

Environmental Protection Agency

§ 716.30

the test substance by weight are not requested at this time.

(8)(i) Reporting requirements apply only to manufacturers (including importers) of consumer products intended for use by children who also manufacture (including import) lead or lead compounds. For the category “lead and lead compounds,” all unpublished health and safety studies that:

(A) Relate to the lead content of consumer products that are “intended for use by children” as that term is defined at 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]

[69 FR 24522, May 4, 2004, as amended at 71 FR 47135, Aug. 16, 2006; 73 FR 5115, Jan. 29, 2008]

§ 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 sub-

stances 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) You must submit copies of health and safety studies and the accompanying cover letters by one of the following methods:

(1) Mail, preferably certified, to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting).

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting). The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted

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during the DCO's normal hours of operation.

[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; 71 FR 47135, Aug. 16, 2006]

§ 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 ad-

dress 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) You must submit lists of health and safety studies by one of the following methods:

(1) Mail, preferably certified, to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting).

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting). The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation.

[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; 71 FR 47135, Aug. 16, 2006]