
TSCA Section 8(e) Reporting Guide



TSCA Section 8(e) Reporting Guide

June 1991

NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS. Any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

--Section 8(e), Toxic Substances Control Act (1976)

Office of Toxic Substances
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, D.C. 20460

TSCA Section 8(e) Reporting Guide

Preface

This "reporting guide" has been compiled by EPA's Office of Toxic Substances (OTS) to assist potential respondents who manufacture, import, process or distribute chemical substances in complying with Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA).

There are two major objectives for presenting this guide. First, the guide will make certain information pertaining to Section 8(e) reporting even more accessible to members of the regulated community and others. Second, the guide will provide reference to both general and specific examples of submitted information as well as EPA's comments regarding such submissions. The examples are intended to help persons who are subject to section 8(e) understand better the types of information that should be submitted to the Agency under this very important mandatory hazard/risk information reporting provision of TSCA.

Most of this TSCA Section 8(e) reporting guide is presented in a basic question and answer format reflecting primarily the most common questions asked about Section 8(e) of TSCA. In addition, this reporting guide contains EPA's comments regarding the TSCA Section 8(e)-applicability/reportability of a number of toxicologic "case studies" provided by the Chemical Manufacturers Association (CMA). The guide also contains an index of Section 8(e) "status reports" reflecting Section 8(e) reporting guidance (Appendix A) and an index of all status reports prepared to date arranged by submitted information type (Appendix B).

EPA recommends that this TSCA Section 8(e) reporting guide be used as a tool in conjunction with EPA's March 16, 1978, Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110). EPA's TSCA Section 8(e) policy statement is included as Appendix C at the back of this reporting guide. Also included is Appendix D which contains a copy of a February 1, 1991 Federal Register notice that announced EPA'S TSCA Section 8(e) "Compliance Audit Program" (CAP) and copies of EPA's April 26, 1991 and encoded June 20, 1991 Federal Register notices announcing certain modifications to the CAP.

This reporting guide is being distributed publicly through the TSCA Assistance Information Service (TSCA Hotline) in the Environmental Assistance Division (EAD/OTS). Persons wishing to obtain a copy of the guide should contact the TSCA Hotline. The telephone numbers, telefax numbers and/or addresses of the TSCA Hotline, other EPA Offices, and other organizations cited throughout this guide are presented for the reader's convenience on the next few pages.



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Existing Chemical Assessment Division/OTS

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TSCA Hotline

Phone: (202) 554-1404

Telefax: (202) 554-5603

Address: TSCA Assistance Information Service
Environmental Assistance Division
Office of Toxic Substances (TS-799)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

TSCA Section 8(e) Document Processing Center

Address: Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

"For Your Information" (FYI) Document Processing Center

Address: Document Processing Center (TS-790)
(Attn: FYI Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
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Washington, D.C. 20460

TSCA Section 8(e) and FYI Document Control Officer

Name: Michel Stewart

Phone: (202) 382-3532
(202) 260-1532 (after 8/24/91)

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TSCA Confidential Business Information (CBI) Issues

Address: Confidential Data Branch
Information Management Division
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-7425
(202) 260-0425 (after 8/24/91)

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Phone: (202) 475-8823
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Public Docket/Office of Toxic Substances

Address: OTS Public Docket
Room G-004, NorthEast Mall
U.S. Environmental Protection Agency
401 "M" Street S.W.
Washington, D.C. 20460

Hours of Operation: 8-12 and 1-4 Monday through Friday
(Closed on Federal Holidays)

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Freedom of Information Office/EPA

Address: Freedom of Information Office (A-101)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Office of Compliance Monitoring

Address: Office of Compliance Monitoring (EN-342)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-3807
(202) 260-3807 (after 8/24/91)

Office of General Counsel

Address: Pesticides and Toxic Substances Division
Office of General Counsel (LE-132-P)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-7505
(202) 260-7505 (after 8/24/91)

Office of Enforcement

Address: Pesticides and Toxics Enforcement Division
Office of Enforcement (LE-134-P)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-8690
(202) 260-8690 (after 8/24/91)

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National Response Center

Toll-Free: (800) 424-8802

Local: (202) 426-2675

EPA Regional Office 24-Hour Phone Numbers

Region 1	(617) 223-7265	Region 6	(214) 655-2222
Region 2	(201) 548-8730	Region 7	(913) 236-3778
Region 3	(215) 597-9898	Region 8	(303) 293-1788
Region 4	(404) 347-4062	Region 9	(415) 744-2000
Region 5	(312) 353-2318	Region 10	(206) 442-1263

National Technical Information Service

Address: National Technical Information Service (NTIS)
U.S. Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22161

Phone: (703) 487-4600

National Library of Medicine (NLM)

Address: National Library of Medicine
U.S. Department of Health and Human Services
8600 Rockville Pike
Bethesda, Maryland 20894

Phone: (301) 496-6193

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Chemical Information Systems, Inc. (CIS)

Address: Chemical Information Systems, Inc.
 7215 York Road
 Baltimore, Maryland 21212

Phone: (800) CIS-USER (Toll-Free)
 (301) 321-8440 (Local)

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APPENDIX C

TSCA Section 8(e) Policy Statement 91
 (March 16, 1978; 43 FR 11110)

Technical Amendment Citation. 98
 (May 29, 1987; 52 FR 20083)

APPENDIX D

TSCA Section 8(e) Compliance Audit Program Notice. 99
 (February 1, 1991: 56 FR 4128)

Compliance Audit Program Modifications. 104
 (April 26, 1991; 56 FR 19514)

Compliance Audit Program Modifications. 107
 (encoded version June 20, 1991: 56 FR Part IV)

APPENDIX E

Support Information for Confidentiality Claims. 111

PUBLISHER’S NOTE: Appendix C above is found on pages F4-F13.

Information in Appendix D above is quoted or referred to on pages F1-F3b.

Appendixes A, B, and E are found beginning on page F62.



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REPORTING UNDER SECTION 8(E) OF TSCA

WHAT IS THE STATUTORY LANGUAGE OF TSCA SECTION 8(E)?

Section 8(e) of the Toxic Substances Control Act (TSCA) states that "any person who manufactures [including imports], processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." [90 Stat. 2029, 15 U.S.C. 2607(e)]

WHY IS SECTION 8(E) REPORTING IMPORTANT?

In general, EPA considers Section 8(e) of TSCA to be a critically important information gathering tool that serves as an "early warning" mechanism for keeping the Agency and others apprised of new-found serious chemical hazards and/or exposures; Section 8(e) data are extremely valuable input for the hazard identification and risk assessment activities within and outside EPA.

HOW WAS EPA'S SECTION 8(E) POLICY STATEMENT DEVELOPED?

The Section 8(e) information reporting requirement took effect on January 1, 1977, the effective date of TSCA. Although Section 8(e) contains self-implementing reporting requirements, EPA sought public comment and input in order to make more informed decisions regarding implementation of Section 8(e). Following receipt and consideration of numerous public comments on a September 9, 1977 proposed policy statement, EPA published its March 16, 1978 final Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FEDERAL REGISTER 11110). [**Publisher's Note:** The March 16, 1998 "Statement of Interpretation" is found on pages F4-F13 of this book.] The 1978 policy statement clarifies the types of information that are required for submission under Section 8(e), and describes the procedures for reporting such information to EPA. A minor technical amendment to EPA's 1978 TSCA Section 8(e) policy statement involved a change in the address to which Section 8(e) notices are to be sent (52 FEDERAL REGISTER 20083; May 29, 1987). For easy referral when using this reporting guide, the Agency's Section 8(e) policy statement has been reproduced as Appendix C at the back of the guide.

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WHAT IS "SUBSTANTIAL RISK" INFORMATION?

The term "substantial risk" information refers to that information which reasonably supports a conclusion that the subject chemical or mixture presents a substantial risk of injury to health or the environment ; however, such information need not and most typically does not establish conclusively that a substantial risk exists.

In deciding whether information is "substantial risk" information, one must consider 1) the seriousness of the adverse effect, and 2) the fact or probability of the effect's occurrence. In determining TSCA Section 8(e)-applicability/reportability, these two criteria should be weighted differently depending upon the **seriousness of the effect** or the **extent of the exposure**, i.e., the more serious the effect, the less heavily one should weigh actual or potential exposure, and vice versa. For example, in cases where serious effects such as birth defects or cancer (as evidenced by benign and/or malignant tumors) are observed, the mere fact that the implicated chemical is in commerce (including chemicals at the research and development stage) constitutes sufficient evidence of exposure to submit the new-found toxicity data.

EPA has also received numerous Section 8(e) submissions alerting the Agency that chemical substances already known to be capable of causing serious health and/or environmental effects were detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air (including workplace air)) or in products not known previously by the Agency to contain such chemicals. In such cases, the discovery of previously unknown and significant human and/or environmental exposure, when combined with knowledge that the subject chemical is already recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious environmental effects (e.g., non-trivial aquatic species toxicity), can provide a sufficient basis to report the new-found exposure data to EPA under Section 8(e) of TSCA.

The decision-making process for Section 8(e)-reportability should focus primarily on whether the toxicity or exposure information offers reasonable support for a conclusion of substantial risk under the criteria described above, but should not focus at all on whether the information is conclusive regarding the risk. A

1 "Substantial risk" information must be reported to EPA unless the subject person has actual knowledge that the Agency has been adequately informed of such information. A detailed discussion of the types of information about which EPA considers itself to be adequately informed is presented on Page 8 of this reporting guide under **WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?**

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decision to report information to the Agency under Section 8(e) should not involve exhaustive health and/or environmental risk assessments of the subject chemical(s). Further, determining reasonable support for a conclusion of substantial risk should not include any evaluation of either the economic or social benefits of the use(s) of the subject chemical substance(s). Finally, determining whether reasonable support exists for "substantial risk" is not synonymous with the determination of an "unreasonable risk" as that term is used elsewhere in TSCA.

WHO IS SUBJECT TO SECTION 8(E) REPORTING?

For the purposes of Section 8(e), the term "person" includes the following: any natural person, corporation, firm, company, sole-proprietorship, joint-venture, partnership, association, or any other business entity, any State or political subdivision of a State, any municipality, any interstate body, and any department or agency of the Federal Government.

Such "persons" are subject to TSCA Section 8(e) only to the extent they are engaged in commercial activities involving manufacture, importation, processing or distribution of chemical substances or mixtures under the jurisdiction of TSCA and therefore covered by Section 8(e) of TSCA. While it is clear that entities such as labor unions, trade associations, contract testing laboratories and agencies of the Federal Government are "persons" covered by TSCA Section 8(e), the mandatory obligation to report substantial risk information is incurred only to the extent that the entity is engaged commercially in manufacturing, importing, processing or distribution of the chemical substance or mixture about which substantial risk information is obtained; however, these particular entities are not typically involved in such commercial activities.

Under Section 8(e), there are no exemptions for small businesses, small production or importation volumes, or commercial activities such as manufacture for export only or research and development. However, Section 8(e) does not require a subject person to submit information about a chemical substance or mixture that the person does not manufacture, import, process or distribute commercially. Further, a person who obtains substantial risk information about a chemical or mixture that the person did at one time, but does not any longer, manufacture, import, process or distribute in commerce, is not required to submit the information under Section 8(e).

Despite these limitations in coverage, EPA has received numerous Section 8(e) submissions from respondents who obtained otherwise reportable Section 8(e) information but for some technical reason did not have any statutory obligation to submit the information to EPA pursuant to Section 8(e). EPA believes that such submissions are of significant benefit, in many cases, to others who currently

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handle the subject chemical(s) and who can take actions that are designed generally or specifically to reduce or eliminate health or environmental hazards/risks. A formal TSCA Section 8(e) or "For Your Information" (FYI) notice under these circumstances is a clear demonstration of the respondent's stewardship. EPA encourages and welcomes these technically voluntary submissions either pursuant to Section 8(e) or on an FYI basis.

In implementing Section 8(e) of TSCA, EPA strives to ensure that pertinent information is reviewed promptly, and given appropriate consideration, by subject persons for submission to EPA, while at the same time minimizing duplicative or ill-considered notices. The Agency believes these objectives are served best by allowing commercial establishments to assume the exclusive responsibility to submit substantial risk information that is obtained by individual employees and officials. Accordingly, EPA's Section 8(e) policy statement explains that individual officers/employees are viewed as having discharged their individual Section 8(e) responsibilities once they notify a designated supervisor or official in full about pertinent information, provided that the employing entity has an established, internally publicized and affirmatively implemented procedure governing such notices. The Agency's Section 8(e) policy statement specifies that such procedures, at a minimum, must:

- (1) specify the information that must be reported;
- (2) indicate how the reports are to be prepared and submitted internally;
- (3) note the Federal civil and criminal penalties for failure to report substantial risk information; and
- (4) provide a mechanism for the timely notification of officers and employees who submitted reports about the disposition of those reports. Such notification should inform the reporting employee/officer as to whether or not the information was submitted to EPA, and if not, inform the employee or officer of their protected right (under Section 23 of TSCA) to report the information directly to EPA.

The Agency believes that the above procedures serve to ensure prompt and appropriate processing and consideration of pertinent information by persons subject to Section 8(e) of TSCA. It is important to note, however, that despite the establishment of such procedures, those employees and officers who are responsible for actual management of the organizations's Section 8(e) reporting obligations retain personal civil and/or criminal liability for ensuring that substantial risk information is submitted to the Agency. In the absence of such established internal procedures, all employees and officers retain their individual responsibilities and liabilities for ensuring that substantial risk information is reported to EPA.

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WHAT CHEMICALS ARE SUBJECT TO SECTION 8(E) REPORTING?

Chemicals not under TSCA jurisdiction and therefore not covered by Section 8(e) are discussed in Section 3 of TSCA and include:

- (1) pesticides (as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)) when manufactured, processed, or distributed in commerce for use as a pesticide;
- (2) tobacco and tobacco products;
- (3) source materials, special nuclear materials and byproducts (as defined in the 1954 Atomic Energy Act (AEA) and regulations issued under the AEA);
- (4) foods, food additives, drugs, cosmetics, and devices (as defined in the Federal Food, Drug and Cosmetic Act (FFDCA)) when manufactured, processed or distributed in commerce as a food, food additive, drug, cosmetic or device.

Except for those chemicals specifically excluded by definition from TSCA jurisdiction, Section 8(e) of TSCA pertains to all chemical substances and mixtures including but not limited to the following:

- (1) research and development (R&D) chemicals (including those intended for use as pesticides prior to application for an Experimental Use Permit (EUP) or a registration under FIFRA);
- (2) laboratory reagents;
- (3) low volume chemicals;
- (4) polymers;
- (5) chemicals that are manufactured solely for export;
- (6) intermediates (including non-isolated intermediates as well as pesticide intermediates);
- (7) catalysts;
- (8) byproducts;
- (9) impurities;
- (10) TSCA-covered microorganisms and products therefrom.

Specifically with regard to "pesticides," a chemical substance that is manufactured, processed or distributed in commerce solely as a pesticide is excluded by Section 3 of TSCA from TSCA regulation. However, **a chemical substance which is in the process of research and development (R&D) as a pesticide is subject to TSCA until such time as the manufacturer or importer demonstrates the intent to**

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produce a pesticide by submitting to the Agency an application for an "Experimental Use Permit" (EUP) or registration under FIFRA. For further information about this TSCA/FIFRA jurisdictional issue, the reader is directed to EPA's initial TSCA Chemical Substance Inventory reporting regulation (43 FR 64585; December 23, 1977; Appendix A Comment 37, 38 and 39) and the 1986 amendments to the TSCA Section 5 "Premanufacture Notification Rule" (51 FR 15098; April 22, 1986). Prior to the FIFRA EUP or registration stage, such R&D materials are chemical substances under the jurisdiction of TSCA including Section 8(e).

It is important to note also that while some rules promulgated by EPA under other sections of TSCA, or under other authorities which are administered by EPA, may exempt certain chemical substances and/or mixtures or certain types of commercial activities, such exemptions typically apply only to the rule issued by the Agency and not to TSCA in general or Section 8(e) of TSCA specifically.

WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN?

Section 8(e) pertains to information that a person possesses or about which the person knows. The Section 8(e) policy statement explains that an establishment obtains information at the time any officer or employee who is capable of appreciating the significance of the information obtains that information. "Known" information includes that information about which a prudent person of similar training, job function, etc., could be reasonably expected to know. Although Section 8(e) of TSCA does not compel subject persons to actively search for reportable information or to undertake extraordinary efforts to retrieve reportable information, negligence or the intentional avoidance of information does not absolve a person of his/her individual Section 8(e) reporting obligations. TSCA Section 8(e)-reportable information that is "obtained" by a company includes:

- a) information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement);
- b) information obtained for the first time after January 1, 1977 but before March 16, 1978; or
- c) information obtained by the company for the first time after March 16, 1978.

NOTE: For information regarding the specific time frames for reporting such "obtained" information, the reader's attention is directed to **WHEN MUST TSCA SECTION 8(E) INFORMATION BE REPORTED TO EPA?** on Page 11 of this guide.

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With regard to a), b) and c) on the preceding page, Section 8(e)-reportable information includes not only written reports, memoranda and other such documents examined after January 1, 1977, but also information referred to in formal or informal discussions and conferences in which a company participated after January 1, 1977.

Specifically with regard to a public scientific conference/meeting, visually or verbally obtained information from such a meeting is subject to Section 8(e) reporting unless the obtained information is captured accurately/adequately in a meeting transcript, abstract or other such written record or document that is to be formally released to the public within a reasonable time frame. Information obtained from a private conference or meeting, however, should be considered for reporting under Section 8(e) within 15 working days.

WHAT ARE THE SOURCES OF SECTION 8(E)-REPORTABLE INFORMATION?

TSCA Section 8(e)-reportable information can come from a variety of sources including, but not limited to draft, interim or final written reports (including study reports, letters, telegrams, telex reports) or verbal reports (received at meetings or by phone) that involve observations (including preliminary observations) from, for example, controlled or uncontrolled:

(1) human or animal studies/events (including but not limited to studies/events that involve high dose levels or non-routine routes of exposure);
or

(2) environmental events/studies (including but not limited to aquatic toxicity studies, bioaccumulation studies, chemical monitoring studies (supplemented if need be by information derived from computer modeling studies based on actual or reasonably anticipated chemical exposures and exposure-related parameters)). It is important to note, however, that modeling studies, including those based solely on theoretical exposure data (e.g., "worst-case" scenarios), are not considered by EPA to be sufficient in and of themselves to meet the Section 8(e) reporting requirements. Further, environmental or health risk assessments (including those using computer modeling) based on either 1) theoretical exposure data, or 2) actual exposure data submitted on a mandatory basis under an EPA-administered statute typically need not be reported under Section 8(e).

The evidence that offers reasonable support for a conclusion of substantial risk need not be complete nor definitive but should provide a plausible link between 1) an observed serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific product/activity and a previously unrecognized exposure to a chemical that is known or reasonably anticipated to cause serious adverse health or environmental effects.

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EPA's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110) also requires immediate reporting of "Emergency Incidents of Environmental Contamination" (EIEC). An EIEC is an environmental contamination (accidental or intentional in nature) involving a chemical known to be a serious human or environmental toxicant and which because of the extent, pattern and amount of the contamination (1) seriously threatens humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation (e.g., neurotoxicologic effects, serious reproductive system effects), or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?

There are several kinds of information about which the Agency considers itself to be adequately informed already for the purposes of Section 8(e) of TSCA. For example, information that otherwise meets the criteria for Section 8(e) reporting need not be submitted if the information meets one or more of the following criteria:

- (1) is contained in an EPA study or report.
- (2) is published in the open scientific literature.
- (3) has been submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.
- (4) is contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.
- (5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a **well-established** adverse effect.

It is important to note, however, that information that newly identifies a serious toxic effect at a lower dose level for example, or confirms a serious effect that was previously only suspected, is **not** considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

- (6) is information for which the EPA Administrator has waived compliance with TSCA in general or Section 8(e) specifically upon a request and determination of the President of the United States that such a waiver is required in the interest of the national defense; Section 22 of TSCA outlines the procedures by which such waivers are to be requested/issued.

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With regard to item (2) on the preceding page, EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is obtained from well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) publications such as Current Contents published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania). Similarly, information that is obtained from major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information obtained from lesser known scientific journals, or from other magazines, newspapers, radio or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information.

Specifically with regard to item (3) on the preceding page, it is clear that information submitted or otherwise formally reported (within 15 working days of obtaining the information) pursuant to a mandatory reporting requirement of a statute administered by EPA need not be submitted duplicatively under Section 8(e) of TSCA. Part VII(b) of EPA's March 16, 1978 Section 8(e) policy statement is illustrative in that it provides a list of only a few such EPA-administered statutes. The following is a more current list of the statutes administered by EPA.

Toxic Substances Control Act (TSCA)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Clean Air Act (CAA)

Clean Water Act (CWA)

Safe Drinking Water Act (SDWA)

Federal Water Pollution Control Act (FWPCA)

Marine Protection, Research and Sanctuaries Act (MPRSA)

Resource Conservation and Recovery Act (RCRA)

RCRA Hazardous and Solid Waste Amendments (HSWA)

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA;
SUPERFUND)

Superfund Amendments Reauthorization Act (SARA)

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Specifically with regard to item (4) on Page 8, it cannot be automatically assumed that the Agency has been adequately informed about information in a report or study by another Federal or other governmental agency if the report or study has not been formally published or otherwise released to the general public. Therefore, if a person obtains (i.e., possesses or knows of), for example, certain unpublished Section 8(e)-reportable information from a study that is conducted by or for an agency of the U.S. Government (other than EPA), that person must consider the need to immediately submit those findings under Section 8(e). Since 1977, EPA has received a number of Section 8(e) notices filed by companies who had obtained unpublished results of studies conducted by or for other Federal or other governmental agencies. In most cases, such submissions are limited to 1-2 pages and the Agency immediately establishes direct contact with the responsible agency to minimize or eliminate the company's Section 8(e) reporting burden.

HOW DOES 8(E) RELATE TO TSCA SECTIONS 4, 5 & 8(D) REPORTING?

The TSCA Section 8(e) reporting requirement applies to "substantial risk" information obtained during any study conducted under TSCA Sections 4 or 5, or any study "listed" under TSCA Section 8(d) as being underway unless such information is otherwise required to be reported immediately to EPA under 1) Sections 4, 5 or 8(d) of TSCA, 2) some other section of TSCA, or 3) some other authority that is administered by EPA. To date, the Agency has received numerous TSCA Section 8(e) notices concerning the interim results of studies conducted pursuant to Sections 4 or 5 of TSCA, or listed under Section 8(d) of TSCA. The Section 8(e) reporting that took place in these instances typically occurred because the obligation to report under Section 8(e) was incurred before reporting of the study findings was required under Sections 4, 5 or 8(d) of TSCA. If other required reporting occurs before or coincidental with incurring a Section 8(e) reporting obligation, that information does not need to be reported also under Section 8(e) of TSCA. This exemption does not change substantially the Section 8(e) reporting obligation; it is designed merely to avoid duplicative notices except in cases where timeliness considerations become paramount.

DOES A "FOR YOUR INFORMATION" SUBMISSION SATISFY 8(E) REQUIREMENTS?

Section 8(e)-reportable information submitted to EPA on a "For Your Information" (FYI) basis does not satisfy the requirements for the submission of information under Section 8(e). TSCA Section 8(e) information must be reported to EPA in full accordance with the procedures outlined in Part IX of the Agency's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110)

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and its technical amendment (52 FR 20083). The TSCA Section 8(e) policy statement/technical amendment appear at the back of this reporting guide as Appendix C. In addition, the reader's attention is directed to **WHERE MUST SECTION 8(E) INFORMATION BE REPORTED?** and **HOW MUST SECTION 8(E) INFORMATION BE REPORTED?** found on Page 12 and Page 13 of this reporting guide, respectively. Finally, it should be noted that EPA's Office of Compliance Monitoring (OCM/OPTS) has issued a number of "Notices of Non-Compliance" to companies that have submitted TSCA Section 8(e)-reportable information in a timely manner but simply on an FYI basis and not under Section 8(e). For further information with regard to EPA's enforcement activities relating to TSCA Section 8(e), the reader's attention is directed also to **HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS?** which can be found on Page 27 of this reporting guide.

DOES REPORTING TO ANOTHER AGENCY SATISFY SECTION 8(E) REQUIREMENTS?

Mandatory or other reporting of information to another agency does not satisfy a company's obligation to immediately inform EPA under Section 8(e) of TSCA. EPA'S TSCA Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110), which appears as Appendix C at the back of this guide, explains clearly that "substantial risk information must be reported to EPA." (emphasis added)

WHEN MUST SECTION 8(E) INFORMATION BE REPORTED?

A person is considered to have discharged the TSCA Section 8(e) reporting obligation if the information is received at EPA Headquarters in writing within 15 working days after the person obtained the information. Relevant or significant supplemental data obtained after an initial Section 8(e) submission should also be reported in writing to EPA immediately (i.e., within 15 working days). The reader's attention is directed to **WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN?** found on Page 6 of this reporting guide.

For an "Emergency Incident of Environmental Contamination" (EIEC), a telephone call to the appropriate EPA Regional Office must be placed immediately (i.e., as soon as reasonably possible); these phone numbers are given in the next section of this guide. A written follow-up report must also sent to EPA Headquarters within 15 working days of the date on which the telephone report was made.

Specifically with regard to 1) Section 8(e)-reportable information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement), or 2) Section 8(e)-reportable

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information obtained for the first time after January 1, 1977 but before March 16, 1978, such information should have been submitted already to EPA on or before the 60th day following March 16, 1978.

TSCA Section 8(e)-reportable information (including pre-1977 information) that is (was) obtained by a company for the first time following March 16, 1978 should be submitted (or should have been submitted already) to EPA within 15 working days of the date on which the information is (was) obtained by the company for the first time after March 16, 1978.

WHERE MUST SECTION 8(E) INFORMATION BE REPORTED?

As explained in a technical amendment (52 FR 20083; May 29, 1987) to EPA'S Section 8(e) policy statement, Section 8(e) submissions (including written follow-up reports for "Emergency Incidents of Environmental Contamination" (EIEC)) must be transmitted to EPA at the following address:

Document Processing Center (TS-790)
 (Attn: Section 8(e) Coordinator)
 Office of Toxic Substances
 U.S. Environmental Protection Agency
 401 "M" Street, S.W.
 Washington, D.C. 20460

The initial phone report for an EIEC should be placed immediately (i.e., as soon as is reasonably possible) to the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered; the current 24-hour phone numbers for EPA'S 10 Regional Offices are as follows.

Region	1	(617) 223-7265	Region	6	(214) 655-2222
Region	2	(201) 548-8730	Region	7	(913) 236-3778
Region	3	(215) 597-9898	Region	8	(303) 293-1788
Region	4	(404) 347-4062	Region	9	(415) 744-2000
Region	5	(312) 353-2318	Region	10	(206) 442-1263

In the event that a respondent cannot reach the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered, the respondent should immediately call the **National Response Center at (800)-424-8802 or 202-426-2675** and provide all known information

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requested by the officer on duty. Under these circumstances, the respondent will be considered to have satisfied the initial phase of the Section 8(e) reporting obligation; a written "follow-up" report regarding the EIEC, however, must still be submitted to EPA Headquarters within 15 working days of the EIEC phone report.

Persons wishing to submit data to EPA's Office of Toxic Substances simply on a "For Your Information" (FYI) basis and not pursuant to Section 8(e) of TSCA should send the information to:

Document Processing Center (TS-790)
(Attn: FYI Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Persons submitting information to EPA on an FYI basis should be aware that the Agency's processing of documents received under mandatory reporting provisions of TSCA always takes precedence over those submitted simply as FYI. The reader should also be aware that the submission of data to the Agency on an FYI basis does not satisfy a TSCA Section 8(e) reporting obligation. For further information on this particular subject, the reader's attention is directed to **DOES A FOR YOUR INFORMATION SUBMISSION SATISFY SECTION 8(E) REQUIREMENTS?** found on Page 10 of this reporting guide.

HOW MUST SECTION 8(E) INFORMATION BE REPORTED?

Section 8(e) submissions must be transmitted to EPA in a manner that permits the Agency to verify receipt of the submission (e.g., certified or registered mail). In addition, the submission must state clearly that it is being provided under Section 8(e) of TSCA. Further, the submission must contain the name, title and telephone number of the person sending the information, the name and address of the establishment with which the reporting person is affiliated, the name(s) (including Chemical Abstract Service (CAS) Registry Number(s), if known) of the subject chemical(s), and a summary describing the nature of adverse effects or exposure being reported together with the source of any supporting technical data.

For an "Emergency Incident of Environmental Contamination" (EIEC), the initial telephone report must provide the time and location of the incident and as much of the above information as is known at the time. A written EIEC follow-up report to EPA Headquarters must contain the same types of information that are required in a non-EIEC initial Section 8(e) submission.

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HOW CAN CONFIDENTIAL DATA BE CLAIMED/SENT UNDER SECTION 8(E)?

In claiming any submitted information to be "Confidential Business Information" (CBI) under TSCA, respondents should be aware that all of the information reported under specific TSCA requirements (e.g., Section 8(e)) or in support of TSCA is subject to 1) provisions of Section 14 of TSCA, and 2) EPA's regulations on confidentiality of business information (40 CFR Part 2). Any person who submits CBI to EPA under Section 8(e) should be aware that **two copies must be provided**. The first copy should be complete, with all CBI marked carefully and clearly by boxing, circling or underlining; all of the pages containing CBI should be stamped "**CONFIDENTIAL**". The other copy should have all of the confidential information excised; this "sanitized" version is required for EPA's public files. Any person who submits CBI to EPA under Section 8(e) of TSCA should also be aware that the Agency does request a **detailed written substantiation** for all TSCA CBI claims. (A copy of a two-page document entitled "Support Information for Confidentiality Claims" is included as Appendix E to this reporting guide.) Finally, a person who submits TSCA CBI to EPA under Section 8(e) should also be aware that the Agency is under no formal obligation to review, and typically does not review, company-sanitized documents for errors made in sanitizing those documents.

HOW DOES EPA IDENTIFY/TRACK INCOMING SECTION 8(E) NOTICES?

A Document Control Number is used by EPA to identify TSCA Section 8(e) submissions and takes the following form: 8EHQ-0000-0000. Starting at the left, the first four symbols identify the information as a Section 8(e) submission received by EPA Headquarters; the next four digits identify the month and year (e.g., -0591-) of the Agency's receipt of the information; the final four digits identify the submission's chronological number. In addition to the basic numerical sequence, additional characters may be added to the right end of the Document Control Number to convey other information. These additional characters and their meaning are as follows:

- S: indicates that the Section 8(e) notice was sanitized to delete information claimed by the submitter to be TSCA Confidential Business Information (TSCA CBI);

- P: indicates that the Section 8(e) notice contained a name or other identification (e.g., a Social Security Number) of an individual, the release of which may violate the Privacy Act; such documents are sanitized by EPA to remove such identifiers;

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*: indicates that based on EPA's preliminary evaluation, the submission was either considered to be unwarranted for reporting under Section 8(e) of TSCA or that it was not clear to EPA that submission was warranted and further clarifying information was requested from the submitter.

INIT: denotes that the submission is an initial submission;

FLWP: indicates that the submission is a followup response; and

SUPP: indicates that the notice is a supplemental submission.

By definition, follow-up response submissions contain information submitted directly in response to a specific EPA request, whereas supplemental submissions are those that contain information not specifically requested by the Agency.

HOW DOES OTS REVIEW/USE SECTION 8(E) INFORMATION?

Although EPA'S receipt of information under Section 8(e) of TSCA does not necessarily trigger immediate regulatory action under TSCA or another authority administered by EPA, the submitted information is processed and evaluated on a priority basis to determine an appropriate level of concern and initial course of Agency action.

Thus far, EPA and the chemical industry have devoted significant efforts in fulfilling their respective responsibilities under Section 8(e) of TSCA. Since January 1, 1977, over 1250 initial Section 8(e) notices covering a broad range of toxicity and exposure-related data on a wide variety of chemicals have been received by OTS and been given priority evaluation and follow-up attention.

In general, each initial TSCA Section 8(e) submission is promptly reviewed and evaluated by OTS scientific staff to determine both the degree of concern that should be attached to the submitted information and the initial course of any warranted OTS follow-up action(s). A "status report" is prepared containing a brief description of the submitted information, the results of the OTS preliminary evaluation, a statement regarding production and use of the subject chemical(s) and recommendations for appropriate follow-

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up actions.² Upon approval of the status report, recommended follow-up actions are initiated. A letter forwarding the status report and any EPA requests for additional information is sent to the submitting organization. In addition, copies of all status reports are transmitted to EPA'S public files, other designated EPA Program Offices and Federal Agencies, and to the OTS Environmental Assistance Division (EAD/OTS) for further distribution.

Other OTS follow-up actions include the consideration of further, more in-depth assessment of the reported chemical's hazard or risk. OTS staff also immediately reviews, evaluates, and initiates appropriate follow-up actions or activities on information that is contained in "follow-up" and "supplemental" TSCA Section 8(e) submissions; over 2000 TSCA Section 8(e) supplemental and follow-up submissions have been received and promptly evaluated by OTS staff since January 1, 1977.

OTS utilizes TSCA Section 8(e) submission data for hazard/risk identification purposes primarily in the initial stages of the OTS Existing Chemical Program (ECP). OTS also uses these data in ongoing health and exposure assessments of both existing and new chemicals and in support of regulation development under TSCA, e.g., development of chemical testing rules under TSCA Section 4.

EPA's proactive implementation of Section 8(e) of TSCA has resulted in heightened overall awareness of the risks posed by exposure to chemical substances and mixtures. Many benefits and impacts are evident from EPA's dissemination of TSCA Section 8(e) and related information to other EPA Offices, other Federal agencies, the general public and the international community. This heightened awareness has led, in many cases, to specific activities designed to directly or indirectly protect health and/or the environment.

OTS has established high level scientific and administrative contacts in each of the major EPA Program Offices and Regional Offices to provide a mechanism for the timely and prioritized dissemination of information about newly discovered chemical hazards or risks. These other EPA Program and Regional Offices effectively and routinely utilize TSCA Section 8(e) information in

² As of October 1, 1990, OTS began to issue "summaries" rather than "status reports" for incoming initial Section 8(e) submissions. These summaries contain a detailed accounting of toxicologic and other information (e.g., voluntary pollution prevention/risk reduction information, exposure data) presented in the initial TSCA Section 8(e) submission. The summaries do not reflect, however, the Agency's evaluation or disposition of the reported information. Copies of Section 8(e) submission summaries can be obtained in the same manner used to obtain copies of Section 8(e) status reports.

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implementing their regulatory programs. The following examples illustrate just some of the actions/activities initiated by other EPA Offices in response to Section 8(e) and related data.

Office of Water (OW/EPA)

- preparing/revising Water Quality Criteria Documents and Drinking Water Standards.

Office of Solid Waste and Emergency Response (OSWER/EPA)

- determining the need for/revision of listing and delisting actions under the Resource Conservation and Recovery Act (RCRA); and
- establishing/revising "Reportable Quantities" (RQs) and "Threshold Planning Quantities" (TPQs) for the chemicals that are under the jurisdiction of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; "Superfund").

Office of Research and Development (ORD/EPA)

- preparing/revising Health and Environmental Effects Profiles (HEEPs), Health Effects Assessments (HEAs) and Acceptable Daily Intakes (ADIs) for use by other EPA Program Offices; and
- determining the need for new EPA research or impact on ongoing EPA research activities.

Office of Air and Radiation (OAR/EPA)

- determining the need for and revising rules which govern chemical substances released to the air from stationary and/or mobile sources.

Office of Pesticide Programs (OPP/OPTS/EPA)

- assessing or reassessing the toxicity of or exposure to active ingredients/inerts in pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

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EPA Regional Offices

- EPA's 10 Regional Offices routinely receive copies of all updated indices for OTS holdings of Section 8(e) and FYI notices. In addition to providing new information about reported chemical hazards/risks, Regional receipt of this information has led numerous cases to compliance inspections under TSCA and other EPA administered authorities.

EPA has also established high level scientific and administrative contacts in other Federal agencies in order to provide a mechanism for the timely and prioritized dissemination of new information on chemical hazards/risks. The following examples illustrate some of the activities that have been initiated by other Federal agencies in direct response to TSCA Section 8(e) and related information supplied to those agencies by EPA.

National Institute for Occupational Safety and Health (NIOSH)

- preparing/revising Current Intelligence Bulletins;
- determining the need for workplace investigations leading to published Health Hazard Evaluations
- recommending to OSHA the need for new workplace standards or revisions to existing workplace standards;
- determining the need for new research or the impact on ongoing chemical research activities; and
- input of data into the Registry of Toxic Effects of Chemical Substances (RTECS) publication and on-line computerized data base.

Occupational Safety and Health Administration(OSHA)

- internally reviewing and distributing information to OSHA Regional/Area Offices and inspectors;
- filling data gaps in ongoing OSHA assessments/studies or determining the need for such assessments/studies; and
- determining the need for new OSHA workplace standards or revising existing workplace standards.



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Consumer Product Safety Commission(CPSC)

- determining the need for new CPSC regulatory efforts or the revision of existing CPSC regulations; and
- internal and external information circulation as part of CPSC's "Current Awareness Activities."

National Library of Medicine(NLM)

- input of toxicologic/exposure information to the NLM's publicly accessible computerized data bases.

National Toxicology Program(NTP)

- evaluating chemicals for toxicologic testing;
- monitoring results of non-NTP toxicity studies; and
- supplementing results of ongoing NTP studies.

Interagency Testing Committee(ITC)

- determining need for recommending chemicals for TSCA Section 4 health/environmental effects testing.

DO STATUS REPORTS REPRESENT EPA'S "BOTTOM LINE" REGARDING RISK?

When reviewing TSCA Section 8(e) status reports, the reader should realize that the purpose of the OTS preliminary evaluation is to determine the significance of the submitted information in terms of a need for possible follow-up action by EPA. This determination involves a critical analysis of the submitted data to assess the extent that the reported hazard/risk is supported by the provided information. The scope of this initial evaluation, however, is generally limited to the submitted documents and to any closely related information known by and/or readily available to the OTS staff reviewer. Neither a literature search to identify other reported effects nor an in-depth analysis of possible sources of exposure to subject chemicals is part of the initial evaluation process. Therefore, a status report should be viewed only as a preliminary evaluation of the submitted information and not as a comprehensive assessment of the chemical substance or mixture for which a TSCA Section 8(e) notice has been filed.

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HAS EPA ISSUED OTHER SECTION 8(E) GUIDANCE-RELATED INFORMATION?

The 1978 Section 8(e) policy statement, as frequently cited and quoted in 1) publicly available EPA "Question and Answer" (Q&A) documents on TSCA implementation issues raised at periodic public and individual meetings with Agency staff and management, and 2) numerous publicly available Section 8(e) "status reports" that provide illustrative examples of Section 8(e)-applicability, continues to serve as a sound and adequate basis for potential respondents to determine their mandatory reporting obligations under Section 8(e) of TSCA. In addition, EPA's publication of bound volumes of Section 8(e) status reports serves a two-fold purpose. First, volumes of status reports with indices help to make the information reported under Section 8(e) more readily accessible. Second, these Section 8(e) status report volumes, by providing easy access to specific examples of submitted information and EPA's preliminary evaluation of the information, help subject persons to understand better the kinds of information that should be reported to EPA under Section 8(e) of TSCA. The six (6) bound Section 8(e) status report volumes published by the Agency to date can be purchased directly from the National Technical Information Service (NTIS). The NTIS publication numbers of, and the TSCA Section 8(e) submission numbers covered by, these volumes are as follows:

<u>NTIS Publication Number</u>		<u>Submission Numbers</u>		
PB#	80-221609	8EHQ-0777-0001	to	8EHQ-0679-0291
PB#	81-145732	8EHQ-0779-0292	to	8EHQ-0180-0330
PB#	83-187815	8EHQ-0280-0331	to	8EHQ-1282-0467
PB#	87-129409	8EHQ-0183-0468	to	8EHQ-1284-0541
PB#	87-176004	8EHQ-0185-0542	to	8EHQ-1286-0648
PB#	89-182687	8EHQ-0187-0649	to	8EHQ-1288-0778

It should be noted that a seventh Section 8(e) status report volume covering initial Section 8(e) submission numbers 8EHQ-0189-0779 to 8EHQ-0989-1084 should be published by EPA in the summer of 1991; notice of the availability of this new status report compendium will be given in the OTS "Chemicals-in-Progress Bulletin." EPA plans to print only a limited number of copies of the new status report volume for distribution by the TSCA Hotline. After that supply is exhausted, copies of the new compendium can be purchased from NTIS. The addresses and telephone numbers for NTIS as well as the TSCA Hotline can be found in the "**Preface**" to this guide.

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With the exception of certain TSCA Section 8(e) Q&As that were made available by EPA in July 1989, all of the Agency's other published Section 8(e)-related Q&As (1986 and 1987) are embodied in full or in part in other sections of this reporting guide. For the sake of completeness, the specific Q&As from that July 1989 Section 8(e) Q&A document follow.

Q. Does Section 8(e) of TSCA intend the submission of animal test information: (a) when a determination of "substantial risk" has been made, or (b) where merely a finding of positive animal test results useful in the further assessment of human risk has been determined?

A. TSCA Section 8(e) requires the timely submission of evidence (including preliminary evidence) from animal studies that implicates the tested chemical as causing serious toxicologic effects (e.g., cancer, neurotoxicity, birth defects). A decision to report the observance of such serious toxicological effects should not hinge in any way on a judgement of either the actual or potential exposure to the chemical or a judgement about the degree of relevancy of the findings to an overall assessment of human risk. In other words, the decision to report under Section 8(e) in such cases should be based simply on the observance of the serious toxicologic effects.

Q. What criteria should be used to determine if the results from cancer bioassay studies in animals should be submitted to the Agency under Section 8(e) of TSCA? For example, when should animal studies showing only a significant increase in benign tumors over controls be submitted?

A. Reporting of benign and/or malignant tumors should take place, for example, when either statistically or biologically significant increases over controls are observed. The observation of such increases are made in many cases at interim sacrifices performed typically during long term exposure studies in animals.

Q. How should reproductive or developmental toxicity data be evaluated for possible Section 8(e) submission if maternal toxicity is also present?

A. Statistically or biologically significant increases in teratogenic effects or other serious embryotoxic or fetotoxic effects (e.g., significant embryo or fetal lethality, spontaneous abortion) should be reported under Section 8(e) regardless of the level of maternal toxicity observed in the study.

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Q. What are the criteria that should be used to determine which reproductive/developmental effects observed in animal tests are reportable under Section 8(e)? For example, should reversible developmental effects, such as reduced birth weight and/or incomplete ossification, trigger TSCA Section 8(e) reporting?

A. In addition to teratogenic effects, serious adverse developmental effects (e.g., significant embryo or fetal lethality, significantly reduced fetal/birth weights, significantly retarded/incomplete skeletal ossification) should be reported. In addition, serious adverse effects on the male/female reproductive system (e.g., significant testicular or ovarian atrophy, significantly reduced fertility, sterility) should be reported under Section 8(e).

Q. What criteria should be used in determining if results of acute toxicity studies constitute information that reasonably supports a conclusion of substantial risk?

A. criteria used to determine Section 8(e) reporting in the case of acute/subacute toxicity findings will depend on the nature of the effects observed and the dose at which the effects occurred. For example, information that shows a tested chemical to be extremely toxic (e.g., causes lethality at very low doses) by, for example, inhalation, dermal application or oral administration should be reported. On the other hand, the reporting of information showing a chemical to be moderately toxic will depend on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable. In addition to extreme toxicity, certain other serious toxicologic effects (e.g., neurotoxicity, adverse reproductive system effects) seen in an acute or subacute animal study should be reported under Section 8(e).

Q. When evaluating subchronic animal studies, what criteria should be used to determine reportability of adverse effects? For example, should increased or decreased organ(s) size in the absence of histopathological changes be reported to EPA under Section 8(e) of TSCA?

A. Serious toxic effects (e.g., neurotoxic effects, serious reproductive system effects) observed during the conduct of subchronic studies should be reported. This includes readily observable serious effects or serious effects seen only as the result of gross and/or histopathological examination. As is the case for acute and

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subacute toxicity studies, the degree of the observed toxicity is important. The more serious (or significant) the observed effect, the less heavily one should consider actual/potential exposure for Section 8(e) reporting and vice versa.

Q. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?

A. Typically, neurotoxic effects seen in dying animals are not, in and of themselves, considered by EPA to be reportable under Section 8(e). In many cases, however, already reportable data regarding extremely or highly toxic (lethal) substances will be accompanied by information concerning observed neurotoxic effects. In short or long term exposure studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, however, specific reporting of the neurotoxic effects should occur.

Q. What criteria should be applied in determining whether positive results of in vivo or in vitro mutagenicity assays trigger Section 8(e) reporting?

A. Serious in vivo genotoxicological effects (e.g., gene or chromosomal mutations) are reportable in and of themselves under Section 8(e). On the other hand, a positive in vitro genotoxicity test, when considered alone, is usually insufficient to cause reporting under Section 8(e). However, EPA believes that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive in vitro genotoxicity test result, in combination with other information (e.g., knowledge of actual/potential exposure to and/or high production of the tested chemical), would suggest the need, in many cases, to conduct further studies designed to determine the toxicity of or the exposure to that chemical. EPA expects the results of such additional studies to be considered also for 8(e) submission.

Any person wishing to obtain full copies of the 1986 and 1987 Q&A documents (which also contain numerous Q&As related to rules that have been promulgated by EPA under other sections of TSCA) should contact the TSCA Hotline at the address or the telephone/telefax numbers listed in the "**Preface**" to this reporting guide.

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HOW CAN THE PUBLIC OBTAIN SECTION 8(E) SUBMISSIONS?

Non-confidential versions of TSCA Section 8(e) initial, followup response and supplemental submissions, status reports, submission summaries, and EPA followup letters can be viewed/copied in the OTS Public Docket. Copies of non-confidential Section 8(e) documents can also be obtained by writing to EPA's Freedom of Information Office. The addresses of the OTS Public Docket and the Freedom of Information Office are given in the "**Preface**" to this guide.

Information on each new initial Section 8(e) and FYI submission (i.e., submission number, name of the subject chemical(s), and nature of the information received) is presented in index form in the OTS "Chemicals-In-Progress Bulletin" published periodically by the Environmental Assistance Division (EAD/OTS) and sent by the TSCA Assistance Information Service (TSCA Hotline) to over 9,000 individuals in industry, environmental groups, labor, academia and Federal, State, and Local Governments. Persons who wish to receive the "Bulletin" should contact the TSCA Hotline via the addresses or phone/telefax numbers in the "**Preface**" to this guide.

As explained in more detail in **HAS EPA ISSUED OTHER SECTION 8(E)-RELATED GUIDANCE?** on Page 20 of this reporting guide, volumes of TSCA Section 8(e) status reports have been published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions) and a seventh volume is scheduled to be published by OTS during the summer of 1991. Persons interested in obtaining copies of these TSCA Section 8(e) status report volumes should contact the TSCA Hotline or the National Technical Information Service (NTIS) at the addresses and phone numbers given in the "**Preface**" to this reporting guide.

Data from TSCA Section 8(e) and FYI submissions are entered into **TSCATS** (Toxic Substances Control Act Test Submissions), a publicly available computerized data base that serves as an on-line index of unpublished health and safety studies submitted to EPA under or in conjunction with TSCA. The submitted studies themselves are stored on microfiche. Persons who wish to obtain access to the on-line TSCATS should contact either the National Library of Medicine (NLM) located in Rockville, Maryland, or Chemical Information Systems, Inc. (CIS) located in Baltimore, Maryland. Microfiche copies of the submitted studies cited in TSCATS can be obtained from either CIS or the National Technical Information Service (NTIS) located in Springfield, Virginia. The addresses/telephone numbers for NLM, CIS and NTIS are presented in the "**Preface**" to this reporting guide.

In order to assure that the public sector is kept apprised about new adverse health effects and exposure information, OTS actively disseminates TSCA Section 8(e) and FYI submission information to many individuals and organizations in the following ways.

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- all non-confidential TSCA Section 8(e) and FYI notices, status reports, summaries and follow-up letters are placed in **public files** located at EPA Headquarters.
- **volumes of Section 8(e) status reports** are published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions); a seventh volume is scheduled to be published by the Agency during the summer of 1991.
- in response to numerous "**Freedom of Information Act**" (FOIA) requests that are received by OTS and that mention a chemical that is the subject of a TSCA Section 8(e) or FYI submission, OTS staff provides appropriate citations for, and in some cases full copies of, all such relevant documents;
- **American Conference of Governmental Industrial Hygienists** (ACGIH) publishes on occasion complete copies of selected Section 8(e) "Status Reports" in the ACGIH scientific journal, Applied Industrial Hygiene.

The international community is routinely notified by EPA about the availability of TSCA Section 8(e) and FYI submissions via the OTS "Chemicals-In-Progress Bulletin." Approximately 1000 persons in international organizations, foreign governments, agencies and companies are on the mailing list. The "Bulletin" is also used to routinely solicit unpublished chemical toxicity/exposure data from the international community. Under the established "Freedom of Information Act" (FOIA) procedures as well as the Organization for Economic Cooperation and Development (OECD) information-gathering "Switchboard" project, OTS responds to numerous international requests for unpublished health and safety data on chemicals of concern to OECD members.

IS THERE A SECTION 8(E) ENFORCEMENT RESPONSE POLICY?

On May 15, 1987, EPA's Office of Compliance Monitoring (OCM) issued a final "Enforcement Response Policy" (ERP) covering Section 8(e) as well as the record-keeping and reporting rules issued by EPA under Sections 8, 12 and 13 of TSCA. This ERP describes various enforcement alternatives (including notices of non-compliance, civil penalties, criminal action and injunctive relief) available to the Agency in enforcing these TSCA record-keeping/reporting provisions. Copies of the TSCA Sections 8, 12 and 13 ERP can be obtained from OCM or the TSCA Hotline; the addresses and/or phone numbers for these EPA offices are presented in the "**PREFACE**" to this reporting guide.

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On Friday, February 1, 1991, EPA announced in the Federal Register (56 FR 4128), a one-time voluntary TSCA Section 8(e) "Compliance Audit Program" (CAP). The Section 8(e) CAP, which incorporates stipulated monetary penalties and an overall monetary penalty ceiling, is designed primarily to 1) achieve the Agency's goal of obtaining any outstanding Section 8(e) information, and 2) provide maximum encouragement to companies to voluntarily audit their files for Section 8(e)-reportable information.

Modifications made to the Section 8(e) CAP were announced by EPA in the Federal Register on Friday, April 26, 1991 (56 FR 19514). The major modifications were 1) an extension of the CAP registration and termination dates, 2) addition of an opportunity to petition EPA for a case-by-case extension of the CAP termination date, 3) modification of the CAP "Agreement" provision involving admission of a Section 8(e) violation, and 4) an announcement of the Agency's plans to prepare and disseminate this TSCA Section 8(e) reporting guide.

Additional modifications to the Section 8(e) CAP were announced in the Federal Register on Thursday, June 20, 1991 (56 FR Part IV). The additional modifications announced by EPA were 1) an extension of the Section 8(e) CAP registration deadline, 2) announcement of the availability of this Section 8(e) reporting guide, 3) addition to the CAP of a "listing" provision and reduced stipulated penalty for certain types of Section 8(e)-reportable information now in EPA's possession as the result of either i) formal submission under a mandatory reporting provision of TSCA or other EPA-administered statute, or ii) submission to EPA and filing within EPA's Office of Toxic Substances formal "For Your Information" (FYI) submission filing system, and 4) suspension of Parts V(b) (1) and V(c) of EPA's TSCA Section 8(e) policy statement for purposes of judging the reportability of information concerning "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination" under the Section 8(e)CAP.

With regard to Parts V(b) (1) and V(c) of the Section 8(e) policy statement, the June 20, 1991 Federal Register announcement also informed the regulated community that until such time as the Agency determines with greater specificity what types of environmental release, environmental detection and environmental contamination information should be submitted under Section 8(e) of TSCA, the statutory language of Section 8(e) was to be utilized to determine reportability of such information for purposes of the Section 8(e) CAP as well as ongoing compliance with Section 8(e).

For the reader's ease, complete copies of EPA's Federal Register announcements of the Section 8(e) CAP and the CAP modifications are presented in chronological order in Appendix D at the back of this reporting guide.

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HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS?

Since 1977, EPA has initiated a number of formal enforcement actions relating to Section 8(e) of TSCA. In almost all cases, EPA's actions have dealt with the late reporting of animal study findings that offer reasonable support for the conclusion that the tested chemical substance(s) presents a substantial risk of injury to health. Persons interested in reviewing the filings pertaining to specific Section 8(e) enforcement-related actions should contact either the Office of Compliance Monitoring (OCM) or the Office of Enforcement (OE) at the addresses in the "**Preface**" to this guide.

DOES EPA'S 8(E) IMPLEMENTATION ENCOURAGE POLLUTION PREVENTION?

EPA's longstanding proactive implementation of Section 8(e) of TSCA has resulted in heightened overall chemical industry awareness of risks posed by exposure to chemical substances and mixtures. This heightened awareness has led, in many cases, to specific voluntary pollution prevention/risk reduction activities designed to directly or indirectly protect health and the environment. It can be argued that EPA's Section 8(e) implementation encourages these voluntary actions to occur earlier than they might occur otherwise. The following discussion describes some of these voluntary actions.

The chemical industry's increased awareness of the potential hazards/risks posed by chemical substances is evidenced in part by the voluntary reporting of over 800 initial "For Your Information" (FYI) submissions containing valuable toxicity and exposure data. In direct response to OTS followup efforts, many chemical companies have established review committees responsible for evaluating chemical toxicity and exposure information to consider the need to report to EPA (e.g., under Section 8(e) of TSCA) or to initiate actions designed to minimize or eliminate chemical exposure. Many companies have also established information distribution networks to facilitate the flow of health/safety data to workers, customers and other producers. Many companies have reported that in direct response to new chemical toxicity or exposure data reported under Section 8(e) or on an FYI basis, the following types of health and/or environmental protection measures have been initiated on a voluntary basis:

Notification

- formal notification of workers, customers, others
- changes made to product labels and/or Material Safety Data Sheets (MSDSs) to ensure proper and safe handling

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Further Study

- additional studies performed in order to determine better the toxicity of and/or the exposure to chemicals

Pollution Prevention/Exposure Reduction

- engineering changes made in manufacturing and processing facilities to reduce/eliminate chemical exposure
- chemical manufacture or use halted temporarily or discontinued altogether.

* * * * *

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TSCA SECTION 8(E)-REPORTABILITY OF TOXICOLOGIC CASE STUDIES**A. NUMERICAL REPORTING GUIDANCE FOR LETHALITY INFORMATION**Case Study

"An acute oral (gavage) LD50 study was conducted on a commercial chemical. Following administration of the test material, rats were observed for 14 days for clinical signs of toxicity. At the end of this observation period, all surviving rats were sacrificed and examined for gross pathological changes. Rats found dead were also subjected to gross pathological examination. The oral LD50 was calculated to be 40 mg/kg. Nonspecific clinical signs were initially observed in all treated rats; all signs had receded by Day 14 in those animals which survived. Gross pathology revealed nothing unexpected."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of this acute oral toxicity study of a commercial chemical substance. Also at issue for this particular case study is the perceived need to have 1) numerical guidance for reporting lethality seen in acute and other types of animal toxicity studies, and 2) reaffirmation of EPA'S policy on whether and how exposure should be considered by companies in evaluating acute lethality data for reporting.

EPA Discussion

The Agency believes that the following general "rules-of-thumb" should be used in determining the Section 8(e)-reportability of significant lethality observed in any animal study (including acute, sub-acute and other types of studies such as teratology studies) of a TSCA-covered chemical substance (including a research and development [R&D] chemical):

o Significant lethality which is observed at a dose or concentration comparable to an acute oral LD50 value of ≤ 5 mg/kg, an acute dermal LD50 value of < 20 mg/kg, or an acute (generally 4-hour) inhalation LC50 value of ≤ 50 ppm (or ≤ 0.5 mg/l) should be recognized immediately as being

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indicative of **"extreme"** toxicity and should be considered for immediate reporting to EPA under Section 8(e) of TSCA **without** any consideration of actual or potential exposure or other factors.

o Significant lethality observed at a dose or concentration comparable to an acute oral LD50 value in the range of >5 mg/kg to \leq 50 mg/kg, an acute dermal LD50 value in the range of >20 mg/kg to \leq 200 mg/kg, or an acute (generally 4-hour) inhalation LC50 value in the range of >50 ppm (or > .0.5 mg/l) to \leq 200 ppm (or \leq 2 mg/l) should be recognized as indicating **"high"** toxicity and should be considered for immediate reporting under Section 8(e) if there is actual or reasonably anticipated exposure to the subject chemical substance.

o Significant lethality observed at doses, greater than those cited previously (i.e., doses indicating **"moderate"** toxicity) should be considered for reporting to EPA under Section 8(e) based on the company's review of additional information (including but not limited to information about actual or potential exposure to the tested chemical substance or mixture).

Specifically regarding findings of **"high"** toxicity, EPA expects a company to be especially prudent and to err on the side of caution for reporting (i.e., there is a clear bias toward reporting). EPA also believes that the greater the toxicity, the less heavily one should weigh the actual or potential exposure to (or other factors involving) the tested chemical. Further, if the tested chemical is a "commercial" substance (e.g., not one that is exclusively R&D), there must be a strong presumption of actual or potential exposure for reporting toxicity data in this range. On the other hand, many exclusively R&D chemical substances with toxicities in the "high" range, would not typically be reported under Section 8(e) of TSCA. It should be noted also that any consideration of exposure and additional information in cases involving the **"high"** toxicity range should be accomplished expeditiously and should not be exhaustive nor equated in any way with the need to conduct a full scale risk assessment for the tested chemical(s).

The preface to Part V of the Agency's March 16, 1978 Section 8(e) policy statement provides further guidance regarding the types of additional factors to consider in determining the need to report information under Section 8(e) of TSCA. For the reader's ease in use, the specific lethality values/ranges discussed herein are presented in **Table 1** at the top of the next page.

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Table 1 Factors to Consider in Determining Reportability of Lethality Information Under TSCA Section 8(e)

LD50 Oral Dose	LD50 Dermal Dose	4-Hour LC50 Inhalation Dose	Consider Exposure/Other Factors?
<5 mg/kg	<20 mg/kg	<50 ppm (0.5 mg/i)	No (EXTREMELY TOXIC)
>5 mg/kg to	>20mg/kg to	>50ppm (>0.5 mg/l) to to	Only to Some Reasonable Degree (HIGHLY TOXIC)
<50 mg/kg	<200 mg/kg	<200 ppm (<2 mg/l)	
>50 mg/kg	>200 mg/kg	>200ppm (>2 mg/l)	Yes (MODERATELY TOXIC)

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute animal lethality study, the oral LD50 value of 40 mg/kg indicates that the tested chemical substance is "highly" toxic (i.e., an oral LD50 of less than 50 mg/kg but greater than 5 mg/kg). Considering that the tested chemical is "commercial," and in the absence of any relevant exposure-related information to the contrary, EPA makes the prudent assumption that there is or there reasonably could be exposure to the tested chemical. Therefore, EPA believes that these acute lethality findings showing the chemical to be highly toxic should be reported immediately under Section 8(e) of TSCA.

B. ACUTE TOXICITY TESTS WITH NON-LETHAL NEUROBEHAVIORAL FINDINGS

Case Study

"An oral LD50 study is conducted in which animals [(rats)] are administered 50, 200, 500, 1000, or 2000 mg/kg of a test material. Shortly after dosing, intermittent lethargy, ataxia and convulsions

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are observed in the 1000 and 2000 mg/kg groups. Salivation, ataxia and lethargy are observed in animals in the 200 and 500 mg/kg groups. No effects are observed in the 50 mg/kg dose group. All rats died at the 2000 mg/kg dose level. The lower dose animals survived to necropsy."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of the findings from this acute oral toxicity study. Also at issue for this study is the need for EPA to verify that statistically or biologically significant "frank" neurotoxicologic effects seen in acute or other animal studies should be reported immediately.

EPA Discussion

In reviewing these results of this acute oral toxicity study, EPA made the following assumptions about the study conduct/findings:

1. the study had a 14-day post-dosing observation period;
2. no animals in the 50, 200, 500 or 1000 mg/kg dose groups were found moribund during the 14-day observation period;
3. "shortly" means a time period of less than a day;
4. "intermittent" means on a number of occasions throughout the observation period;
5. the terms "convulsions" and "ataxia" accurately reflect the observations made during the study; and
6. a significant (biologically or statistically) number of rats in the study were affected.

Given the above assumptions, EPA believes that the findings from this acute oral toxicity study can be meaningfully interpreted. Shortly after dosing and at some unknown time prior to death, the animals in the 2000 mg/kg group exhibited intermittent lethargy, ataxia and convulsions; all of the animals in the 2000 mg/kg dose group died at some unknown point after dosing. Although interpretation of the findings for the 2000 mg/kg dose group animals would depend upon whether the adverse effects were observed in moribund or non-moribund animals, by considering the information provided for the lower dose groups, it is possible to determine that the tested chemical substance caused distinct neurotoxicologic effects. Based on EPA'S assumption that no animals in the 1000 mg/kg dose were found moribund during the study, the observations that a significant number of animals at this dose exhibited intermittent lethargy, convulsions and ataxia, show that the tested chemical caused serious neurotoxicologic effects. Furthermore, although the

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animals in the 200 and 500 mg/kg dose groups did not exhibit convulsions, the animals in both of these groups exhibited a combination of signs indicating a neurotoxicologic effect (i.e., salivation, lethargy and ataxia.) Considering that the oral LD50 of the test material is somewhere between 1000 and 2000 mg/kg, the finding of distinct neurotoxic effects at doses that are perhaps between 10% and 25% of the lethal dose further heightens concern for the tested chemical substance.

In general, the Agency would agree that it may not be possible to distinguish or attribute neurobehavioral effects or neurological signs in moribund animals to a direct neurotoxic action of the tested chemical substance. However, statistically or biologically significant neurotoxic effects observed in non-moribund animals (including animals in groups receiving doses equal to or greater than lethal doses) in any type of study cannot be dismissed simply as reflecting a "system overload" and should be considered for immediate reporting to the Agency under Section 8(e) of TSCA. Further, EPA believes that good product stewardship dictates that studies designed to more specifically assess neurotoxic effects should be considered for any chemical found to produce possible neurotoxic effects during an acute or other general toxicity test.

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute oral toxicity case study, the distinguishable neurotoxicological effects caused by the subject chemical should be reported under Section 8(e). The reportability of the findings would simply be enhanced if the tested chemical was already on the market.

To provide a sense of scale for the Section 8(e)-reportability of neurotoxic/neurobehavioral findings from acute and other types of animal toxicity studies (e.g., 28-day studies, teratology studies), the Agency is most interested in receiving reports that involve "serious or prolonged effects." In general, the acute toxicity LD50 values/ranges listed in Table 1 (found on Page 31 of this reporting guide) should be consulted first and an appropriate level of consideration should be given to exposure and/or other factors in determining reportability based solely on lethality in acute or other types of animal toxicity studies. In those cases involving biologically or statistically significant evidence of serious neurotoxicological effects (e.g., paralysis, convulsions, ataxia), virtually no consideration of exposure or other factors should be given in determining the TSCA Section 8(e)-reportability of such serious toxic effects. As neurotoxicologic observations become more limited or as confidence in the accuracy of such observations becomes more uncertain, the Section 8(e)-reportability of such findings diminishes. In some studies, for example, it may not be possible to determine with any degree of precision if observations

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such as ataxia accurately characterize the study findings or the testing laboratory simply recorded ataxia as indicating a state other than normal. In the above case study, however, the observed convulsions and ataxia were judged by the Agency as being serious neurotoxic effects and the other effects (lethargy and salivation) were viewed as providing additional evidence of neurotoxicity. In the absence of other more serious effects, however, observations of lethargy and/or salivation, in and of themselves, would not be viewed typically as providing reasonable support for a conclusion of substantial risk. Similarly, the Section 8(e)-reportability of effects such as convulsions or ataxia would be diminished if such effects 1) were seen only in moribund animals or in only one or a few isolated cases in non-moribund animals, or 2) were found simply to be transient rather than either intermittent or continuous in nature.

C. SKIN/EYE IRRITATION AND SKIN SENSITIZATION TESTSNote

For the following case study involving three tests on a "moderately acidic" chemical, it was reported that the tests were "performed during the development phase of a new product for primary use as an industrial intermediate, with some consumer use probable." It was also reported that the "present production quantities are therefore quite small, but [are] expected to increase." Also at issue for this particular case study is the need for EPA to 1) reaffirm its position that results from acute skin or eye irritation tests do not routinely warrant submission under Section 8(e) of TSCA, 2) discuss the reportability of skin sensitization study findings, and 3) reaffirm that lethality caused at doses indicative of extreme toxicity or serious or prolonged adverse effects in organs/systems away from the site of exposure may indeed warrant the immediate reporting of such findings.

Skin Irritation Test

"A skin irritation assay is conducted on rabbit skin (in vivo). A series of ten applications are applied to the skin of the abdomen. After three applications, the skin is described as having moderate degrees of hyperemia, edema and necrosis. At the end of the 14 day observation period, the skin reaction is still present, and now includes scab and scar formation. Gross pathological examination reveals no systemic toxicity but does confirm the topical corrosive lesion at the site of application."

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Eye Irritation Test

"An eye irritation study is conducted in the rabbit eye. Instillation of 0.1 ml into the washed and unwashed eye elicits immediate pain and irritation of the conjunctiva, cornea, and iris after days 1, 2, and 9. The animal appears to not be able to see through the treated eye and is sent to necropsy on day 9 because of the advanced state of inflammation in the treated eye."

Skin Sensitization Test

"A guinea pig [dermal] sensitization assay is performed. The test material is applied to the clipped integument of 10 guinea pigs during the induction phase. This is followed by a rest period of 10 days. A challenge application is applied to a previously untreated skin site. The skin response is evaluated at 25 and 48 hours after application. Eight of the 10 animals are considered to have been sensitized by the test material based on the presence of erythema at the challenge site."

EPA Discussion

As stated in EPA's March 16, 1978 Section 8(e) policy statement, as well as numerous Section 8(e) "status reports," the Section 8(e)-reportability of irritation and/or corrosivity findings from acute animal eye or skin irritation studies is quite limited. This should not be interpreted to mean, however, that EPA is not concerned in general about the irritation/corrosion findings from such studies. Further, previously unknown or unexpected effects that occur and are observed/determined during such routine tests may have to be submitted under Section 8(e) if the effects are serious and meet the reporting criteria outlined in Part V of EPA's Section 8(e) policy statement (e.g., lethality, neurotoxicity). Therefore, when evaluating the results of skin and eye irritation studies, EPA expects a company to consider such factors as lethal dose, pH of the test material, the route(s) of administration, occurrence of unexpected serious effects (which can be determined via "cage-side" observation or during necropsy), and the extent and pattern of the actual or potential exposure to the tested chemical or mixture. When evaluating such information for possible TSCA Section 8(e) reporting, the greater the acute toxicity, the less heavily one should weigh the actual or potential exposure to the test materials and vice versa.

With regard to sensitization studies, it must be noted that sensitization is a systemic reaction that is manifested in many cases locally (i.e., directly at the site of re-exposure) but may be manifested also away from the site of exposure. Further, the

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nature of the reaction can vary from slight to severe and can, in some cases, result in death. In reviewing results of sensitization studies for submission under Section 8(e), EPA expects companies to evaluate a variety of factors including, but not limited to, the severity of the response, the site(s) of the response, the number of animals affected, and/or the actual or potential exposure to the tested chemical substance(s). In general, the more severe the observed sensitization response(s) and the greater the number of animals affected, the less heavily one should weigh the actual or potential exposure to the tested chemical(s) and vice versa.

EPA Conclusion

Based on an evaluation of the eye and skin irritation studies and the skin sensitization study, and considering the above discussion, it is the Agency's opinion that, based on the provided information on current exposure, the results of these studies do not appear to be reportable now under Section 8(e) of TSCA. The findings may be reportable, however, at some future date under Section 8(e); this would depend upon an evaluation of new information reflecting a significant change in the magnitude/type of exposure and/or the consideration of other factors such as those previously cited.

D. SUBCHRONIC TOXICITYCase Study

"A subchronic dermal repeated dose study in rats was conducted at doses of 0, 100, 300, and 1000 mg/kg. The tested material is extensively used in consumer products and exposure to the chemical is exclusively dermal. A statistically significant 25% increase in liver weight was observed at the high dose. A statistically significant incidence of clear signs of liver pathology typical of cirrhosis was observed at the mid and high doses. The NOAEL [(No-Observable-Adverse-Effect-Level)] was determined to be 100 mg/kg. No other effects were observed."

As background, it was reported that acute and range-finding data on the tested chemical indicate "it is relatively nontoxic" and the high dose, which was chosen for the subchronic dermal study, was the OECD [(Organization for European Cooperation and Development)] recommended limit of 1 g/kg. Also at issue for this case study is the need for EPA to reaffirm its position that organ weight changes in the absence of concurrent pathology may not routinely reflect serious or prolonged incapacitation and that other factors (e.g., histopathologic findings, dose, or actual/expected exposure, etc.)

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may need to be considered in deciding whether to report such organ weight changes. There is also a need to discuss and reaffirm EPA's position that a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be immediately reported with little if any consideration of factors such as exposure.

EPA Discussion

Although an organ weight change, in and of itself, may not reflect a serious or prolonged incapacitation, the reportability of such a finding could depend upon an evaluation of one or more factors, such as, but not limited to, the overall magnitude of the organ weight change, the biological significance of the change, blood chemistry, dose, route of administration, actual or expected exposure, etc. However, the more significant the magnitude of the organ weight change (e.g., severe atrophy of the testes, thymus, kidneys), much less consideration should be given to such factors in determining reportability of the findings. On the other hand, a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be reported with little if any consideration given to factors such as exposure. When the histopathologic findings are of a less serious or less significant nature, other relevant factors (e.g., actual/expected exposure, dose, etc.) should be considered in determining the TSCA Section 8(e)-reportability of the study results.

The subchronic dermal application case study results clearly show a statistically significant, dose-dependent, relatively rare, and serious toxic effect (cirrhosis) in the liver, accompanied by a 25% increase in liver weight in the high dose animals.

EPA Conclusion

Based on an evaluation of the provided toxicologic findings, and considering the above discussion, it is EPA's position that the results of the subchronic dermal application study are reportable pursuant to Section 8(e) of TSCA. The facts that 1) the tested chemical is a commercial substance, and 2) consumers are dermally exposed to the chemical, simply enhance the reportability of the observed serious toxic effects in the liver.

* * * * *

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APPENDIX ASECTION 8(E) GUIDANCE/POLICY REFLECTED IN STATUS REPORTS

This index is divided into the following two (2) major areas: "TOXICOLOGICAL/EXPOSURE FINDINGS" and "GENERAL ISSUES." In using this particular index, please note that the numbers in the column on the right represent the last four (4) digits of the chronological Section 8(e) submission file number displayed on all status reports; the ascending numerical sequence, therefore, is also chronological. Please note that due to the fact that the majority of the first 200 Section 8(e) notices were submitted by a single company and EPA had asked that company for additional information about the Section 8(e)-applicability of the provided findings, the Agency has chosen to not include in this index any status reports pertaining to those first 200 notices.

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B. ACUTE TOXICITY (HUMAN)

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J. REPRODUCTIVE /DEVELOPMENTAL (HUMAN)

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NOTE: Almost all of the TSCA Section 8(e) status reports pertaining to in vitro genotoxicity test findings contain the following language:

"Although a positive in vitro genotoxicity test result, when considered alone, may not be sufficient to offer reasonable support for a conclusion of substantial risk (as that term is defined in EPA'S Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110; March 16, 1978)), EPA does believe that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive genotoxicity test result, in combination with other important information (e.g., knowledge of the actual/ potential exposure to and/or high production of the tested chemical or mixture),

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suggests the need, in many cases, to conduct further studies that are designed to determine the toxicity of and/or exposure to that chemical substance or mixture. EPA expects the results of such additional studies to be considered also for submission pursuant to Section 8(e) of TSCA."

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J. ACTUAL KNOWLEDGE BY EPA (CON'T)

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0600
0612
0622
0632
0667
0675
0694
0706
0718

TSCA Section 8(e) Reporting Guide

N. RELATIONSHIP TO OTHER TSCA REPORTING REQUIREMENTS (CON'T)

0720
0769
0797
0800
0813
0817
0824
0846
0856
0876
0884
0900
0905
0929

O. RELATIONSHIP TO OTHER EPA ADMINISTERED AUTHORITIES

0466
0485
0494
0502
0508
0542
0566
0583
0600
0706
0712
0718
0720
0726
0769
0797
0800
0813
0815
0818
0823
0824
0835
1034

P. RELATIONSHIP TO AUTHORITIES NOT ADMINISTERED BY EPA

0551
0706
1043

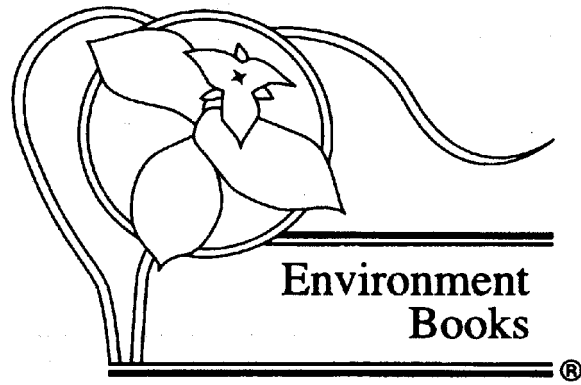
TSCA Section 8(e) Reporting Guide

O. SECTION 8(E) REPORTING PROCEDURES

0234
0324
0330
0369
0463
0543
0546
0566
0587
0626
0653
0681
0698
0701
0705
0855

* * * * *

TSCA Section 8(e) Reporting Guide



APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0977-0004	*	8EHQ-0977-0005	*	8EHQ-0377-0035	
	8EHQ-0178-0039 P	*	8EHQ-0178-0041	*	8EHQ-0278-0042	
	8EHQ-0278-00S0	*	8EHQ-0278-0062		8EHQ-0278-0064	
	8EHQ-0275-0065	*	8EHQ-0278-0066	*	8EHQ-0278-0070	
	8EHQ-0278-0017	*	8EHQ-0278-0074	*	8EHQ-0378-0087	*
	8EHQ-0378-0088	*	8EHQ-0378-0090	*	8EHQ-0378-0091	*
	8EHQ-0378-0042	*	8EHQ-0378-0094	*	8EHQ-0378-0103	*
	8EHQ-0478-0131	*	8EHQ-0478-0134		8EHQ-0478-0137	*
	8EHQ-0578-0143	*	8EHQ-0578-0144	*	8EHQ-0578-0151	
	8EHQ-0578-0152		8EHQ-0578-0153 S	*	8EHQ-0578-0154 P	
	8EHQ-0578-0155	*	8EHQ-0578-0158 S	*	8EHQ-0578-0159 S	*
	8EHQ-0578-0162 S	*	8EHQ-0578-0163		8EHQ-0578-0166	
	8EHQ-0578-0169 S	*	8EHQ-0678-0172	*	8EHQ-0678-0174	*
	8EHQ-0678-0175	*	8EHQ-0678-0176	*	8EHQ-0678-0177	*
	8EHQ-0678-0178		8EHQ-0678-0184	*	8EHQ-0678-0185	*
	8EHQ-0678-0193	*	8EHQ-0678-0194	*	8EHQ-0678-0195	*
	8EHQ-0678-0196	*	8EHQ-0678-0197	*	8EHQ-0618-0198	*
	8EHQ-0678-0199	*	8EHQ-0678-0200	*	8EHQ-0678-0203	*
	8EHQ-0678-0204	*	8EHQ-0678-0205	*	8EHQ-0678-0206	*
	8EHQ-0678-0207	*	8EHQ-0778-0209		8EHQ-0778-0210	*
	8EHQ-0778-0217		8EHQ-0778-0220	*	8EHQ-0771-0222	*
	8EHQ-0778-0224	*	8EHQ-0778-0225	*	8EHQ-0778-0226	*
	8EHQ-0778-0227	*	8EHQ-0778-0229	*	8EHQ-1178-0256	
	8EHQ-1178-0259		8EHQ-1178-0261		8EHQ-1278-0263	*
	8EHQ-0179-0271		8EHQ-0179-0273		8EHQ-0279-0274	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0479-0278		8EHQ-0479-0279		8EHQ-0479-0282
	8EHQ-0579-0284		8EHQ-0779-0293		8EHQ-0779-0296
	8EHQ-0979-0311		8EHQ-0380-0335 S		8EHQ-0480-0340
	8EHQ-0680-0347		8EHQ-0680-0349		8EHQ-0980-0359
	8EHQ-0980-0362		8EHQ-0980-0365		8EHQ-0780-0369
	8EHQ-1180-0372		8EHQ-0181-0380	*	8EHQ-0181-0381
	8EHQ-0281-0382		8EHQ-0381-0392		8EHQ-0581-0398
	8EHQ-0581-0400		8EHQ-0881-0408 S	*	8EHQ-0981-0409
	8EHQ-1081-0417		8EHQ-1081-0418		8EHQ-0282-0427 S
	8EHQ-0282-0428	*	8EHQ-0282-0429	*	8EHQ-0282-0430
	8EHQ-0282-0431	*	8EHQ-0282-0432	*	8EHQ-0282-0433
	8EHQ-0282-0435		8EHQ-0282-0436	*	8EHQ-0282-0437
	8EHQ-0382-0438 S		8EHQ-0382-0440 S		8EHQ-0682-0448
	81H9-0982-0456 S	*	8EHQ-1082-0459		8EHQ-1082-0460
	8EHQ-1182-0462		8EHQ-0183-0468		8EHQ-0283-0471
	8EHQ-0483-0476 S		8EHQ-0583-0478 S		8EHQ-0583-0479 S
	8EHQ-0683-0482		8EHQ-0783-0485 S	*	8EHQ-0783-0486
	8EHQ-0783-0487 S	*	8EHQ-0883-0490		8EHQ-0983-0492 S
	8EHQ-1083-0494	*	8EHQ-1083-0495		8EHQ-1083-0496
	8EHQ-1083-0497		8EHQ-1283-0501		8EHQ-0484-0510
	8EHQ-0484-0513		8EHQ-0584-0519		8EHQ-0884-0528
	8EHQ-0984-0530		8EHQ-0984-0531 S	*	8EHQ-1084-0532
	8EHQ-1084-0535		8EHQ-1284-0540 S	*	8EHQ-0485-0548
	8EHQ-0485-0549 S		8EHQ-0485-0550		8EHQ-0585-0556 S
	8EHQ-0685-0559		8EHQ-0785-0563		8EHQ-0885-0565 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0985-0568 S		8EHQ-1085-0569		8EHQ-1085-0571 S
	8EHQ-1185-0573		8EHQ-1185-0575		8EHQ-1285-0578
	8EHQ-1285-0579 S		8EHQ-1285-0580		8EHQ-1285-0581
	8EHQ-0186-0584		8EHQ-0186-0585 S		8EHQ-0386-0589 S
	8EHQ-0486-0596		8EHQ-0486-0597		8EHQ-0486-0599
	8EHQ-0786-0607 S		8EHQ-0786-0609 S		8EHQ-0786-0616
	8EHQ-0886-0621		8EHQ-0986-0631 S		8EHQ-1086-0636 S
	8EHQ-1086-0638	*	8EHQ-1086-0639 S		8EHQ-1086-0640 S
	8EHQ-1186-0644		8EHQ-1186-0647		8EHQ-0287-0652 S
	8EHQ-0287-0653		8EHQ-0287-0654		8EHQ-0287-0655 S
	8EHQ-0387-0656		8EHQ-0287-0657 S		8EHQ-0387-0659
	8EHQ-0387-0660		8EHQ-0487-0661 S		8EHQ-0487-0663
	8EHQ-0487-0665 S	*	8EHQ-0487-0666 S		8EHQ-0487-0667 S
	8EHQ-0487-0669	*	8EHQ-0487-0670 S		8EHQ-0587-0673
	8EHQ-0587-0678		8EHQ-0687-0680		8EHQ-0787-0686 S
	8EHQ-1087-0696		8EHQ-1287-0700		8EHQ-1287-0706
	8EHQ-1287-0707 S		8EHQ-0188-0714		8EHQ-0388-0721
	8EHQ-0388-0723		8EHQ-0588-0732		8EHQ-0688-0739
	8EHQ-0688-0740 S		8EHQ-0788-0742	*	8EHQ-0788-0744 S
	8EHQ-0988-0753 S		8EHQ-0988-0754		8EHQ-1088-0760 S
	8EHQ-1088-0762		8EHQ-1188-0768 S		8EHQ-1288-0778
	8EHQ-0189-0779		8EHQ-0389-0780		8EHQ-0389-0787 S
	8EHQ-0389-0788 S		8EHQ-0589-0800		8EHQ-0689-0803
	8EHQ-0789-0806 S		8EHQ-0789-0808 S		8EHQ-0789-0809
	8EHQ-0889-0810 S		8EHQ-0889-0818 S		8EHQ-0889-0819 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0989-0826 S		8EHQ-1089-0830		8EHQ-1089-0833 S	
	8EHQ-1089-0834 S		8EHQ-1089-0837 S		8EHQ-1089-0838 S	
	8EHQ-1189-0841		8EHQ-1189-0845		8EHQ-1189-0848 S	
	8EHQ-1289-0850		8EHQ-1289-0852 S		8EHQ-1289-0857 S	
	8EHQ-1289-0859		8EHQ-0190-0860 S		8EHQ-0190-0867	*
	8EHQ-0290-0893		8EHQ-0390-0898		8EHQ-0490-0919 S	
	8EHQ-0490-0920 S		8EHQ-0490-0954 S		8EHQ-0490-0957 S	
	8EHQ-0490-0958 S		8EHQ-0490-0959 S		8EHQ-0590-0964	
	8EHQ-0590-0985	*	8EHQ-0590-0991 S		8EHQ-0690-1003	
	8EHQ-0690-1004 S		8EHQ-0690-1005 S		8EHQ-0690-1009	
	8EHQ-0690-1016 S		8EHQ-0790-1021		8EHQ-0790-1023 S	
	8EHQ-0790-1031 S		8EHQ-0790-1035		8EHQ-0790-1036 S	
	8EHQ-0890-1040		8EHQ-0890-1045		8EHQ-0890-1047	
	8EHQ-0890-1048 S		8EHQ-0890-1052 S		8EHQ-0890-1054 S	
	8EHQ-0990-1057		8EHQ-0990-1058 S		8EHQ-0990-1059 S	*
	8EHQ-0990-1060 S		8EHQ-0990-1061		8EHQ-0990-1062	
	8EHQ-0990-1068		8EHQ-0990-1076 S		8EHQ-0990-1084	

ACUTE TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-0178-0036	*	8EHQ-0178-0038		8EHQ-0176-0039 P	*
	8EHQ-0178-0040		8EHQ-0278-0052 P		8EHQ-0278-0063	*
	8EHQ-0278-0067	*	8EHQ-0278-0075 P	*	8EHQ-0278-0076 P	*
	8EHQ-0278-0077	*	8EHQ-0278-0078 P	*	8EHQ-0278-0079 P	*
	8EHQ-0278-0080	*	8EHQ-0278-0081 P	*	8EHQ-0378-0086	*
	8EHQ-0378-0097	*	8EHQ-0378-0105		8EHQ-0478-0118 P	*

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-0478-0138 P	*	8EHQ-0578-0141	*	8EHQ-0578-0142	*
	8EHQ-0578-0145	*	8EHQ-0578-0146		8EHQ-0578-0149	
	8EHQ-0578-0154 P		8EHQ-0578-0165		8EHQ-0678-0180	*
	8EHQ-0678-0181	*	8EHQ-0678-0182 P	*	8EHQ-0678-0184	*
	8EHQ-0778-0217		8EHQ-0978-0238	*	8EHQ-1178-0258	*
	8EHQ-1178-0260	*	8EHQ-0179-0273		8EHQ-0879-0304	*
	8EHQ-1079-0315	*	8EHQ-1279-0322	*	8EHQ-0180-0324	
	8EHQ-0280-0333		8EHQ-0480-0338		8EHQ-0580-0341	
	8EHQ-0680-0344 P	*	8EHQ-0880-0355		8EHQ-0881-0407	
	8EHQ-0981-0409		8EHQ-1182-0466	*	8EHQ-0283-0471 S	
	8EHQ-0783-0486		8EHQ-0983-0493 S	*	8EHQ-1283-0502 P	*
	8EHQ-0384-0508 P	*	8EHQ-0484-0513		8EHQ-0984-0529	
	8EHQ-1084-0532		8EHQ-1084-0535		8EHQ-0485-0552	
	8EHQ-0985-0566		8EHQ-0186-0585 S		8EHQ-0886-0622 S	
	8EHQ-0986-0632		8EHQ-0487-0666 S		8EHQ-0487-0671	
	8EHQ-1287-0700		8EHQ-0688-0736		8EHQ-1088-0755	
	8EHQ-0889-0818 S		8EHQ-1089-0832		8EHQ-0290-0885	
	8EHQ-0390-0905 S	*	8EHQ-0490-0929 S	*	8EHQ-0590-0991 S	
	8EHQ-0890-1042		8EHQ-0990-1071		8EHQ-0990-1078	

ALLERGENICITY (ANIMAL)

SUBMISSION #:	8EHQ-0578-0152		8EHQ-0578-0156	*	8EHQ-0578-0166	
	8EHQ-0678-0184	*	8EHQ-0678-0185	*	8EHQ-0678-0206	*
	8EHQ-0480-0340		8EHQ-1180-0371		8EHQ-0282-0427 S	
	8EHQ-0682-0448 S		8EHQ-1182-0462		8EHQ-0283-0471 S	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0683-0482	8EHQ-0783-0486	8EHQ-0883-0490
	8EHQ-1083-0495	8EHQ-1084-0532	8EHQ-0485-0550
	8EHQ-1285-0580	8EHQ-0186-0585 S	8EHQ-0386-0589 S
	8EHQ-0486-0597	8EHQ-1186-0647	8EHQ-0287-0653
	8EHQ-0287-0657 S	8EHQ-0487-0661 S	8EHQ-0687-0680
	8EHQ-0787-0686 S	8EHQ-0887-0690	8EHQ-1287-0700
	8EHQ-1287-0711	8EHQ-0188-0712 *	8EHQ-0388-0721
	8EHQ-0588-0733	8EHQ-0688-0739	8EHQ-0688-0740 S
	8EHQ-1188-0768 S	8EHQ-1288-0777	8EHQ-1288-0778
	8EHQ-0489-0795	8EHQ-0589-0796	8EHQ-0689-0802
	8EHQ-0989-0826 S	8EHQ-1189-0839	8EHQ-1189-0845
	8EHQ-1289-0852 S	8EHQ-0290-0876	8EHQ-0290-0894
	8EHQ-0490-0919 S	8EHQ-0790-1033	8EHQ-0990-1062
	8EHQ-0990-1069	8EHQ-0990-1082	

ACUTE TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-1177-0017 PS *	8EHQ-1177-0018 PS *	8EHQ-0178-0031 P *
	8EHQ-0178-0040 P	8EHQ-0278-0081 P *	8EHQ-0578-0164
	8EHQ-0578-0165	8EHQ-0678-0181 *	8EHQ-0678-0182 P *
	8EHQ-0678-0184 *	8EHQ-0678-0185 *	8EHQ-0279-0274
	8EHQ-0379-0280	8EHQ-0779-0292	8EHQ-0880-0355
	8EHQ-0282-0427 S	8EHQ-0283-0471 S	8EHQ-1084-0532
	8EHQ-0485-0550	8EHQ-0186-0585 S	8EHQ-0386-0589 S
	8EHQ-0786-0612	8EHQ-0886-0622 S	8EHQ-0987-0694 *
	8EHQ-0488-0728	8EHQ-0290-0885	8EHQ-0590-0991 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ALLERGENICITY (HUMAN)

SUBMISSION #: 8EHQ-0890-1039 S

CELL TRANSFORMATION (IN VITRO)

SUBMISSION #:	8EHQ-1277-0022		8EHQ-0278-0071		8EHQ-0378-0094	*
	8EHQ-0378-0098	*	8EHQ-0378-0100	*	8EHQ-0478-0132	*
	8EHQ-0578-0141	*	8EHQ-0578-0164		8EHQ-0578-0166	
	8EHQ-0179-0268 S		8EHQ-0479-0278		8EHQ-0479-0279	
	8EHQ-0579-0286		8EHQ-0579-0287		8EHQ-0579-0288	
	8EHQ-0579-0289		8EHQ-0679-0291		8EHQ-0779-0294	
	8EHQ-0280-0334		8EHQ-0281-0385		8EHQ-1280-0401 S	
	8EHQ-0681-0404		8EHQ-0981-0412		8EHQ-1081-0415	
	8EHQ-1081-0418		8EHQ-0982-0455		8EHQ-0583-0477 S	
	8EHQ-0883-0490		8EHQ-1083-0495		8EHQ-1083-0496	
	8EHQ-1083-0498		8EHQ-0484-0511		8EHQ-0484-0512	
	8EHQ-0584-0516 S		8EHQ-1184-0536		8EHQ-1184-0537	
	8EHQ-0685-0558 S		8EHQ-0785-0561 S		8EHQ-0786-0610	
	8EHQ-0786-0613		8EHQ-0886-0620		8EHQ-0886-0621	
	8EHQ-0986-0630		8EHQ-0687-0679		8EHQ-0889-0814	
	8EHQ-0690-1018					

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION #:	8EHQ-0178-0034	8EHQ-0278-0044	8EHQ-0279-0274
	8EHQ-0879-0301	8EHQ-1179-0317	8EHQ-0280-0333
	8EHQ-0480-0340	8EHQ-0680-0348	8EHQ-0780-0353
	8EHQ-1080-0366	8EHQ-0481-0397	8EHQ-0382-0440 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION #: 8EHQ-0483-0475

CHRONIC TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1277-0026 S	8EHQ-0478-0117	*	8EHQ-0578-0140
	8EHQ-0578-0148	8EHQ-0578-0165		8EHQ-0578-0170
	8EHQ-0678-0202	8EHQ-0778-0209		8EHQ-0178-0212
	8EHQ-0778-0215	8EHQ-0878-0234		8EHQ-0878-0236 *
	8EHQ-1078-0248	8EHQ-1078-0250		8EHQ-1078-0251
	8EHQ-1078-0253	8EHQ-1278-0262		8EHQ-0179-0269 S
	8EHQ-0279-0274	8EHQ-0479-0281		8EHQ-0579-0283
	8EHQ-0779-0297	8EHQ-0979-0305		8EHQ-0580-0342
	8EHQ-0481-0397	8EHQ-0282-0439		8EHQ-1282-0467
	8EHQ-0283-0469 S	8EHQ-0283-0472 S		8EHQ-0383-0474
	8EHQ-0683-0480	8EHQ-0683-0483 S		8EHQ-0783-0488
	8EHQ-1083-0491	8EHQ-1283-0503		8EHQ-1083-0509
	8EHQ-0584-0514	8EHQ-0584-0517		8EHQ-0884-0525
	8EHQ-0884-0526	8EHQ-0984-0530		8EHQ-1284-0538
	8EHQ-0285-0545 S	8EHQ-0485-0550		8EHQ-0485-0553
	8EHQ-0785-0562 S	8EHQ-0985-0567		8EHQ-0685-0583 S
	8EHQ-0386-0592	8EHQ-0486-0600		8EHQ-0686-0604
	8EHQ-0786-0606 S	8EHQ-0786-0614		8EHQ-0886-0618 S
	8EHQ-0386-0619	8EHQ-0986-0624 S		8EHQ-0986-0625 S
	8EHQ-1086-0642	8EHQ-0187-0650		8EHQ-0487-0668
	8EHQ-0587-0675 *	8EHQ-0786-0681		8EHQ-0787-0684 S
	8EHQ-0887-0687	8EHQ-0887-0691 S		8EHQ-0987-0692
	8EHQ-1187-0697	8EHQ-1287-0704		8EHQ-1287-0708 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

CHRONIC TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1287-0710	8EHQ-0188-0713	8EHQ-0388-0725
	8EHQ-0588-0730	8EHQ-0788-0741	8EHQ-0788-0745 S
	8EHQ-0988-0752 S	8EHQ-1088-0760 S	8EHQ-1288-0773
	8EHQ-1288-0774	8EHQ-1288-0775	8EHQ-0589-0797
	8EHQ-0889-0812	8EHQ-0989-0822	8EHQ-1189-0847
	8EHQ-1289-0856	8EHQ-1289-0858 S	8EHQ-0290-0873 S
	8EHQ-0290-0881 S	8EHQ-0390-0900	8EHQ-0390-0914 S
	8EHQ-0490-0930 S	8EHQ-0490-0952 S	8EHQ-0490-0960
	8EHQ-0590-0968	8EHQ-0590-0993 S	8EHQ-0790-1029
	8EHQ-0890-1043	8EHQ-0890-1050 S	8EHQ-0890-1053
	8EHQ-0890-1056 S		

CHRONIC TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-0378-0096	*	8EHQ-0878-0230	8EHQ-0978-0241
	8EHQ-0981-0409		8EHQ-0383-0473	8EHQ-0884-0523
	8EHQ-0285-0546		8EHQ-0585-0557	8EHQ-0486-0598
	8EHQ-0586-0601		8EHQ-0786-0615	8EHQ-0986-0629
	8EHQ-0986-0634		8EHQ-0187-0651	8EHQ-0887-0688
	8EHQ-0987-0694	*	8EHQ-1187-0698	8EHQ-1287-0699
	8EHQ-1287-0701	*	8EHQ-1188-0772	8EHQ-1089-0831
	8EHQ-0190-0863		8EHQ-0190-0864	8EHQ-0290-0886
	8EHQ-0390-0915		8EHQ-0490-0917	8EHQ-0490-0924
	8EHQ-0790-1034		8EHQ-0990-1072	8EHQ-0990-1080 S

CLASTOGENICITY ((ANIMAL)

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

CLASTOGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-0579-0287	8EHQ-0779-0294	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-0683-0481	8EHQ-1283-0500 S
	8EHQ-0384-0506 S	8EHQ-1083-0509	8EHQ-0484-0510
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0784-0522	8EHQ-1084-0533 S	8EHQ-1284-0539
	8EHQ-0685-0558 S	8EHQ-1285-0580	8EHQ-0386-0595
	8EHQ-0586-0602 S	8EHQ-0786-0608 S	8EHQ-0786-0610
	8EHQ-0886-0621	8EHQ-0986-0630	8EHQ-1186-0646 S
	8EHQ-1186-0647	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0693	8EHQ-0288-0715
	8EHQ-1088-0758 S	8EHQ-0389-0780	8EHQ-0389-0791 S
	8EHQ-0789-0805 S	8EHQ-0889-0814	8EHQ-1189-0847
	8EHQ-0890-1051 S	8EHQ-0990-1079 S	

DNA ADDUCT (IN VITRO)

SUBMISSION #: 8EHQ-0386-0592

DNA DAMAGE/REPAIR

SUBMISSION #:	8EHQ-0478-0132	*	8EHQ-0578-0165	8EHQ-0678-0191	*
	8EHQ-0678-0206	*	8EHQ-0778-0213	8EHQ-0778-0221	*
	8EHQ-0579-0285		8EHQ-0579-0288	8EHQ-0679-0291	
	8EHQ-0583-0477 S		8EHQ-0683-0481	8EHQ-1283-0503	
	8EHQ-0384-0506 S		8EHQ-1083-0509	8EHQ-0484-0511	
	8EHQ-0484-0512		8EHQ-1184-0536	8EHQ-1184-0537	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

DNA DAMAGE/REPAIR

SUBMISSION #:	8EHQ-0785-0561 S	8EHQ-0586-0602 S	8EHQ-0786-0613
	8EHQ-0886-0621	8EHQ-1186-0646 S	8EHQ-0187-0649 S
	8EHQ-0687-0679	8EHQ-0787-0685	8EHQ-0987-0692
	8EHQ-0288-0715	8EHQ-0688-0737	8EHQ-0889-0814
	8EHQ-1289-0853 S	8EHQ-0890-1051 S	

DNA REPAIR (IN VITRO)

SUBMISSION #:	8EHQ-0280-0334	8EHQ-0980-0359	8EHQ-1080-0366
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ECOTOXICITY/AQUATIC TOXICITY

SUBMISSION #:	8EHQ-0178-0032	8EHQ-0278-0048	8EHQ-0278-0058	*
	8EHQ-0278-0059	*	8EHQ-1277-0060	*
	8EHQ-0378-0108	*	8EHQ-0378-0111	*
	8EHQ-0478-0119	*	8EHQ-0478-0120	*
	8EHQ-0478-0124	*	8EHQ-0478-0125	*
	8EHQ-0478-0132	*	8EHQ-0578-0141	*
	8EHQ-0578-0150	*	8EHQ-0678-0171	*
	8EHQ-0678-0185	*	8EHQ-0678-0201	*
	8EHQ-0778-0223	*	8EHQ-1078-0249	*
	8EHQ-0881-0407		8EHQ-0783-0486	
	8EHQ-1083-0495		8EHQ-0486-0597	
	8EHQ-0487-0666 S		8EHQ-0288-0718	*
	8EHQ-0390-0899	*	8EHQ-0390-0906 S	
	8EHQ-0590-0994	*	8EHQ-0690-1017	
	8EHQ-0990-1083 S		8EHQ-0790-1032	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

EMERGENCY INCIDENT OF ENV. CONTAMINATION

SUBMISSION #:	8EHQ-0378-0084	*	8EHQ-0678-0183		8EHQ-0878-0237	
	8EHQ-0978-0240		8EHQ-1078-0255	*	8EHQ-1178-0260	*
	8EHQ-0379-0277		8EHQ-0779-0299	*	8EHQ-0879-0300	*
	8EHQ-1179-0319		8EHQ-1279-0322	*	8EHQ-1279-0329	*
	8EHQ-0580-0343		8EHQ-0181-0378		8EHQ-0881-0407	
	8EHQ-1182-0466	*	8EHQ-0985-0566		8EHQ-0386-0593	
	8EHQ-0786-0617		8EHQ-1188-0769	*	8EHQ-0490-0921	S
	8EHQ-0490-0933		8EHQ-0790-1032			

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION #:	8EHQ-1077-0008		8EHQ-1177-0013		8EHQ-0178-0037	
	8EHQ-0178-0038		8EHQ-0278-0043		8EHQ-0278-0045	*
	8EHQ-0278-0054		8EHQ-0378-0085		8EHQ-0378-0089	*
	8EHQ-0378-0093	*	8EHQ-0378-0099		8EHQ-0378-0110	
	8EHQ-0478-0129		8EHQ-0578-0146		8EHQ-0578-0147	
	8EHQ-0578-0168		8EHQ-0678-0179	*	8EHQ-0678-0183	
	8EHQ-0678-0184	*	8EHQ-0678-0189	P	8EHQ-0678-0208	
	8EHQ-0778-0209		8EHQ-0878-0237		8EHQ-0978-0240	
	8EHQ-1078-0245		8EHQ-0878-0249		8EHQ-1078-0255	*
	8EHQ-1178-0256		8EHQ-1178-0260	*	8EHQ-1278-0264	
	8EHQ-0179-0266		8EHQ-0379-0277		8EHQ-0779-0299	*
	8EHQ-0879-0300	*	8EHQ-0979-0310		8EHQ-1279-0329	*
	8EHQ-0180-0330		8EHQ-0580-0343		8EHQ-0680-0345	
	8EHQ-0880-0358	*	8EHQ-1080-0368		8EHQ-0181-0378	
	8EHQ-0881-0407		8EHQ-0981-0409		8EHQ-0981-0413	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION #:	8EHQ-1081-0416		8EHQ-0982-0457		8EHQ-1182-0462
	8EHQ-1182-0466	*	8EHQ-0983-0491 S		8EHQ-1083-0495
	8EHQ-0384-0508 P	*	8EHQ-0784-0521 S		8EHQ-0985-0566
	8EHQ-0386-0593		8EHQ-0486-0597		8EHQ-0786-0617
	8EHQ-0287-0653		8EHQ-0487-0662		8EHQ-0487-0671
	8EHQ-0688-0735		8EHQ-1088-0759		8EHQ-1088-0761
	8EHQ-1188-0769	*	8EHQ-0589-0799		8EHQ-0989-0826 S
	8EHQ-0290-0882		8EHQ-0390-0905 S	*	8EHQ-0490-0921 S
	8EHQ-0490-0933		8EHQ-0490-0953		8EHQ-0790-1032
	8EHQ-0890-1038		8EHQ-0990-1077		

EPIDEMIOLOGY/CLINICAL

SUBMISSION #:	8EHQ-1177-0016		8EHQ-1277-0021		8EHQ-0278-0056
	8EHQ-0378-0096	*	8EHQ-0378-0105		8EHQ-0478-0117
	8EHQ-0478-0123		8EHQ-0478-0128		8EHQ-0478-0135
	8EHQ-0578-0146		8EHQ-0578-0149		8EHQ-0578-0167 P
	8EHQ-0578-0168		8EHQ-0678-0192 S		8EHQ-0878-0230
	8EHQ-0978-0241		8EHQ-0978-0246		8EHQ-0379-0280
	8EHQ-0280-0332		8EHQ-0580-0341		8EHQ-1080-0366
	8EHQ-1080-0367		8EHQ-1180-0374 S		8EHQ-0281-0382
	8EHQ-0381-0390		8EHQ-0384-0394 S		8EHQ-1280-0401 S
	8EHQ-0282-0427 S		8EHQ-0382-0440 S		8EHQ-0582-0444
	8EHQ-0383-0473		8EHQ-1083-0497		8EHQ-0884-0523
	8EHQ-0285-0546		8EHQ-0485-0551	*	8EHQ-0485-0552
	8EHQ-0585-0557		8EHQ-0985-0567		8EHQ-0186-0585 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

EPIDEMIOLOGY/CLINICAL

SUBMISSION #:	8EHQ-0286-0588	*	8EHQ-0386-0589	S	8EHQ-0486-0598	
	8EHQ-0586-0601		8EHQ-0768-0611		8EHQ-0786-0612	
	8EHQ-0786-0615		8EHQ-0986-0629		8EHQ-0986-0632	
	8EHQ-0986-0634		8EHQ-1086-0641		8EHQ-0187-0651	*
	8EHQ-0487-0671		8EHQ-0887-0688		8EHQ-0987-0694	*
	8EHQ-1187-0698		8EHQ-1287-0699		8EHQ-1287-0701	*
	8EHQ-0288-0722		8EHQ-0688-0736		8EHQ-1088-0755	
	8EHQ-1188-0722		8EHQ-0889-0818	S	8EHQ-0989-0821	S
	8EHQ-1089-0831		8EHQ-1089-0832		8EHQ-0190-0863	
	8EHQ-0190-0864		8EHQ-0290-0886		8EHQ-0390-0905	S *
	8EHQ-0390-0915		8EHQ-0490-0917		8EHQ-0490-0924	
	8EHQ-0490-0929	S *	8EHQ-0590-0991	S	8EHQ-0790-1034	
	8EHQ-0890-1053		8EHQ-0990-1065		8EHQ-0990-1071	
	8EHQ-0990-1072		8EHQ-0990-1078		8EHQ-0990-1080	S

GROUNDWATER CONTAMINATION

SUBMISSION #:	8EHQ-0578-0147		8EHQ-0678-0189	P	8EHQ-0979-0310
	8EHQ-0180-0330		8EHQ-0680-0345		8EHQ-1080-0368
	8EHQ-0982-0457		8EHQ-0487-0662		8EHQ-1088-0759
	8EHQ-0490-0953				
	8EHQ-0990-1077				

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION #:	8EHQ-1077-0008		8EHQ-1077-0011		8EHQ-0178-0038	
	8EHQ-0278-0067	P *	8EHQ-0278-0075	P *	8EHQ-0278-0076	P *
	8EHQ-0278-0077	P *	8EHQ-0278-0078	P *	8EHQ-0278-0079	P *

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION #:	8EHQ-0278-0080 P *	8EHQ-0378-0086 *	8EHQ-0478-0118 P *
	8EHQ-0578-0146	8EHQ-0578-0149	8EHQ-0578-0154 P
	8EHQ-0678-0180 *	8EHQ-0778-0217	8EHQ-0978-0238 *
	8EHQ-0978-0240	8EHQ-1178-0260 *	8EHQ-0479-0273
	8EHQ-0379-0277	8EHQ-0879-0304 *	8EHQ-1079-0315 *
	8EHQ-1279-0322 *	8EHQ-0180-0324	8EHQ-0480-0338
	8EHQ-0580-0341	8EHQ-0580-0343	8EHQ-0381-0390
	8EHQ-0981-0413	8EHQ-1081-0416	8EHQ-1182-0466 *
	8EHQ-0384-0508 P *	8EHQ-0484-0513	8EHQ-0985-0566
	8EHQ-0786-0617	8EHQ-0487-0671	8EHQ-0688-0736
	8EHQ-1089-0832	8EHQ-0290-0885	8EHQ-0390-0905 S *
	8EHQ-0490-0929 S *	8EHQ-0490-0933	8EHQ-0490-0962
	8EHQ-0990-1065		

HUMAN EXPOSURE (MONITORING)

SUBMISSION #:	8EHQ-1277-0021	8EHQ-0378-0096 *	8EHQ-0378-0109
	8EHQ-0378-0110	8EHQ-0378-0112 *	8EHQ-0378-0113
	8EHQ-0478-0115 *	8EHQ-0578-0146	8EHQ-0578-0147
	8EHQ-0578-0168	8EHQ-0578-0170	8EHQ-0678-0179 *
	8EHQ-0678-0189 P	8EHQ-0678-0208	8EHQ-0778-0209
	8EHQ-0778-0213	8EHQ-0778-0219 *	8EHQ-0778-0228 *
	8EHQ-1278-0264	8EHQ-0179-0267	8EHQ-0479-0281
	8EHQ-0779-0292	8EHQ-0779-0293	8EHQ-0979-0310
	8EHQ-1179-0320	8EHQ-0979-0326 S	8EHQ-0180-0330
	8EHQ-0280-0331 S	8EHQ-0380-0336 S	8EHQ-0580-0343

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (MONITORING)

SUBMISSION #:	8EHQ-0680-0345	8EHQ-0680-0348	8EHQ-1080-0367
	8EHQ-1080-0368	8EHQ-1280-0376	8EHQ-1280-0401 S
	8EHQ-0981-0413	8EHQ-0382-0440 S	8EHQ-0482-0442
	8EHQ-0982-0457	8EHQ-1182-0462	8EHQ-0383-0473
	8EHQ-1083-0495	8EHQ-1083-0497	8EHQ-0184-0504
	8EHQ-0784-0521 S	8EHQ-1084-0535	8EHQ-0185-0542 S
	8EHQ-0285-0546	8EHQ-0385-0547	8EHQ-0485-0550
	8EHQ-0485-0551 *	8EHQ-0485-0553	8EHQ-0585-0554 S
	8EHQ-0985-0566	8EHQ-0286-0588 *	8EHQ-0586-0601
	8EHQ-0986-0633 S	8EHQ-1286-0648	8EHQ-0487-0662
	8EHQ-0487-0671	8EHQ-0587-0672 S	8EHQ-0687-0682
	8EHQ-0288-0722	8EHQ-0688-0735	8EHQ-0988-0752 S
	8EHQ-1088-0761	8EHQ-0289-0784	8EHQ-0389-0789
	8EHQ-0489-0793	8EHQ-0589-0801	8EHQ-0889-0818 S
	8EHQ-1289-0856	8EHQ-0190-0863	8EHQ-0290-0882
	8EHQ-0490-0924	8EHQ-0490-0933	8EHQ-0490-0953
	8EHQ-0490-0962	8EHQ-0690-1018	8EHQ-0890-1038
	8EHQ-0890-1053	8EHQ-0990-1077	8EHQ-0990-1078

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION #:	8EHQ-1077-0012	8EHQ-0378-0104	8EHQ-0378-0113
	8EHQ-0478-0117 *	8EHQ-0478-0133	8EHQ-0578-0139
	8EHQ-0778-0219 *	8EHQ-1278-0264	8EHQ-0579-0284
	8EHQ-0779-0292	8EHQ-1179-0320	8EHQ-0979-0326 S
	8EHQ-0280-0331 S	8EHQ-0380-0336 S	8EHQ-0680-0348

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION #:	8EHQ-0780-0352	8EHQ-0880-0358	*	8EHQ-1280-0376
	8EHQ-0381-0390	8EHQ-0981-0409		8EHQ-1281-0420
	8EHQ-0482-0442	8EHQ-0682-0449 S		8EHQ-0283-0469 S
	8EHQ-0383-0473	8EHQ-0784-0521 S		8EHQ-0185-0542 S
	8EHQ-0585-0554 S	8EHQ-0885-0564 S		8EHQ-1186-0643
	8EHQ-1186-0644	8EHQ-0288-0720		8EHQ-0688-0735
	8EHQ-1088-0761	8EHQ-0589-0799		8EHQ-0688-0804
	8EHQ-0490-0962			

IMMUNOTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0186-0585 S	8EHQ-0386-0594 S	8EHQ-0588-0732
	8EHQ-0889-0817		

IMMUNOTOXICITY (HUMAN)

SUBMISSION #: 8EHQ-0290-0876

MATERIAL SAFETY DATA SHEETS/LABELS

SUBMISSION #:	8EHQ-0190-0867	*	8EHQ-0390-0903 S	8EHQ-0490-0919 S
	8EHQ-0490-0945		8EHQ-0590-0967	8EHQ-0590-0969
	8EHQ-0590-0983		8EHQ-0590-0991 S	8EHQ-0590-1001 S
	8EHQ-0690-1017		8EHQ-0690-1018	8EHQ-0990-1062
	8EHQ-0990-1071		8EHQ-0990-1078	

METABOLISM/PHARMACOKINETICS (ANIMAL)

SUBMISSION #:	8EHQ-1280-0401 S	8EHQ-0780-0350
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APPENDIX : STATUS REPORTS BY INFORMATION TYPE

METABOLISM/PHARMACOKINETICS (ANIMAL)

SUBMISSION #:	8EHQ-0578-0149	8EHQ-0379-0277		8EHQ-0484-0513
	8EHQ-0285-0546	8EHQ-0485-0551	*	8EHQ-0486-0600

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1077-0010	8EHQ-1277-0025		8EHQ-1277-0026 S	
	8EHQ-0178-0030	8EHQ-0278-0047		8EHQ-0278-0051	*
	8EHQ-0278-0053	8EHQ-0278-0057		8EHQ-0278-0073	
	8EHQ-0278-0082	8EHQ-0378-0102		8EHQ-0378-0107	*
	8EHQ-0478-0127 *	8EHQ-0478-0136	*	8EHQ-0578-0164	
	8EHQ-0578-0165	8EHQ-0578-0166		8EHQ-0678-0184	*
	8EHQ-0678-0185 *	8EHQ-0678-0187	*	8EHQ-0778-0213	
	8EHQ-0778-0214	8EHQ-0778-0216		8EHQ-0978-0239	
	8EHQ-1078-0254	8EHQ-0179-0266		8EHQ-0179-0267	
	8EHQ-0179-0268 S	8EHQ-0179-0270		8EHQ-0479-0278	
	8EHQ-0479-0279	8EHQ-0579-0285		8EHQ-0579-0286	
	8EHQ-0579-0287	8EHQ-0579-0288		8EHQ-0579-0289	
	8EHQ-0679-0291	8EHQ-0779-0293		8EHQ-0779-0294	
	8EHQ-0879-0301	8EHQ-1179-0321		8EHQ-1279-0323	
	8EHQ-0180-0328	8EHQ-0280-0333		8EHQ-0280-0334	
	8EHQ-0480-0339	8EHQ-0480-0340		8EHQ-0780-0350	
	8EHQ-0780-0351	8EHQ-0980-0359		8EHQ-0980-0361 S	
	8EHQ-0980-0363	8EHQ-1080-0366		8EHQ-0281-0383	*
	8EHQ-0281-0385	8EHQ-0381-0391		8EHQ-0481-0396	*
	8EHQ-0581-0400	8EHQ-0681-0402		8EHQ-0681-0403 S	
	8EHQ-0681-0404	8EHQ-0781-0406 S		8EHQ-0981-0412	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1081-0415	8EHQ-1081-0417	8EHQ-1081-0418
	8EHQ-1281-0426	8EHQ-0282-0427 S	8EHQ-0682-0448 S
	8EHQ-0982-0455	8EHQ-0982-0458	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-1182-0465	8EHQ-0183-0468
	8EHQ-0283-0470	8EHQ-0283-0471 S	8EHQ-0483-0476 S
	8EHQ-0583-0477 S	8EHQ-0683-0481	8EHQ-0683-0482
	8EHQ-0783-0486	8EHQ-0883-0489	8EHQ-0883-0490
	8EHQ-1083-0495	8EHQ-1083-0496	8EHQ-1283-0500 S
	8EHQ-1283-0503	8EHQ-0384-0506 S	8EHQ-1083-0509
	8EHQ-0484-0510	8EHQ-0484-0511	8EHQ-0484-0512
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0584-0519	8EHQ-0784-0522	8EHQ-0984-0530
	8EHQ-1084-0532	8EHQ-1084-0533 S	8EHQ-1184-0537
	8EHQ-1284-0539	8EHQ-1284-0541 S	8EHQ-0685-0558 S
	8EHQ-0785-0561 S	8EHQ-1085-0571 S	8EHQ-1285-0579 S
	8EHQ-1285-0580	8EHQ-0186-0584	8EHQ-0186-0585 S
	8EHQ-0486-0597	8EHQ-0586-0602	8EHQ-0786-0606 S
	8EHQ-0786-0608 S	8EHQ-0786-0610	8EHQ-0786-0613
	8EHQ-0886-0620	8EHQ-0886-0621	8EHQ-0986-0627
	8EHQ-1286-0645	8EHQ-1186-0646 S	8EHQ-1186-0647
	8EHQ-0187-0649 S	8EHQ-0287-0653	8EHQ-0287-0654
	8EHQ-0687-0677	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0692	8EHQ-0987-0693
	8EHQ-1287-0706	8EHQ-1287-0709 S	8EHQ-0288-0715
	8EHQ-0288-0719	8EHQ-0688-0737	8EHQ-0788-0743

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1088-0758 S	8EHQ-1088-0760 S	8EHQ-0389-0780
	8EHQ-0389-0791 S	8EHQ-0589-0798 S	8EHQ-0789-0805 S
	8EHQ-0889-0814	8EHQ-0989-0826 S	8EHQ-1089-0837 S
	8EHQ-1289-0854 S	8EHQ-1289-0858 S	8EHQ-0390-0903 S
	8EHQ-0390-0916 S *	8EHQ-0490-0930 S	8EHQ-0490-0932
	8EHQ-0490-0960	8EHQ-0690-1009	8EHQ-0690-1015
	8EHQ-0690-1016	8EHQ-0890-1044 S	8EHQ-0890-1051 S
	8EHQ-0990-1066 S	8EHQ-0990-1067	8EHQ-0990-1079 S

MUTAGENICITY (IN VIVO)

SUBMISSION #:	8EHQ-0278-0082	8EHQ-0378-0107	*	8EHQ-0578-0170
	8EHQ-0678-0208	8EHQ-0778-0213		8EHQ-1078-0248
	8EHQ-0179-0267	8EHQ-0579-0285		8EHQ-0579-0287
	8EHQ-0579-0288	8EHQ-0679-0291		8EHQ-0879-0301
	8EHQ-1179-0321	8EHQ-1279-0323		8EHQ-0780-0350
	8EHQ-0980-0359	8EHQ-1080-0366		8EHQ-0281-0384
	8EHQ-0381-0387	8EHQ-0981-0412		8EHQ-1081-0418
	8EHQ-1281-0426	8EHQ-0483-0476 S		8EHQ-1083-0499
	8EHQ-0785-0560	8EHQ-1285-0577		8EHQ-0786-0613
	8EHQ-0290-0892	8EHQ-0390-0916 S	*	8EHQ-0590-0981

NEUROTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1177-0015 S	8EHQ-0278-0055	8EHQ-0678-0173	*
	8EHQ-0678-0188 *	8EHQ-0778-0218	8EHQ-0279-0275	
	8EHQ-0880-0356	8EHQ-0880-0357	8EHQ-0780-0369	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

NEUROTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0382-0440 S	8EHQ-0682-0451		8EHQ-1182-0462
	8EHQ-0583-0478 S	8EHQ-1083-0494	*	8EHQ-1283-0501
	8EHQ-0684-0520	8EHQ-1084-0532		8EHQ-0585-0556 S
	8EHQ-1085-0571 S	8EHQ-0186-0584		8EHQ-0386-0590
	8EHQ-0486-0599	8EHQ-0886-0628		8EHQ-0287-0655 S
	8EHQ-0587-0678	8EHQ-1287-0706		8EHQ-0188-0714
	8EHQ-0588-0733	8EHQ-0688-0739		8EHQ-0688-0740 S
	8EHQ-0788-0744 S	8EHQ-1088-0757		8EHQ-1288-0776
	8EHQ-0489-0793	8EHQ-0489-0794 S		8EHQ-0889-0811 S
	8EHQ-0886-0815	8EHQ-1089-0837 S		8EHQ-1089-0838 S
	8EHQ-1189-0841	8EHQ-1189-0843 S		8EHQ-1189-0846
	8EHQ-1189-0848 S	8EHQ-0190-0867	*	8EHQ-0290-0893
	8EHQ-0390-0898	8EHQ-0390-0913 S		8EHQ-0390-0914 S
	8EHQ-0490-0919 S	8EHQ-0490-0931 S		8EHQ-0490-0934 S
	8EHQ-0490-0936	8EHQ-0490-0954 S		8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S		8EHQ-0490-0963
	8EHQ-0590-0964	8EHQ-0590-0996		8EHQ-0590-1001 S
	8EHQ-0690-1002	8EHQ-0690-1003		8EHQ-0690-1004 S
	8EHQ-0690-1005 S	8EHQ-0690-1007		8EHQ-0790-1028 S
	8EHQ-0890-1041	8EHQ-0890-1043		8EHQ-0890-1052 S
	8EHQ-0990-1057	8EHQ-0990-1063		8EHQ-0990-1076 S

NEUROTOXICITY (HUMAN)

SUBMISSION #:	8EHQ-1277-0021	8EHQ-0378-0105		8EHQ-0478-0118 P	*
	8EHQ-0578-0146	8EHQ-0480-0338		8EHQ-0786-0611	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

NEUROTOXICITY (HUMAN)

SUBMISSION #: 8EHQ-1086-0641 8EHQ-0590-0991 S 8EHQ-0990-1065

ONCOGENICITY (ANIMAL)

SUBMISSION #:	8EHQ-0877-0002	8EHQ-1077-0006	8EHQ-1077-0012
	8EHQ-1177-0016	8EHQ-1177-0019	8EHQ-1277-0026 S
	8EHQ-0178-0028	8EHQ-0178-0029	8EHQ-0278-0044
	8EHQ-0278-0046 *	8EHQ-0278-0083	8EHQ-0478-0117 *
	8EHQ-0578-0140	8EHQ-0578-0148	8EHQ-0578-0165
	8EHQ-0578-0170	8EHQ-0678-0202	8EHQ-0778-0209
	8EHQ-0778-0212	8EHQ-0778-0215	8EHQ-0878-0234
	8EHQ-0878-0236 *	8EHQ-0978-0246	8EHQ-1078-0248
	8EHQ-1078-0251	8EHQ-1078-0253	8EHQ-1278-0262
	8EHQ-0279-0274	8EHQ-0479-0281	8EHQ-0579-0283
	8EHQ-0779-0297	8EHQ-0979-0305	8EHQ-0979-0306
	8EHQ-1079-0314	8EHQ-1179-0316	8EHQ-1179-0318
	8EHQ-0180-0327	8EHQ-0180-0328	8EHQ-0480-0337
	8EHQ-0580-0342	8EHQ-0780-0350	8EHQ-0780-0353
	8EHQ-0980-0360	8EHQ-1080-0370	8EHQ-0381-0389
	8EHQ-0381-0393	8EHQ-0481-0397	8EHQ-0581-0400
	8EHQ-1280-0401 S	8EHQ-0681-0402	8EHQ-0981-0410
	8EHQ-0981-0411	8EHQ-1281-0422	8EHQ-1281-0423
	8EHQ-0282-0434	8EHQ-0282-0439	8EHQ-0482-0443
	8EHQ-0682-0447	8EHQ-0882-0453	8EHQ-0882-0454
	8EHQ-1082-0461	8EHQ-1182-0463	8EHQ-1282-0467
	8EHQ-0283-0469 S	8EHQ-0283-0472 S	8EHQ-0383-0474

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ONCOGENICITY (ANIMAL)

SUBMISSION #:	8EHQ-0683-0480	8EHQ-0683-0483 S	8EHQ-0783-0486	
	8EHQ-0783-0488	8EHQ-1083-0497	8EHQ-1283-0503	
	8EHQ-0384-0507	8EHQ-1083-0509	8EHQ-0584-0514	
	8EHQ-0584-0517	8EHQ-0884-0525	8EHQ-0884-0526	
	8EHQ-0984-0530	8EHQ-1284-0538	8EHQ-0485-0550	
	8EHQ-0485-0553	8EHQ-0785-0561 S	8EHQ-0785-0562 S	
	8EHQ-0985-0567	8EHQ-0685-0583 S	8EHQ-0386-0592	
	8EHQ-0486-0600	8EHQ-0686-0604	8EHQ-0786-0606 S	
	8EHQ-0786-0614	8EHQ-0886-0618 S	8EHQ-0386-0619	
	8EHQ-1086-0642	8EHQ-0187-0650	8EHQ-0587-0675	*
	8EHQ-0786-0681	8EHQ-0787-0684 S	8EHQ-0887-0687	
	8EHQ-0887-0691 S	8EHQ-0987-0692	8EHQ-1187-0697	
	8EHQ-1287-0704	8EHQ-1287-0708 S	8EHQ-1287-0710	
	8EHQ-0188-0713	8EHQ-0388-0725	8EHQ-0588-0730	
	8EHQ-0788-0741	8EHQ-0788-0745 S	8EHQ-1088-0760 S	
	8EHQ-1088-0763 S	8EHQ-1288-0773	8EHQ-1288-0774	
	8EHQ-1288-0775	8EHQ-0789-0809	8EHQ-0889-0812	
	8EHQ-0989-0822	8EHQ-1189-0847	8EHQ-1289-0856	
	8EHQ-1289-0858 S	8EHQ-0290-0873 S	8EHQ-0290-0881 S	
	8EHQ-0490-0952 S	8EHQ-0490-0960	8EHQ-0590-0993 S	
	8EHQ-0790-1029	8EHQ-0890-1050 S		

ONCOGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0777-0001	8EHQ-0378-0096	8EHQ-0478-0117	*
	8EHQ-0478-0135	8EHQ-0578-0167 P	8EHQ-0578-0168	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

ONCOGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0878-0230	8EHQ-0978-0241	8EHQ-0978-0246	
	8EHQ-0582-0444	8EHQ-0383-0473	8EHQ-0884-0523	
	8EHQ-0285-0546	8EHQ-0585-0557	8EHQ-0486-0598	
	8EHQ-0586-0601	8EHQ-0786-0615	8EHQ-0986-0629	
	8EHQ-0986-0634	8EHQ-0187-0651	8EHQ-0887-0688	
	8EHQ-1187-0698	8EHQ-1287-0699	8EHQ-1287-0701	*
	8EHQ-1188-0772	8EHQ-0190-0893	8EHQ-0190-0864	
	8EHQ-0290-0886	8EHQ-0390-0915	8EHQ-0490-0917	
	8EHQ-0490-0924	8EHQ-0790-1034	8EHQ-0890-1053	
	8EHQ-0990-1080 S			

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1077-0008	8EHQ-1077-0011	8EHQ-1177-0014	
	8EHQ-1177-0016	8EHQ-1277-0021	8EHQ-1277-0026 S	
	8EHQ-0278-0044	8EHQ-0278-0045	8EHQ-0278-0054	*
	8EHQ-0378-0085	8EHQ-0378-0089	8EHQ-0378-0093	*
	8EHQ-0378-0104	8EHQ-0378-0105	8EHQ-0478-0117	*
	8EHQ-0478-0133	8EHQ-0578-0139	8EHQ-0578-0150	*
	8EHQ-0578-0153 S	8EHQ-0578-0155	8EHQ-0578-0163	*
	8EHQ-0578-0164	8EHQ-0578-0165	8EHQ-0578-0169 S	*
	8EHQ-0678-0187	8EHQ-0678-0200	8EHQ-0678-0205	*
	8EHQ-0778-0209	8EHQ-0778-0214	8EHQ-0778-0219	*
	8EHQ-0778-0220	8EHQ-0778-0228	8EHQ-0978-0240	*
	8EHQ-1078-0245	8EHQ-1078-0249	8EHQ-1078-0251	
	8EHQ-1078-0253	8EHQ-1078-0255	8EHQ-1178-0256	*

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1178-0260	*	8EHQ-1187-0261		8EHQ-1278-0264
	8EHQ-0179-0268	S	8EHQ-0179-0269	S	8EHQ-0179-0272
	8EHQ-0279-0275		8EHQ-0479-0278		8EHQ-0379-0280
	8EHQ-0579-0283		8EHQ-0579-0288		8EHQ-0779-0292
	8EHQ-0779-0293		8EHQ-0879-0301		8EHQ-1179-0317
	8EHQ-1179-0321		8EHQ-1279-0323		8EHQ-0180-0328
	8EHQ-0280-0331	S	8EHQ-0280-0333		8EHQ-0380-0335
	8EHQ-0380-0336	S	8EHQ-0780-0350		8EHQ-0880-0358
	8EHQ-1180-0373	S	8EHQ-1180-0374	S	8EHQ-1180-0375
	8EHQ-0381-0394	S	8EHQ-0481-0397		8EHQ-0581-0399
	8EHQ-0781-0406	S	8EHQ-0482-0442		8EHQ-0682-0446
	8EHQ-0882-0454		8EHQ-0982-0456	S	8EHQ-0283-0469
	8EHQ-0283-0471	S	8EHQ-0583-0477	S	8EHQ-0583-0479
	8EHQ-0683-0480		8EHQ-0683-0483	S	8EHQ-0683-0484
	8EHQ-0783-0485	S	8EHQ-0783-0487	S	8EHQ-0983-0491
	8EHQ-0983-0492	S	8EHQ-0983-0493	S	8EHQ-1283-0500
	8EHQ-1283-0501		8EHQ-1283-0502	P	8EHQ-1283-0503
	8EHQ-0384-0508	P	8EHQ-0484-0510		8EHQ-0484-0511
	8EHQ-0484-0513		8EHQ-0584-0515	S	8EHQ-0584-0516
	8EHQ-0584-0517		8EHQ-0584-0519		8EHQ-0784-0521
	8EHQ-0884-0526		8EHQ-1284-0540	S	8EHQ-0185-0542
	8EHQ-0285-0545	S	8EHQ-0485-0548		8EHQ-0485-0551
	8EHQ-0485-0553		8EHQ-0585-0554	S	8EHQ-0585-0555
	8EHQ-0585-0556	S	8EHQ-0785-0562	S	8EHQ-0885-0564
	8EHQ-0985-0568	S	8EHQ-1085-0571	S	8EHQ-0585-0572

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1185-0576	8EHQ-1285-0577	8EHQ-0186-0582 S
	8EHQ-0685-0583 S	8EHQ-0386-0589 S	8EHQ-0386-0594 S
	8EHQ-0486-0597	8EHQ-0586-0602 S	8EHQ-0686-0605 S
	8EHQ-0786-0606 S	8EHQ-0786-0608 S	8EHQ-0786-0609 S
	8EHQ-0786-0610	8EHQ-0786-0614	8EHQ-0886-0621
	8EHQ-0986-0623 S	8EHQ-0986-0624 S	8EHQ-0986-0625 S
	8EHQ-0986-0626 S	8EHQ-0986-0627	8EHQ-0986-0631 S
	8EHQ-0986-0632	8EHQ-0986-0633 S	8EHQ-1086-0636 S
	8EHQ-1086-0637	8EHQ-1086-0639 S	8EHQ-1086-0640 S *
	8EHQ-1186-0643	8EHQ-1186-0644	8EHQ-1186-0646 S
	8EHQ-0187-0649 S	8EHQ-0287-0652 S	8EHQ-0287-0655 S
	8EHQ-0387-0656	8EHQ-0487-0661 S	8EHQ-0487-0664 S
	8EHQ-0487-0665 S *	8EHQ-0487-0667 S *	8EHQ-0487-0668
	8EHQ-0487-0669 *	8EHQ-0487-0670 S	8EHQ-0487-0671
	8EHQ-0587-0674 S	8EHQ-0687-0680	8EHQ-0787-0684 S
	8EHQ-0787-0686 S	8EHQ-1187-0697	8EHQ-1287-0707 S
	8EHQ-1287-0708 S	8EHQ-1287-0709 S	8EHQ-0188-0714
	8EHQ-0288-0716 S	8EHQ-0288-0717 S	8EHQ-0288-0720
	8EHQ-0388-0724 S	8EHQ-0388-0725	8EHQ-0488-0727
	8EHQ-0488-0728	8EHQ-0488-0729 S	8EHQ-0588-0731 S
	8EHQ-0588-0733	8EHQ-0688-0734 S	8EHQ-0688-0735
	8EHQ-0688-0740 S	8EHQ-0788-0744 S	8EHQ-0788-0745 S
	8EHQ-0988-0749 S	8EHQ-0988-0750 S	8EHQ-0988-0751 S
	8EHQ-0988-0752 S	8EHQ-0988-0753 S	8EHQ-1088-0755
	8EHQ-1088-0758 S	8EHQ-1088-0760 S	8EHQ-1088-0761

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1088-0763 S	8EHQ-1088-0764 S	8EHQ-1188-0765 S
	8EHQ-1188-0766 S	8EHQ-1188-0767 S	8EHQ-1188-0768 S
	8EHQ-1188-0770 S	8EHQ-1188-0771 S	8EHQ-1288-0776
	8EHQ-0389-0780	8EHQ-0289-0782 S	8EHQ-0289-0783 S
	8EHQ-0289-0784	8EHQ-0289-0785 S	8EHQ-0389-0787 S
	8EHQ-0389-0788 S	8EHQ-0389-0789	8EHQ-0389-0790 S
	8EHQ-0389-0791 S	8EHQ-0489-0794 S	8EHQ-0589-0798 S
	8EHQ-0589-0799	8EHQ-0689-0804	8EHQ-0789-0805 S
	8EHQ-0789-0806 S	8EHQ-0789-0808 S	8EHQ-0889-0811 S
	8EHQ-0889-0816 S	8EHQ-0889-0817	8EHQ-0889-0819 S
	8EHQ-0989-0821 S	8EHQ-0989-0824 S	8EHQ-0989-0825 S
	8EHQ-0989-0827 S	8EHQ-0989-0828 S	8EHQ-1089-0833 S
	8EHQ-1089-0834 S	8EHQ-1089-0835 S	8EHQ-1089-0837 S
	8EHQ-1089-0838 S	8EHQ-1189-0840 S	8EHQ-1189-0842 S
	8EHQ-1189-0843 S	8EHQ-1189-0844	8EHQ-1189-0847
	8EHQ-1189-0848 S	8EHQ-1289-0849 S	8EHQ-1289-0851 S
	8EHQ-1289-0853 S	8EHQ-1289-0854 S	8EHQ-1289-0857 S
	8EHQ-1289-0858 S	8EHQ-1289-0859	8EHQ-0190-0861 S
	8EHQ-0190-0862 S	8EHQ-0190-0865 S	8EHQ-0190-0866 S
	8EHQ-0190-0868 S	8EHQ-0190-0869 S	8EHQ-0190-0870 S
	8EHQ-0190-0871 S	8EHQ-0290-0872 S	8EHQ-0290-0873 S
	8EHQ-0290-0874 S	8EHQ-0290-0875 S	8EHQ-0290-0879 S
	8EHQ-0290-0880	8EHQ-0290-0881 S	8EHQ-0290-0883 S
	8EHQ-0290-0887 S	8EHQ-0290-0888 S	8EHQ-0290-0889 S
	8EHQ-0290-0890 S	8EHQ-0290-0891 S	8EHQ-0390-0895 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-0390-0896 S		8EHQ-0390-0897 S		8EHQ-0390-0903 S
	8EHQ-0390-0905 S	*	8EHQ-0390-0906 S		8EHQ-0390-0907 S
	8EHQ-0390-0908 S		8EHQ-0390-0913 S		8EHQ-0390-0914 S
	8EHQ-0390-0916 S	*	8EHQ-0490-0918 S		8EHQ-0490-0919 S
	8EHQ-0490-0920 S		8EHQ-0490-0921 S		8EHQ-0490-0922 S
	8EHQ-0490-0923 S		8EHQ-0490-0925 S		8EHQ-0490-0926 S
	8EHQ-0490-0927 S		8EHQ-0490-0928 S		8EHQ-0490-0929 S
	8EHQ-0490-0930 S		8EHQ-0490-0931 S		8EHQ-0490-0932
	8EHQ-0490-0934 S		8EHQ-0490-0935 S		8EHQ-0490-0938
	8EHQ-0490-0952 S		8EHQ-0490-0955 S		8EHQ-0490-0956 S
	8EHQ-0490-0957 S		8EHQ-0490-0958 S		8EHQ-0490-0959 S
	8EHQ-0490-0961 S		8EHQ-0490-0962		8EHQ-0590-0983
	8EHQ-0590-0986 S		8EHQ-0590-0987 S		8EHQ-0590-0988 S
	8EHQ-0590-0989 S		8EHQ-0590-0990		8EHQ-0590-0992 S
	8EHQ-0590-0993 S		8EHQ-0590-0995 S		8EHQ-0590-0997 S
	8EHQ-0590-0998 S		8EHQ-0590-1001 S		8EHQ-0690-1004 S
	8EHQ-0690-1005 S		8EHQ-0690-1006 S		8EHQ-0690-1010 S
	8EHQ-0690-1011 S		8EHQ-0690-1012 S		8EHQ-0690-1013 S
	8EHQ-0690-1014 S		8EHQ-0690-1016 S		8EHQ-0790-1022 S
	8EHQ-0790-1023 S		8EHQ-0790-1025 S		8EHQ-0790-1026 S
	8EHQ-0790-1028 S		8EHQ-0790-1029		8EHQ-0790-1031 S
	8EHQ-0790-1036 S		8EHQ-0790-1037 S		8EHQ-0890-1039 S
	8EHQ-0890-1042		8EHQ-0890-1044 S		8EHQ-0890-1048 S
	8EHQ-0890-1049 S		8EHQ-0890-1050 S		8EHQ-0890-1052 S
	8EHQ-0890-1054 S		8EHQ-0890-1056 S		8EHQ-0990-1058 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-0990-1059 S	*	8EHQ-0990-1060 S		8EHQ-0990-1062
	8EHQ-0990-1063		8EHQ-0990-1066 S		8EHQ-0990-1070 S
	8EHQ-0990-1071		8EHQ-0990-1073 S		8EHQ-0990-1075 S
	8EHQ-0990-1076 S		8EHQ-0990-1078		8EHQ-0990-1079 S
	8EHQ-0990-1083 S				

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-1277-0026 S		8EHQ-0378-0096	*	8EHQ-0378-0097	*
	8EHQ-0378-0104		8EHQ-0378-0105		8EHQ-0378-0109	
	8EHQ-0378-0110		8EHQ-0378-0112	*	8EHQ-0378-0113	
	8EHQ-0478-0115	*	8EHQ-0478-0117	*	8EHQ-0478-0118 P	*
	8EHQ-0478-0123		8EHQ-0478-0138 P	*	8EHQ-0578-0139	
	8EHQ-0578-0146		8EHQ-0578-0148		8EHQ-0578-0152	
	8EHQ-0578-0155	*	8EHQ-0578-0157	*	8EHQ-0578-0158 S	*
	8EHQ-0578-0159 S	*	8EHQ-0578-0162 S	*	8EHQ-0578-0163	
	8EHQ-0578-0164		8EHQ-0578-0165		8EHQ-0578-0166	
	8EHQ-0578-0167 P		8EHQ-0578-0168		8EHQ-0578-0169 S	*
	8EHQ-0678-0179	*	8EHQ-0678-0180	*	8EHQ-0678-0200	*
	8EHQ-0678-0202		8EHQ-0778-0209		8EHQ-0778-0217	
	8EHQ-0778-0219	*	8EHQ-0778-0228	*	8EHQ-0878-0230	
	8EHQ-0978-0239		8EHQ-1078-0245		8EHQ-0978-0246	
	8EHQ-1078-0247		8EHQ-1078-0251		8EHQ-1078-0252	
	8EHQ-1078-0253		8EHQ-1178-0256		8EHQ-1178-0261	
	8EHQ-1278-0264		8EHQ-0179-0267		8EHQ-0179-0268 S	
	8EHQ-0179-0270		8EHQ-0179-0271		8EHQ-0179-0272	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0279-0275	8EHQ-0479-0278	8EHQ-0379-0280	
	8EHQ-0479-0282 S	8EHQ-0579-0283	8EHQ-0579-0288	
	8EHQ-0679-0291	8EHQ-0779-0292	8EHQ-0779-0293	
	8EHQ-0779-0294	8EHQ-0779-0296	8EHQ-0779-0297	
	8EHQ-0583-0477 S	8EHQ-0583-0479 S	8EHQ-0683-0480	
	8EHQ-0683-0481	8EHQ-0683-0483 S	8EHQ-0783-0485 S	*
	8EHQ-0783-0487 S *	8EHQ-0883-0490	8EHQ-0983-0492 S	
	8EHQ-0983-0493 S *	8EHQ-1083-0494	8EHQ-1083-0495	*
	8EHQ-1083-0496	8EHQ-1083-0497	8EHQ-1083-0498	
	8EHQ-1283-0500 S	8EHQ-1283-0501	8EHQ-1283-0502 P	*
	8EHQ-1283-0503	8EHQ-0184-0504	8EHQ-0284-0505	
	8EHQ-0384-0506 S	8EHQ-1083-0509	8EHQ-0484-0510	
	8EHQ-0484-0513	8EHQ-0584-0514	8EHQ-0584-0515 S	
	8EHQ-0584-0516 S	8EHQ-0584-0517	8EHQ-0584-0519	
	8EHQ-0684-0520	8EHQ-0784-0521 S	8EHQ-0784-0522	
	8EHQ-0884-0523	8EHQ-0884-0524	8EHQ-0884-0526	
	8EHQ-0884-0528	8EHQ-0984-0529	8EHQ-0984-0531 S	*
	8EHQ-1084-0532	8EHQ-1084-0533 S	8EHQ-1084-0534	
	8EHQ-1084-0535	8EHQ-0185-0542 S	8EHQ-0285-0544	
	8EHQ-0285-0545 S	8EHQ-0285-0546	8EHQ-0385-0547	
	8EHQ-0485-0548	8EHQ-0485-0549 S	8EHQ-0485-0550	
	8EHQ-0485-0551 *	8EHQ-0485-0552	8EHQ-0485-0553	
	8EHQ-0585-0554 S	8EHQ-0585-0555	8EHQ-0585-0556 S	
	8EHQ-0585-0557	8EHQ-0685-0558 S	8EHQ-0685-0559	
	8EHQ-0785-0561 S	8EHQ-0785-0562 S	8EHQ-0785-0563	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0885-0564 S	8EHQ-0885-0565 S	8EHQ-0985-0566
	8EHQ-0985-0568 S	8EHQ-1085-0569	8EHQ-1085-0570
	8EHQ-1085-0571 S	8EHQ-0585-0572	8EHQ-1185-0573
	8EHQ-1185-0574	8EHQ-1185-0575	8EHQ-1185-0576
	8EHQ-1285-0577	8EHQ-1285-0578	8EHQ-1285-0579 S
	8EHQ-1285-0580	8EHQ-1285-0581	8EHQ-0186-0582 S
	8EHQ-0685-0583 S	8EHQ-0186-0584	8EHQ-0186-0585 S
	8EHQ-0186-0586 S	8EHQ-0286-0588	8EHQ-0386-0589 S
	8EHQ-0386-0591	8EHQ-0386-0594 S	8EHQ-0486-0596
	8EHQ-0486-0597	8EHQ-0486-0599	8EHQ-0486-0600
	8EHQ-0586-0601	8EHQ-0586-0602 S	8EHQ-0686-0603
	8EHQ-0786-0606 S	8EHQ-0786-0607 S	8EHQ-0786-0608 S
	8EHQ-0786-0609 S	8EHQ-0786-0613	8EHQ-0786-0614
	8EHQ-0786-0615	8EHQ-0786-0616	8EHQ-0886-0621
	8EHQ-0886-0622 S	8EHQ-0986-0623 S	8EHQ-0986-0624 S
	8EHQ-0986-0625 S	8EHQ-0986-0627	8EHQ-0986-0629
	8EHQ-0986-0630	8EHQ-0986-0631 S	8EHQ-0986-0633 S
	8EHQ-0986-0634	8EHQ-1086-0635	8EHQ-1086-0636 S
	8EHQ-1086-0637	8EHQ-1086-0639 S	8EHQ-1086-0640 S
	8EHQ-1086-0641	8EHQ-1086-0642	8EHQ-1186-0643
	8EHQ-1186-0644	8EHQ-1286-0645	8EHQ-1286-0648
	8EHQ-0187-0649 S	8EHQ-0287-0653	8EHQ-0287-0654
	8EHQ-0287-0655 S	8EHQ-0287-0657 S	8EHQ-0287-0658
	8EHQ-0387-0659	8EHQ-0487-0661 S	8EHQ-0487-0663
	8EHQ-0487-0664 S	8EHQ-0487-0665 S	8EHQ-0487-0667 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0487-0669	*	8EHQ-0487-0670 S	8EHQ-0487-0671
	8EHQ-0587-0672 S		8EHQ-0587-0673	8EHQ-0587-0674 S
	8EHQ-0587-0675	*	8EHQ-0587-0676	8EHQ-0687-0677
	8EHQ-0587-0678		8EHQ-0687-0679	8EHQ-0687-0680
	8EHQ-0687-0682		8EHQ-0687-0683 S	8EHQ-0787-0684 S
	8EHQ-0787-0685		8EHQ-0787-0686	8EHQ-0887-0687
	8EHQ-0887-0688		8EHQ-0887-0689	8EHQ-0887-0690
	8EHQ-0887-0691 S		8EHQ-0987-0692	8EHQ-0987-0694 *
	8EHQ-1087-0695		8EHQ-1187-0698	8EHQ-1287-0699
	8EHQ-1287-0700		8EHQ-1287-0701 S	8EHQ-1287-0704
	8EHQ-1287-0706		8EHQ-1287-0709	8EHQ-1287-0710
	8EHQ-0188-0714		8EHQ-0288-0715	8EHQ-0288-0716 S
	8EHQ-0288-0717 S		8EHQ-0288-0719	8EHQ-0288-0720
	8EHQ-0388-0721		8EHQ-0288-0722	8EHQ-0388-0723
	8EHQ-0388-0724 S		8EHQ-0388-0725 S	8EHQ-0488-0729 S
	8EHQ-0588-0730		8EHQ-0588-0731 S	8EHQ-0588-0732
	8EHQ-0588-0733		8EHQ-0688-0734	8EHQ-0688-0735
	8EHQ-0688-0738		8EHQ-0688-0739 S	8EHQ-0688-0740 S
	8EHQ-0788-0742	*	8EHQ-0788-0744	8EHQ-0788-0745 S
	8EHQ-0888-0746		8EHQ-0888-0747 S	8EHQ-0988-0748
	8EHQ-0988-0749 S		8EHQ-0988-0750 S	8EHQ-0988-0751 S
	8EHQ-0988-0752 S		8EHQ-0988-0753	8EHQ-0988-0754
	8EHQ-1088-0755		8EHQ-1088-0756	8EHQ-1088-0757
	8EHQ-1088-0758 S		8EHQ-1088-0759	8EHQ-1088-0760 S
	8EHQ-1088-0763 S		8EHQ-1188-0765 S	8EHQ-1188-0766 S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-1188-0767	S	8EHQ-1188-0768	S	8EHQ-1188-0770	S
	8EHQ-1188-0771	S	8EHQ-1288-0775		8EHQ-1288-0776	
	8EHQ-1288-0778		8EHQ-0189-0779		8EHQ-0189-0781	S
	8EHQ-0289-0782	S	8EHQ-0289-0783	S	8EHQ-0289-0784	
	8EHQ-0289-0785	S	8EHQ-0389-0787	S	8EHQ-0389-0788	S
	8EHQ-0389-0789		8EHQ-0389-0790	S	8EHQ-0389-0791	S
	8EHQ-0489-0792		8EHQ-0489-0793		8EHQ-0489-0794	S
	8EHQ-0589-0798	S	8EHQ-0589-0799		8EHQ-0589-0800	
	8EHQ-0689-0802		8EHQ-0689-0804		8EHQ-0789-0805	S
	8EHQ-0789-0806	S	8EHQ-0789-0807	S	8EHQ-0789-0808	S
	8EHQ-0889-0810	S	8EHQ-0889-0811	S	8EHQ-0889-0813	
	8EHQ-0889-0814		8EHQ-0886-0815		8EHQ-0889-0816	S
	8EHQ-0889-0817		8EHQ-0889-0818	S	8EHQ-0889-0819	S
	8EHQ-0889-0820		8EHQ-0989-0821	S	8EHQ-0989-0823	
	8EHQ-0989-0824	S	8EHQ-0989-0825	S	8EHQ-0989-0826	S
	8EHQ-0989-0827	S	8EHQ-0989-0828	S	8EHQ-1089-0829	
	8EHQ-1089-0831		8EHQ-1089-0832		8EHQ-1089-0833	S
	8EHQ-1089-0834	S	8EHQ-1089-0835	S	8EHQ-1089-0836	
	8EHQ-1089-0838	S	8EHQ-1189-0839		8EHQ-1189-0840	S
	8EHQ-1189-0841		8EHQ-1189-0842	S	8EHQ-1189-0843	S
	8EHQ-1189-0845		8EHQ-1189-0847		8EHQ-1189-0848	S
	8EHQ-1289-0849	S	8EHQ-1289-0850		8EHQ-1289-0851	S
	8EHQ-1289-0852	S	8EHQ-1289-0853	S	8EHQ-1289-0854	S
	8EHQ-1289-0856		8EHQ-1289-0857	S	8EHQ-1289-0858	S
	8EHQ-0190-0861	S	8EHQ-0190-0862	S	8EHQ-0190-0863	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0190-0864		8EHQ-0190-0865	S		8EHQ-0190-0866	S
	8EHQ-0190-0867	*	8EHQ-0190-0868	S		8EHQ-0190-0869	S
	8EHQ-0190-0870	S	8EHQ-0190-0871	S		8EHQ-0290-0872	S
	8EHQ-0290-0874	S	8EHQ-0290-0875	S		8EHQ-0290-0877	
	8EHQ-0290-0879	S	8EHQ-0290-0881	S		8EHQ-0290-0882	
	8EHQ-0290-0883	S	8EHQ-0290-0885			8EHQ-0290-0886	
	8EHQ-0290-0887	S	8EHQ-0290-0888	S		8EHQ-0290-0889	S
	8EHQ-0290-0890	S	8EHQ-0290-0891	S		8EHQ-0290-0894	
	8EHQ-0390-0898		8EHQ-0390-0899		*	8EHQ-0390-0900	
	8EHQ-0390-0901		8EHQ-0390-0902			8EHQ-0390-0903	S
	8EHQ-0390-0907	S	8EHQ-0390-0913	S		8EHQ-0390-0914	S
	8EHQ-0390-0915		8EHQ-0390-0916	S	*	8EHQ-0490-0917	
	8EHQ-0490-0918	S	8EHQ-0490-0919	S		8EHQ-0490-0924	
	8EHQ-0490-0925	S	8EHQ-0490-0926	S		8EHQ-0490-0928	S
	8EHQ-0490-0930	S	8EHQ-0490-0931	S		8EHQ-0490-0932	
	8EHQ-0490-0933		8EHQ-0490-0934	S		8EHQ-0490-0935	S
	8EHQ-0490-0936		8EHQ-0490-0937			8EHQ-0490-0938	
	8EHQ-0490-0939		8EHQ-0490-0940			8EHQ-0490-0941	
	8EHQ-0490-0943		8EHQ-0490-0944			8EHQ-0490-0945	
	8EHQ-0490-0950		8EHQ-0490-0951			8EHQ-0490-0954	S
	8EHQ-0490-0955	S	8EHQ-0490-0956	S		8EHQ-0490-0957	S
	8EHQ-0490-0958	S	8EHQ-0490-0959	S		8EHQ-0490-0960	
	8EHQ-0490-0962		8EHQ-0590-0964			8EHQ-0590-0968	
	8EHQ-0590-0971		8EHQ-0590-0972			8EHQ-0590-0974	
	8EHQ-0590-0975		8EHQ-0590-0976			8EHQ-0590-0981	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0590-0983		8EHQ-0590-0985	*	8EHQ-0590-0992	S
	8EHQ-0590-0994	*	8EHQ-0590-0995	S	8EHQ-0590-0996	
	8EHQ-0590-0997	S	8EHQ-0590-0998	S	8EHQ-0690-0999	*
	8EHQ-0590-1001	S	8EHQ-0690-1002		8EHQ-0690-1003	
	8EHQ-0690-1004	S	8EHQ-0690-1005	S	8EHQ-0690-1006	S
	8EHQ-0690-1010	S	8EHQ-0690-1011	S	8EHQ-0690-1012	S
	8EHQ-0690-1013	S	8EHQ-0690-1014	S	8EHQ-0690-1015	
	8EHQ-0690-1016	S	8EHQ-0690-1018		8EHQ-0690-1019	
	8EHQ-0790-1021		8EHQ-0790-1023	S	8EHQ-0790-1024	
	8EHQ-0790-1025	S	8EHQ-0790-1026	S	8EHQ-0790-1027	
	8EHQ-0790-1028	S	8EHQ-0790-1029		8EHQ-0790-1031	S
	8EHQ-0790-1033		8EHQ-0790-1034		8EHQ-0790-1036	S
	8EHQ-0790-1037	S	8EHQ-0890-1039	S	8EHQ-0890-1040	
	8EHQ-0890-1041		8EHQ-0890-1042		8EHQ-0890-1043	
	8EHQ-0890-1044	S	8EHQ-0890-1045		8EHQ-0890-1046	
	8EHQ-0890-1047		8EHQ-0890-1048	S	8EHQ-0890-1049	S
	8EHQ-0890-1050	S	8EHQ-0890-1052	S	8EHQ-0890-1053	
	8EHQ-0890-1054	S	8EHQ-0890-1055	S	8EHQ-0890-1056	S
	8EHQ-0990-1058	S	8EHQ-0990-1060	S	8EHQ-0990-1061	
	8EHQ-0990-1062		8EHQ-0990-1063		8EHQ-0990-1065	
	8EHQ-0990-1066	S	8EHQ-0990-1069		8EHQ-0990-1070	S
	8EHQ-0990-1071		8EHQ-0990-1072		8EHQ-0990-1073	S
	8EHQ-0990-1074		8EHQ-0990-1075	S	8EHQ-0990-1076	S
	8EHQ-0990-1078		8EHQ-0990-1079	S	8EHQ-0990-1080	S
	8EHQ-0990-1081		8EHQ-0990-1083	S		

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

REPORTING RATIONALE

SUBMISSION #:	8EHQ-1078-0249		8EHQ-0880-0358	*	8EHQ-0783-0485 S	*
	8EHQ-1083-0494	*	8EHQ-0384-0508 P	*	8EHQ-0587-0672 S	
	8EHQ-1287-0706		8EHQ-0488-0729 S		8EHQ-1188-0772	
	8EHQ-0889-0813		8EHQ-0886-0815		8EHQ-0490-0933	

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-1077-0007		8EHQ-1277-0027		8EHQ-0278-0049	
	8EHQ-0378-0095	*	8EHQ-0378-0101	*	8EHQ-0378-0103	*
	8EHQ-0478-0122	*	8EHQ-0478-0129		8EHQ-0478-0130	*
	8EHQ-0578-0160 S	*	8EHQ-0678-0185	*	8EHQ-0678-0206	*
	8EHQ-0678-0208		8EHQ-0778-0209		8EHQ-0778-0211	
	8EHQ-0978-0244		8EHQ-1078-0245		8EHQ-1078-0247	
	8EHQ-1078-0248		8EHQ-1078-0252		8EHQ-0179-0267	
	8EHQ-0179-0269 S		8EHQ-0779-0293		8EHQ-0680-0346	
	8EHQ-1180-0373 S		8EHQ-1180-0374 S		8EHQ-1180-0375 S	
	8EHQ-0181-0379		8EHQ-0281-0384		8EHQ-0381-0386	
	8EHQ-0381-0388 S		8EHQ-0381-0394 S		8EHQ-0581-0399	
	8EHQ-0781-0405 S		8EHQ-1081-0414		8EHQ-1281-0421 S	
	8EHQ-1281-0424		8EHQ-0382-0440 S		8EHQ-0382-0441	
	8EHQ-0682-0450		8EHQ-0882-0452		8EHQ-1182-0462	
	8EHQ-1182-0464		8EHQ-0483-0475		8EHQ-0783-0485 S	*
	8EHQ-1083-0499		8EHQ-0284-0505		8EHQ-0884-0527	
	8EHQ-0884-0528		8EHQ-1084-0532		8EHQ-1084-0534	
	8EHQ-0185-0543		8EHQ-0285-0544		8EHQ-0385-0547	
	8EHQ-0485-0548		8EHQ-0585-0555		8EHQ-0785-0560	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-0785-0562	S	8EHQ-1085-0570		8EHQ-0585-0572	
	8EHQ-1285-0577		8EHQ-0186-0587		8EHQ-0986-0623	S
	8EHQ-0986-0626	S	8EHQ-0886-0628		8EHQ-0986-0633	S
	8EHQ-0287-0653		8EHQ-0287-0658		8EHQ-0487-0664	S
	8EHQ-0487-0666	S	8EHQ-0587-0672	S	8EHQ-0587-0676	
	8EHQ-0687-0682		8EHQ-1087-0695		8EHQ-1287-0706	
	8EHQ-0288-0716	S	8EHQ-0288-0717	S	8EHQ-0388-0721	
	8EHQ-0388-0726		8EHQ-0488-0727		8EHQ-0488-0729	S
	8EHQ-0588-0731	S	8EHQ-0688-0738		8EHQ-0888-0746	
	8EHQ-0988-0748		8EHQ-0988-0749	S	8EHQ-0988-0750	S
	8EHQ-0988-0751	S	8EHQ-1088-0758	S	8EHQ-1088-0760	S
	8EHQ-1088-0764	S	8EHQ-1188-0765	S	8EHQ-1188-0766	S
	8EHQ-1188-0767	S	8EHQ-1188-0770	S	8EHQ-1188-0771	S
	8EHQ-1288-0778		8EHQ-0289-0783	S	8EHQ-0289-0785	S
	8EHQ-0389-0786	S	8EHQ-0389-0790	S	8EHQ-0489-0792	
	8EHQ-0489-0794	S	8EHQ-0789-0807	S	8EHQ-0889-0810	S
	8EHQ-0889-0811	S	8EHQ-0889-0813		8EHQ-0889-0816	S
	8EHQ-0889-0820		8EHQ-0989-0823		8EHQ-0989-0824	S
	8EHQ-0989-0825	S	8EHQ-0989-0827	S	8EHQ-0989-0828	S
	8EHQ-1089-0829		8EHQ-1089-0835	S	8EHQ-1189-0842	S
	8EHQ-1189-0844		8EHQ-1289-0849	S	8EHQ-1289-0851	S
	8EHQ-1289-0852	S	8EHQ-1289-0855		8EHQ-1289-0858	S
	8EHQ-0190-0861	S	8EHQ-0190-0862	S	8EHQ-0190-0865	S
	8EHQ-0190-0868	S	8EHQ-0190-0869	S	8EHQ-0190-0870	S
	8EHQ-0190-0871	S	8EHQ-0289-0872	S	8EHQ-0290-0874	S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-0290-0875	S	8EHQ-0290-0877		8EHQ-0290-0878	
	8EHQ-0290-0879	S	8EHQ-0290-0881	S	8EHQ-0290-0883	S
	8EHQ-0290-0884		8EHQ-0290-0887	S	8EHQ-0290-0888	S
	8EHQ-0290-0889	S	8EHQ-0290-0890	S	8EHQ-0290-0891	S
	8EHQ-0290-0892		8EHQ-0390-0895	S	8EHQ-0390-0896	S
	8EHQ-0390-0897	S	8EHQ-0390-0904		8EHQ-0390-0907	S
	8EHQ-0390-0910	S	8EHQ-0390-0911	S	8EHQ-0390-0912	S
	8EHQ-0490-0918	S	8EHQ-0490-0922	S	8EHQ-0490-0923	S
	8EHQ-0490-0925	S	8EHQ-0490-0927	S	8EHQ-0490-0928	S
	8EHQ-0490-0930	S	8EHQ-0490-0931	S	8EHQ-0490-0932	
	8EHQ-0490-0935	S	8EHQ-0490-0937		8EHQ-0490-0938	
	8EHQ-0490-0939		8EHQ-0490-0940		8EHQ-0490-0941	
	8EHQ-0490-0942		8EHQ-0490-0943		8EHQ-0490-0944	
	8EHQ-0490-0945		8EHQ-0490-0946		8EHQ-0490-0947	
	8EHQ-0490-0948		8EHQ-0490-0949		8EHQ-0490-0950	
	8EHQ-0490-0951		8EHQ-0490-0955	S	8EHQ-0490-0956	S
	8EHQ-0490-0961	S	8EHQ-0590-0965		8EHQ-0590-0966	
	8EHQ-0590-0967		8EHQ-0590-0968		8EHQ-0590-0969	
	8EHQ-0590-0970		8EHQ-0590-0971		8EHQ-0590-0972	
	8EHQ-0590-0973		8EHQ-0590-0974		8EHQ-0590-0975	
	8EHQ-0590-0976		8EHQ-0590-0977		8EHQ-0590-0978	
	8EHQ-0590-0979		8EHQ-0590-0980		8EHQ-0590-0981	
	8EHQ-0590-0982		8EHQ-0590-0983		8EHQ-0590-0984	
	8EHQ-0590-0986	S	8EHQ-0590-0987	S	8EHQ-0590-0988	S
	8EHQ-0590-0989	S	8EHQ-0590-0990		8EHQ-0590-0992	S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-0590-0995	S		8EHQ-0590-0997	S		8EHQ-0590-0998	S
	8EHQ-0690-0999		*	8EHQ-0690-1000	S		8EHQ-0690-1002	
	8EHQ-0690-1003			8EHQ-0690-1006	S		8EHQ-0690-1008	
	8EHQ-0690-1010	S		8EHQ-0690-1011	S		8EHQ-0690-1012	S
	8EHQ-0690-1013	S		8EHQ-0690-1014	S		8EHQ-0790-1024	
	8EHQ-0790-1025	S		8EHQ-0790-1026	S		8EHQ-0790-1030	
	8EHQ-0790-1037	S		8EHQ-0890-1042			8EHQ-0890-1043	
	8EHQ-0890-1046			8EHQ-0890-1055	S		8EHQ-0990-1063	
	8EHQ-0990-1064			8EHQ-0990-1073	S		8EHQ-0990-1075	S

REPRODUCTIVE TOXICITY/TERATO. (HUMAN)

SUBMISSION #:	8EHQ-0877-0003			8EHQ-1277-0021			8EHQ-0278-0056	
	8EHQ-0478-0123			8EHQ-0478-0128			8EHQ-0578-0146	
	8EHQ-0678-0192	S		8EHQ-1078-0245			8EHQ-1080-0367	
	8EHQ-0382-0440	S		8EHQ-0286-0588		*	8EHQ-0288-0722	
	8EHQ-0989-0821	S						

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1277-0023			8EHQ-1277-0024			8EHQ-0178-0068	*
	8EHQ-0178-0069			8EHQ-0578-0157		*	8EHQ-0678-0178	
	8EHQ-0678-0184		*	8EHQ-0678-0185		*	8EHQ-0279-0274	
	8EHQ-0679-0291			8EHQ-0779-0293			8EHQ-1279-0325	
	8EHQ-0680-0346			8EHQ-1080-0366			8EHQ-0708-0369	
	8EHQ-0181-0377			8EHQ-0281-0384			8EHQ-0381-0392	
	8EHQ-1081-0419			8EHQ-1281-0425	S		8EHQ-0382-0438	S

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0582-0445		8EHQ-0682-0446	S		8EHQ-1182-0462	
	8EHQ-0483-0476	S	8EHQ-0583-0478	S		8EHQ-0683-0483	S
	8EHQ-0683-0484	S	8EHQ-0783-0485	S	*	8EHQ-1083-0495	
	8EHQ-1083-0498		8EHQ-0284-0505			8EHQ-0684-0520	
	8EHQ-1084-0532		8EHQ-1084-0534			8EHQ-0385-0547	
	8EHQ-0485-0549	S	8EHQ-0485-0550			8EHQ-0585-0556	S
	8EHQ-0785-0561	S	8EHQ-0785-0562	S		8EHQ-1085-0571	S
	8EHQ-0184-0585	S	8EHQ-0386-0590			8EHQ-0386-0591	
	8EHQ-0486-0597		8EHQ-0686-0603			8EHQ-0686-0605	S
	8EHQ-0786-0608	S	8EHQ-0986-0627			8EHQ-0986-0633	S
	8EHQ-1086-0637		8EHQ-0287-0653			8EHQ-0487-0664	S
	8EHQ-0587-0674	S	8EHQ-0687-0680			8EHQ-0687-0683	
	8EHQ-0787-0686	S	8EHQ-1287-0700			8EHQ-1287-0703	
	8EHQ-1287-0705		8EHQ-0188-0714			8EHQ-0388-0724	S
	8EHQ-0488-0727		8EHQ-0688-0734	S		8EHQ-1088-0757	
	8EHQ-1288-0777		8EHQ-0389-0780			8EHQ-0189-0781	S
	8EHQ-0289-0782	S	8EHQ-0389-0789			8EHQ-0689-0803	
	8EHQ-0989-0826	S	8EHQ-1089-0837	S		8EHQ-1189-0845	
	8EHQ-0290-0880		8EHQ-0290-0884			8EHQ-0390-0908	S
	8EHQ-0490-0926	S	8EHQ-0490-0931	S		8EHQ-0490-0934	S
	8EHQ-0690-0999	*	8EHQ-0690-1003			8EHQ-0690-1007	
	8EHQ-0690-1019		8EHQ-0690-1020			8EHQ-0790-1022	S
	8EHQ-0690-1027		8EHQ-0790-1028	S		8EHQ-0790-1033	
	8EHQ-0790-1037	S	8EHQ-0890-1041			8EHQ-0890-1046	
	8EHQ-0890-1055		8EHQ-0890-1056	S		8EHQ-0990-1061	

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0990-1062		8EHQ-0990-1070	S		8EHQ-0990-1081
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SUBCHRONIC TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1177-0014		8EHQ-0178-0033			8EHQ-0578-0160	S	*
	8EHQ-0578-0161	S	*	8EHQ-0678-0184	*	8EHQ-0678-0190		*
	8EHQ-0778-0209			8EHQ-0878-0231	*	8EHQ-0279-0274		
	8EHQ-0279-0275			8EHQ-1079-0312		8EHQ-0680-0347		
	8EHQ-0780-0354			8EHQ-0980-0364		8EHQ-0281-0384		
	8EHQ-0682-0446	S		8EHQ-0683-0483	S	8EHQ-1083-0494		*
	8EHQ-0184-0504			8EHQ-0384-0507		8EHQ-0884-0524		
	8EHQ-0984-0529			8EHQ-0785-0561	S	8EHQ-0785-0562	S	
	8EHQ-1185-0574			8EHQ-1185-0576		8EHQ-0186-0582	S	
	8EHQ-0186-0586	S		8EHQ-0386-0594	S	8EHQ-0486-0600		
	8EHQ-1086-0635			8EHQ-1286-0648		8EHQ-0487-0668		
	8EHQ-0587-0676			8EHQ-1287-0702		8EHQ-1287-0706		
	8EHQ-0488-0729	S		8EHQ-0788-0744	S	8EHQ-0888-0747		
	8EHQ-0988-0748			8EHQ-1088-0756		8EHQ-1088-0760	S	
	8EHQ-1088-0763			8EHQ-0489-0793		8EHQ-0889-0817		
	8EHQ-1089-0836			8EHQ-1189-0840	S	8EHQ-1189-0843	S	
	8EHQ-1189-0846			8EHQ-1289-0855		8EHQ-0190-0866	S	
	8EHQ-0290-0881	S		8EHQ-0490-0930	S	8EHQ-0490-0931	S	
	8EHQ-0490-0932			8EHQ-0490-0936		8EHQ-0690-1002		
	8EHQ-0890-1049	S		8EHQ-0990-1063		8EHQ-0990-1074		

TSCA 8(C) ALLEGATION

APPENDIX : STATUS REPORTS BY INFORMATION TYPE

SUBMISSION #:	8EHQ-0378-0097	*	8EHQ-0478-0118	P	*	8EHQ-0478-0129		
	8EHQ-0478-0135		8EHQ-1084-0532			8EHQ-0386-0589	S	
	8EHQ-0786-0612		8EHQ-0886-0622	S		8EHQ-0986-0632		
	8EHQ-0887-0690		8EHQ-0987-0694		*	8EHQ-0889-0818	S	
	8EHQ-0989-0821	S	8EHQ-0390-0905	S	*	8EHQ-0490-0929	S	*
	8EHQ-0590-0991	S	8EHQ-0990-1071			8EHQ-0990-1078		