

§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) All notices must be submitted on EPA Form 7710-25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) Submission via CDX. TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN software.

(ii) You can access the e-PMN software as follows:

(A) Website. Go to EPA's TSCA New Chemicals Program website at <http://www.epa.gov/oppt/newchems> and follow the appropriate links.

(B) Telephone. Call the EPA CDX Help Desk at 1-888-890-1995.

(C) E-mail. HelpDesk@epacdx.net.

(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 or support documents. For submitting notices or support documents via CDX, use the e-PMN software.

(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) If information is claimed as confidential pursuant to §720.80, a person who submits a notice to EPA in the manner set forth in §720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.

(e) Agency or joint submissions—(1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The manufacturer or importer should indicate in a cover letter accompanying the notice which information will be supplied by another person and must identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer

07 February 2019

or importer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

(3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.

(i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices to EPA via CDX.

(ii) An AO may grant access to a support registrant to edit section 5 documents.

(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.

https://ecfr.io/Title-40/pt40.33.716#se40.33.716_13

Extracted by GlobalMSDS Ltd

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