

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: April 17, 1978

SUBJECT: Quat. No. 7 EPA Reg.#6125-GN Caswell#331A (Didecyl dimethyl Ammonium Chloride)

FROM: William Dykstra, Ph.D Toxicology Branch *W.D. 4/17/78*

TO: James Banks Product Manager #33

Registrant: Bixon Chemical Company  
50-19-97th Place  
Corona, N.Y. 11368

Action Type: Resubmission

Recommendations:

1. The toxicology data submitted in support of the registration are not adequate to evaluate the human hazards associated with exposure from the use patterns of this particular formulation. The following toxicology studies on this particular formulation are required to assess the label statements and human hazards of the product.
  - a. Eye irritation - rabbits
  - b. Primary skin irritation - rabbits
  - c. Dermal LD<sub>50</sub> - rabbits
  - d. Skin sensitization - quinea pigs
  - e. Subacute Dermal (21 day) Toxicity Study - Rabbits: Dose levels tested should include use dilution and 5X use dilution (exposure during mixing)
2. The Acute Oral LD<sub>50</sub> of the formulated product can be estimated from comparison with Lonz Disinfectant Cleaner to be in Toxicity Category III: CAUTION
3. A teratogenic evaluation of the active ingredient, tetrasodium ethylenediamine tetraacetate is required. Ethylenediamine tetraacetate (EDTA), as the diethanolamine salt, has been accepted as an RPAR candidate on the basis of teratogenicity (and further testing is needed).
4. Label assessment will be made following evaluation of the Toxicology profile of the formulation and active ingredients.

Formulation:

<u>Chemical Active</u>	<u>Percent Weight</u>
[REDACTED]	8.5
Tetrasodium ethylenediamine tetraacetate	4.0

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Uses: Disinfectant - Cleaner for use on walls, floors and other hard surfaces such as tables, chairs and bed frames in hospitals, schools and industry.

Use dilution: Add 2 ounces per gallon of water (1:64)

Precleaning Instructions: For heavily soiled areas, a preliminary cleaning may be required.

Method Application: With a cloth or mop

Contact time for disinfection: Not specified

Application Frequency: Not specified but assumed to be used daily.

Review:

Toxicology Data Submitted in support of the registration.

1. Method of Support (2.b.) for products based on Lonza Disinfectant Cleaner 30-3.
  - a. 20 day Subacute Dermal toxicity tests, #D-6259 dated 4-13-71.
  - b. Report on eye irritation testing, #D-5093 dated 11-27-70.
  - c. Dermal LD<sub>50</sub> dated 3-8-77, submitted 3-28-77.
  - d. Report on Primary Skin Irritation, #D-5094 dated 11-27-70.
  3. Report on Oral LD<sub>50</sub> tests, #D5092 dated 11-25-70.
  
2. The following are found in EPA Reg. File [REDACTED]
  - a. Teratologic Evaluation of Three (3) Quaternary Compounds, Lab#5155 submitted March 28, 1977.
  - b. Toxicology Summary of [REDACTED] Intravenous LD<sub>50</sub>  
  
Oral LD<sub>50</sub>  
Dermal LD<sub>50</sub>  
Primary Skin Irritation  
Eye Irritation  
Subacute Dermal
  - c. Acute Dermal Toxicity, #C-9919 dated 7/23/68.
  - d. 20 day Subacute Dermal testing, #C-9920 dated 8/6/68 and 8/28/68.
  - e. eye irritation testing, #E899 dated 2/15/72.
  
3. Tetrasodium ethylenediamine tetraacetate (40% active) - Submitted 9/30/76.
  - a. Toxicity Data  
  
Acute Oral LD<sub>50</sub>  
Acute Dermal LD<sub>50</sub>  
Primary Skin Irritation  
Eye Irritation

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

4. Sodium Carbonate - Submitted 9/30/76

a. Toxicity Data

Acute Oral LD<sub>50</sub>  
Primary Skin Irritation  
Eye Irritation

5. Sodium Metasilicate, Anhydrous - Submitted 9/30/76

a. Toxicity Data

Acute Oral LD<sub>50</sub>  
Primary Skin Irritation

Typists: TH

RD initial G.E.W. 4/17/78

*For GEW. 4/18/78*