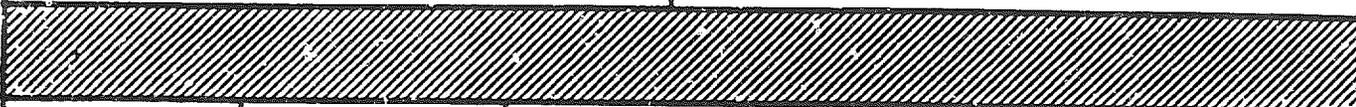
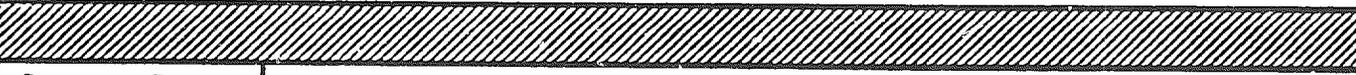


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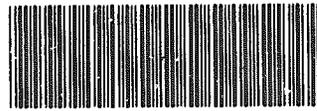
GE Corporate Research and Development

Building K1, Room 1A69
February 14, 1992

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Report of TSCA Section 8(e) Information

The attached information is being submitted to the United States Environmental Protection Agency pursuant to TSCA Section 8(e) (15 U.S.C. 2067(e)). We became aware of these studies during the course of our Consent Order Section 8(e) audit. We are herewith submitting the information as required under the referenced Consent Order.

CASE #1

Study Title: Acute Toxicity Screening Studies in Rats and Rabbits-AR 81242
Substance(s): N,N-di-tertiarybutyl ethylenediamine CAS# 4062-60-6
Adverse Effects: Acute dermal toxicity of possibly less than 200 mg/kg in rabbits.
Comments: A 1973 non-GLP toxicity screening study, which found the material to be an extreme eye irritant, primary skin irritant, as well as moderately toxic by the dermal route. The material is on the TSCA Inventory, and was used as an R&D chemical.

Case #2

Study Title: Acute Toxicity Screening Studies in Rats and Rabbits-AR 84996
Substance: Butyl dimethylamine CAS# 927-62-8
Adverse Effects: Neurotoxicity in non-moribund animals
Comments: A 1975 non-GLP study, which found the material to cause neurotoxic symptoms, during inhalation studies, using rats, at airborne concentrations of 2 mg/L. The material is on the TSCA Inventory and was used as an R&D chemical during the time of the study.

Case #3

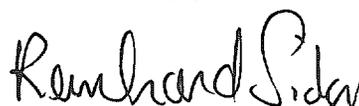
Study Title: Acute Inhalation Toxicity in the Albino Rat-AR85124
Substance: Isobutyl methacrylate CAS# 97-86-9
Adverse Effects: Neurotoxic signs during inhalation study.
Comments: A 1975 non-GLP study, which found the material to be only slightly toxic by inhalation, however noted neurotoxic sign in non-moribund rats. The material is on the TSCA Inventory and was used as an R&D chemical during the time of the study.

Case #:

Study Title: Acute Toxicity Screening Studies in Rats and Rabbits-AR 98447
Substance: Bis-(3-aminopropyl) tetramethyl disiloxane CAS# 2469-55-8
Adverse Effects: Potentially a moderately to highly toxic material, by oral route in rats.
Comments: A 1985 study following GLP. While the study found the material to be maximally irritating to the eyes, and severely irritating to the skin, these results were to be expected of amines; the report is being submitted however because of the finding that this material has an oral LD-50 of less than 500 mg/kg, in rats. This material is on the TSCA inventory.

Please call if there are questions on the above.

Sincerely yours,



Reinhard Sidor, Administrator
Industrial Hygiene/Safety

cc V. Giordano, CEP
J. Magee

**GE-Corporate Research and Development
Schenectady, NY**

TSCA 8(e) Submittal

Case #1

Acute Toxicity Screening Studies in Rats and Rabbits

AR 81242

N,N-di-tertiarybutyl ethylenediamine

CAS#4062-60-6

TS(A 3 (e) Audit
GE-(RD)-91-005

X HN CHL CVL NH X

International Research and Development Corporation

SPONSOR: General Electric Company
COMPOUND: AR 81242
SUBJECT: Acute Toxicity Screening Studies
in Rats and Rabbits.



Francis X. Wazetex, Ph.D.
President



Edwin I. Goldenthal, Ph.D.
Director of Research

Collaborator:

W. P. Dean

Date: May 16, 1973

International Research and Development Corporation

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I. SYNOPSIS

AR 81242 was evaluated for acute toxicity in rats and rabbits. The following screening tests were conducted and the results as indicated were obtained:

Eye Irritation in the Albino Rabbit:

An extreme irritant and corrosive substance to the eyes.

Primary Skin Irritation in the Albino Rabbit:

A primary skin irritant.

Acute Dermal Toxicity in the Albino Rabbit:

A corrosive and a toxic (and a possibly highly toxic) substance by the dermal route of administration.

Acute Oral Toxicity in the Albino Rat:

A toxic but not highly toxic substance by the oral route of administration.

II. COMPOUND

The test compound was received from the General Electric Company, Schenectady, New York on March 27, 1973.

It was identified as "AR 81242, 3-21-73" and was received as a clear liquid.

III. EYE IRRITATION SCREENING TEST IN THE ALBINO RABBIT (Unwashed Technique):

A. METHOD:

Two rabbits (1 male and 1 female) were used in this test. The rabbits weighed 3082 grams (male) and 3439 grams (female). Food and water were available ad libitum.

Prior to compound administration, the eyes of each rabbit were examined with ultraviolet light after instillation of one drop of a 2.0 percent sodium fluorescein solution. Rabbits exhibiting corneal lesions were discarded.

0.1 milliliter of the test material was instilled into the cupped conjunctival sac of one eye of each rabbit.

Examinations were made for ocular irritation at 24, 48 and 72 hours. At the 72 hour examination, sodium fluorescein and ultraviolet light were used again to aid in revealing possible corneal injury.

The scale for scoring ocular irritation appears on the following page.

B. RESULTS:

Examination at 72 hours with sodium fluorescein and ultraviolet light revealed evidence of corneal damage in both rabbits tested.

Table 1 presents a summary of the results obtained at each examination period. The average scores for each examination period are presented in Table 2.

Based upon the results obtained, AR 81242 would be considered an extreme irritant and corrosive substance to the eyes.

(1) Cornea

(A) Opacity-degree of density (area most dense taken for reading)

No opacity	0
Scattered or diffuse area, details of iris clearly visible	1
Easily discernible translucent areas, details of iris slightly obscured.	2
Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
Opaque, iris invisible	4

(B) Area of cornea involved

One quarter (or less) but not zero	1
Greater than one quarter, but less than half	2
Greater than half, but less than three quarters.	3
Greater than three quarters, up to whole area.	4

Score equals A x B x 5 Total maximum = 80

(2) Iris

(A) Values

Normal	0
Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive)	1
No reaction to light, hemorrhage, gross destruction (any or all of these)	2

Score equals A x 5 Total maximum = 10

(3) Conjunctivae

(A) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)

Vessels normal	0
Vessels definitely injected above normal	1
More diffuse, deeper crimson red, individual vessels not easily discernible	2
Diffuse beefy red.	3

(B) Chemosis

No swelling.	0
Any swelling above normal (includes nictitating membrane).	1
Obvious swelling with partial eversion of lids	2
Swelling with lids about half closed	3
Swelling with lids about half closed to completely closed.	4

(C) Discharge

No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals).	1
Discharge with moistening of the lids and hairs just adjacent to the lids	2
Discharge with moistening of the lids and hairs, and considerable area around the eye	3

Score equals (A + B + C) x 2 Total maximum = 20

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae. Total maximum score possible = 110

* Draize, J. H., Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics, Assoc. Food and Drug Officials of the U. S., Austin, Texas, 1959, p. 51, Modified according to revision in 1964. Edited by A. J. Lehman.

AR 81242:

Eye Irritation in the Albino Rabbit.

TABLE 1. Observations.

Observation	Examination Interval			
	(No. Positive/No. Dosed)			
	24	48	72	
<u>Cornea:</u>	Dulling normal corneal luster			
	Corneal opacity: very slight	1/2	0/2	0/2
	slight			
	moderate	1/2	2/2	2/2
	marked			
<u>Iris:</u>	Iridal Irritation	2/2	2/2	2/2
<u>Conjunctivae:</u>	Redness:			
	very slight			
	slight			
	moderate	2/2	2/2	1/2*
	marked			
	Chemosis:			
	very slight			
	slight			
	moderate	1/2	0/2	0/2
	marked	1/2	2/2	2/2
	Discharge:			
	very slight			
	slight			
	moderate	1/2	0/2	1/2
	marked	1/2	2/2	1/2
	Purulent Discharge			
<u>Other:</u>				
	Alopecia, around eye	1/2	1/2	1/2
	Necrosis, conjunctivae	2/2	2/2	2/2
	Blanching, conjunctivae	2/2	2/2	2/2
	Hemorrhage, conjunctivae	1/2	0/2	1/2
	Black staining, around eye	2/2	2/2	0/2
	*Observation for redness precluded by blanching			1/2

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AR 81242:

Eye Irritation in the Albino Rabbit.

TABLE 2.

Average Scores.

Ocular Area		Average Scores (Range)		
		Observation Period		
		24	48	72
Cornea	A	2.5 (1.0-4.0)	4.0 (4.0-4.0)	4.0 (4.0-4.0)
	B	4.0 (4.0-4.0)	2.5 (1.0-4.0)	2.5 (1.0-4.0)
Cornea Score		50.0	50.0	50.0
Iris	A	2.0 (2.0-2.0)	2.0 (2.0-2.0)	2.0 (2.0-2.0)
Iris Score		10.0	10.0	10.0
Conjunctivae	A	3.0 (3.0-3.0)	3.0 (3.0-3.0)	1.5 (0 -3.0)
	B	3.5 (3.0-4.0)	4.0 (4.0-4.0)	4.0 (4.0-4.0)
	C	2.5 (2.0-3.0)	3.0 (3.0-3.0)	2.75 (2.5-3.0)
Conjunctivae Score		18.0	20.0	16.5
Total Score		78.0	80.0	76.5

IV. PRIMARY SKIN IRRITATION SCREENING TEST IN THE ALBINO RABBIT

A. METHOD:

Two New Zealand White rabbits (1 male and 1 female) were used. The rabbits weighed 2623 grams (male) and 2470 grams (female) at the beginning of the study period.

The hair was removed from the back of each rabbit with an electric clipper. Food and water were available ad libitum.

0.5 milliliter of the test material was applied to the back of each rabbit. The area of application was then wrapped with a gauze bandage and occluded with Saran Wrap. Twenty-four hours later the bandages were removed and the area was washed with tepid tap water and examined for skin irritation in accordance with the scale on the following page. These examinations were repeated at 72 hours.

B. RESULTS:

Table 3 presents a summation of the primary skin observations and Table 4 presents the computed primary irritation score of 5.6.

Based upon the results obtained, AR 81241 would be considered a primary skin irritant.

	<u>Value*</u>
<u>Erythema and Eschar Formation:</u>	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
<u>Edema Formation:</u>	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4

*The "Value" recorded for each reading is the average value of six or more animals subjected to the test.

The values for erythema and eschar formation at 24 hours and at 72 hours for the intact animals' skin were added to similar values obtained for the abraded skin animals (a total of 4 values).

Similarly, the values for edema formation at 24 and 72 hours for intact and abraded skin animals were added together (a total of 4 values). The primary irritant score is the sum of the 8 values divided by 4. As scored by this method, a primary irritant is a substance which is not corrosive, but which results in a score of 5 or more. (Section 191.1 (g) (2) of the regulations of the Federal Hazardous Substances Act.)

AR 81242: Primary Skin Irritation in the Albino Rabbit.

TABLE 3. Summation of Primary Skin Observations.

Observation	Examination Interval (No. Reacting/No. Dosed)			
	Intact Sites		Abraded Sites	
	24 hrs	72 hrs	24 hrs	72 hrs
Erythema and Eschar Formation				
No erythema				
Very slight erythema				
Well defined erythema	1/1	1/1	1/1	
Moderate to severe erythema				1/1
Severe erythema				
Edema Formation				
No edema				
Very slight edema				
Slight edema			1/1	
Moderate edema	1/1			
Severe edema		1/1		1/1
<u>Other:</u>				
Black discoloration	1/1	1/1		
Brown discoloration			1/1	1/1
Blanching	1/1	1/1	1/1	1/1

AR 81242: Primary Skin Irritation in the Albino Rabbit.

TABLE 4. Primary Irritation Score.

DermaI Irritation	Observation Time	"Value"
Erythema and eschar formation:	Hours	
Intact skin	24	2.0
	72	2.5
Abraded skin	24	2.0
	72	<u>3.0</u>
Subtotal		9.5
Edema formation:		
Intact skin	24	3.0
	72	4.0
Abraded skin	24	2.0
	72	<u>4.0</u>
Subtotal		<u>13.0</u>
Total		22.5

Primary irritation score is $\underline{22.5 \div 4 = 5.6}$

V. ACUTE DERMAL TOXICITY SCREENING TEST IN THE ALBINO RABBIT

A. METHOD:

Two New Zealand White rabbits (1 male and 1 female) were used at each of two dosage levels. The rabbits weighed from 2795 to 3086 grams at the start of the study period. Food and water were available ad libitum. Body weights were measured initially and at 14 days after compound application.

The hair was removed from the back of each rabbit with an electric clipper.

The compound was applied once only to the back of each rabbit. Two rabbits received 200 mg/kg and two rabbits received 2000 mg/kg of the test material. The area of application was then wrapped with a gauze bandage and occluded with Saran Wrap. Twenty-four hours later the bandages were removed and the backs were washed with tepid tap water. The rabbits were observed for mortality for a period of 14 days.

B. RESULTS:

The male rabbit at the 200 mg/kg dosage level and the female rabbit at the 2000 mg/kg dosage level died on the 2nd day following compound administration. The surviving female at the 200 mg/kg dosage level exhibited a 63 gram body weight loss and the surviving male at the 2000 mg/kg dosage level showed a body weight loss of 155 grams during the observation period. Signs seen during the observation period included black skin discoloration, erythema, edema, blanching, intradermal hemorrhage, necrosis, corrosion of the epithelium exposing muscle tissue, tremors, ataxia and prostration.

Based upon the results obtained, AR 81242 would be considered a corrosive and toxic (and possibly highly toxic) material by the dermal route of administration.

VI. ACUTE ORAL TOXICITY SCREENING TEST IN THE ALBINO RAT

A. METHOD:

Two male albino rats of the Spartan strain were used at each of two dosage levels. The rats weighed from 201 to 205 grams at the initiation of the study period. The animals were maintained in temperature and humidity controlled quarters throughout the study. The rats had food and water available ad libitum except for an overnight period preceding compound administration during which food, but not water, was withheld.

The test material was administered to 2 rats each at dosage levels of 500 and 5000 mg/kg. The test compound was suspended in corn oil at concentrations enabling the administration of 10 ml/kg at both dosage levels. All rats were observed for mortality for a period of 14 days. Body weights were measured initially and at 14 days.

B. RESULTS:

Neither of the rats at the 500 mg/kg dosage level died during the 14 day observation period. Both rats exhibited normal body weight gains.

Both rats at the 5000mg/kg dosage level died within four hours following compound administration.

Based upon the results obtained, AR 81242 would be considered a toxic but not highly toxic material by the oral route of administration.