

US EPA ARCHIVE DOCUMENT

DATA EVALUATION REPORT

PEBULATE

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)

Prepared for

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

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Prepared by

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Disclaimer

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

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DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS 870.2500 [§81-5]

DP BARCODE: D247841

SUBMISSION CODE: S546073

P.C. CODE: 041403

TOX. CHEM. NO.: 710

TEST MATERIAL (PURITY): Pebulate Technical (98.6%, a.i.)

SYNONYMS: Tillam Technical

CITATION: Billow, T.(1990) Pebulate ("Tillam" Technical): skin irritation to the rabbit. Stauffer Chemical Company, Richmond Toxicology Laboratory, Richmond, CA. Report No. T-6548, April 20, 1990. MRID 41591702. Unpublished.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 C was for primary dermal irritation.)

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

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 41591702), six male and six female New Zealand white rabbits were dermally exposed to 0.5 mL Pebulate (98.6%) for 24 hours on an abraded or intact skin sites. Irritation was scored after 24 and 72 hours exposure by the method of Draize.

Erythema, very slight to well defined, was noted on the exposed intact skin of the rabbits at 24 and 72 hour after exposure. On the abraded skin sites, very slight to moderate erythema was noted after 24 and 72 hours. Very slight edema was also noted on the rabbits. **Based on the results, Pebulate is a slight irritant to the skin of rabbits.**

Pebulate is in TOXICITY CATEGORY IV for primary dermal irritation.

This study is classified as Acceptable (**guideline**). It does satisfy the guideline requirement for a primary dermal irritation study (81-5) 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
None
3. Test animals
Species: rabbit
Strain: New Zealand White
Age and weight at dosing: young adult; 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 24, 1979; end: October 27, 1979
2. Animal assignment and treatment
The back of each rabbit was shaved and divided into 4 separate sites. The rabbits were further prepared by making epidermal abrasions, in a criss cross manner on the two posterior sites with a needle. Test material (0.5 mL) was introduced to an one square inch gauze patch and applied to intact or abraded shaved sites on the back of each rabbit. Patches without test material were used as controls. The patches were secured in place by adhesive tape and wrapped with rubberized damming. The site was scored for erythema and edema according to the Draize method after 24 hours of exposure and 72 hours after removal of the dressing and the gauze patches.

II. RESULTS AND DISCUSSION

- A. Intact skin site: Very slight erythema and well defined erythema were noted on 3/6 and 3/6 rabbits, respectively, after 24 hour exposure. By 72 hours, very slight erythema and well defined erythema were noted on 4/6 and 1/6 rabbits, respectively. Very slight edema was noted on 1/6 rabbits at 24 and 72 hours.

Abraded skin site: Very slight erythema, well defined erythema, and moderate erythema were noted on 3/6, 2/6, and 1/6 rabbits, respectively, at 24 hour after exposure. By 72 hours, 2/6 and 3/6 rabbits had very slight erythema and well defined erythema, respectively. Three and two rabbits had very slight edema at 24 and 72 hours, respectively. Based on the results, Pebulate is a slight irritant to the skin of rabbits.

B. DEFICIENCIES

Age of animals and environmental conditions with the exception of temperature were not provided. These deficiencies would not invalidate the results.

PEBULATE

Primary Dermal Irritation Study (81-5)

SignOff Date:	4/13/99
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