§ 716.25 Adequate file search.

(a) Substance by weight must be submitted.

(7) For all voluntary HPV Challenge Program orphan (unsponsored) chemicals:

(i) All unpublished environmental fate studies, meeting the criteria set forth in paragraph (a)(7)(iv) of this section, on water solubility; adsorption/desorption on particulate surfaces, e.g., soil; vapor pressure; octanol/water partition coefficient; density/relative density (specific gravity); particle size distribution for insoluble solids; dissociation constant; degradation by photochemical mechanisms—aqueous and atmospheric; degradation by chemical mechanisms—hydrolytic, reductive, and oxidative; degradation by biological mechanisms—anaerobic and aerobic. 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 In addition, all unpublished studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section on melting point and boiling point must be submitted.

(ii) All unpublished health effects studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section must be reported if performed for the purpose of determining health and safety studies that:

(A) Relate to the content of consumer products that are “intended for use by children” as that term is defined in 40 CFR 710.43 (excluding children’s metal jewelry), or

(B) Assess children’s exposure to lead from such products (including studies of bioavailability).

(ii) With regard to purity, studies showing any measurable lead content in such products must be submitted.

(b) [Reserved]


§ 716.25 Adequate file search.

(a) Substance by weight must be submitted.

(7) For all voluntary HPV Challenge Program orphan (unsponsored) chemicals:

(i) All unpublished environmental fate studies, meeting the criteria set forth in paragraph (a)(7)(iv) of this section, on water solubility; adsorption/desorption on particulate surfaces, e.g., soil; vapor pressure; octanol/water partition coefficient; density/relative density (specific gravity); particle size distribution for insoluble solids; dissociation constant; degradation by photochemical mechanisms—aqueous and atmospheric; degradation by chemical mechanisms—hydrolytic, reductive, and oxidative; degradation by biological mechanisms—anaerobic and aerobic. 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 must be reported if performed for the purpose of determining health and safety studies that:

(A) Relate to the content of consumer products that are “intended for use by children” as that term is defined in 40 CFR 710.43 (excluding children’s metal jewelry), or

(B) Assess children’s exposure to lead from such products (including studies of bioavailability).

(ii) With regard to purity, studies showing any measurable lead content in such products must be submitted.

(b) [Reserved]

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; manufactured, 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.

(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) Persons must use the CISS tool to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(d) To access the CISS tool go to https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx and follow the appropriate links and for further instructions to go http://www.epa.gov/oppt/chemtest/reporting/index.html.

§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