Title 40 —Protection of Environment
Chapter I —Environmental Protection Agency
Subchapter R —Toxic Substances Control Act
Part 716 —Health and Safety Data Reporting
Subpart A —General Provisions

Authority: 15 U.S.C. 2607(d).
Source: 51 FR 32726, Sept. 15, 1986, unless otherwise noted.

§ 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For 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- and imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro-, all unpublished environmental effects studies and health effects studies on pharmacokinetics, genotoxicity, subchronic toxicity, immunotoxicity, carcinogenicity, reproductive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(2) For benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation, and health effects studies on pharmacokinetics,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(3) For stannane, dimethylbis[(1-oxoneodecyl)oxy]-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on hydrolysis and biodegradation and health effects studies on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(4) For benzene, 1,3,5-tribromo-2-(2-propenyloxy)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation and health effects studies on pharmacokinetics,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., soil; vapor pressure; octanol/water partition coefficient; density/relative density (specific gravity); particle size distribution for insoluble solids; dissociation constant; degradation by photochemical mechanisms—aquatic and atmospheric; degradation by chemical mechanisms—hydrolytic, reductive, and oxidative; degradation by biological mechanisms—aerobic and anaerobic. Studies of physical and chemical properties meeting the criteria set forth in paragraph (a)(7)(iv) of this section must be reported if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the properties listed in this paragraph. In addition, all unpublished studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section on melting point and boiling point must be submitted.

(ii) All unpublished health effects studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section including pharmacokinetics, genotoxicity, acute toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, and oncogenicity/carcinogenicity.

(iii) All unpublished environmental effects studies meeting the criteria set forth in paragraph (a)(7)(iv) of this section including acute and chronic toxicity studies of aquatic and terrestrial vertebrates and invertebrates and aquatic plants.

(iv) Only studies where the voluntary HPV Challenge Program orphan (unsponsored) chemical is ≥90% of the test substance by weight should be submitted. In addition, only studies that were conducted using TSCA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Organization for Economic Cooperation and Development (OECD) or other internationally accepted test guidelines or voluntary consensus standards should be submitted. Studies performed where the voluntary HPV Challenge Program orphan (unsponsored) chemical is <90% of 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.

(9) For 1,3-Butadiene (106-99-0), Butyl benzyl phthalate (BBP)—1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester (85-68-7), Dibutyl phthalate (DBP) (1,2-Benzene- dicarboxylic acid, 1,2- dibutyl ester) (84-74-2), o-Dichlorobenzene (95-50-1), p-Dichlorobenzene (106-46-7), trans-1,2-Dichloroethylene (156-60-5), 1,2-Dichloropropane (78-87-5), Dicyclohexyl phthalate (84-61-7), Di-ethylhexyl phthalate (DEHP)—(1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester) (117-81-7), Di-isobutyl phthalate (DIBP)—(1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester) (84-69-5), Formaldehyde (50-00-0), 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB) (1222-05-5), Phthalic anhydride (85-44-9), 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (79-94-7), and 1,1,2-Trichloroethane (79-00-5), all unpublished studies on health effects (including toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity); toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals; environmental effects; environmental fate; physical-chemical properties if performed as described in 40 CFR 716.50; and occupational (both users and non-users), general population, consumer, bystander, and environmental exposure must be submitted. Studies showing any measurable content of the High-Priority Substance in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study. Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

(10) For purposes of this paragraph, the term *organohalogen flame retardant* includes any substances listed in paragraph(d) of this section under the category “Organohalogen flame retardants”. For any organohalogen flame retardant, all unpublished studies on health effects (including toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity); toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals; environmental fate; physical-chemical properties if performed as described in 40 CFR 716.50; and occupational (both users and non-users), general population, consumer, bystander, and environmental exposure must be submitted. Studies showing any measurable content of the organohalogen flame retardant in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study. Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies requirements under 40 CFR 716.35 and the submission of studies requirements under this rule.

(11) For 4,4-Methylene bis(2-chloraniline) (101-14-4); 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (140-66-9); Acetaldehyde (75-07-7); Acrylonitrile (107-13-1); Benzenamine (62-53-3); Benzene (71-43-2); Bisphenol A (80-5-7); Ethylbenzene (100-41-4); Naphthalene (91-20-3); Vinyl Chloride (75-01-4); Styrene (100-42-5); Tribomomethane (Bromoform) (75-25-2); Triglycidyl isocyanurate (2451-62-9); Hydrogen fluoride (7664-39-3); N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) (793-24-8); and 2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (2754428-18-5), all unpublished studies on health effects (including toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity); toxicokinetics (absorption,

distribution, metabolism, or elimination), including modelling studies, in humans or animals; environmental effects; environmental fate; physical-chemical properties if performed as described in 40 CFR 716.50; and occupational (both users and non-users), general population, consumer, bystander, and environmental exposure must be submitted. Studies showing any measurable content of the substance in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study. Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

(b) [Reserved]

[69 FR 24522, May 4, 2004, as amended at 71 FR 47135, Aug. 16, 2006; 73 FR 5115, Jan. 29, 2008; 86 FR 34152, June 29, 2021; 89 FR 100761, Dec. 13, 2024]