

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(6) For the 9 chemicals in the indium compound category, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of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