

developmental toxicity study by the oral route in two species (OPPTS 870.3700 test guideline) would help to characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.2577.

PMN Number P-00-0420

Chemical name: (generic) Substituted phenylazophenylazo phenol.

CAS number: Not available.

Basis for action: The PMN substance will be used as a colorant. Based on structural analogy to phenols, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 1 ppb of the PMN substance in surface waters. Since significant environmental exposure is not expected, as the 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 water 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 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)) 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. The algal test should be conducted with static methods and measured concentrations. Dilution water hardness less than 180.0 mg/L as CaCO₃.

CFR citation: 40 CFR 721.843

PMN Number P-00-0469

Chemical name: Glycine, N-(carboxymethyl)-N-dodecyl-, monosodium salt.

CAS number: 141321-68-8.

Basis for action: The PMN substance will be used as a surfactant. Based on structural analogy to alkyl amphoteric surfactants, 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 environmental exposure is not expected as the PMN substance is not released to surface water above 30 ppb, as described in the PMN, EPA has not determined that the proposed manufacturing, processing, and use of the substance may present an

unreasonable environmental risk. EPA has determined, however, that other uses of the substance resulting in release to surface water above 30 ppb 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 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, dilution water total organic carbon TOC < 2.0 mg TOC/L dilution water hardness < 180.0 mg/L as CaCO₃, and stock solution adjusted to pH 7.0.

CFR citation: 40 CFR 721.3848.

PMN Number P-00-0490

Chemical name: (generic) Substituted acrylamides and acrylic acid copolymer.

CAS number: Not available.

Basis for action: The PMN substance will be used as a delivery substrate. EPA has identified concerns for lung toxicity and carcinogenicity if the substance is inhaled based on data for certain high molecular weight polymers. Since significant worker exposure is unlikely as inhalation exposure to worker is not expected for the use described in the PMN, EPA has not determined that the proposed manufacturing, processing, and use of the substances may present an unreasonable risk. EPA has determined, however, that domestic manufacture, or processing and use of the substance in a powder form may cause serious health effects. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(1)(i)(C).

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 721.321.

PMN Number P-00-0542

Chemical name: (generic) Substituted phenols and formaldehyde polymer, alkylated.

CAS number: Not available.

Basis for action: The PMN substance will be used as a resin for can and tube coatings. Based on structural analogy to polyphenol reaction products, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 4 ppb of the PMN substance in surface waters. Since significant environmental exposure is unlikely, as the 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 prevent an unreasonable risk. EPA has determined, however, that other uses of the substance resulting in releases 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 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)) 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 concentration. The algal test should be conducted with static methods and measured concentration. Dilution water hardness < 180 mg/L as CaCO₃.

CFR citation: 40 CFR 721.3812.

PMN Number P-00-0559

Chemical name: (generic) Methylated-para-rosaniline salt of a trisulfonated triarylmethane dye.

CAS number: Not available.

Basis for action: The PMN substance will be used as a colorant for inks. EPA has identified health concerns for carcinogenicity and developmental toxicity based on analogy to gentian violet. Since significant worker exposure is unlikely when the substance is used as described in the PMN, EPA has not determined that the proposed processing and use of the substance may present an unreasonable risk. EPA has determined however, that domestic manufacturing could result in exposures which may cause serious health effects. Also, based on analogy to cationic dyes, EPA is also concerned that toxicity to aquatic organisms may occur at a concentration as low as 2 ppb of the