

8-4-87

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

Reviewed by IN *James E. Wilson, Jr.* OUT 08/04/87
Date 04/09/87
EPA Reg. No. or File Symbol 777-AO
EPA Petition or EUP No. NONE
Date Division Received _____
Type Product(s): I, (D), H, F, N, R, S
Data Accession No(s) _____
Product Mgr. No. 31 (LEE)
Product Name(s) Extra Care Laundry Detergent
Company Name (s) Lehn & Fink Products Group
Submission Purpose New Application
Chemical & Formulation Liquid

Active Ingredient (s):

8

n-Alkyl(50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl
benzyl ammonium chloride..... 6.4

DLG/TS
02/9/05

SUMMARY

Acute toxicity studies were submitted by Lehn & Fink to support the safety of its product Lysol Brand Extra Care Laundry Detergent (EPA File Symbol 777-AO). Subsequent to the submission the company requested a meeting to discuss the cursory review of the eye irritation data. During that meeting the representatives from EPA/OPP/DB informed the registrants that based on a quick review of the data the product would be placed in toxicity category 1 for eye irritation. The complete review of that study is attached and the original finding is supported by the data. Corneal opacity persisted in two of six eyes through the 21 day observation period. A positive response to this test is an adverse reaction in 2/6 eyes or 1/3 of the test subjects which persists for 21 days. 40 CFR 162.10 (h)(1) contains a Hazard Indicator table which states in part that products which cause irreversible corneal opacity must be placed in toxicity category 1. Some of the requirements for this category are the signal word "Danger" and instructions to wear eye protection when handling.

Corneal opacity was found in two eyes after 21 days. Blistering was found in the rinsed group as well as the non-rinsed group and vascularization was observed in the two eyes which displayed opacity after 21 days. Based on the above facts this product should be placed in toxicity category 1 for eye irritation.

The comparison data was not reviewed.

BACKGROUND

Lehn & Fink submitted an application for registration for a laundry detergent and sanitizer earlier this year. At the company's request a cursory review of the eye irritation study was made. The company requested a meeting with the Agency to discuss the data and the "eyeball" review. This reviewer, after a quick review of the eye irritation study, concluded that the product should be placed in toxicity category 1 for eye irritation since corneal opacity (grade 1 and 2) existed in two eyes after 21 days. The animals were observed for a total of 25 days; no improvement in the condition was noted in the final days of observation. All other signs in all eyes cleared by day 16 except one eye which had mild erythema on day 21.

Comparison eye irritation data developed on other leading brand of liquid laundry detergents were submitted in July but not reviewed.

DATA REVIEW

Eye Irritation

Report by Hill Top Research, Inc., submitted to Lehn & Fink Products Group, Montvale, NJ 07645, dated October 21, 1986.

Method: Nine rabbits received 0.1 ml of the undiluted test material placed directly on the cornea. The lids were not held together. Three of the eyes were rinsed 30 seconds after instillation for 60 seconds with luke warm tap water. Examinations of the eyes were made 1,2,3,4,7,10,13,16,19, 23 and 25 days after application. A 2% solution of sodium fluorescein was also used as an aid in detecting corneal damage.

Results: Grade 1 corneal opacity developed in all non-rinsed eyes within 24 hours; this condition was visible in 5/6 without the use of staining. The condition was clear in 2/6 in 48 hours, 2/6 in 7 days and 13 days (one each) and two did not clear. The grades in the two which did not clear were 1 and 2 both with vascularization. It should also be noted that the two eyes that cleared on days 7 and 13 developed grade 2 opacity and vascularization

was observed in the eye which was cleared in day 13. Iritis was found in all 6 non-rinsed eyes after 1 hour, three were clear in 48 hours and all cleared in 13 days. Moderate to severe conjunctival irritation was found in all non-rinsed eyes after one hour. Blistering was noted in all eyes and a red discharge was seen in 2/6 and persists for no more than two days. The irritation seen was much improved or absent by day 10 and completely clear except for mild erythema and swelling in one eye by day 19. In the rinsed group corneal opacity was found in one eye with stain, one without stain; clearing was accomplished in 24 and 48 hours respectively. Iritis was seen after 1 hour and cleared in 48 hours. Mild to severe conjunctival irritation was seen in all eyes with blistering and cleared in 7 days.

Conclusion - The product produces moderate to severe ocular irritation which is not completely reversible in 21 days.