

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 721 and 799**

[EPA-HQ-OPPT-2010-0520; FRL-8876-6]

RIN 2070-AJ66

Certain High Production Volume Chemicals; Test Rule and Significant New Use Rule; Fourth Group of Chemicals**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: EPA is proposing to issue a test rule under Toxic Substances Control Act (TSCA) section 4(a)(1)(B) to require manufacturers and processors of 23 high production volume (HPV) chemical substances to develop screening-level health, environmental, and fate data based on the potential for substantial exposures of workers and consumers to these chemicals. EPA is also proposing to issue simultaneously a significant new use rule (SNUR) for another 22 HPV chemical substances under TSCA section 5(a)(2). The SNUR would require persons to file a significant new use notice (SNUN) with EPA prior to manufacturing, importing, or processing any of these chemical substances for use in a consumer product or for any use, or combination of uses, that is reasonably likely to expose 1,000 or more workers at a single corporate entity. 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. EPA is also soliciting comment on a number of issues with regard to both the test rule and the SNUR.

DATES: Comments must be received on or before January 19, 2012.

You may submit a request for an opportunity to present oral comments. This request must be made in writing. If such a request is received on or before January 19, 2012, EPA will hold a public meeting on this proposed rule in Washington, DC.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0520, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. *Attention:* Docket ID Number EPA-HQ-OPPT-2010-0520. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2010-0520. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: 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., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically 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 legal 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.

Submission of requests: You may submit a request for an opportunity to present oral comments. This request must be made in writing and submitted to the mailing or hand delivery addresses provided in this unit. If such a request is received, EPA will announce the scheduling of the public meeting in a subsequent document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Robert Jones (test rule) or Amy Breedlove (SNUR), Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (202) 564-8161 or (202) 564-9823; *e-mail address:* jones.robert@epa.gov or breedlove.amy@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; *telephone number:* (202) 554-1404; *e-mail address:* TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this action apply to me?**

You may be potentially affected by these actions if you manufacture (defined by statute to include import) or process any of the chemical substances that are listed in Tables A. or B. in Unit III. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of one or more of the subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

- Processors of one or more of the 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. If you have any questions regarding the applicability of this action to a particular entity, consult either 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. See Unit VI. for export notification requirements.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

C. Can I request an opportunity to present oral comments to the agency?

You may submit a request for an opportunity to present oral comments. This request must be made in writing. If such a request is received on or before January 19, 2012, EPA will hold a public meeting on this proposed rule in Washington, DC. This written request must be submitted to the mailing or hand delivery addresses provided under **ADDRESSES**. If such a request is received, EPA will announce the scheduling of the public meeting in a subsequent document in the **Federal Register**. If a public meeting is announced, and if you are interested in attending or presenting oral and/or written comments at the public meeting, you should follow the instructions provided in the subsequent **Federal Register** document announcing the public meeting.

II. Background

A. What action is the agency taking and why?

Congress gave EPA (also referred to as "Agency") broad authority to require testing of chemical substances when EPA can establish a minimum level of risk concern for a chemical substance (hazard and exposure are considered), and/or when EPA can establish that there is or may be substantial production and release or exposure of a chemical substance (production volume and exposure are considered). HPV chemical substances often have either significant release or human exposure scenarios that would stimulate EPA interest and support an EPA decision to require testing or to require notification before additional exposures occur. EPA is proposing to regulate 45 HPV chemical substances with either a test rule or a SNUR. EPA is proposing a test rule under TSCA section 4(a)(1)(B) for 23 of these 45 HPV chemical substances and a SNUR under TSCA section 5(a)(2) for the other 22 HPV chemical substances (see Tables A. and B. in Unit III.).

These 45 HPV chemical substances are among the chemical substances that were included in EPA's HPV Challenge Program (hereafter HPV Challenge) initiated in 1998. Of the 2,782 chemical substances originally included in the HPV Challenge, 1,858 were officially sponsored either directly in the HPV Challenge or indirectly through international efforts, although 5 were later withdrawn. Another 416 of the 2,782 chemical substances were

removed from the scope of the HPV Challenge for a variety of reasons (e.g., polymers, inorganics, etc.). The remaining 508 of the 2,782 chemical substances were termed "orphans" because they were not sponsored and there were no other factors that removed the chemical substances from the scope of the HPV Challenge. Of the 508 orphans, 405 are no longer produced at HPV levels. Of the remaining 103 chemical substances, 63 have been included in one of three test rules, or EPA has otherwise received data adequate to meet its needs. The remaining 40, plus the 5 chemical substances whose HPV Challenge sponsorships were withdrawn, are the subject of this proposed test rule and SNUR. For more information on the HPV Challenge go to <http://www.epa.gov/hpv/> or see the **Federal Register** of March 16, 2008 (71 FR 13708) (FRL-7335-2). This action contains the fourth and final test rule in the series and includes the last unsponsored/orphan chemical substances in the HPV Challenge.

The data that EPA seeks through the HPV Challenge is the Screening Information Data Set (SIDS) developed by the Organisation for Economic Co-operation and Development (OECD), of which the United States is a member. SIDS consists of tests for six endpoints (Ref. 1), including acute toxicity, repeated dose toxicity, developmental and reproductive toxicity, genetic toxicity, ecotoxicity, and environmental fate. The six SIDS endpoints provide a minimum, internationally-agreed-upon set of test data for screening HPV chemical substances for human and environmental hazards, and assist EPA and others in making an informed, preliminary judgment about the hazards of HPV chemical substances.

B. What is the agency's authority for taking these actions?

1. *Test rule.* EPA is proposing this test rule under TSCA section 4(a)(1)(B) which directs EPA to require by rule that manufacturers and/or processors of chemical substances and mixtures conduct testing, if the EPA Administrator finds that:

- i. A chemical substance or mixture is or will be produced in substantial quantities, and (1) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (2) there is or may be significant or substantial human exposure to such substance or mixture.
- ii. There are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such

substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted.

iii. Testing of such substance or mixture with respect to such effects is necessary to develop such data.

2. *SNUR*. Section 5(a)(2) of TSCA 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) requires persons to submit a SNUN to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

C. Applicability of General Provisions

1. *Test rule*. General provisions for test rules appear under 40 CFR part 790 (subparts A, B, C, and E), 40 CFR part 791, 40 CFR part 792, and 40 CFR part 799 (subpart A). 40 CFR part 790, subpart A, describes the scope, purpose, and authority for test rules and consent agreements, provisions for submitting information to the Agency, and the treatment of confidential business information. 40 CFR part 790, subpart B covers the procedures for developing consent agreements and test rules. 40 CFR part 790, subpart C covers the implementation, enforcement, and modification of test rules. This subpart includes information about persons subject to testing and required to submit letters-of-intent to conduct testing and persons who must submit testing exemption applications, and includes information about the submission of study plans and how to modify test standards and schedules if necessary. Subpart E of 40 CFR part 790 provides detailed information about exemptions from test rules. 40 CFR parts 791 and 792 respectively cover provisions for data reimbursement and required good laboratory practice standards. 40 CFR part 799, subpart A, provides additional information on the scope and purpose of the rule, the applicability of the rule, submitting information, test standards, the availability of test guidelines, distinguishing positive and negative results, the effects of non-compliance, chemicals for which the testing reimbursement period has passed, and imports and exports.

Persons who export or intend to export a chemical substance identified in a final test rule are subject to the export notification provisions of TSCA section 12(b). Regulations that interpret TSCA section 12(b) appear at 40 CFR

part 707, subpart D, notices of export under section 12(b).

2. *SNUR*. 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 SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (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.

D. What is the agency’s “B Policy”?

TSCA section 2(b) states that it is the policy of the United States that: (1) Adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures; (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures which are imminent hazards; and (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment (15 U.S.C. 2601(b)(1)).

TSCA section 4(a)(1)(B) authorizes and requires EPA to issue a test rule for a chemical substance if EPA finds, among other things, that the chemical substance “is or will be produced in substantial quantities” and either “enters or may reasonably be

anticipated to enter the environment in substantial quantities” or “there is or may be significant or substantial human exposure.”

TSCA, however, does not say what is “significant” or “substantial” under TSCA section 4(a)(1)(B). EPA, therefore, published a policy, known as the “B Policy,” in 1993 (Ref. 2) for aiding in the determination of when production or environmental release is substantial or when human exposure is either significant or substantial for the purpose of issuing a test rule under TSCA section 4(a)(1)(B). Under the “B Policy,” “produced in substantial quantities” generally means manufactured or imported in one million pounds or more per year; a “substantial environmental release” is generally either one million pounds per year or ten percent of total manufactured and imported volume, whichever is less; and “substantial human exposure” is generally 100,000 or more people in the general population, or 10,000 or more consumers, or 1,000 or more workers.

E. Why is the agency proposing both a test rule and a SNUR?

EPA is proposing these two actions together because the Agency believes the actions are complementary and will best ensure these HPV chemicals are adequately evaluated by the Agency. For example, if EPA receives comments on this proposal sufficient to establish that one of the 23 chemical substances proposed to be regulated under the test rule is not used in a way that meets the substantial exposure criteria, but information received indicates that the chemical substance meets the criteria for the SNUR, EPA intends to include the chemical substance in the final SNUR rather than the test rule, without further public notice and comment. Simply removing such a chemical substance from the test rule in such circumstances, without including it in the SNUR, would not provide a regulatory mechanism for timely notification to EPA in the event of changed circumstances that would likely justify the issuance of a test rule for the chemical substance. Further, if public comment on these proposed actions is sufficient to establish that any of the uses to be covered for the 22 chemical substances proposed in the SNUR are, in fact, on-going, yet such comments also establish that there is already substantial exposure to the chemical substance, EPA intends to review the status of the chemical substance and, as warranted, take appropriate steps to promulgate a test rule rather than a SNUR for the

chemical substance. Unit IV. of this document details the proposed findings to issue a test rule for the 23 chemical substances listed in Table A. and provides additional discussion pertaining to whether the promulgation of a test rule for 22 chemical substances listed in Table B. may be warranted. Unit V. of this document details the proposed findings to issue a SNUR for the 22 chemical substances listed in Table B. and the basis to issue a SNUR for the 23 chemical substances listed in Table A. in the event that public comments provide additional data establishing that, for one or more of such chemical substances, there is no ongoing use in a consumer product and no ongoing use reasonably likely to expose 1,000 or more workers.

F. What are some future considerations?

One of EPA's top priorities is to assure the safety of chemical substances in commerce. Under TSCA, EPA has a primary mission to identify and, where appropriate, control unreasonable risks of manufacturing, processing, distribution in commerce, use, and disposal of chemical substances. It is essential that chemical substance review be supported by information sufficient to allow informed decision making and that information and decisions are of high quality and are widely understandable. As such, EPA continues to collect information from existing sources, to request new and better information where it is determined to be needed, and to make all supporting information publicly available, to the extent permitted under TSCA section 14 and 40 CFR part 2. Open access to information allows individuals, communities, businesses, and governments to make informed decisions and policies that incorporate environmental and health considerations and minimize external and/or unintended harmful impacts. Therefore, EPA intends to continue to focus on filling data needs on priority chemical substances, including high production volume chemical substances. EPA is interested in stakeholder input on a number of issues described in this section. Some specific issues EPA has identified to date follow.

1. *Coordination of simultaneous test rule and SNUR proposals.* In this action, EPA is simultaneously proposing a test rule and SNUR to regulate two sets of chemical substances. EPA believes that this is an efficient way to require submission of test data on chemical substances that meet all of the necessary test rule criteria and (for the latter group

of chemical substances) to require submission of advance notification to EPA of use in a consumer product or of any use, or combination of uses, that is reasonably likely to expose 1,000 or more workers. With respect to chemical substances that meet some, but potentially not all test rule criteria, the SNUR also facilitates efficiency by mitigating the need for EPA to continually reevaluate each HPV chemical substance to determine whether exposure potential has changed. EPA is considering issuing further coordinated proposals of test rules and SNURs. This would occur in conjunction with future Inventory Update Reporting (IUR) rule data releases, covering all newly-HPV chemical substances. EPA requests comment on this approach. In September 2011, the IUR was renamed Chemical Data Reporting (CDR) and moved from 40 CFR part 710 subpart C to 40 CFR part 711 (76 FR 50816, August 16, 2011) (FRL-8872-9). For more information on this change go to <http://www.epa.gov/cdr>.

2. *Minimum data set.* For more than 15 years, EPA has used OECD's SIDS to facilitate and standardize the screening of the relatively large number of HPV chemical substances on the TSCA Inventory. EPA requests comment on whether SIDS continues to be the most appropriate data set to screen chemical substances for potential environmental and health hazards. Are additional or different tests also appropriate? Should EPA consider having more than one screening data set depending on the nature of exposures (e.g., a different set of tests for children's exposures or environmental releases)?

3. *Computational toxicology.* The U.S. National Academy of Sciences National Research Council in their 2007 report "Toxicity Testing in the 21st Century: A Vision and a Strategy" (Ref. 3) encouraged "work[ing] towards a transition to new integrative and predictive molecular and computational techniques to enhance efficiency and accuracy and to reduce reliance on animal testing." EPA requests suggestions on practical, implementable ways to work toward this goal in its actions under TSCA. Should tools such as ToxCast (at <http://www.epa.gov/comptox/toxcast>) (Ref. 4) be used to prioritize chemical substances and support hazard findings for testing?

III. Chemical Substances Subject to This Action

The 45 chemical substances included in this action are the remaining

unsponsored/orphan chemical substances, which have not previously been subject to test rules or other HPV Challenge-related follow-up actions. EPA is proposing to issue a test rule under TSCA section 4(a)(1)(B) for the 23 chemical substances listed in Table A. in this unit and proposing to establish a SNUR under TSCA section 5(a)(2) for the other 22 chemical substances (see Table B. in this unit). Respecting the 23 chemical substances proposed for a section 4(a)(1)(B) test rule (i.e., those in Table A.), in the event that public comments provide additional data respecting any of these chemical substances, establishing that there is no ongoing use in a consumer product and no ongoing use reasonably likely to expose 1,000 or more workers for any such substance, EPA intends to finalize a SNUR for each such chemical substance. Finally, with respect to the 22 chemical substances proposed for a SNUR (i.e., those in Table B.), in the event that public comments provide additional data establishing that there is already substantial exposure to the chemical substance, EPA intends to review the status of the chemical substance and, as warranted, take appropriate steps to promulgate a section 4(a)(1)(B) test rule for the chemical substance. For each of these chemical substances, Tables A. and B. provide the Chemical Abstract (CA) Index Name, Chemical Abstract Service (CAS) Registry Number (CASRN), and 2006 IUR information on production volume, number of workers exposed, and commercial/consumer uses. Substantial worker exposure is deduced from the number of workers reported. Substantial consumer exposure is deduced from production volume and consumer uses if production volume exceeds one million pounds per year and consumer uses are indicated, it is likely that consumer exposure exceeds ten thousand people.

For each of the test rule candidate chemical substances, EPA has used the 2006 IUR information to preliminarily determine that the chemical substance is produced in substantial quantities and that there is substantial human exposure. For each of the significant new use (SNU) candidates, EPA has considered the 2006 IUR information in determining the proposed SNU designations. These findings are discussed further in Unit IV.A.1., Unit V.A., and Ref. 5.

TABLE A—CHEMICAL SUBSTANCES FOR WHICH A TEST RULE IS PROPOSED AND FOR WHICH A SNUR IS BEING CONSIDERED AS AN ALTERNATIVE OPTION

CASRN	CA Index name	2006 IUR production volume (million lbs.)	2006 IUR number of workers exposed	Chemical substance meets the “B finding” criteria of ≥1,000 work- ers exposed	Commercial/Consumer uses indicated in 2006 IUR	Chemical substance meets the “B finding” criteria of ≥10,000 consumers exposed
56–40–6	Glycine	1 ≤ 10	1,000+	Yes	Other; CBI	Yes.
67–72–1	Ethane, 1,1,1,2,2,2-hexachloro- Plumbane, tetraethyl-	1 ≤ 10	1,000+	Yes	None	No.
78–00–2	Plumbane, tetraethyl-	1 ≤ 10	100–999	No	Lubricants, greases and fuel additives.	Yes.
95–14–7	1H-Benzotriazole	1 ≤ 10	100–999	No	Lubricants, greases and fuel additives; metal products; other.	Yes.
118–48–9	2H-3,1-Benzoxazine-2,4(1H)- dione.	10 ≤ 50	100–999	No	Agricultural products (non-pes- ticial); other.	Yes.
128–44–9	1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1).	1 ≤ 10	100–999	No	Other	Yes.
928–72–3	Glycine, N-(carboxymethyl)-, sodium salt (1:2).	500 ≤ 1,000	1,000+	Yes	None	No.
1809–19–4 ...	Phosphonic acid, dibutyl ester	1 ≤ 10	1,000+	Yes	CBI	Yes.
25377–73–5	2,5-Furandione, 3-(dodecen-1- yl)dihydro-.	1 ≤ 10	1–99	No	Other	Yes.
26544–38–7	2,5-Furandione, dihydro-3- (tetrapropenyl)-.	1 ≤ 10	100–999	No	Lubricants, greases and fuel additives; paints and coat- ings; not readily obtainable (NRO).	Yes.
27859–58–1	Butanedioic acid, 2- (tetrapropenyl)-.	1 ≤ 10	1,000+	Yes	Lubricants, greases and fuel additives; CBI.	Yes.
28777–98–2	2,5-Furandione, dihydro-3- (octadecen-1-yl)-.	10 ≤ 50	100–999	No	Paper products	Yes.
29385–43–1	1H-Benzotriazole, 6(or75)- methyl-.	1 ≤ 10	100–999	No	Lubricants, greases and fuel additives.	Yes.
32072–96–1	2,5-Furandione, 3-(hexadecen- 1-yl)dihydro-.	50 ≤ 100	1,000+	Yes	Paper products	Yes.
61789–73–9	Quaternary ammonium com- pounds, benzylbis(hydrogenated tal- low alkyl)methyl, chlorides.	1 ≤ 10	100–999	No	CBI	Yes.
64665–57–2	1H-Benzotriazole, 6(or7)-meth- yl-, sodium salt.	1 ≤ 10	100–999	No	Other	Yes.
68131–13–5	Naphthenic acids, reaction products with diethylenetriamine.	1 ≤ 10	1,000+	Yes	None	No.
68153–60–6	Fatty acids, tall-oil, reaction products with diethylenetriamine, acetates.	1 ≤ 10	1,000+	Yes	None	No.
68424–85–1	Quaternary ammonium com- pounds, benzyl-C12-16- alkyldimethyl, chlorides.	1 ≤ 10	1,000+	Yes	Other; CBI	Yes.
68442–77–3	2-Butenediamide, (2E)-, N1,N4- bis[2-(4,5-dihydro-2-nortall-oil alkyl-1H-imidazol-1-yl)ethyl] derivs.	1 ≤ 10	1,000+	Yes	None	No.
68607–28–3	Quaternary ammonium com- pounds, (oxydi-2,1- ethanediyl)bis[coco alkyldimethyl, dichlorides.	1 ≤ 10	1,000+	Yes	Other	Yes.
68909–18–2	Pyridinium, 1-(phenylmethyl)-, Et Me derivs., chlorides.	1 ≤ 10	1,000+	Yes	Other	Yes.
69834–17–9	Benzene, decylphenoxy-	1 ≤ 10	100–999	No	Soaps and detergents	Yes.

TABLE B—LIST OF CHEMICAL SUBSTANCES FOR WHICH A SNUR IS PROPOSED AND FOR WHICH A TEST RULE IS BEING CONSIDERED AS AN ALTERNATIVE OPTION

CASRN	CA Index name	2006 IUR production volume (million lbs.)	2006 IUR number of workers exposed	Chemical substance meets the "B finding" criteria of $\geq 1,000$ workers exposed	Commercial/consumer uses indicated in 2006 IUR	Chemical substance meets the "B finding" criteria of $\geq 10,000$ consumers exposed
98-16-8	Benzenamine, 3-(trifluoromethyl)-	1 \leq 10	1-99	No	None	No.
100-53-8	Benzenemethanethiol	1 \leq 10	1-99	No	None	No.
104-91-6	Phenol, 4-nitroso-	1 \leq 10	1-99	No	None	No.
110-03-2	2,5-Hexanediol, 2,5-dimethyl-	1 \leq 10	100-999 ..	No	None	No.
124-63-0	Methanesulfonyl chloride	1 \leq 10	100-999 ..	No	None	No.
142-30-3	3-Hexyne-2,5-diol, 2,5-dimethyl-	1 \leq 10	100-999 ..	No	None	No.
460-00-4	Benzene, 1-bromo-4-fluoro-	1 \leq 10	100-999 ..	No	Not readily obtainable (NRO).	No.
542-92-7	1,3-Cyclopentadiene	1 \leq 10	1-99	No	None	No.
553-26-4	4,4'-Bipyridine	10 \leq 50	100-999 ..	No	None	No.
8007-45-2	Tar, coal	1 \leq 10	1-99	No	None	No.
28106-30-1 ..	Benzene, ethenylethyl-	1 \leq 10	100-999 ..	No	None	No.
35203-06-6 ..	Benzenamine, 2-ethyl-6-methyl-N-methylene-	10 \leq 50	1-99	No	None	No.
35203-08-8 ..	Benzenamine, 2,6-diethyl-N-methylene-	10 \leq 50	1-99	No	None	No.
37734-45-5 ..	Carbonochloridothioic acid, S-(phenylmethyl) ester.	1 \leq 10	100-999 ..	No	None	No.
37764-25-3 ..	Acetamide, 2,2-dichloro-N,N-di-2-propen-1-yl-	1 \leq 10	1-99	No	None	No.
61789-72-8 ..	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides.	1 \leq 10	100-999 ..	No	None	No.
61790-13-4 ..	Naphthenic acids, sodium salts	1 \leq 10	100-999 ..	No	None	No.
65996-91-0 ..	Distillates (coal tar), upper	1 \leq 10	100-999 ..	No	None	No.
68308-01-0 ..	Tail gas (petroleum), cracked distillate hydrotreater stripper.	10 \leq 50	100-999 ..	No	None	No.
68478-20-6 ..	Residues (petroleum), steam-cracked petroleum distillates cyclopentadiene conc., C4-cyclopentadiene-free.	10 \leq 50	1-99	No	None	No.
68526-82-9 ..	Alkenes, C6-10, hydroformylation products, high-boiling.	1 \leq 10	100-999 ..	No	NRO	No.
68909-77-3 ..	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues.	1 \leq 10	100-999 ..	No	None	No.

IV. Proposed Section 4(a)(1)(B) Test Rule and Basis to Also Consider Table B. Chemical Substances for a Section 4(a)(1)(B) Test Rule

A. What are the proposed findings?

1. *Exposure findings.* EPA is proposing to require testing of the chemical substances listed in Table A. based on its preliminary findings under TSCA section 4(a)(1)(B)(i) relating to "substantial" production and "substantial human exposure," as well as findings under TSCA sections 4(a)(1)(B)(ii) and (a)(1)(B)(iii) relating to insufficient data and the need for testing. The chemical substances in Table A. are also listed in Table 2. of § 799.5090(j) of the proposed regulatory text along with their CASRNs.

i. *Are these chemical substances produced in substantial quantities?* EPA has made preliminary findings that each of the chemical substances included in this proposed test rule are produced in substantial quantities. In accordance with the "B policy" (discussed in Unit

II.D.), each of these substances is manufactured (which, as noted in Unit I.A., includes imported) in an amount equal to or greater than 1 million lbs. per year (Ref. 5). These findings are based on information gathered in the 2006 IUR the most recently available compilation of IUR (now CDR) data.

ii. *Are a substantial number of workers exposed to these chemical substances?* EPA has made preliminary findings that the manufacture, processing, and use of 12 of the 23 chemical substances listed in Table A. result or may result in exposure of a substantial number of workers to the chemical substances (Ref. 5).

For chemical substances whose total production volume (manufactured and imported) exceeded 300,000 lbs. at a site during calendar year 2005, manufacturers (which as noted in Unit I.A., includes importers) were required through the 2006 IUR to report the number of potentially exposed workers during industrial processing and use to the extent the information was readily

obtainable. Manufacturers of 12 of the 23 chemical substances listed in Table A. reported that more than 1,000 workers or more were potentially exposed to these chemical substances. Based on the threshold values stated in EPA's "B Policy," EPA believes that an exposure of 1,000 workers or more on a routine or episodic basis to a chemical substance or mixture is "substantial" as that term is used with reference to "human exposure" in TSCA section 4(a)(1)(B)(i). Therefore, EPA's preliminary finding is that there is or may be substantial human exposure (workers) to 12 of these 23 chemical substances.

iii. *Are a substantial number of consumers exposed to these chemical substances?* EPA has made preliminary findings that the manufacture, processing, and use of 18 of the 23 chemical substances listed in Table A. result or may result in exposure of a substantial number of consumers to the chemical substances (Ref. 5).

In addition to worker exposure information, manufacturers of more than 300,000 lbs. of a given chemical substance at a site during calendar year 2005 were required to provide information regarding the commercial and consumer uses of the chemical substance. EPA reviewed the consumer use information reported for the 2006 IUR and carefully considered the nature of those uses. These 18 chemical substances were found to be used in such products as tires, footwear, flooring, bottles, sporting equipment, games, soaps and detergents, and paper products. Based on this review, EPA has preliminarily concluded that the reported consumer uses may result in exposures to at least 10,000 consumers. Based on the threshold values stated in EPA's "B Policy," EPA believes that an exposure of 10,000 consumers or more to a chemical substance is "substantial" as that term is used with reference to "human exposure" in TSCA section 4(a)(1)(B)(i). Therefore, EPA's preliminary finding is that there is or may be substantial human exposure (consumers) to 18 of these 23 chemical substances.

2. *Are sufficient data available to evaluate these chemical substances?* Under TSCA section 4(a)(1)(B)(ii), EPA has preliminarily determined for the chemical substances in Table A. that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of these chemical substances, or of any combination of such activities, on human health or the environment.

In developing the testing requirements for chemical substances contained in Table A., EPA searched for available information on chemical/physical properties, environmental fate, ecotoxicity and human health effects, using the data sources outlined in the OECD guidelines found in section 3.1 (Reliability, Relevance and Adequacy) of the "Manual for the Investigation of HPV Chemicals" (Ref. 1) such as: The Beilstein Database, Chemical Rubber Company's Handbook of Chemistry and Physics, Hawley's Condensed Chemical Dictionary, Illustrated Handbooks of Physical-Chemical Properties and Environmental Fate for Organic Chemicals, Merck Index, Hazardous Substances Data Bank (HSDB), Toxicology Literature Online (TOXLINE), and the National Technical Information Service (NTIS). EPA also searched for available data as summarized in its HPV Information System (HPVIS) (Ref. 6). When appropriate, the Federal Research In

Progress (FEDRIP) database was also searched. Any information that was obtained from these searches was evaluated for data acceptability using the guidelines described on EPA's HPV Challenge Web site (<http://www.epa.gov/hpv>): "Guidance for Meeting the SIDS Requirements (the SIDS Guide)" and "Guidance for Assessing the Adequacy of Existing Data." Furthermore, data adequacy and reliability were evaluated using the OECD guidelines which can be found in section 3.1 of the OECD "Manual for the Investigation of HPV Chemicals" (Ref. 1). The results of EPA's data adequacy analysis can be found in the HPV4 Data Adequacy Evaluations document (Ref. 7).

Section 799.5090(j) of the proposed regulatory text lists each chemical substance and the SIDS tests for which adequate data are not currently available to the Agency. The Agency preliminarily finds that the existing data for one or more of the SIDS testing endpoints for each of the chemical substances listed in Table 2. in § 799.5090(j) of the proposed regulatory text (*i.e.*, chemical substances in Table A.) are insufficient to enable EPA to reasonably determine or predict the human health and environmental effects resulting from manufacture, distribution in commerce, processing, use, and disposal of these chemical substances.

To the extent that additional studies relevant to the testing proposed in this rulemaking are known to exist, EPA strongly encourages the submission of this information as comments to the proposed rule, including full citations for publications and full copies of unpublished studies. If EPA judges such data to be sufficient, corresponding testing will not be included in the final rule. Commenters may prepare a robust summary (Ref. 8) for each such study to facilitate EPA's review of the full study report or publication.

Persons who believe that adequate information regarding a chemical substance subject to this proposed rule can be developed using a category or the Structure-Activity Relationships (SAR) approach are encouraged to submit appropriate information, along with their rationale substantiating this belief, during the comment period on this proposed rule. If, based on submitted information and other information available to EPA, the Agency agrees, EPA will take such measures as are needed to avoid unnecessary testing in the final rule.

3. *Is testing necessary for these chemical substances?* EPA has also found preliminarily that testing the 23 chemical substances identified in Table

A. is necessary to develop the needed data (TSCA section 4(a)(1)(B)(iii)). EPA has not identified any "additional factors" as discussed in the "B Policy" (Ref. 2, p. 28743) to cause the Agency to use decision making criteria other than those described in the "B Policy." EPA knows of no other means to generate the SIDS data other than the testing proposed in this document, and therefore has preliminarily found that conducting the needed SIDS testing identified for the 23 chemical substances in Table A. is necessary to provide data relevant to a determination of whether the manufacture, processing, and use of the chemical substances does or does not present an unreasonable risk of injury to human health and the environment.

B. What is the basis to also consider chemical substances from Table B. for testing under section 4(a)(1)(B)?

As an alternative to issuing a SNUR, EPA is considering requiring testing of one or more of the chemical substances listed in Table B. EPA will consider this approach based on its preliminary findings under TSCA section 4(a)(1)(B)(i) relating to "substantial" production, its further analysis of the factors listed under TSCA sections 4(a)(1)(B)(ii) and (a)(1)(B)(iii) relating to insufficient data and the need for testing and additional data received in public comments. If information received in public comments establishes that consumer uses, or uses that could affect 1,000 workers or more, are already ongoing, then that information may indicate that a SNUR is inappropriate for the particular chemical substance listed in Table B. The same information, however, may prompt EPA to conclude that a test rule is appropriate for such a substance, since evidence of ongoing use may also be evidence of substantial human exposure. If public comments provide the basis to conclude that there is already or may be substantial human exposure to one of the chemical substances in Table B., and there is a basis to make the other findings required under TSCA sections 4(a)(1)(B)(ii) and (a)(1)(B)(iii), then EPA intends to review the status of the chemical substance and, as warranted, take appropriate steps to promulgate a test rule rather than a SNUR for the chemical substance.

EPA has made preliminary findings that each of the chemical substances listed in Table B. are produced in substantial quantities (manufactured, including imported, in an amount equal to or greater than 1 million lbs. per year (Ref. 5)). These findings are based on information gathered in the 2006 IUR

rule. The 2006 data are the most recently available compilation of IUR (now CDR) data.

C. What testing is being proposed in this action and is also being considered for chemical substances in Table B.?

EPA is proposing specific testing and reporting requirements for the chemical substances from Table A. (specified in § 799.5090(j) of the proposed regulatory text) and is also considering the same requirements with respect to the chemical substances listed in Table B. All of the proposed testing requirements are listed in Table 2. in § 799.5090(j) of the proposed regulatory text and consist of a series of test methods covering many of the endpoints in the OECD HPV SIDS testing battery.

EPA's TSCA 799 test guidelines (40 CFR part 799, subparts E and H) have been harmonized with the OECD test guidelines. However, EPA is specifying that the American Society for Testing and Materials International (ASTM International) or the TSCA 799 test guidelines be used rather than OECD test guidelines because the language in the ASTM International standards and the TSCA 799 test guidelines makes clear which steps are mandatory and which steps are only recommended. Accordingly, to comply with the testing being proposed, EPA is proposing that testing must be conducted in accordance with ASTM International or TSCA 799 test guidelines. Note: ASTM issues its test methods under a fixed designation (e.g., E1719); the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last re-approval. A superscript epsilon (e) indicates an editorial change since the last revision or re-approval. Most of the proposed testing requirements for a particular endpoint are specified in one test standard. In the case of certain endpoints, however, any of multiple listed methods could be used. For several of the proposed test standards, EPA has identified and is proposing certain "special conditions" as discussed in this unit. The following endpoints and test standards are included in this proposed test rule.

1. Physical/chemical properties.

Melting Point: ASTM E 324–99 (capillary tube) (Refs. 9 and 10).

Boiling Point: ASTM E 1719–05 (ebulliometry) (Ref. 11). Vapor Pressure:

ASTM E 1782–08 (thermal analysis) (Ref. 12). *n*-Octanol/Water Partition Coefficient: Method A (40 CFR 799.6755—shake flask); Method B (ASTM E 1147–92(2005)—liquid chromatography) (Ref. 13); Method C (40 CFR 799.6756—generator column).

Water Solubility: Method A (ASTM E 1148–02—shake flask) (Ref. 14); Method B (40 CFR 799.6784—shake flask); Method C (40 CFR 799.6784—column elution); Method D (40 CFR 799.6786—generator column).

For those chemical substances needing melting points determinations, EPA is proposing that melting points be determined according to ASTM method E 324–99. Although ASTM International indicates on its Web site, <http://www.astm.org/DATABASE.CART/WITHDRAWN/E324.htm>, that ASTM E 324–99 has been withdrawn, ASTM International's withdrawal of the method means only that ASTM International no longer continues to develop and improve the method. It does not mean that ASTM International no longer considers the method to be valid. ASTM International has explained that ASTM E 324–99 was withdrawn because:

The standard utilizes old, well-developed technology; it is highly unlikely that any additional [changes] and/or modifications will ever be pursued by the E15 [committee]. The time and effort needed to maintain these documents detract from the time available to develop new standards which use modern technology (Ref. 15).

ASTM International still makes the method available for informational purposes and it can still be purchased from ASTM International at the address listed in § 799.5090(h) of the proposed regulatory text.

EPA concludes that ASTM International's withdrawal of ASTM E 324–99 does not have negative implications on the validity of the method, and EPA is proposing that melting points be determined according to ASTM E 324–99.

For those chemical substances that are liquid at room temperature, EPA is proposing a measured freezing point to meet the obligation to report the melting point. Since ASTM E 324–99 (capillary tube) does not specifically include instructions for determining freezing point, EPA is instead proposing to require, for substances which are liquid at room temperature, OECD 102 (melting point/melting range), which

includes guidance for determining freezing point (Ref. 10).

For the "*n*-Octanol/Water Partition Coefficient (log 10 basis)" and water solubility endpoints, EPA is proposing that certain "special conditions" be considered by test sponsors in determining the appropriate test method that would be used from among those included for these endpoints in Table C. of this unit and in Table 3. in § 799.5090(j) of the proposed regulatory text.

For the "*n*-Octanol/Water Partition Coefficient (log 10 basis)" endpoint, also known as log K_{ow} , EPA proposes that an appropriate selection be made from among three alternative methods for measuring the chemical substance's *n*-Octanol/Water Partition Coefficient (log 10 basis; "log K_{ow} "). Prior to determining the appropriate standard to use, if any, to measure the *n*-Octanol/Water Partition Coefficient, EPA is recommending that the log K_{ow} be quantitatively estimated. EPA recommends that the method described in "Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients" (Ref. 16) be used in making such estimation. EPA is proposing that test sponsors must submit with the final study report the underlying rationale for the test standard selected for this endpoint. EPA is proposing this approach recognizing that, depending on the chemical substance's log K_{ow} , one or more test methods may provide adequate information for determining the log K_{ow} , but that in some instances one particular test method may be more appropriate. In general, EPA believes that the more hydrophobic a subject chemical substance is, the less well Method A (40 CFR 799.6755—shake flask) will work and Method B (ASTM E 1147–92(2005)) and Method C (40 CFR 799.6756—generator column) become more suitable, especially Method C. The proposed test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA highly recommends that all required *n*-Octanol/Water Partition Coefficient tests be conducted at pH 7 to ensure environmental relevance." Table C. of this unit shows the proposed test standards and log K_{ow} ranges that would determine which tests must be conducted for this endpoint.

TABLE C—TEST REQUIREMENTS FOR THE *n*-OCTANOL/WATER PARTITION COEFFICIENT ENDPOINT

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	<p><i>n</i>-Octanol/water partition coefficient (log 10 basis) or log K_{ow}:</p> <p>The appropriate log K_{ow} test, if any, would be selected from those listed in this column—see special conditions in the adjacent column.</p> <p>Method A: 40 CFR 799.6755 (shake flask)</p> <p>Method B: ASTM E 1147–92 (2005) (liquid chromatography)</p> <p>Method C: 40 CFR 799.6756 (generator column)</p>	<p><i>n</i>-Octanol/water partition coefficient or log K_{ow}:</p> <p>Which method is required, if any, is determined by the test substance's estimated log K_{ow} as follows:</p> <p>log K_{ow} < 0: no testing required.</p> <p>log K_{ow} range 0–1: Method A or B.</p> <p>log K_{ow} range > 1–4: Method A or B or C.</p> <p>log K_{ow} range > 4–6: Method B or C.</p> <p>log K_{ow} > 6: Method C.</p> <p>Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.</p>

For the “Water Solubility” endpoint, EPA proposes an appropriate selection be made from among four alternative methods for measuring that endpoint. The test method used, if any, would be determined by first quantitatively estimating the test substance's water solubility. One recommended method for estimating water solubility is described in “Improved Method for

Estimating Water Solubility from Octanol/Water Partition Coefficient” (Ref. 17). EPA is also proposing that test sponsors be required to submit in the final study report the underlying rationale for the test standard selected for this endpoint. The proposed test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental

conditions related to pH. Therefore, EPA proposes that all required water solubility tests be conducted starting at pH 7 to ensure environmental relevance. The estimated water solubility ranges that EPA is proposing for use in selecting an appropriate proposed test standard are shown in Table D. of this unit.

TABLE D—TEST REQUIREMENTS FOR THE WATER SOLUBILITY ENDPOINT

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	<p>Water solubility:</p> <p>The appropriate method to use, if any, to test for water solubility would be selected from those listed in this column—see special conditions in the adjacent column</p> <p>Method A: ASTM E 1148–02 (Re-approved 2008) (shake flask)</p> <p>Method B: 40 CFR 799.6784 (shake flask)</p> <p>Method C: 40 CFR 799.6784 (column elution)</p> <p>Method D: 40 CFR 799.6786 (generator column)</p>	<p>Water solubility:</p> <p>Which method is required, if any, would be determined by the test substance's estimated water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7.</p> <p>> 5,000 milligrams/liters (mg/L): Method A or B.</p> <p>> 10 mg/L–5,000 mg/L: Method A, B, C, or D.</p> <p>> 0.001 mg/L–10 mg/L: Method C or D.</p> <p>≤ 0.001 mg/L: No testing required.</p>

2. *Environmental fate and pathways.* Ready Biodegradation: Method A—ASTM E 1720–01(Reapproved 2008) (Sealed vessel CO₂ production test) (Ref. 18); Method B—International Organization for Standardization (ISO) 14593 (CO₂ headspace test) (Ref. 19); Method C—ISO 7827 (Method by analysis of dissolved organic carbon (DOC)) (Ref. 20); Method D—ISO 9408 (Determination of oxygen demand in a closed respirometer) (Ref. 21); Method E—ISO 9439 (Carbon dioxide evolution test) (Ref. 22); Method F—ISO 10707 (Closed bottle test) (Ref. 23); Method

G—ISO 10708 (Two-phase closed bottle test) (Ref. 24).

For the “Ready Biodegradation” endpoint, EPA proposes an appropriate selection be made from among seven alternative methods for measuring the chemical substance's ready biodegradability. For most test substances, EPA considers Method A (ASTM E 1720–01) and Method B (ISO 14593) to be generally applicable, cost effective, and widely accepted internationally. However, any test method used will depend on the physical and chemical properties of the test substance, including its water

solubility. An additional document, ISO 10631 (Ref. 25), provides guidance for selection of an appropriate test method for a given test substance considering the substance's physical and chemical properties. EPA is also proposing that test sponsors be required to submit in the final study report the underlying rationale for the test standard selected for this endpoint.

3. *Aquatic toxicity.* Test Group 1: Acute toxicity to fish (ASTM E 729–96 (2007)) (Ref. 26); Acute toxicity to Daphnia (ASTM E 729–96(2007)) (Ref. 26); and Toxicity to plants (algae) (ASTM E 1218–04e1) (Ref. 27). Test

Group 2: Chronic toxicity to *Daphnia* (ASTM E 1193–97 (2004)) (Ref. 28); and Toxicity to plants (algae) (ASTM E 1218–04e1) (Ref. 27).

For the “Aquatic Toxicity” endpoint, the OECD HPV SIDS Program recognizes that, for certain chemical substances, acute toxicity studies are of limited value in assessing the chemical substance’s aquatic toxicity. This issue arises when considering chemical substances with high log K_{ow} values. In such cases, toxicity is unlikely to be observed over the duration of acute toxicity studies because of reduced uptake and the extended amount of time required for such chemical substances to reach steady state or toxic concentrations in the test organism. For such situations, the OECD HPV SIDS Program recommends use of chronic toxicity testing in *Daphnia* in place of acute toxicity testing in fish and *Daphnia*. EPA is proposing that the aquatic toxicity testing requirement be determined based on the test chemical substance’s measured log K_{ow} as determined by using the approach outlined in this unit in the discussion of “*n*-Octanol/Water Coefficient,” and in Table 3. in § 799.5090(j) of the proposed regulatory text. For test chemical substances determined to have a log K_{ow} of less than 4.2, one or more of the following tests (described as “Test Group 1” in Table 3. in § 799.5090(j) of the proposed regulatory text) are proposed: Acute toxicity to fish (ASTM E 729–96 (2007)); Acute toxicity to *Daphnia* (ASTM E 729–96 (2007)); and Toxicity to plants (algae) (ASTM E 1218–04e1). For test chemical substances determined to have a log K_{ow} that is greater than or equal to 4.2, one or both of the following tests (described as “Test Group 2” in Table 3. in § 799.5090(j) of the proposed regulatory text) are proposed: Chronic toxicity to *Daphnia* (ASTM E 1193–97 (2004)) and Toxicity to plants (algae) (ASTM E 1218–04e1). As outlined in Unit IV.C.3. and in § 799.5090(j) of the proposed regulatory text, depending on the testing proposed in Test Group 1, the Test Group 2 chronic *Daphnia* test may substitute for either or both the acute fish toxicity test and the acute *Daphnia* test.

Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 17, 29, and 30). A chemical substance with a fish BCF value of 1,000 or more is characterized as having a tendency to accumulate in living organisms relative to the concentration of the chemical substance in the surrounding environment (Ref. 30). For the purposes of this proposed rule,

EPA’s use of a log K_{ow} equal to or greater than 4.2 (which corresponds with a fish BCF value of 1,000) is consistent with the approach taken in the Agency’s Final Policy Statement under TSCA section 5 entitled “Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances” (Ref. 31). EPA has also used a measured BCF that is equal to or greater than 1,000 or, in the absence of bioconcentration data, a log P [same as log K_{ow}] value equal to or greater than 4.3 to help define the potential of a new chemical substance to cause significant adverse environmental effects (“Significant New Use Rules; General Provisions For New Chemical Follow-Up” under TSCA sections 5 and 26(c) (Ref. 32; see also 40 CFR 721.3)). EPA considers the difference between the log K_{ow} of 4.3 cited in the 1989 **Federal Register** document (Ref. 32) and the log K_{ow} value of 4.2 cited in this proposed TSCA section 4 test rule to be negligible.

EPA recognizes that in some circumstances, acute aquatic toxicity testing (Test Group 1) may be relevant for certain chemical substances having a log K_{ow} equal to or greater than 4.2. Chemical substances that are dispersible in water (e.g., surfactants, detergents, aliphatic amines, and cationic dyes) may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. For any chemical substance listed in Table 3. in § 799.5090(j) of the proposed regulatory text for which a test sponsor believes that an alternative to the log K_{ow} threshold of 4.2 is appropriate, the test sponsor may request a modification of the test standard in the final rule as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method to be used for determining whether acute or chronic aquatic toxicity testing must be performed for a specific test substance. EPA is soliciting public comment on this approach as well as other alternative approaches in this area.

4. *Mammalian toxicity—acute*. Acute Inhalation Toxicity (rat): Method A (40 CFR 799.9130). Acute Oral Toxicity (rat): Method B (ASTM E 1163–98(2002) (Ref. 33) or 40 CFR 799.9110(d)(1)(i)(A)).

For the “Mammalian Toxicity—Acute” endpoint, EPA is proposing that certain special conditions such as the chemical substance’s physical/chemical properties or physical state be considered in determining the appropriate test method from among those included for this endpoint in Table 3. in § 799.5090(j) of the proposed regulatory text. The OECD HPV SIDS Program recognizes that, for

most chemical substances, the oral route of administration will suffice for this endpoint. However, consistent with the approach taken under the voluntary HPV Challenge, EPA is proposing that, for test chemical substances that are gases at room temperature (25 °C), the acute mammalian toxicity study be conducted using inhalation as the exposure route (described as Method A (40 CFR 799.9130) in Table 3. in § 799.5090(j) of the proposed regulatory text). In the case of a potentially explosive test chemical substance, care must be taken to avoid the generation of explosive concentrations. For all other chemical substances (i.e., those that are either liquids or solids at room temperature), EPA is proposing that acute toxicity testing be conducted via oral administration using an “Up/Down” test method (described as Method B (ASTM E 1163–98 (2002) or 40 CFR 799.9110(d)(1)(i)(A)) in Table 3. in § 799.5090(j) of the proposed regulatory text). Consistent with the voluntary HPV Challenge, EPA is proposing to allow the use of the Neutral Red Uptake (NRU) basal cytotoxicity assay to select the starting dose for the acute oral toxicity test (Refs. 34 and 35). This test is included as a Special Condition in Table 3. in § 799.5090(j) of the proposed regulatory text. A document developed by National Institutes of Health/National Institute of Environmental Health Sciences (NIH/NIEHS) provides guidance on how to use the NRU assay to estimate a starting dose for an acute oral toxicity test (Ref. 36). Recent versions of the standardized protocols for the NRU assay are available at the NIEHS/Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Web site, http://iccvam.niehs.nih.gov/methods/acutetox/invitrocyto/invcyt_proto.htm (Refs. 34, 35, and 37).

Dermal toxicity testing is not proposed in this rulemaking, and the Agency does not intend to include any dermal toxicity testing in any TSCA section 4 HPV SIDS rulemakings.

5. *Mammalian toxicity—genotoxicity*. Gene Mutations. Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510 Chromosomal Damage.

In Vitro Mammalian Chromosome Aberration Test (40 CFR 799.9537), or the *In Vivo* Mammalian Bone Marrow Chromosomal Aberration Test (rodents: Mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9538), or the *In Vivo* Mammalian Erythrocyte Micronucleus Test (sampled in bone marrow) (rodents: Mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9539).

Persons who would be required to conduct testing for chromosomal damage are encouraged to use *in vitro* genetic toxicity testing (*i.e.*, the Mammalian Chromosome Aberration Test) to generate the needed genetic toxicity screening data, unless known chemical properties preclude its use. These could include, for example, physical chemical properties or chemical class characteristics. A primary focus of both the voluntary HPV Challenge and this proposed rule is to implement this program in a manner consistent with the OECD HPV SIDS Program and as part of a larger international activity with global involvement. This proposed approach provides the same degree of flexibility as that which currently exists under the OECD HPV SIDS testing program (Ref. 1). A person subject to this rule who uses one of the *in vivo* methods instead of the *in vitro* method to address this end-point would be required to submit to EPA in the final report a rationale for conducting that alternate test.

6. *Mammalian toxicity—repeated dose/reproduction/developmental.* Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365. Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355. Repeated Dose 28-Day Oral Toxicity Study: 40 CFR 799.9305.

For the “Mammalian Toxicity—Repeated Dose/Reproduction/Developmental” endpoint, EPA recommends the use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365) as the test of choice. EPA recognizes, however, that there may be reasons to test a particular chemical substance using both the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9355) and the Repeated Dose 28-Day Oral Toxicity Study (40 CFR 799.9305) instead of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). With regard to such cases, EPA is proposing that a person subject to this rule, who uses the combination of the Reproduction/Developmental Toxicity Screening Test and the Repeated Dose 28-Day Oral Toxicity Study in place of the Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screen would be required to submit to EPA in the final study reports a rationale for conducting these alternate tests.

Certain of the chemical substances for which Mammalian Toxicity—Repeated Dose/Reproduction/Developmental

testing is proposed may be used solely as “closed system intermediates,” as described in the EPA guidance document developed for the voluntary HPV Challenge (Ref. 38). As described in that guidance, such chemical substances may be eligible for a reduced testing battery which substitutes a developmental toxicity study for the SIDS requirement to address repeated dose (*e.g.*, subchronic), reproductive, and developmental toxicity. In other words, since only the developmental toxicity study would be conducted for those chemical substances that qualify for a reduced testing battery, repeated dose (*e.g.*, subchronic) and reproductive studies would not be conducted. At the present time, EPA does not have sufficient information to know with any degree of certainty which if any of the chemical substances that are listed in the proposed regulatory text are solely closed system intermediates as defined in the voluntary HPV Challenge guidance document (Ref. 38). Persons who believe that a chemical substance fully satisfies the terms outlined in the guidance document are encouraged to submit appropriate information along with their comments on this proposed rule which substantiate this belief. If, based on submitted information and other information available to EPA, the Agency believes that a chemical substance is considered likely to meet the requirements for use solely as a closed system intermediate, EPA would not address any developmental toxicity testing needs in this proposed rule.

D. When would any testing imposed by this proposed rule begin?

The testing requirements contained in this proposed rule are not effective until and unless the Agency issues a final test rule. Based on the effective date of the final test rule, which is typically 30 days after the publication of a final rule in the **Federal Register**, the test sponsor may plan the initiation of any required testing as appropriate to submit the required final report by the deadline indicated in § 799.5090(i) of the proposed regulatory text.

E. How would the studies proposed under this test rule be conducted?

Persons required to comply with the final rule would have to conduct the necessary testing in accordance with the testing and reporting requirements established in the regulatory text of the final rule, with 40 CFR part 790—Procedures Governing Testing Consent Agreements and Test Rules (except for paragraphs (a), (d), (e), and (f) of § 790.45; § 790.48; paragraph (a)(2) and paragraph (b) of § 790.80; paragraph

(e)(1) of § 790.82; and § 790.85), and with 40 CFR part 792—Good Laboratory Practice Standards.

F. What forms of chemical substances would be tested under this rule?

EPA is proposing two distinct approaches for identifying the specific chemical substances that would be tested under a final rule originating from this proposed rule, the application of which would depend on whether the chemical substance is considered to be a “Class 1” or a “Class 2” chemical substance. First introduced when EPA compiled the TSCA Chemical Substance Inventory, the term Class 1 chemical substance refers to a chemical substance having a chemical composition that consists of a single chemical species (not including impurities) that can be represented by a specific, complete structure diagram. By contrast, a Class 2 chemical substance has a composition that cannot be represented by a specific, complete chemical structure diagram, because such a substance generally contains two or more different chemical species (not including impurities). Table 2. in § 799.5090(j) of the proposed regulatory text identifies the listed chemical substances as either Class 1 or Class 2 chemical substances.

EPA is proposing that, for the Class 1 chemical substances that are listed in this proposed rule, the test chemical substance have a purity of 99% or greater. EPA has generally applied this standard of purity to the testing of Class 1 chemical substances in the past under TSCA section 4(a) testing actions, except for chemical substances where it has been shown that such purity is unattainable. EPA is soliciting comment on whether a purity level of 99% or greater cannot be attained for any of the Class 1 chemical substances listed in this proposed rule. For the Class 2 chemical substances that are listed in this proposed rule, EPA is proposing that the test chemical substance be any representative form of the chemical substance, to be defined by the test sponsor(s).

EPA solicits comment on the proposed alternative approach to the testing of Class 2 chemical substances included in this proposed rule.

G. Who would be required to test under this rule?

1. *Would I be subject to this rule?* If this proposed rule becomes final, you would be subject to the final rule and may be required to test if you manufacture (which is defined by statute to include import) or process, or intend to manufacture or process, one or more chemical substances listed in this

proposed rule during the time period described in this unit. However, if you do not know or cannot reasonably ascertain that you manufacture or process a listed test rule chemical substance (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you would not be subject to the rule for that listed chemical substance.

2. *When would my manufacture or processing (or my intent to do so) cause me to be subject to this rule?* You would be subject to this rule if you manufacture or process, or intend to manufacture or process, a chemical substance listed in the rule at any time from the effective date of the final test rule to the end of the test data reimbursement period. The term

“reimbursement period” is defined at 40 CFR 791.3(h) and may vary in length for each substance to be tested under a final TSCA section 4(a) test rule, depending on what testing is required and when testing is completed.

3. *Would I be required to test if I were subject to the rule?* It depends on the nature of your activities. All persons who would be subject to this TSCA section 4(a) test rule, which, unless otherwise noted in the regulatory text, incorporates EPA’s generic procedures applicable to TSCA section 4(a) test rules (contained within 40 CFR part 790), would fall into one of two groups, designated here as Tier 1 and Tier 2. Persons in Tier 1 (those who would have to initially comply with the final rule) would either submit to EPA letters of intent to conduct testing, conduct this testing, and submit the test data to EPA, or apply to and obtain from EPA

exemptions from testing. Addresses of the EPA Document Control Office where this information should be sent are found in this document under

ADDRESSES.

Persons in Tier 2 (those who would not have to initially comply with the final rule) would not need to take any action unless they are notified by EPA that they are required to do so (because, for example, no person in Tier 1 had submitted a letter of intent to conduct testing). Note that both persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who actually conduct the testing.

4. *Who would be in Tier 1 and Tier 2?* All persons who would be subject to the final rule are considered to be in Tier 1 unless they fall within Tier 2. Table E. of this unit describes who is in Tier 1 and Tier 2.

TABLE E—PERSONS SUBJECT TO THE RULE: TIER 1 AND TIER 2

Tier 1 (persons initially required to comply)	Tier 2 (persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture, a test rule chemical substance, and who are not listed under Tier 2.	<p>A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule chemical substance solely as one or more of the following:</p> <ul style="list-style-type: none"> —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring chemical substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kilograms (kg) (1,100 lbs.) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for research and development (R & D) (as described at 40 CFR 790.42(a)(5)). <p>B. Persons who process (as defined at TSCA section 3(10)) or intend to process a test rule substance (see 40 CFR 790.42(a)(2)).</p>

Under 40 CFR 790.2, EPA may establish procedures for specific test rules that differ from the generic procedures governing TSCA section 4(a) test rules in 40 CFR part 790. For purposes of this proposed rule, EPA is proposing to establish certain requirements that differ from those under 40 CFR part 790.

In this proposed test rule, EPA has configured the tiers in 40 CFR 790.42 as in previous HPV test rules (Refs. 39, 40, and 41). In addition to processors, manufacturers of less than 500 kg (1,100 lbs.) per year (“small-volume manufacturers”), and manufacturers of small quantities for research and development (“R&D manufacturers”), EPA has added the following persons to Tier 2: Byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring chemical substances, manufacturers of non-isolated intermediates, and

manufacturers of components of Class 2 chemical substances. The Agency took administrative burden and complexity into account in determining who was to be in Tier 1 in this proposed rule. EPA believes that those persons in Tier 1 who would conduct testing under this proposed rule, when finalized, would generally be large manufacturers of chemical substances who, in the experience of the Agency, have traditionally conducted testing or participated in testing consortia under previous TSCA section 4(a) test rules.

The Agency also believes that byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring chemical substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 chemical substances historically have not themselves participated in testing or contributed to reimbursement of those

persons who have conducted testing. EPA understands that these manufacturers may include persons for whom the marginal transaction costs involved in negotiating and administering testing arrangements are deemed likely to raise the expense and burden of testing to a level that is disproportional to the additional benefits of including these persons in Tier 1. Therefore, EPA does not believe that the likelihood of the persons proposed to be added to Tier 2 actually conducting the testing is sufficiently high to justify burdening these persons with Tier 1 requirements (e.g., submitting requests for exemptions). Nevertheless, these persons, along with all other persons in Tier 2, would be subject to reimbursement obligations to persons who actually conduct the testing.

TSCA section 4(b)(3)(B) requires all manufacturers and/or processors of a

chemical substance to test that chemical substance if EPA has made findings under TSCA sections 4(a)(1)(A)(ii) or (a)(1)(B)(ii) for that chemical substance, and issued a TSCA section 4(a) test rule requiring testing. However, practicality must be a factor in determining who is subject to a particular test rule. Thus, persons who do not know or cannot reasonably ascertain that they are manufacturing or processing a chemical substance subject to this proposed rule, e.g., manufacturers or processors of a chemical substance as a trace contaminant who are not aware of and cannot reasonably ascertain these activities, would not be subject to the rule. See § 799.5090(b)(2) of the proposed regulatory text.

5. *Who is in the Tier 2 subdivisions?*

The Agency is proposing to prioritize which persons in Tier 2 would be required to perform testing, if needed. Specifically, the Agency is proposing that Tier 2 entities be subdivided into:

i. Tier 2A—manufacturers, i.e., those who manufacture, or intend to manufacture, a test rule chemical substance solely as one or more of the following: A byproduct, an impurity, a naturally occurring chemical substance, a non-isolated intermediate, a component of a Class 2 chemical substance, in amounts less than 1,100 lbs. annually, or in small quantities solely for research and development.

ii. Tier 2B—processors, i.e., those who process, or intend to process, a test rule chemical substance (in any form). The terms “process” and “processor” are defined by TSCA sections 3(10) and 3(11), respectively.

If the Agency needs testing from persons in Tier 2, EPA would seek testing from persons in Tier 2A before proceeding to Tier 2B. It is appropriate to require manufacturers in Tier 2A to submit letters of intent to test or exemption applications before processors are called upon because the Agency believes that testing costs are traditionally passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 42). In addition, as stated by EPA in the Data Reimbursement rule, “[t]here are [typically] so many processors [of a given test rule chemical substance] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs” (Ref. 43).

6. *When would it be appropriate for a person who would be required to comply with the rule to apply for an exemption rather than to submit a letter of intent to conduct testing?* You may apply for an exemption if you believe that the required testing will be

performed by another person (or a consortium of persons formed under TSCA section 4(b)(3)(A)). Procedures relating to exemptions are in 40 CFR 790.80 through 790.99, and § 799.5090(c)(2), (c)(5), (c)(7), and (c)(11) of the proposed regulatory text. In this proposed rule, EPA would not require the submission of equivalence data (i.e., data demonstrating that your chemical substance is equivalent to the chemical substance actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 40 CFR 790.85 would not apply to this proposed rule.

7. *What would happen if I submitted an exemption application?* If EPA has received a letter of intent to test from another source or has received (or expects to receive) the test data that would be required under this rule, the Agency may conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate conditional exemptions if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA. EPA may then require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5090(c)(8) of the proposed regulatory text for details on submitting this notice. In addition, the Agency would terminate a conditional exemption if no letter of intent to test has been received from persons required to comply with the rule. See, e.g., § 799.5090(c)(6) of the proposed regulatory text. Note that the provisions at 40 CFR 790.48(b) have been incorporated into the regulatory text of this proposed rule; thus, persons subject to the final rule are not required to comply with 40 CFR 790.48 itself (see § 799.5090(c)(4)–(c)(7) and § 799.5090(d)(3) of the proposed regulatory text). Persons who obtain exemptions or receive them automatically would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit IV.G.4.

8. *What would my obligations be if I were in Tier 2?* If you are in Tier 2, you would be subject to the rule and you would be responsible for providing reimbursement to persons in Tier 1. The obligation to provide reimbursement is not affected by placement in Tier 2A or Tier 2B. Concerning testing, if you are in Tier 2, you are considered to have an automatic conditional exemption. You would not need to submit a letter of intent to test or an exemption application unless you are notified by EPA that you are required to do so. As

previously noted, Tier 2A manufacturers would be notified to test before Tier 2B processors.

If a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA, the Agency may require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5090(c)(10) of the proposed regulatory text.

In addition, you would need to submit a notice of intent to test or an exemption application if: i. no manufacturer in Tier 1 has notified EPA of its intent to conduct testing; and ii. EPA has published a **Federal Register** document directing persons in Tier 2 to submit to EPA letters of intent to conduct testing or exemption applications. See § 799.5090(c)(4), (c)(5), (c)(6), and (c)(7) of the proposed regulatory text. EPA is not aware of any circumstances in which test rule Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791.

9. *What would happen if no one submitted a letter of intent to conduct testing?* EPA anticipates that it will receive letters of intent to conduct testing for all of the tests specified and chemical substances included in the final rule. However, in the event it does not receive a letter of intent for one or more of the tests required by the final rule for any of the chemical substances in the final rule within 30 days after the publication of a **Federal Register** document notifying Tier 2 processors of the obligation to submit a letter of intent to conduct testing or to apply for an exemption from testing, EPA would notify all manufacturers and processors of the chemical substance of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document would additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and would give them an opportunity to take corrective action. If no one has notified EPA of its intent to conduct the required testing of the chemical substance within 30 days after receipt of the certified letter or publication of the **Federal Register** document, all manufacturers and processors subject to the final rule with respect to that chemical substance who are not already in violation of the final

rule would be in violation of the final rule.

10. *What are the reimbursement procedures?* In the past, persons subject to test rules have independently worked out among themselves their respective financial contributions to those persons who have actually conducted the testing. However, if persons are unable to agree privately on reimbursement, they may take advantage of EPA's reimbursement procedures at 40 CFR part 791, promulgated under the authority of TSCA section 4(a). These procedures include: The opportunity for a hearing with the American Arbitration Association; publication by EPA of a document in the **Federal Register** concerning the request for a hearing; and the appointment of a hearing officer to propose an order for fair and equitable reimbursement. The hearing officer may base his or her proposed order on the production volume formula set out at 40 CFR 791.48, but is not obligated to do so. Under this proposed rule, amounts manufactured as impurities would be included in production volume (40 CFR 791.48(b)), subject to the discretion of the hearing officer (40 CFR 791.40(a)). The hearing officer's proposed order may become the Agency's final order, which is reviewable in Federal court (40 CFR 791.60).

H. What reporting requirements would be required under this test rule?

For each test for each chemical substance, you would be required to submit a study plan 90 days after the effective date of the final rule and a final report for a specific test by the deadline indicated as the number of months after the effective date of the final rule, which would be shown in § 799.5090(i) of the regulatory text. Addresses of the EPA Document Control Office where this information should be sent are found in this document under **ADDRESSES**.

I. What would I need to do if I cannot complete the testing required by the final rule?

A company who submits a letter of intent to test under the final rule and who subsequently anticipates difficulties in completing the testing by the deadline set forth in the final rule may submit a modification request to the Agency, pursuant to 40 CFR 790.55. EPA will determine whether modification of the test schedule is appropriate, and may first seek public comment on the modification.

J. Would there be sufficient test facilities and personnel to undertake the testing proposed under this test rule?

EPA's most recent analysis of laboratory capacity (Ref. 44) indicates that available test facilities and personnel would adequately accommodate the testing proposed in this rule.

K. Might EPA seek further testing of the chemical substances in this proposed test rule?

If EPA determines that it needs additional data regarding any of the chemical substances included in this proposed rule, the Agency would seek further health and/or environmental effects testing for these chemical substances. Should the Agency decide to seek such additional testing via a test rule, EPA would initiate a separate action for this purpose.

V. Proposed TSCA Section 5(a)(2) SNUR and Basis To Potentially Add One or More Chemical Substances From Table A. to the SNUR

EPA has preliminarily determined that each of the 45 substances listed in Tables A. and B. in Unit III. is produced in substantial quantities (≥ 1 million lbs./yr) and made preliminary findings that there may be substantial human exposure to 23 of these substances. However, for 22 of the 45 chemical substances, the Agency does not currently have exposure information that would adequately support such findings under TSCA section 4(a)(1)(B). For those remaining 22 chemical substances (*i.e.*, Table B.), EPA is proposing to establish significant new use reporting and recordkeeping requirements under TSCA section 5(a)(2) that would require EPA notification prior to worker or consumer exposures rising to substantial levels.

A. What are the rationale and objectives for taking this action?

1. *Rationale.* Each of the chemical substances included in Table B. is produced in substantial quantities. EPA considered the factors set out in TSCA section 5(a)(2) and the longstanding use of the exposure thresholds in the "B Policy" (see Unit V.B.) to determine that manufacturers and processors of any of these chemical substances should be required to notify EPA if exposure to any of these chemical substances is expected to increase significantly. Accordingly, the significant new uses are: Any use in a consumer product, and any use or combination of uses that is reasonably likely to expose 1,000 or more workers at a single corporate entity (defined as the aggregate of all of

the domestic facilities owned or operated by an individual corporation). The SNUR facilitates efficiency by mitigating the need for EPA to continually reevaluate each HPV chemical substance to determine whether exposure potential has increased so that there is or may be substantial human exposure. EPA recognizes, however, that the proposed SNU designation would not encompass every new use that could potentially give rise to significant or substantial human exposure.

Consistent with EPA's past practice for issuing SNURs under TSCA Section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

2. *Objectives.* Under TSCA section 5(a)(1)(B), any person intending to manufacture, import, or process any of these chemical substances for one or more of the designated SNUs would be required to notify EPA with a SNUN before that activity begins. EPA would then have an opportunity to review and evaluate data submitted in a SNUN and, if warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7, EPA would be able to regulate prospective manufacturers (which, as noted in Unit I.A., includes importers) or processors of the chemical substances before the designated SNUs of the chemical substance occurs.

B. How were the significant new uses determined?

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

1. The projected volume of manufacturing and processing of a chemical substance.
2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors, the statute authorizes EPA to consider any other relevant factors. To determine what would constitute a SNU of the chemical substances listed in Table B. and of the chemical substances listed in Table A., EPA considered the section 5(a)(2) factors, as well as EPA's 1993 "B Policy" (Ref. 2), discussed in Unit II.D.

For the first section 5(a)(2) factor, production volume, EPA considered the fact that all 22 of the chemical substances in Table B., and all 23 of the chemical substances in Table A., have been produced in substantial amounts, *i.e.*, volumes above one million lbs./year. EPA would expect that increased or expanded use of these chemical substances could correspond to a further increase in annual production volume and thereby increase exposures.

Next, EPA considered the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance. Current IUR information available to EPA indicates that all but 2 of the 22 chemical substances in Table B. are used solely for industrial purposes. For the remaining two chemical substances in Table B., EPA could find no evidence of any ongoing consumer uses. With respect to these 22 chemical substances (*i.e.*, Table B.), any use in consumer products would likely result in new consumer exposures to these chemical substances. These potential new users could be exposed via pathways different from industrial users, and consumers may be less likely to use, or have access to, appropriate protective equipment (*e.g.* gloves or respirators) than industrial users. An expansion into use in consumer products may also include new environmental releases, deliberate or accidental (*e.g.*, consumers may dispose of a chemical substance by pouring it down a storm drain or household sink).

With respect to the chemical substances listed in Table A., EPA has information indicating that ongoing use of certain of these chemical substances already involves the exposure of 10,000 or more consumers. If public comment on this proposal is accompanied by additional information that contradicts the information upon which EPA has based its preliminary conclusions (*i.e.*, less than 10,000 consumers are exposed), that information could

potentially also establish that there are no ongoing uses of the chemical substance in consumer products. If EPA concludes, on the basis of public comments, that there is an inadequate basis to issue a test rule for the chemical substance, it would also conclude, as a general matter, that there is an adequate basis to issue a SNUR for the chemical substance. In such a case, EPA intends to incorporate the chemical substance into the final SNUR without further opportunity for public notice and comment. EPA believes that the commencement of consumer uses of the chemical substances in Table A. (if such uses are not currently ongoing) would be a SNU of the chemical substances. This is because potential new users could be exposed via pathways different from industrial users, and may be less likely to use appropriate protective equipment (*e.g.* gloves or respirators) than industrial users. An expansion into use in consumer products may also include new environmental releases (*e.g.*, consumers may dispose of a chemical substance by pouring it down a storm drain or household sink).

EPA also considered the extent to which a use increases the magnitude and duration of human or environmental exposure to a chemical substance. Commencement of a chemical substance's use in a consumer product would increase the amount and time that consumers were exposed to the chemical substance. In determining substantial consumer exposure, EPA considered the production volume and consumer uses. If production volume exceeds one million pounds per year and consumer uses are indicated, it is likely that consumer exposure exceeds the substantial threshold of ten thousand people as defined by the "B Policy." EPA has reached this conclusion with respect to the chemical substances in Table B. and the chemical substances in Table A. (to the extent that use of the chemical substances in Table A. in consumer products is not already ongoing).

EPA also considered how the number of workers exposed (as reported under the IUR rule) might change if use of a chemical substance changed or expanded. For example, the commencement of additional new uses may increase the total production volume of a chemical substance, thereby increasing the magnitude and duration of exposure for industrial workers. None of the 22 chemical substances listed in Table B. are known to meet the "B Policy" threshold for substantial worker exposure ($\geq 1,000$ workers) at this time. However, if exposure were to increase such that 1,000 or more workers at a

single corporate entity were reasonably likely to be exposed, EPA believes that the increased exposure would be a significant change. In this context, "single corporate entity" refers to the aggregate of all of the domestic facilities owned or operated by an individual corporation. Therefore, the SNUR notification requirements would be triggered 90 days before the sum of all potentially exposed workers at domestic facilities comprising the single corporate entity was expected to reach 1,000 workers or more.

With respect to the chemical substances listed in Table A., EPA has information that ongoing use of certain of these chemical substances already involves the exposure of 1,000 or more workers. If EPA concludes, on the basis of public comments, that there is no basis to issue a test rule for such chemical substance then it would also conclude, as a general matter, that there is an adequate basis to issue a SNUR for the chemical substance. In such a case, EPA intends to incorporate the chemical substance into the final SNUR without further opportunity for public notice and comment. Chemical substances from Table A., like the chemical substances from Table B., are high production volume chemical substances. If exposure to a Table A. chemical substance were to increase such that 1,000 or more workers at a single corporate entity were to become reasonably likely to be exposed, EPA believes that the increased exposure would be a significant change.

With respect to the chemical substances in Tables A. and B., EPA also considered the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of these chemical substances in determining what would be a SNU. Given the production volume of these chemical substances, any change in these methods or practices could affect human or environmental exposures, but the lack of available toxicity data, and of more detailed information about existing methods and practices, hampers EPA's ability to more fully consider this fourth factor.

Finally, EPA considered the "B Policy." Since 1993, EPA has used the production, exposure, and release benchmarks in the "B Policy" for making TSCA section 4 test rule findings. EPA has also considered and incorporated the production, worker, and consumer exposure benchmarks in the selection of chemical substances to be included and development of the SNUs included in today's proposed action. These chemical substances have already been in production at high

volumes, and at least some workers are exposed. EPA is proposing to incorporate certain "B Policy" exposure thresholds into its rationale for the proposed SNUs because they are clear numeric criteria that have been used to determine substantial human exposure since 1993. They have provided a clear threshold—well understood by EPA, industry, and other stakeholders—of levels of worker or consumer exposure that are important under TSCA. EPA is interested in receiving comment concerning use of the "B Policy" in this context.

C. What were the alternatives to proposing this SNUR?

Before proposing this SNUR, EPA considered promulgating a TSCA section 8(a) reporting rule. Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture, import, or process a listed chemical substance for a specific use or any use. However, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to assess the risk of the new use prior to commencement of that activity, or, if warranted, to take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins.

D. What would be the applicability of the final rule to uses occurring before the 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 section 5(a)(1)(B) of TSCA is best served by designating a use as a SNU as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule 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 SNU before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who, after publication of the proposed SNUR, begin commercial manufacture, import, or processing of the chemical substance(s) listed in Table B. for a use proposed in this action for a SNU would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice

review period, including all extensions, expires. EPA has promulgated provisions to allow persons to comply with SNURs before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

E. Do test data and other information have to be submitted?

TSCA section 5 does not require developing any particular test data before submission of a SNUN, except where the chemical substance is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)), or when a chemical substance is included on the list described under section 5(b)(4). Unless submission of data is required under section 4 or 5(b)(4), 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). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, import, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical substance.

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

1. Human exposure and environmental releases that may result from the significant new uses 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.

F. How do I submit a SNUN?

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a SNU. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR

721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted to EPA, on EPA Form No. 7710-25 in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40.

EPA published a final rule on January 6, 2010 (75 FR 773) (FRL-8794-5), that established standards and requirements for the use of the electronic-PMN (e-PMN) software and EPA's Central Data Exchange (CDX) to electronically submit these notices. The Agency is introducing electronic reporting via CDX using the e-PMN in three phases over a two-year period. The effective date of the rule was April 6, 2010. Until April 6, 2011, submissions were permitted via CDX, optical disc, or paper. After April 6, 2011, paper submissions are no longer being accepted. After April 6, 2012, all submissions will be required to be submitted electronically via CDX. Regardless of the delivery method, EPA requires that all submissions be generated using the new e-PMN software. For additional information and instructions go to: <http://www.epa.gov/opptintr/newchems/epmn/epmn-index.htm>. Until April 6, 2012, SNUNs may still be mailed to the Environmental Protection Agency, OPPT Document Control Office (7407M), 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001.

G. What are the recordkeeping requirements?

EPA is proposing that persons subject to this proposed SNUR be required to maintain several records in addition to those required by 40 CFR 721.40 (persons required to submit a SNUN must retain documentation of information contained in that SNUN). EPA is proposing to require manufacturers and processors to maintain the records described in 40 CFR 721.125 (a), (b), and (c) in this SNUR. Section 721.125(a) requires records documenting manufacture and importation volume and dates; § 721.125(b) documents volumes purchased in the U.S. by processors, the names and addresses of suppliers, and the dates of purchase; and § 721.125(c) requires records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the chemical

substance, the date, and the quantity of each sale or transfer. These records would help EPA to determine compliance with the SNUR.

VI. Export Notification Requirements

Test rule: Any person who exports, or intends to export, one of the chemical substances contained in this proposed test rule in any form (*e.g.*, as byproducts, impurities, components of Class 2 chemical substances, *etc.*) will be subject to the export notification requirements in TSCA section 12(b)(1) and at 40 CFR part 707, subpart D, but only after the final rule is issued and only if the chemical substance is contained in the final rule. Export notification is generally not required for articles, as provided by 40 CFR 707.60(b). Section 12(b) of TSCA states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 must notify the EPA Administrator of such export or intent to export. The EPA Administrator in turn will notify the government of the importing country of the availability of data.

VII. Economic Impacts

A. What would be the economic impacts of the proposed test rule?

EPA has prepared an economic assessment entitled "Economic Analysis for the Proposed High Production Volume Challenge Chemicals Test Rule—Fourth Group of Chemicals" (Ref. 45), a copy of which has been placed in the docket for this proposed rule. This economic assessment evaluates the potential for significant economic impacts as a result of the testing that would be required by this proposed rule. The analysis covers 23 chemical substances. The total social cost of providing test data on the 23 chemical substances that were evaluated in this economic analysis is estimated to be \$7.72 million assuming an average cost scenario. Total costs of compliance to industry are estimated at \$7.65 million (Ref. 45).

While legally subject to this test rule, processors of a subject chemical substance would be required to comply with the requirements of the final rule only if they are directed to do so by EPA as described in § 799.5090(c)(5) and (c)(6) of the proposed regulatory text. EPA would only require processors to test if no person in Tier 1 has submitted a notice of its intent to conduct testing, or if under 40 CFR 790.93, a problem occurs with the initiation, conduct, or completion of the required testing or the

submission of the required data to EPA. Because EPA has identified at least one manufacturer in Tier 1 for each subject chemical substance, the Agency assumes that, for each chemical substance in this proposed rule, at least one such person will submit a letter of intent to conduct the required testing and that person will conduct such testing and will submit the test data to EPA. Because processors would not need to comply with the proposed rule initially, the economic assessment does not address processors.

Compliance costs include costs of testing and administering the testing, as well as reporting costs. In addition, they include the estimated cost of the TSCA section 12(b) export notification requirements, which, under the final rule, would be required for the first export to a particular country of a chemical substance subject to the final rule, estimated to range from \$27.50 per notice to \$86.99 per notice (Ref. 45). These export notification requirements (included in the total and annualized cost estimates) that would be triggered by the final rule are expected to have a negligible impact on exporters.

The potential for adverse economic impact as a result of the rule is expected to be higher for smaller businesses. Smaller businesses are less likely to have additional revenue sources to cover the compliance costs. Therefore, the Agency compared the costs of compliance to company sales for small businesses. EPA estimates that there are 25 small entities that would be affected by this proposed rule. Of these, EPA estimates that there is no small business for which the cost impact of the testing exceeds 1 percent of the company's revenue. EPA believes, on the basis of these calculations, that the proposed testing of the chemical substances presents a low potential for adverse economic impact for the majority of chemical substances.

The benefits resulting from this proposed test rule are discussed qualitatively in the "Economic Analysis for the Proposed High Production Volume Challenge Chemicals Test Rule—Fourth Group of Chemicals" (Ref. 45). EPA believes that the net benefits of this proposed rule are positive, but quantification of the benefits of the proposed rule would require more specific information about use patterns and preferences than is available.

B. What would be the economic impacts of the proposed SNUR?

1. **SNUNs.** EPA has evaluated the potential costs of establishing SNUR reporting and recordkeeping requirements for potential

manufacturers, importers, and processors of the chemical substance included in this proposed rule. While most businesses are subject to a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), small businesses with an annual sales of less than \$40 million when combined with those of the parent company (if any) are subject to a reduced user fee of \$100 (40 CFR 700.45(b)(1)). The costs of submission of SNUNs will not be incurred by any company unless a company decides to pursue a SNU as defined in this proposed SNUR. However there are limited costs associated with the recordkeeping requirements required by this SNUR, whether or not a SNUN is submitted. Furthermore, while the expense of a notice and the uncertainties of possible EPA regulation may discourage certain innovations, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value. EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 46).

2. **Export notification.** Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a chemical substance the subject of a proposed or final SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical substance, depending on the number of required notifications (*i.e.*, the number of countries to which the chemical substance is exported). Although EPA estimates that an exporting company making notifications may need to prepare 12 notifications per year at a cost of \$78.56 each, EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered in this proposed SNUR (Ref. 46).

VIII. Request for Public Comment

EPA is interested in stakeholder input on a number of issues in this action as well as future actions on high production volume chemical substances.

1. In this document, EPA is proposing either a test rule or SNUR to regulate a given set of chemical substances. EPA believes that this is an efficient way to require submission of test data on chemical substances that meet all of the necessary exposure criteria and require submission of a notification to EPA if

and when additional exposure criteria are met. The SNUR also facilitates efficiency by mitigating the need for EPA to continually reevaluate each HPV chemical substance to determine whether conditions have changed so as to increase potential exposure. EPA is considering proposing further combined test rules/SNURs in conjunction with future CDR data releases, covering all newly-HPV chemical substances. EPA requests comment on this approach.

2. EPA is proposing to incorporate the "B Policy" worker exposure threshold into the proposed SNU designations because it is a clear, numeric criterion that has been used to determine substantial human exposure since 1993. EPA is interested in receiving comment concerning use of the "B Policy" in this context.

3. EPA solicits comment on whether any of the chemical substances proposed for the SNUR are already being manufactured or processed for one of the significant new uses listed in Unit V., and should consequently be included in the test rule. Analogously, EPA solicits comment on whether any of the chemical substances proposed for the test rule are no longer used in applications that meet the substantial human exposure finding described in the "B Policy" and should consequently be included in the SNUR.

4. EPA solicits comment on whether any of the chemical substances proposed for the test rule or the SNUR should be subject to neither a test rule nor a SNUR. EPA requests comment on this topic so as to confirm or refute the Agency's general expectation that either a SNUR or a test rule is warranted for each chemical substance listed in Tables A. and B. of Unit III. EPA's general expectation is as follows: If additional information indicates that a test rule is not warranted for a particular chemical substance listed in Table A. because particular uses are not ongoing, EPA generally anticipates that such information would indicate that a SNUR is warranted instead. Conversely, if additional information indicates that a SNUR is not warranted for a particular chemical substance listed in Table B. because particular uses are already ongoing, EPA generally anticipates that such information would indicate that a test rule is warranted instead.

5. EPA solicits comment on whether there is a better alternative to proposing the SNUR trigger of ≥ 1000 workers exposed at a single corporate entity. The test rule findings are based on ≥ 1000 workers exposed at the national level. EPA asks for comment on whether there is an approach that would reduce the discrepancy between the corporate level

for the SNUR and national level for the test rule.

6. EPA solicits comment respecting relevant trends in production volume for the chemical substances proposed to be subject to either a test rule or a SNUR. EPA is especially interested in such trend information in the case that a commenter believes that neither a test rule nor a SNUR is warranted for a chemical substance because the chemical substance currently has an overall production volume of less than 1 million lbs. per year. Because production volume may vary from year to year, EPA does not believe that the mere fact that the most recent annual production volume is less than 1 million pounds would necessarily establish that a test rule is not warranted (and such information would not by itself suggest that a SNUR is unwarranted, since substantial production is not a required finding for SNURs). More detailed comments, distinguishing a long-term decline in production volume from a short-term dip, would be especially helpful to the Agency in evaluating any comments that current production volumes are too low to warrant the regulatory action proposed.

7. As described in Unit IV.B., to the extent that EPA learns that consumer uses, or uses that could affect 1,000 workers or more, are already ongoing for a chemical substance listed in Table B., it intends to evaluate whether taking steps to promulgate a test rule for the chemical substance is warranted. To assist the Agency in such circumstances, EPA solicits comment respecting the sufficiency of the available data and the need for additional testing on the chemical substances in Table B., consistent with the standards set forth in TSCA sections 4 (a)(1)(B)(ii) and (a)(1)(B)(iii).

8. The U.S. National Academy of Sciences National Research Council in their 2007 report "Toxicity Testing in 21st Century: A Vision and a Strategy" encouraged "work[ing] towards a transition to new integrative and predictive molecular and computational techniques to enhance efficiency and accuracy and to reduce reliance on animal testing." EPA requests suggestions on practical, implementable ways to work toward this goal in its actions under TSCA. Should tools such as ToxCast (<http://www.epa.gov/ncct/toxcast/>) be used to prioritize chemical substances and support hazard findings for testing in the future?

9. EPA solicits comments which identify existing data that may meet the requirements of studies under the proposed test rule. To the extent that

data relevant to the testing specified in the proposed rule are known to exist, EPA strongly encourages the submission of this information as comments to the proposed rule. Data submitted to EPA to meet the requirements of testing under the proposed rule must be in the form of full copies of unpublished studies or full citations of published studies, and may be accompanied by a robust summary (Ref. 8). To the extent that studies required under the proposed rule are currently available, and the data are judged sufficient by EPA, testing for the endpoint/chemical substance combination will not be required in the final test rule based on this proposed rule.

10. Persons who believe that adequate information regarding a chemical substance subject to the proposed test rule can be developed using a category or the SAR approach are encouraged to submit appropriate information, along with their rationale substantiating this belief, during the comment period on the proposed rule.

11. EPA solicits comment on the proposed test rule approaches for Class 1 and Class 2 chemical substances. Should each Class 1 chemical substance be tested at a purity of 99% or more? Should the proposed test substance purity for Class 1 chemical substances be applied to any Class 2 chemical substances? Should the proposed approach for testing Class 2 chemical substances (*i.e.*, that a representative sample of each Class 2 chemical substance be tested) be applied to any Class 1 chemical substances?

12. For more than 15 years, EPA has used OECD's SIDS to facilitate and standardize the screening of the relatively large number of chemical substances on the TSCA Inventory. EPA requests comment on whether SIDS continues to be the most appropriate data set to screen chemical substances for potential environmental and health hazards and whether EPA should consider other data sets in the event of any future test rule on new HPV chemical substances. Are additional or different tests also appropriate? Should EPA consider having more than one screening data set depending on the nature of exposures, *e.g.*, a different set of tests for children's exposures or environmental releases?

13. At the present time, EPA does not have sufficient information to know with any degree of certainty which if any of the chemical substances that are listed in the proposed regulatory text are solely closed system intermediates as defined in the voluntary HPV Challenge guidance document (Ref. 38). Persons who believe that a chemical substance

fully satisfies the terms outlined in the guidance document are encouraged to submit appropriate information along with their comments on this proposed rule which substantiate this belief.

IX. Materials in the Docket

As indicated under **ADDRESSES**, a docket has been established for this proposed rule under docket ID number EPA-HQ-OPPT-2010-0520. The following is a listing of the documents that have been placed in the docket for this proposed rule. The docket includes information considered by EPA in developing this proposed rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult either technical person listed under **FOR FURTHER INFORMATION CONTACT**. The docket is available for review as specified under **ADDRESSES**.

1. OECD Secretariat. Manual for the Investigation of HPV Chemicals. OECD Programme on the Co-Operative Investigation of High Production Volume Chemicals. Paris, France. December, 2009. Available on-line at: http://www.oecd.org/document/7/0,3746,en_2649_34379_1947463_1_1_1_1,00.html.
2. EPA. TSCA section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure; Notice. **Federal Register** (58 FR 28736, May 14, 1993).
3. U.S. National Academy of Sciences, National Research Council. "Toxicity Testing in the 21st Century: A Vision and a Strategy." 2007. Available on-line at: http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity_Testing_final.pdf.
4. EPA. National Center for Computational Toxicology. ToxCast™. 2007. <http://www.epa.gov/ncc/toxcast/>.
5. EPA. OPPT. Testing of Certain High Production Volume Chemicals-4 (Exposure Findings Supporting Information). Prepared by OPPT, Economics, Exposure and Technology Division. March, 2011.
6. EPA. OPPT. High Production Volume Chemical Data Information System (HPVIS). Data from HPVIS on 23 HPV chemicals. June 2011.
7. EPA. OPPT. Risk Assessment Division. HPV4 Data Adequacy Evaluations. 2010.
8. EPA. OPPT. Draft Guidance on Developing Robust Summaries. October 22, 1999. Available on-line at: <http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm>.
9. ASTM International. Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals. ASTM E 324-99. 1999.
10. OECD. Guideline for the Testing of Chemicals: Melting Point/Melting Range. OECD 102. July 27, 1995.
11. ASTM International. Standard Test Method for Vapor Pressure of Liquids by Ebulliometry. ASTM E 1719-05. 2005.
12. ASTM International. Standard Test Method for Determining Vapor Pressure by Thermal Analysis. ASTM E 1782-03 (2008).
13. ASTM International. Standard Test Method for Partition Coefficient (*n*-Octanol/Water) Estimation by Liquid Chromatography. ASTM E 1147-92 (2005).
14. ASTM International. Standard Test Method for Measurements of Aqueous Solubility. ASTM E 1148-02 (2008).
15. ASTM International. Question about ASTM E 324. E-mail from Diane Rehiel, ASTM, to Greg Schweer, CITB, CCD, OPPT, EPA. September 15, 2004.
16. Meylan, W.M. and Howard, P.H. Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients. *Journal of Pharmaceutical Sciences*. Vol. 84(1):83-92. 1995.
17. Meylan, W.M., Howard, P.H., and Boethling, R.S. Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient. *Environmental Toxicology and Chemistry*. Vol. 15(2):100-106. 1996.
18. ASTM International. Standard Test Method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO₂ Production Test. ASTM E 1720-01. (Reapproved 2008).
19. ISO. Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium—Method by analysis of inorganic carbon in sealed vessels (CO₂ headspace test). ISO 14593. 1999.
20. ISO. Water quality—Evaluation in an aqueous medium of the "ultimate" aerobic biodegradability of organic compounds—Method by analysis of dissolved organic carbon (DOC). ISO 7827. 1994.
21. ISO. Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium by determination of oxygen demand in a closed respirometer. ISO 9408. 1999.
22. ISO. Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium—Carbon dioxide evolution test. ISO 9439. 1999.
23. ISO. Water quality—Evaluation in an aqueous medium of the "ultimate" aerobic biodegradability of organic compounds—Method by analysis of biochemical oxygen demand (closed bottle test). ISO 10707. 1994.
24. ISO. Water quality—Evaluation in an aqueous medium of the ultimate aerobic biodegradability of organic compounds—Determination of biochemical oxygen demand in a two-phase closed bottle test (available in English only). ISO 10708. 1997.
25. ISO. Water quality—Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium. ISO 10631. 1995.
26. ASTM International. Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians. ASTM E 729-96 (2007).
27. ASTM International. Standard Guide for Conducting Static Toxicity Tests with Microalgae. ASTM E 1218-04e1. 2004.
28. ASTM International. Standard Guide for Conducting Daphnia magna Life-Cycle Toxicity Tests. ASTM E 1193-97 (2004).
29. Veith, G.D. and Kosian, P. Estimating bioconcentration potential from Octanol/Water Partition Coefficients, in Physical Behavior of PCBs in the Great Lakes (MacKay, Paterson, Eisenreich, and Simmons, eds.), Ann Arbor Science, Ann Arbor, MI. 1982.
30. Bintein, S.; DeVillers, J.; and Karcher, W. Nonlinear dependence of fish bioconcentration on *n*-Octanol/Water Partition Coefficient. *SAR and QSAR in Environmental Research*. Vol. 1, pp. 29-39. 1993.
31. EPA. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances; Notice. **Federal Register** (64 FR 60194, November 4, 1999) (FRL-6097-7). Available online at: <http://www.epa.gov/oppt/newchemicals/pubs/pbtpolicy.htm>.
32. EPA. Significant New Use Rules; General Provisions for New Chemical Follow-Up; Final Rule. **Federal Register** (54 FR 31298, July 27, 1989).
33. ASTM International. Standard Test Method for Estimating Acute Oral Toxicity in Rats. ASTM E 1163-98 (2002).
34. NIEHS 2003b. Test Method Protocol for the BALB/c 3T3 Neutral Red Uptake Cytotoxicity Test, a Test for Basal Cytotoxicity for an *in vitro* Validation Study—Phase III. NTP/NICEATM. November 4, 2003. Available online at: <http://iccvam.niehs.nih.gov/methods/acute/tox/invidocs/phIIIprot/3t3phIII.pdf>.
35. NIEHS 2003c. Test Method Protocol for the NHK Neutral Red Uptake Cytotoxicity Test, a Test for Basal Cytotoxicity for an *in vitro* Validation Study—Phase III. NTP/NICEATM. November 4, 2003. Available online at: <http://iccvam.niehs.nih.gov/methods/acute/tox/invidocs/phIIIprot/nhkphIII.pdf>.
36. NIEHS 2001b. Guidance Document on Using *In Vitro* Data to Estimate *In Vivo* Starting Doses for Acute Toxicity. NIH Publication No. 01-4500. August 2001. Available online at: http://iccvam.niehs.nih.gov/methods/acute/tox/inv_cyto_guide.htm.
37. NIEHS 2003a. Test Method Protocol for Solubility Determination, *in vitro*

- Cytotoxicity Validation Study—Phase III. National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). September 24, 2003. Available online at: <http://iccvam.niehs.nih.gov/methods/acute/tox/invidocs/phillprot/solphill.pdf>.
38. EPA. OPPT. Guidance for Testing Closed System Intermediates for the HPV Challenge Program (Draft) (March 17, 1999). Available online at: <http://www.epa.gov/oppt/chemrtk/pubs/general/closed9.htm>.
 39. EPA. Testing of Certain High Production Volume Chemicals; Final Rule. **Federal Register** (71 FR 13708, March 16, 2006) (FRL-7335-2).
 40. EPA. Testing of Certain High Production Volume Chemicals; Second Group of Chemicals; Proposed Rule. **Federal Register** (73 FR 43314, July 24, 2008) (FRL-8373-9).
 41. EPA. Proposed Test Rule for the Testing of Certain High Production Volume Chemicals; Third Group of Chemicals. **Federal Register** (75 FR, February 25, 2010) (FRL-9116-2).
 42. EPA. Toxic Substances; Test Rule Development and Exemption Procedures; Interim Final Rule. **Federal Register** (50 FR 20652, May 17, 1985).
 43. EPA. Toxic Substances Control Act; Data Reimbursement; Final Rule. **Federal Register** (48 FR 31786, July 11, 1983).
 44. EPA. Analysis of Laboratory Capacity to Support U.S. EPA Chemical Testing Program Initiatives. Economic and Policy Analysis Branch. Washington, DC. October 28, 2010.
 45. EPA. OPPT. Economic Analysis for the Proposed High Production Volume Challenge Chemicals Test Rule—Fourth Group of Chemicals. Prepared by the Economic and Policy Analysis Branch, Economics, Exposure and Technology Division. August 15, 2011.
 46. EPA. OPPT. Economic Analysis of the Significant New Use Rule for High Production Volume Chemical Substances. Prepared by the Economic and Policy Analysis Branch, Economics, Exposure and Technology Division. May 26, 2011.

X. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

This proposed rule is not a “significant regulatory action” under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993) and 13563, entitled (76 FR 3821, January 21, 2011).

B. Paperwork Activities

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 approval by the Office of Management and Budget (OMB) 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.

As defined by PRA and 5 CFR 1320.3(b), “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

For this rulemaking, the paperwork activities are addressed in 3 parts, based on the separate activities.

1. *Paperwork activities related to testing.* The proposed testing in this rulemaking does not impose any new or amended paperwork collection requirements that would require additional review and/or approval by OMB under the PRA. Although the activities are approved, OMB has specified that the additional burden associated with a new test rule is not covered by the ICR until the final rule is effective. The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under PRA, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). In the context of developing a new test rule, the Agency must determine whether the total annual burden covered by the approved ICR needs to be amended to accommodate the burden associated with the new test rule. If so, the Agency must submit an Information Correction Worksheet (ICW) to OMB and obtain OMB approval of an increase in the total approved annual burden in the OMB inventory. The Agency’s estimated burden for this proposed test rule is provided in the economic analysis (Ref. 45).

The standard chemical substance testing program involves the submission of letters of intent to test (or exemption applications), study plans, semi-annual progress reports, test results, and some

administrative costs. For this proposed rule, EPA estimates the public reporting burden for all 23 chemical substances is 38,000 hours (average cost scenario). EPA assumes that industry will form a “task force” or panel to coordinate testing where appropriate. A consortium represents all the manufacturers of a chemical substance. EPA estimates 23 consortia for the proposed rule; with an estimated burden per consortium of 2,000 hours (rounded) (Ref. 45).

2. *Paperwork activities related to SNUNs.* The information collection requirements related to the proposed SNUR have already been approved by OMB pursuant to the PRA under OMB control number 2070–0038 (EPA ICR No. 1188). 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 91.68 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. In addition, depending on whether or not an entity submits a SNUN, EPA has estimated the burden of the associated recordkeeping requirements (Ref. 46).

3. *Paperwork activities related to export notifications.* The information collection activities related to export notification under TSCA section 12(b)(1) are already approved under OMB control number 2070–0030 (EPA ICR No. 0795). This proposed rule does not propose any new or changes to the export notification requirements, and is not expected to result in any substantive changes in the burden estimates for EPA ICR No. 0795 that would require additional review and/or approval by OMB.

The estimated burden of the information collection activities related to export notification is estimated to average 1 burden hour for each chemical substance/country combination for an initial notification and 0.5 hours for each subsequent notification (Ref. 46). In estimating the total burden hours approved for the information collection activities related to export notification, the Agency has included sufficient burden hours to accommodate any export notifications that may be required by the Agency’s issuance of final chemical substance test rules. As such, EPA does not expect to need to request an increase in the total burden hours approved by OMB for export notifications.

Comments are requested on the Agency’s need for this information, the

accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed rule in the manner specified under **ADDRESSES**. In developing the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposed rule.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, after considering the potential economic impacts of this proposed rule on small entities, the Agency hereby certifies that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of each of the economic analyses for this proposed rule (Refs. 45 and 46), which are summarized in Unit VII., and copies of which are available in the docket for this proposed rule. The following is a brief summary of the factual basis for this certification.

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined in accordance with RFA as:

- A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.
- A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.
- A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Based on the industry profile that EPA prepared as part of the economic analysis for this proposed rule (Ref. 45), EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency's analysis presents only the estimated potential impacts on small business.

For this rulemaking, EPA considered the potential impact on small entities associated with the proposed testing, SNU notifications, and export notifications.

1. Potential small entity impacts related to the proposed testing. Two

factors are examined in EPA's small entity impact analysis (Ref. 45) in order to characterize the potential small entity impacts of the proposed testing on small business:

- The size of the adverse economic impact (measured as the ratio of the cost to sales or revenue).
- The total number of small entities that experience the adverse economic impact.

Section 601(3) of RFA establishes as the default definition of "small business" the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which SBA establishes small business size standards (13 CFR 121.201). For this proposed rule, EPA has analyzed the potential small business impacts using the size standards established under this default definition. The SBA size standards, which are primarily intended to determine whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), "seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation." (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act. In analyzing potential impacts, RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of RFA provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. Even though the Agency has used the default SBA definition of small business to conduct its analysis of potential small business impacts for this proposed rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the chemical substance manufacturing industrial sector (*i.e.*, NAICS code 325 and NAICS code 324110), approximately 98% of the firms would be classified as small businesses under the default SBA definition. The SBA size standard for 75% of this industry sector is 500 employees, and the size standard for 23% of this industry sector is either 750, 1,000, or 1,500 employees. When assessing the potential impacts of test rules on chemical substance manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means

to judge the ability of a chemical substance manufacturing firm to support chemical substance testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical substance industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated in this unit, therefore, the factual basis for the RFA determination for this proposed rule is based on an analysis using the default SBA size standards. Although EPA is not currently proposing to establish an alternate definition for use in the analysis conducted for this proposed rule, the analysis for this proposed rule also presents the results of calculations using a standard based on total annual sales (40 CFR 704.3). EPA is interested in receiving comments on whether the Agency should consider establishing an alternate definition for small business to use in the small entity impact analyses for future TSCA section 4(a) test rules and what size cutoff may be appropriate.

SBA has developed 6-digit NAICS code-specific size standards based on employment thresholds. These size standards range from 500 to 1,500 employees for the various 6-digit NAICS codes that are potentially affected (Ref. 45). For a conservative estimate of the number of small businesses affected by the HPV rules, the Agency uses an employment threshold of less than 1,500 employees for all businesses regardless of the NAICS-specific threshold to determine small business status (Ref. 45).

For each manufacturer of the 23 chemical substances covered by the proposed testing, the parent company (ultimate corporate entity or UCE) was identified and sales and employment data were obtained for companies where data was publicly available. The search determined that there were 59 affected UCEs. Sales data could be found for 52 of these UCE's and employment data could be found for 57 of these UCEs. Two companies could not be classified as small or large because there were no employment data available (Ref. 45).

Parent company sales data were collected to identify companies that qualified as a "small business" for purposes of RFA analysis. Based on the SBA size standard applied (1,500 employees or less), 25 companies (42.4%) were identified as small (Ref. 45).

The potential significance of the proposed testing's impact on small businesses was analyzed by examining

the number of small entities that experienced different levels of costs as a percentage of their sales. Small businesses were placed in the following categories on the basis of cost-to sales ratios: Less than 1%, greater than 1%, and greater than 3%. This analysis was conducted under both a least and average cost scenario (Ref. 45).

Of the 25 businesses designated as small business, none had cost-to-sales ratios of greater than 1% and 3% under both the least and average cost scenarios. For the chemical substances where sales data were unavailable, EPA used the median revenue of all other small businesses equal to \$2.56 million. The costs for these companies were estimated to be well below 1% of this sales level. Given these results, the Agency has determined that there is not a significant economic impact on a substantial number of small entities as a result of the proposed testing, if finalized (Ref. 45).

2. Potential small entity impacts related to the SNUR. A SNUR 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." By definition of the word "new" and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since a SNUR only requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN, there are no costs associated with the SNUN until it is submitted. However there are limited costs associated with the recordkeeping requirements required by this SNUR, whether or not a SNUN is submitted. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be.

EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average less than 10 notices per year. Of those SNUNs submitted, none appear to be from small entities in response to any SNUR. In addition, the estimated reporting cost for submission of a SNUN (see Unit VII.), are minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impact of complying with this SNUR is 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 also provided to the Chief Counsel for Advocacy of the Small Business Administration (Ref. 46).

3. Potential small entity impacts related to export notifications. The estimated cost of the TSCA section 12(b)(1) export notification, which, as a result of the final rule, would be required for the first export to a particular country of a chemical substance subject to the final rule, is estimated to be \$85.70 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and \$26.86 for each subsequent export notification submitted by that exporter (Refs. 45 and 46). EPA has concluded that the costs of TSCA section 12(b)(1) export notification would have a negligible impact on exporters of the chemical substances in the final rule, regardless of the size of the exporter.

Any comments regarding the potential adverse economic impacts that this action may impose on small entities, or regarding whether the Agency should consider establishing an alternate definition of small business to be used for analytical purposes for future test rules and what size cutoff may be appropriate, should be submitted to the Agency in the manner specified under **ADDRESSES**.

D. Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. It is estimated that the total aggregate costs of this proposed rule to the private sector, which are summarized in Unit VII., would be \$7.65 million. The total annualized costs of this proposed rule to the private sector are estimated to be \$2.71 and \$2.92 million using a 3% and 7% discount rate over 3 years (average cost scenario).

In addition, since EPA does not have any information to indicate that any State, local, or Tribal government manufactures or processes the chemical substances covered by this action such that the final rule would apply directly to State, local, or Tribal governments, EPA has determined that this proposed test rule and SNUR would not significantly or uniquely affect small governments. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Federalism

Under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have "federalism implications" because they will not have substantial direct effects on the 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 the executive order. This proposed rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by these actions, this proposed test rule and SNUR is not expected to affect any State or local governments. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Indian Tribal Government Implications

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 9, 2000), EPA has determined that this proposed rule does not have Tribal implications because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in the Executive Order. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Protection of Children

This proposed rule 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 the rulemaking does not establish an environmental standard intended to mitigate health or safety risks, will not have an annual effect on the economy of \$100 million or more, nor does it otherwise have a disproportionate effect on children. This proposed rule would establish testing, notification and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances. The development of data about those chemical substances can subsequently be used to assist the Agency and others in determining

whether the chemical substances in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Effect on Energy Supply, Distribution, or Use

This proposed 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 it is not a significant regulatory action under Executive Order 12866.

I. Technical Standards

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The proposed test rule involves technical standards because it proposes to require the use of particular test methods. If the Agency makes findings under TSCA section 4(a), EPA is required by TSCA section 4(b) to include specific standards or test methods that are to be used for the development of the data required in the test rules issued under TSCA section 4. For some of the testing that would be required by the final rule, EPA is proposing the use of voluntary consensus standards issued by ASTM International and ISO which evaluate the same type of toxicity as the TSCA 799 test guidelines and OECD test guidelines, where applicable. Copies of the 17 ASTM International and ISO

standards referenced in the proposed regulatory text at § 799.5090(h) have been placed in the docket for this proposed rule. You may obtain copies of the ASTM International standards from the American Society for Testing and Materials International, 100 Bar Harbor Dr., West Conshohocken, PA 19428–2959, and copies of the ISO standards from the International Organization for Standardization, Case Postale, 56 CH–1211 Geneve 20 Switzerland. In the final rule, EPA intends to seek approval from the Director of the Federal Register for the incorporation by reference of the ASTM International and ISO standards used in the final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

EPA is not aware of any potentially applicable voluntary consensus standards which evaluate partition coefficient (*n*-octanol/water) generator column, water solubility (column elution and generator column), acute inhalation toxicity, bacterial reverse mutations, *in vivo* mammalian bone marrow chromosomal aberrations, combined repeated dose with reproductive/developmental toxicity screen, repeated dose 28-day oral toxicity screen, or the reproductive developmental toxicity screen which could be considered in lieu of the TSCA 799 test guidelines, 40 CFR 799.6756, 799.6784, 799.6786, 799.9130, 799.9510, 799.9538, 799.9365, 799.9305, and 799.9355, respectively, upon which the test standards in this proposed rule are based.

The Agency invites comment on the potential use of voluntary consensus standards in this proposed rule, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

J. Environmental Justice

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under Executive Order 12898, entitled

Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). The Agency believes that the information collected under this proposed test rule, if finalized, will assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by this proposed test rule. Although not directly impacting environmental justice-related concerns, this information will enable the Agency to better protect human health and the environment, including in low-income and minority communities.

List of Subjects

40 CFR Part 721

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

40 CFR Part 799

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

Dated: September 28, 2011.

Stephen A. Owens,
Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be 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. Add § 721.10228 to subpart E to read as follows:

§ 721.10228 High production volume challenge program chemical substances.

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

(1) The chemical substances identified in Table 1. are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

TABLE 1—LIST OF CHEMICAL SUBSTANCES INCLUDED IN THE SNUR

Chemical abstract service registry number (CASRN)	Chemical abstract (CA) index name
98–16–8	Benzenamine, 3-(trifluoromethyl)-.
100–53–8	Benzenemethanethiol.
104–91–6	Phenol, 4-nitroso-.
110–03–2	2,5-Hexanediol, 2,5-dimethyl-.
124–63–0	Methanesulfonyl chloride.
142–30–3	3-Hexyne-2,5-diol, 2,5-dimethyl-.
460–00–4	Benzene, 1-bromo-4-fluoro-.
542–92–7	1,3-Cyclopentadiene.

TABLE 1—LIST OF CHEMICAL SUBSTANCES INCLUDED IN THE SNUR—Continued

Chemical abstract service registry number (CASRN)	Chemical abstract (CA) index name
553-26-4	4,4'-Bipyridine.
8007-45-2	Tar, coal.
28106-30-1	Benzene, ethenylethyl-
35203-06-6	Benzenamine, 2-ethyl-6-methyl-N-methylene-
35203-08-8	Benzenamine, 2,6-diethyl-N-methylene-
37734-45-5	Carbonochloridothioic acid, S-(phenylmethyl) ester.
37764-25-3	Acetamide, 2,2-dichloro-N,N-di-2-propen-1-yl-
61789-72-8	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides.
61790-13-4	Naphthenic acids, sodium salts.
65996-91-0	Distillates (coal tar), upper.
68308-01-0	Tail gas (petroleum), cracked distillate hydrotreater stripper.
68478-20-6	Residues (petroleum), steam-cracked petroleum distillates cyclopentadiene conc., C4-cyclopentadiene-free.
68526-82-9	Alkenes, C6-10, hydroformylation products, high-boiling.
68909-77-3	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues.

(2) The significant new uses are:

(i) Use in a consumer product.

(ii) Any use, or combination of uses, that is reasonably likely to expose 1,000 or more workers at a single corporate entity (defined as the aggregate of all of the domestic facilities owned or operated by an individual corporation).

(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), and (c) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

PART 799—[AMENDED]

3. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

4. Add § 799.5090 to subpart D to read as follows:

§ 799.5090 Chemical testing requirements for certain high production volume chemicals; fourth group of chemicals.

(a) *What substances will be tested under this section?* Table 2. in paragraph (j) of this section identifies the chemical substances that must be tested under this section. For the chemical substances identified as “Class 1” chemical substances in Table 2. in paragraph (j) of this section, the purity of each chemical substance must be 99% or greater, unless otherwise specified in this section. For the chemical substances identified as “Class 2” chemical substances in Table 2. in paragraph (j), a representative form of each chemical substance must be tested. The representative form selected for a given Class 2 chemical substance should meet industry or consensus standards where they exist.

(b) *Am I subject to this section?* (1) If you manufacture (including import) or intend to manufacture, or process or intend to process, any chemical substance listed in Table 2. in paragraph (j) of this section at any time from the effective date of the final rule to the end

of the test data reimbursement period as defined in 40 CFR 791.3(h), you are subject to this section with respect to that chemical substance.

(2) If you do not know or cannot reasonably ascertain that you manufacture or process a chemical substance listed in Table 2. in paragraph (j) of this section during the time period described in paragraph (b)(1) of this section (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you are not subject to this section with respect to that chemical substance.

(c) *If I am subject to this section, when must I comply with it?* (1)(i) Persons subject to this section are divided into two groups, as set forth in Table 1. of this paragraph: Tier 1 (persons initially required to comply) and Tier 2 (persons not initially required to comply). If you are subject to this section, you must determine if you fall within Tier 1 or Tier 2, based on Table 1. of this paragraph.

TABLE 1—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

Persons initially required to comply with this section (Tier 1)	Persons not initially required to comply with this section (Tier 2)
Persons not otherwise specified in column 2 of this table that manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section.	<p>Tier 2A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section solely as one or more of the following:</p> <ul style="list-style-type: none"> —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 chemical substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kg (1,100 lbs.) annually (as described at 40 CFR 790.42(a)(4)); or —For research and development (as described at 40 CFR 790.42(a)(5)).

TABLE 1—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2—Continued

Persons initially required to comply with this section (Tier 1)	Persons not initially required to comply with this section (Tier 2)
	Tier 2B. Persons who process (as defined at TSCA section 3(10)) or intend to process a chemical substance included in this section (see 40 CFR 790.42(a)(2)).

(ii) Table 1. of paragraph (c)(1)(i) of this section expands the list of persons in Tier 2, that is those persons specified in 40 CFR 790.42(a)(2), (a)(4) and (a)(5), who, while legally subject to this section, must comply with the requirements of this section only if directed to do so by EPA under the circumstances set forth in paragraphs (c)(4), (c)(5), (c)(6), (c)(7), and (c)(10) of this section.

(2) If you are in Tier 1 with respect to a chemical substance listed in Table 2. in paragraph (j) of this section, you must, for each test required under this section for that chemical substance, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after the effective date of the final rule.

(3) If you are in Tier 2 with respect to a chemical substance listed in Table 2. in paragraph (j) of this section, you are considered to have an automatic conditional exemption and you will be required to comply with this section with regard to that chemical substance only if directed to do so by EPA under paragraphs (c)(5), (c)(7), or (c)(10) of this section.

(4) If no person in Tier 1 has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2. in paragraph (j) of this section within 30 days after the effective date of the final rule, EPA will publish a **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted and notify manufacturers in Tier 2A of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(5) If you are in Tier 2A (as specified in Table 1. in paragraph (c) of this section) with respect to a chemical substance listed in Table 2. in paragraph (j) of this section, and if you manufacture, or intend to manufacture, this chemical substance as of [date 30 days after date of publication of the final rule in the **Federal Register**], or within 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section, you must, for each test specified for that chemical substance in the document

described in paragraph (c)(4) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section.

(6) If no manufacturer in Tier 1 or Tier 2A has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2. in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(4) of this section, EPA will publish another **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted, and notify processors in Tier 2B of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(7) If you are in Tier 2B (as specified in Table 1. in paragraph (c) of this section) with respect to a chemical substance listed in Table 2. in paragraph (j) of this section, and if you process, or intend to process, this chemical substance as of [date 30 days after date of publication of the final rule in the **Federal Register**], or within 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section, you must, for each test specified for that chemical substance in the **Federal Register** document described in paragraph (c)(6) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section.

(8) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2. in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(6) of this section, EPA will notify all manufacturers and processors

of those chemical substances of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give the manufacturers and processors of the chemical substance(s) an opportunity to take corrective action.

(9) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2. in paragraph (j) of this section within 30 days after receipt of the certified letter or publication of the **Federal Register** document described in paragraph (c)(8) of this section, all manufacturers and processors subject to this section with respect to that chemical substance who are not already in violation of this section will be in violation of this section.

(10) If a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data with respect to a chemical substance listed in Table 2. in paragraph (j) of this section, under the procedures in 40 CFR 790.93 and 790.97, EPA may initiate termination proceedings for all testing exemptions with respect to that chemical substance and may notify persons in Tier 1 and Tier 2 that they are required to submit letters of intent to test or exemption applications within a specified period of time.

(11) If you are required to comply with this section, but your manufacture or processing of, or intent to manufacture or process, a chemical substance listed in Table 2. in paragraph (j) of this section begins after the applicable compliance date referred to in paragraphs (c)(2), (c)(5), or (c)(6) of this section, you must either submit a letter of intent to test or apply to EPA for an exemption. The letter of intent to test or the exemption application must be received by EPA no later than the day you begin manufacture or processing.

(d) *What must I do to comply with this section?* (1) To comply with this section you must either submit to EPA a letter of intent to test, or apply to and

obtain from EPA an exemption from testing.

(2) For each test with respect to which you submit to EPA a letter of intent to test, you must conduct the testing specified in paragraph (h) of this section and submit the test data to EPA.

(3) You must also comply with the procedures governing test rule requirements in part 790 of this chapter, as modified by this section, including the submission of letters of intent to test or exemption applications, the submission of study plans prior to testing, the conduct of testing, and the submission of data; 40 CFR part 792—Good Laboratory Practice Standards; and this section. The following provisions of 40 CFR part 790 do not apply to this section: Paragraphs (a), (d), (e), and (f) of § 790.45; § 790.48; paragraph (a)(2) and paragraph (b) of § 790.80; paragraph (e)(1) of § 790.82; and § 790.85.

(e) *If I do not comply with this section, when will I be considered in violation of it?* You will be considered in violation of this section as of one day after the date by which you are required to comply with this section.

(f) *How are EPA's data reimbursement procedures affected for purposes of this section?* If persons subject to this section are unable to agree on the amount or method of reimbursement for test data

development for one or more chemical substances included in this section, any person may request a hearing as described in 40 CFR part 791. In the determination of fair reimbursement shares under this section, if the hearing officer chooses to use a formula based on production volume, the total production volume amount will include amounts of a chemical substance produced as an impurity.

(g) *Who must comply with the export notification requirements?* Any person who exports, or intends to export, a chemical substance listed in Table 2. in paragraph (j) of this section is subject to 40 CFR part 707, subpart D.

(h) *How must I conduct my testing?* The tests that are required for each chemical substance are indicated in Table 2. in paragraph (j) of this section. The test methods that must be followed are provided in Table 3. in paragraph (j) of this section. You must proceed in accordance with these test methods as required according to Table 3. in paragraph (j) of this section, or as appropriate if more than one alternative is allowed according to Table 3. in paragraph (j) of this section.

(i) *Reporting requirements.* A final report for each specific test for each subject chemical substance must be received by EPA by *[date 13 months after the effective date of publication of*

the final rule in the Federal Register] unless an extension is granted in writing pursuant to 40 CFR 790.55. A robust summary of the final report for each specific test may be submitted electronically in addition to and at the same time as the final report. The term "robust summary" is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled "Draft Guidance on Developing Robust Summaries" which is available on-line at: <http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm>.

(j) *Designation of specific chemical substances and testing requirements.* The chemical substances identified by chemical substance name, Chemical Abstract Service Registry Number (CASRN), and class in Table 2. of this paragraph must be tested in accordance with the requirements designated in Tables 2. and 3. of this paragraph, and the requirements described in 40 CFR part 792—Good Laboratory Practice Standards.

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

Chemical abstract service registry number (CASRN)	Chemical abstract (CA) index name	Class	Required tests (see Table 3. of this section)
56-40-6	Glycine	1	A3
67-72-1	Ethane, 1,1,1,2,2,2-hexachloro-	1	C6
78-00-2	Plumbane, tetraethyl-	1	A4, A5, C6, E2
95-14-7	1H-Benzotriazole	1	A3, C6, F1
118-48-9	2H-3,1-Benzoxazine-2,4(1H)-dione	1	A3, A4, A5, C3, E1, E2, F1
128-44-9	1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	1	A2, A3, A4, A5, C1, F1
928-72-3	Glycine, N-(carboxymethyl)-, sodium salt (1:2)	1	A1, A3, A4, A5, B
1809-19-4	Phosphonic acid, dibutyl ester	1	A1, A4, C1, E1, E2, F1
25377-73-5	2,5-Furandione, 3-(dodecen-1-yl)dihydro-	1	A1, A2, A3, A4, A5, B, C1, D, E2, F1
26544-38-7	2,5-Furandione, dihydro-3-(tetrapropenyl)-	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
27859-58-1	Butanedioic acid, 2-(tetrapropenyl)-	1	A1, A2, A3, A4, A5, C1, D, E1, E2, F1
28777-98-2	2,5-Furandione, dihydro-3-(octadecen-1-yl)-	1	A2, A3, A4, A5, C1, D, E1, E2, F1
29385-43-1	1H-Benzotriazole, 6(or 7)-methyl-	1	A3, A4, A5, E2, F1
32072-96-1	2,5-Furandione, 3-(hexadecen-1-yl)dihydro-	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
61789-73-9	Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, chlorides.	2	A3
64665-57-2	1H-Benzotriazole, 6(or 7)-methyl-, sodium salt	1	A1, A3, A4, A5, E1, E2, F1,
68131-13-5	Naphthenic acids, reaction products with diethylenetriamine	2	C1, D, E1, E2, F1
68153-60-6	Fatty acids, tall-oil, reaction products with diethylenetriamine, acetates	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68424-85-1	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides.	1	A1, A2, A3
68442-77-3	2-Butenediamide, (2E)-, N1,N4-bis[2-(4,5-dihydro-2-nortall-oil alkyl-1H-imidazol-1-yl)ethyl] derivs.	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68607-28-3	Quaternary ammonium compounds, (oxydi-2,1-ethanediyl)bis(coco alkyldimethyl, dichlorides.	2	A1, A2, A3, A4, A5,

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS—Continued

Chemical abstract service registry number (CASRN)	Chemical abstract (CA) index name	Class	Required tests (see Table 3. of this section)
68909–18–2	Pyridinium, 1-(phenylmethyl)-, Et Me derivs., chlorides	2	A1, A2, A3, A4, A5, C1, D, E1, E2, F1
69834–17–9	Benzene, decylphenoxy-	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2

Testing category	Test symbol	Test requirements and references	Special conditions
Physical/chemical properties.	A	1. Melting Point: ASTM E 324–99 (capillary tube), if a Freezing Point: Organisation for Economic Co-operation and Development (OECD) 102 (melting point/melting range). 2. Boiling Point: ASTM E 1719–05 (ebulliometry). 3. Vapor Pressure: ASTM E 1782–03 (thermal analysis).	
Physical/chemical properties (continued).	A	4. <i>n</i> -Octanol/Water Partition Coefficient (log 10 basis) or log K_{ow} : (see special conditions for the log K_{ow} test requirement and select the appropriate method to use, if any, from those listed in this column). Method A: 40 CFR 799.6755 (shake flask). Method B: ASTM E 1147–92(2005) (liquid chromatography). Method C: 40 CFR 799.6756 (generator column) 5. Water Solubility: (See special conditions for the water solubility test requirement and select the appropriate method to use, if any, from those listed in this column). Method A: ASTM E 1148–02 (shake flask) Method B: 40 CFR 799.6784 (shake flask) Method C: 40 CFR 799.6784 (column elution) Method D: 40 CFR 799.6786 (generator column)	<i>n</i> -Octanol/Water Partition Coefficient or log K_{ow} : Which method is required, if any, is determined by the test substance's estimated ¹ log K_{ow} as follows: log K_{ow} <0: no testing required. log K_{ow} range 0–1: Method A or B. log K_{ow} range > 1–4: Method A or B or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. Water Solubility: Which method is required, if any, is determined by the test substance's estimated ² water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 mg/L: Method A or B. > 10 mg/L–5,000 mg/L: Method A, B, C, or D. > 0.001 mg/L–10 mg/L: Method C or D. ≤ 0.001 mg/L: No testing required.
Environmental fate and pathways—ready biodegradation.	B	For B, consult ISO 10631 for guidance, and choose one of the methods listed in this column: 1. ASTM 1720–01 (sealed vessel CO ₂ production test) or 2. ISO 14593 (CO ₂ headspace test) or 3. ISO 7827 (analysis of DOC) or 4. ISO 9408 (determination of oxygen demand in a closed respirometer) or 5. ISO 9439 (CO ₂ evolution test) or 6. ISO 10707 (closed bottle test) or 7. ISO 10708 (two-phase closed bottle test).	Which method is required, if any, is determined by the test substance's physical and chemical properties, including its water solubility. ISO 10631 provides guidance for selection of an appropriate test method for a given test substance. Test sponsors must provide in the final study report the underlying rationale for the method selected.
Aquatic toxicity	C1	For C1, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—see special conditions. Test Group 1 for C1: 1. Acute Toxicity To Fish: ASTM E 729–96 (2007). 2. Acute Toxicity To Daphnia: ASTM E 729–96 (2007). 3. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} . Test Group 2 for C1: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004) 2. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} .	The following are the special conditions for C1, C2, C3, C4, C5, and C7 testing; there are no special conditions for C6. Which test group is required is determined by the test substance's measured log K_{ow} as obtained under Test Category A, or using an existing measured log K_{ow} . ³ If log K_{ow} <4.2: Test Group 1 is required. If log K_{ow} ≥ 4.2: Test Group 2 is required.

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2—Continued

Testing category	Test symbol	Test requirements and references	Special conditions
	C2	For C2, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. Test Group 1 for C2: 1. Acute Toxicity To Daphnia: ASTM E 729–96 (2007). 2. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} . Test Group 2 for C2: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004). 2. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} .	
	C3	For C3, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—see special conditions. Test Group 1 for C3: 1. Acute Toxicity To Fish: ASTM E 729–96 (2007). 2. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} . Test Group 2 for C3: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004). 2. Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} .	
	C4	For C4, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—see special conditions. Test Group 1 for C4: 1. Acute Toxicity To Fish: ASTM E 729–96 (2007). 2. Acute Toxicity To Daphnia: ASTM E 729–96 (2007). Test Group 2 for C4: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004).	
	C5	For C5, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—see special conditions. Test Group 1 for C5: 1. Acute Toxicity To Daphnia: ASTM E 729–96 (2007). Test Group 2 for C5: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004).	
	C6	Toxicity To Plants (Algae): ASTM E 1218–04 ^{e1} .	
	C7	For C7, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—see special conditions. Test Group 1 for C7: 1. Acute Toxicity To Fish: ASTM E 729–96 (2007). Test Group 2 for C7: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004).	
	D	See special conditions for this test requirement and select the method that must be used from those listed in this column. Method A: Acute Inhalation Toxicity (rat): 40 CFR 799.9130. Method B: either: 1. Acute (Up/Down) Oral Toxicity (rat): ASTM E 1163–98 (2002) or 2. Acute (Up/Down) Oral Toxicity (rat): 40 CFR 799.9110(d)(1)(i)(A).	Which testing method is required is determined by the test substance's physical state at room temperature (25 °C). For those test substances that are gases at room temperature, Method A is required; otherwise, use either of the two methods listed under Method B. In Method B, 40 CFR 799.9110(d)(1)(i)(A) refers to the OECD 425 Up/Down Procedure. ⁴ Estimating starting dose for Method B: Data from the neutral red uptake basal cytotoxicity assay ⁵ using normal human keratinocytes or mouse BALB/c 3T3 cells may be used to estimate the starting dose.
Mammalian toxicity—acute			
Mammalian toxicity—genotox-icity.	E1	Bacterial Reverse Mutation Test (<i>in vitro</i>): 40 CFR 799.9510.	None.

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2—Continued

Testing category	Test symbol	Test requirements and references	Special conditions
Mammalian toxicity—repeated dose/reproduction/developmental.	E2	Conduct any one of the following three tests for chromosomal damage: <i>In vitro</i> Mammalian Chromosome Aberration Test: 40 CFR 799.9537 or Mammalian Bone Marrow Chromosomal Aberration Test (<i>in vivo</i> in rodents: Mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9538 or Mammalian Erythrocyte Micronucleus Test [sampled in bone marrow] (<i>in vivo</i> in rodents: mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9539.	Persons required to conduct testing for chromosomal damage are encouraged to use the <i>in vitro</i> Mammalian Chromosome Aberration Test (40 CFR 799.9537) to generate the needed data unless known chemical properties (e.g., physical/chemical properties, chemical class characteristics) preclude its use. A subject person who uses one of the <i>in vivo</i> methods instead of the <i>in vitro</i> method to address a chromosomal damage test requirement must submit to EPA a rationale for conducting that alternate test in the final study report.
	F1	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365. or Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355 and Repeated Dose 28-Day Oral Toxicity Study in rodents: 40 CFR 799.9305.	Where F1 is required, EPA recommends use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). However, there may be valid reasons to test a particular chemical substance using both 40 CFR 799.9355 and 40 CFR 799.9305 to fill Mammalian Toxicity—Repeated Dose/Reproduction/Developmental data needs. A subject person who uses the combination of 40 CFR 799.9355 and 40 CFR 799.9305 in place of 40 CFR 799.9365 must submit to EPA a rationale for conducting these alternate tests in the final study reports. Where F2 or F3 is required, no rationale for conducting the required test need be provided in the final study report.
	F2	Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355.	
	F3	Repeated Dose 28-Day Oral Toxicity Study in rodents: 40 CFR 799.9305.	

¹ EPA recommends, but does not require, that log K_{ow} be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating log K_{ow} is described in the article entitled *Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients* by W.M. Meylan and P.H. Howard in the *Journal of Pharmaceutical Sciences*. 84(1):83–92. January 1992. This reference is available under docket ID number EPA–HQ–OPPT–2010–0520 at the EPA Docket Center, Rm. 3331 in the EPA West Building located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

² EPA recommends, but does not require, that water solubility be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating water solubility is described in the article entitled *Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient* by W.M. Meylan, P.H. Howard, and R.S. Boethling in *Environmental Toxicology and Chemistry*. 15(2):100–106. 1996. This reference is available under docket ID number EPA–HQ–OPPT–2010–0520 at the EPA Docket Center, Rm. 3331 in the EPA West Building located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

³ Chemical substances that are dispersible in water may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. Test sponsors who wish to conduct Test Group 1 studies on such chemical substances may request a modification to the test standard as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method be used for determining whether acute or chronic aquatic toxicity testing be performed for a specific substance.

⁴ The OECD 425 Up/Down Procedure, revised by OECD in December 2001, is available under docket ID number EPA–HQ–OPPT–2010–0520 at the EPA Docket Center, Rm. 3331 in the EPA West Building located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

⁵ The neutral red uptake basal cytotoxicity assay, which may be used to estimate the starting dose for the mammalian toxicity-acute endpoint, is available under docket ID number EPA–HQ–OPPT–2010–0520 at the EPA Docket Center, Rm. 3331 in the EPA West Building located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

(k) *Effective date.* This section is effective on [date 30 days after date of

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