

(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 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 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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§ 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.