

Environmental Protection Agency

§ 716.45

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 The name and address of any person known to them to possess a copy of the unpublished study must accompany each entry on the list. For purposes of this section only, an unpublished study will be considered to be "known to" a person, if the study can be discovered by a file search in accordance with § 716.25.

(4) *Studies previously sent to Federal agencies without confidentiality claims.* A list of unpublished studies which have been sent to a Federal Agency with no claims of confidentiality.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 Persons subject to this requirement may submit either a list of unpublished health and safety studies previously submitted to any Federal agency without claims of confidentiality in accordance with § 716.35(a)(4), or copies of each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.