UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: July 28, 1978

SUBJECT: Registration No. 675-UL, New Product Registration

FROM: John Doherty
Toxicology Branch, HED (TS-769)

TO:
J. Tavano, (PM #31)
Registration Division (TS-767)

Registrant: National Laboratories
Lehn and Fink Industrial
Products Division of Sterling Drug
225 Summit Ave.
Montrale, New Jersey 07645

Product: Quat-Syl 256

Active Ingredients:

Alkyl (C_{14} 50%, C_{12} 40%, C_{16} 10%) dimethyl benzyl ammonium chloride	11.0%
Didecyl dimethyl ammonium chloride	1.2%
Ethyl alcohol	1.2%
Tetrasodium ethylenediamine tetraacetate	1.8%
Isopropy alcohol	0.5%
Inerts	84.3%
	100%

Caswell No's 16, 331A, 430, 846 and 507 or 509

Recommendations:

1. The product in corrosive to both the eyes and skin. Therefore it cannot be approved for general use.

2. The label should contain the word CORROSIVE near the signal word on the front panel (not required by law, but recommeded).

3. This product will be used on food handling, preparative and storage equipment. Therefore the following studies should be referenced or submitted.

    1) teratogenesis
    2) reproduction
    3) oncogenesis

1 2

4. Because this product will be used frequently by cleaning personnel, the following studies should also be referenced or submitted.

    1) dermal sensitization
    2) subacute dermal

5. The above studies need not necessarily be with the product as formulated, but with the components to assure that their toxicological hazard can be evaluated.

Review of Toxicological Data Submitted

Oral LD_{50} in rats, Draize eye irritation study in rabbits, and acute dermal LD_{50} in rabbits.

Cannon Laboratories, Reading, PA, 19605, dated October 9, 1975 and studies No. 5E-8623, 5E-8624 and 5E-8625.

A. Rat Oral LD_{50}

25 M and 25 F albino rats weighing between 200 and 300 gms were fasted for 24 hours prior to being dosed by gavage with test material (Concentrated Disinfectant #J1931-3). Five groups of 5M and 5F were dosed with either 1,050, 2,100, 3,150, 4,200, or 5,250 mg/kg in a single administration. The rats were observed for signs of toxicity and mortality at 1, 3, 6, 24, 48, 72 hours and daily thereafter for a total of 14 days. All animals were autopsied and observed for gross pathological organ changes.

Results:

The animals showed signs of decreased locomotor activity, ptosis, piloerection, ataxia, respiratory depression, loss of righting reflex, straub tail, diarrhea and in same cases death.

The autopsies revealed no outstanding gross pathological organ changes.

The LD_{50} of 2,100 $\pm$ 307 mg/kg was determined. The rats died within 72 hours after administration of test material.

This test is CORE MINIMUM. The product is a category III toxicant by this method of administration.

B. Draize eye irritation study in rabbits

6 New Zealand rabbits were instilled with 0.1 ml of test material (Concentrated Disinfectant #J1931-3) in the left eye and the untreated eye served as control. The eyes of three of the rabbits were washed 4 seconds after instillation. The other rabbits were not washed.

Severe eye irritation was noted after 24 hours in all animals (washed or unwashed). After 7 days the Draize scores were 77/110, 92/110, 92/110, 92/110, 92/110, 92/110 and 92/110. Indicating that the product is corrosive to the eyes. This test is CORE MINIMUM. The product is a category I toxicant.

C. Acute dermal LD_{50} on rabbits

12 New Zealand albino rabbits, 4 per group were prepared by clipping and further abrading their backs. Doses of 2.0, 6.0 and 9.2 gm/kg of test material (Concentrated Disinfectant #J-1931-3) were applied and kept in place for 24 hours.

Two of the rabbits died at the highest dose, none of the rabbits died at the lower doses. The LD_{50} was calculated to be 9.2 to 2.3 mg/kg. The rabbits developed erythema, edema and eschar at the area of contact.

This test in CORE MINIMUM. The product is a category III toxicant by this route of administration.

D. Primary skin irritation, rabbit

Consumer Product Testing, Fairfield, New Jersey, #76153, October 15, 1976.

1. With concentrated product

Six rabbits, 3M and 3F, were prepared by shaving and further abrading the skin of their backs. 0.5 ml of the concentrated product (J-1931-3) were applied and held in place for 24 hours. Observations were made at 72 hours.

The primary irritation index was 7.12. This test is CORE MINIMUM. The product is corrosive to skin.

2. J-1931-3 was diluted 1:256 v/v with water (the use dilution) and six freshly prepared rabbits were tested as described above.

   The primary irritation index was 0.3. This test is CORE MINIMUM.

E. Acute oral toxicity (Supplement report from Cannon Laboratories)

Consumer Product Testing, Fairfield, New Jersey, #76153, October 14, 1976.

A single dose of 3 g/kg of the concentrated product (J-1931-3) was given to a single group of 5M and 5F rats. 70% of these rats (4M and 3F) died. Thus the LD_{50} was reported as < 3.0 gm/kg. This is in agreement with the result of Cannon Labs. This test is CORE SUPPLEMENTARY.

R/D Init: REngler 7/27/78
JD/ccw

E 8/7/78