

8EHQ-0600-14489¹⁵

8EHQ-99-14489

89 000 000 263

TSCA HEALTH & SAFETY STUDY COVER SHEET

PUBLIC DISPLAY COPY

RECEIVED
7/26/00
TOB/RAD

1.0 SUBMISSION TYPE - Contains CBI <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ Intial Submission <input checked="" type="checkbox"/> 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) <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID P 917 006 966 00-2-14	2.3 FOR EPA USE ONLY						
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY - Contains CBI <u>Reported Chemical Name (specify nomenclature if other than CAS name):</u> CAS# _____ - _____ - _____ N/A phenyllactone Purity _____ % <input type="checkbox"/> Single Ingredient <input type="checkbox"/> Commerical/Tech Grade <input type="checkbox"/> Mixture Trade Name: _____ Common Name: <u>AMS 13630</u> <table border="1"> <thead> <tr> <th>CAS Number</th> <th>NAME</th> <th>% WEIGHT</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> Other chemical(s) present In tested mixture <input type="checkbox"/> continuation sheet attached			CAS Number	NAME	% WEIGHT			
CAS Number	NAME	% WEIGHT						
4.0 REPORT/STUDY TITLE <input type="checkbox"/> Contains CBI Review of preliminary data : Study of Chronic Toxicity & Carcinogenicity in Wistar Rats <input type="checkbox"/> continuation sheet attached								
5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE] HEALTH EFFECTS (HE): <input checked="" type="checkbox"/> ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____								
5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes) STUDY TYPE: <u>CTOX</u> SUBJECT ORGANISM (HE, EE only): <u>RATS</u> ROUTE OF EXPOSURE (HE only): _____ VEHICLE OF EXPOSURE (HE only): _____ Other: _____ Other: _____ Other: _____ Other: _____								
6.0 REPORT/STUDY INFORMATION <input type="checkbox"/> Contains CBI <input type="checkbox"/> Study is GLP Laboratory _____ Report/Study Date _____ Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _____ <input type="checkbox"/> continuation sheet attached								
7.0 SUBMITTER INFORMATION <input type="checkbox"/> Contains CBI Submitter: <u>Donald W. Lamb, Ph.D.</u> Title: <u>V.P. Product Safety & Reg. Affairs</u> Phone: (412) <u>777-7431</u> Company Name: <u>Bayer Corporation</u> Company Address: <u>100 Bayer Road</u> <u>Pittsburgh, PA 15205-9741</u> Submitter Address (if different): _____ Technical Contact: _____ Same as above Phone: () _____ <input type="checkbox"/> continuation sheet attached								
8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS - Contains CBI <p style="text-align: center;">Company Sanitized</p> <input type="checkbox"/> continuation sheet attached								

RECEIVED
OPTT 0100
2000 JUN 19 11:11 AM

2000 JUL 20 AM 8:46

RECEIVED
OPTT NCIC

Submitter Signature: Ronald W Lamb Date: 6/12/00

MR 36841

9.0 CONTINUATION SHEET
PUBLIC DISPLAY COPY

Submitter Tracking Number/Internal ID

P 917 006 966

00-2-14

CONTINUED FROM COVER SHEET SECTION # 2.1

As a follow-up to previous submitted results with the same compound, the preliminary information from this chronic rat study shows a statistically significant increase in the incidence of Leydig cell adenomas and of focal Leydig cell hyperplasia in the highest dose group. Thus, the reporting.

Abstract

In this study, groups of Wistar rats (50 animals/dose/sex) were exposed over a two year period to technical-grade test substance in the diet using nominal concentrations of 0 (control), 50, 100, 350, and 2500 ppm.

Histopathological investigations have shown a statistically significant increase (Fisher exact test) in the incidence of Leydig cell adenomas (2/1/-/4/10, $p < 0.05$) and of focal Leydig cell hyperplasia (4/4/4/7/19, $p < 0.01$) at the highest dose level (i.e., 2500 ppm).