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(1) For 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- and imidazo[4,5-d]imidazo[2,5-(1H,3H)-dione, tetrahydro-, all unpublished environmental effects studies and health effects studies on pharmacokinetics, genotoxicity, subchronic toxicity, immunotoxicity, carcinogenicity, reproductive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

(2) For benzene, 1,3,5-tribromo-2-(2-propenyloxy)-, all unpublished environmental effects studies including biocaccumulation, environmental fate studies on biodegradation, and health effects studies on pharmacokinetics,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 benzene, 1,3,5-tribromo-2-(2-propenyloxy)- 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(3) For stannane, dimethylbis[1-oxoneodecyl]oxy]-, all unpublished environmental effects studies including biocaccumulation, environmental fate studies on hydrolysis and biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, 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(4) For 1-triazene, 1,3-diphenyl-, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of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.

(5) For 1-triazene, 1,3-diphenyl-, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of the 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.,
§ 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; and propose.

(b)(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]

§ 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]

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