TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 01-27-86 OUT 02-14-86

Reviewed By Dorothy M. Portner Date 02-14-86

EPA Reg. No. 8383-5

EPA Petition or EUP No. None

Date Division Received 11-07-85 & 01-27-86

Type Product Disinfecting/Sterilizing Solution

Data Accession No(s). Not Accessioned

Product Manager PM-31 (Lee)

Product Name Sporicidin

Company Name The Sporicidin Company

Submission Purpose Resubmission with efficacy data and proposed labeling to support disinfectant reuse claims for manual systems

Type Formulation Liquid concentrate to be activated and used diluted and undiluted

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

200.0 Introduction

200.1 Use

The proposed product labeling submitted is attached.

200.2 Background Information

A. The submission, received 11-7-85 in response to our letter of 9-24-85, included the following information:

1. Proposed revised labeling: (a) the product label for the phenolic buffer solution, (b) the product label for the 25% glutaraldehyde activator solution, and (c) collateral labeling.

2. An amended report from R.E. Pepper for the 2nd reuse study (Report No. 101) involving Solutions "C" and "D" - See TSS Review of 8-12-85 for the previous evaluation of this report.

3. Additional virucidal data developed on Solution "C" against Influenza A_2 (Japan) and Herpes simplex, Type 2 viruses by H.N. Prince, Gibraltar Biological Laboratories, Inc. Fairfield, New Jersey.

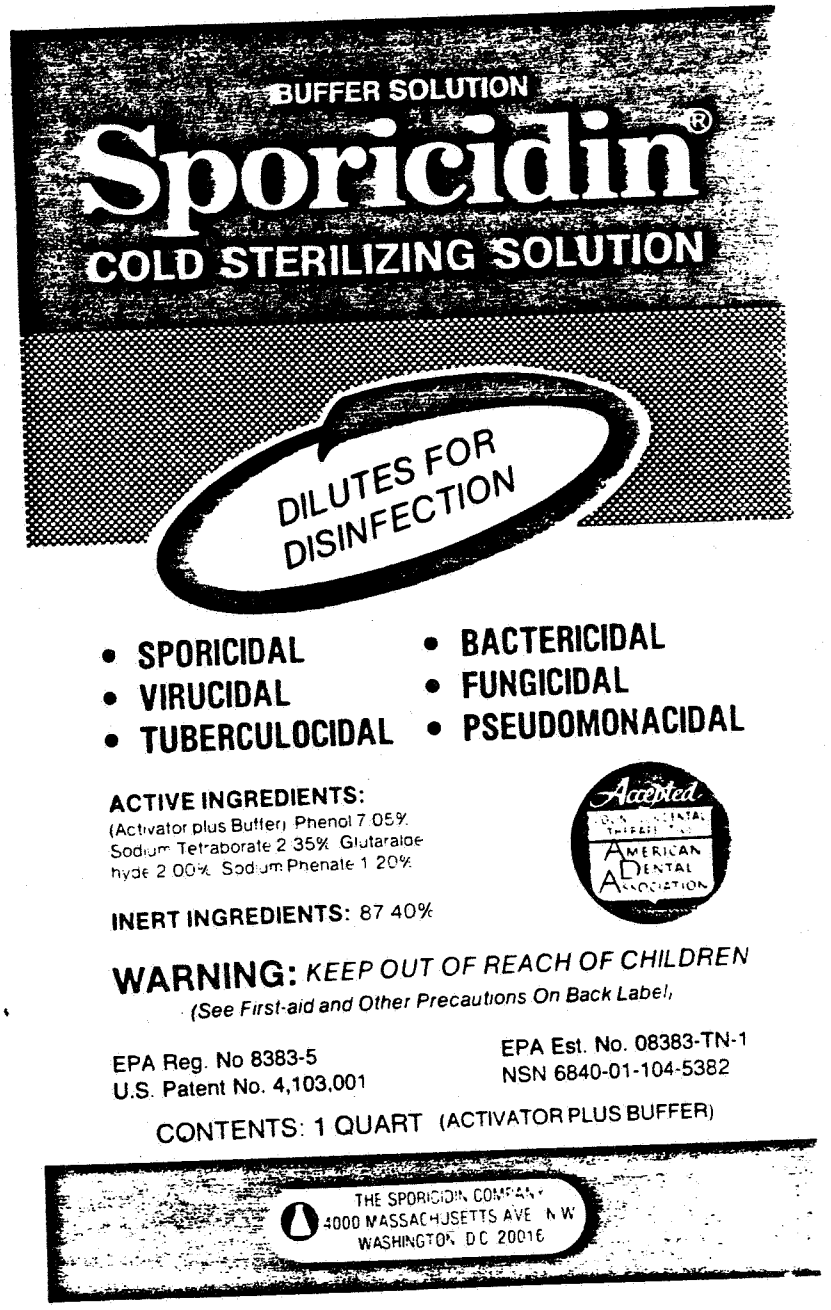
4. A 3rd reuse study conducted to derive additional supplemental data to support claims for the reuse solution as a pathogenic fungicide, tuberculocide, and virucide against Coxsackie B virus.

B. The submission, received 1-27-86, included:

1. Additional virucidal data developed on Solution "C" against Poliovirus, Type 1 and Herpes simplex, Type 1 virus by H.N. Prince.

2. An AIDS study conducted by S.C. Tondreau of Bionetics Research Inc., Kensington, Maryland.

3. Revised collateral labeling with additional efficacy claims for tuberculocidal reuse and against AIDS HTLV III virus.


BUFFER SOLUTION
Sporicidin®
COLD STERILIZING SOLUTION
DILUTES FOR DISINFECTION
• SPORICIDAL
• VIRUCIDAL
• TUBERCULOCIDAL
• BACTERICIDAL
• FUNGICIDAL
• PSEUDOMONACIDAL
ACTIVE INGREDIENTS:
(Activator plus Buffer) Phenol 7.05%
Sodium Tetraborate 2.35% Glutaraldehyde 2.00% Sodium Phenate 1.20%
INERT INGREDIENTS: 87.40%
Accepted
AMERICAN DENTAL ASSOCIATION
WARNING: KEEP OUT OF REACH OF CHILDREN
(See First-aid and Other Precautions On Back Label)
EPA Reg. No 8383-5
U.S. Patent No. 4,103,001
EPA Est. No. 08383-TN-1
NSN 6840-01-104-5382
CONTENTS: 1 QUART (ACTIVATOR PLUS BUFFER)
THE SPORICIDIN COMPANY
4000 MASSACHUSETTS AVE N.W.
WASHINGTON, D.C. 20016

SPORICIDIN
Reg. No. 8383-5

Back Label

For Medical and Dental Instruments and Equipment in Surgery, Endoscopy (Gastroenterology, Urology, etc.), Respiratory Therapy, Anesthesiology, and Dentistry.

SPORICIDIN
COLD STERILIZING SOLUTION

Sporicidin (1:16) can be used and reused for 100% disinfection in 10 minutes at room temperature (20°C 68°F). It is bactericidal, fungicidal, tuberculocidal and virucidal (i.e. Influenza A_2 (Japan), Polio I, Coxsackie B-1, Herpes Simplex Type 1 and 2).

DIRECTIONS

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

1. Add Activator Solution to this Buffer Solution. The activated 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. Disinfection: For complete disinfection immerse articles in a 1:16 dilution of Sporicidin at room temperature (20°C 68°F) for 10 minutes. Solution may be used and reused for 30 days in manual (buckets or trays) procedures.

4. Tuberculocidal action: For 100% kill, immerse article in a 1:16 dilution of Sporicidin for 10 minutes at room temperature (20°C 68°F) for the first 14 days of use and reuse and for 40 minutes thereafter through 30 days use and reuse in manual (buckets or trays) procedures.

   NOTE: A 1:32 dilution of unused undiluted solution activated up to 21 days will disinfect in 10 minutes with bactericidal, fungicidal and virucidal action shown above.

5. For Sporicidal Action and Sterilization: Immerse articles in unused undiluted solution at room temperature. Kills aerobic spores, including Bacillus subtilis in 3 hours and achieves complete sterilization in 6-3/4 hours.

   To Prepare: For 1:16 dilution, add 1 part of activated solution to 15 parts of tap water; i.e., add 8 oz. of solution to 120 oz. of tap water to make 1 gallon.

   For 1:32 dilution, add 1 part of activated solution to 31 parts of tap water; 8 ozs. of solution makes 2 gallons (256 ozs.).

6. Articles: For plastics, rubber, and carbon steel, use disinfection directions. Not recommended for tungsten carbide inserts or as an overnight holding solution for carbon steel and dental burs. Should not be used for injection needles.

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

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

COLLATERAL LABELING ORIGINALLY PROPOSED

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 adapted 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.

Product Name: SPORICIDIN
Registration No. 8383-5

COLLATERAL LABELING REVISED PROPOSAL

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 adapted 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.

(2) Can be used and reused for tuberculocidal activity for 30 days at 68°F (20°C) - For 100% kill, immerse articles in 1:16 dilution of Sporicidin for 10 minutes for the first 14 days of use and reuse; for 25 minutes for days 15 thru 21, and for 40 minutes from day 22 thru day 30.

(3) Sporicidin diluted 1:16 kills AIDS HTLV III virus on inanimate, hard surfaces in 1 minute at 68°F (20°C).

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

(5) Non-flammable.

(6) Water soluble.

201.0 Data Summary (Unaccessioned Data)

A. Amended Report No. 101

Included with the attached amended Report No. 101 were previously submitted chromatographs and the test schedules for Solution "C" and "D" which indicated that the simulated-reuse procedure was performed for 30 days before the study was terminated. However, the amended report indicated that on the 29th day the required bioburden (390 carriers) was added to the liter to be used for the microbiological assays. Thus, to continue the simulated-reuse procedure on the 30th day would be meaningless. Further clarification of the simulated-reuse procedure employed in this study is required to consider these basic bactericidal data in support of disinfecting activity for reused solutions and for acceptance of the additional virucidal data developed on Solution "C" reused throughout the study.

B. Virucidal Testing On Reused Solution "C"

Method: 0.2 ml of virus pool spread onto the surfaces (petri dishes) and allowed to dry to a film at 35°C for 30-45 minutes. 2.0 ml of use dilution was spread over the virus film and allowed to remain in contact for 10 minutes at 20-25°C. Then the virus-germicide mixture was removed by pipet and diluted in trypticase soy broth up to 10^5 to 10^7. Decimal dilutions were then inoculated into an appropriate host. The virus-germicide mixture represents 10^1 virus in the presence of the test germicide.

Organic Soil: 5% Serum (Poliovirus, Type 1,and Herpes simplex virus, Types 1 and 2)
100% CAF (Influenza A_2, J-305 Virus)

Controls: Virus control, 0.2 ml viral film treated with 2.0 ml TSB and titrated ED_{50}.

Results:

Influenza A_2 Virus (Japan)

	Sol. "C"
Virus titer $TCID_{50}$	4.8
Virus + disinfectant $TCLD_{50}$	NVD
Cytotoxicity $TCTD_{50}$	NCO
Log reduction in titer	4.8

NVD = No virus detected.
NCO = No cytotoxicity observed in chick embryos.

The 5-7-85 sample solution was refrigerated until assayed on 6-19-85.

8

Herpes Simplex virus. Type 2

	Sol. "C"
Virus titer $TCID_{50}$	6.3
Virus + disinfectant $TCLD_{50}$	$\leq$1.5
Cytotoxicity $TCTD_{50}$	1.5*
Log reduction in titer	$\geq$4.8

* Hep-2 cells

The 5-7-85 sample solution was refrigerated until assayed on 7-22-85.

Herpes Simplex virus, Type 1

	Sol. "C"
Virus titer $TCID_{50}$	6.5
Virus + disinfectant $TCLD_{50}$	$\leq$2.5
Cytotoxicity $TCTD_{50}$	2.5*
Log reduction in titer	$\geq$4.0

* Hep-2 cells

The 5-7-85 sample solution was refrigerated until assayed on 1-3-86.

Poliovirus, Type 1

	Sol. "C"
Virus titer $TCID_{50}$	5.5
Virus + disinfectant $TCLD_{50}$	$\leq$2.5
Cytotoxicity $TCTD_{50}$	2.5*
Log reduction in titer	$\geq$3.0

* Hep-2 cells

The 5-7-85 sample solution was refrigerated until assayed on 12-13-85.

C. The 3rd Simulated-Reuse Study

The 3rd simulated-reuse study was conducted according to the attached protocol. Pertinent information reported in the daily test schedule for each test sample is indicated below:

Sample	Sampling Period	Bioburden Load/L
S10A*	@ 14 days. 08-29-85	270 carriers
S10B*	@ 21 days, 09-05-85	270 carriers
	@ 30 days. 09-14-85	390 carriers
S10C**	@ 14 days, 09-14-85	270 carriers
S10D**	@ 21 days. 09-11-85	270 carriers
	@ 30 days. 09-14-85	390 carriers

* Testing Period - From 08-16-85 Thru 09-14-85.
** Testing Period - From 08-22-85 Thru 09-20-85.

The determinations on the test solutions for glutaraldehyde and phenol concentration (by chromatography) and pH, which were done periodically during the study, are indicated below:

Day	Percent Glutaraldehyde				Percent Phenol			
	S10A	S10B	S10C	S10D	S10A	S10B	S10C	S10D
0	2.32	2.24	2.13	2.16	10.73	10.94	8.92	9.79
7	2.20	2.10	2.10	2.12	9.50	9.03	10.29	10.33
14	2.06	2.18	2.10	1.87	10.11	10.11	10.37	9.64
21	1.82	1.77	1.89	1.99	9.54	9.24	10.46	10.50
30	1.71	1.69	1.97	1.72	9.99	10.54	10.58	10.42

pH = 8.0 to 8.1 for each sample during the 30-day study.

D. Fungicidal Testing On Reused S10C Solution

The attached fungicidal data were developed in the 3rd reuse study.

E. Virucidal Testing On Reused S10C And S10D Solutions

The attached procedural description was provided with the virucidal data developed for the 3rd reuse study by P.R. Roane of Integrity Bioservices Inc., Rockville. Maryland.

Results

Coxsackievirus B_1 (Strain VR-28ATCC)

	Sol. S10C	Sol. S10D
Virus titer $TCID_{50}$	4.5	6.0
Virus + disinfectant $TCLD_{50}$	≤ 0.5	≤ 0.5
Cytotoxicity $TCTD_{50}$	≤ 0.5	≤ 0.5
Log reduction in titer	>4.0	≥ 5.5

Sporicidin efficacy review

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Pages _____ through _____ are not included in this copy.

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 product 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

X FIFRA registration data

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F. Tuberculocidal Testing On 4 Reused Solutions (S10A, S10B. S10C. And S10D)

The attached quantitative protocol was employed in developing the submitted tuberculocidal data.

Results

14 Days Reuse

Time Min.	Sol. S10A CFU/ml	Sol. S10B CFU/ml	Sol. S10C CFU/ ml	Sol. S10D CFU/ml
0	4.30×10^7	4.30×10^7	3.80×10^7	3.80×10^7
2	2.10×10^6	1.65×10^6	2.35×10^6	2.40×10^6
4	1.05×10^6	1.02×10^6	1.03×10^6	1.35×10^6
6	1.90×10^4	1.95×10^4	1.61×10^4	2.30×10^4
8	4.90×10^3	3.53×10^3	3.05×10^3	2.30×10^3
	S/S_o	S/S_o	S/S_o	S/S_o
2	0.049	0.038	0.062	0.063
4	0.024	0.024	0.027	0.036
6	0.00044	0.00045	0.00042	0.00061
8	0.00011	0.000082	0.000080	0.000061

21 Days Reuse

Time Min.	Sol. S10A CFU/ml	Sol. S10B CFU/ml	Sol. S10C CFU/ml	Sol. S10D CFU/ml
0	4.10×10^7	4.10×10^7	3.90×10^7	3.90×10^7
4	3.70×10^6	3.83×10^6	3.30×10^6	3.10×10^6
6	3.03×10^6	3.23×10^6	3.60×10^6	3.40×10^6
8	2.63×10^5	3.18×10^5	3.15×10^5	2.88×10^5
18	3.08×10^3	3.35×10^3	3.53×10^3	3.65×10^3
22	3.25×10^2	4.50×10^2	4.25×10^2	4.00×10^2
28	0*	0*	0*	0*
	S/S_o	S/S_o	S/S_o	S/S_o
4	0.090	0.093	0.085	0.079
6	0.074	0.079	0.092	0.087
8	0.0064	0.0078	0.0081	0.0074
18	0.000075	0.000082	0.000091	0.000094
22	0.0000079	0.000011	0.000011	0.000010

* $< 1.0 \times 10^2$ CFU/ml

30 Days Reuse

Time Min.	Sol. S10A CFU/ml	Sol. S10B CFU/ml	Sol. S10C CFU/ml	Sol. S10D CFU/ml
0	4.40×10^7	4.40×10^7	4.10×10^7	4.10×10^7
8	2.40×10^6	3.20×10^6	3.48×10^6	2.75×10^6
12	1.95×10^6	2.53×10^6	2.48×10^6	2.65×10^6
16	1.85×10^6	1.73×10^6	1.83×10^6	1.78×10^6
20	8.35×10^5	1.55×10^6	1.01×10^6	9.85×10^5
24	4.75×10^5	5.00×10^5	4.80×10^5	4.50×10^5
28	2.83×10^4	3.65×10^4	3.33×10^4	2.65×10^4
32	1.83×10^4	2.50×10^4	2.43×10^4	2.03×10^4
36	4.70×10^3	3.83×10^3	3.08×10^3	2.65×10^3
40	0*	0*	0*	0*
	S/S_o	S/S_o	S/S_o	S/S_o
8	0.055	0.072	0.084	0.067
12	0.044	0.058	0.060	0.065
16	0.042	0.039	0.045	0.043
20	0.019	0.035	0.025	0.024
24	0.011	0.011	0.012	0.011
28	0.00064	0.00083	0.00081	0.00065
32	0.00042	0.00057	0.00059	0.00050
36	0.00011	0.000087	0.000075	0.000065

* $<1.0 \times 10^2$ CFU/ml

Phenol Controls

Time Min.	14 Day Reuse CFU/ml	S/S_o	21 Day Reuse CFU/ml	S/S_o	30 Day Reuse CFU/ml	S/S_o
10	5.8×10^6	0.14	5.6×10^6	0.14	6.0×10^6	0.14
20	5.0×10^6	0.12	4.8×10^6	0.12	5.0×10^6	0.12
30	3.6×10^6	0.09	3.5×10^6	0.09	3.6×10^6	0.09

The data are presented graphically in TSS Efficacy Review II.

G. AIDS Virus Testing

S.C. Tondreau of Bionetics Research Inc., Kensington, Maryland employed the attached protocol (Method 1 with dry virus dried in tubes and Method 2 with a virus suspension) to demonstrate the effectiveness of a 1:16 dilution of Sporicidin (presumably, a freshly activated solution) to inactivate HTLV-III virus.

The testing procedures are inadequate because:

1. Evidence that HTLV-III virus can be recovered from a surface is not provided by the meaningless and very low 10^2 positive virus control titer, prepared in Method 1 by dilution in 1:1600 Sporicidin during the 90-minute virus adsorption period.

2. Neither method employed a neutralizer to stop the antimicrobial reaction of Sporicidin after the exposure period.

3. The two methods do not provide comparable results. A 1:16 dilution demonstrated inconclusive results at 1 and 5 minutes by Method 1 with a low virus control titer; whereas an effective inactivation was indicated in 1 minute by Method 2.

201.1 Conclusions

The submitted mixture of fragmented data appear to show a satisfactory performance of a 1:16 dilution of the product under the following use conditions at room temperature ($\geq$ 20°C):

1. As a disinfectant [bactericide and virucide against Influenza A_2 (Japan), Herpes simplex, Types 1 and 2, and Polio, Type 1)] at a 10-minute contact time for 29 days of reuse.

2. As a pathogenic fungicide and virucide against Cocksakievirus B1 at a 10-minute contact time for 30 days of reuse.

3. As a tuberculocide in 15 minutes for a 14-day reuse solution, in 25 minutes for a 21-day reuse solution, and in 55 minutes for a 30-day reuse solution.

The claimed effectiveness of a 1:16 dilution of the product against AIDS HTLV III virus dried on an inanimate surface in 1 minute was not demonstrated by the data submitted.

Sporicidin efficacy review

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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

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Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 8383-5

Data Division Received 11-07-85 & 01-27-86

Data Accession No(s). Not Accessioned

Product Manager No. PM 31 (Lee)

Product Name Sporicidin

Company Name The Sporicidin Company

202.0 Recommendations

202.1 Amended Data Report No. 101

The intent of amending Data Report No. 101 was to clarify the test protocol and to verify that adequate bioburden was present in the liter of solution used to develop the required basic bactericidal data and the supplemental virucidal data. However, the amended report is ambiguous and must clarify why the required 390 carriers were added to the liter of solution to be used for the microbiological assay on the 29th day, when, according to the submitted test schedule, the simulated reuse procdure continued one more day before the study was terminated. According to the accepted protocol, the simulated-reuse procedure was to be completed before the required bioburden load was added to the liter of reuse solution removed from the bucket for the microbiological assays. The addition of the required bioburden load on the 29th day means that the study was terminated then; continuation of the simulated-reuse procedure thereafter would be superfluous.

The bactericidal data developed in the simulated-reuse study indicated in Data Report No. 101 appear to support a 1:16 dilution of the product as a disinfectant in 10 minutes at 20°C when reused for 29 days on precleaned, hard, non-porous surfaces.

The virucidal data developed on reuse solutions stressed in this study appear to support efficacy of a 1:16 dilution of the product as a virucide against Poliovirus, Type 1, Herpes simplex viruses, Type 1 and 2, and Influenza A_2 (Japan) virus in 10 minutes when reused for 29 days in accordance disinfecting label directions.

However, based on presumptive evidence for similar products, Coxsackievirus and tubercle bacilli seem to be the most difficult microorganisms to kill. Since the third reuse study demonstrated that 1:16 dilution was efficacious for a 30-day reuse period against these hardy microorganisms, the above efficacy claims will be considered acceptable for a 30-day reuse period on the label without any additional data.

202.2 Tuberculocidal Efficacy

The submitted data, developed by the new quantitative method, do not indicate that a 1:16 dilution of the product will be an effective tuberculocide at 20°C in 10 minutes for 14 days of reuse and in 40 minutes for 30 days of reuse as reported because:

1. On the submitted graph for the 14-day reuse solution, the determined S/S_o values do not correlate with the bacterial recovery results reported and the indicated P1 line does not correspond with the the other graphs.

2. On the submitted graph for the 30-day reuse solution, the indicated "0" at 40 minutes is an anomaly from the linear death rate. The "0" observation, derived at 10^2 dilution, is not a precise indication that no viable cells remain in the test solution.

Since the submitted data show considerable deviation from linearity, regression curves were calculated by the least squares method in order obtain the best linear fit for determining the exposure time for tuberculocidal efficacy. The attached graphs indicate the range of S/S_o data values obtained at the time periods sampled in the tests conducted on reused solutions stressed for 14, 21, and 30 days and provide a calculated linear regression curve which best describes these data. The P1 line (one survivor S/S_o) indicated on these graphs is based upon an initial concentration of 4×10^6 CFU, rather than the actual level of 4×10^7 CFU employed in these tests, to correspond to the concentration level specified in the method. The minimum time that will be acceptable to support tuberculocidal claims at 20°C for the reused 1:16 dilution is determined at the intersect of the calculated regression curve and the P1 line. On this basis, the recommended contact time for tuberculocidal efficacy would be 15 minutes for a 14-day reuse solution, 25 minutes for 21-day reuse solution, and 55 minutes for 30-day reuse solution.

202.3 Additional Supplemental Data

The additional supplemental data developed on reuse solutions stressed for 30 days in the 3rd simulated-reuse study support efficacy of a 1:16 dilution of the product as a pathogenic fungicide and virucide against Coxsackievirus B1 in 10 minutes when reused for 30 days.

202.4 AIDS Efficacy Claims

The submitted data developed against HTLV-III virus are not acceptable to support the proposed efficacy claim against AIDS virus. The methodology employed was inadequate for evaluating a disinfectant on an inaminate surface because the required survival of viable dry virus on a surface was not demonstrated and the test solution was not neutralized after the exposure period.

The efficacy data requirements for demonstration of virucidal activity by disinfectants on dry, inanimate objects, such as those recommended in your labeling, are indicated in the DIS/TSS-7 enclosure.

202.5 Labeling

1. The proposed back label must be revised to include the efficacy claims and complete labeling directions for disinfection and sterilization, that reflect supporting data. The attached label is recommended.

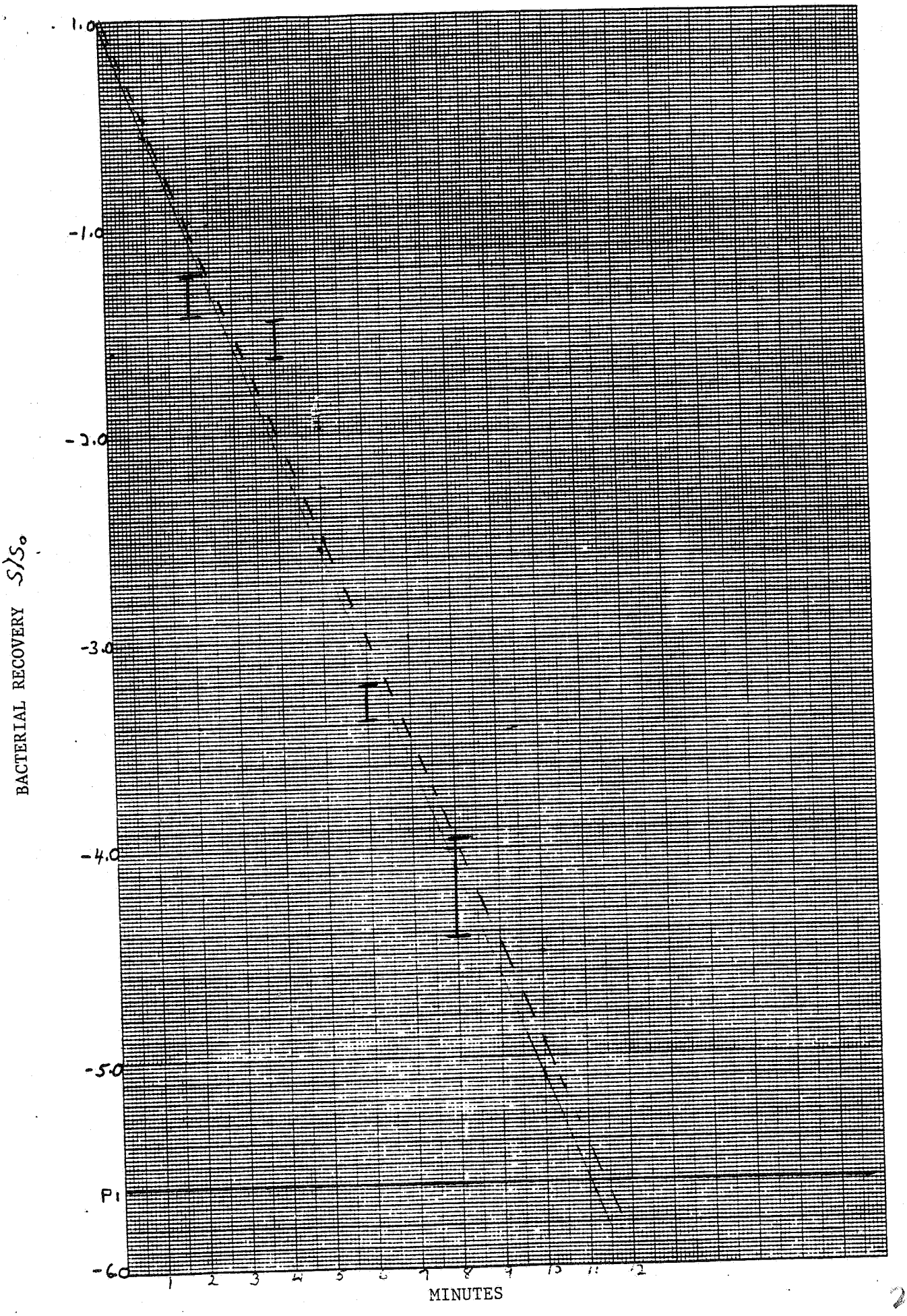
2. The proposed label recommendation for disinfection at a 1:32 dilution is unacceptable because this special use pattern is not applicable to the intended reuse pattern and the efficacy claimed for the solution prepared with an activated stock solution during the 30-day shelf-life period. However, special use patterns for disinfection under restrictive conditions for a one day's use would be acceptable on collateral labeling provided that efficacy claims and complete labeling directions for disinfection, that reflect supporting data, are indicated. These revisions apply to both the recommended 1:32 dilution in 10 minutes and the freshly activated undiluted stock solution in 1 minute.

3. The sporicidal claim against Bacillus subtilis spores is meaningless and unacceptable because there are no directions for using this product for 3 hours. Sporicidal and sterilizing are synonomous. Any claim in this respect must represent the required contact time to kill both test microorganisms, which is 6 3/4 hours.

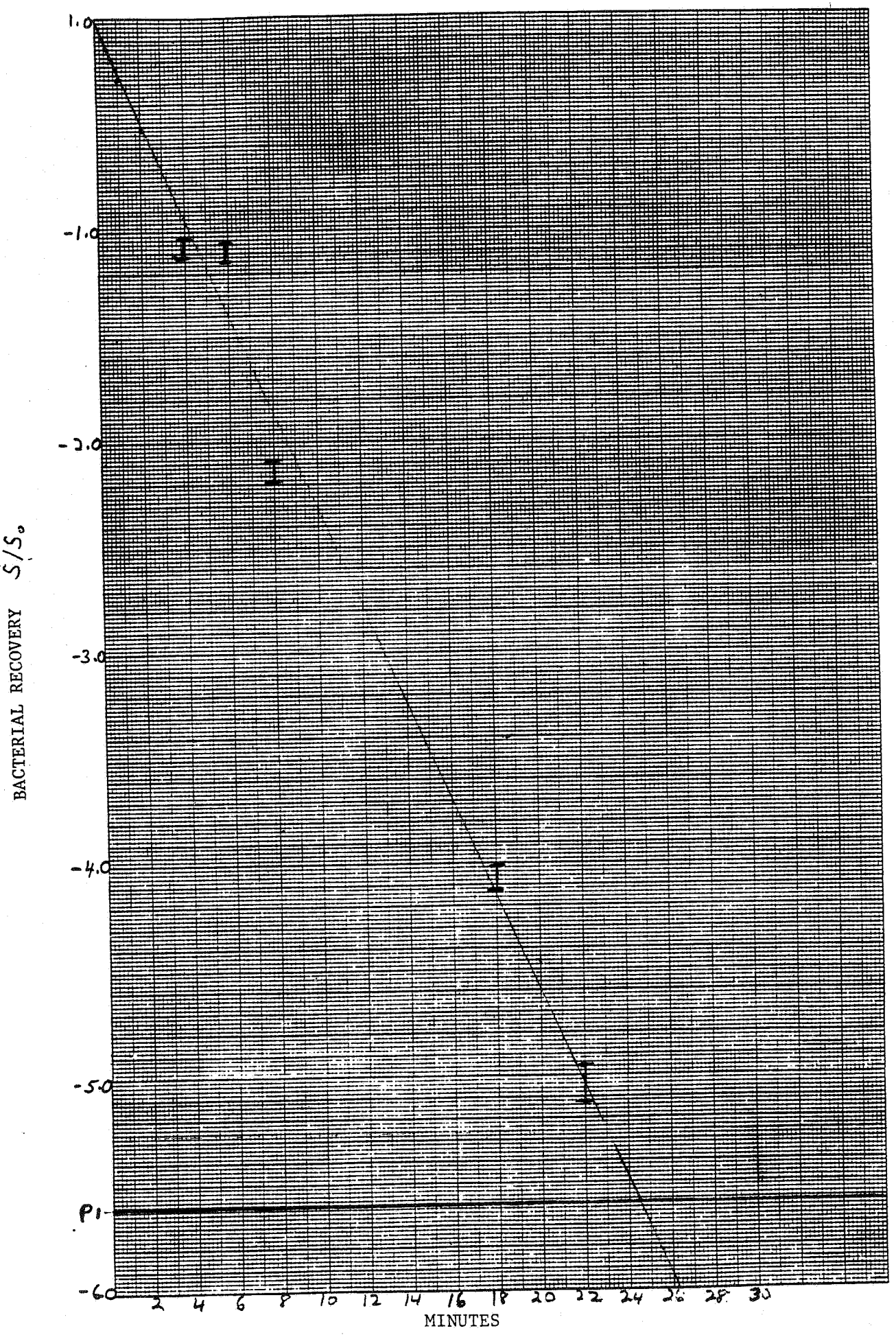
4. The accepted reuse tuberculocidal claim for a 1:16 dilution is 55 minutes at 20°C, which is in accord with the intended 30-day reuse pattern. The tuberculocidal claims for 14 and 21-day reuse solutions, which are intermediate results from the 30-day simulated-reuse study, would be appropriate on collateral labeling if presented with the intent to show that product effectiveness is decreased with repeated use.

5. The proposed efficacy claim against AIDS HTLV III virus indicated on the collateral labeling is not supported by acceptable data and must be deleted.

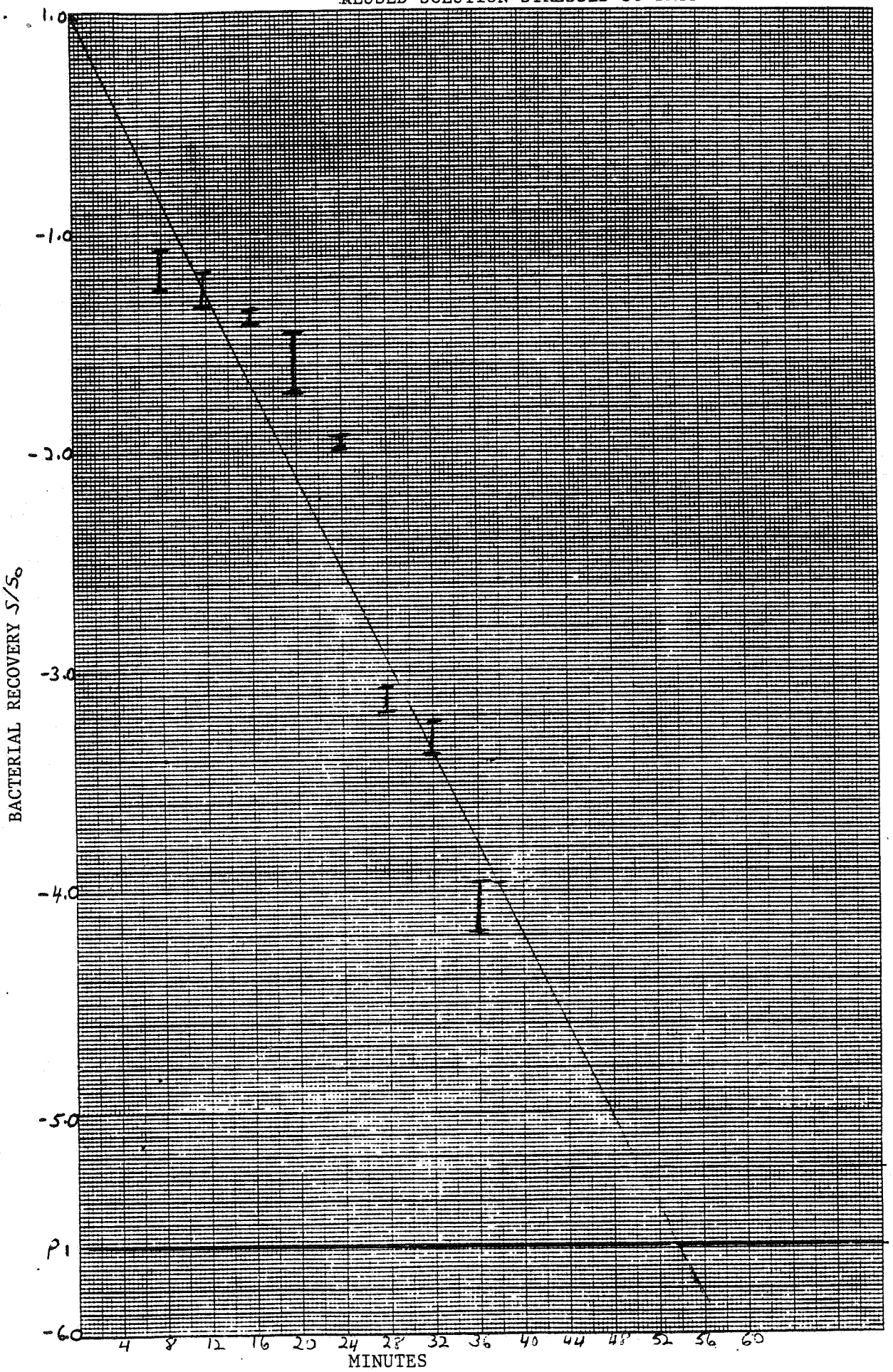
REUSED SOLUTION STRESSED 14 DAYS



REUSED SOLUTION STRESSED 21 DAYS



REUSED SOLUTION STRESSED 30 DAYS



RECOMMENDED LABEL

For Medical and Dental Instruments and Equipment in Surgery, Endoscopy (Gastroenterology, Urology), Respiratory Therapy, Anesthesiology, and Dentistry.

SPORICIDIN
COLD STERILIZATION SOLUTION

Sporicidin (1:16) can be used and reused for 30 days at room temperature (20°C/68°F) for 100% disinfection. It is bactericidal, fungicidal, virucidal (i.e., Influenza A_2 (Japan), Polio 1, Coxsackie B-1, Herpes simplex, Type 1 and 2) in 10 minutes and tuberculocidal in 55 minutes.

DIRECTIONS

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

1. Add Activator Solution to this Buffer Solution. The activated 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. STERILIZATION: Immerse articles for 6 3/4 hours in an unused, undiluted activated stock solution at room temperature. Do not use this solution for more than one day. (Discard the used solution after one day's use.)

4. DISINFECTION: To prepare a 1:16 dilution, add 1 part of activated stock solution to 15 parts of tap water; i.e., add 8 oz. of solution to 120 oz, of tap water to make 1 gallon.

   Immerse articles for 10 minutes in a 1:16 dilution of Sporicidin at room temperature. The solution may be used and reused for 30 days in manual (buckets or trays) procedures.

   Use disinfection directions for plastics, rubber, and carbon steel. Not recommended for tungsten carbide inserts or as an overnight holding solution for carbon steel and dental burs. Do not use for injection needles.

5. TUBERCULOCIDAL ACTION: Leave immerse articles for 55 minutes in a 1:16 dilution of Sporcidin at room temperature. The solution may be used or reused for 30 days in manual procedures.

6. Remove articles from the solution after sterilization or disinfection using aseptic technique. Rinse with sterile water.