

significant worker exposure is unlikely when used as described in the PMN, EPA has not determined that the proposed manufacturing, processing, and use of the substance may cause significant adverse effects. EPA has determined, however, that use of the PMN substance other than as described in the PMN could result in exposures which may cause serious health effects. In addition, EPA has identified health concerns for potential incineration products for the PMN substance based on analogy to perfluorinated octane sulfonate (PFOS) and perfluorinated octanoic acid (PFOA). These incineration products are PBT. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that a 90-day inhalation toxicity study in rats with a 60-day holding period (OPPTS 870.3465 test guideline) would help characterize the human health effects of the PMN substance. Special attention should be given to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF), e.g., marker enzyme activities, total protein content, total cell count, cell differential, and cell viability. It is not necessary to look at internal organs. The Agency has also determined that the following tests would help characterize fate and ecotoxicity of the PMN substance: A Decomposition Kinetics by Thermogravimeter (ASTM E1641), a Compositional Analysis by Thermogravimeter (ASTM E1131), and a Laboratory "Burn" test - protocol to be agreed upon by EPA and the Company. The purpose of this test is to determine the disposition of the material and to identify degradates, especially the presence of components that can lead to the formation of perfluoro alkyl carboxylic acid after burning or incineration.

CFR citation: 40 CFR 721.9502.

PMN Number P-00-1195

Chemical name: Xanthylum, 9-(2-(ethoxycarbonyl)phenyl)-3,6-bis(ethylamino)-2,7-dimethyl-, ethyl sulfate.

CAS number: 26694-69-9.

Basis for action: The PMN substance will be used as a dye for complex basic dye pigment manufacture. Based on submitted test data for an analog, EPA has identified health concerns for toxic effects to the liver and heart. Since significant worker exposure is unlikely when used 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 domestic manufacture or use of the PMN substance other than as an intermediate could result in serious health effects. Also, based on structural analogy to cationic dyes, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 2 ppb of the PMN substance in surface waters. Since significant environmental exposure is not expected when the PMN substance is used as described in the PMN, EPA has not determined that the proposed use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN may cause significant adverse environmental effects. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that an acute oral toxicity study (40 CFR part 799.9110(d)(1)(i)(A)), a Salmonella typhimurium reverse mutation assay (OPPTS 870.5100 test guideline), a 28-day oral toxicity study Organization for Economic Cooperation and Development (OECD) guideline no. 407 or OPPTS 870.3050 test guideline), and an *in vivo* mammalian cytogenetics test by the intraperitoneal (i.p.) route: micronucleus assay (OPPTS 870.5395 test guideline) would help to characterize the human health effects of the PMN substance. EPA has also 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 acute 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 721.2465.

PMN Number P-01-0432

Chemical name: (generic) Bis heterocyclic phenylene derivative.

CAS number: Not available.

Basis for action: The PMN substance will be used as a reactive modifier for polymeric substances. EPA has identified health concerns for neurotoxicity, developmental toxicity, mutagenicity, carcinogenicity, lung and liver toxicity, and sensitization based on test data. Since significant worker exposure is unlikely because there

would not be significant inhalation exposure for the use identified in the PMN, EPA has not determined that the proposed manufacturing, processing, and use of the substance as described in the PMN present an unreasonable risk. EPA has determined, however, that an increase in production volume over that described in the PMN could result in significant exposure to human health. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(1)(i)(A).

Recommended testing: EPA has determined that a mouse micronucleus test by the i.p. route (OPPTS 870.5395 test guideline) and a 28-day oral toxicity in rats OECD guideline number 407 or (OPPTS 870.3050) with a Functional Observational Battery (FOB) would help to characterize the health effects of the substance. If the above tests indicate a health concern, then the following tests may be necessary to qualify the potential health effects: a 90-day subchronic oral study in rats (OPPTS 870.3100 test guideline), a prenatal development toxicity study by oral route in two species (OPPTS 870.3700 test guideline), a reproduction and fertility effects (OPPTS 870.3800 test guideline), and a carcinogenicity study (OPPTS 870.4200 test guideline).

CFR citation: 40 CFR 721.5925.

IV. Objectives and Rationale of the Rule

During review of the PMNs submitted for the chemical substances that are subject to this SNUR, EPA concluded that for 3 of the 62 substances, regulation was warranted under section 5(e) of TSCA, pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the substances. The basis for such findings is outlined in Unit III. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters; the SNUR provisions for these substances designated herein are consistent with the provisions of the TSCA section 5(e) consent orders.

In the other 59 cases for which the proposed uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at 40 CFR 721.170 were met.

EPA is issuing this SNUR for specific chemical substances which have undergone premanufacture review to ensure that:

1. EPA will receive notice of any company's intent to manufacture, import, or process a listed chemical