

Environmental Protection Agency

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order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph, a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer distributes a chemical substance manufactured under this section to persons not in its employ, the manufacturer must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer.

(d) A chemical substance is not exempt from reporting under this part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than re-

search and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures a chemical substance in small quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide.

[51 FR 15102, Apr. 22, 1986, as amended at 87 FR 39763, July 5, 2022]

§ 720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

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

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(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 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.

(6) A fee payment identity number, as required in 40 CFR 700.45(g)(4).

(7) Any safety data sheet already developed for the chemical substance, including draft safety data sheets.

(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.

(f) When applying for a test marketing exemption, persons are subject

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to fees in accordance with 40 CFR 700.45.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 83 FR 52719, Oct. 17, 2018; 87 FR 39763, July 5, 2022]

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) 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 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 in the notice form, to the extent such information is known to or reasonably ascertainable