

Environmental Protection Agency

§ 716.35

pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of 1-triazene, 1,3-diphenyl- is greater than or equal to 90% of the test substance by weight must be submitted.

(6) For the 9 chemicals in the indium compound category, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of the indium compound is greater than or equal to 90% of the test substance by weight must be submitted.

(b) [Reserved]

[69 FR 24522, May 4, 2004]

§ 716.25 Adequate file search.

The scope of a person's responsibility to search records is limited to records in the location(s) where the required information is typically kept, and to records kept by the person or the person's individual employee(s) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals. Persons are not required to search for reportable information dated before January 1, 1977, to comply with this subpart unless specifically required to do so in a rule.

[63 FR 15773, Apr. 1, 1998]

§ 716.30 Submission of copies of studies.

(a)(1) Except as provided in §§ 716.5, 716.20, and 716.50, persons must send to EPA copies of any health and safety studies in their possession for the substances or mixtures listed in § 716.120. Persons are responsible for submitting copies on only the substances or listed mixtures which they: Have manufactured, imported, or processed or proposed to manufacture, import, or process (including as known byproducts) within the 10 years preceding the effective date for reporting on the substances or listed mixtures; manufacture, import, or process on the effective date for reporting on the substances or listed mixtures; and propose to manufacture, import, or process following the effective date for reporting

on the substances or listed mixtures. Persons who list studies as ongoing or initiated under § 716.35(a) (1) and (2) must submit them when they are completed.

(2) [Reserved]

(b) Submissions 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 number of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made. In the cover letter, submitters must identify any impurity or additive known to have been present in the substance or listed mixtures as studied unless its presence is specifically noted in the study itself. The cover letter accompanying a study submitted by a trade association must also state that the submission is to satisfy reporting requirements under this part.

(c) Copies of health and safety studies and the accompanying cover letters must 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; 60 FR 34463, July 3, 1995; 63 FR 15773, Apr. 1, 1998]

§ 716.35 Submission of lists of studies.

(a) Except as provided in §§ 716.5, 716.20, and 716.50, persons subject to this rule must send lists of studies to EPA for each of the listed substances or listed mixtures (including as a known byproduct) in § 716.120 which they are manufacturing, importing, or processing, or which they propose to manufacture (including import) or process.

(1) *Ongoing studies.* As of the date a person becomes subject to this part, a list of ongoing health and safety studies being conducted by or initiated for

them, noting for each entry: The beginning date of the study, the purpose of the study, the types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study.

(2) *Initiated studies.* After the date a person becomes subject to this part, a list of studies initiated by or for them, noting for each entry: The beginning date of the study, the purpose of the study, the types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study.

(3) *Studies which are known but without possession of copies.* As of the date a person becomes subject to this part, a list of unpublished health and safety studies known to them of which they 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 offi-

cial, 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),