(2) The significant new uses are:

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

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

(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.

[55 FR 26102, June 26, 1990. Redesignated and amended at 58 FR 29947, May 24, 1993; 58 FR 34204, June 23, 1993]

§ 721.9920 Urea, (hexahydro-6-methyl-2-oxopyrimidinyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance urea, (hexahydro-6-methyl-2oxopyrimidinyl)- (PMN P-89–303) 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(p) (level set at 1,975,000 and 2,200,000 kg).

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

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

[55 FR 26102, June 26, 1990. Redesignated at 58 FR 29947, May 24, 1993, as amended at 58 FR 34204, June 23, 1993]

§ 721.9925 Aminoethylethylene urea methacrylamide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an aminoethylethylene urea methacrylamide (PMN P-89–1038) 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(f).

(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) 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.

[58 FR 51709, Oct. 4, 1993]

§ 721.9928 Urea, tetraethyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as urea, tetraethyl- (PMN P-94–1017; CAS No. 1187–03–7) 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) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), and (a)(3).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(r) (445,000 kg) (a dermal developmental toxicity study in mice and rats and either a chromosome aberration assay in mice (40 CFR 798.5385) or a micronucleus assay in mice (40 CFR 798.5395)). A person may not manufacture or import the substance beyond the following aggregate production volume limits, unless that person conducts the following corresponding studies 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)(ii)(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 paragraph (a)(2)(ii)(D)(*2*)(*i*) or (a)(2)(ii)(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)(ii)(C)(*3*) of this section, the person shall comply with paragraph (a)(2)(ii)(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)(ii)(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)(ii)(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.

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(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), (d), (e), (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.

[63 FR 3440, Jan. 22, 1998]