

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,