8EHQ-0992-13138

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FORM LG-4878

DUPONT

ESTABLISHED 1802

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

LEGAL DEPARTMENT

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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 6/28/91CAP 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.

8E CAP

For Regulatee,

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

RECEIVED
3/27/95

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[2]. 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).

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[2]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".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a 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[4], 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.
- othe "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];

- othe "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.
- othe "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 .

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[4]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.

[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 Environemntal 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.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
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]

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[6] 43 Fed Reg at 11114, comment 14:

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

[7] Guide at pp.22, 29-31.

[8] Guide at pp-34-36.

[9] Guide at pp-34-36.

[10] Guide at pp-34-36.

[11] Guide at pp-22; 36-37.

[12] Guide at pp-22

[13] 43 Fed Reg at 11112

"Birth Defects" listed.

[14] Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	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
Reprodcutive	N	N

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[15] Guide at pp-23; 33-34.

[16] 43 Fed Reg at 11112
"Cancer" listed

[17] Guide at pp-21.

[18] 43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19] Guide at pp-23.

[20] 43 Fed Reg at 11112; 11115 at Comment 16.

CAS #50-000-0

Chem: Formaldehyde

Title: A Teratology Study of Inhaled Formaldehyde in the Rat

Date: June 12, 1989

Summary of Effects: Increased incidence of reduced ossification of public and ischial bones and slightly lower fetal weights at 5 and 10 ppm

JUN 12 ...

A TERATOLOGY STUDY OF INHALED FORMALDEHYDE IN THE RAT

W. J. Martin, M.D.
Formaldehyde Council of Canada

A teratology study of inhaled formaldehyde in the rat was undertaken by the Formaldehyde Council of Canada. The study was initiated by a range-finding study. Thirty mated rats were used for the study. The females were between 13 and 14 weeks of age and weighed between 242 and 280 g. The female rats were treated by the whole-body exposure technique for 6 hours per day with formaldehyde at dosages of 2,5,10 or 16 ppm from day 6 to day 15 of gestation inclusive. No deaths either maternal or foetal occurred during the study.

The formal study consisted of exposing groups of 25 mated Sprague-Dawley rats by the whole-body exposure technique for 6 hours/day, with formaldehyde at dosages of 2,5, or 10 ppm from day 6 to day 15 of gestation inclusive. Two control groups were included in the study; one was handled in an identical manner to the formaldehyde-treated groups except that it was treated with air, and the other was maintained in the animal room throughout the study. The females used for the study were 13 weeks of age and weighed between 221 and 277 g. Proven males of the same strain and source were used for mating.

All animals were housed individually, except during the mating period, in stainless steel mesh-bottomed cages. Animals were given Pelleted Certified Purina Rodent Chow No. 5002 and municipal tap water ad libitum, except during inhalation exposure periods. The temperature and humidity in the animal room were controlled (temperature 21 ± 3°C, humidity 50 ± 20%), and the photoperiod was 12 hours light/12 hours dark.

Following mating, the female rats were randomly assigned to groups, used a computer-generated set of random numbers and were individually identified using an ear-notch technique. Formaldehyde was evolved from paraformaldehyde. The purity of the paraformaldehyde was at least 95%, with the majority of the remaining 5% being water with a trace of formic acid.

Rats were treated daily by whole-body exposure from day 6 to day 15 of gestation, inclusive. At each treatment, the animals in the air control group and treated groups were placed in the chambers and for the formaldehyde dosage groups the formaldehyde was introduced into the chamber for a half hour equilibration period, followed by a further 5 and a half hours of continuous introduction. Test article flow into the chamber was then stopped, and the animals were removed from the chamber a half hour later. The various groups were treated as follows:

(cont.)

Group	Treatment	Chamber Concentration (ppm) Target	Achieved	Number of Females Examined at Cesarean
1	Room Control	--	----	25
2	Air Control	0	0.01	25
3	Formaldehyde	2	1.88	25
4	Formaldehyde	5	4.88	25
5	Formaldehyde	10	9.45	25

Animals in the room control group were maintained in the animal room throughout the study. Five 32-inch cubed (600-litre volume) stainless steel whole-body exposure chambers were utilized. Neither food nor water was available while the animals were in the inhalation chambers.

Air was drawn through the chambers at a flow rate of 60 L/min using a low-pressure vacuum pump. Flow rate through the chamber was measured in the exhaust line of each chamber by measuring the pressure differential across an orifice plate on a magnehelic gauge. This gauge was calibrated against a conventional ball-type flowmeter. Pressure within the chamber was slightly negative with respect to the room.

Formaldehyde wsa generated by depolymerizing paraformaldehyde at constant temperature (80°C) and pressure (2 psi). The evolving formaldehyde gas was carried from the generator at a rate of 0.5 L/min into a heated manifold and was diluted with 4.5 L/min of dehumidified compressed air.

The diluted formaldehyde gas (at a concentration of approximately 1000 ug/L) was split into 4 streams and was metered into the inhalation chambers of the 3 treated groups to achieve the desired chamber concentrations.

Three samples, each approximately 1.75 h in duration, were collected daily from each chamber by passing air through a glass impinger containing 1% sodium bisulfite. Samples were analyzed by the chromotropic acid method (Appendix 11) for formaldehyde content.

Temperature and relative humidity, both within the inhalation chamber and the inhalation room, were monitored on an hourly basis during treatment (Abbeon-Lufft thermometer and hygrometer). Airflow rates through the inhalation chamber and the generating equipment were monitored continuously and recorded hourly. Mean chamber concentration was calculated for each day of exposure from the 3 daily chromotropic acid analysis results.

All statistical comparisons were made between the air control and treated groups unless otherwise stated. For each group, mean (S.D.) daily chamber concentration was calculated for each day of exposure from the 3 daily chromotropic acid analysis results, and from these the overall mean (S.D.) chamber concentration was calculated. In addition, the mean (S.D.) concentration for each sampling period was calculated.

(cont.)

Group mean values (S.D.) for pregnant rats were calculated for body weights, food consumption, gravid uterine weights and corrected body weights (body weight on day 20 minus gravid uterine weight). The individual and group mean (S.D.) body weight gains and corrected body weight gains (body weight gain days 6 to 20 of gestation minus gravid uterine weight) for the period day 6 to day 20 were calculated. These aforementioned parameters were analyzed using one-way analysis of variance, and, where the F value was found to be of significance ($P < 0.05$), intergroup differences between air control and treated groups were examined using Student's "t" test.

The pregnancy rate was calculated as follows:

$$\text{Pregnancy Rate} = \frac{\text{Number of Pregnant Rats}}{\text{Number of Mated Rats}} \times 100$$

RESULTS:

Chamber levels of formaldehyde for all groups were relatively stable within a given day, and throughout the entire treatment period. The mean achieved concentrations for Groups 3, 4, and 5 were 1.88, 4.88 and 9.45 ppm, respectively. Occasionally very low levels of formaldehyde were detected in the air control group chamber; these were not considered to be of any consequence.

Mean chamber temperature ranged from 17 to 23°C, and mean relative humidity ranged from 48 to 77%.

Yellow discoloration of the fur was noted among rats in the 10 ppm treated group.

At the 10 ppm dose level the weight gain between day 6 and day 9 of gestation was significantly ($P < 0.05$) reduced, and between days 9 and 13 and days 13 and 16 of gestation the weight gains were slightly less than values in the control groups. These lower weight gains resulted in significantly lower body weights on days 13 and 16 of gestation.

The corrected body weights (body weights on day 20 of gestation minus gravid uterine weight) and the corrected body weight gains (body weight gain day 6 to day 20 of gestation minus gravid uterine weight) were significantly decreased ($P < 0.02$ and $P < 0.01$, respectively) in the 10 ppm dose group.

Body weights, body weight gains and corrected body weights and body weight gains in the 2 and 5 ppm dose groups were comparable with values in the air control group.

In the 3 intervals, days 6 to 9, 9 to 13 and 13 to 16 of gestation, the food intake of the 10 ppm treated group was significantly decreased.

The food consumption of the 2 and 5 ppm treatment level animals was similar to that of the air control group.

(cont.)

The incidences of major malformations and minor anomalies were reported as the number of litters with abnormalities in each group and the number of fetuses affected. Statistical analyses comparing the number of litters (containing major malformations) in east test group with the control values (air control group) were performed using either the chi-square test of Fischer's exact probability test; the incidence of minor anomalies was analyzed in the same manner. In addition, skeletal findings in the pelvic girdle were compared to those of the room control group. The incidence of common variants was reported as the number of litters affected, the number of fetuses affected and the litter mean percentage of fetuses affected. Statistical analyses were performed by comparing the litter mean percentage incidences of each test group with the air control group using the Mann-Whitney "U" test.

The pregnancy rate in all groups was at least 80%. Uterine parameters including numbers of corpora lutea, implantation sites, live fetuses, dead fetuses and resorptions and fetal weights, sex ratios and pre- and post-implantation losses were unaffected by treatment.

The overall incidences of litters and fetuses with major malformations, minor external and visceral anomalies and minor skeletal anomalies were not affected by treatment with formaldehyde.

The incidences of reduced ossification of the pubic and ischial bones in the 5 and 10 ppm treated groups were significantly increased when compared to the air control group but not the room control group. These findings were considered to be related to slightly larger litter sizes and slightly lower fetal weights in the 5 and 10 ppm treated groups.

Sternebral and thoracic centrum common skeletal variants in the treated groups were similar to control values.

CONCLUSION:

Treatment of pregnant rats with formaldehyde by the whole-body exposure route for 6 hours/day at dosages of 2,5 and 10 ppm from day 6 to day 15 of gestation inclusive resulted in a significant level of material toxicity in terms of decreased weight gain and reduced food consumption at the 10 ppm level. There was no evidence of material toxicity at the 2 and 5 ppm dosage levels.

At the 5 and 10 ppm levels, a significant concentration related decrease in fetal ossification was detected, but this was associated with decreased fetal weights due to a larger number of implantations and fetuses among the dams of these two groups than in the remaining groups. Therefore, no adverse effects on the conceptus were demonstrated to be due to formaldehyde exposure at the levels tested in this study.

At dosages of up to 10 ppm of formaldehyde, a dose level at which a significant level of maternal toxicity occurred, there was no evidence of embryolethality, fetotoxity or teratogenicity.

Acknowledgement to Dr. J. Munigle for her valuable assistance and to Bio-Research Laboratories Ltd., Montreal, Quebec.

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

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E. I. Du Pont De Nemours and Company
Legal D-7010-1
1007 Market Street
Wilmington, Delaware 19898

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 0 8 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

13138A

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: MAY 0 9 1995

NON-CAP CAP

Submission number: 13138A

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 RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

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entire document 0 1 2 pages 1, 1st PAGE pages 1, DATES

Notes:

Contractor reviewer : FOR Date: 4/26/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA/ Submission # 8EHQ- 0992-13138 SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: E. I. Dupont de Nemours and Company

INFORMATION REQUESTED; FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0570) REFER TO CHEMICAL SCREENING
(0578) CAP NOTICE

VOLUNTARY ACTIONS:
0501 NO ACTION REPORTED
0502 STUDIES PLANNED/UNDERWAY
0503 NOTIFICATION OF WORKERS/USERS
0504 LABELS/MSDS CHANGES
0505 PROCESS/MANUF CHANGES
0506 APPLIC DISCONTINUED
0507 PRODUCTION DISCONTINUED
0508 CONFIDENTIAL

SUB. DATE: 09/11/92 OTS DATE: 09/22/92 CSRAD DATE: 03/27/95

CHEMICAL NAME:

CASE
50-00-0

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
(0207)	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPICLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECOTOXICITY	01 02 04
0221	ENV. OCCURRENCE/FATE	01 02 04
0222	OTHER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQUEST DELAY	01 02 04
0224	PROD COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0229	METABPHARMACO (ANIMAL)	01 02 04
0240	METABPHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	BIOLOGY (ANIMAL)	01 02 04
0242	BIOLOGY (HUMAN)	01 02 04
0243	CHEMPHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAMAGE/REPAIR	01 02 04
0248	PRODUSE/PROC	01 02 04
0251	MIXS	01 02 04
0299	OTHER	01 02 04

TRIAGE REVIEW: CAS SR

NON-CBI INVENTORY: (YES) NO (N/R/UNKN)

CSRD/OPPTS REVIEW: YES (DROP/REFER) NO (CONTINUE) REFER

SPECIES: RAT

TOXICOLOGICAL CONCERN: LOW (MED) HIGH

USE:

PRODUCTION:

inhalation

10 ppm - dec BW & food consumption; dec ossification & fetal wt but may have been due to large litters

50 ppm - some fetal effects

2 ppm - NOAEL