

## Environmental Protection Agency

## § 720.75

the FEDERAL REGISTER unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 720.87(b) will be published.

(3) A list of data submitted in accordance with § 720.50(a) will be published. In addition, for test data submitted in accordance with § 720.40(g), a summary of the data will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

### § 720.75 Notice review period.

(a) *Length of notice review period.* The notice review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete notice, or the date EPA determines the notice is complete under § 720.65(c), unless the Agency extends the period under section 5(c) of TSCA and paragraph (c) of this section.

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the notice review period. The suspension must be for a specified period of time.

(2) A request for suspension may be made in writing to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice. EPA will send the submitter a written confirmation that the suspension has been granted.

(i) An oral request may be granted for 15 days only. To obtain a longer suspension, the Document Control Officer for the Office of Pollution Prevention and Toxics must receive written confirmation of the oral request. The notice review period is suspended as of the date of the oral request.

(ii) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written request by the Document Control Officer for the Office of Pollution Prevention and Toxics.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice review period specified in paragraph (a) of this section.

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the notice review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the notice review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions may not exceed 90 days for any notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notice review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information.

(iii) EPA has received significant additional information during the notice review period.

(iv) The submitter has failed to correct a notice after receiving EPA's request under § 720.65(b).

(d) *Notice of expiration of notice review period.* EPA will notify the submitter

## § 720.78

## 40 CFR Ch. I (7-1-03 Edition)

that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. After expiration of the statutory notice review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the chemical substance even if the submitter has not received notice of expiration.

(e) *Withdrawal of a notice by the submitter.* (1) A submitter may withdraw a notice during the notice review period. A statement of withdrawal must be made in writing to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The withdrawal is effective upon receipt of the statement by the Document Control Officer.

(2) If a manufacturer or importer which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995]

### § 720.78 Recordkeeping.

(a) Any person who submits a notice under this part must retain documentation of information in the notice, including (1) other data, as defined in § 720.50(b), in the submitter's possession or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture or import.

(b)(1) Persons who manufacture or import a chemical substance under § 720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under § 720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under § 720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under § 720.36(b)(2).

(iv) The names and addresses of any persons other than the manufacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under § 720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures or imports a chemical substance under § 720.36 and who manufactures or imports the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

(c) Any person who obtains a test-marketing exemption under this part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption.

[48 FR 21742, May 13, 1983; 48 FR 33872, July 26, 1983, as amended at 51 FR 15102, Apr. 22, 1986; 58 FR 34204, June 23, 1993]

## Subpart E—Confidentiality and Public Access to Information

### § 720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this part.