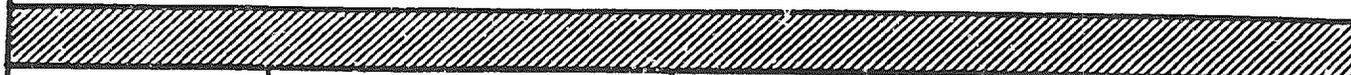
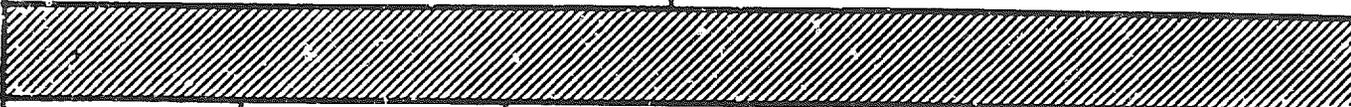
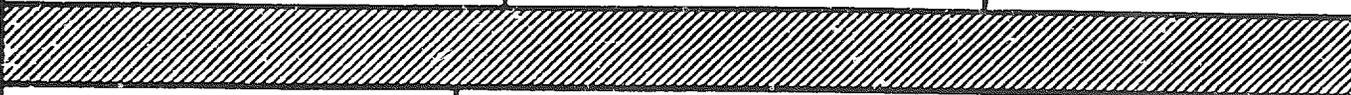
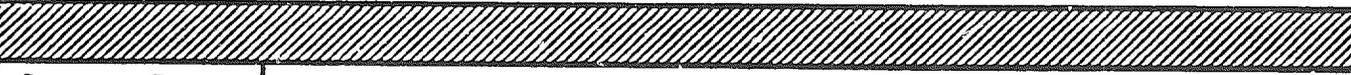


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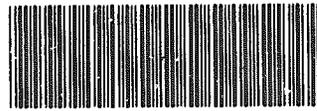
GE Corporate Research and Development

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-moribound 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

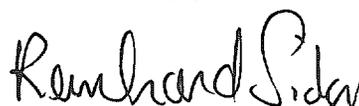
Study Title: Acute Inhalation Toxicity in the Albino Rat-AR85124
Substance: Isobutyl methacrylate CAS# 97-86-9
Adverse Effects: Neurotoxic signs during inhalation study.
Comments: A 1975 non-GLP study, which found the material to be only slightly toxic by inhalation, however noted neurotoxic sign in non-moribound 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

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

TSCA 8(e) Submittal

Case #2

Acute Toxicity Screening Studies in Rats and Rabbits

AR 84996

Butyl dimethylamine

CAS#927-62-8

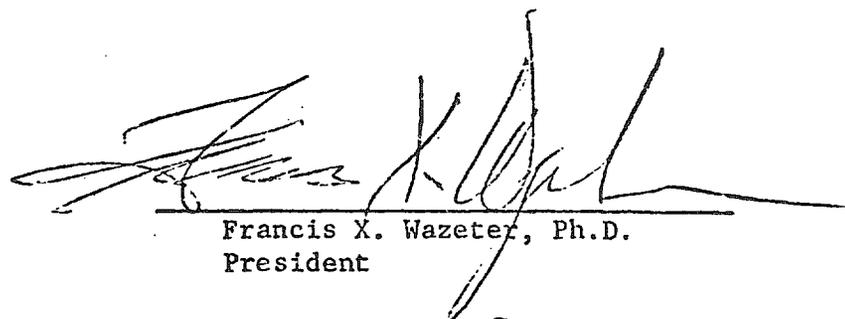
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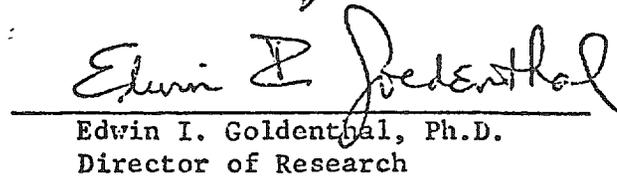
International Research and Development Corporation

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SPONSOR: General Electric Company
COMPOUND: AR 84996
SUBJECT: Acute Toxicity Screening
Studies in Rats and Rabbits.



Francis X. Wazeter, Ph.D.
President



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

Collaborator:

W. P. Dean, B.A.,
Director of Acute Toxicology

Date: November 5, 1975

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I. SYNOPSIS

AR 84996 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 eye irritant.

Primary Skin Irritation in the Albino Rabbit:

Not a primary skin irritant.

Acute Dermal Toxicity in the Albino Rabbit:

Not a toxic substance by the dermal route of administration.

Acute Inhalation Toxicity in the Albino Rat:

A toxic, but not highly toxic, substance by the inhalation 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

Two samples of the test compound were received from the General Electric Company, Schenectady, New York. One sample was received on September 17, 1975. The second sample was received on October 2, 1975. Both samples were identified as "AR 84996" and were received as clear liquids.

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 2941 grams (male) and 2706 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. This procedure is employed routinely so that only those rabbits with normal eyes are used in eye irritation studies.

0.1 milliliter of the test material was instilled into the 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 of the treated eyes.

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 84996 would be considered an eye irritant.

(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 84996:

Eye Irritation in the Albino Rabbit.

TABLE 1. Observations.

Observation	Examination Interval			
	(No. Positive/No. Dosed)			
	Hours			
	24	48	72	
<u>Cornea:</u>	Cornea Normal			
	Dulling normal corneal luster	1/2		
	Corneal opacity: very slight	1/2	2/2	2/2
	slight			
	moderate			
	marked			
<u>Iris:</u>	Iris Normal			
	Iridal Irritation	2/2	2/2	2/2
<u>Conjunctivae:</u>	Redness:	normal		
		very slight		
		slight		
		moderate	2/2	2/2
		marked		2/2
	Chemosis:	normal		
		very slight		
		slight	1/2	
		moderate	1/2	2/2
		marked		1/2
	Discharge:	normal		
		very slight		
		slight		
		moderate	2/2	1/2
		marked		1/2
	Purulent Discharge		0/2	2/2
<u>Sodium Fluorescein/ Ultraviolet light examination:</u>	Negative: (normal)	---	---	0/2
	Positive: (corneal injury)	---	---	2/2
<u>Other:</u>	Vocalization upon compound instillation	1/2	---	---
	Blanching, conjunctivae	2/2	2/2	2/2

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AR 84996:

Eye Irritation in the Albino Rabbit.

TABLE 2. Average Scores.

Ocular Area		Average Scores (Range)		
		Observation Period		
		24 Hrs.	48 Hrs.	72 Hrs.
Cornea	A	0.8 (0.5-1.0)	1.0 (1.0)	1.0 (1.0)
	B	3.0 (2.0-4.0)	2.0 (2.0)	3.0 (2.0-4.0)
Cornea Score		12.0	10.0	15.0
Iris	A	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)
Iris Score		5.0	5.0	5.0
Conjunctivae	A	2.0 (2.0)	2.3 (2.0-2.5)	2.0 (2.0)
	B	2.8 (2.5-3.0)	3.0 (3.0)	3.8 (3.5-4.0)
	C	2.5 (2.5)	2.5 (2.0-3.0)	2.8 (2.5-3.0)
Conjunctivae Score		14.6	15.6	17.2
Total Score		31.6	30.6	37.2

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 3552 grams (male) and 3251 grams (female) at the beginning of the study period.

The hair was removed from the back of each rabbit with an electric clipper. The skin of one of the rabbits (female #23292) was abraded with a scalpel blade. 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 1.9.

Based upon the results obtained, AR 84996 would not be considered a primary skin irritant.

Value*

Erythema and Eschar Formation:

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

Edema Formation:

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.)

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AR 84996:

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		1/1		1/1
Very slight erythema	1/1			
Well defined erythema			1/1	
Moderate to severe erythema				
Severe erythema				
Edema Formation				
No edema				
Very slight edema		1/1	1/1	1/1
Slight edema	1/1			
Moderate edema				
Severe edema				
Other:				
Atonia	0/1	1/1	0/1	0/1
Coriaceousness	0/1	0/1	0/1	1/1

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AR 84996: Primary Skin Irritation in the Rabbit.

TABLE 4. Primary Irritation Score

Dermal Irritation	Observation Time	"Value"
Erythema and eschar formation:	Hours	
Intact skin	24	1.5
	72	0
Abraded skin	24	2.0
	72	<u>0</u>
Subtotal		3.5
Edema formation:		
Intact skin	24	2.0
	72	0.5
Abraded skin	24	1.0
	72	<u>0.5</u>
Subtotal		<u>4.0</u>
Total		<u>7.5</u>

Primary irritation score is 7.5 ÷ 4 = 1.9

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 2304 to 2487 grams at the beginning 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:

Neither of the rabbits at either dosage level died during the 14 day period of observation. Three of the rabbits exhibited normal body weight gains during the observation period. The male rabbit at the 2000 mg/kg dosage level (#23351) exhibited a 1082 gram loss in body weight.

Based upon the results obtained, AR 84996 would not be considered a toxic material by the dermal route of administration.

VI. ACUTE INHALATION TOXICITY IN THE ALBINO RAT

A. Method:

1. General Procedure:

Ten male and ten female rats of the Charles River CD strain, weighing from 205 to 230 grams, were used in this test. The rats were housed by sex in groups of five in metal cages elevated above the droppings and maintained in temperature and humidity controlled quarters throughout the pre-exposure and post-exposure periods. Purina Laboratory Chow and water were available ad libitum. The rats were divided into 2 groups of five male and five female rats each. One group received the test material at an atmospheric concentration of 2 mg/L., the second group at a concentration of 200 mg/L.

During the 4 hour exposure period to the test compound the rats were observed continuously for changes in behavior and/or appearance. Immediately following the exposure and for a period of 14 days thereafter, the rats were examined closely for pharmacodynamic and/or toxic signs.

2. Compound Administration:

Each group of ten rats was placed in a sealed 59.1 liter glass chamber and exposed for 4 hours to a dynamic atmosphere containing the mist of the test material. In order to prevent "piling up" during the exposure, the rats were separated into 4 units of two or three rats each.

Addition of the test compound to the test chamber atmosphere was controlled by a Harvard Infusion Pump at the 2.0 mg/L. level,

and by a Dow Dual Syringe Feeder at the 200 mg/L. level. Dried and filtered air was passed through the mechanism and directly into the exposure chamber. Airflow was regulated by means of a flowmeter¹.

The calculated atmospheric concentrations administered were approximately 2.0 and 200 mg/L. of AR 84996.

B. Results:

1. 2.0 mg/L:

All of the rats exposed to the 2.0 mg/L. atmospheric concentration survived the 14 day observation period.

Signs observed during the 4 hour exposure period included decreased motor activity, eye squint, erythema, salivation, lacrimation, clear nasal discharge, both ocular and nasal porphyrin discharge, tachypnea, both slight and marked dyspnea, gasping dyspnea, soft stool, ataxia, intermittent subconvulsive body jerking, intermittent tonic convulsions and prostration. At the termination of the exposure period, the same signs were observed as during the exposure period, with the exception of both slight and gasping dyspnea, and erythema, and with the addition of respiratory congestion.

Signs observed during the 14 day observation period following exposure included decreased limb tone in from one to four rats at 24 and 48 hours and 6 through 14 days; corneal opacity in two or three rats from 48 hours through 14 days; ocular porphyrin discharge in two rats at 24 hours; nasal porphyrin discharge in one rat at 24 hours and in two rats at 13 days; decreased motor activity in one rat at 5 and 7 days; respiratory congestion in one rat from 4 through 8 days; and ataxia in one rat at 5, 6 and 7 days.

¹Gelman Instrument Company, Ann Arbor, Michigan, Model No. 8221

VII. ACUTE ORAL TOXICITY SCREENING TEST IN THE ALBINO RAT

A. Method:

Two male albino rats of the Charles River CD strain were used at each of three dosage levels. The rats weighed from 210 to 236 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 two rats each at dosage levels of 50, 500 and 5000 mg/kg. The test compound was suspended in corn oil at concentrations enabling the administration of 10 ml/kg at all 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 50 mg/kg dosage level died during the 14 day observation period. These rats exhibited normal body weight gains.

Both rats at the 500 and 5000 mg/kg level were dead with four hours.

Based upon the results obtained, AR 84996 would be considered a toxic, but not highly toxic, material by the oral route of administration.