

3-25-93

REG. NO: 57978-U  
FILE SYMBOL: \_\_\_\_\_

PRODUCT CHEMISTRY REVIEW FOR END USE PRODUCTS

TO: PM 31 (Lee) PRODUCT NAMES: \_\_\_\_\_

FROM: Anna Skapars

THRU: Harold Podall, Section Head

CHEMICAL: Seftocide A 50% Solution

MRID NOS: ~~419800-1~~, ~~419800-2~~, ~~419800-3~~

Food Use \_\_\_\_\_ Non Food Use

Inerts cleared: c ( ) d ( ) e ( ) yes ( ) no ( )

Inerts List 1 ( ) Other ( )

Please provide the requested information for the following checked items:

1.  Submit the product specific product chemistry data for your product. { } If submitted earlier, provide MRID Number(s). { } Your product is not sufficiently similar to the product your referenced.
2. In reference to the Confidential Statement of Formula (CSF), please provide the following:
  - a. pH of product at a specified water dilution.
  - b. Density of product.
  - c. Flash point of product.
  - d. Flash point of product with propellant as per item #6(q) or item #5(c).
  - e. Flash extension of product including flashbacks if noted.

*PM Review  
10-24-94  
① TIAF  
Previously addressed  
concern (-9).  
② label comment  
with 2 addresses  
later  
③ FDA statement  
not necessary since  
label already  
restriction statement.*

Guideline Reference  
No. (40 CFR 158.155, 160, 162, 165 + 167)

Series 61

- 61-1 Product Identity and Disclosure of ingredients  
MRID No. 419800-1  
Confidential Statement of Fo
- 61-2 Description of starting materials and manufacturing process.  
MRID No. 419800-1
- 61-3 Discussion of Formation of Impurities  
MRID No. 419800-1

Series 62

- 62-1 Preliminary analysis  
MRID No. 419800-2
- 62-2 Certification of ingredient limits  
MRID No. 419800-2
- 62-3 Analytical methods to verify certified limits.  
MRID No. 419800-2  
(Method is being developed)

Series 63

- 63-2 Color.  
very pale to pale yellow
- 63-4 Odor  
Mild odor of aromatic compounds
- 63-3 Physical state  
liquid.
- 63-5 Melting point  
NOT given
- 63-6 Boiling point  
not given
- 63-7 Density, Bulk density  
Specific gravity  
1.28 at 25°C.
- 63-8 Solubility  
not given.
- 63-9 Vapor pressure  
not given
- 63-10 Dissociation constant  
not given

Series 63 (cont)

- 63 - 11 Octanol/water partition coefficient not given
- 63 - 12 pH 11 - 12
- 63 - 13 Stability not given
- 63 - 14 Oxidizing or reducing action - minimal reducing agent
- 63 - 15 Flammability - does not contain combustible liquids
- 63 - 16 Explodability - not potentially explosive
- 63 - 17 Storage stability - in development - will be submi.
- 63 - 18 Viscosity - 21 centipoises at 23°C
- 63 - 19 Miscibility - not emulsifiable liquid
- 63 - 20 Corrosion characteristics - minimally corrosive to steel will repair with 1 yr storage stability
- 63 - 21 Dielectric breakdown - not to be used around electrical equipment.

The following physical and chemical characteristics data series 63 have not been provided and it shall be provided:

Guidelines ref. No. 63-6 - boiling point must be provided, Guidelines Ref. No. 63-9 - vapor pressure not provided it must be provided, Guidelines Ref. No. 63-10 - dissociation constant not provided it should be provided, Guidelines Ref. No. 63-11 Octanol/water partition coefficient not provided should be provided, Guidelines Ref. No. 63-17 - storage and stability not provided must be provided.

## Conclusions and Recommendations

The product chemistry data requirements for this 50% product have not been completely satisfied. The following physical and chemical characteristics data is required to be submitted

TGAI 63-6	Boiling point
TGAI 63-9	Vapor pressure
TGAI 63-10	Dissociation constant
PGAI 63-11	Octanol/water partition coefficient
EP 63-17	Storage stability data

### 1. Proposal Labeling

The preferred declaration of the active ingredient in the ingredient statement should be:  
"Sodium hydroxymethylaminoacetate"

The net contents must be declared on the label or on the container.

### 2. Product Identity and Composition.

Submit revised legible Confidential Statement of Formula including legible certified limits, date and signature.

Product chemistry data under MRID No's 419800-1, 419800-2 and 419800-3 includes complete manufacturing process and analytical methods used. Development of direct analytical method is in progress.

This formulation is not cleared by FDA for use to manufacture paper + paperboard products that may contact food.

Anna Skajars  
3-25-93  
H.S. 63-2582

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