

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS: NONE

BEHQ-0103-15255

1.0 SUBMISSION TYPE

8(d) **8(e)** FYI 4 OTHER: Specify _____

XX- Initial Submission - Follow-up Submission Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: _____

Docket Number, if any: # _____

continuation sheet attached

2.1 SUMMARY/ABSTRACT ATTACHED

(may be required for 8(e): optional for §4, 8(d) & FYI)

X- YES NO

2.2 SUBMITTER TRACKING

NUMBER OR INTERNAL ID

7106 4575 1292 0338 1545

02-2-26

2.3 FOR EPA USE ONLY

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY

Reported Chemical Name (specify nomenclature if other than CAS name):

CAS#: N/A

Purity ___%

X- Single Ingredient

Commercial/Tech Grade

Mixture

Trade Name AE0317309

Common Name: Triketone

CAS Number

NAME

% WEIGHT

Other chemical(s) present in tested mixture

continuation sheet attached

Contain NO CBI

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OPPT NCIC
2003 JAN 13 11:19

2003 JAN 23 AM 9:49

RECEIVED
OPPT NCIC

4.0 REPORT/STUDY TITLE

Summary results of Exploratory 14-Day Toxicity Study in the Mouse by Gavage

continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): ENVIRONMENTAL FATE (EF):

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY SUBJECT ROUTE OF VEHICLE OF
TYPE: TOX ORGANISM (HE, EE) MICE EXPOSURE (HE only): EXPOSURE (HE only):
Other: Other: Other: Other:

6.0 REPORT/STUDY INFORMATION Study is GLP

Laboratory Bayer Toxicology Report/Study Date: 12/5/02

Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _

continuation sheet attached

7.0 SUBMITTER INFORMATION

Janet M. Mostowy, Ph.D.
VP, Product Safety & Regulatory Affairs
Bayer Corporation - 100 Bayer Road, Pittsburgh, PA. 15205

Phone: 412-777-3490

Technical Contact: SAME AS ABOVE Phone: ()

continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS

This compound is an experimental herbicide.

continuation sheet attached



BEHQ-03-15255

Submitter Signature: [Signature] Date: 12/18/02



88030000050

42 66240

9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0338 1545
02-2-26

Continuation of 2.1

TSCA 8(e) Evaluation

Study results reporting is based on: 1) the death of two females at 1000 mg/kg which could not be attributed to an error in gavaging the animals, 2) treatment-related multi focal cortical renal tubuloepithelial degeneration and/or multi focal basophilic tubules in the animals which were found dead, and 3) multifocal basophilic tubules, often associated with tubular dilatation, in the kidneys of both sexes at 1000 and 300 mg/kg/day and in females at 100 mg/kg/day.

Abstract

The potential systemic toxicity of the test substance, an herbicide of the triketone family (batch number STTI-19W25/30, 99.0% purity) was assessed after oral administration by gavage at dose levels of 100, 300 and 1000 mg/kg/day for fourteen days in groups of 5 male and 5 female C57BL mice. A similarly constituted group of 5 mice per sex received the vehicle alone (0.5% methylcellulose) at the same dosage volume of 5 ml/kg/day and acted as a control. Clinical signs were recorded daily, body weights were recorded on Days 1, 7, and 14 and food consumption was measured on Days 7 and 14. Blood samples were taken before necropsy for plasma chemistry determinations. All surviving animals were necropsied, selected organs weighed and a range of tissues were taken, fixed and examined microscopically.

The test substance was administered to male and female C57BL mice at 100, 300 and 1000 mg/kg/day for 14 days resulting in the death of one male and two females at 1000 mg/kg/day. In the decedent male, intratracheal and intrapulmonary blood was seen histopathologically and suggested a gavage error as cause of death. No clear cause of death could be established for the females. Kidneys of the decedent animals showed a treatment-related multi focal cortical tubuloepithelial degeneration and/or multi focal basophilic tubules. Clinical signs were limited to females at 1000 mg/kg/day and consisted of reduced motor activity in two females and prostration, reduced motor activity and absence of grasping reflex in one of the females which died. The overall body weight evolution and food consumption were unaffected by treatment. In clinical chemistry, a dose related increase in the mean total cholesterol concentrations was observed in both sexes at 300 and 1000 mg/kg/day. No gross organ changes were observed at terminal sacrifice. Effects on organ weights were restricted to the top dose group and comprised slightly higher liver weights in both sexes and slightly higher kidney weights in females only. Histopathological examinations revealed a slight diffuse centrilobular hepatocellular hypertrophy in male mice at 1000 mg/kg/day and multifocal basophilic tubules, often associated with tubular dilatation, in the kidneys of both sexes at 1000 and 300 mg/kg/day and in females at 100 mg/kg/day.

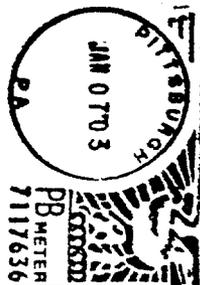
The No Effect Level could not be determined in this study.



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