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 3428, Jan. 22, 1998]

§ 721.4467 Quaternary ammonium hydroxide.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as a quaternary ammonium hydroxide (PMN P-95–1806) 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) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(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 (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 3429, Jan. 22, 1998]

§ 721.4468 1H-Imidazole, 2-ethyl-4,5-dihydro-4-methyl-.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1H-imidazole, 2-ethyl-4,5-dihydro-4-methyl- (PMN P-97–217; CAS No. 931–35–1) 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) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N = 40).

(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 (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 3429, Jan. 22, 1998]

§ 721.4469 Imidazolethione.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as an imidazolethione (PMNs P-91–1131 and P-90–564) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. Formulations or mixtures containing the PMN substance in concentrations at or below 10 percent by weight or volume are exempt from the provisions of this rule.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(3), (b) (concentration set at 0.1 percent), and (c).

(ii) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(ix), (g)(2)(i), (g)(2)(v), and (g)(5). The label and MSDS as required by this paragraph shall also include the following statements: This substance may cause thyroid cancer. This substance may cause thyroid effects.

(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), (f), (g), and (h) 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 3429, Jan. 22, 1998]

§ 721.4470 2,4-Imidazolidinedione, bromochloro-5,5-dimethyl-.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance 2,4-

imidazolidinedione, bromochloro-5,5-dimethyl- (PMN P-94–34) 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 (v)(3), (w)(3), and (x)(3).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (where N = 10 ppb).

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

(1) *Recordkeeping requirements.* Recordkeeping requirements specified in § 721.125 (a), (b), (c), (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.

[60 FR 11043, Mar. 1, 1995]

§ 721.4472 Phenyl, alkyl, hydroxyalkyl substituted imidazole (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenyl, alkyl, hydroxyalkyl substituted imidazole (PMNs P-98–843 and P-86–65) are 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)(3), (a)(4), (a)(5)(iv), (a)(5)(v), (a)(5)(vi), (b) (concentration set at 1.0 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), and (g)(1)(iii).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(r) (56,000 kg) (acute oral study (OPPTS 870.1100 test guideline) followed by a (90-day subchronic inhalation study in rats (40 CFR 799.9346). 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)(iii)(A), (a)(2)(iii)(B), (a)(2)(iii)(C), and (a)(2)(iii)(D) of this section.

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

(*1*) The test guidelines specified in paragraph (a)(2)(iii) 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)(iii) 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)(iii) 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)(iii)(D)(*2*), 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.