A 01

CODING FORMS FOR SRC INDEXING

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Date Produced	**Date Received**	**TSCA Section**
11/23/99	11/26/99	8E
Submitting Organization		
BAYER CORP		
Contractor		
BAYER TOXICOLOGY		
Document Title		
INITIAL SUBMISSION: TSCA HLTH & SFTY STUDY CVR SHT W/CONTINUATION SHT SUMMARIZING RESULTS IN DEVELOPMENTAL TOXICITY STUDY IN RAT (PILOT STUDY #T6068624) W/ALM 1195, DATED 112399		
Chemical Category		
ALM 1195 (SULFONYLIMIDAZOLE)		

A 02

INITIAL SUB-MISSION

A 03

8EHQ-1199-14598

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 (* Contains CBI).
Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

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1.0 SUBMISSION TYPE - *Contains CBI*

8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify

XX Intial 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

Cert# P 917006944

99-2-775

2.3 FOR EPA USE ONLY

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY -*Contains CBI*

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

CAS#: Not yet assigned

Purity _____%

- Single Ingredient

☐ Commerical/Tech Grade

-Mixture

Contains No CBI

Trade Name: FALM 11959 *Common Name:* Sulfonylimidazole

4.0 REPORT/STUDY TITLE - *Contains CBI*

Developmental toxicity study in rat summary . (Pilot Study # T6068624)

☐ 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 TYPE: TOX *Other:* Developmental

SUBJECT ORGANISM (HE, EE only): RATT Other:

ROUTE OF EXPOSURE (HE only): *Other:*

VEHICLE OF EXPOSURE (HEonly) *Other:*

6.0 REPORT/STUDY INFORMATION ☐ *Contains CBI* ☐ Study is GLP

Laboratory Bayer Toxicology, Wuppertal Report/Study Date: n/a

Source of Data/Study Sponsor (if different than submitter) Bayer AG Number of pages 2

☐ continuation sheet attached

7.0 SUBMITTER INFORMATION ☐ *Contains CBI*

Submitter: Donald W. Lamb, Ph.D Title: V. P., Prod. Safety & Reg. Affrs Phone: 412-777-7431

Company Name: Bayer Corporation Company Address: 100 Bayer Road

Pittsburgh, PA 15205-9741 Submitter Address (if different):

Technical Contact: Donald W. Lamb, Ph.D Phone: (412)777-7431

☐ continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS ☐ *Contains CBI*

This compound is an experimental fungicide in the L3 stage of development.
As this is a pilot study, this summary comprises the report for this study.

☐ continuation sheet attached

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Submitter Signature: Donald W. Lamb Date: 11/23/99

Page 1 of 2

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A 05

9.0 CONTINUATION SHEET

TSCA CBI STATUS:

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CONTINUED FROM COVER SHEET SECTION # 2.1

TSCA 8(e) Review

In this study, malformations of the heart (interatrial septal defects) were observed at a dose level of 500 mg/kg bw/day, thus the reporting.

Abstract

Groups of eight inseminated female Wistar rats were treated daily from day 6 to day 19 p.c., by gavage, with doses of 0, 30, 100, and 500 mg/kg body weight (dose volume 10 ml/kg bw) of ALM 1195 in 0.5% aqueous carboxymethylcellulose. The fetuses were delivered by cesarean section on day 20 p.c. Investigations were performed for the general tolerance of the test compound by the females as well as on its effect on intrauterine development. 2/3 of the fetuses underwent skeletal evaluation while 1/3 of fetuses were evaluated viscerally.

Mortality of the females was not affected by treatment. Increased water consumption and urination was observed in a single female in the 500 mg/kg dose group for one day only, so that toxicological relevance of these findings remains equivocal. Maternal feed intake was not affected to a toxicologically relevant degree at a dose level up to and including 500 mg/kg, while corrected body weight change was marginally decreased at the 500 mg/kg dose level. Necropsy revealed no treatment- related gross pathological findings at a dose level up to and including 500 mg/kg bw/day.

Reproductive parameters, i.e. gestation rate, postimplantation loss, number of live fetuses per litter, fetal weight, placental weight, and appearance were not affected by treatment at a dose level up to and including 500 mg/kg. The mean percentage of male fetuses per litter was low in the 500 mg/kg dose group in comparison to the current control, but the value was in the range of historical control data and dose relationship was not evident. Therefore, this finding is regarded as incidental and toxicological relevance is not assumed.

Visceral evaluation of fetuses revealed a high number of malformed hearts (interatrial septal defects) in the 500 mg/kg dose group, affecting 28.6% of the fetuses and 33.3% of litters examined viscerally. During the external and skeletal evaluation, treatment-related alterations were not observed at a dose level up to and including 500 mg/kg.

Summarizing all findings, maternal toxicity could not be completely excluded at the 500 mg/kg dose level (impaired body weight development, increased water intake and urination). The incidence of fetal malformations (interatrial septal defect of the heart) was distinctly increased at the 500 mg/kg dose level.

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A 05

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