

A 01

CODING FORMS FOR SRC INDEXING

Microfiche No.	OTS0559779		
New Doc ID	88990000251	Old Doc ID	8EHQ-0899-14532
Date Produced	08/16/99	Date Received	08/23/99
		TSCA Section	8E
Submitting Organization	BAYER CORP		
Contractor	BAYER AG		
Document Title	INITIAL SUBMISSION: TSCA HL1H & SAFETY STUDY CVR SHT REPORTING PRELIM RESULTS FROM DEVELOPMENTAL TOXICITY SCREENING IN RATS AFTER ORAL ADMINISTRATION OF AND 7370, DATED 08/16/1999		
Chemical Category	AND 7370, EXPERIMENTAL HERBICIDE		

**INITIAL
SUB-
MISSION**

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS:

-CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (L Contains CBI). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

1.0 SUBMISSION TYPE - Contains CBI <input type="checkbox"/> S(d) <input checked="" type="checkbox"/> S(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify 8EHQ-0899-14532 <input checked="" type="checkbox"/> Initial Submission <input 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 S(e): optional for S4, S(d) & FYI) <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID Cert# P 917006923 99-2-58	2.3 FOR EPA USE ONLY
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY - Contains CBI <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS#: Not yet assigned Purity _____ % <input type="checkbox"/> - Single Ingredient <input type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture Trade Name: <u>AND 7370</u> Common Name: <u>8EHQ-99-14532</u>		
4.0 REPORT/STUDY TITLE - Contains CBI Developmental Toxicity Screening in Rats After Oral Administration - Study # T3068036 - Preliminary Data <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 SUBJECT ROUTE OF VEHICLE OF TYPE: <u>TOX</u> ORGANISM (HE, EE only): <u>RAT</u> EXPOSURE (HE only): _____ EXPOSURE (HE only) _____ Other: <u>DEVELOPMENTAL</u> Other: _____ Other: _____		
6.0 REPORT/STUDY INFORMATION L Contains CBI - Study is GLP Laboratory <u>N/A</u> Report/Study Date: <u>N/A</u> Source of Data/Study Sponsor (if different than submitter) <u>Bayer AG</u> Number of pages _____ <input type="checkbox"/> continuation sheet attached		
7.0 SUBMITTER INFORMATION L Contains CBI Submitter: <u>Donald W. Lamb, Ph.D</u> Title: <u>V. P., Prod. Safety & Reg. Affrs</u> Phone: <u>412-777-7431</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: <u>Donald W. Lamb, Ph.D</u> Phone: <u>(412)777-7431</u> <input type="checkbox"/> continuation sheet attached		
8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS L Contains CBI This compound is an experimental herbicide. <div style="text-align: right; font-size: 2em; font-weight: bold; transform: rotate(-5deg);">Contains No CBI</div> <input type="checkbox"/> continuation sheet attached		

Submitter Signature: Donald W. Lamb

Date: 22/16/99 1999 AUG 23 02:16:54



RECEIVED OPT CBI

RECEIVED OPT CBI

9.0 CONTINUATION SHEET

Page 2 of 2
TSCA CBI STATUS:

 CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (*i.e.* Contains CBI).
Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

Submitter Tracking Number/Internal ID

P917006923
99-2-58

CONTINUED FROM COVER SHEET SECTION # 2.1

In this study, the dose of 1000 mg/kg revealed skeletal variations and malformations at low incidences, for which a treatment related effect cannot be completely excluded. Thus, these findings are being reported. Final evaluation of these findings, however, should be based on a succeeding guideline study and not on the limited data available from this screening study.

Abstract

Four inseminated Wistar rats (two rats in the 100 mg/kg dose group had implantation sites; i.e., were pregnant) were treated daily from day 6 to day 19 p.c. by gavage, with 100 or 1000 mg/kg body weight/day of AND 7370 in 0.5 % carboxymethylcellulose in demineralized water. The fetuses were delivered by cesarean section on day 20 p.c. Investigations were performed on the general tolerance of the test compound by the females as well as on its effects on intrauterine development (pregnancy rate, number of fetuses and resorptions, external findings in the fetuses, fetal weight, fetal skeletal malformations, and fetal skeletal variations (wavy ribs only)).

There were no compound-related effects on appearance, behavior, and mortality of the females. Furthermore, there was no indication of a compound-related effect on feed intake, excretory products, or body weight gain. Gross necropsy of the females did not reveal compound-related findings.

There was no compound-related effect on the pregnancy rate, the resorption rate, the number of fetuses, and fetal weight.

External evaluation of the fetuses did not reveal compound-related effects. Skeletal evaluation showed a slightly increased incidence of variations (wavy ribs in seven fetuses; 13.7 %, two affected litter) in the 1000 mg/kg dose group. Additionally, skeletal malformations (thickening and shortening of the humerus and scapula) occurred in 2 fetuses (3.9 % one affected litter) in the 1000 mg/kg dose group. The incidence of fetuses with wavy ribs in the 1000 mg/kg dose group was at the upper end of the spontaneous range for the strain of rat used in this study, and the forelimb malformations were limited to a single litter. As, however, wavy ribs and dysplasia of limb bones may occur with this class of compounds, a compound-related effect cannot be completely excluded for these findings at the 1000 mg/kg dose level. However, a final assessment is not possible due to the low number of females in this screening study.

CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

Data produced 08 - 04 - 2000 Susan Rivera
(Month) (Day) (Year) Camera Operator

Place Syracuse New York
(City) (State)



A 06

END