TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 10-01-85 OUT 10-02-85

Dorothy M Portner 10/2/85

Reviewed By Dorothy M. Portner Date 10-02-85

EPA Reg. No. 46781-1 & 46781-2

EPA Petition or EUP No. None

Date Division Received 09-30-85

Type Product Disinfecting/Sterilizing Solution

Data Accession No(s).

Product Manager PM-31 (Lee)

Product Name Metricide MX-1400 & Metricide MX-2800

Company Name Metrex Research Corporation

Submission Purpose Review of the attached proposed reuse protocol

Type Formulation Liquid concentrate to be activated & used undiluted

Active Ingredient(s):	%
Glutaraldehye	2.0

Review of Reuse Protocol

The submitted protocol does not adequately address the following factors that should be considered in conducting a reuse study:

A. Test Equipment

The protocol should specify that the following equipment (representative of 2 complete anesthesia sets) for 5 gallons of activated solution will be employed in conducting 3 simulated-use cycles per day (involving a washing step with soap or detergent, followed by a water rinse, then a soaking step in the activated solution):

Corrugated rubber tubing, 4 sections each 3-4 feet long
2 rebreathing bags (2-3 liter)
2 endotracheal tubes
2 "Y" connectors
2 face masks

B. Organic Soil

Blood serum, in a concentration of 2%, may be added to the freshly activated solution in the bucket to simulate the realistic organic soil that would be innate in equipment, such as corrugated rubber tubing. The proposed use of 5% blood serum in testing the stressed solution by the AOAC Use Dilution Method is inappropriate because the subject product is intended to treat only clean items.

C. Bioburden Load

The protocol should indicate that 60 carriers contaminated with <u>each</u> of the above microorganism, one per day, will be added to 1 liter of use solution removed from the 5 gallon batch after the third cycle each day.

D. Test Design

The protocol should indicate that 2 simulated reuse studies will be conducted on the activated solution from 2 different product batches. Reuse solutions from both studies should be used to develop the basic bactericidal data employing 60 stainless steel carriers against <u>Staphylococcus aureus</u>, <u>Salmonella choleraesuis</u>, and <u>Pseudomonas aeruginosa</u>, respectively, by the AOAC Use Dilution Method, and the basic sporicidal data employing 60 porcelain penicylinder and 60 silk suture loop carriers against spores of both <u>Bacillus subtilis</u> and <u>Clostridium sporogenes</u> by the AOAC Sporicidal Test. A reuse solution from only one of the two studies will be required for developing the supplemental fungicidal, tuberculocidal, and virucidal data.

E. Reuse Period

The protocol indicates a 14-day study to support a 14-day reuse claim but a 30-day study to support a 28-day reuse claim. The additional 2 days of simulated reuse is not required to support a 28-day reuse claim. Acceptable data derived from a 30-day study will support a 30-day reuse claim.

F. Tuberculocidal Testing Policy

You should be aware of the recently formulated Agency policy with regard to acceptable tuberculocidal test methodology, as follows:

Pending completion of an EPA-initiated peer review process concerning the methodology, the Agency will permit registrants who have successfully relied on the existing AOAC method to also rely on the new quantitative tuberculocidal activity on a voluntary basis in those cases where use directions would be revised to be more stringent, and thus more protective. This policy applies to all tuberculocidal claims, including reuse claims.

Since adherence to the "existing AOAC method" limits exposure conditions to 10 minutes at 20°C, the effectiveness of the reuse solution as a tuberculocide under these conditions may be shorter than a 14 or 30 day period. Therefore, additional sampling and tuberculocidal testing during the simulated-reuse study may be desirable to determine the period of reuse for tuberculocidal effectiveness. The addition of bioburden to the liter of stress solution to constitute the final appropriate bioburden level for testing at different periods of reuse will vary, e.g. 90 carriers for 7 days reuse; 130 carriers for 10 days reuse; 270 carriers for 21 days reuse.

G. Additional Measurements

The protocol should also indicate that pH determinations will be done on the samples withdrawn for chemical analysis.