TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07/13/84 OUT 8/16/84

Reviewed by James E. Wilson, Jr. Date 08/10/84

EPA Reg. No. or File Symbol 21164-L, A

EPA Petition or EUP No.

Date Division Received 06/26/84

Type Product(s): I,(D,) H, F, N, R, S

Data Accession No(s) 253741

Product Mgr. No. 32 (Castillo)

Product Name(s) Akta Klor 80, 25

Company Name (s) Rio Linda Chemical Company, Inc

Submission Purpose New Application

Chemical & Formulation Powder

Active Ingredient(s)	%
Sodium chlorite	80.0

1/3

BACKGROUND

The product is a reformulating use only chemical.

RECOMMENDATIONS

The letter dated May 17, 1984, under item 3 states that all toxicological testing was done using the 80% formulation. However, the acute oral study identifies the test sample as a 25% solution. Please have the registrant to clarify the test material used.

The product should be placed in following toxicity categories based on the data submitted.

Acute Dermal - 3*
Skin Irritation - 1
Eye Irritation - 1*

*Studies were not done; waiver requested based on the severe irritation produced in the skin study.

All of the rats tested orally at 5.0 g/kg died. Therefore, the study must be repeated to establish the oral toxicity of the chemical.

LABEL

Revise statements "Cause eye damage" to read "Causes eye and skin damage". The statement "May cause burns to broken skin" is misleading since the product will burn the unbroken skin. Revise the Statement of Practical Treatment to read as follows:

If in eyes:	Flush with plenty of water Get medical attention.
If on skin:	Wash with plenty of soap and water. Get medical attention.
If swallowed:	Drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.
NOTE TO PHYSICIAN:	Probable micosal damage may constraindicate the use of gastaraic lavage.

DATA REVIEW

Reports by Northview Pacific Laboratories, Inc. submitted to Rio Linda Chemical Company, Inc., Rio Linda, CA 95673, dated April 16, 1984. (Accession No. 253741).

Acute Oral

Method - Five male and five female rats were dosed with 5.0 g/kg with the test material. Two untreated controls were used in the study. Body weights were taken on day 0, 7 and 14. Gross necropsy examinations were performed on all rats.

Results - All test animals died within one hour after dosing. Lethargy, paleness and severe diarrhea were the signs observed. Gross necropsy examinations revealed brown lungs and dark spleens, kidneys and livers. The vessels of the stomach appeared emptied of blood.

Conclusion - The oral LD_{50} is less than 5.0 g/kg to rats.

Skin Irritation

Method - One intact site on each of 6 rabbits was was chosen to receive 0.5 ml of the test material. The material remained in contact for 4 hours. Irritation was assessed 5, 24, 48 and 72 hours and 7 and 14 days after application.

Results - After 24 hours erythema was moderate to severe at 5/6 sites, mild edema was noted at 2/8 sites. Reactions for erythema had decreased slightly after 72 hours while edema increased from mild to moderate at one site. Eschar formations were noted after 7 days.

Conclusion - The product is corrosive to skin of rabbits.

A primary skin irritation study was done using the 80% powder. The same method as described above was used. The irritation produced by the 80% formulation exceeded that of the 25% solution.