

§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.

https://ecfr.io/Title-40/pt40.33.716#se40.33.716_13

Extracted by GlobalMSDS Ltd

07 February 2019

(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.