

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture or import for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the FEDERAL REGISTER explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

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

## Subpart C—Notice Form

### § 720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) Information may be submitted on paper, or electronically, as follows:

(i) Information submitted on paper must be submitted in the form and manner set forth in EPA Form No. 7710-25, which is available from the Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Information which is not submitted on the EPA Form No. 7710-25 or a photocopy thereof (e.g., on a form created by commercial form-making software) must be in a format pre-approved by the Agency.

(ii) Information may be submitted electronically (on magnetic or other media) pursuant to an EPA published format for electronic submissions. Such submissions must comply with this format and all other media specifications published by EPA. Persons submitting electronically must still complete and submit on paper the Certification and Submitter Identification sections of Form 7710-25.

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture or import of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice.* Each person who submits a notice must submit it to the address listed on the notice form.

(d) *General notice requirements.* (1) Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with

§ 720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

(2) A person who submits a notice to EPA under this part must provide EPA with an original and two complete copies of the notice, including all test data and any other information attached to the notice form. If information is claimed as confidential pursuant to § 720.80, a sanitized copy must also be provided.

(e) *Agency or joint submissions.* (1) A manufacturer or importer may designate an agent to submit the notice. Both the manufacturer or importer and the agent must sign the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a foreign manufacturer or supplier, or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. If separate portions of a joint notice are not submitted together, the submitter should indicate which information will be supplied by another person and identify that person. The other person must submit the information on the appropriate part of the notice form. The manufacturer or importer and any other person supplying the information must sign the certification provided on their respective notice forms.

(3) If EPA receives a submission which does not include information required by this rule, which the submitter indicates that it has authorized another person to provide, the notice review period will not begin until EPA receives that information.

(f) *New information.* During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must that information to the address listed on the notice form within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission must clearly identify

the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the notice review period, the submitter must immediately inform its EPA contract for that notice by telephone.

(g) *Chemical substances subject to a section 4 test rule.* (1) Except as provided in paragraph (g)(3) of this section, if (i) A person intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part, and (ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(h) *Chemical substances subject to a section 5(b)(4) rule.* (1) If a person (i) intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must

submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16309, Mar. 29, 1995]

**§ 720.45 Information that must be included in the notice form.**

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chem-

ical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

(ii) The currently correct CASRN for the substance if a CASRN already exists for the substance.

(iii) For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.

(iv) For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

(2) For a polymer, the submitter must also report the following:

(i) The specific chemical name and CASRN, if the number is available, of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent by weight of each monomer and other reactant in the polymer (weight of the monomer or other reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured), and the maximum residual amount of each monomer present in the polymer.

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of monomer or other reactant actually charged to the reaction vessel, or (B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.

(iv) For a determination that 2 weight percent or less of a monomer or