

TSCA HEALTH & SAFETY STUDY COVER SHEET

TECA CBI STATUS: NONE

8EHQ-0102-15042

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2002 JAN 10 AM 11:08

1.0 SUBMISSION TYPE 8(d) <input checked="" type="checkbox"/> XX 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 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 <input checked="" type="checkbox"/> NO <input type="checkbox"/>	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID 7166 4575 1292 0337 7968 01-2-23	2.3 FOR EPA USE ONLY						
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS# 64265-57-2 1-Aziridinepropanoic acid, 2-methyl-, 2-ethyl-2-((3-(2-methyl-1-aziridinyl)-1-oxopropoxy)methyl)-1,3-propanediyl ester Purity ___% X- Single Ingredient Commercial/Tech Grade Mixture Trade Name: XAMA-220 Common Name: _____ <table border="1"> <thead> <tr> <th>CAS Number</th> <th>NAME</th> <th>% WEIGHT</th> </tr> </thead> <tbody> <tr> <td colspan="3">Other chemical(s) present in tested mixture</td> </tr> </tbody> </table> continuation sheet attached			CAS Number	NAME	% WEIGHT	Other chemical(s) present in tested mixture		
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Other chemical(s) present in tested mixture								
4.0 REPORT/STUDY TITLE Acute Inhalation Study in Rats, T4071024 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 SUBJECT ROUTE OF EXPOSURE (HE only): _____ VEHICLE OF EXPOSURE (HE only): _____ TYPE: <u>AIHT</u> ORGANISM (HE, EE only) <u>RATS</u> EXPOSURE (HE only): _____ Other: _____ Other: _____ Other: _____ Other: _____								
6.0 REPORT/STUDY INFORMATION Study is GLP Laboratory <u>Bayer Toxicology</u> 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 Phone: 412-777-3490 Bayer Corporation - 100 Bayer Road, Pittsburgh, PA. 15205 Technical Contact: <u>SAME AS ABOVE</u> 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. continuation sheet attached								

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Submitter Signature: [Signature] Date: 10/25/01



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9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0337 7968

01-2-23

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-220 was evaluated using five groups of rats. The rats were nose-only exposed to a mean liquid aerosol concentration of 105, 164.4, 280.8, 403.8 and 478.0 mg test substance/m³ air.

The LC50 = 252 mg/m³ (0.252 mg/l) for males and females.

The NO(A)EL = < 105 mg/m³ (0.105 mg/l) for males and females.

Mortality occurred at exposure concentrations of 105 mg/m³ and above and rats succumbed on the day of exposure until post-exposure day 8. In all groups, clinical signs were governed by respiratory tract irritation and related effects which, in some rats, did not resolve entirely during the 2-week post-exposure period. Detailed clinical observation revealed piloerection, ungroomed hair-coat, bradypnea, labored and irregular breathing pattern, dyspnea, tachypnea, breathing sounds (rales and stridor), cyanosis, serous nasal discharge, nostrils/muzzle reddened and with red encrustations, motility reduced, limp, high-legged and uncoordinated gait, giddiness, hyper-alert, apathy, emaciation, 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-220 (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.