TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 04-05-84 OUT 05-10-84

Dennis G. Guse 5/10/84

Reviewed By Dennis G. Guse Date 05-10-84

EPA Reg. No. or File Symbol 7078-13

EPA Petition or EUP No. None

Date Division Received 04-02-84 & 04-04-84

Type Product Hospital sterilant/disinfectant (hemodialyzers)

Data Accession No(s). 249246 (old) & 252871 (new)

Product Manager 31 (Lee)

Product Name Cidex Dialyzer Sterilizing/Disinfecting Solution Concentrate

Company Name Surgikos, Inc.

Submission Purpose Resubmission for previous application with additional data & new amendment with data and label

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

Active Ingredient(s):	%
Glutaraldehyde	26

62

200.0 Introduction

200.1 Use(s)

The product is registered as a disinfectant for pre-cleaned hemodialyzer units of the reusable type for use in hospitals, dialysis centers, and health care institutions.

200.2 Background

Refer to the previous review for this product by TSS (Efficacy), DB, RD, dated 02-04-83. The registrant has submitted additional data to complete the previously submitted efficacy test report for atypical water mycobacteria (M. chelonei and M. fortuitum). In addition, the registrant has submitted a new amendment to add a sterilization claim with additional efficacy data and a revised label.

201.0 Data Summary

201.1 Brief Description of Tests

a. Additional Data Concerning Effectiveness of Cidex Dialyzer Solution Against Atypical Water Mycobacteria (Accession No. 249246). Report by T. M. Wendt, Surgikos, Inc., Arlington, TX 76010, dated 03-30-84 (Unaccessioned).

b. Efficacy Testing of Cidex Dialyzer Disinfecting Solution Concentrate: AOAC Sporicidal Test for Sterilizers. Report by R. F. Berry, Surgikos, Inc., Arlington, TX 76010, dated 07-21 & 22-83 (Accession No. 252871).

201.2 Test Summaries

A. Additional Data Concerning Effectiveness of Cidex Dialyzer Solution Against Atypical Water Mycobacteria

1. Dilution: The use-dilution employed in the test was 1:31, resulting in concentrations of active ingredient of 0.87%, 0.9% and 0.86%, respectively, for the 3 test lots.

2. Test Bacteria: The strain numbers were Mycobacterium chelonei ATCC 14472 and Mycobacterium fortuitum ATCC 6841.

3. Subculture Medium and Incubation conditions: Middlebrook 7H9 using incubation for 7 days at 37C.

4. Referenced Report: A copy of the cited report entitled "Microbiologic Evaluation of a New Glutaraldehyde-Based Disinfectant for Hemodialysis Systems" by N. J. Petersen, L. A. Carson, I. L. Doto, S. M. Aguero and M. S. Favero, Centers for Disease Control, Phoenix, Arizona 85014, was submitted for our information.

b. Efficacy Testing of Cidex Dialyzer Disinfecting Solution Concentrate: AOAC Sporicidal Test for Sterilizers

1. Method: A.O.A.C. Sporicidal Test.

2. Modifications: None reported.

3. Samples: Lot I (655-78A), Lot II (655-78B), and Lot III (623-1-1) of Cidex Dialyzer Disinfecting Solution Concentrate (one of which was aged 60 days).

4. Activation and Dilution: Samples were activated and diluted by mixing 1 part of activated concentrate to 32 parts of deionized water.

5. Exposure: 24 hours at 25C and 36 hours at 25C.

6. Test Organisms: Bacillus subtilis ATCC 19659 (resisted 2.5 N HCl for 20 min. on suture loops and 2 min. on porcelain cylinders) and Clostridium sporogenes ATCC 3584 (resisted 2.5 N HCl for 20 min. on suture loops and 5 min. on porcelain cylinders).

7. Subculture Media/Neutralizer: Fluid thioglycollate medium for subculture and resubculture.

8. Incubation: Per method.

9. Results:

Sample	Test Organism	Carrier	Exposure (Hrs.)	Positive/Total Carriers
I	Bacillus subtilis	Loops	36	0/60
"	"	Cyl	24	0/60
"	Clostridium sporogenes	Loops	24	0/60
"	"	Cyl	24	0/60
II	Bacillus subtilis	Loops	36	0/60
"	"	Cyl	24	0/60
"	Clostridium sporogenes	Loops	24	0/60
"	"	Cyl	24	0/60
III	Bacillus subtilis	Loops	36	0/60
"	"	Cyl	24	0/60
"	Clostridium sporogenes	Loops	24	0/60
"	"	Cyl	24	0/60

10. Conclusions: No failures reported out of 720 carriers tested.

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Product Manager No. 31 (Lee)

Product Name Cidex Dialyzer Sterilizing/Disinfecting Solution Conc.

Company Name Surgikos, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data by the AOAC Sporicidal Test is acceptable to support effectiveness of the product as a sterilizer for previously cleaned surfaces which are immersed in the freshly activated solution, diluted 1:32 (1 part activated concentrate to 32 parts water), for a contact time of 36 hours at 25C.

However, acceptance of the sterilizing claim is conditional upon confirmatory testing of this product by the AOAC Sporicidal Test conducted by a second, independent laboratory. Refer to 202.3 below.

202.2 Efficacy Not Supported by the Data

The additional data/information submitted concerning the testing of this product against atypical water mycobacteria (Mycobacterium chelonei and Mycobacterium fortuitum) by the AOAC Use-Dilution Method failed to verify that the use-dilution employed in the tests was a 1:32 dilution. (Comment 3(a) which accompanied the registration notice, dated February 17, 1984, contained a typographical error; the comment should have read "Verify that the use-dilution employed in the tests was the recommended 1:32 dilution.")

The submitted report states "The use-dilution employed in the tests was 1:31 . . ." Therefore, effectiveness of the product as a disinfectant against these organisms at a 1:32 (1 part activated concentrate to 32 parts water) dilution is not supported. In view of this, one of the following alternatives must be performed: (a) Redevelop the data at a 1:32 dilution, (b) Revise the recommended use-dilution to 1:31, or (c) Delete the claims against these organisms.

202.3 Additional Data Required to Support Efficacy

Due to the curtailment of laboratory operations at the EPA Microbiology laboratory at Beltsville, the required confirmatory validation data for this product as a sterilizer may be conducted by a second, independent laboratory of your choice. The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of the two types of surfaces (silk suture loops and porcelain penicylinders) against spores of both Bacillus subtilis and Clostridium sporogenes (a total of 120 carriers) by the AOAC Sporicidal Test.

203.0 Labeling

Although the current label states that the product ". . . is designed to be used at a 32:1 dilution . . .", the "Directions For Activation" state ". . . dilute the activated concentrate to 8 gallons with . . . water . . ." According to our calculations, diluting the activated concentrate (28.6 fluid ounces) to 8 gallons (1024 fluid ounces) would require 995.4 fluid ounces of water, which would be a dilution of 1 part activated concentrate to 35 parts water. The recommended dilution cannot be greater than that shown to be effective in efficacy testing, therefore, this discrepancy must be corrected.

Again, according to our calculations, it would require 31 fluid ounces of activated concentrate diluted with 993 fluid ounces of water to make 8 gallons (1024 fluid ounces), which would provide a 1:32 dilution (1 part activated concentrate to 32 parts water) on a volume to volume basis. If these calculations are correct, the basis for diluting the product must be revised accordingly.

The use-dilution recommended for this product must be clarified or corrected to correspond to the minimum dilution shown to be effective in efficacy testing.