(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]

§716.21 Chemical specific reporting requirements.

(a) Health and safety studies reportable under part 716 for the following chemical substances, mixtures, or categories of chemical substances, as listed in §716.120, must be submitted or listed only as specified in this section:

(1) For 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- and imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro-, all unpublished environmental effects studies and health effects studies on pharmacokinetics, genotoxicity, subchronic toxicity, immunotoxicity, carcinogenicity, reproductive effects, and developmental toxicity where the purity of 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- or imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro- is greater than or equal to 90% of the test substance by weight must be submitted.

(2) For benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation, and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)- is greater than or equal to 90% of the test substance by weight must be submitted.

(3) For stannane, dimethylbis[(1-oxoneodecyl)oxy]-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on hydrolysis and biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, neurotoxicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of stannane, dimethylbis[(1-oxoneodecyl)oxy]- is greater than or equal to 90% of the test substance by weight must be submitted.

(4) For benzene, 1,3,5-tribromo-2-(2-propenyloxy)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, neurotoxicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of benzene, 1,3,5-tribromo-2-(2-propenyloxy)- is greater than or equal to 90% of the test substance by weight must be submitted.

(5) For 1-triazene, 1,3-diphenyl-, all unpublished health effects studies on

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