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October 15, 1992

Document Processing Center (TS-790)  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
401 M Street., S.W.  
Washington, D.C. 20460  
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 6/28/91 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 information. 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.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

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

RECEIVED  
2/15/95

## 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 standard<sup>2</sup>. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.<sup>3</sup> 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).

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<sup>2</sup>In 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".

<sup>3</sup>A 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 criteri. 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 intent<sup>4</sup>, 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.<sup>5</sup>;
- 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.

<sup>4</sup>The '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.

<sup>5</sup> 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 urges 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*.

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

<sup>6</sup>43 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."

<sup>7</sup>Guide at pp.22, 29-31.

<sup>8</sup>Guide at pp-34-36.

<sup>9</sup>Guide at pp-34-36.

<sup>10</sup>Guide at pp-34-36.

<sup>11</sup>Guide at pp-22; 36-37.

<sup>12</sup>Guide at pp-22

<sup>13</sup>43 Fed Reg at 11112

"Birth Defects" listed.

<sup>14</sup>Guide at pp-22

<b>NEUROTOXICITY</b>	N	Y <sup>15</sup>
<b>CARCINOGENICITY</b>	Y <sup>16</sup>	Y <sup>17</sup>
<b>MUTAGENICITY</b>		
<i>In Vitro</i>	Y <sup>18</sup>	Y <sup>19</sup>
<i>In Vivo</i>	Y}	Y}
<b>ENVIRONMENTAL</b>		
Bioaccumulation	Y}	N
Bioconcentration	Y <sup>20</sup>	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
<b>AVIAN</b>		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

<sup>15</sup>Guide at pp-23; 33-34.

<sup>16</sup>43 Fed Reg at 11112  
"Cancer" listed

<sup>17</sup>Guide at pp-21.

<sup>18</sup>43 Fed Reg at 11112; 11115 at Comment 15

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

<sup>19</sup>Guide at pp-23.

<sup>20</sup>43 Fed Reg at 11112; 11115 at Comment 16.

**CAS #77-78-1**

**Chem: Dimethyl sulfate**

**Title: Acute inhalation toxicity**

**Date: 10/21/71**

**Summary of Effects: LC50 100 ppm, v/v**

E. I. du Pont de Nemours and Company  
 Haskell Laboratory for Toxicology and Industrial Medicine

HASKELL LABORATORY REPORT NO. 318-71 MR NO. 1387

Material Tested: Dimethyl sulfate Haskell No.: 6804

Material Submitted by: R. W. Luckenbaugh, Industrial and Biochemicals Other Codes: DMS; D18, 630-9  
 Department, Experimental Station

ACUTE INHALATION TOXICITY

Procedure: The test sample was delivered by a syringe drive into a stainless steel T-tube whose internal temperature was 180°C. A metered stream of air passing through the T-tube carried the resultant vapors to the exposure chamber. Chamber atmosphere was analyzed two or three times by a turbidimetric procedure during each one-hour exposure. Six young adult male Chr-CD rats of initial body weight 250-285 grams were used. Survivors were held 14 days after exposure for observation.

There was gross and histopathologic examination of the tissues.†

Results: Analytical Concentration (ppm, v/v)	Mortality Ratio	Clinical Signs	
		During Exposure	Post-Exposure
120	6/6	Lacrimation, difficulty in breathing, gasping.	Down to 80% of their initial body weight on the first day of recovery. All were gasping with nasal discharge and all were found dead within two day
90	2/6	Lacrimation, gasping.	Down to 82% of their initial body weight the first day of recovery. All gasping and had corneal opacity. 2/6 died on the 2nd day of recovery while the rest were down to 75% of their initial body weight. Down to 70% of their initial body weight on the 6th day of recovery. Started to gain weight thereafter; corneal opacity persisted.

Results: (Continued)

- 2 -

Analytical Concentration (ppm, v/v)	Mortality Ratio	Clinical Signs	
		During Exposure	Post-Exposure
90	1/6	Lacrimation, difficulty in breathing, face pawing, gasping.	1/6 died while the rest were down to 75% of their initial body weight on the 2nd day of recovery. All were gasping; corneal opacity. Down to 70% of their initial body weight on the 3rd day of recovery. Normal weight gain thereafter. Corneal opacity persisted.
105	1/6	Same as above.	1/6 died and the rest were down to 75% of their initial body weight on the 2nd day of recovery; gasping; opaque corneas. Down to 71% of their initial body weight on the 3rd day of recovery. Normal rate of weight gain thereafter. Corneal opacity persisted.
58	0/6	Some face washing, and difficulty in breathing, slight gasping.	These rats used for serial sacrifice.

1 hour LC<sub>50</sub> = 100 [C.L. = 88-113] ppm, v/v†

Pathology: Rats were sacrificed at 1, 2, and 7 days after exposure to 58 ppm and 14 days after exposure to 90 ppm.

Histologically, rats exposed to 58 ppm of DMS with a recovery time of 1, 2, or 7 days showed degeneration and necrosis of the cornea and an acute inflammatory reaction in the upper trachea. One rat developed bronchopneumonia which may have been related to the exposure. Two of two rats, exposed to about 90 ppm DMS and given a 14-day recovery period, showed the cornea in a reparative process with new capillary growth in the stroma and regeneration of the corneal epithelium. These two rats, in addition, showed multinucleated giant cell microgranulomata in the alveoli of the lungs. Some giant cells contained a crystalline material. This lung change was related to the exposure as it is rarely seen in stock rats. The absence of this lesion in the other rats may be related to the dose and/or recovery time. The outer ear skin did not show the necrotic changes found when five milligrams of DMS in methanol was applied to rabbit skin. (Pathology Report No. 22-71)

ANTIDOTE STUDY

Groups of rats, 12 per group, were exposed to a dosage of DMS, established by acute inhalation studies, which produced a definite pulmonary effect. One-half of the animals in each group were treated by one of the following therapeutic regimens, while the remainder served as untreated controls; all treatments were started immediately after the exposure to DMS.

Therapy A: A corticosteroid (Decadron®) - 10 µg/ml in 0.15 M NaCl) was administered intraperitoneally followed by exposure to 50% O<sub>2</sub> (v/v) for an hour.

Therapy B: Rats were exposed to a mist of Decadron® (10 µg/ml in 0.15 M NaCl) for an hour.

Therapy C: Rats were exposed to a mist of 0.15 M NaHCO<sub>3</sub> for an hour followed by exposure to 100% O<sub>2</sub> for another hour.

Results:

Therapy	DMS Analytical Concentration (ppm, v/v)	Mortality Ratio		Clinical Signs		Therapy
		Control	Therapy	Control	Post-Exposure	
A	78	1/6	0/6	Down to 68% of their initial body weight on the 3rd day of recovery with gasping and cloudy cornea. One was still losing weight and found dead on the 6th day of recovery while the rest recovered normally.	Down to 63% of their initial body weight on the 4th day of recovery with some gasping and cloudy corneas. One rat was down to 62% of his initial weight on the 8th day of recovery. All recovered normally thereafter.	
98	3/6	3/6	3/6	3/6 were dead and the rest were down to 74% of their initial body weight on the 2nd day; gasping and corneal opacity. Survivors were down to 62% of their initial weight on the 7th day of recovery. Normal rate of weight gain thereafter.	1/6 died on the 2nd day. 1/5 died on the 3rd day, and 1/4 died on the 4th day of recovery; also gasping and corneal opacity. One rat was down to 58% of his initial body weight on the 8th day of recovery.	

Results: (Continued)

DMS

Analytical  
Concentration  
Therapy (ppm, v/v)

Clinical Signs  
Control      Post-Exposure      Therapy

Mortality Ratio  
Control      Therapy

During Exposure

Therapy	Analytical Concentration (ppm, v/v)	Mortality Ratio		During Exposure	Clinical Signs		
		Control	Therapy		Control	Post-Exposure	Therapy
	120	5/6	6/6	Same as above.	2/6 died on the 2nd day of recovery. Rest were losing weight, gasping and had corneal opacity; 1/4 died on the 4th day of recovery while the rest were down to 62% of their initial body weight. 2/3 continued to lose; they were gasping and had corneal opacity with stained perineal area on the 7th day of recovery; found dead the next day. The last surviving rat recovered.	3/6 died on the 1st day. 1/3 died on the 2nd day. 2 surviving rats died on the 4th day of recovery.	
B	104	2/6	1/6	Same as above.	1/6 died on the 1st day of recovery. Rest were losing weight, gasping, and had corneal opacity. Down to 57% of their initial body weight on the 7th day of recovery. 1/5 found dead on the 8th day while the rest started to gain normally.	1/6 died on the 2nd day, rest were down to 70% of their initial body weight and had corneal opacity. Down to 68% of their initial body weight on the 6th day of recovery; started to gain normally thereafter.	
C	72	0/6	1/6	Same as above.	Down to 75% of their initial body weight on the 2nd day of recovery. Some gasping and corneal opacity. 1 rat was still losing weight while the rest started to recover.	1/6 found dead on the 1st day of recovery, rest were gasping and had corneal opacity; losing weight. Down to 65% of their initial body weight on the 4th day. Gained normally thereafter.	

Summary: Dimethyl sulfate, having an LC50 of 100 [95% C.L. = 88-113] ppm, v/v† for a one-hour inhalation exposure in rats, is highly toxic by inhalation. It caused delayed deaths and permanent eye damage at the lowest level tested, 58 ppm. Different therapies given as mentioned had no apparent effect. Histology suggests acidic type of attack to lungs and eyes at the lower concentrations.

† Tissues examined included: lungs, liver, kidney, brain, heart, spleen, testes, gastrointestinal tract, thyroid, skin, bone marrow, pancreas, epididymis, thymus, and eye

‡ Statistical analysis by method of Litchfield, J. T., Jr., and F. Wilcoxon, J. Pharmacol. and Expt'l. Therap., 96: 99 (1949)

§ Decadron® phosphate (Dexamethasone sodium phosphate, USD)

Report by:

F.O. Taylor  
Figen O. Taylor

Inhalation Toxicology Section

Approved by:

Charles F. Reinhardt

Charles F. Reinhardt  
Assistant Director



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

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Legal D-7010-1  
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Wilmington, Delaware 19898

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

APR 18 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

12178A



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**Triage of 8(e) Submissions**

Date sent to triage: APR 20 1995

NON-CAP

CAP

Submission number: 12178A

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

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GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

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4/3/95

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CECATS DATA: Submission # SEHQ 1092-12178 SEQ. A

TYPE: INT SUPP FLWP  
 SUBMITTER NAME: E. I. DuPont de Nemours and Company

SUB. DATE: 10/15/92 OTS DATE: 10/27/92 CSRAD DATE: 02/15/95

CHEMICAL NAME: Decadron CASE: 77-78-1

- VOLUNTARY ACTIONS:**  
 0401 NO ACTION REPORTED  
 0402 STUDY'S PLANNING IN WAY  
 0403 NOTIFICATION OF WORKING CONDITIONS  
 0404 LABELS/MSDS CHANGES  
 0405 PROCESS/HANDLING CHANGES  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONT. DENTAL

- INFORMATION REQUESTED: FLWP DATE:  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL. ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONALE)  
 DISPOSITION:  
 0579 REFER TO CHEMICAL SCREENING  
 0578 CAP NOTICE

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	ECOVAQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	REPORTING RATIONALE	01 02 04	0259 <del>CONFIDENTIAL</del>	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04		

**ANTIOXIDE INFORMATION**

TRIAJE DATA	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE	PRODUCTION:
<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	YES (DROP/REFER)	<u>RAT</u>	LOW		
CAS SR	NO (CONTINUE)	NO (CONTINUE)		MED		
	REFR			<u>HIGH</u>		

11-555-113

8(E) -12178A

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ACUTE INHALATION TOXICITY IN MALE CD RATS IS OF HIGH CONCERN BASED ON AN LC50 OF 100 PPM AND OCULAR NECROSIS. DOSAGES (ANALYTICAL, 1-HOUR) AND MORTALITY DATA ARE AS FOLLOWS: 58 PPM (0/6); 90 PPM (3/12) (TWO GROUPS WERE EXPOSED TO THIS CONCENTRATION); 105 PPM (1/6); AND 120 PPM (6/6). TOXIC SIGNS INCLUDED LACRIMATION, GASPING, LOSS OF BODY WEIGHT, AND CORNEAL OPACITY. HISTOPATHOLOGY REVEALED DEGENERATION AND NECROSIS OF THE CORNEA, AN ACUTE INFLAMMATORY REACTION IN THE UPPER TRACHEA, AND MULTINUCLEATED GIANT CELL ALVEOLAR MICROGRANULOMATA.