

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS: NONE

BEHQ-0103-15256

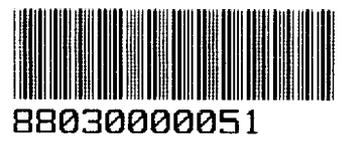
1.0 SUBMISSION TYPE <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ XX- Initial Submission - Follow-up Submission <input type="checkbox"/> Final Report Submission Previous EPA Submission Number or Title if update or follow-up: _____ Docket Number, if any: # _____ <input type="checkbox"/> continuation sheet attached		
2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI) X- YES <input type="checkbox"/> NO	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID 7106 4575 1292 0338 1545 02-2-27	2.3 FOR EPA USE ONLY <div style="text-align: right; font-size: small;"> RECEIVED DPT 0318 2003 JAN 13 AM 11:19 </div>
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS#: N/A Purity ___% X- Single Ingredient <input type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture Trade Name <u>AE0317309</u> Common Name: <u>Triketone</u> CAS Number _____ NAME _____ % WEIGHT _____ Other chemical(s) present in tested mixture _____ <input type="checkbox"/> continuation sheet attached		
4.0 REPORT/STUDY TITLE Summary results of Preliminary 28-Day Toxicity Study in the Mouse by Dietary Administration <input type="checkbox"/> continuation sheet attached		
5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE] HEALTH EFFECTS (HE): <u>X</u> 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) <u>MICE</u> EXPOSURE (HE only): _____ EXPOSURE (HE only) _____ Other: _____ Other: _____ Other: _____		
6.0 REPORT/STUDY INFORMATION <input type="checkbox"/> Study is GLP Laboratory <u>Bayer Toxicology</u> Report/Study Date: <u>12/5/02</u> Source of Data/Study Sponsor (if different than submitter) _____ Number of pages: _____ <input type="checkbox"/> 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: <u>SAME AS ABOVE</u> Phone: () _____ <input type="checkbox"/> continuation sheet attached		
8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS This compound is an experimental herbicide. <input type="checkbox"/> continuation sheet attached		

RECEIVED
 DPT 0318
 2003 JAN 23 AM 9:49



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

Page 1 of 1



MR 66241

9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0338 1545
02-2-27

Continuation of 2.1

TSCA 8(e) Evaluation

Study results reporting is based on: 1) diffuse urothelial hyperplasia was observed in the urinary bladder of males exposed to 5000 ppm and 2) the bladder change was associated with diffuse submucosal granulation tissue and diffuse suburothelial mixed-cell infiltrate.

Abstract

The test substance, a herbicide of the triketone family (batch number H2235, yellow crystals, 97.4% purity) was administered continuously via the diet to groups of C57BL mice (10/sex/group) for at least 28 days at concentrations of 200, 1000 and 5000 ppm. A similarly constituted group received untreated diet and acted as a control. Clinical signs and mortality were recorded daily, body weights and food consumption were recorded once weekly. Physical examinations were performed weekly. Selected plasma chemistry parameters were determined at the end of the study. All animals were necropsied, selected organs weighed and a range of tissues were taken, fixed and examined microscopically.

There were no mortalities or clinical signs observed during the course of the study. Body weight evolution and food consumption were unaffected by the treatment with the test substance.

No treatment-related changes were noted in plasma chemistry parameters.

At necropsy, no treatment-related changes were noted in organ weights. Treatment-related changes were observed in the urinary bladder of a proportion of the male animals exposed to 5000 ppm, where a diffuse urothelial hyperplasia was observed in 3/10 animals. This finding was associated with a diffuse submucosal granulation tissue and with diffuse suburothelial mixed-cell infiltrate. These observations were correlated to a gritty content found macroscopically in the urinary bladder of two of the three affected males.

Based on the absence of any toxicological effects of the test substance to female C5BL mice over a 28-day period at levels up to 5000 ppm (equivalent to 1082 mg/kg/day for females) it can be considered that the No Observable Adverse Effect Level of the test substance is 5000 ppm for females.

Based on treatment related changes affecting the urinary bladder in male animals at the highest dose level of 5000 ppm (equivalent to 961 mg/kg/day) the NOEL of the test substance to male C57BL mice over a 28-day period was considered to be 1000 ppm (equivalent to 192 mg/kg/day).