(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

[58 FR 51681, Oct. 4, 1993]

§ 721.537 Organosilane ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an organosilane ester (PMN P-96–1661/P-95–1654) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(r) (370,000 kilogram (kg)) (90-day subchronic inhalation study in rats-(40 CFR 799.9346) (62 FR 43828, August 15, 1997) (FRL–5719–5). A person may not manufacture or import the substance beyond the aggregate production volume limit, unless that person conducts this study on the substance and submits all final reports and underlying data in accordance with the procedures and criteria specified in paragraphs (a)(2)(i)(A), (a)(2)(i)(B), (a)(2)(i)(C), and (a)(2)(i)(D) of this section.

(A) Each study required to be performed pursuant to this section must be scientifically valid. *Scientific valid* means that the study was conducted according to:

(*1*) The test guidelines specified in paragraph (a)(2)(i) of this section.

(*2*) An EPA-approved protocol.

(*3*) TSCA Good Laboratory Practice Standards at 40 CFR part 792.

(*4*) Using methodologies generally accepted at the time the study is initiated.

(*5*) Any deviation from these requirements must be approved in writing by EPA.

(B) Before starting to conduct any of the studies in paragraph (a)(2)(i) of this section, the person must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the person within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (a)(2)(i) of this section (e.g., 40 CFR part 797 or part 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(C) The person shall:

(*1*) Conduct each study in good faith with due care.

(*2*) Promptly furnish to EPA the results of any interim phase of each study.

(*3*) Submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data (''the report and data'') to EPA no later than 14 weeks prior to exceeding the applicable production volume limit. The final report shall contain the contents specified in 40 CFR 792.185.

(D)(*1*) Except as described in paragraph (a)(2)(i)(D)(*2*) of this section, if, within 6 weeks of EPA's receipt of a test report and data, the person receives written notice that EPA finds that the data generated by a study are scientifically invalid, the person is prohibited from further manufacture and import of the PMN substance beyond the applicable production volume limit.

(*2*) The person may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the person's compliance with either of the following paragraphs (a)(2)(i)(D)(*2*)(*i*) or (a)(2)(i)(D)(*2*)(*ii*) of this section.

(*i*) The person may reconduct the study. If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by paragraph (a)(2)(i)(C)(*3*) of this section, the person shall comply with paragraph (a)(2)(i)(C)(*3*) of this section. If there is insufficient time for the person to comply with paragraph (a)(2)(ii)(C)(*3*) of this section, the person may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in paragraph (a)(2)(i)(D)(*1*) of this section. EPA will respond to the person in writing, within 6 weeks of receiving the person's report and data.

(*ii*) The person may, within 4 weeks of receiving from EPA the notice described in paragraph (a)(2)(i)(D)(*1*) of this section, submit to EPA a written report refuting EPA's finding. EPA will respond to the person in writing, within 4 weeks of receiving the person's report.

(E) The person is not required to conduct a study specified in paragraph (a)(2)(i) of this section if notified in writing by EPA that it is unnecessary to conduct that study.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[63 FR 3419, Jan. 22, 1998]

§ 721.538 Phenol, 4-(1,1-dimethylethyl)-, homopolymer.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phenol, 4-(1,1-dimethylethyl)-, homopolymer (PMN P-95–243; CAS No. 30813–81–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(3) of this section.

(2) *High moleculation weight exemption.* A batch of the chemical substance may be exempt from the provisions of this rule if the average number molecular weight of the substance is greater than 1,000 and the low molecular weight species below 1,000 and 500 are less than 25 percent and 10 percent, respectively. To be eligible for this exemption, the batch must be individually measured.

(3) The significant new uses are:

(i) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (d), (f), (g)(3)(i), (g)(4)(i), and (g)(5). The label and material safety data sheet (MSDS) as required by this paragraph shall also include the following statement: This substance is toxic to aquatic invertebrate.

(ii) *Industrial, commercial, and consumer activites.* Requirements as specified in § 721.80(q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(4) and (b)(4) (N = 9). When calculating the surface water concentrations according to the instructions in § 721.91, the statement that the amount of the substance that will be released will be calculated before the substance enters control technology does not apply. Instead, if the waste stream containing the substance will be treated using primary and secondary wastewater treatment with control of suspended solids, before release, then the amount of the substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 95 percent removal efficiency may be attributed to such treatment. These requirements do not apply to the sites specifically exempted in the TSCA section 5(e) consent order for this substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), (g), (h), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

[63 FR 3420, Jan. 22, 1998]

§ 721.539 Poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-[(4-nonylphenoxy)methyl]-2-(2-propenyloxy)ethoxy]-, branched, ammonium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-[(4-nonylphenoxy)methyl]-2-(2-propenyloxy)ethoxy]-, branched, ammonium salts (PMN P-96–1240; CAS No. 184719–88–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.