

Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

(ee) *Technically qualified individual* means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

(ff) *Test data* means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

(gg) *Test marketing* means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

(hh) *United States*, when used in the geographic sense, means all of the States.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986]

Subpart B—Applicability

§ 720.22 Persons who must report.

(a)(1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice unless the substance is excluded under § 720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

§ 720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is any chemical substance that is not currently listed on the Inventory.

(b)(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture or import a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA

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whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or import the chemical substance for commercial purposes.

(2) To establish a *bona fide* intent to manufacture or import a chemical substance, the person who proposes to manufacture or import the substance must submit to EPA:

(i) Except as provided in paragraphs (b)(3) (i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture or import, using the currently, correct CA name for the substance and the other correct chemical identity information in accordance with §§720.45(a) (1), (2), and (3).

(ii) A signed statement that the person intends to manufacture or import that chemical substance for commercial purposes.

(iii)(A) A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.

(B) If an importer is unable to provide the information requested in paragraph (b)(2)(iii)(A) of this section from the foreign manufacturer or supplier, the following information shall be submitted:

(1) A brief statement indicating how long the substance has been in commercial use outside of the United States.

(2) The name of a country in which it has been commercially used.

(3) Whether the importer believes that the substance has already been used commercially, in any country, for

the same purpose or application that the importer is intending.

(iv) A specific description of the major intended application or use of the substance.

(v) An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.

(vi) The estimated date (month/year) in which the person intends to submit a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(vii) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur. For an imported substance, the facility under the control of the importer at which processing of the substance would likely occur, if any.

(viii)(A) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(B) For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

(3)(i) If an importer cannot provide the chemical identity information required by paragraph (b)(2) (i) and (v) of this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with §720.45(a) (1), (2), and (3) and reference the importer's notice. If the

appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.

(ii) If a manufacturer cannot provide all of the required information in accordance with § 720.45(a) (1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant. The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.

(4) EPA will review the information submitted by the proposed manufacturer or importer under this paragraph to determine whether it has a *bona fide* intent to manufacture or import the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under § 710.7(e)(2)(v) of this chapter or the information requested under § 720.85(b)(3)(iii).

(5) If the proposed manufacturer or importer has shown a *bona fide* intent to manufacture or import the substance, and provide sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer or importer whether the chemical substance is on the confidential Inventory.

(6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture or import the substance and therefore was

told that the chemical substance is on the Inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture or import the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

(8) EPA will answer an inquiry on whether a particular chemical substance is on the confidential Inventory within 30 days after receipt of a complete submission under paragraph (b)(2) of this section.

(9) If the required chemical identity information has not been reported correctly or completely in the notice (except as provided under paragraph (b)(3)(ii) of this section) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice directly to the submitter. The submitter must then resubmit the whole, completed *bona fide* notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

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

§ 720.30 Chemicals not subject to notification requirements.

The following substances are not subject to the notification requirements of this part:

(a) Any substance which is not a "chemical substance" as defined in § 720.3(e).

(b) Any mixture as defined in § 720.3(u).¹

(c) Any new chemical substance which will be manufactured or imported in small quantities solely for research and development under § 720.36.

¹A new chemical substance that is manufactured or imported as part of a mixture is subject to the requirements of this part. This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.