

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 EC_{50} of 1 mg/L or less.

(2) An acute aquatic EC_{50} of 20 mg/L or less where the ratio of aquatic vertebrate 24-hour to 48-hour EC_{50} 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 EC_{50} 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, 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, 1200 Pennsylvania Ave., N.W., Washington, DC, 20044.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a notice under this part, the manufacturer, importer, or processor shall im-

mediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a significant new use notice under this part and the notice review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a notice under this part, the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.

(ii) The recipient has submitted a significant new use notice under this part and the notice review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995]

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture (including import) or process a chemical substance which is described by a generic chemical name in subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture (including import) or process the chemical substance for commercial purposes.

(b) To establish a *bona fide* intent to manufacture (including import) or