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CODING FORMS FOR SRC INDEXING

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Date Produced	Date Received	TSCA Section	
07/14/80	12/13/99	8E	
Submitting Organization			
BAYER CORP			
Contractor			
CIVO INST TNO, NETHERLANDS			
Document Title			
INITIAL SUBMISSION: SUBCHRONIC (13-WEEK) INHALATION TOXICITY STUDY WITH ISODODECANE IN RATS, WITH TSCA HLTH & SFTY STUDY CVR SHT & CONTINUATION SHT DATED 120899			
Chemical Category			
ISODODECANE			

**INITIAL
SUB-
MISSION**

A 03

8EHQ-1299-14610

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.

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 _____ <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 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 Cert# P 91700694 5 99-2-78	2.3 FOR EPA USE ONLY RECEIVED 00 JAN 11 AM 11:52
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY - Contains CBI <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS#: 13475-82-6 Purity _____ % <input type="checkbox"/> - Single Ingredient <input checked="" type="checkbox"/> - Commercial/Tech Grade <input type="checkbox"/> - Mixture Trade Name: <u>Isododecane</u> Common Name: _____		
4.0 REPORT/STUDY TITLE - Contains CBI Subchronic (13-Week) Inhalation Toxicity Study in Rats, Report # V81.069/292473 <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>STOX</u> SUBJECT ORGANISM (HE, EE only): <u>RATS</u> ROUTE OF EXPOSURE (HE only): _____ VEHICLE OF EXPOSURE (HE only): _____ Other: _____ Other: _____ Other: _____		
6.0 REPORT/STUDY INFORMATION <i>Contains CBI</i> <input checked="" type="checkbox"/> Study is GLP Laboratory: <u>CIVO Institutes Tno, Netherlands</u> Report/Study Date: <u>3/81</u>		
Source of Data/Study Sponsor (if different than submitter): <u>Bayer AG</u> Number of pages: <u>4</u> <input type="checkbox"/> continuation sheet attached		
7.0 SUBMITTER INFORMATION <i>Contains CBI</i> 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 <i>Contains CBI</i> The four pages that we are submitting are all that we have in our possession. <input type="checkbox"/> continuation sheet attached 		

8EHQ-99-14610

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Submitter Signature: Ronald W. Lamb

Date: 1/2/99

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9.0 CONTINUATION SHEET
Submitter Tracking Number/Internal ID

P917006945
99-2-78

CONTINUED FROM COVER SHEET SECTION # 2.1

TSCA 8(e) Evaluation:

The reporting is based on the kidney nephrosis which was observed in this subchronic inhalation rat study with isododecane.

Abstract

1. A subchronic inhalation toxicity study with isododecane was carried out by exposing groups of twenty male and twenty female rats to atmospheres containing 0, 200, 600, or 1800 ppm (0, 1.4, 4.2, or 12.6 g/m³ air) isododecane 6 hours a day, 5 days a week, for a period of 13 weeks.
2. The actual mean concentrations of isododecane in the test atmospheres were 0, 200.3, 599.3, and 1799 ppm.
3. Growth retardation was observed in females in the 1800 ppm dose group.
4. In week 5, red blood cell counts were lower for males and females in the 1800 ppm dose group than in controls. At the end of the 13-week exposure period, the red blood cell values for this test group were similar to the control values.
5. Plasma alkaline phosphatase activity was increased for females in the 1800 ppm dose group.
6. Males and females in the 1800 ppm dose group and males in the 600 ppm dose group produced relatively large amounts of urine of low density at the end of the experimental period. This was also observed in week 5 for females in the 200 and 1800 ppm dose groups. Furthermore, sperm cells were more frequently absent in urine samples from males in the 600 and 1800 ppm dose groups than from males in the control- and 200 ppm dose groups in weeks 5 and 13.
7. The relative weights of the gonads and kidneys for males and females in the 1800 ppm dose group as well as the relative kidney weights for males in the 600 ppm group were increased.
8. When the animals were necropsied, the incidence of greenish kidneys appeared to be increased for males in the 1800 ppm dose group.
9. Histological examination of the kidneys showed a dose-related increase in the incidence of tubular nephrosis for males in each of the exposure levels tested.
10. The degree and incidence of inflammatory reactions in the respiratory tract appeared to be lower for males in the 1800 ppm and for females in the 600 and 1800 ppm dose groups than in controls.
11. It was concluded, that under the experimental conditions of the present study, the no-adverse-effect level of isododecane in rats was lower than 200 ppm.

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3700 AJ zeist

V81.069/292473

SUBCHRONIC (13-WEEK) INHALATION
TOXICITY STUDY WITH ISODODECANE

IN RATS (som März 1981)

Start der Studie : 14.4.1980
Ende der Studie : 14.7.1980

Authors : Drs L.M. Appelman, drs M.C. Bosland and
J.P. Bruyntjes

At the request of : EC. Erdölchemie GmbH, Cologne, Germany

Project number : B79/2473

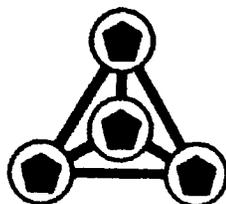
Date : March 1981

Approved by : Dr V.J. Feron

Start of the study : 14 April 1980

End of the study : 14 July 1980

Study director : Drs L.M. Appelman



SUMMARY

1. A subchronic inhalation toxicity study with isododecane was carried out by exposing groups of twenty male and twenty female rats to atmospheres containing 0, 200, 600 or 1800 ppm (0, 1.4, 4.2 or 12.6 g/m³ air) isododecane 6 hours a day, 5 days a week, for a period of 13 weeks.
2. The actual mean concentrations of isododecane in the test atmospheres were 0, 200.3, 599.3 and 1799 ppm.
3. Growth retardation was observed in females of the 1800 ppm group.
4. In week 5 red blood cell counts were lower in males and females of the 1800 ppm group than in controls. At the end of the 13-week exposure period the red blood cell values of this test group were similar to the control values.
5. The plasma alkaline phosphatase activity was increased in females of the 1800 ppm group.
6. Males and females of the 1800 ppm group and the males of the 600 ppm group produced relatively large amounts of urine of low density at the end of the experimental period. This was also observed in week 5 in females of the 200 and 1800 ppm groups. Furthermore, sperm cells were more frequently absent in urine samples of the males of the 600 and 1800 ppm groups than in those of the control- and 200 ppm groups, both in week 5 and 13.
7. The relative weights of the gonads and ^{*Gonads and kidneys*} kidneys of the males and females of the 1800 ppm group as well as the relative kidney weights of the males of the 600 ppm group were increased.
8. Upon gross examination at autopsy the incidence of greenish kidneys appeared to be increased in males at the 1800 ppm level.

V 81.069

9. A dose related increase in the incidence of histopathological changes was found in the kidneys of males at each of the exposure levels tested. These changes consisted of tubular nephrosis.
10. Degree and incidence of inflammatory reactions in the respiratory tract appeared to be lower in males at the 1800 ppm and in females at the 600 and 1800 ppm level than in controls.
11. It was concluded that under the experimental conditions of the present study the no-adverse-effect level of isododecane in rats was lower than 200 ppm.

QUALITY ASSURANCE UNIT TWO - P.O. Box 360, 3700 AJ ZEIST, Netherlands

STATEMENT OF GLP COMPLIANCE

On study : Subchronic (13-week) inhalation toxicity study with isododecane in rats

Report no.: V 81.069/292473

Date : March 1981

The study was carried out under conditions of good laboratory practice. Within reason there have been no circumstances that might have affected the quality and integrity of the results obtained.

Dates and number of inspections:

- 4 February 1980 (1)
- 7 July 1980 (1)
- 8 July 1980 (3)
- 16 July 1980 (1)
- 30-31 July 1980 (5)
- 27 February 1981 (1)

Final report audit:

24-27 February 1981

Dates of reports to management:

- 5 February 1980
- 8 July 1980
- 8 July 1980
- 17 July 1980
- 5 August 1980
- 27 February 1981

27 February 1981

Drs. D. van Battum
Quality Assurance Manager

date: 27 February 1981

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actice.
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