DATE: September 5, 1978

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

FROM: William Dykstra, Ph.D
       Toxicology Branch/HED

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 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.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Percent Weight</th>
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<tbody>
<tr>
<td>Didecyldimethyl ammonium chloride</td>
<td>4.25</td>
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<tr>
<td>tetrasodium ethylenediamine tetraacetate</td>
<td>1.60</td>
</tr>
<tr>
<td>sodium carbonate</td>
<td>2.00</td>
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<tr>
<td>sodium metasilicate, anhydrous</td>
<td>.50</td>
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<tr>
<td>Inerts</td>
<td>91.65</td>
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<td></td>
<td>100.00</td>
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</tbody>
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Review:
1. Dermal LD$_{50}$ (Leberco Laboratories Assay No. 73133, Sept. 15, 1977)

Test Material: Disinfectant Cleaner 30-3
One group of 4% and 4F rabbits, 2.0-3.1 kg each, 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, dermal 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.