SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT

PART 723—PREMANUFACTURE NOTIFICATION EXEMPTIONS

Subpart A [Reserved]

Subpart B—Specific Exemptions

Sec.

AUTHORITY: 15 U.S.C. 2604.

Subpart A [Reserved]

Subpart B—Specific Exemptions

§ 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:

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710–25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of § 720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§ 720.45(a)).

(iii) Impurities (§ 720.45(b)).

(iv) Known synonyms or trade names (§ 720.45(c)).

(v) Byproducts (§ 720.45(d)).

(vi) Production volume (§ 720.45(e)). (A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000–kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12–month period during the first 3 years of production.

(vii) Description of intended categories of use (§ 720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§ 720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§ 720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply ''bounding estimates'' (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a ''TSCA section 5(h)(4) exemption notice,'' and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§ 720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710–25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period.

(xii) Sanitized copy of notice. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under this paragraph (e) of this section, the submission will be determined to be incomplete by EPA. When a submission for a new chemical substance has been determined to be incomplete, a manufacturer reapplying for an exemption for the new chemical substance must submit a new exemption notice containing all the information required under this paragraph (e) of this section including a certification page containing an original dated signature; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Multiple exemption holders.* (1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the

provisions of paragraph (h)(2) of this section.

(g) *Review period.* (1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of § 720.75(b) of this chapter.

(2) Upon expiration of the 30–day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(h) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) *After the review period.* (i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (''the Assistant Administrator'') makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of

the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new information, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(j) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a nonvolatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (*1*) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (*2*) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§ 721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software.

(k) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial

users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(l) *Confidentiality.* (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph (l) must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the manufacturer will be subject to EPA review and approval in accordance with the procedures specified in §720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing

to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) *Recordkeeping.* (1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume.

(ii) Records documenting compliance with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

[60 FR 16346, Mar. 29, 1995, as amended at 60 FR 34465, July 3, 1995; 62 FR 17932, Apr. 11, 1997; 64 FR 31989, June 15, 1999; 71 FR 33642, June 12, 2006; 75 FR 787, Jan. 6, 2010; 77 FR 46292, Aug. 3, 2012; 78 FR 72828, Dec. 4, 2013; 80 FR 42746, July 20, 2015]

§ 723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

(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 and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. 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 exemption, a manufacturer of instant photographic or peel-apart film articles must:

(i) Submit an exemption notice when manufacture begins under paragraph (i) of this section.

(ii) Comply with certain requirements to limit exposure to the new chemical substance under paragraphs (e), (f), (g), and (h) of this section.

(iii) Comply with all recordkeeping requirements under paragraph (j) of this section.

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

(2) An *article* is a manufactured item (i) which is formed to a specific shape or design during manufacture, (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (iii) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.2 of this chapter except that fluids and particles are not considered articles regardless of shape or design.

(3) The terms *byproduct*, *EPA*, *impurities*, *person*, and *site* have the same meanings as in § 710.3 of this chapter.

(4) The term *category of chemical substances* has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

(5) The terms *chemical substance*, *distribute in commerce*, *distribution in commerce*, *environment*, *manufacture*, *new chemical substance*, and *process* have the same meanings as in section 3 of the Act (15 U.S.C. 2602).

(6) *Director of the Office of Pollution Prevention and Toxics* means the Director of the EPA Office of Pollution Prevention and Toxics or any EPA employee designated by the Office Director to carry out the Office Director's functions under this section.

(7) The term *exemption category* means a category of chemical substances for which a person(s) has applied for or been granted an exemption under section 5(h)(4) of the Act (15 U.S.C. 2604).

(8) The term *instant photographic film article* means a self-developing photographic film article designed so that all the chemical substances contained in the article, including the chemical substances required to process the film, remain sealed during distribution and use.

(9) *Intermediate* means any chemical substance which is consumed in whole or in part in a chemical reaction(s) used for the intentional manufacture of another chemical substance.

(10) *Known to or reasonably ascertainable* means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, our could obtain without unreasonable burden or cost.

(11) The term *peel-apart film article* means a self-developing photographic film article consisting of a positive image receiving sheet, a light sensitive negative sheet, and a sealed reagent pod containing a developer reagent and designed so that all the chemical substances required to develop or process the film will not remain sealed within the article during and after the development of the film.

(12) *Photographic article* means any article which will become a component of an instant photographic or peel-apart film article.

(13) *Special production area* means a demarcated area within which all manufacturing, processing, and use of a new chemical substance takes place, except as provided in paragraph (f) of this section, in accordance with the requirements of paragraph (e) of this section.

(14) *Test data* means:

(i) Data from a formal or informal study, test, experiment, recorded observation, monitoring, or measurement.

(ii) Information concerning the objectives, experimental methods and materials, protocols, results, data analyses (including risk assessments), and conclusions from a study, test, experiment, recorded observation, monitoring, or measurement.

(15) *Used in or for the manufacturing or processing of an instant photographic or peel-apart film article*, when used to describe activities involving a new chemical substance, means the new chemical substance (i) is included in the article, or (ii) is an intermediate to a chemical substance included in the article or is one of a series of intermediates used to manufacture a chemical substance included in the article.

(16) *Wet mixture* means a water or organic solvent-based suspension, solution, dispersion, or emulsion used in the manufacture of an instant photographic or peel-apart film article.

(c) *Exemption category.* The exemption category includes new chemical substances used in or for the manufacture or processing of instant photographic or peel-apart film articles which are manufactured and processed under the terms of this section.

(d) *Applicability.* This exemption applies only to manufacturers of instant photographic or peel-apart film articles who:

(1) Manufacture the new chemical substances used in or for the manufacture or processing of the instant photographic or peel-apart film articles.

(2) Limit manufacture and processing of a new chemical substance to the site(s) listed in the exemption notice for that new chemical substance submitted under paragraph (i) of this section.

(3) Comply with the requirements of paragraphs (e), (f), (g), (h), and (j) of this section.

(4) Do not distribute in commerce or use a peel-apart film article containing a new chemical substance until submission of a premanufacture notice under section 5(a)(1)(A) of the Act (15 U.S.C. 2604) and until the review period for the notice has ended without EPA action to prevent distribution or use.

(e) *Conditions of manufacture and processing in the special production area.* All manufacturing, processing, and use operations involving the new chemical substance must be performed in a special production area under the conditions set forth in this paragraph until the new chemical substance has been incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article.

(1) *Exposure limits.* In the special production area, the ambient air concentration of the new chemical substance during manufacture, processing, and use cannot exceed an 8-hour time weighted average (TWA) of 10 ppm for gases and vapors and 50 $\mu g/m^3$ for particulates, with an allowable TWA excursion of 50 percent above those concentrations for a duration of 30 minutes or less.

(2) *Respiratory protection*—(i) *Respirator requirement.* Except as specified in paragraph (e)(2)(ii) of this section, each person in the special production area must wear an appropriate respiratory protection device to protect against dusts, fumes, vapors, and other airborne contaminants, as described in 29 CFR 1910.134. Selection of an appropriate respirator must be made according to the guidance of American National Standard Practices for Respiratory Protection Z88.2–1969 and the NIOSH Certified Equipment List, U.S. Department of Health and Human Services, NIOSH publication No. 80–144.

(ii) *Waiver of respirator requirement.* Employees are not required to wear respirators if monitoring information collected and analyzed in accordance with paragraph (e)(3) of this section demonstrates that the ambient 8-hour TWA concentration of the new chemical substance in the area is less than 1 ppm for gases and vapors and 5 $\mu g/m^3$ for particulates with an allowable TWA excursion of 50 percent above these concentrations for a duration of 30 minutes or less.

(iii) *Quantitative fit test.* Each respirator must be issued to a specific individual for personal use. A quantitative fit test must be performed for each respirator before its first use by that person in a special production area.

(3) *Monitoring*—(i) *When to monitor.* (A) When suitable sampling and analytic methods exist, periodic monitoring in accordance with this paragraph must be done to ensure compliance with the exposure limits of paragraphs (e)(1) and (2)(ii) of this section.

(B) When suitable sampling and analytic methods do not exist, compliance with the exposure limits of paragraph (e)(1) and the requirements of paragraph (e)(10) of this section must be determined by an evaluation of monitoring data developed for a surrogate chemical substance possessing comparable physical-chemical properties under similar manufacturing and processing conditions.

(ii) *Monitoring methods.* A suitable air sampling method must permit personal or fixed location sampling by conventional collection methods. A suitable analytic method must have adequate sensitivity for the volume of sample available and be specific for the new chemical substance being monitored. If chemical-specific monitoring methods are not available, nonspecific methods may be used if the concentration of the new chemical substance is assumed to be the total concentration of chemical substances monitored.

(iii) *Monitoring frequency.* (A) When suitable air sampling and analytical procedures are available, monitoring must be done in each special production area during the first three 8-hour work shifts involving the manufacture or processing of each new chemical substance. Thereafter, monitoring must be done in each special production area for at least one 8-hour period per month, during a production run in which the new chemical substance is manufactured or processed. Samples must be of such frequency and pattern as to represent with reasonable accuracy the mean level and maximum 30-

minute level of employee exposure during an 8-hour work shift. In monitoring for an 8-hour work shift or the equivalent, samples must be collected periodically or continuously for the duration of the 8-hour work shift. Samples must be taken during a period which is likely to represent the maximum employee exposure.

(B) If the manufacturer demonstrates compliance with the exposure limits for 3 consecutive months, further monitoring of the identical process must be performed only every 6 months thereafter, unless there is a significant change in the process, process design, or equipment. If there is such a change, the manufacturer must begin monitoring again according to the schedule in paragraph (e)(3)(iii)(A) of this section.

(iv) *Location of monitoring.* Air samples must be taken so as to ensure that the samples adequately represent the ambient air concentration of a new chemical substance present in each worker's breathing zone.

(4) *Engineering controls and exposure safeguards.* Engineering controls such as, but not limited to, isolation, enclosure, local exhaust ventilation, and dust collection must be used to ensure compliance with the exposure limits prescribed in paragraphs (e)(1) or (e)(2)(ii) of this section.

(5) *Training, hygiene, and work practices*—(i) *Training.* No employee may enter a special production area before the completion of a training program. The training program must be adapted to the individual circumstances of the manufacturer and must address: The known physical-chemical and toxicological properties of the chemical substances handled in the area; procedures for using and maintaining respirators and other personal safeguards; applicable principles of hygiene; special handling procedures designed to limit personal exposure to, and inadvertent release of, chemical substances; and procedures for responding to emergencies or spills.

(ii) *Hygiene.* Appropriate standards of hygiene must be observed by all employees handling a new chemical substance in manufacturing, processing, or transfer operations. The manufacturer must provide appropriate facilities for employee changing and wash-up. Food, beverages, tobacco products, and cosmetics must not be allowed in special production areas.

(iii) *Work practices.* Operating procedures such as those related to chemical weighing and filtering, or the charging, discharging and clean-up of process equipment, must be designed and conducted to ensure compliance with the exposure limits prescribed in paragraph (e)(1) or (e)(2)(ii) of this section. Written procedures and all materials necessary for responding to emergency situations must be immediately accessible to all employees in a special production area. Any spill or unanticipated emission must be controlled by specially trained personnel using the equipment and protective clothing described in paragraph (e)(6) of this section.

(6) *Personal protection devices.* All workers engaged in the manufacture and processing of a new chemical substance in the special production area must wear suitable protective clothing or equipment, such as chemical-resistant coveralls, protective eyewear, and gloves.

(7) *Caution signs.* Each special production area must be clearly posted with signs identifying the area as a special production area where new chemical substances are manufactured and processed under controlled conditions. Each sign must clearly restrict entry into the special production area to qualified personnel who are properly trained and equipped with appropriate personal exposure safeguards.

(8) *Removal for storage or transportation.* A new chemical substance that is not incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article may be removed from the special production area for purposes of storage between operational steps or for purposes of transportation to another special production area. Such storage or transportation must be conducted in a manner that limits worker and environmental exposure through the use of engineering controls, training, hygiene, work practices, and personal protective devices appropriate to the chemical substance in question.

(9) *Labeling.* (i) Any new chemical substance removed from a special production area or stored or transported between operational steps must be clearly labeled. The label must show the identity of the new chemical substance or an appropriate identification code, a statement of any known hazards associated with it, a list of special handling instructions, first aid information, spill control directions, and where applicable, the appropriate U.S. Department of Transportation notations.

(ii) No label is required if the new chemical substance has been incorporated into a photographic article, or if it is contained in a sealed reaction vessel or pipeline, or if it has been incorporated into an instant photographic or peel-apart film article.

(10) *Areas immediately adjacent to the special production area.* The ambient air concentration of the new chemical substance in areas immediately adjacent to the special production area must not exceed the exposure limit established in paragraph (e)(2)(ii) of this section for waiver of respirator protection within the special production area. Periodic monitoring in accordance with paragraph (e)(3) of this section must be performed in immediately adjacent areas where it is reasonable to expect a risk of inhalation exposure.

(f) *Conditions of processing outside the special production area.* A wet mixture may be incorporated into a photographic article or an instant photographic or peel-apart film article outside the special production area under the conditions listed in this paragraph:

(1) *Engineering controls and exposure safeguards.* Engineering controls must limit the exposure to a new chemical substance contained in a wet mixture.

(2) *Training, hygiene and work practices*—(i) *Training.* Training of employees involved in the handling of wet mixtures containing a new chemical substance must be adapted to the individual circumstances of the employees' activities and must address: Procedures for using personal exposure safeguards, applicable principles of hygiene, handling procedures designed to limit personal exposure, and procedures for responding to emergencies and spills.

(ii) *Hygiene.* Appropriate standards of hygiene that limit exposure must be observed by all employees handling wet mixtures that contain new chemical substances.

(iii) *Work practices.* Work practices and operating procedures must be designed to limit exposure to any new chemical substance contained in wet mixtures. Any spills or unanticipated releases of a wet mixture must be controlled by trained personnel wearing appropriate protective clothing or equipment such as gloves, eye protection, and, where necessary, respirators or chemically imprevious clothing.

(3) *Personal protection devices.* All workers engaged in the processing of a wet mixture containing a new chemical substance must wear suitable protective clothing or equipment such as coveralls, protective eyewear, respirators, and gloves.

(g) *Incorporation of photographic articles into instant photographic and peel-apart film articles.* A photographic article may be incorporated into the instant photographic or peel-apart film article outside the special production area. The manufacturer must take measures to limit worker and environmental exposure to new chemcial substances during these operations using engineering controls, training, hygiene, work practices, and personal protective devices.

(h) *Environmental release and waste treatment*—(1) *Release to land.* Process waste from manufacturing and processing operations in the special production area that contain a new chemical substance are considered to be hazardous waste and must be handled in accordance with the requirements of parts 262 through 267 and parts 122 and 124 of this chapter.

(2) *Release to water.* All wastewater or discharge which contain the new chemcial subtance must be appropriately pretreated before release to a Publicly Owned Treatment Works (POTW) or other receiving body of water. In the case of release to a POTW, the pretreatment must prevent structural damage to, obstruction of, or interference with the operation of the POTW. The treatment of direct release to a receiving body of water must be appropriate for the new chemical

substance's physical-chemical properties and potential toxicity.

(3) *Release to air.* All process emissions released to the air which contain the new chemical substance must be vented through control devices appropriate for the new chemical substance's physical-chemical properties and potential toxicity.

(i) *Exemption notice.* An exemption notices must be submitted to EPA when manufacture of the new chemical substance begins.

(1) *Contents of exemption notice.* The exemption notice must include the following information:

(i) *Manufacturer and sites.* The notice must identify the manufacturer and the sites and locations where the new chemical substance and the instant photographic or peel-apart film articles will be manufactured and processed.

(ii) *Chemical identification.* The notice must identify the new chemical substance as follows:

(A) *Class 1 substances.* For chemical substances whose composition can be represented by a definite structural disagram (Class 1 substances), the notice must provide the chemical name (preferably CAS or IUPAC nomenclature), the molecular formula, CAS Registry Number (if available), known synonyms (including trade names), and a structural diagram.

(B) *Class 2 substances.* For chemical substances that cannot be fully represented by a structural diagram, (Class 2 substances), the notice must provide the chemical name, the molecular formula, the CAS Registry Number (if available), and known synonyms (including trade names). The notice must identify the immediate precursors and reactants by name and CAS Registry Number (if available). The notice must include a partial or incomplete structural diagram, if available.

(C) *Polymers.* For a polymer, the notice must indentify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number. The notice must indicate the amount of each monomer used (by weight percent of total monomer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if available. The notice must indicate the number average molecular weight of the polymer and characterize the anticipated low molecular weight species. The notice must include this information for each typical average molecular weight composition of the polymer to be manufactured.

(iii) *Impurities.* The notice must identify the impurities that can be reasonably anticipated to be present in the new chemcial substance when manufactured under the exemption by name and CAS Registry Number, by class of substances, or by process or source. The notice also must estimate the maximum percent (by weight) of each impurity in the new chemical substance and the percent of unknown impurities present.

(iv) *Physical-chemical properties.* The notice must describe the physical-chemical properties of the new chemical substance. Where specific physical-chemical data are not available, reasonable estimates and the techniques used to develop these estimates must be provided.

(v) *Byproducts.* The notice must identify the name, CAS Registry number (if available), and the volume of each byproduct that would be manufactured during manufacture of the new chemical substance.

(vi) *Production volume.* The notice must include an estimate of the anticipated maximum annual production volume.

(vii) *Test data.* The notice must include all information and test data on the new chemical substance's health and environmental effects that are known to or reasonably ascertainable by the manufacturer.

(viii) *Identity of the article.* The notice must identify and describe the instant photographic film article(s) or peel-apart film article(s) that will contain the new chemical substance.

(ix) *Release to water.* The notice must include a description of the methods used to control and treat wastewater or discharge released to a POTW or other receiving body of water. The notice must also identify the POTW or receiving body of water.

(x) *Certification.* The manufacturer must certify in the notice that it is familiar with the terms of the exemption

and that the manufacture, processing, distribution, use, and disposal of the new chemical substance will comply with those terms.

(2) *Duplication of information in premanufacture notice.* If a manufacturer who submits an exemption notice under this paragraph has already submitted, or simultaneously submits, a premanufacture notice under section 5(a)(1)(A) of the Act for the new chemical substance, it may, in lieu of submitting the information required by this paragraph, reference the required information to the extent it is included in the premanufacture notice. At a minimum, the exemption notice must identify the manufacturer and the new chemical substance, and contain the certification required by paragraph (i)(1)(x) of this section.

(3) *Address.* The exemption notice must be addressed to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(j) *Recordkeeping.* (1) Manufacturers of a new chemical substance under this exemption must keep the following records for 30 years from the final date of manufacture.

(i) *Production records.* Each manufacturer must maintain records of the annual production volume of each new chemical substance manufactured under the terms of the exemption. This record must indicate when manufacture of the new chemical substance began.

(ii) *Exposure monitoring records.* Manufacturers must maintain an accurate record of all monitoring required by this section. Monitoring records may be adapted to the individual circumstances of the manufacturer but, at a minimum, must contain the following information: The chemical identity of the new chemical substance, date of the monitoring, the actual monitoring data for each monitoring location and sampling, and a reference to or description of the collection and analytic techniques. If the manufacturer does not monitor, the manufacturer must maintain a record of the reasons for not monitoring and the methods used to determine compliance with the exposure limits of paragraph (e)(1) of this section.

(iii) *Training and exposure records.* For each employee engaged in the manufacture or processing of a new chemical substance, the company must develop and maintain a record of the worker's participation in required training. This record must also demonstrate the regular use of personal exposure safeguards, including the results of any personal exposure monitoring, the results of the quantitative fit test for the worker's personal respirator, and any additional information related to the worker's occupational exposure.

(iv) *Treatment records.* Manufacturers who release treated wastewater or discharge containing a new chemical substance to a POTW or other receiving body of water must maintain records of the method of treatment.

(2) The manufacturer must make the records listed in paragraph (j)(1) of this section available to EPA upon written request by the Director of the Office of Pollution Prevention and Toxics. The manufacturer must provide these records within 15 working days of receipt of this request.

(k) *Confidentiality.* If the manufacturer submits information under paragraph (i) or (j) of this section which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to the Agency by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission will be made available to the public without further notice to the submitter.

(l) *Amendment and repeal.* (1) EPA may amend or repeal any term of this exemption if it determines that the manufacture, processing, distribution, use, and disposal of new chemical substances under the terms of the exemption may present an unreasonable risk of injury to health or the environment. EPA also may amend this exemption to enlarge the exemption category or to reduce the restrictions or conditions of the exemption.

(2) As required by section 5(h)(4) of the Act, EPA will amend or repeal the substantive terms of an exemption granted under this part only by the formal rulemaking procedures described in section 6(c)(2) and (3) of the Act (15 U.S.C. 2605(c)).

(m) *Prohibition of use of the exemption.* The Director of the Office of Pollution Prevention and Toxics may prohibit the manufacture, processing, distribution, use, or disposal of any new chemical substance under the terms of this exemption if he or she determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance may present an unreasonable risk of injury to health or the environment.

(n) *Enforcement.* (1) A failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this part is a violation of this regulation and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture of a new chemical substance in violation of this exemption or act to seize any chemical substances manufactured in violation of the exemption under the authority of section 17 of the Act (15 U.S.C. 2616).

[47 FR 24317, June 4, 1982, as amended at 53 FR 12523, Apr. 15, 1988; 60 FR 34465, July 3, 1995; 62 FR 17932, Apr. 11, 1997; 68 FR 906, Jan. 7, 2003; 71 FR 33642, June 12, 2006]

§ 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-CH_2CH_2-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.

Polymer molecule means a molecule which contains a sequence of at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant.

Reactant means a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition.

Reactive functional group means an atom or associated group of atoms in a chemical substance that is intended or can reasonably be anticipated to undergo further chemical reaction.

Reasonably anticipated means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions.

(c) *Applicability*. This section applies to manufacturers of new chemical substances that otherwise must submit a premanufacture notice to EPA under §720.22 of this chapter. New substances are eligible for exemption under this section if they meet the definition of ''polymer'' in paragraph (b) of this section, and the criteria in paragraph (e) of this section, and if they are not excluded from the exemption under paragraph (d) of this section.

(d) *Polymers that cannot be manufactured under this section*—(1) *Cationic polymers*. A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes) unless:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (e.g., polymers that will be used as ion exchange beads), or

(ii) The combined (total) functional group equivalent weight of cationic groups in the polymer is equal to or greater than 5,000.

(2) *Elemental limitations*. (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) The elements listed in paragraph (d)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions Na^{+}, Mg^{+2}, Al^{+3}, K^{+}, Ca^{+2}, Cl^{-}, Br^{-}, or I^{-}.

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

(3) *Polymers which degrade, decompose, or depolymerize*. A polymer cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. For the purposes of this section, degradation, decomposition, or depolymerization mean those types of chemical change that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light, or microbial action.

(4) *Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory*. A polymer cannot be manufactured under this section if the polymer being manufactured or imported is prepared from monomers and/or other reactants (that are either charged to the reaction vessel or incorporated in the polymer at levels of greater than 2 weight percent) that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

(5) *Water absorbing polymers with number average molecular weight (MW) 10,000 and greater*. A polymer cannot be manufactured under this section if the polymer being manufactured or imported is a water absorbing polymer and has a number average MW greater than or equal to 10,000 daltons. For purposes of this section, a water-absorbing polymer is a polymeric substance that is capable of absorbing its weight of water.

(6) *Polymers which contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length*. Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012.

(ii) [Reserved]

(e) *Exemption criteria.* To be manufactured under this section, the polymer must meet one of the following criteria:

(1) *Polymers with number average MW greater than or equal to 1,000 and less than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000).* (i) The polymer must have a number average MW greater than or equal to 1,000 and less than 10,000 daltons and contain less than 10 percent oligomeric material below MW 500 and less than 25 percent oligomeric material below MW 1,000.

(ii) The polymer cannot contain reactive functional groups unless it meets one of the following criteria:

(A) The polymer contains only the following reactive functional groups: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered ''ordinary,''(i.e., not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, e.g., strongly electron-withdrawing sulfone group with which the olefinic groups interact), butenedioic acid groups, those conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids, blocked isocyanates (including ketoxime-blocked isocyanates), thiols, unconjugated nitrile groups, and halogens (except that reactive halogen-containing groups such as benzylic or allylichalides cannot be included).

(B) The polymer has a combined (total) reactive group equivalent weight greater than or equal to 1,000 for the following reactive functional groups: acidhalides; acid anhydrides; aldehydes, hemiacetals; methylolamides,- amines or,- ureas; alkoxysilanes with alkoxy greater than C_2-alkoxysilanes; allyl ethers; conjugated olefins; cyanates; epoxides; imines; or unsubstituted positions *ortho* or *para* to phenolic hydroxyl; or

(C) If any reactive functional groups not included in paragraph (e)(1)(ii)(A) and (B) of this section are present, the combined (total) reactive group equivalent weight, including any groups listed in paragraph (e)(1)(ii)(B), is greater than or equal to 5,000.

(2) *Polymers with number average MW greater than or equal to 10,000 (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000)* . The polymer must have a number average MW greater than or equal to 10,000 daltons and contain less than 2 percent oligomeric material below MW 500 and less than 5 percent oligomeric material below MW 1000.

(3) *Polyester polymers.* The polymer is a polyester as defined in paragraph (b) of this section and is manufactured solely from one or more of the reactants in the following table 1:

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS No.
Monobasic Acids and Natural Oils	
Benzoic acid	65–85–0
Canola oil	120962–03–0
Coconut oil	8001–31–8*
Corn oil	8001–30–7*
Cottonseed oil	8001–29–4*
Dodecanoic acid	143–07–7
Fats and glyceridic oils, anchovy	128952–11–4*
Fats and glyceridic oils, babassu	91078–92–1*
Fats and glyceridic oils, herring	68153–06–0*
Fats and glyceridic oils, menhaden	8002–50–4*
Fats and glyceridic oils, sardine	93334–41–9*
Fats and glyceridic oils, oiticica	8016–35–1*
Fatty acids,C_{16-18} and C_{18}-unsatd.	67701–08–0*
Fatty acids, castor-oil	61789–44–4*
Fatty acids, coco	61788–47–4*
Fatty acids, dehydrated castor-oil	61789–45–5*
Fatty acids, linseed oil	68424–45–3*
Fatty acids, safflower oil.	

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Fatty acids, soya	68308–53–2*
Fatty acids, sunflower oil	84625–38–7*
Fatty acids, sunflower-oil, conjugated	68953–27–5*
Fatty acids, tall-oil	61790–12–3*
Fatty acids, tall-oil, conjugated*.	
Fatty acids, vegetable oil	61788–66–7*
Glycerides, C_{16-18} and C_{18}-unsatd.	67701–30–8*
Heptanoic acid	111–14–8
Hexanoic acid	142–62–1
Hexanoic acid, 3,3,5-trimethyl-	3302–10–1
Linseed oil	8001–26–1*
Linseed oil, oxidized	68649–95–6*
Nonanoic acid	112–05–0
Oils, Cannabis*.	
Oils, palm kernel	8023–79–8*
Oils, perilla	68132–21–8*
Oils, walnut	8024–09–7
Safflower oil	8001–23–8*
Soybean oil	8001–22–7*
Sunflower oil	8001–21–6*
Tung oil	8001–20–5*
Di and Tri Basic Acids:	
1,2-Benzenedicarboxylic acid	88–99–3
1,3-Benzenedicarboxylic acid	121–91–5
1,3-Benzenedicarboxylic acid, dimethyl ester	1459–93–4
1,4-Benzenedicarboxylic acid	100–21–0
1,4-Benzenedicarboxylic acid, diethyl ester	636–09–9
1,4-Benzenedicarboxylic acid, dimethyl ester	120–61–6
1,2,4-Benzenetricarboxylic acid	528–44–9
Butanedioic acid	110–15–6
Butanedioic acid, diethyl ester	123–25–1
Butanedioic acid, dimethyl ester	106–65–0
2-Butenedioic acid (E)–	110–17–8
Decanedioic acid	111–20–6
Decanedioic acid, diethyl ester	110–40–7
Decanedioic acid, dimethyl ester	106–79–6
Dodecanedioic acid	693–23–2
Fatty acids, C_{18}-unsatd., dimers	61788–89–4*
Heptanedioic acid	111–16–0
Heptanedioic acid, dimethyl ester	1732–08–7
Hexanedioic acid	124–04–9
Hexanedioic acid, dimethyl ester	627–93–0
Hexanedioic acid, diethyl ester	141–28–6
Nonanedioic acid	123–99–9
Nonanedioic acid, dimethyl ester	1732–10–1
Nonanedioic acid, diethyl ester	624–17–9
Octanedioic acid	(505–48–6)
Octanedioic acid, dimethyl ester	1732–09–8
Pentanedioic acid	(110–94–1)
Pentanedioic acid, dimethyl ester	1119–40–0
Pentanedioic acid, diethyl ester	818–38–2
Undecanedioic acid	1852–04–6
Polyols	
1,3-Butanediol	107–88–0
1,4-Butanediol	110–63–4
1,4-Cyclohexanedimethanol	105–08–8
1,2-Ethanediol	107–21–1
Ethanol, 2,2′-oxybis-	111–46–6
1,6-Hexanediol	629–11–8
1,3-Pentanediol, 2,2,4-trimethyl-	144–19–4
1,2-Propanediol,	57–55–6
1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115–77–5
1,3-Propanediol, 2,2-dimethyl-	126–30–7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77–99–6
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-	77–85–0
1,3-propanediol, 2-methyl	2163–42–0
1,2,3-Propanetriol	56–81–5
1,2,3-Propanetriol, homopolymer	25618–55–7
2-Propen-1-ol, polymer with ethenylbenzene	25119-62–4
Modifiers	
Acetic acid, 2,2′-oxybis-	110–99–6

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
1-Butanol	71–36–3**
Cyclohexanol	108–93–0
Cyclohexanol, 4,4′-(1-methylethylidene)bis-	80–04–6
Ethanol, 2-(2-butoxyethoxy)-	112–34–5
1-Hexanol	111–27–3
Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane	72318–84–4*
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-	13393–93–6
Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2,2′- [(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane].	25036-25–3
Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated	68440–65–3*
Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated	68957–04–0*
Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated.	[1]68957–06–2*
Silsesquioxanes, Ph Pr	[1]68037–90–1*

* Chemical substance of unknown or variable composition,complex reaction products, and biological materials (UVCB). The CAS Registry Numbers for UVCB substances are not used in CHEMICAL ABSTRACTS and its indexes.

** These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of these reactants.

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1), (e)(2), and (e)(3) of this section a report of manufacture or import must be submitted (postmarked) by January 31 of the year subsequent to initial manufacture. The notice must include:

(1) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact.

(2) *Number of substances manufactured.* Number of substances manufactured. The manufacturer must identify the number of polymers manufactured under terms of the exemption for the first time in the year preceding the notice.

(g) *Chemical identity information.* For substances exempt under paragraph (e) of this section the manufacturer must to the extent known to or reasonably ascertainable by the manufacturer identify the following and maintain the records in accordance with paragraph (j) of this section:

(1) A specific chemical name and CAS Registry Number (or EPA assigned Accession Number) for each ''reactant,'' as that term is defined in paragraph (b) of this section, used at any weight in the manufacture of the polymer. For purposes of determining chemical identity, the manufacturer may determine whether a reactant is used at greater than two weight percent according to either the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. Manufacturers who choose the ''incorporated'' method must have analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate compliance with this paragraph. Reactants that introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption are not allowed at any level.

(2) A representative structural diagram, if possible.

(h) *Certification.* To manufacture a substance under the terms of this section, a manufacturer must as of the date of first manufacture, make the following certification statements and maintain them in accordance with paragraph (j) of this section:

(1) The substance is manufactured or imported for a commercial purpose other than for research and development.

(2) All information in the certification is truthful.

(3) The new chemical substance meets the definition of a polymer, is not specifically excluded from the exemption in paragraph (d) of this section, and meets the conditions of the exemption in paragraph (e) of this section.

(i) *Exemptions granted under superseded regulations.* Manufacturers granted exemptions under the superseded requirements of § 723.250 (as in effect on

May 26, 1995) shall either continue to comply with those requirements or follow all procedural and recordkeeping requirements pursuant to this section. If an exemption holder continues to follow the superseded regulations, the Notice of Commencement requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria and exemption category restrictions on residual monomer/reactant and low molecular weight species content limitations.

(j) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e) of this section, must retain the records described in this paragraph at the manufacturing site for a period of 5 years from the date of commencement of manufacture or import.

(2) The records must include the following to demonstrate compliance with the terms of this section:

(i) Chemical identity information as required in paragraph (g) of this section.

(ii) Information to demonstrate that the new polymer is not specifically excluded from the exemption.

(iii) Records of production volume for the first 3 years of manufacture and the date of commencement of manufacture.

(iv) Information to demonstrate that the new polymer meets the exemption criteria in paragraphs (e)(1), (e)(2), or (e)(3) of this section.

(v) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the number-average MW exemption criteria in paragraphs (e)(1) or (e)(2) of this section. The analytical tests may include gel permeation chromatography (GPC).vapor pressure osmometry (VPO), or other such tests which will demonstrate that the polymer meets the number-average MW criterion.

(vi) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the criteria in paragraphs (e)(1) or (e)(2) of this section, meets the low MW content criteria in paragraphs (e)(1) or (e)(2) of this section.

(vii) If applicable, analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary) required in paragraph (g) of this section for determining monomers or reactants charged to the reaction vessel at greater than 2 weight percent but incorporated at 2 weight percent or less in the manufactured polymer.

(viii) The certification statements as required under paragraph (h) of this section.

(3) The manufacturer must submit the records listed in paragraph (j)(2) of this section to EPA upon written request by EPA. The manufacturer must provide these records within 15 working days of receipt of this request. In addition, any person who manufactures a new chemical substance under the terms of this section, upon request of EPA, must permit such person at all reasonable times to have access to and to copy these records.

(k) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(l) *Compliance.* (1) A person who manufactures or imports a new chemical substance and fails to comply with any provision of this section is in violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties in section

16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(m) *Inspections.* EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

(n) *Confidentiality.* If a manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

[60 FR 16332, Mar. 29, 1995, as amended at 62 FR 17932, Apr. 11, 1997; 75 FR 4305, Jan. 27, 2010]

PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

Subpart A—General Provisions and Applicability

Subpart B—Administrative Procedures

Subpart C—Confidentiality and Public Access to Information

Subpart D—Microbial Commercial Activities Notification Requirements

Subpart E—Exemptions for Research and Development Activities