

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

§ 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 [\(e\)](#) through (h) of this section.
- (iii) Comply with all recordkeeping requirements under [paragraph \(j\)](#) of this section.
- (iv) Remit the applicable fee specified in [§ 700.45\(c\)](#) of this chapter.

(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.

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(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, or 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

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average (TWA) of 10 ppm for gases and vapors and 50 µg/m³ 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 µg/m³ 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 (e)(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.

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(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 paragraph (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

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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 impervious 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 chemical 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 chemical substance 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 diagram (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 identify [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 chemical 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.

(xi)**Fee payment ID number.** The manufacturer or processor must include a payment identity number on the front page of the notice.

(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

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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

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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 \(15 U.S.C. 2616\)](#).

[[83 FR 52719](#), Oct. 17, 2018]