

US EPA ARCHIVE DOCUMENT

DATA EVALUATION REPORT

PEBULATE

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (81-4)

Prepared for

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

4/13/1999

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 98-18G

Primary Reviewer:

Susan Chang, M.S.

Signature: _____

Date: _____

Secondary Reviewers:

H. Tim Borges, M.T. (A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____

Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____

Date: _____

Quality Assurance:

LeeAnn Wilson, M.A.

Signature: _____

Date: _____

Disclaimer

This review may have been altered subsequently to the contractor's signatures above.

EPA Reviewer: Yung G. Yang, Ph.D. _____, Date _____
Toxicology Branch 1 (7509C)
EPA Work Assignment Manager: S. Diwan, Ph.D. _____, Date _____
Toxicology Branch 1(7509C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS 870.2400 [§81-4]

DP BARCODE: D247841

SUBMISSION CODE: S546073

P.C. CODE: 041403

TOX. CHEM. NO.: 710

TEST MATERIAL (PURITY): Pebulate Technical (98.6%)

SYNONYMS: Tillam Technical

CITATION: Billow, T.(1990) Pebulate ("Tillam" Technical): Eye irritation to the rabbit. Stauffer Chemical Company, Richmond Toxicology Laboratory, Richmond, CA. Report No. T-6548, April 20, 1990. MRID 41591703. Unpublished. (The original study report for Tillam Technical was written by T.R. Billow on August 12, 1981 and reformatted by R.J. Parr-Dobrzanski on April 20, 1990. There were four sections in the original study report, Section D was for primary eye irritation.)

SPONSOR: ICI Agrochemicals, Fernhurst, Haslemere, Surrey, UK

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 41591703), 0.1 mL of Pebulate Technical (98.6%) was instilled into the lower lid of nine New Zealand White rabbits (sex was not specified). The contralateral eye served as untreated control. On 3 of the treated rabbits, the treated eyes were washed with lukewarm water for one minute twenty to thirty seconds after instillation. For the remaining 6 animals, the eyes were not washed. The eyes were examined for ocular irritation 24, 48, 72 hours and 4 and 7 days after instillation. Irritation was scored according to the Draize method.

Conjunctival irritation was observed on 5/6 rabbits with unwashed eyes at 24 hours and on 1/6 rabbit at 48 hours. All irritation had resolved by 72 hours. The rabbits with washed eyes had no irritation.

Under the conditions of this study, Pebulate was a mild eye irritant and was in TOXICITY CATEGORY III for primary eye irritation.

This study is classified as **Acceptable (Guideline)** and does satisfy the guideline requirement for a primary eye irritation study (81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Signed and dated flagging statements were not provided. A Certification of Accuracy of the Summary and Adequacy of the Study was included.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Pebulate (Tillam Technical)
Description: clear golden colored liquid
Lot/Batch #: H-40, 5625-19
Purity: 98.6% a.i.
2. Vehicle and/or positive control
None
3. Test animals
Species: rabbit
Strain: New Zealand White
Age and weight at dosing: age unknown; 1.3-2.0 kg
Source: Phillips Rabbitry, Soquel, CA
Acclimation period: not given
Diet: Special Mixture, Gunter Bros., Morgan Hill, CA), *ad libitum*
Water: drinking water, *ad libitum*
Housing: two/cage in suspended steel cage
Environmental conditions:
 Temperature: 65-70°F
 Humidity: not reported
 Air changes: not reported
 Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates
Start: October 22, 1979; end: October 29, 1979
2. Animal assignment and treatment
The undiluted test material (0.1 mL) was instilled into the lower lid of nine rabbits (sex was not specified) and the eyelids held together for approximately one second. Twenty to thirty seconds after instillation, the treated eyes of 3 rabbits were washed with lukewarm water for one minute. The remaining 6 animals were not washed. The contralateral eye served as an untreated control. The eyes were examined for ocular irritation 24, 48, and 72 hours and at 4 and 7 days post-treatment. Irritation was scored according to the Draize method.

II. RESULTS AND DISCUSSION

- A. The corneal, iridal, and conjunctival observations for each rabbit were not reported. A total score of each rabbit was reported. Conjunctival irritation was observed on 5/6 rabbits with unwashed eyes 24 hours after treatment (scores= 2-6). At 48 hours, only one rabbit showed conjunctival irritation (score= 2). The irritation had resolved on all rabbits by 72 hours. The rabbits with washed eyes did not develop ocular irritation.

The test material was a mild eye irritant and was in TOXICITY CATEGORY III for primary eye irritation.

B. DEFICIENCIES

Age of animals and environmental conditions with the exception of temperature were not provided. Scores recorded one hour after treatments were not reported. Ocular irritation scores for each rabbit included in the study were not reported. These deficiencies would not invalidate the results.

PEBULATE

Primary Eye Irritation Study (81-4)

SignOff Date:	4/13/99
DP Barcode:	D254687
HED DOC Number:	013311
Toxicology Branch:	TOX1