CONTAINS NO CBI

The Dow Chemical Company

2030 Dow Center
March 27, 1992

8EHQ-0492-3079 Int

CONTAINS NO CONFIDENTIAL BUSINESS INFORMATION

Document Processing Center
Office of Toxic Substances
Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

88920001721

Attn: 8(e) Coordinator

Re: AMINOETHYLETHANOLAMINE
CAP Agreement No. CAP-0111
Dow Reference No. CAP00112

Dear Sir/Madam:

The Dow Chemical Co. submits the enclosed document titled:

ACUTE TOXICOLOGICAL PROPERTIES AND SKIN SENSITIZATION POTENTIAL OF AMINOETHYLETHANOLAMINE

pursuant to TSCA Section 8(e) Compliance Audit Program.

The document contains information which may reasonably support the conclusion that the referenced chemical may present a substantial risk of injury to human health or the environment, as indicated in the Reporting Guide provided by EPA in connection with the CAP. Dow has not, however, determined that any risk actually exists. The information is summarized below:

A SAMPLE OF AMINOETHYLETHANOLAMINE (AEEA), WAS SUBMITTED TO THE TOXICOLOGY RESEARCH LABORATORY FOR TOXICOLOGICAL EVALUATION, INCLUDING SKIN SENSITIZATION POTENTIAL, AND DEFINITION OF INDUSTRIAL HANDLING HAZARDS. AEEA SHOULD BE CONSIDERED A POTENTIAL HUMAN SKIN SENSITIZER, AS INDICATED BY A POSITIVE GUINEA PIG SENSITIZATION TEST. ALL 10 GUINEA PIGS EXPOSED TO THE TEST MATERIAL WERE SENSITIZED.

Dow requests guidance from EPA whether the Agency believes the information contained in this document satisfies the criteria in the CAP Reporting Guide. Any correspondence relating to this submission should reference document number CAP00112.

Where appropriate, three types of information have been removed from the document: the term "Dow Confidential", individual employee/researcher names (due to privacy considerations); and Dow internal number systems. This is done with prior agreement from EPA. The original documents containing this information are retained by Dow according to a document retention policy.

Sincerely,

Paul A. Wright

Paul A. Wright
Attorney
517/636-1853

R & D REPORT

DOW CHEMICAL U.S.A.

CRI NUMBER

LABORATORY REPORT CODE

DATE ISSUED: November 13, 1980

DEPARTMENT: HEALTH AND ENVIRONMENTAL SCIENCES-TEXAS

LAB. NO. | PROBLEM NO.

TITLE: ACUTE TOXICOLOGICAL PROPERTIES AND SKIN SENSITIZATION POTENTIAL OF AMINOETHYLETHANOLAMINE

PAGES IN FULL REPORT

AUTHOR(S)

AUTHOR(S) SIGNATURE(S)

REVIEWER'S SIGNATURE 11/13/80. 11-13-80

11-13-80
D. V. M.

This report is: ☐ INTERIM ☒ FINAL and mainly: ☒ NEW ☐ REVIEW

DESCRIPTIVE SUMMARY WITH CONCLUSIONS:

A sample of aminoethylethanolamine (AEEA), also known as 2-(2-amino-ethylamino) ethanol, was submitted to the Toxicology Research Laboratory of Health and Environmental Sciences-Texas for toxicological evaluation, including skin sensitization potential, and definition of industrial handling hazards. The test material contains < 100 ppm ethylenediamine.

Eye and skin irritation tests were conducted using New Zealand albino rabbits (Ray Nichols Rabbitry, Lumberton, Texas) and acute oral studies were conducted using Sprague-Dawley rats (Timco Breeding Laboratories, Inc., Pasadena, Texas). Skin sensitization potential was evaluated using male Hartley albino guinea pigs (Buckberg Lab Animals, Inc., Tompkins Cove, N.Y.)

Instillation of the test material into the eyes of a rabbit resulted in moderate pain, very severe redness and swelling of the conjunctiva, and very severe necrosis of the cornea. These severe effects pre-sisted 14 days post-treatment. Every precaution should be taken to prevent eye contact, as an exposure may lead to permanent impairment of vision, even blindness. Chemical workers' goggles should be worn whenever the likelihood of eye contact exists. If contact should occur, flush eyes with plenty of flowing water for at least 15 minutes. Medical attention should be obtained immediately.

Skin irritation properties were evaluated by the method of testing primary irritant substances in accordance with the procedure outlined in the Federal Register, Volume 38, Number 187, Part II, Section 1500.41. A primary irritant is defined as a substance

000112

DISTRIBUTION:

Distribution list is continued on attached page.

FORM C-4300 PRINTED R-3-80

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that human experience data indicates is a primary irritant and/or a substance that results in an empirical score of 5 or more.

Prolonged contact (24 hours) resulted in moderate redness and swelling with irreversible necrosis to the skin of 6 albino rabbits. Because the test material was corrosive to the skin, no primary irritation score could be calculated.

Subsequently, a Department of Transportation (DOT) test for corrosiveness was conducted. A corrosive material is one that causes irreversible change or destruction to the intact skin of an albino rabbit after an exposure period of 4 hours or less. The test procedure used is described in the Code of Federal Regulations, Title 49, Section 173.240, Appendix A. A 4-hour exposure resulted in no irritation to the skin of 6 rabbits. Therefore, the material is not considered corrosive by this test.

Aminoethylethanolamine should be considered a potential human skin sensitizer, as indicated by a positive guinea pig sensitization test. Ten male Hartley albino guinea pigs were exposed in a repeated insult patch test to a 10% solution of AEEA in DOWANOL* DPM glycol ether product: Tween 80 surfactant (9:1). A similar group was exposed to a known mild sensitizer (diglycidyl ether of bisphenol A) as a positive control. All 10 guinea pigs exposed to the test material, as well as all 10 animals exposed to the positive control were sensitized.

Precautions should be taken to avoid skin contact. If contact occurs, the skin should be decontaminated with plenty of water from a safety shower or other suitable device and contaminated clothing thoroughly cleaned before re-use. Protective clothing, impervious to the test material should be worn as required by circumstances.

The acute oral toxicity is low; range-finding tests indicate the single-dose oral LD50 for female rats is between 2000 and 4000 mg/kg when fed undiluted. Before death, rats at the 4000 mg/kg level were lethargic, had shallow breathing, and diarrhea. All rats at the 2000 mg/kg level and below appeared healthy, gained weight, and no visible lesions were observed upon gross pathological examination at 14 days post-treatment. No problem is anticipated from ingestion incidental to industrial handling.

*Trademark of The Dow Chemical Company

HEALTH & ENVIRONMENTAL SCIENCES—TEXAS

LAKE JACKSON, TEXAS

THE DOW CHEMICAL COMPANY

DATA SHEET OF PROPERTIES, HEALTH HAZARDS, AND PRECAUTIONS FOR SAFE HANDLING OF MATERIALS

MOLECULAR FORMULA	NAME
$C_4H_{12}N_2O$	Aminoethylethanol amine
MOLECULAR WEIGHT / INDUSTRIAL HYGIENE GUIDE	SYNONYMS
104.2	AEEA, 2-(2-aminoethylamino) ethanol

STRUCTURAL FORMULA OR COMPOSITION

$H_2N-CH_2-CH_2-NH-CH_2-CH_2-OH$

contains <100 ppm ethylenediamine

PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT	EXPLOSIVE LIMITS % VOL IN AIR	FLASH PT. °F	IGNITION TEMP.	MELTING POINT	VAPOR PRESS. mm. Hg.
242 °C 760 mm.		270 °F	°C	°C	<.01

COMMERCIAL PURITY (% Composition, Assay)	PHYSICAL STATE	COLOR
	liquid	colorless

CHEMICAL REACTIVITY	ODOR (Barely Detectable Concentration in Air)
Incompatible with acid, oxidizing material, copper	mildly ammoniacal

STABILITY (Light, Heat, Shock, Heat, Liquid)

stable

TOXIC PROPERTIES

TYPE OF CONTACT		CLASSIFICATION OF TOXIC PROPERTIES	
EYE		☐ MAY CAUSE NO RESPONSE OR NO MORE THAN VERY SLIGHT TO SLIGHT TRANSITORY PAIN AND OR SLIGHT TRANSIENT CORNEAL INJURY AND/OR IRRITATION OF THE EYELIDS.	☒ MAY CAUSE SOME PERMANENT LOSS OF VISION (THIS INCLUDES DAMAGE TO CORNEA OR INTERNAL INJURY WHICH IS INCOMPLETELY HEALED IN ONE WEEK.)
		☐ MAY CAUSE SUFFICIENT INJURY TO THE EYE TO RESULT IN LOSS OF TIME FROM WORK. (THIS INCLUDES DAMAGE TO THE CORNEA WHICH HEALS OR NEARLY HEALS IN A WEEK AND/OR CONSIDERABLE CONJUNCTIVAL IRRITATION WITH EDEMA.)	☐ VAPOR EXPOSURE MAY CAUSE SEVERE PAIN, LACRYMATION OR SERIOUS INJURY TO THE EYES.
SKIN [1]		☐ SINGLE PROLONGED EXPOSURE (HOURS) CAUSES NO EFFECT SEVERAL REPEATED PROLONGED EXPOSURES MAY OR MAY NOT CAUSE THE DEVELOPMENT OF SOME SLIGHT IRRITATION	☒ SINGLE SHORT EXPOSURE (MINUTES) MAY CAUSE CONSIDERABLE IRRITATION AND OR SINGLE PROLONGED OR FREQUENTLY REPEATED SHORT EXPOSURES CAUSE A BURN AND OR MAY CAUSE SYSTEMIC INJURY AND OR DEATH.
		☐ SINGLE PROLONGED EXPOSURE MAY CAUSE SOME REDDENING OF THE SKIN. REPEATED PROLONGED CONTACTS MAY CAUSE APPRECIABLE IRRITATION, POSSIBLY A MILD BURN AND OR MAY CAUSE APPRECIABLE SYSTEMIC INJURY DUE TO ABSORPTION.	☐ AN EXPOSURE RAPIDLY CAUSES SEVERE BURNS AND OR SERIOUS SYSTEMIC INJURY, EVEN DEATH.
INHALATION	DUST OR MIST	☐ NO SYSTEMIC INJURY EXPECTED. NO IRRITATION TO NOSE AND THROAT IN DUSTY OR MISTY ATMOSPHERES	☐ DUSTY OR MISTY ATMOSPHERE PAINFUL TO NOSE AND THROAT (INTOLERABLE TO MOST PEOPLE) AND OR EXPOSURE MAY CAUSE SERIOUS SYSTEMIC INJURY, EVEN DEATH.
		☐ THROAT AND NOSE IRRITATION IN A DUSTY OR MISTY ATMOSPHERE IS PAINFUL BUT NOT INTOLERABLE AND OR PROLONGED OR REPEATED EXPOSURES MAY CAUSE SYSTEMIC INJURY.	☐ SHORT EXPOSURE (MINUTES) MAY CAUSE DEATH OR SERIOUS SYSTEMIC INJURY
	VAPOR Tested at room temperature unless otherwise indicated.	☒ EXPOSURES DO NOT CAUSE ANY EFFECTS OTHER THAN SOME VERY SLIGHT IRRITATION OR PAIN TO THE EYES OR RESPIRATORY PASSAGES AT THE MOST.	☐ EXPOSURES MAY CAUSE EXTREME DROWSINESS, AND OR SERIOUS SYSTEMIC INJURY, AND OR MAY CAUSE INTOLERABLE IRRITATION TO THE RESPIRATORY PASSAGES.
		☐ SINGLE EXPOSURES EXCEEDING 1/2 HOUR, OR FREQUENTLY REPEATED EXPOSURES OF SHORTER DURATION, MAY CAUSE SLIGHT ANESTHESIA AND OR SLIGHT SYSTEMIC INJURY, AND OR CAUSE APPRECIABLE, BUT NOT INTOLERABLE, IRRITATION OF RESPIRATORY PASSAGES.	☐ SHORT EXPOSURES MAY CAUSE UNCONSCIOUSNESS, AND OR SERIOUS SYSTEMIC INJURY, INCLUDING DEATH.
			☐ EVEN VERY SHORT EXPOSURE WILL CAUSE SERIOUS SYSTEMIC INJURY OR DEATH.
INGESTION		☒ AMOUNTS WHICH MAY BE SWALLOWED INCIDENTAL TO INDUSTRIAL HANDLING WILL NOT CAUSE INJURY. HOWEVER, IF SUBSTANTIAL QUANTITIES SHOULD BE SWALLOWED, MORE OR LESS SERIOUS EFFECTS MAY OCCUR.	☐ AMOUNTS WHICH MAY BE SWALLOWED INCIDENTAL TO INDUSTRIAL HANDLING AND USE MAY CAUSE SERIOUS INJURY.

COMMENTS

[1] Possible human skin sensitizer as indicated by positive guir a pig sensitization test.

Aminoethylethanolamine

	DEGREES OF EXPOSURE RELATED TO TYPES OF OPERATION	PRECAUTIONS USE CODE BELOW: EYES	SKIN	INHALATION*: DUST OR MIST	INHALATION*: VAPOR	INGESTION
I NO CONTACT	CHARACTERIZED BY REMOTE OPERATION WITH EQUIPMENT ISOLATED FROM THE WORK AREA. THE PERSONS ENTERING ISOLATED AREAS WILL REQUIRE THE PERSONAL PROTECTION OUTLINED FOR IV BELOW.	A	A		A	A
II MINOR CONTACT	CHARACTERIZED BY CLOSED SYSTEMS WITH EQUIPMENT VENTED OUTSIDE THE WORK AREA. INSTRUMENT CONTROL, ADDITIONAL HANDLING OF MATERIALS IN BULK. EXAMPLES ARE: CONTAINING REACTORS, STILLS AND FILTERS, ENCLOSED CONVEYORS, VENTILATED PACKAGING.	D	D		A	A
III OCCASIONAL DAILY CONTACT	CHARACTERIZED BY MANUAL HANDLING OF MATERIALS IN PACKAGES SUCH AS BAGS, DRUMS AND BOOKPAKS. VENTILATION MAY BE PROVIDED FOR SPECIFIC JOBS. MANY BATCH OPERATIONS FALL INTO THIS CATEGORY.	D	D		A	A
IV GROSS CONTACT LIKELY	CHARACTERIZED BY HAND OPERATION. EXAMPLES ARE: EMERGENCY REPAIRS, CLEANING EQUIPMENT, CLEANING FILTERS, TAKING CARE OF SPILLS, PACKAGING VOLATILE OR DUSTY MATERIALS WITHOUT VENTILATION, WIDELINE AND THAT DRYING.	D	D		B	B

EYE CONTACT	A NO EYE PROTECTION NEEDED. B USE SAFETY GLASSES WITHOUT SIDE SHIELDS. C USE SAFETY GLASSES WITH SIDE SHIELDS.	D USE CHEMICAL WORKERS GOGGLES. E USE GAS TIGHT GOGGLES OR A FULL FACE GAS MASK.
SKIN** CONTACT	A A BATH AND CLEAN CLOTHES ONCE PER WEEK ALONG WITH THE USUAL WASHING AT MEALTIMES SHOULD BE ADEQUATE PRECAUTIONS. B GROSSLY CONTAMINATED CLOTHING AND SHOES MUST BE REMOVED NOT LATER THAN THE END OF THE WORK PERIOD AND MUST BE THOROUGHLY CLEANED BEFORE RE-USE. C REQUIRE SHOWER AT THE END OF THE WORK PERIOD AND CLEAN CLOTHING FROM THE SKIN OUT AT THE START OF EACH WORK DAY.	D CLOTHING SHOULD BE CHANGED AND SKIN WASHED PROMPTLY UPON ANY DETECTABLE CONTACT. EACH USE WILL REQUIRE SPECIAL CONSIDERATION TO DETERMINE SUITABLE PROTECTIVE DEVICES AND STANDARDS OF PERSONAL CLEANLINESS. E IMPERVIOUS CLOTHING SUCH AS RUBBER BOOTS, RUBBER APRONS, AND RUBBER GLOVES WILL BE REQUIRED. SPECIFIC ITEMS WILL BE DICTATED AS REQUIRED BY CIRCUMSTANCE.
INHALATION: DUST OR MIST	A NO RESPIRATORY PROTECTION. B NO PROTECTION REQUIRED FOR EXPOSURE OF THIRTY MIN. DURATION OR LESS TO OBVIOUSLY DUSTY ATMOSPHERES. EXPOSURES OF LONGER DURATION WILL REQUIRE THE USE OF A DUST RESPIRATOR BEARING THE APPROVAL OF THE U.S. BUREAU OF MINES FOR THE USE WITH TOXIC DUSTS.	D ANY EXPOSURE TO OBVIOUSLY DUSTY ATMOSPHERES WILL REQUIRE A DUST RESPIRATOR BEARING THE APPROVAL OF THE U.S. BUREAU OF MINES FOR USE WITH TOXIC DUSTS. E ANY EXPOSURE TO DUSTY ATMOSPHERES WILL REQUIRE THE USE OF AN AIRLINE RESPIRATOR, BLOWER MASK, OR CHEMOX MASK.
INHALATION: VAPOR	A NO PRECAUTIONS NECESSARY. B NO PRECAUTIONS NECESSARY FOR SINGLE EXPOSURES OF LESS THAN 15 MIN. LONGER SINGLE EXPOSURES, OR FREQUENTLY REPEATED EXPOSURES WILL REQUIRE A GAS MASK OR RESPIRATOR EQUIPPED WITH APPROPRIATE CANISTER.	C NO PRECAUTIONS NECESSARY FOR SINGLE EXPOSURES OF NO MORE THAN TEN MINUTES. LONGER EXPOSURES EITHER SINGLE OR REPEATED, WILL REQUIRE GAS MASK OR RESPIRATOR EQUIPPED WITH APPROPRIATE CANISTER. D GAS MASK WITH APPROPRIATE CANISTER REQUIRED AT ALL TIMES. E EVACUATE AREA AT ONCE AND ENTER ONLY WITH AIRLINE RESPIRATOR, BLOWER MASK OR CHEMOX MASK.
INGESTION	A NO UNUSUAL PROCEDURES REQUIRED. B RECOMMEND PRECAUTIONS SHOWN IN E AS NORMAL WORK PRACTICE	E FOOD AND TOBACCO SHOULD NOT BE PRESENT IN THE WORK AREA. HANDS AND FACE SHOULD BE WASHED BEFORE SMOKING AND EATING.

COMMENTS: **GOOD PRACTICE REQUIRES THAT GROSS AMOUNTS OF ANY CHEMICAL BE REMOVED FROM THE SKIN AS SOON AS IS PRACTICAL.

*SUITABLE GAS MASK CANISTER

Ammonia

SIGNED 11/13/80 CHECKED 11-13-80 D. V. [illegible]

DATE REVISED: November 13, 1980 DATE November 13, 1980

(BACK)

TOXICOLOGY RESEARCH LA...
THE DOW CHEMICAL COMPANY
MIDLAND, MICHIGAN TEXAS

ACUTE ORAL TOXICITY

MATERIAL: Amines E Myl Ethanol Amine

10 CC - SYRINGE 19.35 g.
EMPTY SYRINGE 9.05 g.
10 CC 10.30 g.
SP GRAVITY 1.03

☐ SOLUTION ☐ SUSPENSION
g IN cc = %
☐ WATER ☐ CORN OIL
☐ OTHER

SPECIES: ☑ RAT ☐ CAVY ☐ RABBIT ☐ MOUSE
SEX: ☐ M ☑ F

CAGE	DATE FED	ANIMAL MARKING	WEIGHT Gm.	DOSE Gm KG	DOSE CC.	ANIMAL WEIGHT (Gm.) 7-18-80	7-24-80	7-31-80	7-31-80 — DATE
		No. Color							
1	7-17-80	1176 black	206	4.0	0.80				
	10:00 am	1177 red	238		0.90		7-19-80		
		1178 blue	210		0.81		7-19-80		
		1179	200		0.78				
		No. Color							
2		1180 black	256	2.0	0.50		290	310	
		1181 red	210		0.41		268	290	
		1182 blue	256		0.50		306	324	
		1183	218		0.42		266	288	
		No. Color							
3		1184 black	252	1.0	0.24		306	318	
		1185 red	226		0.22		264	280	
		1186 blue	214		0.21		256	274	
		1187	250		0.24		300	324	SAC 7-31-80
		No. Color							
4		1188 black	218	0.5	0.11		264	276	
		1189 red	218		0.11		262	274	
		1190 blue	224		0.11		260	272	
		1191	216		0.10		242	260	

OBSERVATION BY:

COMMENTS ON BACK OF THIS PAGE

SIGNED:

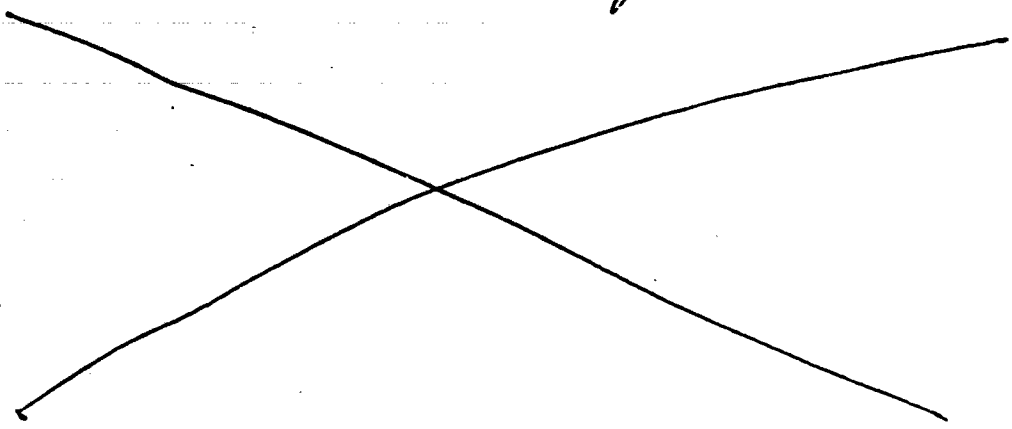
Aug. 1, 1980

(FRONT)

METHODOLOGY

Animals used for acute oral toxicity tests are fed by single-dose gavage using a calibrated syringe and a blunt feeding needle (rats, mice, guinea pigs) or catheter (rabbits). The animals are fasted overnight (except rabbits) and are weighed before dosing, the day after dosing, and at 1 and 2 weeks after dosing. The animals are observed closely the day of treatment, then periodically for the 2-week observation period. Unless otherwise noted, 6-8 week old Sprague-Dawley rats, 6-8 week old CF_1 mice, 6-8 week old Hartley guinea pigs, or 3-3 1/2 month old New Zealand albino rabbits are used. For range studies, 2 or 3 animals of one sex per dose level for 2 to 5 levels are used; the third animal (if used) is sent to pathology for a gross examination at 24 hours after treatment. For LD50 studies, 5 animals per sex per dose level for 2 to 6 levels are used; all survivors are submitted for a gross pathological examination after the 2-week weighing. Non-corrosive liquids are dosed as received, corrosive liquids are diluted in water or corn oil. Pastes and solids are prepared as solutions or suspensions in water, corn oil, or 0.5% methocel.

DATE	COMMENTS
7-17-80	10:30 [illegible]
	[illegible]
7-17-80	2:30 Pm. [illegible]
7-17-80	3:45 Pm. [illegible]
7-18-80	8:00 Am [illegible]
	[illegible]
7-18-80	[illegible]
7-19-80	rats # 1177, 1178 died all other still look normal.
7-24-80	8:10 Am all rats look fine.
7-31-80	9:30 Am all rats still look fine



GUINEA PIG SENSITIZATION

TOXICOLOGY RESEARCH LABORATORY

INSULT MATERIAL: Control D.E.R. 331 epoxy resin

CHALLENGE MATERIAL:

SOLVENT: ☐ UNDILUTED ☒ DOWANOL DPM (TWEEN 80 9:1) ☐ WATER

CONCENTRATION: 10 % W.V.

SOLVENT:

CONCENTRATION:

	PACK AND CAGE	ANIMAL NO.	INSULT 0.1 ml OF 10 %						CHALLENGE A TEST MATERIAL 0.1 ml OF 10 %			CHALLENGE B SOLVENT 0.1 ml OF 100 %		
DATE			8/14/80	8/20	8/22	8/25	8/27	8/29	9/10/80	9/11	9/12	9/10/80	9/11	9/12
APPLICATION NO.				1	2	3	4	—	1	—	—	1	—	—
DAYS ON EXPOSURE				0	2	5	7	9	0	1	2	0	1	2
Animal #		BLACK 1358			1/1	"	1/1	1/1		4/2	4/2		1/1	1/1
107-4		RED 1359			1/1	1/1	1/1	1/1		2/1	2/1		1/1	1/1
		ORANGE 1360			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		GREEN 1361			1/1	1/1	1/1	1/1		4/2	3/1		1/1	1/1
		BLUE 1362			1/1	1/1	2/1	1/1		4/2	4/1		1/1	1/1
		BLACK 1363			1/1	1/1	1/1	1/1		4/2	3/1		1/1	1/1
107-5		RED 1364			1/1	1/1	1/1	1/1		3/1	3/1		1/1	1/1
		ORANGE 1365			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		GREEN 1366			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		BLUE 1351			1/1	1/1	1/1	1/1		4/2	4/1		1/1	1/1
	DEPILATORY		✓											
	OBSERVED BY													

* 0.2 ml Freund's adjuvant applied

INSULT

BACK- A B

SIGNED

DATE September 12, 1980

FORM C-29660

GUINEA PIG SENSITIZATION

TOXICOLOGY RESEARCH LABORATORY

INSULT MATERIAL: Amino ethyl ethanolamine

CHALLENGE MATERIAL:

SOLVENT: ☐ UNDILUTED ☒ DOWANOL DPM/TWEEN 80 9:1 ☐ WATER

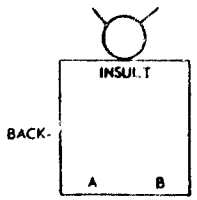
CONCENTRATION: 10 % W/V

SOLVENT:

CONCENTRATION:

	RACK AND CAGE	ANIMAL NO.	INSULT 0.1 ml OF 10 %						CHALLENGE A TEST MATERIAL 0.1 ml OF 10%			CHALLENGE B SOLVENT 0.1 ml OF 100 %		
DATE →			8/19/80	8/20	8/22	8/25*	8/27	8/29	9/10/80	9/11	9/12	9/10/80	9/11	9/12
APPLICATION NO.				1	2	3	4	—	1	—	—	1	—	—
DAYS ON EXPOSURE				0	2	5	7	9	0	1	2	0	1	2
107-1		BLACK 1343			2/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		RED 1344			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		ORANGE 1345			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		GREEN 1346			1/1	1/1	1/1	1/1		3/1	4/1		1/1	1/1
		BLUE 1347			1/1	1/1	1/1	1/1		4/2	3/2		1/1	1/1
107-3		BLACK 1350			1/1	1/1	1/1	1/1		4/2	3/1		1/1	1/1
		RED 1354			1/1	1/1	1/1	1/1		4/2	4/1		1/1	1/1
		ORANGE 1355			1/1	1/1	1/1	1/1		4/2	4/2		1/1	1/1
		GREEN 1356			1/1	1/1	1/1	1/1		4/2	4/1		1/1	1/1
		BLUE 1357			1/1	1/1	1/1	1/1		4/2	4/1		1/1	1/1
		DEPILATORY	✓											
		OBSERVED BY												

* 0.2 ml Freunds adjuvant applied



BACK- INSULT A B

SIGNED

DATE: September 12, 1980

FORM C-29660

(FRONT)

This method is a modification of the Maguire method (H.C. Maguire (1973). The Bioassay of Contact Allergens in the Guinea Pig. J. Soc. Cosmet. Chem., 24, 151-162). Test materials in 0.1 ml aliquots are applied to the clipped and depilated backs of Hartley albino guinea pigs, 6-8 weeks old, four times in ten days. At the time of the third application, 0.2 ml of Freund's* adjuvant is injected intradermally at several points adjacent to the insult site. After a 2-week rest period, the animals are challenged on other sites, such as the clipped flanks with the test material and with the solvent. Test solutions are applied as received (if they are not corrosive or irritant), or as a solution or suspension in a penetrating solvent. (A corrosive or irritant response would mask the redness or swelling of the sensitization response).

*Bacto-Adjuvant Complete, H37Ra, DIFCO Laboratories, Detroit, Michigan.

GRADING OF RESPONSE

HYPEREMIA/EDEMA

HYPEREMIA

1. NONE
2. VERY SLIGHT PINK
3. SLIGHT PINK
4. MODERATE RED
5. VERY RED

EDEMA

1. NONE
2. VERY SLIGHT
3. SLIGHT
4. MODERATE
5. MARKED

N - NECROSIS

S - SCAB

COMMENTS:

8/18/80 Skin irritation test run on pig # 1352. 1% and 10% AEEA in DOWANOL DPM/Tween 80 9:1 put on back and taped. 1% upper patch, 10% lower patch. Also uncovered on flanks: 1% on left flank, 10% on right flank.

8/19/80 Very slight irritation noted both on back and flank with 10% AEEA. No irritation with 1% AEEA.

SPECIES Guinea Pigs

SEX ♂

K NO.

MATERIAL Amino Ethyl Ethanol Amine CONC.

Skin Sensitization

TOXICOLOGY LABORATORY

WEIGHT RECORD

FILE NO. T

EXPT. NO.

TEST NO.

PROBLEM NO.

ACCT. NO.

CAGE AND DOSE	DATE → / DAYS ON EXPOSURE → / DAYS ON EXPT. →			8-2-80	8-11-80	8-18-80	8-25-80	8-5-80	9-4-80	9-15-80
	BIRTH	EAR MARK	PATHOLOGY NO.							
R-107 Cage 1	7-30-80	1343		316	358	394	410	478	500	536
		1344		290	345	394	420	520	540	566
		1345		318	380	430	450	560	588	604
		1346		290	330	368	386	470	496	514
		1347		290	350	394	430	538	578	600
R-107 Cage 2		1348		280	340	346	392	500	534 NOT USE	546
		1349		298	352	330	K 8-22-80	PNEUMONITIS - PNEUMONIC PATCHES MIDDLE EAR INFECTION		
		1350		322	368	386	448	530	556	580
	to cage 5 on 8/18/80	1351		320	383	430	460	540	568	594
		1352		300	348	384	420	540	568 NOT USE	598
R-107 Cage 3	to cage 2 8/20/80	1353		300	348	348	K 8-22-80	PNEUMONIA IN APICAL LOBE ABSCESS (3mm) IN LIVER		
		1354		300	358	404	425	494	528	564
		1355		304	356	390	420	504	542	580
		1356		335	392	404	454	540	570	598
		1357		304	362	380	392	468	482	508
R-107 Cage 4		1358		340	394	435	466	534	580	610
		1359		330	390	434	470	564	592	610
		1360		306	365	406	466	518	550	578
		1361		288	334	376	398	462	490	518
		1362		328	378	418	436	530	554	588
R-107 Cage 5		1363		315	374	416	466	550	590	614
		1364		340	376	440	400	512	555	586
		1365		308	378	420	446	530	562	588
		1366		335	386	425	468	550	590	614

Sac 9-15-80

SKIN CORROSIVENESS — RABBIT

DOW

TOXICOLOGY RESEARCH LABORATORY

MATERIAL: Amino Ethyl Ethanol Amine

PHYSICAL STATE OF MATERIAL: Liquid

DATE: 7-29-80	DATE: 7-29-80	DATE: 7-29-80	DATE: 7-29-80	DATE: 7-29-80	DATE: 7-29-80
CAGE NUMBER: R-104-7	CAGE NUMBER: R104-8	CAGE NUMBER: R104-9	CAGE NUMBER: R109-1	CAGE NUMBER: R109-4	CAGE NUMBER: R-109-7
RABBIT NUMBER: ♂ 1295	RABBIT NUMBER: ♂ 1296	RABBIT NUMBER: ♂ 1297	RABBIT NUMBER: ♂ 1298	RABBIT NUMBER: ♂ 1299	RABBIT NUMBER: ♂ 1300
9:08 am	9:10 am	9:11 am	9:14 am	9:16 am	9:19 am

ON BACK INTACT

OBSERVATION TIME (HOURS) →	4	24	48	4	24	48	4	24	48	4	24	48	4	24	48	4	24	48
ERYTHEMA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EDEMA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
NECROSIS	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1

SITE: [X] [X] [X] [X] [X] [X]

COMMENTS: Material not corrosive.

SIGNATURE

DATE: Aug. 1, 1980

METHODOLOGY ON BACK OF THIS PAGE

FORM C-6457 REVISED 8-77

METHODOLOGY

Six New Zealand albino rabbits are prepared for this test by clipping the hair from an area at least 4 x 4 in. in size on the back with electric clippers 24 hours before application of the materials to be evaluated. The rabbits are restrained in a stock, and the material to be tested is applied under a 1 x 1 in. gauze pad held in place with adhesive tape. Aliquots of 0.5 ml of a liquid, or 500 mg of a solid under a moist patch, are used. Each rabbit is loosely covered with heavy gauge plastic. At the end of four hours, the gauze patches are removed and the application sites graded for erythema, edema, and necrosis according to the grading system indicated in the table below. The application sites are washed with soap and water and held for additional readings at 24 hours and 48 hours if necessary. Up to 4 materials can be tested on each set of 6 rabbits by rotating the positions of the sites (top left, top right, bottom right, and bottom left). If a material produces at least a moderate burn in 4 hours or less, it must be labeled as corrosive for the Department of Transportation.

GRADE	ERYTHEMA	EDEMA	NECROSIS
1	NONE	NONE	NONE
2	very slight	very slight	very slight
3	SLIGHT PINK	SLIGHT	SUPERFICIAL
4	MODERATE PINK	MODERATE	MODERATE
5	RED	MARKED	DEEP
6	VERY RED	SEVERE	VERY DEEP

COMMENTS

FORM C-46570 PRINTED R-3-77

(BACK)

PRIMARY SKIN IRRITATION — PATCH TEST (Household Chemical).

TOXICOLOGY RESEARCH LABORATORY

MATERIAL Amino ETHYL ETHANOL AMINE

PHYSICAL STATE OF MATERIAL Liquid

I=INTACT
A=ABRADED
N=IRREVERSIBLE NECROSIS
S = SUPERFICIAL NECROSIS
☐ SALINE ☐ WATER

8:30 Am

		DATE 7-15-80	DATE 7-15-80	DATE 7-15-80	DATE 7-15-80	DATE 7-15-80	DATE 7-15-80	PRIMARY IRRITATION SCORE= Corrosive
		CAGE NO. R105-7	CAGE NO. R105-4	CAGE NO. R105-1	CAGE NO. R105-2	CAGE NO. R105-3	CAGE NO. R105-6	
		RABBIT NO. ♀1009	RABBIT NO. ♀1006	RABBIT NO. ♀1003	RABBIT NO. ♀1004	RABBIT NO. ♀1005	RABBIT NO. ♀1008	
HYPEREMIA & ESCHAR	EXPOSURE TIME HOURS	EXPOSURE UNIT VALUE	EXPOSURE UNIT VALUE	EXPOSURE UNIT VALUE	EXPOSURE UNIT VALUE	EXPOSURE UNIT VALUE	EXPOSURE UNIT VALUE	AVERAGE VALUE
INTACT	24	2S	3S	2S	2	3S	3S	
INTACT	72	1	2N	1		1N	2N	
ABRADED	24	2 Bent	3	2	2	3	3	
ABRADED	72	2	2	1		1	2	
SUB-TOTAL								
EDEMA FORMATION								
INTACT	24	3	3	1	1S	3S	3S	
INTACT	72		2	1	1	1	2	
ABRADED	24	3	3	1	1	3	3	
ABRADED	72		2	1	2		2	
SUB-TOTAL								
TOTAL								
PATCH POSITION		I A	A I	I A	A I	I A	A I	

COMMENTS: The experimental procedure and the method of rating are those recommended by the Consumer Product Safety Commission for compliance with the Federal Hazardous Substances Act., paragraph 119.11 under sec. 10, 74 Stat. 378:15 U.S.C.A. 1269.

#1009 & 1006 7-18-80 SMALL BURNS ON ABRADED SIDE ALSO
#1003 7-18-80 BURN ON THE ABRADED SIDE.
#1004 7-18-80 BURN ON THE ABRADED SIDE ONLY
#1005 7-18-80 [illegible] ON ABRADED SIDE ALSO.
#1008 7-18-80 [illegible] ON ABRADED SIDE

S

DATE Aug. 1, 1980

FORM C-[illegible]

(FRONT)

METHODOLOGY

The backs of 6 rabbits are clipped free of hair with electric clippers 24 hours prior to treatment. Under a surgical gauze patch held in place with adhesive tape, 0.5 ml or 0.5 g of the test material is applied to an intact and an abraded site on each animal. Abrasions are made in a tic-tac-toe pattern with a hypodermic needle, deep enough to penetrate the outer layer of skin, but not so deep as to promote bleeding. In case of a solid, the patches are moistened with saline or deionized water. The patches are loosely covered with a piece of heavy gauge plastic to retard evaporation. ~~Plastic collars are placed on the rabbits to prevent them from licking the material.~~ After 24 hours, the patches are removed and each site is assessed according to the table below; the severity of the reaction is recorded then, and at 72 hours from the beginning of the test. The average values are calculated and placed in the last column on the right. The average values are totaled and divided by 4 to obtain the Primary Irritation Score. If a material produces an irreversible burn, that material is considered to be corrosive and the Primary Irritation Score is not calculated.

Evaluation of skin reactions	*Value*
Erythema formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness)	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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

FILE NO.

EYE IRRITATION TEST

TOXICOLOGY RESEARCH LABORATORY

MATERIAL: Amino Ethyl Ethanol Amine

RABBIT NO.: 1011

SEX: ☐ MALE ☒ FEMALE

CONCENTRATION: % W/V ☒ UNDILUTED

CAGE NO.: R-R105-9

SOLUBILITY: WATER ☒ YES ☐ NO CORN OIL ☒ YES ☐ NO

COMMENTS

IMMEDIATE:

AFTER ONE HOUR (OR 1 HOURS)
* blood - colored eyedate, lower lid dk - red.

AFTER 24 HOURS
Conjunctivae & nictitating membrane, necrotic.

AFTER 48 HOURS

AFTER 7 DAYS
necrosis over whole area which may result in loss of eye.

AFTER 14 DAYS
sacrificed because of extreme damage loss of eyes.

AFTER ____ DAYS

SIGNED

RESPONSE		NOT WASHED (LEFT)	WASHED (RIGHT)	DATE AND INITIALS
PAIN		4	3	
CONJUNCTIVA		3	4	7-15-80
CORNEA		1	1	8:30AM
CONJUNCTIVA		*4	*4	7-15-80
CORNEA	BEFORE STAIN	3	3	9:30am
	AFTER STAIN	3	3	
IRIS		can't see	can't see	
CONJUNCTIVA		5	5	7-16-80
CORNEA	BEFORE STAIN	5	3	
	AFTER STAIN	4	4	
IRIS		can't see	3	
CONJUNCTIVA		6	4	7-17-80
CORNEA	BEFORE STAIN	6	4	
	AFTER STAIN	5	4	
IRIS		CAN'T SEE	4	
CONJUNCTIVA		6	5	7-22-80
CORNEA	BEFORE STAIN	6	6	
	AFTER STAIN	5	5	
IRIS		can't see	can't see	
CONJUNCTIVA		6	5	7-29-80
CORNEA	BEFORE STAIN	6	5	
	AFTER STAIN	6	5	
IRIS		can't see	can't see	
CONJUNCTIVA				
CORNEA	BEFORE STAIN			
	AFTER STAIN			
IRIS				

DATE 7-29-80

(FRONT)

DATE OF RECEIPT OIP
92 APR 17 AM 10: 03

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