

US EPA ARCHIVE DOCUMENT

4-14-86

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN	04/01/86	OUT	04/11/86
Reviewed by	<u>James E. Wilson, Jr.</u>	Date	04/11/86
EPA Reg. No. or File Symbol	5813-21		
EPA Petition or EUP No.	NONE		
Date Division Received	Internal Memorandum		
Type Product(s):	I, (D), H, F, N, R, S		
Data Accession No(s)	None		
Product Mgr. No.	32 (Kempter)		
Product Name(s)	Tackle Cleaner		
Company Name (s)	Cloxox Company		
Submission Purpose	Requesting comments on memorandum		
Chemical & Formulation	Liquid		

The memo from Frank Davido, HED/EAB, suggests a modification in the subject label as a result of a person using the product with surgical gloves and experiencing burns and other medical discomforts.

Surgical gloves are made of thin latex which permits a surgeon the "feel" necessary to perform his or her duties. These gloves are not routinely available to the average household. Generally, the gloves available to the public are made of a much heavier latex which can endure the rough action associated with cleaning. Surgical gloves are not intended for heavy cleaning operations.

No changes in the label precautions are warranted.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tackle Cleaner, EPA Reg. No. 5813-21

TO: Arturo E. Castillo
Product Manager 32
Registration Division

Attached is information about a report of Tackle Cleaner disinfectant eating through rubber gloves and producing a severe reaction to the user.

A brief description of what we know about this problem is as follows:

The user [REDACTED] was using Tackle cleaner in a 5' x 12' bathroom to disinfect and clean tile. She had followed the label directions for sensitive skin and wore surgical rubber gloves for protection. After approximately five minutes, the fingers of the gloves began to stick together and the gloves began to dissolve. The product caused her to cough up blood, and produced second degree burns on her wrist. This was the first time she had used the product. She still has the bottle. The lot number is F5264A.

Based on the above information, I suggest we consider a label modification regarding gloves and sensitive skin. Art, what is your opinion?

Sincerely,

Frank L. Davido, Chief
Field Studies and Special
Projects Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attachment

INFORMATION PROTECTED BY THE PRIVACY
ACT IS NOT INCLUDED



THIS REPORT WAS TAKEN BY TELEPHONE AND TYPED AT USP

Form approved: OMB No. 57-R0059

DO NOT USE THIS SPACE

DATE RECEIVED USP OCT 10 1985

REFERENCE NO. X-1193

1. PRODUCT NAME, DOSAGE FORM, STRENGTH, NDC NUMBER

DATE:

Tackle, cleaner disinfectant

laser code 4460003701

2. LOT NUMBER(s) AND EXPIRATION DATE(s)

F5264A

3. DATE PURCHASED (If known)

6/85

4. SOURCE OF PRODUCT (Where purchased, if known)

IGA, McAdoo

5. NAME AND ADDRESS OF THE MANUFACTURER, PACKAGER AND/OR DISTRIBUTOR ON THE LABEL

Clorox Co.

Oakland, CA 94612

6. REPORTER'S NAME (Please print or type)

Bill Durdon R:Ph

7. NAME AND ADDRESS OF PRACTICE LOCATION (Include Zip Code)

Union Prescription Center 195

8 West Broad Street, W. Hazelton, PA 18201

8. PHONE NUMBER AT PRACTICE LOCATION (Include area code)

717-455-9581

9. PROBLEMS NOTED OR SUSPECTED CONCERN RELAYED BY REPORTER TO USP:

On the evening of 10/7/85, a woman received 2nd degree burns on right wrist and possible lung damage. She coughed up a little blood. She was wearing rubber gloves, as per product label instructions for sensitive skin, but the product ate through the gloves. Physician prescribed ampicillin 250 mg 4 x daily for 10 days, and Silvadene dressing 2 x daily. The day after the occurrence, the woman's wrist was still hurting, but she was losing the cough. Product label warns against eye irritation and swallowing of product. Product label has "questions or comment?" phone number 800-227-1860, in CA 800-772-2469, and EPA registration number is 5813-21. Pharmacist was returning the product in question to the customer after making this report. Ampicillin Rx no. 127089.

Reporter will be contacting the manufacturer directly.

doctor.

Dr. Michael A Reznick

459-2226

F5264A - bathroom = 5' x 12'

INFORMATION PROTECTED BY THE PRIVACY ACT IS NOT INCLUDED

RETURN TO United States Pharmacopeia 12601 Twinbrook Parkway Rockville, Maryland 20852 Attention: Dr. Joseph G. Valentino

OR

CALL TOLL FREE ANYTIME 800-638-6725* IN THE CONTINENTAL UNITED STATES

*In Maryland, call collect (301) 681-0256 between 9:00 AM and 4:30 PM



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

October 11 1985

Food and Drug Administration
Rockville MD 20857

Jean McCaulley
Consumer Product Safety Commission
Room 724
5401 Westbard Avenue
Bethesda, MD 20207

Ref. #: X-1193

Dear Mrs. McCaulley:

The attached report was received through the Drug Product Problem Reporting Program and is being forwarded to you for appropriate action. Preliminary evaluation suggests that certain aspects of the reported problem falls within your jurisdictional responsibilities. We have also forwarded copies of the report along with appropriate assignments to our FDA-District Office. They will take whatever action is indicated under the Food, Drug and Cosmetic Act. In addition, the report has been entered in our DPPR Computerized Data System for identifying trends and developing drug or firm profiles.

Please be advised that information identifying the originator of the report or the originator's address is exempt from disclosure to the public under FDA's Freedom of Information regulations (21 CFR 20.113 Revision of April 1, 1981).

We would appreciate receiving your evaluation and/or inspectional findings. If you need additional information on the report, please call me at (301) 443-7263.

Sincerely,

George Bolger
Product Surveillance Branch (HFN-333)
Center for Drugs and Biologics