April 17, 1978

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

William Dykstra, Ph.D
Toxicology Branch

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 LD50 - 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 LD50 of the formulated product can be estimated from comparison with Lohnza Disinfectant Cleaner to be in Toxicity Category III: CAUTION

3. A teratogenic evaluation of the active ingredient, tetrassium 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:

Chemical Active Percent Weight

[Redacted]
Tetrasodium ethylenediamine tetraacetate 8.5
  4.0
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.
   c. Dermal LD50 dated 3-8-77, submitted 3-28-77.

2. The following are found in EPA Reg. File
   b. Toxicology Summary of Oral LD50
      Dermal LD50
      Primary Skin Irritation
      Eye Irritation
      Subacute Dermal
      Intravenous LD50

3. 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 LD50
      Acute Dermal LD50
      Primary Skin Irritation
      Eye Irritation
4. Sodium Carbonate - Submitted 9/30/76
   a. Toxicity Data
      
      Acute Oral LD₅₀
      Primary Skin Irritation
      Eye Irritation

5. Sodium Metasilicate, Anhydrous - Submitted 9/30/76
   a. Toxicity Data
      
      Acute Oral LD₅₀
      Primary Skin Irritation

Typists: TH
RD initial G.E.W. 4/17/78

G.E.W. 4/18/78