

PROTOTYPE FORMULATIONS

TECHNICAL SUPPORT SECTION EFFICACY REVIEW: INCOMPLETE APPLICATION

Disinfectants Branch

IN 07-21-87

OUT 09-21-87

EPA Reg. No. or File Symbol 46781-G

Product Name MetriCide Plus 14™

Company Name Metrex Research Corporation

Date Application Received 07-01-87

Submission Purpose New Application based on Metrex Research Corporation's
Prototype Formulation "MetriCide MX-1400", EPA Reg.No.
46781-1. Proposed product labels and data references
were provided.

Type Product Hospital Disinfectant/Stelilant

Product Manager 31(Lee)

Active Ingredients

8

Glutaraldehyde.....3.2

Recommendations:

The application is incomplete for the following reasons:

a. The subject product is not identical to the referenced product.

Additional Data Required to support efficacy

- a To support basic efficacy of the product as a hospital disinfectant/sterilant, fungicidal, virucidal, and tuberculocidal, data must be developed as indicated in the attached enclosures DIS/TSS-1, item (c), DIS/TSS-6, items (A) and (B), DIS/TSS-7 and DIS/TSS-9. Data must be developed on 14 days aged (shelf-life) activated stock solution.
- b. 14 day re-use (disinfecting and sterilizing) data must be developed in accordance with EPA approved re-use protocol. Refer to the attached Re-Use Test Protocol Specifications.

Labeling:

- a. Label review cannot be completed until the above efficacy data requirements have been met.

Srinivas Gowda

Reviewed By Srinivas Gowda

Date 09-21-87

*9-22-87
WEL*

1/1