

Environmental Protection Agency

§ 716.30

- (i) Acute oral toxicity studies.
- (ii) Acute dermal toxicity studies.
- (iii) Acute inhalation toxicity studies.
- (iv) Primary eye irritation studies.
- (v) Primary dermal irritation studies.
- (vi) Dermal sensitization studies.
- (vii) Physical and chemical properties.

If the substance or listed mixture is an impurity, no reporting is required (see paragraph (a)(9) of this section).

(7) Analyzed aggregations of monitoring data based on monitoring data acquired more than 5 years preceding the date the substance or listed mixture was added to the list under § 716.120.

(8) Analyzed aggregations of monitoring data on mixtures known to contain one or more substances or listed mixtures listed in § 716.120, when the monitoring data are not analyzed to determine the exposure or concentration levels of the substances or listed mixture listed under § 716.120.

(9) Studies on a substance or listed mixture listed under § 716.120 that the person who is reporting has manufactured, imported, or processed or proposed to manufacture, import, or process only as an impurity. When reporting of such studies is to be required, that reporting will be separately proposed in the FEDERAL REGISTER.

(10) Studies of chemical substances or listed mixtures previously submitted by trade associations in accordance with the provisions of § 716.30.

(b) The following types of studies on substances or listed mixtures listed under § 716.120 are exempt from the copy and list submission requirements of §§ 716.30 and 716.35.

(1) For the listed ureaformaldehyde resins (CAS Nos. 9011-05-6 and 68611-64-3), studies on agronomic plant growth or damage which demonstrate only that the resins stimulate plant growth or cause plant damage when applied as a fertilizer.

(2) For the specified chemicals in § 716.120(d) under the category "Siloxanes," acute oral, dermal, and inhalation toxicity studies and primary eye and dermal irritation studies.

(3) For the listed chemicals under § 716.120(d) in the category "OSHA

Chemicals in Need of Dermal Absorption Testing," studies on ecological effects.

(4) For the chemicals listed at § 716.120 with a special exemption referencing this paragraph, studies on mixtures containing the listed substance at levels below 1 percent of the mixture, except when a purpose of the study includes the investigation of the effects of the listed substance at levels below 1 percent.

(5) Rulemaking proceedings that add substances and mixtures to § 716.120 will specify the types of health and/or environmental effects studies that must be reported and will specify the chemical grade/purity requirements that must be met or exceeded in individual studies. Chemical grade/purity requirements will be specified on a per chemical basis or for a category of chemicals for which reporting is required.

[51 FR 32726, Sept. 15, 1986, as amended at 58 FR 47649, Sept. 10, 1993; 58 FR 68315, Dec. 27, 1993; 60 FR 34884, July 5, 1995; 63 FR 15773, Apr. 1, 1998]

§ 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)

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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. 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, 401 M St., SW., 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.