

8EHQ-1192-13155

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October 18, 1992

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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)

8EHQ-92-13155  
INIT  
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92 NOV -2 AM 10:50

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.

8ECAP

For Regulatee,

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

RECEIVED  
3/23/95

**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.

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<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*.

| <u>TEST TYPE</u>                               | <u>1978 POLICY<br/>CRITERIA EXIST?</u> | <u>New 1991 GUIDE<br/>CRITERIA EXIST?</u> |
|--|--|---|
| <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<br/>(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               |
| Reproductive           | N                | N               |

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<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 # 502-55-66

Chem: Diethylxanthogen Disulfide

Title: Acute Inhalation Toxicity

Date: 6/17/69

Summary of effects: Severe respiratory irritant causing the formation of scar tissue in the lungs

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

HASKELL LABORATORY REPORT NO. 159-69MR NO. 1137

Material Tested: Diethyl Xanthogen Disulfide

Haskell No.: 6043

Material Submitted by: P. R. Johnson, Elastomer Chemicals Department  
Experimental Station

Other Codes: LR 14-171; EXD

ACUTE INHALATION TOXICITY

Procedure: The weighed sample was poured into a three-neck flask in a heated (35-40°C) mineral oil bath. Air, at the rate of 3 L/minute, was introduced into the flask through a borosilicate glass tube submerged in the liquid. The 16-liter exposure chamber contained six young adult male Chr-CD rats of initial body weight 250-268 grams for each four-hour exposure. After exposure, the surviving rats were returned to their regular housing cages for observation for 14 days. The chamber atmosphere was analyzed at least hourly by a gas chromatographic procedure. The infrared spectrum of the residue in the flask after each exposure was determined and compared with that of the original sample. Nominal concentrations were calculated from flask and contents weight loss and volume of air used.

There was histopathologic examination of tissues\*at each of 1, 2, 7, 13 and 14 days after exposure.

Results:

| Exposure No. | Melt Temperature (°C) | Nominal Concentration (mg/L) | Mortality Ratio | Clinical Observations   |  |
|--------------|-----------------------|------------------------------|-----------------|---|--|
|              |                       |                              |                 | During Exposure   | After Exposure   |
| 1            | 35                    | 0.42                         | 1/6             | Lacrimation, irregular breathing, hyperemia, reddish discharge from eyes and nose | Minor weight losses the first day after exposure, normal recovery thereafter; one died on the sixth recovery day, probably unrelated to exposure |
| 6            | 50                    | 0.27                         | 0/6             | Same as above   | Minor weight losses the first day after the exposure; normal recovery thereafter   |

Results (Cont'd.):

| Exposure No. | Melt Temperature (°C) | Nominal Concentration (mg/L) | Mortality Ratio | Clinical Observations                               |   |
|--------------|-----------------------|------------------------------|-----------------|---|---|
|              |                       |                              |                 | During Exposure                                     | After Exposure  |
| 5            | 75                    | §                            | 0/6             | Same as Page 1; cloud in chamber                    | Severe weight losses first day after exposure; normal weight gain until seventh day when severe weight losses again occurred        |
| 3            | 95                    | 5.3                          | 3/6             | Same as above plus gasping; one death at 3:45 hours | Severe weight losses first day with continuing moderate daily weight losses for 14 days; deaths at one and seven days post-exposure |
| 4            | 125                   | 5.3                          | 6/6             | Same as above; death from 2:00 to 2:40 hours        | --  |
| 2            | 140                   | §                            | 6/6             | Same as above; death from 0:30 to 0:35 hours        | --  |

The gas chromatographic analysis (flame ionization detection) did not show any volatile components in the chamber atmosphere. The infrared spectra were identical before and after heating. All clinical signs increased in intensity with increasing sample temperature.

Pathology: Two rats from Exposure 5 were sacrificed at each of 1, 2, and 7 days after exposure and one from Exposure 3 at each of 13 (sacrificed in extremis) and 14 days post-exposure for histopathologic examination. Two rats dying during Exposure 2 were also necropsied for gross and histopathologic examination.

The rats dying during exposure had mildly hyperinflated lungs. Lungs from all rats sacrificed at 7 and 14 days post-exposure were hyperinflated and heavier than normal. Microscopic examination of tissues from the rats disclosed acute, progressive and severe damage to the lining of the trachea and bronchi. This was of such a nature that some of the lining became detached and there was an exudate of pus which plugged up some branches of the bronchi. Injury was so severe that healing took place with small amounts of scar tissue. This type of healing might easily lead to permanent obstruction of some of the bronchi. No direct effect attributable to the exposures was observed in the other tissues examined.

Summary: The Approximate Lethal Concentration (ALC) of diethyl xanthogen disulfide (EXD) for a four-hour rat exposure is 5.3 mg/L when the aerosol is generated from EXD heated at 95°C. Clinical signs indicative of respiratory irritation were seen with concentrations as low as 0.42 mg/L (sample temperatures as low as 35°C). The test material (or its decomposition products) was a severe respiratory irritant causing formation of scar tissue in the lungs during healing. This response could lead to permanent obstruction of some lung portions.

IR spectra of the original material and the samples after heating were the same. No volatile decomposition products could be detected with the gas chromatograph column and detector used.

Diethyl xanthogen disulfide should only be handled with adequate ventilation.

\* Tissues examined included lungs, trachea, bronchi, liver, spleen, pancreas, kidney, testis, esophagus, stomach, brain, heart, thymus, thyroid, adrenal, skin, eye, and bone marrow.

§ Not determined.

Report by:

*Figen O. Tayfun*  
Figen O. Tayfun

Inhalation Toxicology Section

*Richard S. Waritz*

Richard S. Waritz

Chief, Inhalation Toxicology Section

Approved by:

*John A. Capp, Jr.*  
John A. Capp, Jr.  
Director

**Triage of 8(e) Submissions**

Date sent to triage: 2/5/96

NON-CAP

CAP

Submission number: 13155A

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:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

|  |                          |
|--|--------------------------|
| <b>For Contractor Use Only</b>                                   |                          |
| entire document: <u>0</u> 1 2 pages <u>1, 1<sup>st</sup> tab</u> | pages <u>1, all tabs</u> |
| Notes:   |                          |
| Contractor reviewer: <u>LPS</u>                                  | Date: <u>5/11/95</u>     |

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ 1192-13155 SEQ. A

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

SUB. DATE: 10/16/92 OTS DATE: 11/02/92 CSRAD DATE: 03/23/95

CHEMICAL NAME: \_\_\_\_\_  
 CAS# 502-55-6

- COLLUTARY ACTIONS:  
 0400 NO ACTION REPORTED  
 0402 STUDIES PLANNED/IN PROGRESS  
 0403 NOTIFICATION OF WORK RUMORS  
 0404 LABEL/MSDS CHANGES  
 0405 PROCESS/AND/OR CHANGES  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

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

| INFORMATION TYPE:             | P F C    | INFORMATION TYPE:              | P F C    | INFORMATION TYPE:      | P F C    |
|-------------------------------|----------|--------------------------------|----------|------------------------|----------|
| 0201 ONCO (HUMAN)             | 01 02 04 | 0216 EPICLIN                   | 01 02 04 | 0241 IMMUNO (ANIMAL)   | 01 02 04 |
| 0202 ONCO (ANIMAL)            | 01 02 04 | 0217 HUMAN EXPOS (PROD CONTAM) | 01 02 04 | 0242 IMMUNO (HUMAN)    | 01 02 04 |
| 0203 CELL TRANS (IN VITRO)    | 01 02 04 | 0218 HUMAN EXPOS (ACCIDENTAL)  | 01 02 04 | 0243 CHEM/PHYS PROP    | 01 02 04 |
| 0204 MUTA (IN VITRO)          | 01 02 04 | 0219 HUMAN EXPOS (MONITORING)  | 01 02 04 | 0244 CLASTO (IN VITRO) | 01 02 04 |
| 0205 MUTA (IN VIVO)           | 01 02 04 | 0220 ECO/AQUA TOX              | 01 02 04 | 0245 CLASTO (ANIMAL)   | 01 02 04 |
| 0206 REPRC/TERATO (HUMAN)     | 01 02 04 | 0221 ENV. OCCUREL/FATE         | 01 02 04 | 0246 CLASTO (HUMAN)    | 01 02 04 |
| 0207 REPRC/TERATO (ANIMAL)    | 01 02 04 | 0222 EMER INCI OF ENV CONTAM   | 01 02 04 | 0247 DNA DAM/REPAIR    | 01 02 04 |
| 0208 NEURO (HUMAN)            | 01 02 04 | 0223 RESPONSE REQEST DELAY     | 01 02 04 | 0248 PROD/USE/PROC     | 01 02 04 |
| 0209 NEURO (ANIMAL)           | 01 02 04 | 0224 PROD/COMP/CHEM ID         | 01 02 04 | 0251 MSDS              | 01 02 04 |
| 0210 ACUTE TOX. (HUMAN)       | 01 02 04 | 0225 REPORTING RATIONALE       | 01 02 04 | 0299 OTHER             | 01 02 04 |
| 0211 CHR. TOX. (HUMAN)        | 01 02 04 | 0226 CONFIDENTIAL              | 01 02 04 |                        |          |
| 0212 ACUTE TOX. (ANIMAL)      | 01 02 04 | 0227 ALLERG (HUMAN)            | 01 02 04 |                        |          |
| 0213 SUB ACUTE TOX (ANIMAL)   | 01 02 04 | 0228 ALLERG (ANIMAL)           | 01 02 04 |                        |          |
| 0214 SUB CHRONIC TOX (ANIMAL) | 01 02 04 | 0239 METAB/PHARMACO (ANIMAL)   | 01 02 04 |                        |          |
| 0215 CHRONIC TOX (ANIMAL)     | 01 02 04 | 0240 METAB/PHARMACO (HUMAN)    | 01 02 04 |                        |          |

TRIAGE DATA: NON-CBI INVENTORY  YES  
 CAS SR NO (CONTINUE) REFTR  
 SPECIES RAT TOXICOLOGICAL CONCERN: LOW Acute Inhalation Toxicity  
 USE: PRODUCTION  
 MED HIGH

CONFIDENTIAL

#13155A

L

Acute inhalation toxicity is of low concern based on an approximate lethal concentration of 5.3 g/m<sup>3</sup> in rats. Mortality and corresponding doses (g/m<sup>3</sup>) were 0/6 (0.27), 1/6 (0.42), and 9/12 (5.3). Respiratory irritation (all doses), and minor (0.27, 0.42) to severe (5.3) weight loss were reported. Acute, progressive and severe damage to the lining of the trachea and bronchi was noted upon histological examination.