

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 2-3-83 OUT 2-7-83

Reviewed By Dorothy M Portner *DP* *2/15/83* Date 2-7-83

EPA Reg. No. or File Symbol 46781-R

EPA Petition or EUP No. \_\_\_\_\_

Date Division Received 2-3-83

Type Product Sterilizing/Disinfecting Solution

Data Accession No(s). Not Accessioned

Product Manager 31

Product Name Activated Dialdehyde Sterilizing and Disinfecting Solution

Company Name Metrex Research Corporation

Submission Purpose Resubmission with confirmatory efficacy data

Type Formulation Liquid Concentrate to be activated and used undiluted

Active Ingredient(s):

Glutaraldehyde

%

2.0

## 200.0 Introduction

## 200.1 Use

See attached proposed label.

## 200.2 Background Information

The submission, received 2-3-83, included efficacy data requested in our letter of 10-1-82.

## 201.0 Data Summary (Data Not Accessioned)

The submitted data were developed by Benedicte Gantois and William E. McCullough at BioSearch, Inc., Arlington, Texas (reports dated 1-30-83). The testing was conducted on Product B, identified as Activated Dialdehyde Solution (manufactured 4-7-82) with Powdered Activator (manufactured 1-12-82), and Product D, identified as Activated Dialdehyde Solution with [REDACTED] (manufactured 4-7-82) with Powder Activator (manufactured 1-12-82).

## A. Sporicidal Data

A 14-day post-activated solution of each product was tested after a 10-hour contact time at 20 C by the AOAC Sporicidal Test employing Thioglycollate Medium for primary and secondary subcultures that were incubated 21 days at 37 C, then heat shocked at 80 C for 20 minutes and reincubated 3 days at 37 C. (Test dates: Dec. 3-9, 82)

Test Results

Test Organism	Test Carrier	Acid. Resistance	No. Positive/Total Carriers	
			Product B	Product D
B. subtilis	Cylinders	10 min.	0/30	0/30
	Loops	5 min.	0/30	0/30
C. sporogenes	Cylinders	10 min.	0/30	0/30
	Loops	10 min.	0/30	0/30

## B. Basic Bactericidal Data

A 14-day post-activated solution of each product was tested after a 10-minute contact time at 20 C by the AOAC Use Dilution Method employing Thioglycollate Medium for the subcultures incubated 48 hours at 37 C. (Test dates: Nov. 19-24, 82)

Test Results

Test Organism	Phenol Resistance	No. Positive/Total Carriers	
		Product B	Product D
S. aureus	1:60	0/10	0/10
S. choleraesuis	1:90	0/10	0/10
P. aeruginosa	1:80	0/10	0/10

RIN 7832-94

EFFICACY REVIEWS FOR EPA REG NO 46781-1

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Pages   3   through   4   are not included.

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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.
- 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.

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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.

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