

(i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(B) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and EPA will issue a proposed rule in the proposed rule section of the FEDERAL REGISTER. The proposed rule will establish a 30-day comment period.

(C) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(ii)(A) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposed rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(B) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this

part and designating the significant new uses subject to notification.

(iii)(A) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(1) The significant new use rule will take effect on the date of publication.

(2) Persons will be given 30 days from the date of publication to submit comments.

(B) An interim final rule issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (d)(4)(iii)(A)(2) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(e) *Schedule for issuing significant new use rules.* (1) EPA will issue a proposed rule, an interim final rule, or a direct final rule within 270 days of receipt of the notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

[54 FR 31314, July 27, 1989, as amended at 60 FR 16316, Mar. 29, 1995]

§ 721.185 Limitation or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to subpart E of this part using the procedures under § 721.160 or § 721.170. Such action may be taken under this section if EPA makes one of the following determinations,

unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to subpart E of this part under § 721.170 and has concluded that the substance does not meet the criteria under § 721.170(b).

(5) For a substance added to subpart E of this part under § 721.160, EPA has examined new information, or has reexamined the test data or other information or analysis supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act, and has concluded that a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

(6) For a substance added to subpart E of this part under § 721.160, certain activities involving the substance have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described under § 721.160

or § 721.170 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a chemical substance that has been added to subpart E of this part using the procedures described in § 721.160 or § 721.170 by submitting a request that is accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain the e-PMN software. Support documents related to these requests must also be submitted to EPA in the manner set forth in 40 CFR 720.40(c).

(2) The Director of the Office of Pollution Prevention and Toxics will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that substance should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a substance should be limited or revoked, EPA will propose the changes in the FEDERAL REGISTER, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[54 FR 31314, July 27, 1989, as amended at 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 76 FR 30836, May 27, 2011; 78 FR 72827, Dec. 4, 2013]

Subpart E—Significant New Uses for Specific Chemical Substances

§ 721.225 2-Chloro-N-methyl-N-substituted acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance 2-chloro-N-methyl-N-substituted acetamide (PMN P-84-393) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.