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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)

BEHQ-92-12394
INIT
88920010603

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.

For Regulatee,

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

4/27/95

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 standard². This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.³ Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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

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

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

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

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should *not* be regarded as final EPA policy or intent⁴, the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- o the "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.⁵;
- o the "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.
- o the "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

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

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

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

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

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

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

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

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

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation 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

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# 79-41-4; 25087-26-7; 25033-53-6

**Chem: Methacrylic acid monomer (inhibited, polymethacrylic acid,
and a benzene extract of an ethylene-methacrylic acid
copolymer**

**Title: Acute Toxicity Studies with Ethylene/Methacrylic Acid
Copolymers**

Date: 12/28/62

Summary of Effects: Kidney lesions and degenerative changes in testes

ACUTE TOXICITY STUDIES WITH ETHYLENE/METHACRYLIC
ACID COPOLYMERS

Medical Research Project No. MR-630

Report No. 98-62

Three samples - methacrylic acid monomer (inhibited), polymethacrylic acid, and a benzene extract of an ethylene - methacrylic acid copolymer - were submitted for acute oral toxicity studies by R. D. Nelson of the Polyolefins Division, Plastics Department. This preliminary investigation was initiated because one of the proposed uses for this group of compounds involves potential contact with food.

Test Materials

The test materials and their identification numbers are listed below:

	<u>Haskell No.</u>	<u>Code No.</u>
Methacrylic acid monomer (inhibited)	3092	8070-18
Polymethacrylic acid	3128	8070-17A
Benzene extract of an ethylene-methacrylic acid copolymer	3130	8070-20

Procedure

The test materials were administered by stomach tube to young adult ChR-CD male rats in single doses. The methacrylic acid was given in undiluted form or as an aqueous solution. The other two compounds were given as peanut oil suspensions. Survivors were killed for histopathological evaluation 14 days after having received the dose.

A. METHACRYLIC ACID

The Approximate Lethal Dose (ALD) of methacrylic acid by the oral route for the rat was 1000 mg/kg of body weight. At dosage levels of 3400, 2250, 1500, and 1000 mg/kg, two rats each were dosed, one with the undiluted material, the other with a 10% or 30% aqueous solution. Doses above 3400 mg/kg were with the undiluted acid, whereas those below 1000 mg/kg were with 5% or 10% aqueous solutions. Only the undiluted dosages were lethal at 1500 and 1000 mg/kg, the rats dying in 19 hours and 21 days, respectively. The lowest lethal dose for rats in the dilution series was 2250 mg/kg.

Lethal doses above 1000 mg/kg produced gasping, labored respiration, prostration, and hematuria. The animal that succumbed after 1000 mg/kg exhibited inactivity, discomfort, decreased water intake, and severe weight loss.

Animals that received nonlethal doses showed inactivity, poorly-formed feces for 2-7 days, slight initial weight losses, and some decreased water intake. Hematuria was observed on the day of dosing with the animal that received 1500 mg/kg as an aqueous solution. The lowest dose administered was 60 mg/kg.

Necropsy of animals that died indicated that death resulted from necrosis of the esophagus, stomach, intestines, and organs adjacent to the gastrointestinal tract. These lesions were accompanied by secondary effects in other organs denoting circulatory failure attendant upon the primary injury to the alimentary tract. At sublethal dosages, the gross changes observed were considered inconsequential.

Microscopic examination of organs confirmed that the compound exerted its most intense action at the primary site of contact, viz., the alimentary tract, causing acute tissue destruction and degenerative changes. Changes observed microscopically at all sublethal levels were less severe and generally dose related. Organs exhibiting slight to moderate degenerative changes with some evidence of recovery in the 14-day period were: brain, heart, kidney, thymus, testes, pituitary, and spleen.

The pH of the undiluted material was < 1, while that of the aqueous solutions was approximately 2. Many of the adverse effects of the compound are ascribable to this acidic nature.

B. POLYMETHACRYLIC ACID

The oral ALD of polymethacrylic acid for the rat was greater than 5000 mg/kg of body weight, the maximum feasible dose. There was a slight initial weight loss, but no clinical signs of toxicity were observed in the two animals, one dosed at 3400 mg/kg, the other at 5000 mg/kg. A lack of material precluded further doses. Histology of the two rats sacrificed 14 days after dosing disclosed slight injury to the alimentary tract in both. Of the other organs studied at 14 days, only the kidneys and testes displayed degenerative changes. None of the changes observed appeared progressive, and recovery was evident in several organs. All tissue changes at the doses of 5000 and 3400 mg/kg were of less consequence than those observed at 3400 mg/kg of methacrylic acid.

With only the two rats available in this particular test it is not possible to achieve a good comparison between monomeric methacrylic acid and the polymeric form. However, the observations indicate that polymethacrylic acid is less active biologically than the monomeric acid.

C. BENZENE EXTRACT OF AN ETHYLENE-METHACRYLIC ACID COPOLYMER

The oral ALD of this material for the rat was greater than 7500 mg/kg of body weight, the maximum feasible dose. No clinical signs of toxicity were observed in the two animals dosed at 2250 mg/kg and 7500 mg/kg. The material supplied was insufficient for additional doses. Microscopic examination of organs of the animals sacrificed 14 days after dosing indicated that the same organs were similarly affected by this compound as had been affected by the polymethacrylic acid. However, the testicular response was more severe with the benzene extract.

Conclusions

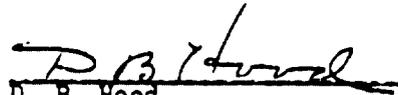
On the basis of these preliminary tests, with only two rats dosed for each sample of the polymethacrylic acid and the benzene extract of an ethylene-methacrylic acid copolymer, the monomeric methacrylic acid was more toxic than both of the polymeric materials. The tissue changes observed were qualitatively similar, but were more severe in the case of methacrylic acid as judged by the reactions at lower doses. Comparison between polymethacrylic acid and the benzene extract of an ethylene-methacrylic acid copolymer is based on too small a sample to be adequate, but the kidney lesions merit attention as well as the degenerative changes in the testes, which appeared more severe in the rats receiving the copolymer-benzene extract.

In view of these results, it would be desirable to have a better characterization of the polymers involved since the presence of unreacted monomer or other impurities may have exerted some influence. Before an opinion can be formed on the suitability of these materials for potential food contact, additional studies to define chronic toxicity are necessary.

Report by:


Henry Sherman
Toxicologist

Approved by:


D. B. Hood
Chief, Toxicology Section


J. Wesley Clayton, Jr.
Assistant Director

HS/jtd
December 28, 1962
Report No. 98-62

Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP

CAP

Submission number: 12394A

TSCA Inventory:

Y

N

5

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

For Contractor Use Only

entire document: 0 1 2 pages 1,9 pages _____

Notes:

Contractor reviewer : JW Date: 1/17/96



CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ 1092-12394 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: E. J. Dupont de

Nemours and Company

SUB. DATE: 10/15/92 OTR DATE: 10/27/92 CSRAD DATE: 04/27/95

CHEMICAL NAME:

Methacrylic acid copolymer, benzene extract of an ethylene-

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
- 0676 CAP NOTICE

VOLUNTARY ACTIONS:

- 0407 NO ACTION REPORTED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION OF WORK IN PROGRESS
- 0404 LAB/PLANS/CS/CHANGES
- 0405 PROCEEDING/CHANGES
- 0406 APPROUSE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

CASE#

79-41-4
25087-26-7
25033-53-6

unknown

INFORMATION TYPE:

- 0201 ONCO (HUMAN)
- 0202 ONCO (ANIMAL)
- 0203 CELL TRANS (IN VITRO)
- 0204 MUTA (IN VITRO)
- 0205 MUTA (IN VIVO)
- 0206 REPRO/TERATO (HUMAN)
- 0207 REPRO/TERATO (ANIMAL)
- 0208 NEURO (HUMAN)
- 0209 NEURO (ANIMAL)
- 0210 ACUTE TOX. (HUMAN)
- 0211 CHR. TOX. (HUMAN)
- 0212 ACUTE TOX. (ANIMAL)
- 0213 SUB ACUTE TOX (ANIMAL)
- 0214 SUB CHRONIC TOX (ANIMAL)
- 0215 CHRONIC TOX (ANIMAL)

INFORMATION TYPE:

- 0216 EPICLIN
- 0217 HUMAN EXPOS (PROD CONTAM)
- 0218 HUMAN EXPOS (ACCIDENTAL)
- 0219 HUMAN EXPOS (MONITORING)
- 0220 BIOAQUA TOX
- 0221 ENV. OCCURRENCE/FATE
- 0222 EMER INCI OF ENV CONTAM
- 0223 RESPONSE REQUEST DELAY
- 0224 PROD/COMP/CHEM ID
- 0225 REPORTING RATIONALE
- 0226 CONFIDENTIAL
- 0227 ALLERG (HUMAN)
- 0228 ALLERG (ANIMAL)
- 0229 METAB/PHARMACO (ANIMAL)
- 0230 METAB/PHARMACO (HUMAN)

INFORMATION TYPE:

- 0241 IMMUNO (ANIMAL)
- 0242 IMMUNO (HUMAN)
- 0243 CHEM/PHYS PROP
- 0244 CLASTO (IN VITRO)
- 0245 CLASTO (ANIMAL)
- 0246 CLASTO (HUMAN)
- 0247 DNA DAM/REPAIR
- 0248 PRODUCE/PROC
- 0251 MSDS
- 0259 OTHER

P F C

- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04
- 01 02 04

TRIAGE DATA: NON-CBI INVENTORY

YES

NO

IN IT-AMING

CAS SR

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFTR

SPECIES

RAT

TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

USE

PRODUCTION:

12394A

L

Methacrylic acid: Acute oral toxicity in rats is of low concern. Single oral gavage doses of the undiluted material to male ChR-CD rats were lethal at $\geq 1,000$ mg/kg. Single oral gavage doses of the diluted material (5-30% aqueous solutions) to male ChR-CD rats were lethal at $\geq 2,250$ mg/kg. Clinical signs in animals that received lethal doses included gasping, labored respiration, prostration, and hematuria. Necropsy revealed acute destruction of the alimentary tissues and adjacent organs in animals that died. Other organs exhibited slight to moderate degenerative changes, including the brain, heart, kidneys, thymus, testes, pituitary, and spleen. The pH of the undiluted material was < 1 ; the pH of the aqueous solutions was approximately 2.

L

Polymethacrylic acid: Acute oral toxicity in rats is of low concern. Single oral gavage doses to male ChR-CD rats (1/dose) at levels of 3,400 or 5,000 mg/kg were not lethal. Necropsy revealed slight injury to the alimentary tract. Degenerative changes were also seen in the kidneys and testes.

L

Benzene extract of an ethylene-methacrylic acid copolymer: Acute oral toxicity in rats is of low concern. Single oral gavage doses to male ChR-CD rats (1/dose) at levels of 2,250 or 7,500 mg/kg were not lethal. Necropsy revealed slight injury to the alimentary tract. Degenerative changes were also seen in the kidneys and testes.