

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS: NONE

8EHQ-0105-15923

RECEIVED  
OPPT/CBIC

05 FEB -8 AM 7:20

Docket Number, if any: #

1.0 SUBMISSION TYPE

8(d)  8(e)  FYI  4  OTHER: Specify \_\_\_\_\_  
 XX- Initial Submission - Follow-up Submission  Final Report Submission  
 Previous EPA Submission Number or Title if update or follow-up: \_\_\_\_\_

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  
 7106 4575 1292 0338 0043  
 05-2-01

2.3 FOR EPA USE ONLY

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY

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

CAS#: 4098-71-9

Isophorondiisocyanate (IPDI)

Purity \_\_\_%

X- Single Ingredient

Commercial/Tech Grade

Mixture

Trade Name *Desmodur I*

Common Name:

CAS Number

NAME

% WEIGHT

Other chemical(s) present  
 in tested mixture

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CONTAINS NO CBI

2005 FEB 15 AM 9:03

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4.0 REPORT/STUDY TITLE

Isophorondiisocyanate (IPDI): Developmental toxicity study in rats after inhalation - T7072620

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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 SUBJECT ROUTE OF VEHICLE OF  
 TYPE: DTOX ORGANISM (HE, EE) RAT EXPOSURE (HE only): EXPOSURE (HE only)  
 Other: Other: Other: Other:

6.0 REPORT/STUDY INFORMATION

Study is GLP

Laboratory Bayer Toxicology Report/Study Date: 1/3/2005

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

continuation sheet attached

7.0 SUBMITTER INFORMATION

Janet M. Mostowy, Ph.D.

VP, Product Safety & Regulatory Affairs

Phone: 412-777-3490

Bayer Material Science Corporation - 100 Bayer Road, Pittsburgh, PA. 15205

Technical Contact: SAME AS ABOVE Phone: ( )

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8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS

This compound is a commercial product.

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Submitter Signature: [Signature]

Date: 1/18/05

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## 9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0338 0043  
05-2-01

### Continuation of 2.1

#### **Reporting was based on the following results:**

Wistar rats were treated daily for 6 hours/day by inhalation (nose-only exposure) with Isophorondiisocyanat (IPDI; active ingredient 99.8%) from day 6 to day 19 p.c. Air concentrations were 0, 0.25, 1 and 4 mg/m<sup>3</sup>.

Treatment with Isophorondiisocyanat at the 4 mg/m<sup>3</sup> exposure level affected the respiratory tract (bradypnea, laboured breathing, breathing sounds, reddish encrusted nostrils, serous nasal discharge). Furthermore, decreased feed intake, body weight loss for 2 days and reduced body weight gain were evident in the 4 mg/m<sup>3</sup> exposure group. Necropsy revealed no treatment related gross pathological findings at an exposure level up to and including 4 mg/m<sup>3</sup>. Intrauterine development, gestation rate, postimplantation loss, mean litter size, fetal sex distribution and placental appearance were not affected by treatment. Reduced fetal weight, and marginally reduced placental weight were observed at the 4 mg/m<sup>3</sup> exposure level. No treatment related effect on the incidence and type of fetal malformations was evident. Slightly retarded ossification (phalanges, sternbrae, sacral and caudal vertebrae) was found and slightly delayed descensus testis could not be completely excluded at the 4 mg/m<sup>3</sup> exposure level in relation to decreased fetal weights and dose dependency.

The TSCA 8(e) Reporting Guidance states "serious adverse developmental effects (e.g., significant embryo or fetal lethality, significantly reduced fetal/birth weights, significantly retarded/incomplete skeletal ossification) should be reported." In this report reduced fetal weight, delayed descensus testis, and slightly retarded ossification were indicative of delayed fetal development and were only seen in the presence of maternal toxicity and thus considered secondary effects. These findings may be reportable under TSCA 8(e).