

EFFICACY & SCIENCE SUPPORT BRANCH

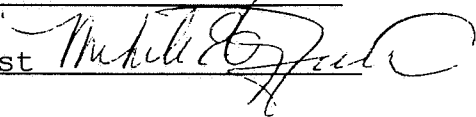
EFFICACY EVALUATION

ANTIMICROBIALS DIVISION

Date EPA Rec'd: 31 March 1998 Date EET Rec'd: 10 April 1998

Project Return Date: 27 Sept 1998 Review Start Date: 24 Sept 1998

Review Completion Date: 24 September 1998

Reviewed By: Michele E. Wingfield, Microbiologist 

LAN Code: 59839-1.998

EPA Reg. No. or File Symbol: 59839-1

EPA Petition or EUP No.: None

Product Name: Premicide

Company Name: OBF Industries

Product Type: Medical Waste Solidifier/Encapsulant

Product Formulation: Liquid to be added to suction canisters

Product Manager & Team No.: Marshall Swindell PM-33 (K. Munk)

MRID No(s): 439666-01 - 02

Submission Purpose: Amendment to increase level of activity from sanitizer to disinfectant.

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Glutaraldehyde	9.61%

RECOMMENDATION:

The submitted efficacy data are unacceptable to support the proposed label claim as a disinfectant of medical waste. The Agency's present policy is to only accept a sanitization level of activity for medical waste treatment products. EPA defines sanitization as a level of antimicrobial activity achieving at least a 99.9% reduction of the microbial population. Disinfectant and sterilization claims imply a complete kill of vegetative pathogens and microorganisms, respectively. The demonstrated 99.999% reduction in microorganisms does not meet EPA's standard as a disinfectant.