

## Environmental Protection Agency

§ 721.2582

chemical substance identified generically as disubstituted diphenylsulfone (PMN P-92-1119) 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)(3), (a)(4), (a)(5)(i), (a)(5)(ii), (a)(5)(iv), (a)(5)(v), (a)(6)(i), (a)(6)(ii), (b) (concentration set at 0.1 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(1)(vi), (g)(1)(vii), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(ii), (g)(4)(iii), and (g)(5). The following additional statements shall appear on each label and MSDS as required by this paragraph: This substance may cause blood effects.

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

(iv) *Release to water.* Requirements as specified in § 721.90 (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) through (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.

[58 FR 51683, Oct. 4, 1993]

### § 721.2577 Copper complex of (substituted sulfonaphthyl azo substituted phenyl) disulfonaphthyl azo, amine salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as copper complex of (substituted sulfonaphthyl azo substituted phenyl) disulfonaphthyl azo, amine salt (PMNs P-00-0364 and P-00-0365) are subject to reporting under this section for the significant new use 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)(1), (w)(1), (x)(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 (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.

[68 FR 15082, Mar. 28, 2003]

### § 721.2580 C.I. Disperse Red 152 (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as C.I. disperse red 152 (PMN P-97-820) 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)(1), (w)(1), and (x)(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 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 44577, Aug. 20, 1998]

### § 721.2582 Reaction product of alkylene diamine, MDI, substituted carbomonocyclic amine and alkylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as reaction product of alkylene diamine, MDI, substituted carbomonocyclic amine and alkylamine (PMN P-98-1262) is subject to reporting under this section for the

significant new use 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.

[68 FR 15083, Mar. 28, 2003]

**§ 721.2584 Dodecanoic acid, 12-amino-**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as dodecanoic acid, 12-amino- (PMN P-98-0823; CAS No. 693-57-2) 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)(4), (a)(5)(iii), (a)(5)(iv), (a)(5)(v), (a)(5)(vi), (a)(5)(vii), (a)(6)(i), (b) (concentration set at 0.1 percent), and (g). As an alternative to the respiratory requirements listed here, a manufacturer, importer, or processor may choose to follow the NCEL provision listed in the 5(e) consent order for this substance. The NCEL is 1.0 mg/m<sup>3</sup> as an 8-hour time-weighted average verified by actual monitoring data.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e), (f), (g)(1)(ii), (g)(1)(vii), (g)(2)(ii), and (g)(2)(iv).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (g), (r) (6,000,000 kg.), and a carcinogenicity study (OPPTS 870.4200). 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) 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.