

Environmental Protection Agency

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(j) Degradation by biological mechanisms—aerobic and anaerobic.

§ 716.55 Confidentiality claims.

(a)(1) Section 14(b) of TSCA provides that EPA may not withhold from disclosure, on the grounds that they are confidential business information, health and safety studies of any substance or mixture that has been offered for commercial distribution (including for test marketing purposes and for use in research and development), any substance or mixture for which testing is required under TSCA section 4, or any substance for which notice is required under TSCA section 5, except to the extent that disclosure of data from such studies would reveal—

(i) Processes used in the manufacturing, importing, or processing of the substance or mixture, or

(ii) The portion of a mixture comprised by any of the substances in the mixture.

(2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because disclosure would reveal a confidential process or quantitative mixture composition should briefly state the basis of the claim, e.g., by saying “reveals confidential mixture proportion data,” and clearly identify the material subject to the claim.

(3) Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company. This information will not be subject to the disclosure requirements of section 14(b) of TSCA.

(4) Information other than company name or address, financial statistics, and product codes used by a company, which is contained in a study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), will be considered confidential by EPA as provided in Title 5, United States Code, section 552(b)(6).

(b) To assert a claim of confidentiality for data contained in a submitted document, the respondent must submit two copies of the document:

(1) One copy must be complete. In that copy, the respondent must indicate what data, if any, are claimed as

confidential by bracketing or underlining the specific information. Each page containing data claimed as confidential must also contain a brief statement for the basis of the claim as well as a label such as “confidential,” “proprietary,” or “trade secret.”

(2) The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted. The second copy will be immediately subject to public disclosure.

(3) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of his or her receipt of this notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

(c) If no claim of confidentiality accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

§ 716.60 Reporting schedule.

(a) *General requirements.* Except as provided in § 716.5 and paragraphs (b) and (c) of this section, submissions under §§ 716.30 and 716.35 must be post-marked on or before 60 days after the effective date of the listing of a substance or mixture in § 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in § 716.120.

(b)(1) *Submission of lists of initiated studies.* Persons subject to the listing requirements of § 716.35(a)(2) must inform EPA of the initiated study within 30 days of its initiation.

(2) *Submission of copies of completed studies.* Persons must submit copies of studies listed as ongoing or initiated

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under § 716.35(a) (1) and (2) within 30 days of completing the study.

(c) *Requests for extensions of time.* Respondents who cannot meet a deadline under this section may apply for a reasonable extension of time. Extension requests must be postmarked on or before 40 days after the effective date of the listing of a substance or mixture in § 716.120. The Director of EPA's Office of Pollution Prevention and Toxics will grant or deny extension requests.

(d) *Submission methods.* You must submit a request for an extension of time in writing by one of the following methods:

(1) Mail, preferably certified, to the Director, Office of Pollution Prevention and Toxics (OPPT) (7401M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: Section 8(d) Extension.

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, ATTN: Section 8(d) Extension. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation.

[51 FR 32726, Sept. 15, 1986, as amended at 60 FR 34464, July 3, 1995; 63 FR 15774, Apr. 1, 1998; 71 FR 47135, Aug. 16, 2006]

§ 716.65 Reporting period.

Unless otherwise required in a rule promulgated under 15 U.S.C. 2607(d) relating to a listed chemical substance or listed mixture [hereinafter "rule"], the reporting period for a listed chemical substance or listed mixture will terminate 60 days after the effective date on which the listed chemical substance or listed mixture is added to 40 CFR 716.120. EPA may require reporting for a listed chemical substance or listed mixture beyond the 60 day period in a rule promulgated under 15 U.S.C. 2607(d), however EPA will not extend any reporting period later than 2 years after the effective date on which a listed chemical substance or listed mixture is added to 40 CFR 716.120. After the applicable reporting period terminates, any person subject to the rule

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under 40 CFR 716.5 (a)(2) or (a)(3) and who has submitted to EPA lists of ongoing or initiated studies under 40 CFR 716.35 (a)(1) or (a)(2) must submit a copy of any such study within 30 days after its completion, regardless of the study's completion date.

[63 FR 15774, Apr. 1, 1998]

Subpart B—Specific Chemical Listings

§ 716.105 Additions of substances and mixtures to which this subpart applies.

The requirements of this subpart will be extended periodically to cover additional substances and mixtures. Two procedures will be used to add substances and mixtures.

(a) Except as provided in paragraph (b) of this section, substances and mixtures will be added to § 716.120 after publication in the FEDERAL REGISTER of a notice of proposed amendment to this subpart. There will be at least a 30-day public comment period on the notice. After consideration of the comments, EPA will amend § 716.120 by final rule to add the substances and listed mixtures.

(b) Except as provided in paragraph (c) of this section, chemical substances, mixtures, and categories of chemical substances that have been added to the TSCA section 4(e) Priority List by the Interagency Testing Committee, established under section 4 of TSCA, will be added to § 716.120 but only to the extent that the total number of designated and recommended substances, mixtures and categories of chemical substances has not exceeded 50 in any 1 year. The addition of such chemical substances, mixtures, and categories of chemical substances to § 716.120 will be effective 30 days after publication of a notice to that effect in the FEDERAL REGISTER.

(c) Prior to the effective date of an amendment under paragraph (b) of this section, the Assistant Administrator for Prevention, Pesticides and Toxic Substances may for good cause withdraw a chemical substance, mixture, or category of chemical substances from § 716.120. Any information submitted showing why a chemical substance,