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October 16, 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
2/23/95

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 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 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 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 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 CRITERIA EXIST?</u>	<u>New 1991 GUIDE CRITERIA EXIST?</u>
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	N} ⁶	Y} 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 # 7646-85-7 and 14639-98-6

Chem: Zinc Chloride and Zinc Ammonium Galvanizing Flux

Title: Eye Irritation Test in Rabbits

Date: 1-20-72

Summary of Effects: Irreversible eye damage when tested as a solid material.

Copies to: F. H. Backus (1)
 P. C. Haworth (6)

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

HASKELL LABORATORY REPORT NO. 26-72 MR NO. 1548

Materials Tested:	Haskell No's.	Other Codes
1) Zinc Chloride	1) 7301	1) None
2) "Zaclon" C	2) 7302	2) Zinc ammonium chloride galvanizing flux
3) "Zaclon" L	3) 7303	3) Zinc ammonium chloride galvanizing flux
4) "Zaclon" LF	4) 7304	4) Zinc ammonium chloride galvanizing flux

Materials Submitted by: F. H. Backus, Industrial Chemicals Department
 Chestnut Run

EYE IRRITATION TEST IN RABBITS

Procedure: The four products were tested for eye irritation on albino rabbits. Ten mg of each test product (crystals) was placed into the right conjunctival sac of each of two rabbits. Two additional rabbits for each test compound were similarly treated using the test material as a 10% solution (Haskell No. 7302) or as a 10% suspension of flocculent precipitate in distilled water (Haskell No. 7301, Haskell No. 7303 and Haskell No. 7304). Twenty seconds after contact, one treated eye of each pair was washed with tap water for one minute. The other exposed eyes were not washed. Observations of the cornea, iris and conjunctiva were made with a hand slit lamp at one and four hours, and at one, two, three, seven and 14 days. A biomicroscope and 5% aqueous fluorescein stain were used at examinations after the day of treatment.

Results:

Guide for Interpreting the Data

Corneal changes:

- N = No evidence of corneal change at the microscopic level
- sl = Microscopic corneal injury, or localized mild injury seen with the hand slit lamp
- mild = Mild corneal injury seen with the biomicroscope and the hand slit lamp (not seen grossly)
- mod = Moderate injury which can be seen grossly and is reversible in nature
- sv mod = Moderate but penetrating injury which is reversible in nature
- sv = Severe irreversible injury
- ? = No reading due to conjunctival swelling and/or adhering fibrinous discharge
- D = Corneal curvature grossly distorted

Results: (Continued)

Guide for Interpreting the Data (Continued)

Iritic changes:

- N = Negative
- inj = Injection of iritic blood vessels
- mild = Mild iritis
- mod = Moderate iritis
- sv = Severe iritis
- ? = No reading due to any one or combination of: conjunctival swelling; adhering fibrinous discharge; corneal opacity

Conjunctivitis:

- Redness, chemosis and/or discharge graded as:
- N = Negative
 - min = Minimal
 - mild = Mild
 - mod = Moderate
 - sv = Severe

Haskell No.	Dose	Treatment of Eyes	Changes in	1 Day		2 Days		3 Days		7 Days		14 Days	
				sv	mild	sv	mod	sv	sv	sv, D	sv, D	sv	sv, D
7301	10 mg Solid	Not washed	Cornea Iris Conj.	sv mild sv	sv sv sv	sv sv sv	sv sv sv	sv sv sv	sv, D sv sv				
7301	10 mg Solid	Washed	Cornea Iris Conj.	sv mild sv	sv mod sv	sv sv sv	sv sv sv	sv sv sv	sv, D sv sv				
7301	0.1 ml 10% Aqueous suspension ^{a)}	Not washed	Cornea Iris Conj.	sv mod mild mod	sv mod N mild	mod sv sv	sv sv sv	sv sv sv	sv, D sv sv				
7301	0.1 ml 10% Aqueous suspension ^{a)}	Washed	Cornea Iris Conj.	N N mir	N N N	N N N	N N N	N N N	N N N	N N N	N N N	N N N	N N N

a) Suspension of flocculent precipitate

Results: (Continued)

Haskell No.	Dose	Treatment of Eyes	Changes in	1 Day	2 Days	3 Days	7 Days	14 Days
7302	10 mg Solid	Not washed	Cornea Iris Conj.	sv mild sv	sv mild sv	sv mod sv	sv, D N sv	sv, D N sv
7302	10 mg Solid	Washed	Cornea Iris Conj.	sv mod mild sv	sv mod mod sv	sv mod mild sv	sv mod, D N sv	mod N sv
7302	0.1 ml 10% Aqueous solution	Not washed	Cornea ^{b)} Iris Conj.	N N mod	N N mild	N N mild	N N N	N N N
7302	0.1 ml 10% Aqueous solution	Washed	Cornea Iris Conj.	N N min	N N N	N N N	N N N	N N N
7303	10 mg Solid	Not washed	Cornea Iris Conj.	mod sv mild sv	mod sv mild sv	mod sv N mod	mod N mild	mild N mild
7303	10 mg Solid	Washed	Cornea Iris Conj.	mod sv sv sv	mod sv sv sv	mod sv sv sv	mod N mod	sv, D N mod
7303	0.1 ml 10% Aqueous suspension ^{a)}	Not washed	Cornea Iris Conj.	N N mild	N N min	N N N	N N N	N N N
7303	0.1 ml 10% Aqueous suspension ^{a)}	Washed	Cornea Iris Conj.	N N N	N N N	N N N	N N N	N N N

b) Minimal corneal haziness seen under magnification 1-4 hours

Results: (Continued)

askell No.	Dose	Treatment of Eyes	Changes in	1 Day.	2 Days	3 Days	7 Days	14 Days
7304	10 mg Solid	Not washed	Cornea Iris Conj.	SV mod SV	SV mod SV	SV mod SV	SV, D ? SV	SV, D ? SV
7304	10 mg Solid	Washed	Cornea Iris Conj.	SV SV SV	SV SV SV	SV SV SV	SV, D N SV	SV, D mod,c) SV
7304	0.1 ml 10% Aqueous suspension ^{a)}	Not washed	Cornea Iris Conj.	N N mild	N N min	N N N	N N N	N N N
7304	0.1 ml 10% Aqueous suspension ^{a)}	Washed	Cornea Iris Conj.	N N N	N N N	N N N	N N N	N N N

Summary: Zinc chloride, "Zaclon" C, "Zaclon" L, and "Zaclon" LF as solids are capable of producing severe, penetrating, irreversible corneal damage, severe iritis, and severe conjunctivitis in rabbit eyes. Prompt washing of rabbit eyes exposed to these compounds as solids may or may not alleviate ocular injury. Considerably less ocular damage resulted when eyes were exposed to these compounds as 10% aqueous solutions or suspensions^{a)}. Corneal injury varied from moderate but penetrating to no damage, and iritic effects were either mild or negligible, while conjunctivitis was mild or moderate. Prompt washing of eyes dosed with the compounds as solutions or suspensions^{a)} tended to reduce ocular effects. All of the ocular effects produced by the compounds as solutions or suspensions^{a)} were reversible.

Zinc chloride, "Zaclon" C, "Zaclon" L, and "Zaclon" LF are corrosive or highly injurious to eyes. In the event of any eye exposure to these compounds, immediate copious flushing with water is mandatory and must be followed by prompt expert medical attention.

c) Examination of iris limited due to corneal damage

Report by: 
Karen M. Frank

KMF:dhg
Date: January 20, 1972
Report No. 26-72
N.B. 977:78, 84, 94, 100.

Approved by: 
Charles F. Reinhardt
Assistant Director



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

Mark H. Christman
Counsel
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 08 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

12362A



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Triage of 8(e) Submissions

Date sent to triage: 12/4/95

NON-CAP

CAP

Submission number: 12362A

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

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entire document: 0 1 2 pages 1, 1st tab pages 1, all tabs

Notes:

Contractor reviewer: LPS

Date: 4/11/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # BEHQ- 1092-12362 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:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/IN PROGRESS
0403 NOTIFICATION OF WORKERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/16/92 OTS DATE: 10/27/92 CSRAD DATE: 02/23/95

CHEMICAL NAME:

CAS#
7646-85-7 | Zalcon C Unknown
14639-98-6
Unknown

~~Zalcon C~~
Zalcon L
Zalcon LF

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	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 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCC/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/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 REQUEST 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		

TRIAJE DATA: NON-CBI INVENTORY YES
CAS SR: NO
ONGOING REVIEW: YES (DROP/REFER)
NO (CONTINUE)
REPTR

SPECIES: RAT

TOXICOLOGICAL CONCERN: LOW Eye RBT (Zalcon L solution); Eye RBT (Zalcon LF solution)
MED Eye RBT (Zinc Chloride solution); Eye RBT (Zalcon C solution)
HIGH Eye RBT (Zinc chloride solid); Eye RBT (Zalcon C solid); Eye RBT (Zalcon L solid); Eye RRT (Zalcon LF solid)

USE: _____ PRODUCTION: _____

COMMENTS:

12362A

H

Zinc chloride (solid): Eye irritation in rabbits is of high concern. Instillation of 0.01 mL as a solid into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in severe, penetrating, irreversible corneal damage, severe iritis, and severe conjunctivitis in the washed and unwashed eye.

H

Zalcon C (solid): Eye irritation in rabbits is of high concern. Instillation of 0.01 mL as a solid into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in severe, penetrating, irreversible corneal damage, mild to moderate transient iritis, and severe conjunctivitis in the washed and unwashed eye.

H

Zalcon L (solid): Eye irritation in rabbits is of high concern. Instillation of 0.01 mL as a solid into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in moderate to severe, reversible corneal injury and conjunctivitis in the unwashed eye. In the washed eye, severe, irreversible corneal damage and severe, transient iritis and conjunctivitis were noted.

Zalcon LF (solid): Eye irritation in rabbits is of high concern. Instillation of 0.01 mL as a solid into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in severe, penetrating, irreversible corneal damage and severe conjunctivitis in the washed and unwashed eye. Moderate to severe, reversible iritis was also noted in both eyes.

M

Zinc chloride (10% solution): Eye irritation in rabbits is of moderate concern. Instillation of 0.01 mL as a 10% solution into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in moderate, reversible corneal injury and mild, transient iritis and conjunctivitis in the unwashed eye. There were no effects in the washed eye.

M

Zalcon C (10% solution): Eye irritation in rabbits is of moderate concern. Instillation of 0.01 mL as a 10% solution into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in moderate, reversible conjunctivitis in the unwashed eye only.

L

Zalcon L (10% solution): Eye irritation in rabbits is of low concern. Instillation of 0.01 mL as a 10% solution into the right conjunctival sac of two rabbits (1 washed/1 unwashed)

resulted in mild, reversible conjunctivitis in the unwashed eye only.

L

Zalcon LF (10% solution): Eye irritation in rabbits is of low concern. Instillation of 0.01 mL as a 10% solution into the right conjunctival sac of two rabbits (1 washed/1 unwashed) resulted in mild, reversible conjunctivitis in the unwashed eye only.