US EPA ARCHIVE DOCUMENT

DATA EVALUATION REPORT

PEBULATE

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (81-2)

Prepared for

4/13/1999

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

Prepared by

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Task Order No. 98-18E

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

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DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat
OPPTS 870.1200 [§81-2]

DP BARCODE: D247841 SUBMISSION CODE: S546073
P.C. CODE: 041403 TOX. CHEM. NO.: 710
TEST MATERIAL (PURITY): Pebulate Technical (97.1%)
SYNONYMS: Tillam
CITATION: McCall, J. (1990) Pebulate: Acute dermal toxicity to the rat. ICI Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. Report No. CTL/P/3098, Study No. CR2779, July 31, 1990. MRID 41677301. Unpublished.
SPONSOR: ICI Agrochemicals, Fernhurst, Haslemere, Surrey, UK

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 41677301), a 10 cm X 5 cm area of the dorso-lumber skin was shaved on five male and five female young adult Wistar rats and a dose equivalent to 2000 mg/kg Pebulate (97.1%) was applied to the site. Twenty-four hours later, the test material was removed and the animals observed for 14 days.

None of the animals died during the study. Moderate skin irritation (erythema, edema, and thickening) was noted on all rats. The irritation cleared by day 8. No significant signs of systemic toxicity were reported. Most rats lost body weight at the beginning of the study, but gained weight by day 6 or day 8. All rats had increased body weight at the end of the study. No macroscopic abnormalities were found at necropsy.

Dermal LD_{50} for male and female Wistar albino rats is > 2000 mg/kg (Limit Dose).

Pebulate (Technical) is in TOXICITY CATEGORY III.

This acute dermal study is classified as acceptable (guideline). It does satisfy the guideline requirement for an acute dermal study (81-2) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and flagging statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Pebulate
   Description: amber colored liquid
   Lot/Batch #: CTL reference No. Y06381/001
   Purity: 97.1% (MRID# 41614808)

2. Vehicle and/or positive control
   None

3. Test animals
   Species: rat
   Strain: Wistar-derived albino Alpk:APfSD
   Age and/or weight at dosing: young adult; males: 319-360 g, females: 212-226 g
   Source: Barriered Animal Breeding Unit, ICI Pharmaceuticals, Alderley Park, Macclesfield, Cheshire, UK
   Acclimation period: ≥6 days
   Diet: Porton Combined Diet (Special Diet Services Ltd), *ad libitum*
   Water: drinking water, *ad libitum*
   Housing:individually in one of the two compartments of a stainless steel cage with a polycarbonate front
   Environmental conditions:
   Temperature: 15-24°C
   Humidity: 50±10%
   Air changes: 20-30/hour
   Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS

1. In life dates

   Start: February 5, 1990; end: February 19, 1990

2. Animal assignment and treatment

   The study was conducted as a limit test using five male and five female rats. Sixteen to thirty-two hours prior to treatment, hair was removed from an area approximately 10 cm X 5 cm on the dorso-lumbar region of each rat. A single 2000 mg/kg dose of Pebulate (Technical) was applied to the prepared skin. The application site was covered with gauze, plastic film, and secured with an impermeable dressing encircled around the trunk. The covering was removed 24 hours later and the site cleaned with cotton wool soaked in warm water. The animals were observed for clinical signs of toxicity once between one and four hours after treatment, then daily through day 15 for toxicity and skin irritation. They were weigh-

ed on study days 1, 3, 6, 8, and 15. At the termination of the study, all rats were sacrificed under halothane BP anesthesia by cervical dislocation and necropsied.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	Males	Females	Combined
2000	0/5	0/5	0/10

Data taken from Table 1, p. 16-24, MRID 41677301.

3. Statistics

Calculation of the dermal LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rats died of Pebulate (Technical) toxicity.

The dermal LD_{50} for male and female Wistar albino rats is > 2000 mg/kg.

B. CLINICAL OBSERVATIONS

Moderate skin irritation (erythema, edema, and thickening) was noted on all rats. By day 8, all rats cleared of any irritation. No significant signs of systemic toxicity in response to treatment were reported.

C. BODY WEIGHT

Most rats lost body weight at the beginning of the study, but gained weight by day 6 or day 8. All rats had increased body weight at the end of the study.

D. NECROPSY

No macroscopic abnormalities were found at necropsy.

E. DEFICIENCIES

No study deficiencies were identified.

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