/Clarification Required

a. The reference in the data report title to "Tuberculocidal Efficacy Tests with 5% Added Soil" is not documented in either the Shaldra re-use protocol or Shaldra test reports. Only the Gibraltar test reports specify the addition of 5% blood serum, which is neither necessary or sufficient to support efficacy in this regard, since the basic data and pattern of use for this product is for previously cleaned surfaces. Please explain.

b. The submitted chemical analysis data for this and previous re-use testing show the initial pH of the activated, diluted solution to be about 8. The most recently submitted CSF for this product indicates the pH of the activated solution to be between 7.0 and 7.4. Please clarify.

203.0 Labeling

203.1 Labels Received 10-28-86

a. Container Label - Front Panel

1. The unqualified "Virucidal" claim must be keyed by an asterisk to the specific test viruses named on the back panel.

2. The unqualified "Fungicidal" claim must be qualified here or elsewhere on the label as referring to pathogenic fungi and/or Trichophyton mentagrophytes/interdigitale (athlete's foot fungi).

[redacted] and must be deleted from the list of active ingredients and included with the inert ingredients in the ingredient statement. Refer to 40 CFR 162.60(d) [redacted]

b. Container Label - Back Panel

1. Under "Sporicidin Cold Sterilizing Solution", delete "tuberculocidal" from the list of efficacy claims for the solution used and reused for 30 da at room temperature in 10 minutes. Separate claims/directions for tuberculocidal efficacy of the 1:16 dilution for 30 days reuse must be provided as indicated in 202.1(a) above.

2. In the same paragraph, the claim "can be used and reused for 30 days" must be revised to read "can be used and reused for 30 days as a disinfectant in manual (bucket or tray) systems."

3. The unqualified "fungicidal" claim must be qualified here or elsewhere on the label as indicated in 203.1(a)(2) above.

4. Under the heading "Directions" in #3, add a statement such as "Prepare a fresh solution for each day's use."

5. Under "Directions" in #4, delete "Mycobacterium tuberculosis" and provide separate claims/directions for tuberculocidal efficay as indicated in 202.1(a) above.

6. After the heading "Special Use Patterns", add a statement such as "Prepare a fresh solution for each day's use" immediately following and on the same line as the heading.

7. Under "Special Use Patterns" in (1), the claim "Freshly activated undiluted solution disinfects immersed articles in 1 minute" must be revised to read "Freshly activated undiluted solution is bactericidal only for immersed articles in 1 minute, and is bactericidal only in 2 minutes with a shelf life of 30 days"; and the claim "a 1:32 dilution disinfects articles in 10 minutes" must be revised to read "a 1:32 dilution is bactericidal, fungicidal, and virucidal (Influenza A2/Japan, Polio Type 1, and Herpes simplex Type 2) for immersed articles in 10 minutes with a shelf life of 30 days."

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INERT INGREDIENT INFORMATION IS NOT INCLUDED

8. Under "Special Use Patterns" in (2), the recommendation to use the [redacted] delete paragraph (2).

9. Following "Special Use Patterns" the paragraph beginning "To prepare a 1:16 dilution . . ." must be relocated to immediately follow the first paragraph of #4, which provides the claims/recommendations for the 1:16 dilution and precedes "Special Use Patterns." Also, change "Fully effective for 30 days" to read "Fully effective for reuse for 30 days in manual systems."

c. Carton Label - Front Panel

1. The unqualified "Virucidal" claim must be keyed to the specific test viruses named somewhere on the carton label as indicated in 203.1(a)(1) above.

2. The unqualified "Fungicidal" claim must be qualified here or elsewhere on the label as indicated in 203.1(a)(2) above.

d. Carton Label - Back Panel

1. The "Directions" on the carton label must be revised to agree with the "Directions" on the container label - back panel.

e. Carton Label - Top Panel

No comments.

f. Carton Label - Left Panel

1. In the claim "The only cold sterilizer . . .", delete "only". Claims that any product possesses unique characteristics are not acceptable (49 FR, No. 188, dated 09-26-84, p. 37974).

2. In the claim "This unique ability . . .", delete "unique" for the same reason.

g. Carton Label - Right Panel

1. In the claim "Sporicidin is a new chemosterilizer . . .", delete "new. The claim "new" may not be used on the labeling of a product after 6 montl from the time of its approval (49 FR, No. 188, dated 09-26-84, p. 37974).

2. The claim "100% kill of all organisms" must be qualified by a phrase such as "when used for sterilization procedures."

h. Collateral Labeling

1. 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. The only virucidal claim that could be considered for this product against HBV would be as a sterilizer when used in accordance with label directions for the sterilization procedure, i. e., for the activated, undiluted solution at an exposure of 6 3/4 hours at 20°C.

203.2 Labels Received 08-07-86

a. Container Label - Front Panel
" " - Back Panel
Carton Label - Front Panel
" " - Back Panel
" " - Right Panel
" " - Left Panel
" " - Top Panel
Collateral Labeling

It is assumed that the above were superceded by the resubmitted labels of the same items received 10-28-86.

b. Activator Label - Front and Back Panels

No comments.

c. Sporicidin-D Label

1. The above comments concerning [redacted] qualification of the "Fungicidal" claim are also applicable to this label. Refer to 203.1(a)(2) and (3) above.

d. Sporicidin Brochure

1. On pages 1 and 2, delete the claim "New". Refer to 203.1(g)(1).

2. On page 3, delete all comparative claims and references to "Cidex" products. Claims that a product possesses unique characteristics because of its composition and comparative claims concerning effectiveness of a product are unacceptable (49 FR, No. 188, dated 09-26-84, p. 37974).

3. On pages 3 and 4, delete all references to the Environmental Protection Agency. Claims implying recommendation or endorsement by EPA are unwarranted and unacceptable. Only a statement of the fact of EPA registration (registration number and establishment number) are permitted, provided that is not highlighted by type size, placement, color, or prominence. Refer to 49 CFR, No. 188, dated 09-26-84, p. 37975.

4. On page 3, all references to "University Studies", which have not been accepted in connection with registration of this product, must be deleted.

5. On page 4 under "Advantages", in the claim "33% more effective . . .", delete "33% more"; in the claim "30 times more effective . . .", delete "30 times more". Refer to 203.2(d)(3) above.

6. On page 4 under "References", delete all references which are not keyed to acceptable statements or claims in the brochure, including the reference to "Cidex".