4-8-83

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 3/1/83 OUT 4/8/83

Reviewed by James E. Wilson, Jr. James E. Wilson, Jr. WEC 4/7/83 Date 4/4/83

EPA Reg. No. or File Symbol 10182-19, 45

EPA Petition or EUP No. _____

Date Division Received 2/8/83

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

Data Accession No(s). 249561

Product Mgr. No. 32 (Castillo)

Product Name(s) Baquacil, Vantocil P

Company Name(s) ICI Americas, Inc.

Submission Purpose Resubmission - Tox Data

Chemical & Formulation Liquid Concentrate

Active Ingredient(s):	%
Poly(iminoimidocarbonyliminioidocarbonyl-iminohexamethylene)hydrochloride	20.0

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300.0 Introduction

The initial supporting data for this product were submitted under File No. 10182-EUP-11 and reviewed by HED/TB in a memo dated June 15, 1978. That review assessed, in addition to other routes of exposure, the ocular irritation produced by the subject chemical when one drop of a 25% concentrate is placed in the eye.

Data showed that the corneal opacity and conjunctival irritation did not reverse in 7 days, therefore, the signal word "Danger" was required.

Data on a 20% formulation is being submitted which the registrant feels will show that the signal word should be "Warning."

301.0 Data Summary

301.1 Brief Description of Study

Eye Irritation in Rabbits. Report by ICI Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, U.K., dated November 3, 1981.

a. Method

Nine female rabbits had 0.1 ml of the test material instilled into one eye. Three of the eyes were rinsed 20-30 seconds after instillation for 1 minute with 200 ml of water; the other six were not irrigated. The eyes were examined after 1-2 hours and 1, 2, 3, 4, 7, 8, 15, 18, 25, 26, 29 and 35 days after instillation.

b. Results

Signs of slight to moderate initial pain were shown following instillation. Conjunctivitis appeared in all eyes by the first observation period; mild iritis was found in all non-rinsed eyes and 1 rinsed eye. Mild corneal opacity developed only in the non-rinsed eyes. Opacity cleared in 2 by day 7 and in the remaining 2 by day 25. Iritis cleared in 4/6 by day 3 and 2/6 by day 18; in the rinsed eye iritis cleared in 3 days. Conjunctivitis persisted for 26 days in two eyes, 18 days in 3 and 2 days in 1. Rinsed eyes cleared in 4, 14 and 22 days respectively.

c. Conclusion

The product produces mild transient corneal opacity (clear in 18 days) and conjunctival irritation which persists for 25 days in 1/3 of the eyes. The product is a moderate eye irritant.

302.0 Recommendations

Data show that the irritation produced by this product persisted for more than 21 days. It should be noted that a slight discharge was the only sign seen in the tested eyes at this time. Since the more serious signs cleared during the 18-25 day period, this reviewer recommends that the present toxicity category of 1 for eye irritation be reduced to 2.

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303.0 Labeling

a. The signal word should be changed to "Warning."

b. The word "concentrate" should be deleted from the statement "Do not get concentrate in eyes." Also "concentrate" should be deleted from the First Aid section.

304.0 CRP Status

Special packaging is not required for this product based on toxicity.