12-5-83

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 10/25/83 OUT 12/5 /83

Reviewed by James E. Wilson 12/5/83 Date 11/28/83

EPA Reg. No. or File Symbol 5813-ER (21)

EPA Petition or EUP No. _____

Date Division Received 10/17/83

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

Data Accession No(s). 251518

Product Mgr. No. 32 (Castillo)

Product Name (s) TACKLE

Company Name(s) THE CLOROX COMPANY

Submission Purpose NEW APPLICATION

Chemical & Formulation LIQUID

Active Ingredient	%
Sodium Hypochlorite	2.0

300.0 Introduction

301.0 Data Summary

301.1 Brief Description of Studies

a. Acute oral Toxicity in Rats. Report by Microbiological Development and Control, Inc., submitted to the Clorox Company, Pleasanton, Ca 94566, dated August 24, 1983. (Accession No. 251518).

b. Acute Dermal Toxicity in Rabbits. Report by ... (same as above)...

c. Primary Eye Irritation in Rabbits. Report by ...(same as above) ... dated May 11, 1983.

d. Primary Skin Irritation in Rabbits. Report by ... (same as above) ... dated August 12, 1983.

301.2 Study Summaries

a. Acute Oral

1. Method

Five male and five rats were dosed orally with 5g/kg of the test material. All animals were observed for signs of toxicity and mortality for 24 days. Body weights were recorded on days 0, 7 and 14. Gross necropsy examinations were made on all animals found dead during the study or after sacrifice.

2. Results

Behavioral sedation was observed after 4 hours; the animals appeared normal at all other observation periods. Body weight gains were in the normal range and gross necropsy findings were unremarkable.

3. Conclusion

The acute oral LD_{50} is greater than 5g/kg.

b. Acute Dermal

1. Method

Two ml per kg weight of the test material were applied to the clipped backs of five male and five female rabbits. The sample remained in contact with the abraded skin for 24 hours and any residual left was wiped away. Animals were observed for signs of toxicity and mortality for 14 days 0, 7 and 14. Gross necropsy examinations were made on all animals when found dead or after sacrifice.

2. Results

No deaths nor toxic signs were recorded. Body weight gains were normal and gross necropsy findings unremarkable.

3. Conclusion

The acute dermal LD_{50} is greater than 2.0 ml/kg

C. Eye Irritation

1. Method

One tenth milliliter of the test substance was placed in one eye each of nine rabbits. Three of the eyes were rinsed within twenty to thirty seconds after dosing. The remaining six were not rinsed. Observations were made after 24, 48 and 72 hours and 7 and 14 days.

2. Results

Mild to moderate conjunctival irritation was observed after 24 hours. Iritis was seen in 1/3 washed and 5/6 non-rinsed eyes. After 48 hours mild corneal opacity was seen in 2/6 non-rinsed eyes. By the 72 hour reading the corneal opacity had cleared. Iritis disappeared by the day 4 reading and mild conjunctival irritation was observed in 3/6 non-rinsed eyes. All rinsed eyes were clear after 7 days. Conjunctivitis cleared in 2 of the 3 within 10 days and the final eye cleared in 21 days.

3. Conclusion

The product produces moderate ocular irritation which clears in 21 days.

d. Skin Irritation

1. Method

After the dorsal fur was clipped from the abdomen of six rabbits, four sites were selected to receive 0.5 ml of the liquid which remained in contact with the intact sites for 24 hours and was then removed. The degree of irritation was evaluated 5, 24 and 72 hours and 4, 5, 6, and 7 days after application.

2. Results

Moderate erythema was found after 24 hours; scores were reduced after 72 hours to grade 1 (mild). Grade one erythema was recorded in 5/6 after 5 days and 2/6 after 7 days.

3. Conclusion

The product produces mild skin irritation when placed on intact rabbit skin.

302.0 Recommendations

The data are adequate to place the product in the following toxicity categories:

Acute Oral	-	4
Acute Dermal	-	3
Eye Irritation	-	2
Skin Irritation	-	3

303.0 Labeling

In the Practical Treatment section delete the phrase "remove contact lenses."

304.0 CRP Status

This product does not meet or exceed the criteria set forth in 162.16.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW: INCOMPLETE APPLICATION
Disinfectants Branch

IN 10-24-83 OUT 12-01-83

EPA Reg. No. or File Symbol 5813-ER

Product Name Tackle

Company Name The Clorox Co.,

Date Appl. Rec. 10-07-83

Type Product General Disinfectant

Active Ingredients %

Sodium Hypochlorite 2.0

The application is incomplete for the following reasons:
No data submitted to review.

Additional Data Required to Initiate Review:
See the attached comments under 202.3.

Additional Labeling Information Required to Initiate Review:
See the attached comments under 203.0

Reviewer: Bruce H. Mann Rec'd 11/30/83 Date: 12-01-83

12/5/83

202.3 Additional Data Required to Support Efficacy:

A. For the general disinfectant claim, the applicant must submit data on 60 carriers tested against each of both S. aureus and S. choleraesuis with each of 3 samples, representing 3 different batches, one of which is at least 60 days old(120 carriers per sample). In addition, the test conditions described in DIS/TSS-2 enclosure, item 4 and 6 must be used to develop the data in support of the proposed "One-Step"label claim. All of the derived data must be develpoed by the AOAC Use-Dilution Method. For a hospital claim, refer to DIS/TSS-1, item (C).

B. For the fungicidal claim, the applicant must submit data against T. mentagrophytes (Pathogenic Fungi) on 60 carriers from each of 2 samples representing 2 different batches. The submitted data must be tested by the modified conditions described in DIS/TSS-2 enclosure, item 4 and 7.

C. For additional test organisms, Streptococcus species or other bacterial species , 60 carriers derived from from each of 2 samples representing 2 different batches developped by the AOAC Use-Dilution Method must be submitted. The derived data must be performed under the test conditions in DIS/TSS-2 enclosure, item 4 and 6. Refer to DIS/TSS-1, item (D).

203.0 Additional Labeling Information Required to Initiate Review:

The applicant's label must be upgraded to reflect current requirements for pesticidal usage on hard surfaces as described in DIS/TSS-15 enclosure.

A. The proposed label must reflect items 1, 2, 3, 5, 6 and 7 in DIS/TSS-15.
B. The label directions for disinfection of toilet bowl surfaces must specify either removal of bowl water prior to applying the use solution, or the amount of undiluted product to be added to the residual bowl water that will supply the use solution, and must indicate the thorough swabbing of all bowl surfaces with the use solution.
C. Under the directions of use for disinfecting, each condition of use intended for the product must be added to the label, and each use for the product must be provided with adequate directions for use, including the recommended use dilutions.
D. All submitted data must reflect a 5.0 minute contact time which is proposed in the label claim.