

## § 720.50

## 40 CFR Ch. I (7–1–10 Edition)

chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN User Fee Identification Number under § 700.45(c)(3) of this chapter. The statutory review period will commence upon receipt of both the notice and the letter of support.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) The estimated maximum amount to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first three years of production.

(f) A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.

(g) For sites controlled by the submitter:

(1) The identity of sites where the new substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.

(3) Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.

(4) Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.

(h) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.

[48 FR 21742, May 13, 1983, as amended at 60 FR 16310, Mar. 29, 1995]

### **§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.**

(a) *Test data on the new chemical substance in the possession or control of the submitter.* (1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

- (i) Health effects data.
- (ii) Ecological effects data.
- (iii) Physical and chemical properties data.
- (iv) Environmental fate characteristics.
- (v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental

## Environmental Protection Agency

## § 720.50

methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the notice review period ends, the person must submit the study, report, or test to the address listed on the notice form, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.*

(1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, proc-

essing, distribution in commerce, use, or disposal of the new chemical substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) [Reserved]

(d) *Data that need not be submitted*—(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data

## § 720.57

with the notice and any claim of confidentiality, under § 720.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

## § 720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this subpart C apply to each person who submits a notice for a new chemical substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under § 720.22(b)(2), liable for complying with this part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

## Subpart D—Disposition of Notices

### § 720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

### § 720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the chemical substance is subject to the requirements of this part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the substance and

## 40 CFR Ch. I (7–1–10 Edition)

that the submission is not a notice under this part.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

### § 720.65 Acknowledgement of receipt of a notice; errors in the notice; incomplete submissions; and false and misleading statements.

(a) *Notification to the submitter.* EPA will acknowledge receipt of each notice by sending a letter via CDX or U.S. mail to the submitter that identifies the premanufacture notice number assigned to the new chemical substance and date on which the review period begins. The review period will begin on the date the notice is received by the Office of Pollution Prevention and Toxics Document Control Officer. The acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this part.

(b) *Errors in the notice.* (1) Within 30 days of receipt of the notice, EPA may request that the submitter remedy errors in the notice. The following are examples of such errors:

(i) Failure to date the notice form.

(ii) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(iii) Contradictory information.

(iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request, EPA may extend the notice period under section (5)(c) of the Act, in accordance with § 720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification period does not begin, if:

(i) The wrong person submits the notice form.

(ii) The submitter does not sign the notice form.

(iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.

(iv) The submitter does not submit the notice in the manner set forth in § 720.40(a)(2).