

7-28-83

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 6-27-83 OUT 7-26-83

Reviewed By Dorothy M. Portner *DD 7/25/83* Date 7-26-83

EPA Reg. No. or File Symbol 46781-1

EPA Petition or EUP No. _____

Date Division Received 6-14-83

Type Product Sterilizing/Disinfecting Solution

Data Accession No(s). _____

Product Manager 31

Product Name Activated Dialdehyde Sterilizing and Disinfecting Solution

Company Name Metrex Research Corporation

Submission Purpose To comment on the relevancy of the submitted revised Confidential Statement of Formula to fulfill the documentation request indicated in the TSS Efficacy Review of 2-7-83 and our letter of 2-25-83.

Type Formulation Liquid concentrate to be activated and used undiluted

<u>Active Ingredient(s):</u>	<u>%</u>
<u>Glutaraldehyde</u>	<u>2.0</u>

When the TSS Chemist accepts a revised Confidential Statement of Formula for the alternate formulation with [REDACTED] the requested documentation, indicated in our letter of 2-25-83, will be fulfilled.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Disinfectants Branch

PA Reg. No. or File Symbol 46781-1
 ace Division Received 6-14-83
 roducts Manager No. 31 (Lee)
 roduct Name Activated Dialdehyde
 ompany Name Metrex Research Corporation

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Comments:

- a. The product name must be the same in the Confidential Formula and in the label.
- b. Submit chemical composition of [REDACTED] Tell us how much of [REDACTED] is added to this formulation.
- c. Please note that the total weight of batch in your revised Confidential Formula is [REDACTED] pounds not [REDACTED] pounds as you state.
- d. Submit revised Confidential Formula with correct total weight of batch and correct percent by weight in column 19.
- e. The words "Inert Ingredient" in the ingredient statement must be in plural "Inert Ingredients."
- f. In the activator label the ingredients as listed are not equal 24.4 grams.
 If you wish to list ingredients in the activator label then you must list all ingredients present in powder activator.
 The amounts of [REDACTED] as given in the label do not agree with the Confidential Formula. Please clarify this discrepancy.
 Also clarify whether you use [REDACTED]

- g. The alternate formulation for the liquid solution, one without [REDACTED] and one with [REDACTED] and [REDACTED] is acceptable.

8/2/83
 A-S.

7-8-83

Anna Skopas AS 7/25/83

INERT INGREDIENT INFORMATION IS NOT INCLUDED