EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §716.120, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EFFECTIVE DATE NOTE: At 59 FR 14115, Mar. 25, 1994, in §716.120 paragraph (d), the chemical substances under the category ''propylene glycol ethers and esters'' and all related dates, were stayed effective Mar. 25, 1994.

PART 717—RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT

Subpart A—General Provisions

Sec.

AUTHORITY: 15 U.S.C. 2607(c).

SOURCE: 48 FR 38187, Aug. 22, 1983, unless otherwise noted.

Subpart A—General Provisions

§717.1 Scope and compliance.

Section 8 (c) of the Toxic Substances Control Act (TSCA) requires manufacturers, processors, and distributors of chemical substances and mixtures:

(a) To keep ''records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture.''

(b) To ''permit inspection and submit copies of such records'', upon request of any designated representative of the Administrator. This rule implements section 8(c) of TSCA. It describes the records to be kept and prescribes the conditions under which certain firms must submit or make the records available to a duly designated representative of the Administrator.

§717.3 Definitions.

The definitions set forth in section 3 of TSCA and the following definitions apply to this part:

(a) *Allegation* means a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

(b) *Firm* or *company* means any person, that is subject to this part, as defined in §717.5.

(c)(1) *Known human effects* means a commonly recognized human health effect of a particular substance or mixture as described either in:

(i) Scientific articles or publications abstracted in standard reference sources.

(ii) The firm's product labeling or material safety data sheets (MSDS).

(2) However, an effect is not a ''known human effect'' if it:

(i) Was a significantly more severe toxic effect than previously described.

(ii) Was a manifestation of a toxic effect after a significantly shorter exposure period or lower exposure level than described.

(iii) Was a manifestation of a toxic effect by an exposure route different from that described.

(d) *Manufacture* or *process* means to manufacture or process for commercial purposes.

(e)(1) *Manufacture for commercial purposes* means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such ''manufacture'' of any amount of a chemical substance or mixture:

(i) For distribution in commerce, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) *Manufacture for commercial purposes* also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substances or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

(f) *Person* includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, and any department, agency, or instrumentally of the Federal Government.

(g) *Process for commercial purposes* means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(h) *Retailer* means a person who distributes in commerce a chemical substance, mixture, or article to ultimate purchasers who are not commercial entities.

(i) *Significant adverse reactions* are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

(j) *Site* means a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be multiple manufacturing, processing, or distribution activities occurring within a single site.

(k) *Substance* means a chemical substance or mixture unless otherwise indicated.

§ 717.5 Persons subject to this part.

(a) *Manufacturers.* (1) All manufacturers of chemical substances are subject to this part except as provided in § 717.7(a). If manufacture of a chemcial substance occurs at any site owned or controlled by a firm then that firm is subject to this part.

(2) A manufacturer must collect:

(i) Any allegation identifying a chemical substance it manufactures and any allegation identifying the operations in the manufacture of any chemical substance it manufactures.

(ii) Any allegation identifying any of its own processing or distribution in commerce activities with respect to any chemical substance it manufactures.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during processing, use, storage or disposal of a chemical substance it manufactures.

(3) For the purpose of this part, owned or controlled means ownership of 50 percent or more of a firm's voting stock or other equity rights, or the power to control the management and policies of that firm.

(b) *Processors.* (1) A person who processes chemical substances, who is not also a manufacturer of those chemical substances, is subject to this part if (i) the person processes chemical substances to produce mixtures, or (ii) the person repackages chemical substances or mixtures.

(2) As a processor subject to this part such person must collect:

(i) Any allegation identifying any mixture it produces and distributes in commerce and any allegation identifying any chemical substance or mixture it repackages and distributes in commerce.

(ii) Any allegation identifying any of its own further processing or distribution in commerce activities of the products described in paragraph (b)(2)(i) of this section.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during the processing, use, storage or disposal of the products described in paragraph (b)(2)(i) of this section.

(c) *SIC code.* SIC codes applicable to this part are published in Standard Industrial Classification Manual—1972 and the 1977 Supplement. This manual and supplement may be obtained from the U.S. Government Printing Office, Washington, D.C. 20402—stock number 4101–0006 and stock number 003–005–0170–0 respectively. Where there is a conflict between the SIC code use of a term and the definition of that term in this part, the definition in this part applies.

[48 FR 38187, Aug. 22, 1983, as amended at 50 FR 46769, Nov. 13, 1985]

§ 717.7 Persons not subject to this part.

(a) *Manufacturers.* (1) Persons or site activities are exempt from this part if the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions, e.g., those companies or sites within a company whose sole function is to mine mineral ores, extract petroleum or natural gas, quarry non-metallic minerals (including extraction of salts from seawater or brines), mine or otherwise extract coal, or separate gases from the atmosphere. This exemption may include, but is not necessarily limited to, firms engaged in activities as described in SIC Division B—Mining and SIC Code 2813—Industrial Gases.

(2) A person is not subject to this part if the chemical substances that person causes to be produced are limited to:

(i) Chemical substances that result from chemical reactions that occur incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(ii) Chemical substances that result from chemical reactions that occur incidental to storage or disposal of other chemical substances, mixtures, or articles.

(iii) Chemical substances that result from chemical reactions that occur upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleaners or other housekeeping products, fuel additives, water softening and treatment agents, photographic films, batteries, matches, or safety flares, and that are not themselves manufactured or imported for distribution in commerce for use as chemical intermediates.

(iv) Chemical substances that result from chemical reactions that occur upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance.

(v) Chemical substances that result from chemical reactions that occur when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation-inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH adjuster, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(b) [Reserved]

(c) *Sole distributors.* A person solely engaged in the distribution of chemical substances is exempt from this part, unless such person is also a manufacturer or processor subject to this part. For example, a ''distributor'' who repackages chemical substances or mixtures is considered to be a processor and, thus, is not a sole distributor. Sole distributors may include, but are not limited to, those firms that distribute chemical substances as described in the wholesale trade SIC codes 5161—Chemicals and Allied Products, 5171—Petroleum Bulk Stations and Terminals, and 5172—Petroleum and Petroleum Products Wholesalers, Except Bulk Stations and Terminals.

(d) *Retailers.* A person who is a retailer is exempt from this part unless

such person is also a manufacturer or a processor subject to this part.

[48 FR 38187, Aug. 22, 1983, as amended at 50 FR 46770, Nov. 13, 1985]

§ 717.10 Allegations subject to this part.

(a) Allegations subject to this part are those allegations received on or after November 21, 1983 by persons subject to this part.

(b) Allegations subject to this part are those that:

(1) Are submitted either in writing and are signed by the alleger, or are submitted orally. In the case of an oral allegation, the firm must transcribe the allegation into written form, or it must inform the alleger that such allegation may be subject to this part and request that the alleger submit such allegation to the firm in writing and signed.

(2) Implicate a substance that caused the stated significant adverse reaction by one of the following:

(i) Naming the specific substance.

(ii) Naming a mixture that contains a specific substance.

(iii) Naming an article that contains a specific substance.

(iv) Naming a company process or operation in which substances are involved.

(v) Identifying an effluent, emission, or other discharge from a site of manufacturing, processing or distribution of a substance.

(c) Allegations subject to this part may be made to a firm by any person, such as an employee of the firm, individual consumer, a neighbor of the firm's plant, another firm on behalf of its employees or an organization on behalf of its members.

(d) EPA intends that firms should, to the maximum practical extent, provide allegers with information regarding the ultimate disposition of their allegations. For example, firms could provide a brief notice to the alleger stating that a record was created under this part based upon their allegation, or that a record was not created and briefly explain the reasons why not.

§ 717.12 Significant adverse reactions that must be recorded.

(a) Except as provided in paragraph (b) of this section, significant adverse reactions to human health that must be recorded include but are not limited to:

(1) Long-lasting or irreversible damage, such as cancer or birth defects.

(2) Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders or blood disorders.

(3) An impairment of normal activities experienced by all or most of the persons exposed at one time.

(4) An impairment of normal activities which is experienced each time an individual is exposed.

(b) Firms are not required to record significant adverse reactions that are known human effects as defined in § 717.3(c).

(c) Except as provided in paragraph (d) of this section, significant adverse reactions to the environment that must be recorded, even if restricted to the environs of a plant or disposal site, include but are not limited to:

(1) Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area.

(2) Abnormal number of deaths of organisms (e.g., fish kills).

(3) Reduction of the reproductive success or the vigor of a species.

(4) Reduction in agricultural productivity, whether crops or livestock.

(5) Alterations in the behavior or distribution of a species.

(6) Long lasting or irreversible contamination of components of the physical environment, especially in the case of ground water, and surface water and soil resources that have limited self-cleansing capability.

(d) Firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to

the Federal Government under any applicable authority.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 58 FR 34204, June 23, 1993]

§ 717.15 Recordkeeping requirements.

(a) *Establishment and location of records.* A firm subject to this part shall establish and maintain records of significant adverse reactions alleged to have been caused by chemical substances or mixtures manufactured or processed by the firm. Such records shall be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations.

(b) *Content of records.* The record shall consist of the following:

(1) The original allegation as received.

(2) An abstract of the allegation and other pertinent information as follows:

(i) The name and address of the plant site which received the allegation.

(ii) The date the allegation was received at that site.

(iii) The implicated substance, mixture, article, company process or operation, or site discharge.

(iv) A description of the alleger (e.g., ''company employee,'' ''individual consumer,'' ''plant neighbor''). If the allegation involves a health effect, the sex and year of birth of the individual should be recorded, if ascertainable.

(v) A description of the alleged health effect(s). The description must relate how the effect(s) became known and the route of exposure, if explained in the allegation.

(vi) A description of the nature of the alleged environmental effect(s), identifying the affected plant and/or animal species, or contaminated portion of the physical environment.

(3) The results of any self-initiated investigation with respect to an allegation. (EPA does not require persons subject to this part to investigate allegations received, and no provision of this part shall be construed to imply that EPA recommends, encourages or requires such investigation.)

(4) Copies of any further required records or reports relating to the allegation. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Form 101 or appropriate substitute (see 29 CFR part 1904 for requirements under the Occupational Safety and Health Act of 1970), a copy of that OSHA record must be included in the allegation record.

(c) *File structure.* Records must be retrievable by the alleged cause of the significant adverse reaction, which cause may be one of the following:

(1) A specific chemical identity.

(2) A mixture.

(3) An article.

(4) A company process or operation.

(5) A site emission, effluent or other discharge.

(d) *Retention period.* Records of significant adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. This provision requires persons subject to this part to retain for 30 years an employee health related allegation, arising from any employment related exposure, whether or not such allegation was submitted by or on the behalf of that recordkeeper's own employee. Any other record of significant adverse reactions shall be maintained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record.

(e) *Transfer of records.* (1) If a firm ceases to do business, the successor must receive and keep all the records that must be kept under this part.

(2) If a firm ceases to do business and there is no successor to receive and keep the records for the prescribed period, these records must be transmitted to EPA. See §717.17(c) for the address to which such records must be sent.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 58 FR 34204, June 23, 1993]

§ 717.17 Inspection and reporting requirements.

(a) *Inspection.* Firms must make records of allegations available for inspection by any duly designated representative of the Administrator.

(b) *Reporting.* Each person who is required to keep records under this part must submit copies of those records to

the Agency as required by the EPA Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements for submitting copies of records by a notice in the FEDERAL REGISTER. Such letter or notice will be signed by the Administrator or appropriate designee, and will specify which records or portion of records must be submitted. The reporting period will be specified by the letter or notice but in no case will such reporting period be less than 45 days from the date of the letter or the effective date of the notice.

(c) *How to report.* When required to report, firms must submit copies of records via CDX *https://cdx.epa.gov/* using the EPA provided electronic reporting application.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 52 FR 20084, May 29, 1987; 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 88 FR 37172, June 7, 2023]

§ 717.19 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

[88 FR 37172, June 7, 2023]

PART 720—PREMANUFACTURE NOTIFICATION

Subpart A—General Provisions

Subpart B—Applicability

Subpart C—Notice Form

Subpart D—Disposition of Notices

Subpart E—Confidentiality and Public Access to Information

Subpart F—Commencement of Manufacture or Import

Subpart G—Compliance and Inspections

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

SOURCE: 48 FR 21742, May 13, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 720.1 Scope.

This part establishes procedures for the reporting of new chemical substances by manufacturers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. This part applies to microorganisms only to the extent provided by part 725 of this chapter. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 62 FR 17932, Apr. 11, 1997; 87 FR 39763, July 5, 2022]

§ 720.3 Definitions.

(a)(1) For the purposes of this part, the terms *cosmetic*, *device*, *drug*, *food*,