

5-21-85

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 46781-1

Data Division Received 05-21-85

Data Accession No(s). 258391 & 258392

Product Manager No. PM 31 (Lee)

Product Name Metricide MX-1400

Company Name Metrex Research Corporation

202.0 Recommendations

202.1 Insufficient Data/Information

The submitted data provide presumptive evidence to support efficacy of the subject product when activated and reused in a manual application system for disinfection and/or sterilization in accordance with label directions for a 14-day period.

However, for validation and acceptance of these data, the following additional data/information must be submitted:

1. The daily test schedule with the record of the date and time that each described activity (the 3 daily washing/disinfecting cycles, bioburden additions, etc.) was conducted in the simulated-reuse study is required to document the preparation of each reuse sample tested.
2. To support the tuberculocidal reuse claim, the test results after the specified 90 days incubation are required. The test results submitted for a shorter incubation period are unacceptable. Moreover, the raw phenol resistance data against Mycobacterium bovis BCG in the three test media are required to clarify and complete this data report.
3. The chemical analytical procedure employed in the determination of the glutaraldehyde concentration is required to clarify and complete the test report.