
40 C.F.R. § 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.

(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.

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