

subchronic study in rats (OPPTS 870.3465 test guideline) would help characterize the human health effects of the PMN substance. EPA has also determined that a fish acute toxicity study (OPPTS 850.1075 test guideline), a daphnid acute toxicity study (OPPTS 850.1010 test guideline), and an algal acute toxicity study (OPPTS 850.5400 test guideline) would help to characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.1747.

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 5 of the 65 chemical 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 chemical 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 chemical substances listed in this document are consistent with the provisions of the TSCA section 5(e) consent orders.

In the other 60 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 substance for a significant new use before that activity begins.
 2. EPA will have an opportunity to review and evaluate data submitted in a SNUR notice before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for a significant new use.
 3. When necessary, to prevent unreasonable risks, EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before a significant new use of that chemical substance occurs.
 4. All manufacturers, importers, and processors of the same chemical substance which is subject to a TSCA section 5(e) consent order are subject to similar requirements.
- Issuance of a SNUR for a chemical substance does not signify that the

chemical substance is listed on the TSCA Inventory. Manufacturers, importers, and processors are responsible for ensuring that a new chemical substance subject to a final SNUR is listed on the TSCA Inventory.

V. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in 40 CFR 721.160(c)(3) and 721.170(d)(4). In accordance with 40 CFR 721.160(c)(3)(ii), this rule will be effective February 17, 2004, unless EPA receives a written notice by January 16, 2004, of adverse or critical comments, or notice of intent to submit adverse or critical comments on EPA's action. If EPA receives such a notice, EPA will publish a document to withdraw the direct final SNUR for the specific chemical substance to which the adverse or critical comments apply. EPA will then propose a SNUR for the specific chemical substance providing a 30-day comment period.

This action establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in a notice.

VI. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them. In cases where a TSCA section 5(e) consent order requires or recommends certain testing, Unit III. lists those recommended tests.

However, EPA has established production limits in the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These production limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the

TSCA section 5(e) consent orders are included in Unit III. The SNURs contain the same production volume limits as the consent orders. Exceeding these production limits is defined as a significant new use.

The recommended studies may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on:

1. Human exposure and environmental release that may result from the significant new use of the chemical substances.
2. Potential benefits of the chemical substances.
3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VII. Procedural Determinations

EPA is establishing through this rule some significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2. EPA is required to keep this information confidential to protect the CBI of the original PMN submitter. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This procedure appears in 40 CFR 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the chemical substance subject to a SNUR is CBI. This procedure is cross-referenced in each of these SNURs.

A manufacturer or importer may request EPA to determine whether a proposed use would be a significant new use under this rule. Under the procedure in § 721.1725(b)(1), a manufacturer or importer must show that it has a *bona fide* intent to manufacture or import the chemical substance and must identify the specific use for which it intends to manufacture or import the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or import the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances