

that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 25, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In §180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * * *	*	*
Polyglyceryl phthalate ester of coconut oil fatty acids (CAS Reg. Nos. 67746-6070-9		Surfactants, related adjuvants of surfactants
* * * *	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2006-0898; FRL-8398-5]

RIN 2070-AB27

Dodecanedioic acid, 1, 12-dihydrazide and Thiophene, 2,5-dibromo-3-hexyl-; Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances which were the subject of premanufacture notices (PMNs). The two substances are dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555) and thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283). Today's action requires persons who intend to manufacture, import, or process either of these two substances for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because these chemical substances may be hazardous to human health and the environment. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective August 7, 2009

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2006-0898. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some

information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Karen Chu, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8773; e-mail address: chu.karen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use either of the chemical substances contained in this rule: Dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555) and thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283). Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325

and 324110), e.g., Chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

II. Background

A. What Action is the Agency Taking?

EPA is finalizing SNURs under section 5(a)(2) of TSCA for two chemical substances which were the subject of premanufacture notices (PMNs). The two substances are dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555) and thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283). This action requires persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** of September 19, 2007 (72 FR 53470)

(FRL-8135-8), EPA issued direct final SNURs on these two substances (see 40 CFR 721.10057 and 721.10088).

However, EPA received notices of intent to submit adverse comments on these SNURs. Therefore, as required by 40 CFR 721.170(d)(4)(i)(B), EPA withdrew the direct final SNURs on these two substances and subsequently proposed SNURs under notice and comment procedures (June 9, 2008 (73 FR 32508) (FRL-8351-4)). The record for the direct final and proposed SNURs for these substances was established as docket EPA-HQ-OPPT-2006-0898. That record includes information considered by the Agency in developing the direct final rule and this final rule including comments on the direct final and proposed rules.

EPA received no comments regarding the proposed SNUR on dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555) and is finalizing the rule as proposed. Significant new use designations for this substance are summarized as follows: Use of the substance without 1) workers wearing gloves, 2) workers wearing a National Institute for Occupational Safety and Health (NIOSH) approved full-face respirator with an assigned protection factor (APF) of at least 50, and 3) appropriate hazard communication. See the proposed rule for a complete discussion of the basis for EPA's action, including hazard concerns for the substance and recommended testing.

EPA received comments from Plextronics, the submitter of the PMN on thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283) (Ref. 1). A discussion of EPA's response to these comments is included in Unit V. Based on these comments, EPA is issuing a modified final rule on this substance that (1) retains the proposed maximum surface water concentration limit trigger of 1 part per billion (ppb) from manufacturing, processing, and use, and (2) raises the annual company manufacture and import volume limit trigger from 500 kilograms to 4,500 kilograms.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) (15 U.S.C. 2604(a)(1)(B)) requires persons to

submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must submit a SNUN are described in 40 CFR 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy statement in support of the import certification appears at 40 CFR part 707, subpart B.

III. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA determined that one or more of the criteria of concern established at 40 CFR 721.170 were met. For a discussion of the rationale for the SNUR on dodecanedioic acid, 1, 12-dihydrazide

(CAS No. 4080-98-2; PMNs P-01-759 and P-05-555), see Unit III. of the direct final SNUR (September 19, 2007 (72 FR 53470)) and Unit IV. of the proposed SNUR (June 9, 2008 (73 FR 32508)). For a discussion of the rationale for the SNUR on thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283), see Units IV. and V. of this document, as well as Unit III. of the direct final SNUR (September 19, 2007 (72 FR 53470)) and Unit IV. of the proposed SNUR (June 9, 2008 (73 FR 32508)).

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUR before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

EPA's decision to designate a maximum surface water concentration of 1 ppb as a significant new use for thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283) primarily reflects consideration of the third and fourth factors listed in the bulleted items in Unit IV. Based on structure activity relationship analyses for thiophenes, EPA is concerned that toxicity to aquatic organisms may occur at concentrations above 1 ppb of the PMN substance in surface waters. Initial review of the PMN showed that releases of the PMN substance to surface waters from manufacturing, processing, and use of the PMN substance at sites other than those identified in the PMN that have less protective management practices could result in surface water concentrations above 1 ppb for more than 20 days per year, thereby presenting a chronic risk to aquatic organisms (Ref. 2). Additionally, the substance is expected to significantly bioaccumulate (Ref. 5).

EPA's decision to also designate an annual manufacture and import volume of 4,500 kilograms as a significant new use for thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283) reflects consideration of the first factor, the projected volume of manufacturing and processing of a chemical substance. The use of thiophene and its derivatives in electronic applications is escalating. Plextronics' website indicates the technology involving this substance 1) is capable of "commercial-scale manufacturability," and 2) that the market for such "printed electronics was approximately \$1 billion in 2006 and is expected to exceed \$300 billion within 20 years" (Ref. 3). Thus, it is reasonable to expect that use of the substance may grow significantly beyond the 3rd-year estimate in the PMN and that those higher manufacture and import volumes would result in increased environmental exposure to the PMN substance.

V. Response to Comments on Proposed SNUR on Thiophene, 2,5-dibromo-3-hexyl-

EPA received comments from the submitter, Plextronics, on the proposed SNUR for thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283) (Ref. 1). A discussion of the comments and the Agency's responses follows.

Comment 1: EPA's structure activity relationship analysis is not supported by valid test data on analogous substances.

Response: EPA's Structure Activity Relationships (SARs) predictions for thiophenes are supported by

scientifically valid ecotoxicity test results on algae, daphnia, and fish on multiple thiophene substances (Ref. 4). For example, the measured daphnid chronic value was 1.8 parts per million (ppm) for one thiophene substance, whose chemical identity was claimed as TSCA confidential business information. The measured log octanol/water partition coefficient (log K_{ow}) value for this CBI substance was 1.7. The difference between the measured toxicity values supporting the thiophene SARs and the predicted chronic aquatic concentration of concern of 1 ppb for thiophene, 2,5-dibromo-3-hexyl is almost completely due to differences in their measured or estimated log K_{ow} values. This is especially the case at relatively high log K_{ow} values. The estimated log K_{ow} for thiophene, 2,5-dibromo-3-hexyl is 6.6.

Importantly, because the toxicity of chemical classes converge at log K_{ow} values of 5-8, the 1 ppb level is also supported by use of neutral organic SARs, which are supported by many valid test data points (Ref. 4). The predicted chronic concentration of concern for thiophene, 2,5-dibromo-3-hexyl (CAS No. 116971-11-0; PMN P-07-283) using neutral organic SARs is also 1 ppb. Thus, based on this further examination of the data and calculations regarding the aquatic toxicity of the substance, the Agency finds that the PMN substance meets the concern criteria at § 721.170(b)(4)(iii) as well as the concern criteria at § 721.170(b)(4)(ii), which was indicated in the previous direct final rule and proposed rule on the substance.

Comment 2: The rulemaking record does not contain information indicating that release of the substance may present an unreasonable risk, i.e., result in surface water concentrations above the 1 ppb concentration of concern, at an annual production volume of 500 kilograms or greater. Therefore, the Agency has not justified the need for a production volume limit.

Response: Congress did not require in TSCA that EPA must find that a significant new use may present unreasonable risk. Rather, TSCA section 5(a)(2) requires only that EPA "consider all relevant factors" when promulgating a SNUR. According to 40 CFR 721.170(a), EPA may issue significant new use notification and recordkeeping requirements if EPA determines that "activities other than those in the premanufacture notice may result in significant changes in human exposure or environment release levels and/or concern exists about the substance's health or environmental effects" (also see 40 CFR 721.170(c)(2)). As discussed

in Unit IV., it is reasonable to expect that use of the substance may grow significantly beyond the 3rd-year estimate stated in the PMN and that higher production volumes will result in increased environmental exposure to the PMN substance. Also, EPA has hazard concerns for the substance; the Agency has determined that the substance may be highly toxic to aquatic organisms and meets the concern criterion at § 721.170(b)(4)(ii) and § 721.170(b)(4)(iii). Receipt of a SNUN allows EPA to review and assess potential risks that might be presented by significant new use activities.

Additionally, the EPA exposure report in the docket that predicts low concern for aquatic toxicity effects at the stated PMN production volume reflects surface water concentration estimates based on the site, operations, and management practices identified in the PMN and subsequent submitter correspondence. Initial review of the PMN showed that manufacturing, processing, and use of the PMN at sites other than those identified in the PMN that have less protective management practices could result in releases of the substance that would result in surface water concentrations above 1 ppb for more than 20 days per year (Ref. 2). This difference in risk estimates based on site and management practices further supports the Agency's concerns regarding the chemical substance and the basis for this SNUR.

Comment 3: Designation of both annual production (i.e., manufacture and import) volume and water release triggers as a significant new use is unjustified.

Response: EPA respectfully disagrees. Unit IV. contains the justifications for the water release and production volume significant new use triggers. Surface water concentration and production volume each may make an independent contribution to risk. This is because production volume can be highly related to exposure even where surface water concentration remains the same. The Agency currently uses the industry-provided, 3rd-year production volume estimate in the PMN to assess the potential environmental and health effects of a new chemical. Thus, if EPA has reason to believe that the production volume for a substance of concern could significantly surpass that designated in the PMN for the first three years of manufacture, EPA will consider taking regulatory action and designating some production volume as a significant new use.

Comment 4: If a production (i.e., manufacture and import) volume limit is justified, it should be set at a

significant level above the 3rd-year volume in the PMN and also be set at a level where the recommended testing is economically feasible.

Response: In consideration of the comments received on the proposed SNUR, expected market growth, and review of analogous substances, EPA is raising the annual company production volume limit in the final SNUR to 4,500 kilograms. EPA views this volume as significantly different from the 3rd-year production volume estimate in the PMN. Notably, in designating this volume as a significant new use, EPA is not trying to predict or imply at what volume a risk could occur or to estimate at what aggregate volume would any recommended testing on the substance be economically feasible.

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication of the proposed SNUR were considered ongoing, rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Any person who began commercial manufacture, import, or processing of dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555) or thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283) for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR must stop that activity before the effective date of this rule. Persons who ceased those activities will have to meet all SNUR notice requirements and wait until the end of the notification review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who began manufacture, import, or processing of either of these chemical substances between the date of publication of the proposed SNUR and the effective date of this final SNUR meet the conditions of advance compliance as codified at 40 CFR 721.45(h), those persons would be

considered to have met the final SNUR requirements for those activities.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN (except where the chemical substance subject to the SNUN is also subject to a section 4 test rule). 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 (40 CFR 721.25(a) and 720.50.) However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit III. of the proposed rule (June 9, 2008 (73 FR 32508)) lists recommended testing for these two substances. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Many test guidelines are now available on the Internet at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

The recommended tests 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 the following:

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

VIII. SNUN Submissions

SNUNs must be mailed to the Environmental Protection Agency, OPPT Document Control Office (7407M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Information must be submitted in the form and manner set forth in EPA Form No. 7710-25. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 (see 40 CFR 721.25 and 720.40). Forms

and information are also available electronically at <http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm>.

IX. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of these two chemical substances at the time of the direct final rule. The Agency's complete Economic Analysis is available in the public docket for the direct final rule (Ref. 6). For dodecanedioic acid, 1, 12-dihydrazide (CAS No. 4080-98-2; PMNs P-01-759 and P-05-555), the difference in hazard communication requirements between this final SNUR and the direct final SNUR (i.e., removal of the requirement for specific identification of cancer and developmental toxicity endpoints in workplace hazard communication materials) could slightly reduce estimated costs to regulated entities. For thiophene, 2,5-dibromo-3-hexyl- (CAS No. 116971-11-0; PMN P-07-283), the manufacture and import volume limit is higher in the final SNUR than in the direct final SNUR (4,500 kg/yr vs. 500 kg/yr). While the higher manufacture and import volume limit does not directly change SNUN costs, it should make it more feasible for regulated entities to elect to submit the recommended testing for the substance with the SNUN.

X. References

The official record for this final rule has been established. The following is a listing of the documents referenced in this preamble that have been placed in the docket for this final rule under docket ID number EPA-HQ-OPPT-2006-0898, which is available for inspection as specified under

ADDRESSES.

1. Plextronics. Comments on the Proposed Significant New Use Rule for the Chemical Substance under Premanufacture Notice Case Number P-07-0283. July 8, 2008. EPA-HQ-OPPT-2006-0898-0069.2.
2. EPA. Sanitized Initial Review Exposure Report for P-07-283 at SIC Code. March 16, 2007. EPA-HQ-OPPT-2006-0898-0083.
3. Plextronics. Plextronics Webpage (www.plextronics.com/aboutus.aspx). November 5, 2008. EPA-HQ-OPPT-2006-0898-0084.
4. EPA. Ecological Structure Activity Relationships for Neutral Organics and Thiophenes. 2007. EPA-HQ-OPPT-2006-0898-0086.
5. EPA. Sanitized Engineering and Structure Activity Team Reports for P-

07-283. March, 2007. EPA-HQ-OPPT-2006-0898-0057.

6. EPA. Economic Analysis of Expedited Significant New Use Rule for 38 Chemical Substances. August 13, 2007. EPA-OPPT-2006-0898-0058.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070-0012 (EPA ICR No. 0574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 110 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006-2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit IX.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with these SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published on June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rulemaking. As such, EPA has determined that this regulatory action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates

Reform Act of 1995 (UMRA) (Public Law 104-4).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly or uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental*

Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: June 30, 2009.

Wendy C. Hamnett,

Acting Director, Office of Pollution Prevention and Toxics.

■ Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. By adding new § 721.10057 to subpart E to read as follows:

§ 721.10057 Dodecanedioic acid, 1, 12-dihydrazide.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as dodecanedioic acid, 1, 12-dihydrazide (PMNs P-01-759 and P-05-555; CAS No. 4080-98-2) 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)(1), (a)(2)(i), (a)(3), (a)(4), (a)(5), (a)(6)(i), (a)(6)(ii), (b), and (c).

Respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. The following NIOSH-approved respirators meet the minimum requirement for § 721.63(a)(4): Air-purifying, tight-fitting full-face respirator equipped with N100

(if oil aerosols absent), R100, or P100 filters; powered air-purifying respirator equipped with a tight-fitting full facepiece and High Efficiency Particulate Air (HEPA) filters; supplied air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece. Because the substance is a dermal sensitizer and irritates mucous membranes, half-face respirators do not provide adequate protection.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(i), and (g)(2)(i).

(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), (d), (e), (f), (g), and (h) 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. By adding new § 721.10088 to subpart E to read as follows:

§ 721.10088 Thiophene, 2,5-dibromo-3-hexyl-.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as thiophene, 2,5-dibromo-3-hexyl- (PMN P-07-283; CAS No. 116971-11-0) 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(s) (4,500 kilograms).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=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), (b), (c), (i), 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.

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