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Title 40 –Protection of Environment
Chapter I –Environmental Protection Agency
Subchapter R –Toxic Substances Control Act
Part 720 –Premanufacture Notification
Subpart F –Commencement of Manufacture or Import

Authority: 15 U.S.C. 2604, 2607, and 2613.

Source: 48 FR 21742, May 13, 1983, unless otherwise noted.

§ 720.102 Notice of commencement of manufacture.

- (a) **Applicability.** Any person who commences the manufacture of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement of manufacture.
- (b) **When to report.**
- (1) If manufacture for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture.
 - (2) If manufacture for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.
- (c) **Information to be reported on form.**
- (1) The notice must be submitted on EPA Form 7710-56, which is available as part of EPA's e-PMN software. See § 720.40(a)(2)(iv) for information on how to obtain e-PMN software. The form must be signed and dated by an Authorized Official (AO). All information specified on the form must be provided. The notice must contain the following information:
 - (i) The specific chemical identity of the PMN substance.
 - (ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).
 - (iii) The premanufacture notice (PMN) number assigned by EPA.
 - (iv) The date of commencement for the submitter's manufacture for a non-exempt commercial purpose (indicating whether the substance was initially manufactured in the United States or imported). The date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) of new chemical substance identified in the submitter's PMN. For importers, the date of commencement is the date the new chemical substance clears United States customs.
 - (v) The name and address of the submitter.
 - (vi) The name of the authorized official.
 - (vii) The name and telephone number of a technical contact in the United States.
 - (viii) The address of the site where commencement of manufacture occurred.

(ix) Clear indications of whether the chemical identity, submitter identity, and/or other information are claimed as confidential by the submitter.

(2) If the submitter claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in 40 CFR part 703 and must be submitted via EPA Form 7710-56. If the submitter wants the chemical identity to be listed on the confidential portion of the TSCA Inventory, the chemical identity must be claimed as confidential and the submitter must also follow the certification, substantiation, and generic name requirements described 40 CFR part 703 and paragraphs (e) and (f) of this section. Otherwise, EPA will list the specific chemical identity on the public TSCA Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

(d)

(1) **Where to submit.** All notices of commencement must be submitted to EPA on EPA Form 7710-56. Notices may only be submitted in a manner set forth in this paragraph.

(2) **Submission of notice of commencement.** EPA will accept notices of commencement only if submitted in accordance with this paragraph. All notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(e) **Confidentiality.**

(1) Any person who asserts a confidentiality claim for chemical identity in a Notice of Commencement submitted under this section must:

(i) Comply with generic name requirements described in 40 CFR part 703 and as specified in paragraph (f) of this section.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(2) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

(f) **Generic name.** If a submitter asserts a claim of confidentiality for chemical identity in a notice of commencement, they must provide a structurally descriptive generic name.

(1) Generic names must:

(i) Be structurally descriptive (e.g., not a trade name);

- (ii) Describe the chemical structure of the chemical substance as specifically as practicable while protecting only those features of the chemical structure that are claimed as confidential and disclosure of which would likely cause substantial harm to the competitive position of the person—the generic name should generally only obscure one structural feature, but in any case, should conceal only the feature(s) necessary to avoid a likelihood of substantial competitive harm to the submitter; and
 - (iii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with TSCA section 14(c)(4)(A) (e.g., Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA; available at <https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting>).
- (2) Generic names will be reviewed by EPA at the time of submission.
- (i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.
 - (ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in 40 CFR 703.5(f). EPA will provide 10 business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if the submitter does not respond within the 10-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the submitter's revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the substance will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the chemical identity claim and will likely deny the claim.

[48 FR 21742, May 13, 1983, as amended at 48 FR 41140, Sept. 13, 1983; 51 FR 15103, Apr. 22, 1986; 53 FR 12523, Apr. 15, 1988; 60 FR 16311, Mar. 29, 1995; 60 FR 34464, July 3, 1995; 65 FR 39304, June 26, 2000; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 87 FR 39764, July 5, 2022; 88 FR 37172, June 7, 2023]