

Environmental Protection Agency

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do not have copies. The name and address of any person known to them to possess a copy of the unpublished study must accompany each entry on the list. For purposes of this section only, an unpublished study will be considered to be "known to" a person, if the study can be discovered by a file search in accordance with § 716.25.

(4) *Studies previously sent to Federal agencies without confidentiality claims.* A list of unpublished studies which have been sent to a Federal Agency with no claims of confidentiality. The submission must for each study: Identify the study by title, state the name and address to whom the study was sent, and the month and year in which the study was submitted. Any study identified will be treated as if it were submitted under section 8(d) and will be available for public disclosure under section 14(b) of TSCA. Persons subject to this requirement may submit either a list of unpublished health and safety studies previously submitted to any Federal agency without claims of confidentiality in accordance with § 716.35(a)(4), or copies of each such study in accordance with § 716.30.

(b) Submission under paragraph (a) of this section must be identified either on the face of the study or otherwise by the applicable chemical name and CAS number (if any) listed in § 716.120(a) (1) and (2), and must be accompanied by a cover letter containing the name, job title, address and telephone numbers of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made.

(c) Lists of health and safety studies should be submitted, preferably by certified mail, to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: 8(d) Health and Safety Reporting Rule (Notification Reporting).

[51 FR 32726, Sept. 15, 1986, as amended at 52 FR 20084, May 29, 1987; 52 FR 44828, Nov. 20, 1987; 53 FR 12523, Apr. 15, 1988; 53 FR 46746, Nov. 18, 1988; 60 FR 34463, July 3, 1995; 63 FR 15774, Apr. 1, 1998]

§ 716.40 EPA requests for submission of further information.

EPA may, by letter, request a person to submit or make available for review the following information after the initial reporting under §§ 716.30 and 716.35. If the requested submissions are not made, EPA may subpoena them under section 11 of TSCA, 15 U.S.C. 2610.

(a) Submission of underlying data of the kind described in § 716.10(a)(4) by persons who submit copies of studies under § 716.30 or list studies under § 716.35(a)(1) or § 716.35(a)(2).

(b) Submission of preliminary reports of ongoing studies by persons who list the studies under § 716.35(a)(1) or § 716.35(a)(2).

(c) Submission of copies of studies by persons listed under § 716.35(a)(3) as possessing them.

§ 716.45 How to report on substances and mixtures.

Section 716.120 lists substances and mixtures, in order by Chemical Abstract Service Registry Number and by alphabetical order. Studies of listed substances and listed mixtures shall be reported as follows:

(a) When a substance is individually listed under § 716.120(a), studies of the substance and studies of mixtures known to contain the substance must be reported as studies of that substance.

(b) When two or more substances are listed as a mixture under § 716.120(b), studies of the listed mixture and studies of any mixture known to contain the listed mixture must be reported as studies of the listed mixture.

(c) Studies of the following preparations of a substance must be reported as studies of the substance itself, not as studies of mixtures known to contain the substance.

(1) The substance in aqueous solution.

(2) The substance containing a small amount of an additive, such as a stabilizer, emulsifier, or other chemical added for purposes of maintaining the integrity or physical form of the substance.

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(3) The substance of the grade/purity specified in each rule promulgated under 15 U.S.C. 2607(d).

[51 FR 32726, Sept. 15, 1986, as amended at 63 FR 15774, Apr. 1, 1998]

§ 716.50 Reporting physical and chemical properties.

Studies of physical and chemical properties must be reported under this subpart if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the following properties:

- (a) Water solubility.
- (b) Adsorption/desorption on particulate surfaces, e.g., soil.
- (c) Vapor pressure.
- (d) Octanol/water partition coefficient.
- (e) Density/relative density (specific gravity).
- (f) Particle size distribution for insoluble solids.
- (g) Dissociation constant.
- (h) Degradation by photochemical mechanisms—aquatic and atmospheric.
- (i) Degradation by chemical mechanisms—hydrolytic, reductive, and oxidative.
- (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

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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.