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DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation - rabbits

TOX CHEM NO: 454E

ACCESSION NUMBER:

MRID NO: 406126-09

TEST MATERIAL N-Ethyl Perflourooctanesulfonamide

SYNONYMS: GX-071

STUDY NUMBER: PROJECT NO .: 85G-0033

SPONSOR: Griffin corporation

TESTING FACILITY: Toxikon Corporation

TITLE OF REPORT: Primary Ocular Irritation Study Of GX-071 In Rabbits

AUTHORS: Richard Adams , Ph. D.

REPORT ISSUED: September 30, 1985; amended March 21, 1988

CONCLUSIONS: The test material did not produce ocular irritation.

GX-071 is not considered an eye irritant.

CLASSIFICATION: Core minimum.

A. MATERIALS:

1. Test Compound: GX-071

Description: white needle crystals

Batch # not specified

Purity: 99+%

2. Test Animals:

Species: male and female rabbits

Strain: New Zealand White

Age: 11 months of age

Weight: 3.0-3.7 kilograms

Source: registered commercial breeding laboratory

Study Design: GX-071 (100 mg of solid test material) was introduced into the eye of 6 rabbits by placement on the lower lid of the left eye everted by gently pulling it away from the eyeball to form a cup into which the test material was dropped. The upper and lower lids were gently held together for an instant. The right eye remained untreated (control). Three rabbits also received the test substance in the left eye (as above) and after 30 seconds, the eye was flushed for one minute. The right eye served as control. The animals were examined for evidence of eye irritation at approximately 1, 24, 48, and 72 hours after treatment for macroscopic findings. Fluorescein sodium opthalmic solution was used at the 24, 48, and 72 hours observation periods. Body weights were recorded at 72 hours

Results: There was no evidence reported of corneal opacity, iris abnormality, or conjunctival chemosis at any time point (see attached tables). Animals in the treated-unwashed group exhibited slight conjunctival redness and discharge following instillation of the test substance. Slight fluorescein staining was noted in one animal of the group. One animal in the treated-washed group exhibited slight conjunctival redness. No fluorescein staining was noted in this group.

Conclusion: The test material was not shown to be an eye irritant.

No rabbit exhibited a positive response and all changes were reversible.