
40 C.F.R. § 723.250

Polymers.

(a) *Purpose and scope.* (1) This section grants an exemption from certain of 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 certain polymers. This section does not apply to microorganisms subject to part 725 of this chapter.

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

- (i) Determine that the substance meets the definition of polymer in paragraph (b) of this section.
- (ii) Determine that the substance is not specifically excluded by paragraph (d) of this section.
- (iii) Ensure that the substance meets the exemption criteria of paragraph (e) of this section.
- (iv) Submit a report as required under paragraph (f) of this section.
- (v) Comply with the recordkeeping requirements of paragraph (j) of this section.

(b) *Definitions.* In addition to the definitions under section 3 of the Act, 15 U.S.C. 2602, the following definitions apply to this part.

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

Biopolymer means a polymer directly produced by living or once-living cells or cellular components.

Category of chemical substances has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

Cationic polymer means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.

Chemical substance, Director, EPA, importer, impurity, Inventory, known to or reasonably ascertainable, manufacture, manufacturer, mixture, new chemical, person, possession or control, process and test data have the same meanings as in § 720.3 of this chapter.

Equivalent weight of a functional group means the ratio of the molecular weight to the number of occurrences of that functional group in the molecule. It is the weight of substance that contains one formula-weight of the functional group.

Fluorotelomers means the products of telomerization, which is the reaction of a telogen (such as pentafluoroethyl iodide) with an ethylenic compound (such as tetrafluoroethylene) to form low molecular weight polymeric compounds, which contain an array of saturated carbon atoms covalently bonded to each other (C-C bonds) and to fluorine atoms (C-F bonds). This array is predominantly a straight chain, and depending on the telogen used produces a compound having an even number of carbon atoms. However, the carbon chain length of the

fluorotelomer varies widely. The perfluoroalkyl groups formed by this process are usually, but do not have to be, connected to the polymer through a functionalized ethylene group as indicated by the following structural diagram: (Rf-CH₂CH₂-Anything).

Internal monomer unit means a monomer unit that is covalently bonded to at least two other molecules. Internal monomer units of polymer molecules are chemically derived from monomer molecules that have formed covalent bonds between two or more other monomer molecules or other reactants.

Monomer means a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

Monomer Unit means the reacted form of the monomer in a polymer.

Number-average molecular weight means the arithmetic average (mean) of the molecular weight of all molecules in a polymer.

Oligomer means a polymer molecule consisting of only a few monomer units (dimer, trimer, tetramer)

Other reactant means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.

Perfluoroalkyl carboxylate (PFAC) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a carbonyl moiety and where all carbon-hydrogen (C-H) bonds have been replaced with carbon-fluorine (C-F) bonds. The carbonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

Perfluoroalkyl sulfonate (PFAS) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a sulfonyl moiety and where all carbon - hydrogen (C-H) bonds have been replaced with carbon - fluorine (C-F) bonds. The sulfonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

Polyester means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.

Polymer means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units.

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