

TSCA HEALTH & SAFETY STUDY COVER SHEET

281741

TSCA CBI STATUS: NONE

8HQ-1204-15880

RECEIVED
OCT 22 2004

21 DEC 22 11:18

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: _____

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

7106 4575 1292 0338 1231
04-2-25

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

NO CBI

continuation sheet attached

4.0 REPORT/STUDY TITLE

Isophorondiisocyanate (IPDI): Pilot-subacute inhalation toxicity on rats (exposure 5 x 6 hours/day)

continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

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

6.0 REPORT/STUDY INFORMATION Study is GLP

Laboratory Bayer AG CropScience Toxicology Report/Study Date: 12/8/04

Source of Data/Study Sponsor (if different than submitter) Bayer 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: () _____

continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS

This compound is a commercial product.

continuation sheet attached

Submitter Signature: _____

Date: 12/15/04



RECEIVED
OCT 22 2004

9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0338 1231

04-2-25

Continuation of 2.1

Male and female rats were exposed to aerosol concentrations of 0, 1.04, 4.08 and 15.3 mg/m³ and a subgroup was maintained for a 2-week recovery period. A significant observation was limp in both male and female rats exposed to 15 mg/m³. The highest prevalence occurred on the first day of exposure and diminished with each daily exposure. This sign was not observed in females 24 hours post-exposure, however, it persisted for three days post-exposure in males. Other findings suggestive of effects on respiratory system (observations of breathing abnormalities) and spleen (decreased weights) were observed but the absence of histopathological evaluations precludes a more definitive assessment of the adversity of these findings. Thus, the observation of limp as a neuromuscular effect may be reportable because it persisted for more than 2 days post-exposure.