

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Lonza Disinfectant Cleaner (19-a)  
EPA Reg. No. 6836-28  
CASwell # 331D, 846, 752, 779A  
SHAOSHEW # 06419, 039107, 073506, 072604  
FROM: Toxicology Branch  
Registration Division

DATE: 7/2/77

TO: Mr. Joseph Tavano  
Product Manager #31

Recommendation: 1) acute dermal LD<sub>50</sub> is inadequate.  
2) human patch test requires clarification of protocol

Review:

- 1) Acute Dermal LD<sub>50</sub>-(Leberco Laboratories, Report #73134, 3/8/77)  
4 female rabbits had their hair removed from 10% of their bodies. The material was applied at 5 ml/kg-the highest dose that could be applied. After a 24 hr. contact period the material was washed off the animals backs and the animals kept for an observation period of 14 days. No animal died during the 14-day observation period. Body weights were slightly depressed.

Deficiencies:

- (1) Skin was not abraded--the question whether the hazard would possibly increase when handled by humans with broken skin has not been answered.
- (2) Males were not tested--the question whether a significant sex difference exists, with respect to toxicity, has not been answered.
- (3) Toxic signs not reported--the question as to how animals respond to an exposure has not been answered (i.e. will an exposure produce convulsions, skin damage, etc.).

Classification: Supplementary Data

- 1) The core-minimum data requirement of 4 animals/sex per each of 3 dosage levels with half of the animals with intact and half with abraded skin was not met.
- (2) Human Skin Patch Test--(Wells Laboratory, Report #D-9366, 10/26)  
0.5 ml of a 1:64 dilution of the formulation was deposited on 1 skin of the forearm of 10 human subjects. Results were scored at 24, 48 and 72 hours. The forearm was rewet as necessary.

No response, either erythema or edema was noted at 24, 48 and 72 hours.

The study cannot be evaluated until the following points have been clarified:

- 1) Of what race were the human subjects, i.e., oriental, etc.?
- 2) Were the test sites occluded?
- 3) Of what purpose did rewetting the forearm serve at what times and how often were the forearms rewet?

*William Greear*  
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*E for OEP 8/9/77*