

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS: NONE

8EHQ-0202-15081

RECEIVED
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2002 FEB 21 AM 11:00

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 0338 1408

02-2-05

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

polyfunctional aziridine

Purity ___%

X- Single Ingredient

Commercial/Tech Grade

Mixture

Trade Name IONAC XAMA-7

Common Name: _____

CAS Number

NAME

% WEIGHT

Other chemical(s) present
in tested mixture

continuation sheet attached

4.0 REPORT/STUDY TITLE

Micronucleus Test on the Male Mouse

continuation sheet attached

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 TYPE:	SUBJECT	ROUTE OF EXPOSURE (HE only):	VEHICLE OF EXPOSURE (HE only):
Other:	ORGANISM (HE, EE only) <u>MICE</u>	Other:	Other:

6.0 REPORT/STUDY INFORMATION

Study is GLP

Laboratory Bayer Toxicology Report/Study Date : 1/28/02

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

Contain NO CBI

This compound is a commercial product and information will be made know in product literature.

continuation sheet attached

Submitter Signature: [Signature] Date: 1/30/02

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18051-20-0188

9.0 CONTINUATION SHEET

Submitter Tracking Number/Internal ID

7106 4575 1292 0338 1408
02-2-5

Continuation of 2.1

As this study showed that IONAC XAMA-7 was clastogenic in an in vivo system, thus the reporting.

Summary

The micronucleus test was used to investigate the clastogenic effect of IONAC XAMA-7 on the chromosomes of bone-marrow erythroblasts in male NMRI mice. The known clastogen and cytostatic agent, cyclophosphamide, served as a positive control.

Five mice per dose group were dosed with two intraperitoneal injections, separated by 24 hours, of 0, 1.25, 2.5, and 5 mg/kg of IONAC XAMA-7. Mice in the positive control group received a single intraperitoneal injection of 20 mg/kg of cyclophosphamide. The femoral marrow of all groups was prepared 24 hours after the last test substance administration.

Males treated twice with IONAC XAMA-7 showed symptoms of toxicity after administration, starting at 1.25 mg/kg. These symptoms demonstrate relevant systemic exposure of the mice to IONAC XAMA-7. One animal died after treatment with 1.25 mg/kg of IONAC XAMA-7 and 1 animal died after treatment with 5 mg/kg of IONAC XAMA-7.

There was an altered ratio between polychromatic and normochromatic erythrocytes. This finding demonstrated a relevant systemic exposure of the mice to IONAC XAMA-7.

After two intraperitoneal treatments with IONAC XAMA-7, there were clear indications of a clastogenic effect in all IONAC XAMA-7 dose groups.

Cyclophosphamide, the positive control, had a clear clastogenic effect, as demonstrated by the biologically relevant increase in polychromatic erythrocytes with micronuclei. The ratio of polychromatic to normochromatic erythrocytes was not altered.