UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: September 5, 1978

SUBJECT: Lonza Disinfectant Cleaner 30-3 EPA Registration#6836-22
Caswell#331A

FROM: William Dykstra, Ph.D
Toxicology Branch/HED WJD 9/5/78

TO: James Banks
Product Manager#33

Registrant: Lonza, Inc.
22-10 Route 208
Fairlawn, N.J. 07410

Action Type: Completeness Review for Toxicology DATA

Recommendations:

1. The acute dermal LD_{50} is acceptable as core minimum data. A dermal skin sensitization toxicity study of the formulated product is required. This toxicology study is referred to in a memo of 6/21/78 from W. Dykstra to Mr. Banks.

Product Name: Lonza Disinfectant Cleaner (30-3)

Cleaner-Disinfectant-Deodorizer-Fungicide-Virucide for Hospital and Institutional Use.

Ingredient	Percent Weight
Didecyldimethyl ammonium chloride	4.25
tetrasodium ethylenediamine tetraacetate	1.60
sodium carbonate	2.00
sodium metasilicate, anhydrous	.50
Inerts	91.65
	100.00

Review:

1. Dermal LD_{50} (Leberco Laboratories Assay No. 73133, Sept. 15, 1977)

Test Material: Disinfectant Cleaner 30-3

One group of 4M and 4F rabbits, 2.0-3.1 kg BW, had 10% of their hair from their hair removed from their backs with an electric clipper. One half of the animals of each sex were further abraded. 5 ml/kg of test material was applied dermally under an impervious cuff for 24 hours. Observation for 14 days.

Results: one intact male and one abraded male rabbit died out of 8 rabbits; $LD_{50} > 5.0$ ml/kg

Toxic Signs: erythema

Body Weight: Survivors gained weight

Necropsy: No observable gross changes

Classification: Core-Minimum Data

TOX Category III: CAUTION

Hazard Assessment from Label Use Patterns:

At the use dilution of the formulated product, derma exposure to the hands of the user is expected on a daily basis. Since the active ingredients are salts, penetration through the skin resulting in systemic toxicity is unlikely. Therefore, a subacute dermal toxicity evaluation or a teratologic evaluation are not considered necessary. At the use level of two ounces of formulated product per gallon of water, there is a possibility of dermal sensitization from exposure. Therefore, a dermal sensitization evaluation is required. In my memo of 6/21/78, Mr. Gottlieb of Lonza Chemicals stated that a dermal sensitization study would be provided in connection with another registration, which has the identical composition to the formulated product.

TOX/HED:th:Reto Engler:9/1/78

E 8/5/78