2-4-83

043901

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 01-14-83 OUT 02-04-83

Dennis G. Guse 2/1/83

Reviewed By Dennis G. Guse Date 02-04-83

EPA Reg. No. or File Symbol 7078-RG

EPA Petition or EUP No. None

Date Division Received 12-13-82

Type Product Hospital disinfectant (hemodializers)

Data Accession No(s). 249246

Product Manager 31 (Lee)

Product Name Cidex Dializer Disinfecting Solution

Company Name Surgikos, Inc.

Submission Purpose New product and use pattern based on Cidex HD Disinfecting Solution (EPA Reg. No. 7078-7)

Type Formulation Liquid concentrate and activator solution to be combined and diluted with water for use

Active Ingredient(s):	%
Glutaraldehyde	26.0

1

185

INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

200.0 Introduction.

200.1 Use(s).

Proposed disinfectant for reusable hemodializer units in hospitals, dialysis centers, and health care institutions.

200.2 Background.

The proposed product is identical in formulation to Cidex HD Disinfecting Solution (EPA Reg. No. 7078-7) except for deletion of the small amount of [redacted] from the glutaraldehyde component, and substitution of a [redacted] in the activator component. Therefore, all efficacy data previously submitted and accepted for EPA Reg. No. 7078-7 is applicable to this product also.

201.0 Data Summary.

201.1 Brief Description of Tests.

a. Previously Submitted and Accepted Data for Cidex HD Disinfecting Solution (EPA Reg. No. 7078-7).

1. Efficacy Testing of Cidex HD Disinfecting Solution with Liquid Activator Salts: AOAC Use-Dilution, Fungicidal, and Virucidal Tests. Reports by N. I. Bruckner, R. F. Berry, and T. M. Wendt, Arbrook (now Surgikos), Inc., Arlington, TX 76010, and by Microbiological Associates (M A Bioproducts), Walkersville, MD 21793, dated from 06-11-79 to 01-30-80 (Accession No. 241911).

2. Virucidal Testing of Cidex HD Disinfecting Solution. Reports by T. M. Wendt, Surgikos, Inc., Arlington, TX 76010, and by M A Bioproducts, Walkersville, MD 21793, and Microbiological Associates, Bethesda, MD 20016, dated from 11-21-80 to 04-03-81 (Accession No. 244976).

3. AOAC Use-Dilution Testing of Cidex HD Disinfecting Solution (Minor Formula Change). Report by J. M. Ascenzi, Surgikos, Inc., Arlington, TX 76010, dated 09-25-81 (Accession No. 246146).

b. Currently Submitted and Accepted for Cidex Dializer Disinfecting Solution (EPA File Symbol 7078-RG).

1. Effectiveness of Cidex Dializer Solution Against Atypical Water Mycobacteria. Report by J. M. Ascenzi, Surgikos, Inc., Arlington, TX 76010, dated 11-18-82 (Accession No. 249246).

201.2 Test Summaries.

a. Previously Submitted and Accepted Data for Cidex HD Disinfecting Solution (EPA Reg. No. 7078-7).

1. These data were previously summarized in the reviews for the above product by TSS (Efficacy), DB, dated 02-28-80, 06-29-81, and 11-12-81.

2. Conclusions: The data support effectiveness of the product as a disinfectant (hospital), fungicide (pathogenic), and virucide (Herpes Simplex Type 1 and Influenza A2 Hong Kong) on clean, hard surfaces which are thoroughly wet by the activated, diluted (1:34) solution for a contact time of 10 minutes, and additionally as a virucide (Coxsackie B Type 1 and Poliovirus Type 1) for a contact time of 15 minutes.

b. Currently Submitted Data for Cidex Dializer Disinfecting Solution (EPA Reg. No. 7078-RG).

1. Method: AOAC Use-Dilution Method.

2. Modifications: None.

3. Dilution: Not reported.

4. Samples: Cidex Dializer Solution, Lots I, II, and III.

5. Test Bacteria: Mycobacterium chelonei and Mycobacterium fortuitum. Source or strains not identified.

6. Media/Neutralizer: Middlebrook 7H9 broth with Tween 80 (growth medium); saline with Tween 80 (diluent); tryptic soy agar (plating medium). Subculture medium not reported.

7. Growth Conditions: 48 hours at 37C (broth cultures); 5 days at 37C (plates). Subculture conditions not identified.

8. Carrier Preparation: Carriers exposed to cell suspension for 15 minutes at room temperature; carriers dried for 30 minutes at 37C.

9. Germicide Exposure: 15 and 30 minutes at 25C.

10. Results:

Test Organism	Average Organisms/Carrier After Drying	Positive/Total Carriers* Lot I 15 min	Lot I 30 min	Lot II 15 min	Lot II 30 min	Lot III 15 min	Lot III 30 min
M. chelonei	8.02×10^6	0/10	0/10	0/10	0/10	1/10	0/10
M. fortuitum	3.14×10^6	0/10	0/10	0/10	0/10	0/10	0/10

*Static activity controls positive for each organism when tested against each of the three lots indicating negative tubes not artifactual.

11. Conclusions: Satisfactory performance vs. both test bacteria in 30 minutes under the experimental conditions. Howver, the the test report was incomplete.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 7078-RG

Date Division Received 12-13-82

Data Accession No(s). 249246

Product Manager No. 31 (Lee)

Product Name Cidex Dializer Disinfecting Solution

Company Name Surgikos, Inc.

202.0 Recommendations.

202.1 Efficacy Supported by Previously Submitted/Referenced Data.

Previously submitted and accepted efficacy data for Cidex HD Disinfecting Solution (EPA Reg. No. 7078-7) also serve to support effectiveness of this product for the claimed pattern of use as a hospital disinfectant (Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa), virucide (Herpes Simplex Type 1, Influenza A2 Hong Kong, Coxsackie B Type 1, and Poliovirus Type 1), and fungicide (pathogenic fungi) for disinfection of reusable hemodializer units which are thoroughly wet by the freshly activated, diluted (1:32) solution for a contact time of 30 minutes.

202.2 Efficacy Supported by Currently Submitted Data.

The submitted efficacy data for Cidex Dialyzer Disinfecting Solution (EPA File Symbol 7078-RG) appear adequate to additionally support effectiveness of this product for the above pattern of use against the atypical water mycobacteria (Mycobacterium chelonei and Mycobacterium fortuitum) under the same conditions. However, certain relevant information was not specified in the efficacy test report. The following information must be submitted in order to complete the data file for this product:

a. Verify that the use-dilution employed in the tests was the recommended 1:32 dilution;

b. Identify the strains or source of the test bacteria;

c. Specify the subculture medium and incubation conditions (time and temperature) employed for the exposed carriers.

202.3 Additional Information Requested:

Please provide a bibliographic reference (author, journal, etc.) and/or a copy of the cited report by CDC entitled "Microbiologic Evaluation of a New Glutaraldehyde-Based Disinfectant for Hemodialysis Systems".

203.0 Labeling.

The "virucidal" claim must be keyed by a symbol to the paragraph listing the specific tested viruses.

Expand "Herpes Simplex" to read "Herpes Simplex Type 1".

The "fungicidal" claim should be qualified as for "pathogenic fungi".

We question whether "sterile water" should be specified for rinsing the disinfected unit to prevent recontamination. The present directions only indicate a rinse with "water".

6

130