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Date Produced	11/14/86	Date Received	09/03/92
		TSCA Section	8ECP
Submitting Organization	E I DUPONT DE NEMOURS & CO		
Contractor	HASKELL LABORATORY		
Document Title	INITIAL SUBMISSION: SKIN CORROSION TEST OF 2 DIAMINE IN RABBITS WITH COVER LETTER DATED 09/02/92		
Chemical Category	2-METHYLPENTAMETHYLENEDIAMINE		

8(e)

CAP

(COMPLIANCE AUDIT PROGRAM)

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E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

1992 SEP -3 PM 1:46

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LEGAL DEPARTMENT

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September 2, 1992

Document Processing Center (TS-790)
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Environmental Protection Agency
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Attn: Section 8(e) Coordinator (CAP Agreement)

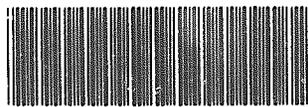
Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information¹. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.



8EMQ-92-10707
INIT 09/03/92



88920000996

For Regulatee,

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
(302) 774-6443

¹For several of the old studies, submission is made because the words "ataxia" or "tremor" appear in the study report and do not represent a determination that the information reasonably supports a conclusion of substantial risk.

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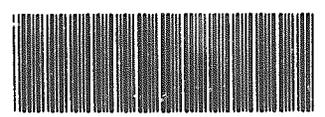
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ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation's TSCA §8(e) reporting standard². This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.³ Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

²In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment. See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

³A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteria. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent⁴, the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- o the "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.⁵

o the "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

o the "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

⁴The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

⁵ See, e.g., 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). See also, Rollins Environmental Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urge: persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

"a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, See, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy", 43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide*.

<u>TEST TYPE</u>	<u>1978 POLICY CRITERIA EXIST?</u>	<u>New 1991 GUIDE CRITERIA EXIST?</u>
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	} ⁶	} ⁷
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	y ⁸
SKIN SENSITIZATION (ANIMALS)	N	y ⁹
EYE IRRITATION	N	y ¹⁰
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	y ¹¹
REPRODUCTION STUDY	N	y ¹²
DEVELOPMENTAL TOX	y ¹³	y ¹⁴

⁶43 Fed Reg at 11114, comment 14:

"This policy statements directs the reporting of specific effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical. Unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VII."

⁷Guide at pp.22, 29-31.

⁸Guide at pp-34-36.

⁹Guide at pp-34-36.

¹⁰Guide at pp-34-36.

¹¹Guide at pp-22; 36-37.

¹²Guide at pp-22

¹³43 Fed Reg at 11112

"Birth Defects" listed.

¹⁴Guide at pp-22

NEUROTOXICITY	N	Y ¹⁵
CARCINOGENICITY	Y ¹⁶	Y ¹⁷
MUTAGENICITY		
<i>In Vitro</i>	Y ¹⁸	Y ¹⁹
<i>In Vivo</i>	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y} ²⁰	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reproductive	N	N

¹⁵Guide at pp-23; 33-34.

¹⁶43 Fed Reg at 11112
"Cancer" listed

¹⁷Guide at pp-21.

¹⁸43 Fed Reg at 11112; 11115 at Comment 15

"Mutagenicity" listed; *in vivo* vs *in vitro* discussed; discussion of "Ames test".

¹⁹Guide at pp-23.

²⁰43 Fed Reg at 11112; 11115 at Comment 16.

CAS #15520-10-2

Chem: 2-Methylpentamethylenediamine

Title: Skin Corrosion Test of 2-Methylpentamethylenediamine in Rabbits

Date: November 14, 1986

Summary of Effects: Visible necrosis of skin when tested for 3 minutes

FOR DU PONT USE ONLY

SKIN CORROSION TEST OF
2-METHYLPENTAMETHYLENEDIAMINE IN RABBITS
FOR INTERNATIONAL MARITIME ORGANIZATION PACKAGING CLASSIFICATION

Haskell Laboratory Report No. 620-86

MR No. 7978-001

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
P. O. Box 50, Elkton Road
Newark, Delaware 19714

Date Issued: November 14, 1986

Skin Corrosion Test of
2-Methylpentamethylenediamine in Rabbits
for International Maritime Organization Packaging Classification

SUMMARY

2-Methylpentamethylenediamine (98.5% pure) was evaluated for acute skin corrosion potential in male and female rabbits. 2-Methylpentamethylenediamine produced severe erythema with necrosis in all rabbits approximately 3 minutes after treatment. Severe erythema with necrosis persisted in all rabbits throughout the 48 hour test period. Blanching was also observed 48 hours post treatment. Moderate edema was observed in all rabbits at 24 and 48 hours post treatment.

Under the conditions of this study, 2-methylpentamethylenediamine was a skin corrosive agent when applied to the clipped intact skin of rabbits. For purposes of International Maritime Organization packaging classification, 2-methylpentamethylenediamine should be classified as Packaging Group I (substances that cause visible necrosis of the skin when tested on the intact skin for a period of not more than 3 minutes).

Work by: Deborah A. Vick 11/14/86
Deborah A. Vick
Technician

Study Director: John W. Sarver 11/14/86
John W. Sarver
Technologist

Approved by: R. C. Chorney for R. Valentine 11/14/86
Rudolph Valentine, Ph.D.
Research Toxicologist

Nancy C. Chorney 11/14/86
Nancy C. Chorney, Ph.D.
Section Supervisor
Acute and Developmental Toxicology Section

Haskell Laboratory Report No. 620-86

MR No. 7978-001

Haskell No. 16,449

Material Tested: 1,5-Pentanediamine, 2-methyl-

Sponsor: Petrochemicals Department
E. I. du Pont de Nemours and Company
Wilmington, Delaware

Material Submitted By: F. E. Herkes
Petrochemicals Department
E. I. du Pont de Nemours and Company
Pontchartrain, Louisiana

Test Facility: E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and
Industrial Medicine
P. O. Box 50, Elkton Road
Newark, Delaware 19714

Study Initiated - Completed: 8/27/86 - 8/29/86

Notebook E-45966, pp. 86-93.
There are 8 pages in this report.

Distribution: J. C. Olguin (1)
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J. W. Sarver/D. A. Vick (1)

INTRODUCTION

The purpose of this study was to evaluate the skin corrosive potential of 2-methylpentamethylenediamine when applied to the clipped intact skin of New Zealand White rabbits. Data from this study may serve as a basis for classification and labeling of the test material according to International Maritime Organization Packaging Classifications.

MATERIALS AND METHODS

A. Animal Husbandry

Young adult male and female New Zealand White rabbits were received from Hare Marland, Hewitt, New Jersey. The rabbits were housed singly in suspended, stainless steel, wire-mesh cages. Each rabbit was assigned a unique identification number which was recorded on a card affixed to the cage. Purina Certified Rabbit Chow® #5322 and water were available ad libitum. Rabbits were quarantined, weighed and observed for general health for approximately 2 weeks. Animal rooms were maintained on a timer-controlled, 12 hour/12 hour light/dark cycle. Environmental conditions of the rooms were targeted for a temperature of $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and relative humidity of $50\% \pm 10\%$. Excursions outside these ranges were of small magnitude and/or brief duration and did not adversely affect the validity of the study.

B. Protocol

On the day prior to study initiation, the hair of 6 New Zealand White rabbits was closely clipped to expose the back from the scapular to the lumbar region. The rabbits weighed from 2985 to 3567 grams on the day of treatment. Each rabbit was placed in a stock. A 0.5 mL aliquot of 2-methylpentamethylenediamine was applied directly on the test site beneath a 1-inch gauze square that was held in place with tape. Three minutes after application of the test material, the test sites were gently washed with warm water to remove excess test material and the skin was gently patted dry. After evaluation of the test sites for skin irritation, the animals were returned to their cages.

Approximately 24 and 48 hours after application of the test material, the test sites were again evaluated for necrosis, erythema, edema and other evidence of dermal effects. Each test site was scored according to the Draize scale (Table I). The adjacent areas of untreated skin were used for comparison.

C. Test Material

Physical Form: Clear liquid
 Purity: 98.5%
 Contaminants: Ethyltetramethylenediamine
 Synonyms: 2-Methylpentamethylenediamine
 Other Codes: PD-Dytek A
 CAS Registry No.: 15520-10-2
 Stability: The test material was assumed to be stable under the conditions of administration.

D. Records Retention

All raw data and the final report will be stored in the archives of Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company, Newark, Delaware or in the Du Pont Records Management Center, Wilmington, Delaware.

RESULTS AND CONCLUSIONS

2-Methylpentamethylenediamine produced severe erythema with necrosis in all rabbits 3 minutes after treatment. Severe erythema with necrosis was still present 48 hours after treatment. Blanching was also present at the 48-hour evaluation. Moderate edema was present in all rabbits at the 24 and 48 hour evaluations. Individual skin irritation scores are presented in Table II. A summary of responses is presented in the following table.

Summary of Skin Responses to 2-Methylpentamethylenediamine

<u>Response</u>	<u>Erythema</u>			<u>Edema</u>		
	<u>3 min</u>	<u>24 hr</u>	<u>48 hr</u>	<u>3 min</u>	<u>24 hr</u>	<u>48 hr</u>
Severe	6N/6	6N/6	6N,B/6	0/6	0/6	0/6
Moderate	0/6	0/6	0/6	0/6	6/6	6/6
No Response	0/6	0/6	0/6	6/6	0/6	0/6

2-Methylpentamethylenediamine was a skin corrosive agent when applied to the clipped intact skin of rabbits. For purposes of International Maritime Organization packaging classification, 2-methylpentamethylenediamine should be classified as Packaging Group I (substances that cause visible necrosis of the skin when tested on the intact skin for a period of not more than 3 minutes).

¹ International Maritime Organization, International Dangerous Goods Code, Volume V, Class 8, 1982.

TABLE I
DRAIZE SCALE FOR SCORING PRIMARY SKIN IRRITATION²

<u>Evaluation of Skin Reactions</u>	<u>Value</u>	
Erythema and eschar formation:		
No erythema	0	
Very slight erythema (barely perceptible)	1 (Slight)	
Well-defined erythema	2 (Mild)	
Moderate to severe erythema	3 (Moderate)	
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4 (Severe)	
Edema formation:		
No edema	0	
Very slight edema (barely perceptible)	1 (Slight)	
Slight edema (edges of area well defined by definite raising)	2 (Mild)	
Moderate edema (raised approximately 1.0 mm)	3 (Moderate)	
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4 (Severe)	
A = Abraded	F = Fissuring	L = Sloughing
I = Intact	N = Necrosis	R = Raw Areas
T = Thickening	G = Fissuring with Bleeding	X = Compound Adhered to Skin
C = Eschar	S = Epidermal Scaling	SN = Superficial Necrosis
- = No Effect		
B = Blanching		

² Draize, J. H., "Dermal Toxicity." Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. The Editorial Committee of the Association of Food and Drug Officials of the United States, Austin, Texas, 1959, pp. 46-59.

TABLE II
RABBIT SKIN CORROSION TEST

SKIN RESPONSES OBSERVED IN TEST
RABBITS FOLLOWING TOPICAL EXPOSURE TO
2-METHYLPENTAMETHYLENEDIAMINE

Rabbit Number	Erythema			Edema		
	3 Minutes	24 Hours	48 Hours	3 Minutes	24 Hours	48 Hours
20323	4N	4N	4N,B	0	3	3
20451	4N	4N	4N,B	0	3	3
20452	4N	4N	4N,B	0	3	3
20411	4N	4N	4N,B	0	3	3
20419	4N	4N	4N,B	0	3	3
20421	4N	4N	4N,B	0	3	3

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