

7-25-85

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 06-21-85

OUT 07-17-85

Reviewed By Dorothy M. Portner 7/25/85 Date 07-17-85

EPA Reg. No. 46781-1

EPA Petition or EUP No. None

Date Division Received 06-21-85

Type Product Disinfecting/Sanitizing Solution

Data Accession No(s). 258391 & 258392

Product Manager PM-31 (Lee)

Product Name Metricide MX-1400

Company Name Metrex Research Corporation

Submission Purpose Amended application with efficacy data to
support disinfectant/sterilization manual
reuse claims

Type Formulation Liquid concentrate to be activated & used
undiluted

Active Ingredient(s): %

Glutaraldehyde2.00

200.0 Introduction

200.1 Use

The proposed label for the subject product is attached.

200.2 Background Information

The submission, received 6-21-85, is an amended application to include a manual re-use claim to the label. A proposed label and efficacy data were provided.

The data to support reuse efficacy of two different formulations, Metricide 1400 (EPA Reg. No. 46781-1) and Metricide 2800 (EPA Reg. No. 46781-2) were included in a single package (under two accession numbers). The data for both products will be evaluated in one review (TSS Efficacy Review I), but the recommendations from the review (TSS Efficacy Review II) will be indicated separately for each product.

201.0 Data Summary (Accession Nos. 258391 & 258392)

The submitted data report, dated 5-24-85, included bactericidal, fungicidal and tuberculocidal data for reuse solutions developed by K.H. Sibinovic, Shaladra Biotest Inc., W. Bethesda, MD; the virucidal data for the reuse solutions were developed by P.R. Roane, Integrity Bioservices Inc., Rockville, MD.

201.1 Test Protocol

The general test protocol and summary of reuse conducted are attached. The specific test schedule to document the activities actually performed during the study were not provided.

Brief Description Of Test Conducted On The Reuse Solution

A. Bactericidal Testing

Method: AOAC Use Dilution Test with 5% soil
Exposure Time: 10 minutes at 20°C
Neutralizer Time: NaHSO₃ for 10 minutes at 20°C
Subculture Medium: Nutrient Broth
Incubation Period: 48 Hours at 37°C

B. Fungicidal Testing

Method: AOAC Use Dilution Test with 5% soil
Exposure Time: 10 minutes at 20°C
Neutralizer Time: NaHSO₃ for 10 minutes at 20°C
Subculture Medium: Glucose Broth
Incubation Period: 10 days at 26°C

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C. Tuberculocidal Testing

Method: AOAC Tuberculocidal Activity Test

Exposure Time: 10 minutes at 20°C

Neutralizer Time: NaHSO₃ for 10 minutes at 20°C

Incubation Period: 90 days at 37°C

D. Sporocidal Testing

Method: AOAC Sporocidal Test

Exposure Time: 10 hours at 20°C

Neutralizer Time: NaHSO₃ for 10 minutes at 20°C

Subculture Medium: Fluid Thioglycollate Medium USP XX

Incubation Period: 21 days at 37°C; Heat Shock 20 min.
at 80°C, reincubate 3 days at 37°C

E. Virucidal Testing

The virucidal methodology employed is attached.

F. Determination of pH and Glutaraldehyde Concentration

No analytical procedures were indicated.

201.2 Test Results

A. Bactericidal Testing

Test Organism	Number Positive/Total Carriers Tested			
	0328517 ¹	0298517 ²	0368517 ³	0448517 ⁴
S. aureus (PR = 1:65)	0/180	0/180	0/180	0/180
P. aeruginosa (PR = 1:85)	0/180	0/180	0/180	0/180
S. choleraesuis (PR = 1:95)	0/180	0/180	0/180	0/180

PR = Phenol Resistance

1 = Metricide 1400, Sample A (mfd. 1-3-85) with Activator Lot #1067 (mfd. 12-15-84).

2 = Metricide 1400, Sample B (mfd. 1-3-85) with Activator Lot #1067 (mfd. 12-5-84).

3 = Metricide 2800, Sample A (mfd. 1-3-85) with Activator Lot #023852 (mfd. 12-12-84).

4 = Metricide 2800, Sample B (mfd. 1-3-85) with Activator Lot #023852 (mfd. 12-12-84).

B. Fungicidal Testing

Test Organism	Number Positive/Total Carriers Tested			
	0328517 ¹	0298517 ²	0368517 ³	0448517 ⁴

T. mentagrophytes*	0/20	0/20	0/20	NTDS
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* Phenol Resistance = 1:70

1 = Metricide 1400, Sample A (Conidia count = 6.1×10^6 /ml)

2 = Metricide 1400, Sample B (Conidia count = 5.9×10^6 /ml)

3 = Metricide 2800, Sample A (Conidia count = 5.9×10^6 /ml)

4 = Metricide 2800, Sample B

NTDS = No test data submitted.

C. Tuberculocidal Testing

Lot	No. Positive/Total Tubes Tested					
	Proskauer-Beck		Middlebrook		Kirchner's	
	NaHSO ₃	HS	NaHSO ₃	HS	NaHSO ₃	HS
0298517*	0/10	0/10	0/10	0/10	0/10	0/10
0368517**	0/10	0/10	0/10	0/10	0/10	0/10

* Metricide 1400, Sample B (after 87 days incubation; same results indicated for the data also submitted after 70 days incubation).

** Metricide 2800, Sample A (after 73 days incubation; same results indicated for the data also submitted after 56 days incubation).

HS = Horse Serum.

Phenol Resistance indicated as "phenol sensitivity at 1:50 in 10 minutes at 20°C" and "phenol resistance at 1:70 in 10 minutes at 20°C."

D. Sporocidal Testing

Test Sample	Type Carrier	No. +/Total Tested	
		B. subtilis*	C. sporogenes**
0328517 ¹	Cylinder	0/60	0/60
	Loop	0/60	0/60
0298517 ²	Cylinder	0/60	0/60
	Loop	0/60	0/60
0368517 ³	Cylinder	NTDS	NTDS
	Loop	NTDS	NTDS
0448517 ⁴	Cylinder	0/60	0/60
	Loop	0/60	0/60

* Acid Resistance for Cylinder = 15 minutes

* Acid Resistance for Loop = 20 minutes

** Acid Resistance for Cylinder = 20 minutes

** Acid Resistance for Loop = >20 minutes

1 Metricide 1400, Sample A

2 Metricide 1400, Sample B

3 Metricide 2800, Sample A; NTDS = No test data submitted

4 Metricide 2800, Sample B

E. Virucidal Testing

Herpes simplex virus Type 1 (Macroplaque Strain)

	1400A	2800B
Virus titer TCID ₅₀	6.3	5.9
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>5.3</u>	<u>>4.9</u>

Herpes simplex virus Type 2 (G Strain)

	1400A	2800B
Virus titer TCID ₅₀	4.5	5.0
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>3.5</u>	<u>>4.0</u>

Adenovirus 2 (NIAID-Straus)

	1400A	2800B
Virus titer TCID ₅₀	6.5	7.0
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>5.5</u>	<u>>6.0</u>

Coxsackievirus B5 (NIAID V032)

	1400A	2800B
Virus titer TCID ₅₀	6.0	5.5
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>5.0</u>	<u>>4.5</u>

Echovirus 8 (Strain NIAID V-041)

	1400A	2800B
Virus titer TCID ₅₀	6.7	6.7
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>5.7</u>	<u>>5.7</u>

Poliovirus Type 2 Strain TN(M-29)

	1400A	2800B
Virus titer TCID ₅₀	4.5	5.5
Virus + disinfectant TCLD ₅₀	<1.0	<1.0
Cytotoxicity TCTD ₅₀	<1.0	<1.0
Log reduction in titer	<u>>3.5</u>	<u>>4.5</u>

F. Determination of pH and Glutaraldehyde Concentration

The submitted test results are attached.

201.3 Conclusions

1. A satisfactory performance for bactericidal, fungicidal, tuberculocidal, sporicidal and virucidal activity of the reuse activated solution was demonstrated for a 14-day period with Metricide 1400 and for a 30-day period with Metricide 2800.
2. However, the following data/information is required to complete and clarify the submitted data package for validation:
 - a. The test schedules to document the preparation of the 4 reuse solutions tested for antimicrobial activity.
 - b. The chemical analytical procedure employed in the determination of the glutaraldehyde concentration.
 - c. Tuberculocidal data after the specified 90 days incubation.
 - d. The raw tuberculocidal phenol resistance data developed with the 3 test media.
 - e. Sporicidal data developed for Metricide 2800, Sample A.
 - f. The raw data for the fungicidal testing with Metricide 2800, Sample B which was reported in the summary table but not submitted.

RIN 7832-94

EFFICACY REVIEW FOR EPA REG NO 46781-1

Page is not included in this copy.

Pages 7 through 12 are not included.

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 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.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) .
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
