
40 C.F.R. § 723.50

Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

- (i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.
- (ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

- (i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.
- (ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

(b) *Definitions.* The following definitions apply to this subpart.

(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 et seq).

(2) *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.

(3) *Environment* has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) *Environmental transformation product* means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) *Metabolite* means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) *Serious acute effects* means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) *Serious chronic effects* means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe

or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) *Significant environmental effects* means:

- (i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;
- (ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or
- (iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) *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.

(10) The terms *byproduct*, *EPA*, *importer*, *impurity*, *known to or reasonably ascertainable*, *manufacture*, *manufacturer*, *new chemical substance*, *person*, *possession or control*, and *test data* have the same meanings as in § 720.3 of this chapter.

(c) *Exemption categories*. Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) *Consumers and the general population*. For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section).

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) *Workers*. For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) *Ambient surface water*. For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§ 721.90 and 721.91, unless

EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) *Incineration.* For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) *Land or groundwater.* For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) *Chemical substances that cannot be manufactured under this exemption.* A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c) (2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

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