

Contains No CBI



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92 SEP 24 PM 1:14

September 15, 1992

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460
Attn: 8(e) Coordinator (CAP Agreement)

8EHQ-92-12502

88920010687

INIT

Dear Sir or Madam:

Subject: Report submitted in accordance with guidelines established by the U. S. Environmental Protection Agency Registration and Agreement for the TSCA 8(e) Compliance Audit Program

Report submitted by: Eastman Kodak Company
343 State Street
Rochester, NY 14650
(716) 724-4000
CAP Agreement Identification Number (8ECAP-0039)

This report pertains to 2-[[ethyl-(3-methyl-4-nitrosophenyl)]amino]ethanol (synonym: N-ethyl-N-(2-hydroxyethyl)-3-methyl-4-nitrosoaniline) [CAS# 58066-96-9] and is being submitted because of effects observed during a study conducted by multiple routes of exposure. The test material caused severe eye irritation in rabbits; washing the eyes after application of the test material was palliative. The test material also was a potent skin sensitizer in guinea pigs. The title of the report being submitted is "Basic Toxicity of N-Ethyl-N-(2-hydroxyethyl)-3-methyl-4-nitrosoaniline". In a subacute study, the 1.0% diet was unpalatable. This resulted in stopping the 1.0% exposure after four days. The 0.1% dose group ate normally and showed no overt signs of toxicity. This report is being identified as a study involving other than human effects (Unit II.B.2.b of CAP Agreement).

This material is used internally at a single site and is not sold as a pure chemical or in a mixture.

Questions regarding this submission should be addressed to:
Mr. William Hart, Eastman Kodak Company
Corporate Health and Environment Laboratories
Rochester, NY 14652-3615
(716) 722-5991

Sincerely,

R. Hays Bell

R. Hays Bell, Ph.D., Vice President
Corporate Health, Safety and Environment
(716) 722-5036

mm
2/9/95

RHB:DRG
Enclosure



2
TL-77-74

Basic Toxicity of N-Ethyl-N-(2-hydroxyethyl)-3-methyl-
4-nitrosoaniline

Toxicology Section

Written by: C. J. Terhaar

September 16, 1977

Basic Toxicity of N-Ethyl-N-(2-hydroxyethyl)-3-methyl-
4-nitrosoaniline

The approximate oral LD₅₀ was 336 mg/kg and 179 mg/kg for rats and mice respectively. It caused only slight skin irritation when held under an occlusive patch for 24 hours. However, when applied daily for two work weeks on uncovered guinea pig skin, an exacerbation of the reaction resulted in the formation of heavy black eschars. It elicited a potent allergic contact dermatitis in 5/10 guinea pigs. When the powder was placed in the lower conjunctival sac, it caused nearly total destruction of 3/3 eyes and their adnexae. However, when 3/3 eyes were washed with water promptly (approximately 30 seconds) after contact, only slight irritation and no tissue destruction was seen.

Rats were placed on diets containing 1.0%, 0.1% and 0.0% of the compound. The rats exposed to the 1.0% diet refused to eat, lost weight and were discarded after four days. The 0.1% group ate, gained weight normally and showed no overt signs of toxicity. They consumed approximately 100 mg cpd/kg b.w./day for 12 days. Their urines were colored more deeply yellow than normal. Their hemoglobin concentration, hematocrit, white blood cell count and differential counts were normal. There was a slight increase in polychromasia and macrocytes in 3/5 animals. The following sera components were assayed and found to be normal: glutamic oxaloacetic transaminase, glutamic pyruvic transaminase, lactic dehydrogenase, urea nitrogen glucose and alkaline phosphatase. At necropsy, the mean absolute and relative liver, kidney and spleen weights were

comparable to the control group. No treatment related gross or microscopic lesions were seen. The hematopoietic system may be the primary site of toxic action.

The 96 hour static LC_{50} was 0.6 mg/l for fathead minnows and 3.2 mg/l for daphnids, snails and flatworms. A saturated aqueous solution had no effect on germination of ryegrass, radish or lettuce seeds. Root growth of the germinating plants was inhibited at concentrations above 10 mg/l as was hypocotyl growth of radish and lettuce; ryegrass hypocotyl growth was inhibited at concentrations greater than 100 mg/l. Young corn and marigold plants were unaffected by saturated aqueous solutions while radish and lettuce plant growth was inhibited at concentrations greater than 100 mg/l. The Industrial Laboratory, Kodak Park, reported that BOD tests could not be made because of the insolubility of the compound. They reported a TOD of 2.10 and a COD of 1.70, both expressed as g O_2 /g sample.

CTJ:bdo

Summary of Basic Toxicity

Chemical N-Ethyl-N-(2-hydroxyethyl)-3-methyl-4-nitrosoaniline

Date 9-16-77

LD ₅₀ mg/kg	P.O.	I.P.
Rats	336(239-472)	ND
Mice	179(100-283)	ND

Remarks:

Skin Irritation (covered) Slight Moderate Strong Absorption: Not evident

Remarks:

Eye Irritation

	Slight	Moderate	Strong	<u>Fluorescein stain</u>	
				Cornea	Adnexa
No. washed	3/3				
No. unwashed			3/3*		

Remarks: *Animals sacrificed. Massive necrosis of orb and adnexa.

Skin Sensitization Potential No. guinea pigs 10

None 5/10 Weak Moderate Potent 5/10

Remarks:

Repeated (10 days) Skin Application (uncovered) No. guinea pigs 5

Remarks: Day 1: Slight erythema. Day 6: Moderate erythema, small eschars.
Day 10: Erythema, moderate edema, heavy black eschars.

Other Tests

6

Summary of Basic Toxicity--2

Repeated Feeding	No. rats/group <u>5</u>		No. days <u>12</u>		Added to diet in corn oil	
	<u>1.0 %</u>	<u>0.1%</u>	<u>1.0 %</u>	<u>0.1 %</u>		
Weight gain	<u>+3</u>	<u>N</u>	Hematology			
Feed intake	<u>+3</u>	<u>N</u>	Hgb.	<u> </u>	<u>N</u>	Slight increase in polychromasia and macrocytes.
Signs/behavior	<u>*</u>	<u>N</u>	Hct.	<u> </u>	<u>N</u>	
*Animals discarded.			WBC	<u> </u>	<u>N</u>	
Clinical Chemistry:			Diff.	<u> </u>	<u>N</u>	
			Organ weight:			
GOT	<u> </u>	<u>N</u>	Liver		Spleen	
GPT	<u> </u>	<u>N</u>	Abs.	<u> </u>	Abs.	<u>N</u>
LDH	<u> </u>	<u>N</u>	Rel.	<u> </u>	Rel.	<u>N</u>
UN	<u> </u>	<u>N</u>	Kidney			
Gluc.	<u> </u>	<u>N</u>	Abs.	<u> </u>		
AP	<u> </u>	<u>N</u>	Rel.	<u> </u>		

Urine colored yellow

Pathology

No treatment related gross or microscopic lesions were seen.

Repeated Inhalation	ND	Concn. <u> </u>	No. rats <u> </u>	No. days <u> </u>
Wt. change	<u> </u>	Signs/behavior	<u> </u>	
Hemat.:	Hgb. <u> </u>	Hct. <u> </u>	WBC <u> </u>	Diff. <u> </u>
Clin. Chem.:	GOT <u> </u>	GPT <u> </u>	AP <u> </u>	LDH <u> </u>
			UN <u> </u>	Gluc. <u> </u>

Pathology

Static 96 hour LC₅₀ (mg/l ~~XXXXXX~~ Added to aquaria in acetone

Fathead minnows	<u>0.6</u>	Snails	<u>3.2</u>	Daphnids	<u>3.2</u>	Flatworms	<u>3.2</u>
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No effect concn.	Germination	Root Growth	Hypocotyl Growth
Ryegrass	<u>1000</u>	<u>10</u>	<u>100</u>
Radish	<u>"</u>	<u>"</u>	<u>10</u>
Lettuce	<u>"</u>	<u>"</u>	<u>10</u>

Remarks:

7

Summary of Basic Toxicity--3

No effect concn. Early Plant Growth

Marigold	<u>1000</u>
Radish	<u>100</u>
Corn	<u>1000</u>
Lettuce	<u>100</u>

Remarks:

Industrial Laboratory (g O₂/g sample)

BOD₅ ND BOD₂₀ ND TOD 2.10 COD 1.70

Insoluble

Legend

- ↑ Increased
- ↓ Decreased
- 1 Slight
- 2 Moderate
- 3 Great
- N Normal
- ND Not done



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

R. Hays Bell, Ph.D.
Vice President, Corporate Health, Safety, and Environment
Eastman Kodak Company
343 State Street
Rochester, New York 14650

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 06 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12502A



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Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 17502A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

~~ECO~~

~~AQUATO~~

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 1

pages 4, 5, 6, 7

Notes:

Contractor reviewer: PAR

Date: 3/13/95



CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ-0902-12502 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Eastman Kodak
Company

INFORMATION REQUESTED: FLWP DATE: _____
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONALE)
 DISPOSITION:
 0639 REFER TO CHEMICAL SCREENING
 0678 CAP NOTICE

VOLUNTARY ACTIONS:
 0401 NO ACTION REPORTED
 0402 STUDIES PLANNED/IN PROGRESS
 0403 NOTIFICATION OF WORKER RESOLUTIONS
 0404 LABEL/MSDS CHANGES
 0405 PROCESS/HANDLING CHANGES
 0406 APP/USE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB. DATE: 09/15/92 OTS DATE: 09/24/92 CSRAD DATE: 02/09/95

CHEMICAL NAME: _____

CASE# 58066-96-9

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCC/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0239 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY

YES

CAS SR

NO

IN TERMINI

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

SPECIES

RBT, DUCK, SP, RAT, MUS, FISH

TOXICOLOGICAL CONCERN:

LOW SBTX
MED ATOX (oral, dermal irr.)
HIGH ATOX (eye irr.)

USE:

INTERNAL

PRODUCTION:

at single site

12502A

M

Acute oral toxicity in rats and mice is of moderate concern. Single oral doses to rats and mice resulted in LD₅₀ values of 336 and 179 mg/kg, respectively.

M

Dermal irritation in guinea pigs is of moderate concern. A single application resulted in only slight irritation. However, repeated application (10 doses) to guinea pig skin resulted in the formation of heavy black eschars.

M

Dermal sensitization in guinea pigs is of moderate concern. The compound elicited a potent allergic contact dermatitis in 5/10 guinea pigs.

H

Eye irritation is of high concern. Application to the lower conjunctival sac caused nearly total destruction of 3/3 unwashed eyes and their adnexae. In 3/3 washed eyes, only slight irritation and no destruction were seen.

L

Subacute oral toxicity in rats is of low concern. Repeated oral doses were given to rats (5/group) at levels of 0, 0.1, and 1.0% in diet for 12 days. The rats given 1.0% exhibited decreased food consumption and weight loss and were sacrificed after four days. Rats given 0.1% (50 mg/kg/day) exhibited a slight increase in polychromasia and macrocytes. There were no adverse findings at necropsy.