

E of this part identifies chemical substances and their significant new uses.

(b) This subpart A contains provisions governing submission and review of notices for the chemical substances and significant new uses identified in subpart E of this part. The provisions of this subpart A apply to the chemical substances and significant new uses identified in subpart E of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart E of this part. In the event of a conflict between the provisions of this subpart A and the provisions of subpart E of this part, the provisions of subpart E of this part shall govern.

(c) The provisions of part 720 of this chapter apply to this part 721. For purposes of this part 721, wherever the phrase "new chemical substance" appears in part 720 of this chapter, it shall mean the chemical substance subject to this part 721. In the event of a conflict between the provisions of part 720 of this chapter and the provisions of this part 721, the provisions of this part 721 shall govern.

[53 FR 28358, July 27, 1988, as amended at 62 FR 17932, Apr. 11, 1997]

§ 721.3 Definitions.

The definitions in section 3 of the Act, 15 U.S.C. 2602, and § 720.3 of this chapter apply to this part. In addition, the following definitions apply to this part:

Acutely toxic effects A chemical substance produces acutely toxic effects if it kills within a short time period (usually 14 days):

(1) At least 50 percent of the exposed mammalian test animals following oral administration of a single dose of the test substance at 25 milligrams or less per kilogram of body weight (LD₅₀).

(2) At least 50 percent of the exposed mammalian test animals following dermal administration of a single dose of the test substance at 50 milligrams or less per kilogram of body weight (LD₅₀).

(3) At least 50 percent of the exposed mammalian test animals following administration of the test substance for 8 hours or less by continuous inhalation at a steady concentration in air at 0.5

milligrams or less per liter of air (LC₅₀).

CAS Number means Chemical Abstracts Service Registry Number assigned to a chemical substance on the Inventory.

Chemical name means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

Chemical protective clothing means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

Commercial use means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

Common name means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

Consumer means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

Consumer product means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

Customer means any person to whom a manufacturer, importer, or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

Director of the Office of Pollution Prevention and Toxics means the Director

Environmental Protection Agency

§ 721.3

of the EPA Office of Pollution Prevention and Toxics or any EPA employee delegated by the Office Director to carry out the Office Director's functions under this part.

Employer means any manufacturer, importer, processor, or user of chemical substances or mixtures.

Environmentally transformed A chemical substance is "environmentally transformed" when its chemical structure changes as a result of the action of environmental processes on it.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person).

Identity means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

Immediate use A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

Impervious Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

Manufacturing stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

Metalworking fluid means a liquid of any viscosity or color containing intentionally added water and used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

MSDS means material safety data sheet, the written listing of data for the chemical substance as required under § 721.72(c).

NIOSH means the National Institute for Occupational Safety and Health of

the U.S. Department of Health and Human Services.

Non-enclosed process means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

Non-industrial use means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

Personal protective equipment means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

Powder or dry solid form means a state where all or part of the substance would have the potential to become fine, loose, solid particles.

Principal importer means the first importer who, knowing that a chemical substance will be imported for a significant new use rather than manufactured in the United States, specifies the chemical substance and the amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

Process for commercial purposes means the preparation of a chemical substance or mixture containing the chemical substance, after manufacture of the substance, 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 containing the chemical substance is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, the impurities also are processed for commercial purposes.

Process solely for export means to process for commercial purposes solely for export from the United States

under the following restrictions on activity in the United States: Processing must be performed at sites under the control of the processor; distribution in commerce is limited to purposes of export; and the processor may not use the chemical substance except in small quantities solely for research and development.

Process stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

Recipient means any person who purchases or otherwise obtains a chemical substance directly from a person who manufactures, imports, or processes the substance.

Serious acute effects means human injury or human disease processes that have a short latency period for development, result from short-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Serious chronic effects means human injury or human disease processes that have a long latency period for development, result from long-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Short-term test indicative of carcinogenic potential means either any limited bioassay that measures tumor or preneoplastic induction, or any test indicative of interaction of a chemical substance with DNA (i.e., positive response in assays for gene mutation, chromosomal aberrations, DNA damage and repair, or cellular transformation).

Short-term test indicative of the potential to cause a developmentally toxic effect means either any *in vivo* preliminary development toxicity screen conducted in a mammalian species, or any *in vitro* developmental toxicity screen, including any test system other than the intact pregnant mammal, that has been extensively evaluated and judged reliable for its ability to predict the potential to cause developmentally toxic effects in intact systems across a broad

range of chemicals or within a class of chemicals that includes the substance of concern.

Significant adverse environmental effects means injury to the environment by a chemical substance which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or which may adversely affect a threatened or endangered species. A substance will be considered to have the potential for significant adverse environmental effects if it has one of the following:

(1) An acute aquatic EC₅₀ of 1 mg/L or less.

(2) An acute aquatic EC₅₀ of 20 mg/L or less where the ratio of aquatic vertebrate 24-hour to 48-hour EC₅₀ is greater than or equal to 2.0.

(3) A Maximum Acceptable Toxicant Concentration (MATC) of less than or equal to 100 parts per billion (100 ppb).

(4) An acute aquatic EC₅₀ of 20 mg/L or less coupled with either a measured bioconcentration factor (BCF) equal to or greater than 1,000x or in the absence of bioconcentration data a log P value equal to or greater than 4.3.

Site means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

Site-limited intermediate means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

Spray application means any method of projecting a jet of vapor of finely divided liquid onto a surface to be coated; whether by compressed air, hydraulic pressure, electrostatic forces, or other methods of generating a spray.

Use stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

Waters of the United States has the meaning set forth in 40 CFR 122.2.

Work area means a room or defined space in a workplace where a chemical substance is manufactured, processed,

Environmental Protection Agency

§ 721.5

or used and where employees are present.

Workplace means an establishment at one geographic location containing one or more work areas.

[53 FR 28358, July 27, 1988, as amended at 54 FR 31306, July 27, 1989; 58 FR 63516, Dec. 1, 1993]

§ 721.5 Persons who must report.

(a) The following persons must submit a significant new use notice as specified under the provisions of section 5(a)(1)(B) of the Act, part 720 of this chapter, and § 721.25:

(1) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to engage in a significant new use of the substance identified in that section.

(2) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to distribute the substance in commerce. A person described in this paragraph is not required to submit a significant new use notice if that person can document one or more of the following as to each recipient of the substance from that person:

(i) That the person has notified the recipient, in writing, of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(ii) That the recipient has knowledge of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(iii) That the recipient cannot undertake any significant new use described in the specific section in subpart E of this part.

(b) A person described in paragraph (a)(2) of this section must submit a significant new use notice if that person has knowledge at the time of commercial distribution of the substance identified in the specific section in subpart E of this part that a recipient intends to engage in a designated significant new use of that substance without submitting a notice under this part.

(c) A person who processes a chemical substance identified in a specific section in subpart E of this part for a significant new use of that substance is not required to submit a significant new use notice if that person can document each of the following:

(1) That the person does not know the specific chemical identity of the chemical substance being processed.

(2) That the person is processing the chemical substance without knowledge that the substance is identified in subpart E of this part.

(d)(1) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in subpart E of this part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a significant new use notice.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart E of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios,