

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

Subpart A—General Provisions

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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,

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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 chemical 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 further 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.

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