

**Basis for action:** The PMN substance will be used as a chemical intermediate. Based on data for monoepoxides, EPA has identified health concerns for mutagenicity, carcinogenicity, male reproductive toxicity, developmental toxicity, and liver and kidney toxicity for the epoxide. Also, based on analogy to epoxides, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 30 ppb of the PMN substance in surface waters. Since significant worker and environmental exposure is unlikely when the substance is used as described in the PMN, EPA has not determined that the manufacturing, processing, and use of the PMN substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as an intermediate could result in exposures which may cause serious health effects and significant adverse environmental effects. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii), (b)(1)(i) (C), and (b)(4)(ii).

**Recommended testing:** EPA has determined that a 90-day subchronic oral toxicity study in rodents (OPPTS 870.3100 test guideline), with attention to pathology of the reproductive organs, and a carcinogenicity study (OPPTS 870.4200 test guideline) would help to characterize the health effects of the substance. In addition, the following acute aquatic toxicity tests would help to characterize the environmental effects. A fish acute toxicity study (OPPTS 850.1075 test guideline (public draft)), a daphnid acute toxicity study (OPPTS 850.1010 test guideline (public draft)), and an algal toxicity study (OPPTS 850.5400 test guideline (public draft)). The fish and daphnid tests should be conducted with flow-through methods and measured concentrations. The algal test should be conducted with static methods and measured concentrations.

**CFR citation:** 40 CFR 721.5590.

**PMN Numbers P-00-0333 and P-00-0334**

**Chemical name:** (generic) Salt of an acrylate copolymer.

**CAS number:** Not available.

**Basis for action:** The PMN substances will be used as an additive. EPA has identified concerns for lung toxicity and lung tumors based on data on certain high molecular weight polymers. Since significant worker exposure is unlikely as inhalation exposure is not expected for the uses described in the PMNs, EPA has not determined that the proposed manufacturing, processing, and use of the substances may present an

unreasonable risk. EPA has determined, however, that uses of the substances in a solid form may cause serious health effects. Based on this information the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

**Recommended testing:** EPA has determined that a 90-day inhalation toxicity study with a 60-day holding period (OPPTS 870.3465 test guideline) would help characterize the human health effects of the PMN substance. Attention should be given to the lungs, including histopathology of the lungs (inflammation, epithelial hyperplasia, and fibrosis), bronchoalveolar lavage (BAL) analysis for markers of lung injury, and lung burden analysis for clearance of the test material (EPA-748-R-96-001). The neurotoxicity components and examination of organs other than the lungs are not required.

**CFR citation:** 40 CFR 721.338.

**PMN Number P-00-0351**

**Chemical name:** (generic) Amino-hydroxy sulfonaphthylazo-disubstituted phenyl azo benzene carboxylate salt.

**CAS number:** Not available.

**Basis for action:** The PMN substance will be used as described in the PMN. Based on submitted data on a 28-day study in rats with a no observed adverse effect level (NOAEL) of 25 mg/kg/day, EPA has identified concerns for liver and kidney effects. Additionally, based on analogy of the azo reduction product of the PMN substance, EPA has concerns for carcinogenicity, developmental toxicity, and immunotoxicity. Since significant worker exposure is unlikely as inhalation exposure is not expected for the use described in the PMN, EPA has not determined that manufacturing, processing, and use of the substance as described in the PMN may present an unreasonable risk. EPA has determined, however, that use of the substance as a solid may cause serious health effects. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii), (b)(3)(iii), and (b)(1)(i)(D).

**Recommended testing:** EPA has determined that a prenatal developmental toxicity study by the oral route in two species (OPPTS 870.3700 test guideline) and an Ames assay with the Prival modification and a concurrent positive control (OPPTS 870.5100 test guideline) would help to characterize the human health effects of the PMN substance.

**CFR citation:** 40 CFR 721.984.

**PMN Number P-00-0353**

**Chemical name:** (generic) Alkoxyated aliphatic diisocyanate allyl ether.

**CAS number:** Not available.

**Basis for action:** The PMN substance will be used as an additive for surface coatings and for plastics and plastic surfaces. Based on structural analogy to esters and allylic and vinyl ethers, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 9 ppb of the PMN substance in surface waters. Since significant environmental exposure is not expected, as the PMN substance is not released to surface waters, as described in the PMN, EPA has not determined that the proposed manufacturing, processing, and use of the substance may present an unreasonable risk. EPA has determined, however, that other uses of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

**Recommended testing:** EPA has determined that a fish chronic toxicity study (OPPTS 850.1400 test guideline (public draft)), a daphnid chronic toxicity study (OPPTS 850.1300 test guideline (public draft)), and an algal toxicity study (OPPTS 850.5400 test guideline (public draft)) would help to characterize the environmental effects of the PMN substance. The fish and daphnid tests should be conducted with flow-through methods and measured concentrations, dilution water hardness less than 180.0 mg/L as CaCO<sub>3</sub>. The algal test should be conducted with static methods and measured concentrations.

**CFR citation:** 40 CFR 721.9952.

**PMN Numbers P-00-0364 and P-00-0365**

**Chemical name:** (generic) Copper complex of (substituted sulfonaphthyl azo substituted phenyl) disulfonaphthyl azo, amine salt.

**CAS number:** Not available.

**Basis for action:** The PMN substances will be used as described in the PMNs. Based on analogy to structurally similar substances, EPA has identified concerns for mutagenicity, carcinogenicity, and developmental toxicity. Since significant worker exposure is unlikely as inhalation exposure is not expected for the uses described in the PMNs, EPA has not determined that the proposed manufacturing, processing, and use of the substances may present an unreasonable risk. EPA has determined, however, that use of the substances as a powder may cause serious health effects. Based on this information the PMN substances meet the concern criteria at § 721.170(b)(3)(ii) and (b)(1)(i)(C).

**Recommended testing:** EPA has determined that a prenatal