TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 08-15-85 OUT 08-21-85

Reviewed By Dorothy M. Portner Dorothy M Portner 8/9/85 Date 08-21-85

EPA Reg. No. 46781-1

EPA Petition or EUP No. None

Date Division Received 08-14-85

Type Product Disinfecting/Sterilizing Solution

Data Accession No(s).

Product Manager PM-31 (Lee)

Product Name Metricide MX-1400

Company Name Metrex Research Corporation

Submission Purpose Resubmission with additional data/information

Type Formulation Liquid concentrate to be activated & used undiluted

Active Ingredient(s):	%
Glutaraldehyde	2.00

200.0 Introduction

200.1 Use

Proposed revised label is attached.

200.2 Background Information

The submission, received 8-14-85, included the information requested in our letter of 8-14-85.

201.0 Data Summary (Not Accessioned)

The following data/information was submitted:

Daily Test Schedule

The attached test schedule indicates that the equipment (2 sets of anesthesia equipment) were subjected daily to 3 complete simulated-use treatments in a bucket containing 5 gallons of test solution. After the 3rd treatment each day, 60 carriers contaminated with P. aeruginosa, B. subtilis C. sporogenes, S. choleraesuis, or S. aureus were added on an alternating basis to a liter of solution from the bucket; the stressed solution was subsequently returned to the bucket. After 14 days of simulated-use, a liter of Solution A was stressed with 60 carriers contaminated with P. aeruginosa and a liter of Solution B was stressed with 60 carriers contaminated with S. choleraesuis and subsequently dispensed to conduct the microbiological assays.

Tuberculocidal Data

The final tuberculocidal data report after a 90-day incubation and the raw phenol resistance data derived for the 14-day reuse study are attached.

Chemical Analytical Procedure

The analytical procedure employed in determining the glutaraldehyde concentration of the reuse solution is attached.

201.2 Conclusions

The submitted data/information complete and clarify the reuse study report.

The TSS Efficacy Review of 7-17-85 concluded that the submitted data provided presumptive evidence to support the subject product for disinfecting and sterilizing for a 14-day reuse period in a manual system. However, the submitted daily test schedule shows that bioburden load was inadequate as indicated in the TSS Efficacy Review II. This deficiency was not apparent for the protocol description previously submitted. EPA did not review and approve this protocol before the study was initiated.

Based on the data submitted to the Agency for glutaraldehyde-based products, reuse solutions for 14 days or longer have been shown to be effective against vegetative bacteria, fungal conidia, and viruses in 10 minutes at 20°C, but not against M. tuberculosis. However, the submitted data indicate that the subject product is effective as a tuberculocide in 10 minutes at 20°C (by the AOAC Tuberculocidal Activity Test) for 14-days under the conditions of test. Tuberculocidal effectiveness for the 14-day reuse solution may not be evident in the presence of an adequate bioburden load.