TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectant Branch

IN 07/15/87 OUT 09/02/87

Srinivas Gowda DSG 9-4-87

Reviewed By Srinivas Gowda Date 09/02/87

EPA Reg. No. or File Symbol 46781-1

EPA Petition or EUP NO. NONE

Data Division Received 07-15-87

Type Product Hospital Disinfectant/Sterilant

Date Accession No.(s) 402521-01 & 402521-02

Product Manager PM 31 (Lee)

Product Name Metricide MX-1400 Activated Dialdehyde Solution

Company Name Metrex Research Corporation

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

Type Formulation Two-component Activated Alkaline Glutaraldehyde Solution

Active Ingredient(s):	%
Glutaraldehyde	2.00

200.0 Introduction

200.1 Use(s)

A sterilizing and disinfecting solution for use in hospitals, dental offices, nursing homes and health care institutions on pre-cleaned medical instruments, and equipments. Label bears sporicidal, virucidal, bactericidal, tuberculocidal, pseudomonacidal, and fungicidal claims. Label also bears 14 days repeated reuse claims as a disinfectant (undiluted) in manual systems.

200.2 Background Information

The submission received 07-01-87 is an amended application to include 14 day reuse sporicidal claims. Efficacy data developed in accordance with an EPA approved reuse protocol accompanied the application.

201.0 Data Summary

201.1 Brief Description of Test

"Efficacy tests using two lots of Metricide M1400 disinfectant sterilant after 14 days of reuse stress tested in A.O.A.C. Sporicidal Tests using a 8 hour exposure time at 20°C" by Kyle Sibinovic, Shaldra Biotest, Inc., P.O. Box 34317 W. Bethesda, MD. 20817, dated 06-10-86 (Accession No. 402521-01).

"Confirmatory Sporicidal Tests Metricide Dialdehyde Disinfectant / Sterilant tested in the A. O. A. C. Sporicidal Test (Confirmatory) using 14 day stressed solution from a manual reuse test M1400Q exposed for 8 hours at 20°C" by Richard Gammon, Presque Isle Cultures, P.O. Box 8191, Presque Isle, PA 16505, dated 10-03-86 (Accession No. 402521-02).

201.2 Test Results

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: "Metricide M1400", activated solution from 2 different batches, Lots M1400K 242851, and M1400L244851 manufactured 08-30-85, and 09-01-85 respectively. Activator Lot # 1812. 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 on 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

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 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.	Mfg.Dates	Test Dates
M1400K 242851	08-30-85	01-28-86
Activator#1816	Not Listed	"
M1400L 244851	09-01-85	03-04-86
Activator#1816	Not Listed	"

4. Dilution: Undiluted (2% Glutaraldehyde)

5. Exposure: 8 hours at 20°C

6. Subculture Medium: Fluid Thioglycolate Medium USP XX
Neutralizer: $NaHSO_3$ 4%
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	242851	14	Cylinders	60	0/60
	244851	"	"	60	0/60
	242851	"	Loops	60	0/60
	244851	"	"	60	0/60
B. subtilis	242851	"	Cylinders	60	0/60
	244851	"	"	60.	0/60
	242851	"	Loops	60	0/60
	244851	"	"	60	0/60

11. Conclusions: The submitted data demonstrate a satisfactory sterilizing performance at a contact time of 8 hours at 20°C for a 2% glutarldehyde solution reused 42 cycles in 14 days.