

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 46781-R

Date Division Received 2-3-83

Data Accession No(s). Not Accessioned

Product Manager No. 31

Product Name Activated Dialdehyde Sterilizing and Disinfecting Solution

Company Name Metrex Research Corporation

INERT INGREDIENT INFORMATION IS NOT INCLUDED

202.0 Recommendations

202.1 Efficacy Claims Supported By Data

The submitted confirmatory data are acceptable in support of efficacy for the formulation without [REDACTED] when used according to the following patterns of use:

For a one day usage period in the treatment of precleaned items that have been thoroughly wetted with an activated, unused solution, aged as long as 14 days,

1. For sterilization in 10 hours at room temperature.
2. For disinfection in 10 minutes at room temperature.

In order for the confirmatory data developed on an alternate formulation with [REDACTED] to have relevance to this registration, a revised Confidential Statement of Formula that declares the existence or intent of an alternate formulation with [REDACTED] is required.

202.2 Confirmation Of Sporicidal Activity

As indicated in our letter of October 1, 1982, the sporicidal activity of this product must be confirmed in the EPA Microbiology Laboratory, within six (6) months after registration. Arrangements for testing a production batch of the product formulation (s) should be made by written request through the Branch Chief, Chemical and Biological Investigations Branch, Benefits and Field Studies Division, Building No. 402, ARC East (TS-768C), Beltsville, Maryland 20705.

202.3 Labeling

Label directions must be revised to meet up-graded labeling requirements relative to the supporting data.

1. The claim "Do not use this solution beyond 14 days after mixing" must be revised to read "The shelf-life of the activated unused stock solution is 14 days."
2. Instructions to discard the used solution after each day's usage must be included in the directions for use.