

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Lomox Disinfectant Cleaner 30-3
EPA Reg. No. 6836-22
FROM: Toxicology Branch / Registration Division

DATE: 6/29/77

TO: Mr. Elmer Beathens
Product Manager #32

Recommendation: The study, when considered alone, is unacceptable for the deficiencies stated below (1), (2), (3). The study is considered to be "supplementary data."

Review:

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 were 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.)

The study* has failed to answer very pertinent questions for which the study was designed; therefore, the submitted study can not be accepted.

William Greer

* Study must be classified as supplementary data because:

- (i) the Core-Minimum Data requirement of 4 animals/sex per each of 3 dose levels with half of the animals with intact and half with abraded skin was not met.

Didecyl dimethyl ammonium chloride

Page 3 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☐ Description of the product manufacturing process
 - ☐ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☒ A draft product label
 - ☐ The product confidential statement of formula
 - ☐ Information about a pending registration action
 - ☐ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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