## TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I Disinfectants Branch

IN 05-21-86 OUT 06-23-86
Reviewed By Dorothy M. Portner Date 06-23-86  EPA Reg. No. 46781-1
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EPA Reg. No. 46781-1
EPA Petition or EUP No. None
Date Division Received 05-21-86
Type Product Sterilizing/Disinfecting Solution
Data Accession No(s). Unaccessioned
Product Manager PM-31
Product Name Metricde Activated Dialdehyde Solution
Company Name Metrex Research Corporation
Submission Purpose Additional virucidal data on a 31-day reus
solution against Coxsackievirus B 5a
Type Formulation Liquid concentrate to be used undiluted
Active Ingredient(s):
Clutaraldehyde

## 200.0 Introduction

## 200.1 Background Information

The submission, received 5-21-86 included the attached data report, dated 5-9-86, to show that Coxsackievirus B 5a is inactivated by a 14-day stressed reuse solution.

The original submitted virucidal data reviewed in TSS Review of 3-17-86 for the 14-day stressed reuse solution (batch 240851) showed a 3.5 log Coxsackievirus B 5a titer at a 2-minute contact time and no cytotoxicity.

The submitted data, developed on a 14-day stressed reuse solution (batch 244851), indicate a  $\geq$  4.0 log viral reduction and a 3.5 log cytotoxicity titer, but no detectable Coxsackievirus, at a 4-minute contact time.

Therefore, the submitted virucidal data demonstrate a satisfactory performance for acceptance of the proposed label claim for virucidal activity in 10 minutes against Coxsackievirus B 5. However, to complete the file record, procedural documental evidence for the additional reuse study on the batch 244851 sample should be provided by submission of the schedule of bioburden tasks.