

US EPA ARCHIVE DOCUMENT

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
 A MANUFACTURING-USE [] OR AN END-USE PRODUCT [✓]
 DP Barcode D230843 Reg. No. or File Symbol No. 70087-R

TO: (PM Team Reviewer)
 PM Team No. 31 *Marion Johnson / Karen Leary*

FROM: (Chemist/Date) *Anna Skapars 10-29-96*
 Product Chemistry Review Section
 Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head *Harold Podall*
 Registration Support Branch/RD (WH7505W) *10/30*

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of new ready to use product using unregistered source of active ingredient.

- A. For unregistered source of active ingredient all product chemistry data required in 40 CFR part 158.153 - 158.190 must be submitted.
- B. For manufacturing process submit detailed narrative description of manufacturing process including chemical names of all starting materials.
- C. Submit correct Confidential Statement of Formula and for each component enter correct purpose in formulation and list all impurities that may be present.
 Please note that current Confidential Statement of Formula dated 6-11-96 does not agree with the proposed label.
 Based on the label this product is an aerosol, however there is no propellant in Confidential Statement of Formula.
- D. The correct chemical name in the ingredient statement in the label for active ingredient should be:
 "3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride."

WH705W:RD:ESB:PCRS:CS-1:Rmxxx:Reviewer:Typist Initials:xx/xx/96:703-308-xxxx Code No. (Reg or Rereg No.)

(see page 2)

The ingredient statement in the label should declare the name and percentage of each active ingredient and the total percentage of all inert ingredients.

Active Ingredient

3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride — %

Inert Ingredients — %

Contains Methanol

- E. For the claim "ZODONOCIDE has a shelf life of 1 year" submit one year storage and stability data. For one year shelf life in the label registrant should give an expiration date one year from the date of manufacture.
- F. This product is not substantially similar to product EPA Reg. No. 34292-1.

Note to PM:

Please note all proposed uses for this product. Among other uses there are: premoistened towelettes, napkins, diapers, humidifiers, air conditioners, air filters. There may be needed additional data for all those uses.

Anna Skogas
10-29-96