

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CB

E

BEHQ-0102-15041

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2002 JAN 10 AM 11:08

1.0 SUBMISSION TYPE

8(d) XX 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 0337 7968
01-2-22

2.3 FOR EPA USE ONLY

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY

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

CAS# 57116-45-7 1-Aziridinepropanoic acid, 2-((3-(1-aziridinyl)-1-oxopropoxy)methyl)-2-(hydroxymethyl)-1,3-propanediyl ester

Purity ___%

X- Single Ingredient

† Commercial/Tech Grade

Mixture

Trade Name: XAMA-7

Common Name:

CAS Number

NAME

% WEIGHT

Other chemical(s) present in tested mixture

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4.0 REPORT/STUDY TITLE

Acute Inhalation Study in Rats, T2070988

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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 SUBJECT ROUTE OF VEHICLE OF
TYPE: AIHT ORGANISM (HE, EE only) RATS EXPOSURE (HE only): _____ EXPOSURE (HE only) _____
Other: _____ Other: _____ Other: _____ Other: _____

6.0 REPORT/STUDY INFORMATION

Study is GLP

Laboratory Bayer Toxicology Report/Study Date: 10/12/01

Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _ _

continuation sheet attached

7.0 SUBMITTER INFORMATION

Janet M. Mostowy, Ph.D.
VP, Product Safety & Regulatory Affairs
Bayer Corporation - 100 Bayer Road, Pittsburgh, PA. 15205

Phone: 412-777-3490

Technical Contact: SAME AS ABOVE

Phone: _____

continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS

This compound is a commercial product. Information will be made known to appropriate personnel and sources.

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Submitter Signature: _____

Date: 10/25/01

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9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0337 7968

01-2-22

Continuation of 2.1

TSCA 8(e) Evaluation: As the LC50 was less than 2 mg/l for males and females, the results from this study are being reported.

Summary

The acute inhalation toxicity of IONAC XAMA-7 was evaluated using four groups of rats. The rats were nose-only exposed to a mean liquid aerosol concentration of 107, 303, 377, and 490 mg test substance/m³ air.

The LC50 = 338 mg/m³ (0.338 mg/l) for males and females.

The NO(A)EL = < 107 mg/m³ (0.107 mg/l) for males and females.

Mortality occurred at exposure concentrations of 303 mg/m³ and above and most rats succumbed between post-exposure days 2-3. A delayed onset of mortality was not observed. In all groups, clinical signs were governed by respiratory tract irritation and related effects. Detailed clinical observations revealed piloerection, ungroomed hair-coat, bradypnea, labored and irregular breathing pattern, dyspnea, tachypnea, breathing sounds and stridor, cyanosis, serous nasal discharge, nostrils/muzzle reddened and with red encrustations, motility reduced, limp, high-legged gait, salivation, emesis, mydriasis, decreased reflexes, tremor, hypothermia, and decreased body weights. Necropsy findings were suggestive of lung edema and associated damage of the entire respiratory tract. Evidence of lung injury was also observed in surviving rats.

In summary, the aerosolized IONAC XAMA-7 (liquid aerosol) proved to have a moderate to high acute inhalation toxicity to rats. Mortality was considered to be causally related to respiratory tract irritation and ensuing damage.