

§ 716.25

soil; vapor pressure; octanol/water partition coefficient; density/relative density (specific gravity); particle size distribution for insoluble solids; dissociation constant; degradation by photochemical mechanisms—aquatic and atmospheric; degradation by chemical mechanisms—hydrolytic, reductive, and oxidative; degradation by biological mechanisms—aerobic and anaerobic. Studies of physical and chemical properties meeting the criteria set forth in paragraph (a)(7)(iv) of this section must be reported 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 properties listed in this paragraph. In addition, all unpublished studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section on melting point and boiling point must be submitted.

(ii) All unpublished health effects studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section including pharmacokinetics, genotoxicity, acute toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, and oncogenicity/carcinogenicity.

(iii) All unpublished environmental effects studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section including acute and chronic toxicity studies of aquatic and terrestrial vertebrates and invertebrates and aquatic plants.

(iv) Only studies where the voluntary HPV Challenge Program orphan (unsponsored) chemical is $\geq 90\%$ of the test substance by weight should be submitted. In addition, only studies that were conducted using TSCA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Organization for Economic Cooperation and Development (OECD) or other internationally accepted test guidelines or voluntary consensus standards should be submitted. Studies performed where the voluntary HPV Challenge Program orphan (unsponsored) chemical is $< 90\%$ of the test substance by weight are not requested at this time.

40 CFR Ch. I (7–1–07 Edition)

(b) [Reserved]

[69 FR 24522, May 4, 2004, as amended at 71 FR 47135, Aug. 16, 2006]

§ 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