notebooks, and daily monitoring records supporting studies do not have to be submitted initially. EPA may request underlying data later under § 716.40.

(b) [Reserved]

§ 716.20 Studies not subject to the reporting requirements.

(a) Excluding paragraph (a)(3) of this section, the following types of studies are exempt from the copy and list submission requirements of §§ 716.30 and 716.35.

(1) Studies which have been published in the scientific literature.

(2) Studies previously submitted to the EPA Office of Pollution Prevention and Toxics. These studies are limited to section 8(e) submissions, studies submitted during section 4 proceedings, studies submitted with premanufacture notices or significant new use notices, and studies submitted ''for your information'' (FYI submissions) in support of EPA's TSCA Existing Chemicals Program. Studies which have been initiated pursuant to a TSCA section 4(a) test rule, for which the person has submitted a letter of intent to conduct testing in accordance with the provisions of § 790.25 of part 790 of this chapter, are exempt from the list submission requirements of § 716.35.

(3) Except for those studies described in paragraph (a)(2) of this section, studies previously submitted to any Federal agency with no claims of confidentiality are exempt only from the copy submission requirements of § 716.30, and must be listed in accordance with the provisions of § 716.35.

(4) Studies conducted or initiated by or for another person who is subject to, and who will report the studies under §§ 716.30 and 716.35.

(5) Studies of chemical substances which are not on the TSCA Chemical Substances Inventory. This exemption applies only to those substances within categories listed under § 716.120(c).

(6) The following types of studies when the subject of the study is a mixture known to contain a substance or listed mixture listed under § 716.120.

(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]

§ 716.21 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.

(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.,