

Technical Support Section Efficacy Review-II

Disinfectants Branch

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

Data Division Received 08-14-85

Data Accession No(s).

Product Manager No. PM 31 (Lee)

Product Name Metricide MX-1400

Company Name Metrex Research Corporation

202.0 Recommendations

202.1 Lesser Efficacy Claims

The data/information submitted completes the data report and clarifies the reuse study.

The bioburden load used to stress the solutions in the reuse study, which was not clearly described in the previously submitted test protocol, was clarified in the daily test schedule, so that the minimal cumulative bioburden load for this study could be computed by the following equation, which is also indicated in the attached "Re-Use Test Protocol Specifications."

$$K = \frac{B_c}{(T_r)(V_t)}, \text{ where } K = \text{Constant approaching } 0.02$$

B = Bioburden (no. cont. carriers)
T = Time for reuse (days)
V = Volume (total ml)

The computed minimal cumulative bioburden in this reuse study is shown below:

$$K = \frac{780}{13 \times 18,925} + \frac{60}{14 \times 1,000} = 0.0032 + 0.0043 = 0.008$$

The computed K value of 0.008 is only 50% of the K constant. A total of 180 contaminated carriers rather than 60 is the minimal bioburden challenge for the liter of solution taken from the 5-gallon test solution in the bucket to conduct the microbiological assays after a 14-day reuse period. The cumulative bioburden equivalent to the K constant in this study is only for 7 days as shown below:

$$K = \frac{780}{6 \times 18,925} + \frac{60}{7 \times 1,000} = 0.007 + 0.009 = 0.016$$

Efficacy data accepted to support reuse claims must meet the EPA minimal specifications including an adequate cumulative bioburden load. Therefore, the submitted data will only support reuse claims for a 7-day period.

The submission of the proposed protocol for review and approval by the Agency is suggested before undertaking any simulated-use study under reuse conditions in the future.

202.2 Labeling

To reflect the supporting data, revise the reuse claim to read: "This solution may be reused for up to 7 days after activation for both disinfection and sterilization. Do not use the activated stock solution beyond 14 days."