ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 799

[EPA–HQ–OPPT–2005–0033; FRL–7335–2]

RIN 2070–AD16

Testing of Certain High Production Volume Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a final rule under the Toxic Substances Control Act (TSCA) that requires manufacturers (including importers) and processors of 17 high production volume (HPV) chemicals to conduct acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (in fish, Daphnia, and algae), and environmental fate (including 5 tests for physical chemical properties and biodegradation) testing. EPA has determined that each of the 17 chemicals included in this final rule is produced in substantial quantities and that there is or may be substantial human exposure to each of them. Moreover, EPA has determined that there are insufficient data to reasonably determine or predict the effects on health or the environment of the manufacture, distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that this testing program is necessary and appropriate for developing such data. Data developed under this final rule will provide critical information about the environmental fate and potential hazards of these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate potential health and environmental risks and take appropriate actions. Persons who export or intend to export any chemical included in this final rule, regardless of the form in which it is exported, are subject to the export notification requirements of TSCA section 12(b).

DATES: This final rule is effective on April 17, 2006. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of April 17, 2006. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on March 30, 2006.

ADDRESSES: *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2005–0033. All documents in the docket are listed on the regulations.gov web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the OPPT Docket, EPA Docket Center (EPA/DC), EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

TSCA section 4 submissions. For submission instructions, see Unit IX. of the **SUPPLEMENTARY INFORMATION**.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process any of the chemical substances that are listed in Table 2 in § 799.5085(j) of the regulatory text. Any use of the term ''manufacture'' in this final rule will encompass ''import,'' unless otherwise stated. In addition, as described in Unit VI., any person who exports or intends to export any of the chemical substances in this final rule, regardless of the form in which it is exported, is subject to the export notification requirements in 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of one or more of the 17 subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.
- Processors of one or more of the 17 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 Industry Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit V.E. and consult § 799.5085(b) of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using the online docket system, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. A frequently updated electronic version of 40 CFR part 9 and part 799 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr*.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating a final test rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)) that requires manufacturers and processors of 17 chemical substances to conduct acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity, ecotoxicity, and environmental fate testing. The chemicals are HPV chemicals, i.e., chemicals with a production/import volume equal to or greater than 1 million pounds per year. A detailed discussion regarding efforts to enhance the availability of screening level hazard and environmental fate information about HPV chemicals can be found in a **Federal Register** document which published on December 26, 2000 (Ref. 1).

The tests are screening level tests which in combination are known as the

Screening Information Data Set (SIDS) (see Unit II.D.). Some or all of these tests are required for a particular chemical substance, depending upon what data are already available for that substance.

In the proposal to this final rule, published in the **Federal Register** of December 26, 2000, EPA proposed SIDS testing for 37 HPV chemicals (Ref. 2). Numerous comments were received on the proposed rule. In consideration of those comments, EPA changed some testing requirements for certain chemicals as explained in Unit III. As a result of recent commitments to a voluntary EPA testing program known as the HPV Challenge Program (see Unit II.C.), and updated production volume data (i.e., 2002 Inventory Update Rule (IUR) data) made available after the publication of the proposal preceding this final rule (i.e., the ''proposed rule''), EPA is requiring testing for 17 of the 37 chemicals originally proposed for testing in 2000. EPA's decision to not finalize testing requirements for the remaining 20 chemicals is described in Unit VII.

At a future date, EPA may propose testing for additional HPV chemicals as the Agency learns more about the chemicals with respect to human exposure, release, and sufficiency of the data and experience available on their potential hazards.

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

This final rule is being promulgated under TSCA section 4(a) (15 U.S.C. 2603(a)), which directs EPA to require the development of data relevant to assessing whether activities associated with chemical substances and mixtures present an unreasonable risk of injury to health or the environment, when appropriate findings are made.

Section 2(b)(1) of TSCA (15 U.S.C. 2603(b)(1)) states that it is the policy of the United States that:

> . . . 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 [which is defined by statute to include import] and those who process such chemical substances and mixtures[.]

To implement this policy, TSCA section 4(a) mandates that EPA require by rule that manufacturers and/or processors of chemical substances and mixtures conduct testing if the Administrator finds that:

> (1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
>
> (ii) There are insufficient data and experience upon which the effects of such 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, and
>
> (iii) Testing of such substance or mixture with respect to such effects is necessary to develop such data; or
>
> (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) 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, and(iii) Testing of such substance or mixture with respect to such effects is necessary to develop such data [.].

If EPA makes these findings for a chemical substance or mixture, the Administrator shall require by rule that testing be conducted on that chemical substance or mixture. The purpose of the testing is to develop data about the substance's or mixture's health or environmental effects for which there is an insufficiency of data and experience, and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings, as long as EPA finds that 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 any combination of such activities on health or the environment can be reasonably determined or predicted, and that testing is necessary to develop the data. This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) (frequently described as the ''B'' policy) (Ref. 3, pp. 28738–28739).

In this final rule, EPA is using its broad TSCA section 4(a) authority to obtain data necessary to support the development of preliminary or ''screening level'' determinations of the effects on health and the environment from exposure to the 17 chemical substances specified in Table 2 in § 799.5085(j) of the regulatory text. Following consideration of the public comments received by EPA on the proposed test rule (Ref. 2) and updated production volume information (i.e., 2002 IUR data), EPA is making the following findings for the 17 chemical substances under TSCA section 4(a)(1)(B): They are produced in substantial quantities; there is or may be substantial human exposure to them; existing data are insufficient to determine or predict their health and environmental effects; and testing is necessary to develop such data.

C. Why is EPA Taking this Action?

On April 21, 1998, EPA initiated a national effort to empower citizens with knowledge about the most widespread chemicals in commerce. A major objective of this effort is to make certain basic information about the environmental fate and potential health and environmental hazards associated with HPV chemicals available to the public. Mechanisms to collect or, where necessary, develop needed data on U.S. HPV chemicals include the voluntary HPV Challenge Program, certain international efforts, and TSCA section 4 rules.

1. *Voluntary HPV Challenge Program.* The voluntary HPV Challenge Program, officially launched in late 1998, was created to ensure that a baseline set of data on approximately 2,800 HPV chemicals would be made available to the public. HPV chemicals are manufactured or imported in amounts equal to or greater than 1 million pounds per year and were identified for this program through data reported under the TSCA Inventory Update Rule (IUR) during 1990.

EPA challenged U.S. manufacturers and importers of HPV chemicals to voluntarily sponsor chemicals in the Program. Sponsorship entails making screening-level health and environmental data available to the public. Public availability of these data, a fundamental principle of the Program, enables the public to know about the hazards associated with chemicals in their environment. The data set sought by the HPV Challenge Program is known as the Screening Information Data Set (SIDS) that was developed by the Organization for Economic Cooperation and Development (OECD). The SIDS provides an internationally agreed upon set of test data for screening high production volume chemicals for human and environmental hazards, and will allow the Agency and others to make an informed, preliminary

judgment about the hazards of HPV chemicals.

As part of their commitment to the HPV Challenge Program, sponsors submit data summaries of existing information along with a test plan that proposes a strategy to fill data gaps. Sponsors submit test plans for either individual chemicals or for a category of chemicals. A chemical category comprises a group of substances, usually similar in chemical structure, with a regular pattern of properties and effects. Data for chemicals in the category can be used to estimate the chemical properties and effects of other category members.

A 120–day comment period begins when test plans and data summaries submitted directly to the HPV Challenge Program are posted to the Program website. It is at this time when all stakeholders—industry, environmental protection groups, animal welfare groups, private citizens, etc.—can comment on the data summary and test plan submissions. EPA comments on all of the submissions as well. Comments are important because sponsors consider this feedback when revising their test plans and data summaries. All comments are posted to the Program website for public availability.

Since the Program's inception in 1998, industry chemical manufacturers and importers have participated in the Challenge by sponsoring over 2,200 chemicals. More than 400 companies and 100 consortia have sponsored chemicals directly in the Program while additional companies/consortia have sponsored chemicals indirectly in an international counterpart to the HPV challenge Program, the International Council of Chemical Associations (ICCA) HPV Initiative. HPV chemicals that are not sponsored in the Program may be subject to a test rule under TSCA Section 4 because these chemicals lack needed testing. The voluntary HPV Challenge Program is further described in a **Federal Register** document which published on December 26, 2000 (Ref. 1).

2. *Certain international efforts.* The voluntary HPV Challenge Program is designed to make maximum use of scientifically adequate existing test data and to avoid unnecessary and duplicative testing of U.S. HPV chemicals. Therefore, EPA is continuing to participate in the voluntary international efforts, complementary to the voluntary HPV Challenge Program, that are being coordinated by the OECD to secure basic hazard information on HPV chemicals in use worldwide, including some of those on the U.S. (1990) HPV chemicals list (Ref. 4). This includes agreements to sponsor a U.S. HPV chemical under either the OECD HPV SIDS Program (Ref. 5), including sponsorship by OECD member countries beyond the United States, or the international HPV Initiative that is being organized by the International Council of Chemical Associations (ICCA) (Ref. 6).

The OECD HPV SIDS Program includes information on the identity of each chemical, its uses, sources and extent of exposure; physical and chemical properties; environmental fate; and certain limited toxicity data for humans and the environment. The SIDS is not intended to describe a chemical thoroughly, but rather is intended to provide enough information to support an initial (or screening level) assessment and to assign a priority for further work, if necessary. The OECD HPV SIDS Program seeks the development of test data, if such data are not already available, related to six health and environmental effects endpoints for international HPV chemicals (see Unit II.D.). The SIDS data set has been internationally agreed upon by the 29 member countries of the OECD as providing the minimum data set required to make an informed preliminary judgment about the hazards of a given HPV chemical.

The ICCA consists of representatives of chemical industry trade associations from the United States, Europe, Japan, Australia, Canada, Mexico, Brazil, New Zealand, and Argentina. The intended goal of the ICCA HPV Initiative was to complete screening-level hazard assessments on 1,000 ''high priority'' chemicals by the end of the year 2004. The progress of the ICCA HPV Initiative to date can be checked on ICCA's HPV Chemical Tracking System website at *http://www.iccahpv.com/reports/reportsmain.cfm*. Most of the chemicals on the ICCA working list (Ref. 6) are also U.S. HPV chemicals. The ICCA testing/assessment work will be tied directly to that under the OECD HPV SIDS Program and to the U.S. voluntary HPV Challenge Program and any associated TSCA section 4 HPV SIDS rules. Any U.S. HPV chemicals that are handled under the OECD HPV SIDS Program or the ICCA HPV Initiative are considered by EPA to be ''sponsored'' and are not anticipated to be addressed in the voluntary HPV Challenge Program unless the international commitments are not met. Nor does EPA intend to evaluate these chemicals for possible TSCA section 4 HPV SIDS rulemaking unless the international commitments are not met.

3. *TSCA rulemaking.* U.S. data needs which remain unmet in the voluntary HPV Challenge Program or through international efforts may be addressed through TSCA section 4 rulemaking, such as this final rule, where EPA determines that the statutory findings can be made. This final rule is the first TSCA section 4 HPV SIDS rule, and addresses the unmet data needs of 17 chemicals.

Data collected and/or developed under this final rule and the voluntary HPV Challenge Program, when combined with information about exposure and uses, will allow the Agency and others to better assess the potential risk to health and the environment from these chemicals. EPA intends to make the information collected under this final rule available to the public, other Federal agencies, and any other interested parties on its website (*http://www.epa.gov/chemrtk/volchall.htm*) and in the public docket for this final rule identified under **ADDRESSES**. As appropriate, this information will be used to ensure a scientifically sound basis for risk assessment/management actions. This effort will serve to further the Agency's goal of identifying and controlling human and environmental risks as well as providing greater protection and knowledge to the public. By using the same approach to testing as that of the OECD Program, EPA is assuring that the data developed under this rule and the voluntary HPV Challenge Program will be comparable to the data being developed in other countries, thereby enabling an international sharing of data and the prevention of unnecessary and duplicative testing. See Refs. 1 and 2, pp. 81662–81664 for further information about the voluntary HPV Challenge Program and international efforts.

D. Why is EPA Focusing on HPV Chemicals and SIDS Testing?

EPA is focusing on HPV chemicals, which it defines as being manufactured in amounts equal to or greater that 1 million pounds, because although those chemicals cover only about 11% of the TSCA Inventory of chemical substances (see TSCA sections 8(a) and 8(b)), using Inventory information available in 1988 (Ref. 10, p. 32296), that small percentage of the Inventory accounts for 95% of total chemical production in the United States.

EPA is focusing on Screening Information Data Set (SIDS) testing because it is comprised of a battery of tests agreed upon by the international community through the OECD, of which the United States is a member country, as appropriate for screening HPV chemical substances for toxicity and produces information relevant to

understanding the basic health and environmental hazards and fate of HPV chemicals. The six basic testing endpoints comprising this battery of tests, known as the SIDS, have been adopted by the OECD as the minimum required to screen HPV chemical substances for toxicity and environmental fate. The content of SIDS was agreed upon at the 13th Joint Meeting of the OECD Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals (Refs. 7 and 8). The United States believes these are the right tests for our domestic needs, i.e., screening U.S. HPV chemicals for health and environmental effects and environmental fate.

SIDS testing evaluates the following six testing endpoints (Ref. 5):

- Acute toxicity.
- Repeat dose toxicity.
- Developmental and reproductive toxicity.
- Genetic toxicity (gene mutations and chromosomal aberrations).
- Ecotoxicity (studies in fish, Daphnia, and algae).
- Environmental fate (including physical/chemical properties (melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility), photolysis, hydrolysis, transport/distribution, and biodegradation).

While data on the six SIDS endpoints do not fully measure a chemical's toxicity, they do provide a consistent minimum set of information that can be used to determine the relative hazards of chemicals and to judge if additional testing or assessment is necessary.

E. How Does EPA's HPV Work Relate to That of the OECD?

As noted in Unit II.C.2., the OECD SIDS Program is complementary to the voluntary HPV Challenge Program. However, EPA's definition of an HPV chemical differs from that of the OECD. EPA defines an HPV chemical as having an annual production or importation volume of 1 million pounds or more. The OECD defines an HPV chemical as having an annual production volume of 2.2 million pounds (equivalent to 1 million kilograms (kg)) reported in any member country.

The presence of a chemical on the OECD's list of HPV chemicals was and continues to be accepted by OECD member countries as providing a sufficient indicator of potential exposure to warrant testing at the SIDS level (Ref. 9).

EPA, however, does not believe that a production volume threshold which is chosen for an international program on existing chemicals and which is the only trigger for entry into that program should be determinative of the threshold chosen for ''substantial production'' under TSCA section 4(a)(1)(B)(i). See EPA's ''B'' policy (Ref. 3). Among the reasons is that the TSCA section 4(a)(1)(B)(i) finding of substantial production is not the sole finding EPA must make to require testing based on TSCA section 4(a)(1)(B). EPA must also find that there is substantial release, or substantial or significant human exposure under TSCA sections 4(a)(1)(B)(i)(I) and (II). In addition, EPA must find that data are insufficient and testing is necessary under TSCA sections 4(a)(1)(B)(ii) and (iii). Accordingly, a finding that a chemical is produced in substantial quantities alone is not a sufficient basis to require testing under TSCA section 4.

In response to EPA's proposed ''B'' policy (Ref. 10), both the American Chemistry Council (ACC, formerly the Chemical Manufacturers Association (CMA)) and the Society of the Plastics Industry, Inc. commented that EPA's proposed production volume threshold of 1 million pounds is a reasonable interpretation of ''substantial production'' under TSCA (Refs. 11 and 12). Additionally, they indicated that the OECD's 2.2 million pound threshold would be preferable to achieve consistency between EPA's activities under TSCA section 4 and the OECD HPV SIDS Program. Although the United States and OECD differ in their definition of an HPV chemical and what should trigger basic screening tests of an HPV chemical, both the U.S. and OECD HPV Programs are alike in their information needs for an HPV chemical. Both the U.S. and OECD HPV Programs have identified the SIDS battery of tests as the basic screening tests needed to provide enough information to support a screening level assessment of the health and environmental effects of a chemical.

F. Why is EPA Pursuing Hazard Information on HPV Chemicals?

EPA found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million pounds per year based on 1990 IUR reporting, only 7% had a full set of publicly available and internationally recognized basic screening test data for health and environmental effects (Ref. 13). Of the over 2,800 U.S. HPV chemicals based on 1990 IUR data, 43% had no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data were available. This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's ability to know about the hazards of chemicals that may be found in their environment, their homes, their workplaces, and the products they buy.

G. What is the Role of this Final Rule and Any Future TSCA Section 4 HPV SIDS Rulemaking with Regard to the Voluntary HPV Challenge Program?

As indicated in the December 26, 2000 **Federal Register** document (Ref. 1) describing the voluntary HPV Challenge Program, EPA intends to use rulemaking under TSCA where appropriate to help fill data gaps not addressed as part of the voluntary HPV Challenge Program or international efforts. EPA does not intend at this time to evaluate U.S. HPV chemicals that have been or are being handled through the OECD HPV SIDS Program or under a complementary program being coordinated by the ICCA (Ref. 6) for screening level testing under TSCA section 4 HPV SIDS rulemaking, although the Agency may revisit this question if commitments under those international programs are not met. See Unit III.G. of Ref. 1 for more information on these programs. EPA is evaluating the extent to which additional nonsponsored HPV chemicals meet the threshold criteria for rulemaking under TSCA section 4.

H. How Will the Data Developed Under this Final Rule Be Used?

The availability of hazard data on certain individual chemicals is fundamental to EPA's ability to accomplish its mission of environmental protection. Hazard data are used in risk assessment and risk management, and ultimately to inform the public and promote the pollution prevention ethic. Activities to ensure the availability of basic hazard information on HPV chemicals support EPA's objectives.

EPA will use the data obtained from this final rule to support development of preliminary hazard and risk assessments for the 17 HPV chemicals subject to this rule. The data will also be used by EPA to set priorities for further testing that may produce hazard information on these chemicals that may be needed by EPA, other Federal agencies, the public, industry, and others, to support adequate risk assessments. As appropriate, this information will be used to ensure a scientifically sound basis for risk characterizations and risk management actions. As such, this effort will serve to further the Agency's goal of identifying and controlling human

and environmental risks as well as providing greater knowledge and protection to the public. In the past, EPA has used data from test rules to support such activities as the development of water quality criteria, Toxic Release Inventory (TRI) listings, chemical advisories, and reduction of workplace exposures.

Finally, because the SIDS data to be developed under this final rule will be comparable to the type of data agreed to as being appropriate and being developed by the OECD HPV SIDS Program, the development of these data will enable an international sharing of data. As conceived by the OECD, the SIDS battery of tests can be used by governments and others worldwide to conduct an initial assessment of the hazards and risks posed by HPV chemicals and prioritize HPV chemicals to identify those in need of additional, more in-depth testing and assessment, as well as those of lesser concern. Not only can the data generated from this and any future TSCA section 4 HPV SIDS test rules contribute to the international effort, but also international SIDS testing and assessments can be used to fill the data gaps identified as part of the voluntary HPV Challenge Program. Additional detailed information is available on the SIDS website (*http://cs3-hq.oecd.org/scripts/hpv*) and EPA's voluntary HPV Challenge Program website (*http://www.epa.gov/chemrtk/volchall.htm*).

Data collected or developed for each sponsored chemical in the voluntary HPV Challenge Program are provided in the format of a ''robust'' (i.e., detailed) summary. A robust summary contains 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 either be an experiment or in some cases an estimation or prediction method. (See Ref. 14, also at *http://www.epa.gov/chemrtk/robsumgd.htm*). A robust summary provides sufficient information to allow a technically qualified person to make an independent assessment of a given study without having to read the full study report, and thereby facilitates the evaluation of existing data and the identification of additional data needs. EPA suggests that existing data relevant to this final rule be submitted to the Agency in robust summary format and, for any data developed under this rule, that a robust summary of the final report for each specific test be submitted in addition to the final report itself (see § 799.5085(i) of the regulatory text).

III. Response to Public Comments

EPA received a number of comments in response to the proposal (Ref. 2) to this final rule. A summary of those comments and EPA's response to each comment are presented in the document entitled *Response to Public Comments* (Ref. 40). Both the comments and EPA's *Response to Public Comments* (Ref. 40) are available in the public docket under **ADDRESSES**. The comments on the proposed test rule (Ref. 2) were submitted by the American Chemistry Council (ACC), American Petroleum Institute (API), Synthetic Organic Chemical Manufacturers Association (SOCMA), Center for Regulatory Effectiveness (CRE), Environmental Defense (ED), American Coke and Coal Chemicals Institute (ACCCI), Color Pigments Manufacturers Association, Inc. (CPMA), Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), Merisol USA LLC (Merisol), Ashland Distribution Company (Ashland), Dow Chemical Company (Dow), ExxonMobil Chemical Company (EMCC), Lonza Group, Dyno Nobel, Inc. (Dyno Nobel), Sciences International Inc.(SII), Institute of Makers of Explosives (IME), People for the Ethical Treatment of Animals (PETA), Physicians Committee for Responsible Medicine (PCRM), Doris Day Animal League (DDAL), The Humane Society of the United States (HSUS), Alternative Research & Development Foundation (ARDF), American Anti-Vivisection Society (AAVS), New England Anti-Vivisection Society (NEAVS), Silicones Environmental, Health and Safety Council (SEHSC), and numerous private citizens (Refs. 15–39).

After review and analysis of the submitted comments, EPA made the following changes to the regulatory text as proposed in response to those comments:

1. The tests for melting point, boiling point and vapor pressure are not required for 1,3-propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester) (CAS No. 78–11–5), also known as pentaerythritol tetranitrate (PETN). This change is further discussed in Unit VII.C.1. and in the document entitled *Response to Public Comments* (Ref. 40).

2. The screening test for reproduction/developmental toxicity is not required for 2,4-hexadienoic acid, (2E,4E)- (CAS No. 110–44–1), also known as sorbic acid. This change is further discussed in Unit VII.C.2. and in the document entitled *Response to Public Comments* (Ref. 40).

3. The neutral red uptake basal cytotoxicity assay may be used to estimate the starting dose for the mammalian acute toxicity test. The test is included as a special condition in Table 3 in § 799.5085(j) of the regulatory text. This change is further discussed in Unit V.A.4. and in the document entitled *Response to Public Comments* (Ref. 40).

IV. Findings

A. What is the Basis for EPA's Final Rule to Test These Chemical Substances?

As indicated in Unit II.B., in order to promulgate a rule under TSCA section 4(a) requiring testing of chemical substances or mixtures, EPA must, among other things, make certain findings for those chemical substances or mixtures regarding either hazard (TSCA section 4(a)(1)(A)(i)) or production and either chemical release or human exposure (TSCA section 4(a)(1)(B)(i)). EPA is requiring testing of the chemical substances included in this final rule based on its 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 (iii) relating to sufficient data and the need for testing. The chemical substances included in this final rule are listed in Table 2 in § 799.5085(j) of the regulatory text along with their CAS numbers.

''Substantial production'' of a chemical substance or mixture under TSCA section 4(a)(1)(B)(i) is generally interpreted by EPA to be aggregate production (including import) volume equaling or exceeding 1 million pounds per year and exposure of 1,000 workers or more on a routine or episodic basis to a chemical substance or mixture is considered to be ''substantial exposure.'' See EPA's ''B'' policy (Ref. 3) for further discussion on how EPA generally makes decisions under TSCA section 4(a)(1)(B)(i).

EPA finds that, under TSCA section 4(a)(1)(B)(i), each of the 17 chemical substances included in this final rule is produced in ''substantial quantities'' and there is or may be ''substantial human exposure'' to each chemical substance (Ref. 41). In addition, under TSCA section 4(a)(1)(B)(ii), EPA finds that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, or use of these chemical substances, or of any combination of such activities, on human health or the environment. EPA also finds that testing of the 17 chemical substances is necessary to develop such data (TSCA section 4(a)(1)(B)(iii)) (see Unit IV.E.).

EPA has not identified any factors to cause the Agency to use decisionmaking criteria other than the general thresholds described in the ''B'' policy with respect to the chemicals included in this final rule.

B. Are These Chemical Substances Produced and/or Imported in Substantial Quantities?

EPA finds that each of the chemical substances included in this final rule is produced and/or imported in an amount equal to or greater than 1 million pounds per year based on information gathered pursuant to the 2002 IUR (40 CFR part 710, subpart B). The 2002 IUR is the most recently available compilation of TSCA section 8(a) Inventory Update Reporting data, and the IUR data have been compiled into a database called the TSCA Chemical Update System. EPA also considered the fact that all of these chemicals were produced and/or imported above 1 million pounds annually based on the 1990, 1994, and 1998 IUR. EPA concludes that the annual production volume of each chemical is ''substantial'' as that term is used with reference to production in TSCA section 4(a)(1)(B)(i) (Ref. 3).

C. Are a Substantial Number of Workers Exposed to These Chemicals?

EPA finds that the manufacture, processing, and use of the chemical substances included in this action result or may result in exposure to a substantial number of workers. These chemical substances are used in a wide variety of industrial applications which result in potential exposures to workers, as described in the exposure support document for this final rule (Ref. 41).

EPA defines human exposure as the contact with a chemical or agent at the visible exterior of a person (i.e., skin and openings into the body such as mouth and nostrils) (Ref. 42, p. 22891). Worker exposure is the human exposure to a chemical or agent that occurs while a person is working. Worker exposure may have various causes, with chemical releases being a common cause of exposure. Chemical manufacturing and processing plants can release chemicals from pumps as fugitive emissions, from reactor and condenser vents as stack emissions, in the form of a vapor and/or as a particulate. Diffusion and air currents may carry a chemical throughout the plant and workers may breathe air containing the chemical, resulting in exposures. Certain human activities such as manually transferring a chemical from one container to another may also cause exposures.

Each of the chemicals in this final rule was identified in the National Occupational Exposure Survey (NOES) as having a total worker exposure of 1,000 workers or more (Ref. 41). EPA concludes that an exposure of 1,000 workers or more to a chemical substance is or may be ''substantial'' as that term is used with reference to ''human exposure'' in TSCA section 4(a)(1)(B)(i) (Ref. 3).

D. Do Sufficient Data Exist for These Chemical Substances?

As discussed in Unit II.D., data on SIDS testing endpoints, including acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (tests in fish, Daphnia, and algae), and environmental fate (five tests for physical/chemical properties (melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility) and biodegradation), are necessary in ascertaining the health and environmental effects of the 17 chemicals in this final rule. EPA has determined that for the 17 chemicals for which testing is required under this final rule, there are either no data available on SIDS testing endpoints or, where there is some information, these data are insufficient (See Unit II.D. and II.E.). Therefore, existing data are insufficient to reasonably determine or predict the effects on human health that may result from exposures to the chemical substances included in this final rule during the manufacturing, processing, or use of the subject chemical substances. EPA also sought existing information on the SIDS testing endpoints of chemical fate and ecotoxicity and found it to be insufficient. EPA undertook this evaluation because once the Administrator has made a finding under TSCA section 4(a)(1), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of a chemical (Ref. 2, p. 81660). The finding for insufficient data is based on the results of searches for data on SIDS endpoints by EPA (Ref. 13) and ACC (Ref. 43), and EPA's review of studies/data identified by commenters in response to the proposal or identified by EPA after the publication of the proposal to this final rule. The studies and data submitted or identified subsequent to the proposal were found to be sufficient for some proposed tests of certain chemicals and those tests are not required for those chemicals in this final rule (See Unit VII.C.). Table 2 of § 799.5085(j) of the regulatory text lists the SIDS endpoint tests for each of the remaining 17 chemicals for which no data are currently available to the Agency or, where some information is available, the data are not sufficient.

In the proposal to this final rule, EPA encouraged the submission of existing data on SIDS testing endpoints which are relevant to characterizing the hazard of those chemicals for which testing was proposed. All such submitted information was carefully evaluated by EPA in the development of the final testing requirements in this rule. However, if persons required to test under this final rule become aware of additional relevant scientifically adequate existing data (including structure-activity relationships (SAR) information or a scientifically defensible category approach) and submit this information to EPA at any time before testing is initiated, the Agency would consider such data to determine if they satisfy the testing requirement and would take appropriate necessary action to ensure that the testing in this rule is no longer required. In fact, they may submit such information as a requested modification to the testing requirements under 40 CFR 790.55 at anytime as long as the request is made at least 60 days before the reporting deadline for the test in question.

E. Is Testing Necessary for These Chemical Substances?

As discussed in Unit IV.D., the lack of sufficient data for these 17 chemicals compromises EPA's and others' ability to determine whether each chemical poses an unreasonable risk to human health or the environment. EPA believes that conducting SIDS testing for the 17 subject chemical substances is necessary to provide data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of the chemical substances or of any combination of such activities on health or the environment can reasonably be determined or predicted. EPA has determined that testing is necessary in order to obtain these relevant data.

EPA will use the data obtained from this final rule to support development of preliminary hazard assessments for these 17 HPV chemicals and to set priorities for obtaining exposure information and further testing that will produce more definitive hazard information where needed. Such additional information is needed by EPA, other Federal agencies, the public, industry, and others to ensure that adequate risk assessments can be conducted on these chemicals. EPA has

used data from test rules to support such activities as the development of water quality criteria, TRI listings, chemical advisories, and input for actions resulting in reduction of workplace exposures. (See Unit II.C. thru II.G.).

V. Final Rule

A. What Testing is Being Required in this Action?

EPA is requiring specific testing and reporting requirements for the chemical substances listed in Table 2 in § 799.5085(j) of the regulatory text. The testing requirements for each chemical are denoted by alphanumeric symbols in Table 2 in § 799.5085(j) of the regulatory text. Table 3 in § 799.5085(j) of the regulatory text provides the key to identify the tests denoted by the alphanumeric symbols and lists special conditions which might apply when conducting some of those tests. The test methods listed in Table 3 in § 799.5085(j) of the regulatory text are grouped according to the endpoint that they address. The following endpoints and test standards are required under this final rule; also discussed in this Unit V.A. are the special conditions which EPA has identified and is requiring for several of the required test standards.

1. *Physical/chemical properties.*

Melting Point: American Society for Testing and Materials (ASTM) E 324 (capillary tube) (Ref. 44).
Boiling Point: ASTM E 1719 (ebulliometry) (Ref. 45).
Vapor Pressure: ASTM E 1782 (thermal analysis) (Ref. 46).
n-Octanol/Water Partition Coefficient:
Method A (40 CFR 799.6755—shake flask).
Method B (ASTM E 1147—liquid chromatography) (Ref. 47).
Method C (40 CFR 799.6756—generator column).
Water Solubility:
Method A: (ASTM E 1148—shake flask) (Ref. 48).
Method B: (40 CFR 799.6784—shake flask).
Method C: (40 CFR 799.6784—column elution).
Method D: (40 CFR 799.6786—generator column).

EPA proposed determining the melting point of all 17 chemicals in this final rule using the method ASTM E 324. Since the publication of the proposal to this final rule, ASTM has indicated on its website, *http://www.astm.org/cgi-bin/SoftCart.exe/index.shtml?E+mystore*, that ASTM E 324 has been withdrawn. To quote the ASTM rationale for the withdrawal of ASTM E 324:

> 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 detracts from the time available to develop new standards which use modern technology (Ref. 49).

Note that withdrawal of the method by ASTM means only that ASTM no longer continues to develop and improve the method. It does not mean that ASTM no longer considers the method to be valid. ASTM still makes the method available for informational purposes and it can still be purchased from ASTM at the address listed in § 799.5085(h) of the regulatory text. EPA concludes that ASTM's withdrawal of E 324 does not have negative implications on the validity of the method; therefore, EPA is still requiring, for those chemicals for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324.

For the *n*-octanol/water partition coefficient and water solubility endpoints, EPA is requiring 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 3 in § 799.5085(j) of the regulatory text.

For the ''*n*-octanol/water partition coefficient (log 10 basis)'' endpoint, also known as log K_{ow}, the test method required, if any, will be determined by the test substance's estimated log K_{ow}. EPA provides three methods for measuring the substance's log K_{ow}, but prior to selecting an appropriate method to use, if any, EPA is recommending that the log K_{ow} be quantitatively estimated by using the method described in the article entitled *Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients* (Ref. 50). EPA is recommending that the K_{ow} be estimated in recognition of the fact that, depending on the chemical substance's log K_{ow}, one or more test methods can be expected to provide adequate information for determining the log K_{ow}. In general, EPA believes that the more hydrophobic a subject chemical is, the less well Method A (40 CFR 799.6755—shake flask) will work, and that Method B (ASTM E 1147—liquid chromotography) and Method C (40 CFR 799.6756—generator column) become more suitable, especially Method C. Whether the test sponsor chooses to quantitatively estimate the log K_{ow} or not, EPA requires that the test sponsor provide with the final study report the underlying rationale for the test method selected to measure log K_{ow}. The required test methods 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 log K_{ow} tests be conducted at pH 7 to ensure environmental relevance. The required test methods and estimated log K_{ow} ranges that determine which test method must be used for this endpoint for a given chemical are shown in Table 1 of this unit. The ranges of the estimated log K_{ow}s have been modified slightly since the proposal to eliminate the overlap of ranges stated in the proposal.

TABLE 1.—TEST REQUIREMENTS FOR THE *n*-OCTANOL/WATER PARTITION COEFFICIENT ENDPOINT

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	*n*-Octanol/water partition coefficient (log 10 basis) or log K_{ow}: The appropriate log K_{ow} test, if any, must be selected from those listed in this column—see special conditions in the adjacent column. Method A: 40 CFR 799.6755 (shake flask) Method B: ASTM E 1147 (liquid chromatography) Method C: 40 CFR 799.6756 (generator column)	*n*-Octanol/water partition coefficient or log K_{ow}: Which method is required, if any, is determined by the test substance's estimated 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 are required to provide in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.

For the ''water solubility'' endpoint, the test method, if any, will be determined by the test substance's estimated water solubility. EPA recommends that water solubility be quantitatively estimated prior to initiating this study. One recommended method for estimating water solubility is described in the article entitled *Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient* (Ref. 51). EPA requires that test sponsors provide in the final study report the underlying rationale for the test standard selected for this endpoint. The required test methods 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 water solubility tests be conducted at pH 7 to ensure environmental relevance. The estimated water solubility ranges that EPA proposed for use in selecting an appropriate test standard have been modified slightly since the proposal to eliminate overlaps. The estimated water solubility ranges that EPA is requiring in this final rule to select an appropriate test standard are shown in Table 2 of this unit.

TABLE 2.—TEST REQUIREMENTS FOR THE WATER SOLUBILITY ENDPOINT

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	Water solubility: The appropriate method to use, if any, to test for water solubility must be selected from those listed in this column—see special conditions in the adjacent column. Method A: ASTM E 1148 (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)	Water solubility: Which method is required, if any, is determined by the test substance's estimated water solubility. Test sponsors are required to provide in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. >5,000 milligrams/liters (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.

2. *Environmental fate and pathways.*

Inherent Biodegradation: ASTM 1625 (semicontinuous activated sludge test) (Ref. 52) or
ISO 9888 (Zahn-Wellens Method) (Ref. 53).

Either method may be used, and no special conditions apply.

3. *Aquatic toxicity.*

Test Group 1: Acute toxicity to fish (ASTM E 729) (Ref. 54).
Acute toxicity to Daphnia (ASTM E 729) (Ref. 54).
Toxicity to plants (algae) (ASTM E 1218) (Ref. 55).
Test Group 2: Chronic toxicity to Daphnia (ASTM E 1193) (Ref. 56).
Toxicity to plants (algae) (ASTM E 1218) (Ref. 55).

For the ''aquatic toxicity'' endpoint, the OECD HPV SIDS Program recognizes that, for certain chemicals, acute toxicity studies are of limited value in assessing the substances' aquatic toxicity. This issue arises with respect to chemicals 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 substances to reach 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 requiring that the aquatic toxicity testing requirement be determined based on the test substance's measured log K_{ow} as determined by using the approach outlined in Unit V.A.1., in the discussion of ''*n*-octanol/water partition coefficient,'' and in Table 3 in § 799.5085(j) of the regulatory text. For test 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 § 799.5085(j) of the regulatory text) are required: Acute toxicity to fish (ASTM E 729), Acute toxicity to Daphnia (ASTM E 729), and Toxicity to plants (algae) (ASTM E 1218). For test 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 § 799.5085(j) of the regulatory text) are required: Chronic toxicity to Daphnia (ASTM E 1193) and Toxicity to plants (algae) (ASTM E 1218). As outlined in Table 3 in § 799.5085(j) of the regulatory text, depending on the testing required 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.

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. Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 57–59). A chemical 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 in the surrounding environment (Ref. 60). For the purposes of this final 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 proposed (Ref. 61) and final (Ref. 62) Policy Statement under TSCA section 5 entitled *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*. EPA has also used a measured BCF that is equal to or greater than 1,000 or, in the absence of a BCF, a 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 (Ref. 63). EPA considers the difference between the log K_{ow} of 4.3 used with new chemical substances (Ref. 63) and the log K_{ow} value of 4.2 cited in this final TSCA section 4 test rule to be negligible.

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. To deal with such chemicals, EPA is recommending that test sponsors who wish to conduct Test Group 1 studies on chemicals with a log K_{ow} greater than or equal to 4.2 submit to EPA for approval a written request to conduct Test Group 1 studies 90 days prior to conducting such studies. EPA solicited public comment on this approach as well as other alternative approaches in this area but did not receive comments on this matter.

4. *Mammalian toxicity—acute*.

Acute Inhalation Toxicity (rat): Method A (40 CFR 799.9130)
Acute Oral Toxicity (rat): Method B (ASTM E 1163 or 40 CFR 799.9110(d)(1)(i)(A)) (Ref. 64).

For the ''mammalian toxicity—acute'' endpoint, EPA is requiring that certain ''special conditions'' be considered in determining the appropriate test method that would be used from among those included for this endpoint in Table 3 in § 799.5085(j) of the 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 Program, EPA is requiring that for test 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 § 799.5085(j) of the regulatory text). For all other chemicals (i.e., those that are either liquids or solids at room temperature), EPA is requiring that the mammalian acute toxicity testing be conducted via oral administration using an ''Up/Down'' test method (described as Method B (ASTM E 1163 or 40 CFR 799.9110(d)(1)(i)(A)) in Table 3 in § 799.5085(j) of the regulatory text). Consistent with the voluntary HPV Challenge Program, EPA is allowing the use of the neutral red uptake basal cytotoxicity assay to select the starting dose for the acute oral toxicity test as noted in Unit III. and discussed in the document *Response to Public Comments* (Ref. 40). This test is included as a special condition in Table 3 in § 799.5085(j) of the regulatory text.

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 Mammalian Bone Marrow Chromosomal Aberration Test (*in vivo* in rodents: Mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9538), or
Mammalian Erythrocyte Micronucleus Test (sampled in bone marrow) (*in vivo* 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 *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 Program and this final 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 approach provides the same degree of flexibility as that which currently exists under the OECD HPV SIDS testing program (Ref. 5). A subject person who uses one of the *in vivo* methods instead of the *in vitro* method to address a chromosomal damage test requirement must submit to EPA a rationale for conducting that alternate test in the final study report. EPA solicited comment on whether the Agency should instead require that a subject person wishing to use an alternate testing scheme submit to EPA a notice that includes the rationale for conducting the alternative tests prior to initiation of those studies. The comments received on this issue are addressed in Unit M.4. of the *Response to Public Comments* document (Ref. 40).

6. *Mammalian toxicity—repeated dose/reproduction/developmental*.

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.

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). EPA recognizes, however, that there may be reasons to test a particular chemical using both the reproduction/developmental toxicity screening test (40 CFR 799.9355) and the repeated dose 28–day oral toxicity study in rodents (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, a subject person who uses the combination of the reproduction/developmental toxicity screening test and the repeated dose 28–day oral toxicity study in rodents in place of the combined repeated dose toxicity study with reproduction/developmental toxicity screening test must submit to EPA a rationale for conducting these alternate tests in the final study reports. EPA solicited comment on whether the Agency should instead require that a subject person wishing to use an alternate testing scheme submit to EPA a notice that includes the rationale for conducting the alternative tests prior to initiation of those studies. The comments received on this issue are addressed in Unit M.4. of the *Response to Public Comments* document (Ref. 40).

In the proposal (Ref. 2) to this final rule, EPA stated that certain of the chemicals for which mammalian toxicity—repeated dose/reproduction/developmental toxicity testing is required may be used solely as ''closed system intermediates,'' and if that were the case, such chemicals may be eligible

for a reduced testing battery which substitutes a developmental toxicity study for the SIDS requirement to address repeated dose, reproduction, and developmental toxicity. EPA requested persons who believe their chemical is used solely as a closed system intermediate to submit appropriate information along with their comments which substantiate this belief. If EPA agreed that the chemical is used solely as a closed system intermediate it would address any developmental toxicity testing need in a subsequent rulemaking (Ref. 2, p. 81671). In its comments on the proposal to this final rule, ExxonMobil (Ref. 26) claimed that methyl heptenone is a closed system intermediate. EPA's response to ExxonMobil's claim is discussed in Unit K.5. of the *Response to Public Comments* document (Ref. 40).

B. When Will the Testing Imposed by this Final Rule Begin?

Once this final rule is effective, which will be 30 days after its publication in the Federal Register, the required testing must be initiated at a time sufficient to allow the final report to be submitted by the deadline indicated in § 799.5085(i) of the regulatory text, i.e., 13 months after the effective date of the rule.

C. How Must the Studies Required Under this Final Rule be Conducted?

Persons required to comply with this final rule must conduct the necessary testing in accordance with the testing requirements listed in Tables 2 and 3 in § 799.5085(j) of the regulatory text, the reporting requirements described in § 799.5085(i) of the regulatory text, and with 40 CFR Part 792—TSCA Good Laboratory Practice Standards (GLPS).

D. What Substances Will be Tested Under this Final Rule?

With one exception, the ''Class 1'' chemical substances listed in Table 2 in § 799.5085(j) of the regulatory text (i.e., 12 of the 17 chemical substances included in this final rule) must be tested at a purity of at least 99%. The exception is 1,3- propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester) (CAS No. 78–11–5), also known as pentaerythritol tetranitrate (PETN), which cannot be tested at 99% purity because of its explosive properties and must either be diluted in water or tested in a mixture with an appropriate stabilizing compound (e.g., D-lactose monohydrate is the stabilizer in PETN, NF which is a mixture that is 20% by weight PETN and 80% by weight D-lactose monohydrate. PETN, NF is the form of PETN which was tested by NTP in several toxicity studies (Ref. 65)). EPA has specified in § 799.5085 (a) of the regulatory text that, if the test sponsor elects to test this chemical in a mixture with a stabilizing compound (as opposed to dilution of the chemical in water), then the stabilizer used must be tested as a control.

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. In those instances in which the test sponsor(s) believes that a 99% level of purity is unattainable for a given chemical, the sponsor may request a modification under the procedures described in 40 CFR 790.55.

For the ''Class 2'' chemical substances listed in Table 2 in § 799.5085(j) of the regulatory text (i.e., 5 of the 17 chemical substances included in this final rule), EPA is requiring that the substance to be tested be any representative form of the chemical substance. The term Class 2 chemical substance refers to a chemical substance having a composition that cannot be represented by a specific complete chemical diagram, because such a substance generally contains two or more different chemical species (not including impurities).

In providing a different approach for identifying the substance to be tested with regard to Class 2 substances, EPA recognizes two characteristics which further distinguish Class 2 from Class 1 chemical substances. First, unlike for Class 1 substances, knowledge of the composition of commercial Class 2 substances can vary in quality and specificity from substance to substance.

The composition of the chemical species which comprise a Class 2 substance may be:

- Well characterized in terms of molecular formula, structural diagrams, and compositional percentages of all species present (for example, methyl phenol);
- Less well-characterized, for example, characterized only by molecular formula, non-specific structural diagrams, and/or by incomplete or unknown compositional percentages of the species present (for example C_{12}–C_{14} tert-alkyl amines); or
- Poorly characterized because all that is known is the identity of only some of the chemical species present and their percentages of composition, or of only the feedstocks and method used to manufacture the substance (for example, nut shell liquor of cashew).

Second, the composition of some Class 2 substances may vary from one manufacturer to another, or, for a single manufacturer, from production run to production run, because of small variations in feedstocks, manufacturing methods, or other production variables. Small variations in the feedstock or in chemical production methods or conditions can account for the types of small variations in composition typically allowable within a given Class 2 listing on the TSCA Inventory. By contrast, a ''Class 1'' designation generally applies to a substance which is an individual chemical whose only variables are its impurities.

EPA believes that, for purposes of this final rule, the testing of any representative form of a subject Class 2 substance would provide data necessary to support the development of preliminary or screening level hazard and risk characterizations for the subject Class 2 substance. However, EPA encourages the selection of representative forms of the test substances that meet industry or consensus standards, where they exist. In accordance with TSCA GLPS at 40 CFR part 792, the final study report must include test substance identification information, including name, CAS number, strength, purity, and composition, or other appropriate characteristics. (See 40 CFR 792.185). In future TSCA section 4 test rules involving Class 2 substances, testing requirements relative to the number and specificity of the representative form of the substance may differ from the testing requirement in this final rule (i.e., testing of any representative form of the subject Class 2 substances). For example, EPA may require testing of more than one representative form of a Class 2 substance or may specify the representative form to be tested and/or may specify equivalence data that must be submitted by exemption applicants. (See 40 CFR 790.82).

E. Am I Required to Test Under this Final Rule?

1. *Am I subject to this final rule*? You are subject to this 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 Table 2 in § 799.5085(j) of the regulatory text during the time period discussed in Unit V.E.2. However, if you do not know or cannot reasonably ascertain that you manufacture or process a listed test rule 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 an unreasonable burden), you are not

subject to the rule for that listed substance.

2. *When will my manufacture or processing (or my intent to do so) cause me to be subject to this final rule*? You are subject to this final rule if you manufacture or process, or intend to manufacture or process, a substance listed in Table 2 in § 799.5085(j) of the regulatory text at any time from the effective date of the final test rule to the end of the test cost 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. (See Unit V.E.4.).

3. *Will I be required to test if I am subject to the rule*? It depends on the nature of your activities. All persons who are 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), fall into one of two groups, designated here as Tier 1 and Tier 2. Persons in Tier 1 (those who must initially comply with the rule) must 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.

Persons in Tier 2 (those who do not have to initially comply with the rule) need not take any action unless they are notified by EPA that they are required to do so, as described in Unit V.E.3.d. Note that persons in Tier 1 who obtain exemptions and persons in Tier 2 are nonetheless subject to providing reimbursement to persons who actually conduct the testing, as described in Unit V.E.4.

a. *Who is in Tier 1 and Tier 2*? All persons subject to this final rule are considered to be in Tier 1 unless they fall within Tier 2. Table 3 of this unit describes who is in Tier 1 and Tier 2.

TABLE 3.—PERSONS SUBJECT TO THE RULE: PERSONS IN 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 substance, and who are not listed under Tier 2	A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule substance solely as one or more of the following: —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 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)). 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)).

b. *When is it appropriate for a person 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)). You can find procedures relating to exemptions in 40 CFR 790.80 through 790.99, and § 799.5085(c)(2), (c)(5), and (c)(9) of the regulatory text. In this final rule, EPA will not require the submission of equivalence data (i.e., data demonstrating that your substance is equivalent to the substance actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 40 CFR 790.85 do not apply to this final rule.

c. *What will happen if I submit an exemption application*? EPA believes that requiring the collection of duplicative data is unnecessarily burdensome. As a result, if EPA receives a letter of intent to test from another source or has received (or expects to receive) the test data that are required under this final rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate a conditional exemption 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 letter of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5085(c)(8) of the regulatory text. In addition, the Agency would terminate a conditional exemption if no letter of intent to test has been received by persons required to comply with the rule. See, e.g., § 799.5085(c)(6) of the regulatory text. (Note that the provisions at 40 CFR 790.48(b) have been incorporated into the regulatory text of this rule, thus persons subject to this rule are not required to comply with 40 CFR 790.48 itself (see § 799.5085(c)(4), (c)(5), (c)(6), (c)(7), and (d)(3))

Persons who obtain exemptions or receive them automatically will nonetheless be subject to providing reimbursement to persons who actually conduct the testing, as described in Unit V.E.4.

d. *What are my obligations if I am in Tier 2*? If you are in Tier 2, you are subject to the rule and you are responsible for providing reimbursement to persons in Tier 1, as described in Unit V.E.4. You are considered to have an automatic conditional exemption. You do 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.

If a problem occurs with the initiation, conduct, or completion of the required testing, or the submission of the required data to EPA, the Agency may require you to submit a letter of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5085(c)(8) of the regulatory text.

In addition, you will need to submit a letter of intent to test or an exemption application if:

- No manufacturer in Tier 1 has notified EPA of its intent to conduct testing.
- 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 § 799.5085(c)(4) and (c)(5) of the regulatory text.)

The Agency would conditionally approve an exemption application under 40 CFR 790.87, if EPA has received a letter of intent to test or has received (or expects to receive) the test data required under this final rule.

e. *Subdivision of Tier 2 entities.* If the Agency needs testing from persons in Tier 2, EPA may propose to subdivide the group of subject persons in Tier 2 into Tier 2A (Tier 2 manufacturers, i.e., those who manufacture, or intend to manufacture a test rule substance solely as one or more of the following: A byproduct; an impurity; a naturally occurring substance; a non-isolated intermediate; a component of a Class 2 substance; in amounts less than 1,100 lbs. annually; or in small quantities solely for R & D) and Tier 2B (all processors, i.e., those who process, or intend to process, a test rule substance (in any form). The terms ''process'' and ''processor'' are defined by TSCA section 3(10) and 3(11) respectively). The Agency may propose to seek testing from Tier 2A manufacturers before proceeding to Tier 2B processors.

EPA solicited comment on the subdivision of Tier 2 entities in another recent proposed TSCA section 4 test rule pertaining to dermal absorption rate testing (Ref. 55, pp. 31081–31082). Although commenters did not favor the subdivision of Tier 2 entities as a general matter, EPA decided to implement the approach in the final rule (Ref. 67, pp. 22417, 22426, and 22437–22438). The Agency indicated that subdividing Tier 2 up front in test rules may facilitate compliance by requiring Tier 2 manufacturers, when required to comply, to submit letters of intent to test or exemption applications before processors are called upon to do so. The Agency's expectation was that it may generally be less administratively complex for manufacturers to conduct the testing (including coordinating efforts to determine who will actually conduct testing) than for processors to do so. This is because there may generally be fewer manufacturers (even as byproducts, impurities, etc.) than processors (Ref. 68, p. 31789). EPA also believes that testing costs have traditionally been passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 69, p. 20654), and has not received evidence to the contrary.

Although the subdivision of Tier 2 entities was not included in the proposal to this final rule, and is thus not being implemented in this final rule, such an approach could be proposed, if needed, to facilitate compliance with the rule.

f. *How did EPA decide who would be in Tier 1 and Tier 2 and who would be excluded from the rule*? Under 40 CFR 790.2, EPA may establish procedures applying to specific test rules that differ from the generic procedures governing TSCA section 4 test rules in 40 CFR part 790. For the purposes of this final rule, EPA is setting forth certain requirements that differ from those under 40 CFR part 790.

In this final rule, EPA has reconfigured the tiers in 40 CFR 790.42. 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 substances; manufacturers of non-isolated intermediates; and manufacturers of components of Class 2 substances. For further discussion on this point, see Unit F. of the *Response to Public Comments* document (Ref. 40).

TSCA section 4(b)(3)(B) requires all manufacturers and processors of a chemical substance to test that chemical substance if EPA has made findings for that chemical substance, and therefore 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 any of the substances subject to this final rule, e.g., manufacturers or processors of a substance as a trace contaminant who are not aware of these activities, are not subject to the rule. (See Unit V.E.1. and § 799.5085(b)(2) of the regulatory text.)

4. *How do the reimbursement procedures work*? 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(c). These procedures include:

- The opportunity for a hearing with the American Arbitration Association.
- Publication by EPA of a **Federal Register** document concerning the request for a hearing.
- 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 final rule, amounts manufactured as impurities will 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).

F. What are the Reporting Requirements Under this Final Rule?

A final report must be submitted for each test for each chemical 13 months after the effective date of the final rule, i.e., by the deadline indicated in § 799.5085(i) of the regulatory text. EPA requests that a robust summary of each final test report be prepared and submitted with each 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 either be an experiment or in some cases an estimation or prediction method. ''Draft Guidance on Developing Robust Summaries'' (Ref. 14) is available on the website of the voluntary HPV Challenge Program, *http://www.epa.gov/chemrtk/robsumgd.htm*, and in the public docket for this final rule. EPA is not requiring the submission of interim progress reports for the testing required in this final rule. For the short-term studies required by this final rule, interim progress reports would likely yield little useful information. Furthermore, by not requiring interim progress reports for these short-term studies, the overall burden of the rule will be somewhat reduced.

G. What Would I Need to Do If I Cannot Complete the Testing?

A company that submits a letter of intent to test under this final rule and that subsequently anticipates difficulties in completing the testing by the deadline may submit a request to the Agency to modify the test schedule, 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.

H. Will There Be Sufficient Test Facilities and Personnel to Undertake the Testing in this Final Rule?

Various surveys of the availability of test facilities and personnel to handle the additional demand for testing services created by TSCA section 4(a) test rules indicate that available test facilities and personnel will adequately accommodate the testing specified in this final rule (Refs. 70 and 71). For further discussion on this point, see Unit J. of the *Response to Public Comments* document (Ref. 40).

I. Might EPA Seek Further Testing of the Chemicals in this Final Rule?

If EPA determines that it needs additional data regarding any of the chemical substances included in this final rule, the Agency might seek further health and/or environmental effects testing for those chemical substances. Should the Agency decide to seek such additional testing, EPA would initiate a separate action under TSCA section 4 for that purpose.

VI. Export Notification

Any person who exports, or who intends to export, one of the chemical substances contained in this final rule in any form (e.g., as components of Class 2 substances, byproducts, impurities, etc.) is subject to the export notification requirements in TSCA section 12(b)(1) and at 40 CFR part 707, subpart D. This approach is consistent with the Agency's approach when the export notification regulations were originally promulgated in 1980 (Ref. 72). 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 section 4 must notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance.

VII. Decision Not to Pursue Rulemaking

EPA has decided to withdraw 20 chemicals included in the proposal for this final rule for the reasons presented in Unit VII.A. and B.

A. Voluntary Commitments to the HPV Challenge Program

Since the publication of the proposed rule (Ref. 2), commitments have been made to sponsor 13 of the 37 chemicals originally proposed for testing. ''Viable'' commitments have been made for 11 chemicals through the voluntary HPV Challenge Program and 2 chemicals are now sponsored through the ICCA HPV Initiative (Ref. 6). Any U.S. HPV chemicals that are handled under the ICCA HPV Initiative are considered by EPA to be ''sponsored'' and are not anticipated to be addressed in either the voluntary HPV Challenge Program or in any TSCA section 4 HPV SIDS rulemaking unless the international commitments are not met. These 13 chemicals are:

- 1,2,3-Propanetriol, trinitrate (CAS No. 55–63–0).
- Methanesulfonic acid (CAS No. 75–75–2).
- Phenol, 2-(1,1-dimethylethyl)- (CAS No. 88–18–6).
- Phenol, 2-ethyl- (CAS No. 90–00–6).
- 1-Naphthalenol (CAS No. 90–15–3).
- Benzenesulfonic acid (CAS No. 98–11–3).
- Phenol, 2,4-dimethyl- (CAS No. 105–67–9).
- 2-Propen-1-ol (CAS No. 107–18–6).
- Phenol, 2,4,6-tris(1,1-dimethylethyl)- (CAS No. 732–26–3).
- Benzensulfonic acid, hydroxy- (CAS No. 1333–39–7).
- Benzenesulfonamide, N-butyl- (CAS No. 3622–84–2).
- Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, salts with bentonite (CAS No. 68153–30–0).
- Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, salts with bentonite (CAS No. 68953–58–2).

EPA believes that these voluntary commitments will result in the generation of data necessary to support development of preliminary or screening level hazard and risk determinations for these chemicals. Therefore, testing of these chemicals under TSCA section 4 is not necessary at the present time. EPA is not including these chemicals in the final rule, and testing of these chemicals under this final rule is not required. Specific information on sponsorship, test plans, and other pertinent information may be obtained by visiting EPA's voluntary HPV Challenge Program website at *http://www.epa.gov/chemrtk/viewsrch.htm*. This approach is not intended to set a precedent for how EPA will address this issue in future HPV SIDS test rules.

B. TSCA Section 4(a)(1)(B)(i) Finding Not Made

In developing the finding of substantial production for this final rule, EPA determined that, based on 2002 IUR data, seven chemicals that had been included in the proposed rule are no longer produced or imported in amounts equal to or greater than 1 million pounds per year. Because the 2002 IUR data show manufacture (including import) below the 1 million pounds per year threshold which EPA generally relies upon as ''substantial production'' under TSCA section 4(a)(1)(B)(i), the following seven chemicals are not included in the final rule:

- Thiourea (CAS No. 62–56–6).
- 1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester (CAS. No. 84–69–5).
- Acetonitrile, hydroxy- (CAS No. 107–16–4).
- Methanone, (2-hydroxy-4-methoxyphenyl)phenyl- (CAS No. 131–57–7).
- 2-Naphthalenesulfonic acid, 6-[(2,4-diaminophenyl)azo]-3-[[4-[[4-[[7-[(2,4-diaminophenyl)azo]-1-hydroxy-3-sulfo-2-naphthalenyl]azo]phenyl]amino]-3-sulfophenyl]azo]-4-hydroxy-, trisodium salt (CAS No. 6473–13–8).
- Methanesulfonic acid, hydroxy-, monosodium salt (CAS No. 870–72–4).
- Octadecanoic acid, 2-(hydroxymethyl)-2-[[(1-oxooctadecyl)oxy]methyl]-1,3-propanediyl ester (CAS No. 28188–24–1).

C. TSCA Section 4(a)(1)(B)(ii) Finding Not Made

1. *Melting point, boiling point and vapor pressure of PETN.* As discussed in Unit K.2. of the *Response to Public Comments* document (Ref. 40), EPA reviewed data submitted by SII (Ref. 28) on the physical/chemical properties of PETN (CAS No. 78–11–5). EPA believes those data are sufficient for melting point, boiling point and vapor pressure, but that data are still needed on the *n*-octanol/water partition coefficient and water solubility (Ref. 73). Therefore, EPA is not finalizing the proposed testing to determine the melting point, boiling point and vapor pressure of PETN in this final rule, but EPA is still requiring the testing of PETN for *n*-octanol/water partition coefficient and water solubility, as well as environmental fate, toxicity to algae, and screening level reproduction/developmental toxicity.

2. *Reproduction/developmental toxicity screening test of sorbic acid.* As discussed in Unit K.3. of the *Response*

to Public Comments document (Ref. 40), EPA reviewed four studies on sorbic acid (2,4-hexadienoic acid, (2E,4E)-) (CAS No. 110–44–1) which ADC (Ref. 24) thought might satisfy the testing proposed to be conducted according to 40 CFR 799.9355 to obtain screening level data on the reproductive and developmental toxicity of sorbic acid. EPA determined that the studies provided sufficient information on this endpoint(s) at this time for sorbic acid (Ref. 74). Therefore, EPA is not requiring the reproduction/developmental toxicity screening test of sorbic acid in this final rule. EPA is still requiring the testing of sorbic acid for aquatic toxicity and the determination of melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility.

VIII. Economic Impacts

EPA has prepared an economic assessment entitled *Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals* (Ref. 75), a copy of which has been placed in the public docket. This economic assessment evaluates the potential for significant economic impacts as a result of the testing that would be required by this final rule. The total social cost of this final rule is estimated to be $4.08 million, using a social discount rate of 3% over a 3–year period (Ref. 75).

While legally subject to this final rule, Tier 2 manufacturers and all processors of a subject chemical would only be required to comply with the requirements of the rule if they are directed to do so by EPA as described in § 799.5085(c)(5) and (c)(8) of the regulatory text. EPA would require Tier 2 manufacturers or processors to test only if no Tier 1 manufacturer has submitted a letter 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, the Agency expects that, for each chemical in this final 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. EPA believes that there will not be any costs to Tier 2 manufacturers or processors for conducting the testing required by the final rule because EPA is not aware of any circumstances in which 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. Given this consistent experience with previous test rules, EPA does not believe that there will be any administrative, negotiation, or any other costs associated with seeking reimbursement from Tier 2 companies.

To evaluate the potential for an adverse economic impact of testing on manufacturers of the chemical substances in this final rule, EPA employed a screening approach that compares the annual revenues from the sale of a chemical to the annualized testing costs for that chemical and expresses the testing costs as a percent of revenues generated from each chemical. Annualized testing costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are annualized over 15 years (the expected life of a chemical) using a 7% discount rate. Annualized testing costs are then divided by the estimated annual revenue of the chemical to derive the cost-to-sales ratio.

EPA estimates the cost to industry of testing the 17 chemicals evaluated in the economic analysis to be $4.03 million with an average cost of $237,000 per chemical (Ref. 75). In addition, the TSCA section 12(b) export notification, that is required only for the first export by a particular exporter to a particular country of each chemical subject to the rule, is estimated to average $67.35 (Ref. 75). The Agency's estimated total costs of testing (including both laboratory and administrative costs), annualized testing costs, price impacts, and public reporting burden hours for this final rule are presented in the economic impact analysis (Ref. 75).

Price data were available for 16 of the 17 chemicals, with an average price of $2.62 per pound for those 16 chemicals. The price impact of the test costs is a function of the chemical's price per pound and the production volume. For 12 of the chemicals (75%) for which price data were available, the price impact is less than 1.0%. With a price impact of less than 1.0%, EPA concludes that for these chemicals the potential for adverse economic impacts is low.

For 4 of the 16 chemicals (25%) with price data, the price impact is in excess of 1.0%. For chemicals where the profit margins are low, the costs of testing may use a significant part of the profits generated by the chemical.

The Agency computed ''critical prices'' for the remaining chemical for which price data were not available. The ''critical price'' is the price per pound below which there would be an impact of 1.0% or greater. The production volume for this chemical falls between 10 million to 50 million pounds. Assuming a production volume at the midpoint of that range equal to 30 million pounds per year and annualized testing costs of $33,585, the critical price is $0.11 per pound. Below that price, the testing costs would represent more than 1.0% of the revenues from the chemical. The average price for the 16 chemicals with actual price data available is $2.62 per pound. Thus, the critical price is substantially below this average. Only 2 of the 16 chemicals with price data were estimated to have prices below $0.11 per pound. While it cannot be shown conclusively that the price impacts will be less than or greater than 1.0% of the sales for this chemical, the Agency believes that adverse impacts are unlikely.

On the basis of these calculations, EPA believes that the required chemical testing presents a low potential for adverse economic impact for the majority of the chemicals subject to the rule. Because the subject chemical substances have relatively large production volumes, the annualized costs of testing, expressed as a percentage of annual revenues, are very small for most chemicals. There are, however, four chemicals for which it cannot be shown that the price impact will be below 1.0% of the revenue for these chemicals. For these chemicals, companies may choose to use revenue sources other than profits from the individual chemicals to pay for testing. To account for this, the Agency also compared the costs of compliance to company sales data. These calculations were made as part of the Agency's small entity impact analysis (Ref. 75), conducted in accordance with the requirements of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act. These results are presented in Unit XI.C.

IX. Submissions to EPA

You may make submissions such as letters of intent to test, applications for exemption from testing, study plans, applications for modification, and final study reports through the mail or in person. To ensure proper receipt by EPA, it is imperative that you direct such submissions to the attention of ''TSCA Section 4.''

1. *By mail.* Mail your submission to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460–0001 (Attention: TSCA Section 4).

2. *In person or by courier*. Deliver your submission to: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. (Attention: TSCA Section 4). 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.

X. Materials in the Docket

As indicated under **ADDRESSES** at the beginning of this document, an official docket was established for this final rule under docket ID number EPA–HQ–OPPT–2005–0033. The docket includes information considered by EPA in developing this final rule, such as the documents specifically referenced in this action, any public comments received, and other information related to this action. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the public docket, regardless of whether these referenced documents are physically located in the public docket. For assistance in locating documents that are referenced in documents that EPA has placed in the public docket, but that are not physically located in the docket, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**. The public docket is available for review as specified under **ADDRESSES**.

A. Supporting Documentation

The items listed in this Unit X.A., although supporting documentation for this final rule, are not referenced in this preamble, but they are available in the public docket for this final rule:

Anon. Final report on the safety assessment of sorbic acid and potassium sorbate. *Journal of the American College of Toxicology*. 7(6): 837–880. 1988.

Buell, D.A., Blaustein, M.B., and Lynch, J.R. An Assessment of the National Occupational Exposure Survey. Prepared by Temple, Barker & Sloane, Inc. and Exxon Corp. Undated.

Demaree, G.E., et al. Preliminary studies on the effect of feeding sorbic acid upon growth, reproduction and cellular metabolism of albino rats. *Journal of the American Pharmaceutical Association*. 44:619–621. 1955.

Environmental Defense (ED) (formerly Environmental Defense Fund, Inc.) Toxic Ignorance. 1997.

EPA 1983. Ethyltoluenes, Trimethylbenzenes, and the C_9 Aromatic Hydrocarbon Fraction; Proposed Test Rule. **Federal Register** (48 FR 23088, May 23, 1983).

EPA 1985a. Identification of Specific Chemical Substance and Mixture Testing Requirements; Ethyltoluenes, Trimethylbenzenes, and the C_9 Aromatic Hydrocarbon Fraction. **Federal Register** (50 FR 20662, May 17, 1985).

EPA 1985b. Toxic Substances; Biphenyl; Final Test Rule. **Federal Register** (50 FR 37182, September 12, 1985).

EPA 1986. Methylcyclopentane and Commercial Hexane; Proposed Test Rule. **Federal Register** (51 FR 17854, May 15, 1986).

EPA 1988. Commercial Hexane and Methylcyclopentane; Final Test Rule. **Federal Register** (53 FR 3382, February 5, 1988).

EPA 1990. Testing Consent Agreements and Test Rules; Final Rule. **Federal Register** (55 FR 18881, May 7, 1990).

EPA 1994. Office of Water Chemicals, Final Test Rule; Clarification. **Federal Register** (59 FR 45629, September 2, 1994).

EPA 1996. Announcement of the availability of draft test guidelines and solicitation of public comment. **Federal Register** (61 FR 31522, June 20, 1996) (FRL–5367–7).

EPA 1998. Announcement of the availability of the final harmonized test guidelines. **Federal Register** (63 FR 41845, August 5, 1998) (FRL–5740–1).

EPA 1999a. OPPT. Determining the Adequacy of Existing Data. February 10, 1999. Available online at: *http://www.epa.gov/chemrtk/datadfin.htm*.

EPA 1999b. OPPT. Development of Chemical Categories in the HPV Challenge Program (Draft). August 25, 1999. Available online at: *http://www.epa.gov/chemrtk/categuid.htm*.

EPA 1999c. OPPT. The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. August 26, 1999. Available online at: *http://www.epa.gov/chemrtk/sarfinl1.htm*.

EPA 1999d. Office of Prevention, Pesticides, and Toxic Substances (OPPTS). Letter from Susan H. Wayland, Deputy Assistant Administrator, to participants in the voluntary HPV Challenge Program. October 14, 1999. Available online at: *http://www.epa.gov/chemrtk/ceoltr2.htm*.

EPA 2000a. OPPT. Economic Impact of a Section 4 Test Rule for High Production Volume Chemicals. Prepared by the Economic Policy and Analysis Branch (EPAB), Economics, Exposure, and Technology Division (EETD), OPPT. December 2000.

EPA 2000b. Toxic Substance Control Act Test Guidelines; Final Rule. **Federal Register** (65 FR 78746, December 15, 2000) (FRL–6551–2).

EPA 2002a. Agency Information Collection Activities; OMB Responses. **Federal Register** (67 FR 39712, June 10, 2002) (FRL–7225–8).

EPA 2002b. Notification of Chemical Exports—TSCA Section 12(b): Request for Comment on Renewal of Information Collection Activities. **Federal Register** (67 FR 53792, August 19, 2002) (FRL–7192–7).

EPA 2002c. Revised final health effects test guidelines; acute toxicity testing—Background and acute oral toxicity; Notice of availability. **Federal Register** (67 FR 77064, December 16, 2002) (FRL–7282–3).

EPA 2003. Review of comments on biodegradation testing of a proposed test rule chemical (PETN). Memorandum from Dr. Robert Boethling, Exposure Assessment Branch (EAB), EETD to Paul Campanella, Chemical Information and Testing Branch (CITB), Chemical Control Division (CCD). February 26, 2003.

EPA 2004a. HPV Challenge Program Disclaimer on posted robust summaries and test plans. May 13, 2004. (For example, see *http://www.epa.gov/chemrtk/quatcatg/c15210tc.htm*).

EPA 2004b. IUR Data on methyl heptenone. E-mail message from Lynne Blake-Hedges, EPAB, EETD to Catherine Roman, EPA. July 8, 2004.

EPA 2004c. IUR Data on PETN. E-mail message from Lynne Blake-Hedges, EPAB, EETD to Catherine Roman, EPA. July 22, 2004.

EPA 2004d. Memorandum from Larry Newsome, High Production Volume Chemicals Branch (HPVCB), Risk Assessment Division (RAD) to Greg Schweer, CITB, CCD. August 5, 2004.

EPA 2004e. Memorandum from Katherine Anitole, Existing Chemicals Assessment Branch (ECAB), RAD to Greg Schweer, CITB, CCD. August 13, 2004.

EPA 2004f. 1-Chlorododecane. E-mail from Lynne Blake-Hedges, EPAB, EETD to Catherine Roman, EPA. August 25, 2004.

EPA 2004g. TETRATOX test. Memorandum from Donald Rodier, RAD, to Greg Schweer, CITB, CCD. November 1, 2004.

EPA 2004h. OPPT. Status and Future Directions of the High Production Volume Challenge Program. December 1, 2004. Available online at: *http://www.epa.gov/chemrtk/hpvstatr.htm*.

FDRL 1975. Food and Drug Research Labs. Teratologic evaluation of FDA 73–4 (potassium sorbate: Sorbistat) in mice and rats. Prepared under DHEW

Contract No: FDA 223–74–2176. NTIS No. PB–245520. Waverly, NY. 1975.

Hawley's Condensed Chemical Dictionary. 14th Edition. Revised by Richard J. Lewis, Sr. Publisher: John Wiley & Sons, Inc. 2002.

Larsen, J., Schultz, T.W., Rasmussen, L., Hooftman, R., and Pauli, W. Progress in an ecotoxicological standard protocol with protozoa: Results from a pilot ring test with Tetrahymena pyriformis. *Chemosphere*. 35(5): 1023–1041. 1997.

LeBlanc, G.A. Interspecies relationships in acute toxicity of chemicals to aquatic organisms. *Environmental Toxicology and Chemistry*. 3: 47–60. 1984.

National Institute of Environmental Health Sciences (NIEHS) 1997. Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIH Publication No: 97–3981. 1997. Available online at: *http://iccvam.niehs.nih.gov/docs/guidelines/validate.pdf*.

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XI. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this rule is a ''significant regulatory action'' because this action may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in section 3(f)(4) of the Executive Order. Accordingly, this final rule was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made based on OMB recommendations have been documented in the public docket for this rulemaking as required by section 6(a)(3)(E) of the Executive Order.

In addition, EPA has prepared an economic assessment entitled *Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals* (Ref. 75), a copy of which has been placed in the public docket for this rulemaking. This economic assessment evaluates the economic impacts of the testing that would be required by this final rule. The total social cost of providing the test data on the 17 chemicals that were evaluated in this economic analysis is estimated to be $4.08 million (Ref. 75). The annualized social costs of the final rule are

estimated to be $1.44 million, using a social discount rate of 3% over a 3–year period (Ref. 75).

While legally subject to this final rule, Tier 2 manufacturers and processors of a subject chemical would be required to comply with the requirements of the rule only if they are directed to do so by EPA as described in § 799.5085(c)(5) and (c)(6) of the regulatory text. EPA would only require such entities to test if no person in Tier 1 has submitted a letter of intent to test, 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, the Agency assumes that, for each chemical in this final rule, at least one such person will submit a letter of intent to test and that person will conduct such testing and will submit the test data to EPA. Because Tier 2 manufacturers and processors do not need to comply with the rule initially, the economic assessment does not address these entities.

To evaluate the potential for an adverse economic impact of testing on manufacturers of the chemical substances in this final rule, EPA employed a screening approach that estimated the impact of testing requirements as a percentage of each chemical's sale price. This measure compares annual revenues from the sale of a chemical to the annualized testing costs for that chemical to assess the percentage of testing costs that can be accommodated by the revenue generated by that chemical. Annualized testing costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are annualized over 15 years using a 7% discount rate. Annualized testing costs are then divided by the estimated annual revenue of the chemical to derive the cost-to-sales ratio. EPA estimates the total annualized compliance cost of testing for the 17 chemicals evaluated in the economic analysis to be $0.44 million under the average cost scenario. In addition, the TSCA section 12(b) export notification requirements (included in the total and annualized cost estimates) that would be triggered by the rule are expected to have a negligible impact on exporters. The TSCA section 12(b) export notification requirements under the final rule would be required for the first export to a particular country of a chemical subject to the rule. The Agency's estimated total costs of testing (including both laboratory and administrative costs), annualized testing cost, price impacts, and public reporting burden hours for this final rule are presented in the economic assessment.

Under a least cost scenario, 12 out of the 16 chemicals for which price data were available (75%) would have a price impact at less than the 1% level. Similarly, 12 out of the 16 chemicals (75%) would be impacted at less than the 1% level under an average cost scenario. Thus, the potential for adverse economic impact due to the rule is low for at least 75% of the chemicals in the rule. Approximately 4 chemicals (25%) of the 16 chemicals for which price data are available would have a price impact at a level greater than or equal to 1% under the least and average cost scenario.

The Agency computed a ''critical price'' for the chemical without price data. This price is the maximum price per pound, at which the ratio of testing costs to annual revenue would be 1%. The critical price is informative because it represents the minimum price that is required to support testing at the one percent level. The production volume for isocyanatomethane (CAS No. 624–83–9) ranges from 10 million to 50 million pounds. With an annualized testing cost estimated at $33,585, the critical price is $0.11 per pound. Below that price, the testing costs would represent more than 1.0% of the revenues from the chemical. The average price for the 16 chemicals with actual price data available is $2.67 per pound. Thus, the critical price is substantially below this average. Only 2 of the 16 chemicals with price data were estimated to have prices below $.11 per pound. While it cannot be shown conclusively that the price impacts will be less than or greater than 1.0% of the sales for this chemical, the Agency believes that adverse impacts are unlikely.

EPA believes, on the basis of these calculations, that the testing of the chemicals presents a low potential for adverse economic impact for the majority of chemicals. Because the subject chemical substances have relatively large production volumes, the annualized costs of testing, expressed as a percentage of annual revenue, are very small for most chemicals. There are, however, some chemicals for which the price impact is expected to exceed 1% of the revenue from that chemical. The potential for adverse economic impact is expected to be higher for these chemicals. In these cases, companies may choose to use revenue sources other than the profits from the individual chemicals to pay for testing.

B. Paperwork Reduction Act

The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under the provisions of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). 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 final rule does not contain any new or amended requirements that would require additional review and/or approval by OMB.

The standard chemical testing program involves the submission of letters of intent to test (or exemption applications), study plans, progress reports, and test results. EPA estimates that the information collection activities related to chemical testing for all chemicals in this final rule (representing the submission of letters of intent or exemption applications, study plans, and the final reports; progress reports are not required by this final rule because testing will be completed within about 1 year) would result in an annual public reporting burden of 1,179 hours per chemical or a total of 20,039 hours for the17 chemicals (Ref. 75).

The annual public reporting burden related to export notification is estimated to be 0.5 to 1.5 burden hours for each chemical/country combination (Ref. 75). 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 test rules (Ref. 75).

For each manufacturer of the 17 chemicals identified in the economic analysis, the parent company (ultimate corporate entity, or UCE) was also identified. The economic analysis identified a total of 52 UCEs that EPA believes would be the likely respondents to the final rule. The public reporting burden for this collection of information is estimated to be 20,039 hours total. Dividing 20,039 hours by 52 UCEs, results in a per respondent estimated burden of 304 hours. This burden estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

As defined by the 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 which have subsequently changed; 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.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and included on the related collection instrument. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. This ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(1)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(1)(B), to amend this table without further notice and comment.

C. Regulatory Flexibility Act

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 final rule on small entities, the Agency hereby certifies that this final rule will not have a significant adverse economic impact on a substantial number of small entities. The Agency's determination is based on the small entity impact analysis prepared as part of the economic analysis for this final rule (Ref. 75), which is summarized in Unit XI.A., and a copy of which is available in the docket for this final rule. The following is a brief summary of the factual basis for this certification.

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

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.

2. 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.

3. 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 for this rule that EPA prepared as part of the Economic Analysis prepared for this final rule, EPA has determined that this rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency evaluated small businesses as the small entities potentially impacted by this final rule.

Three factors are examined in EPA's small entity assessment (Ref. 75) in order to characterize the potential small entity impacts of this final rule:

- The size of the adverse impact (measured as the ratio of the cost to sales or revenue).
- The total number of small entities that experience the adverse impact.
- The percentage of the total number of small entities that experience the adverse 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 the SBA establishes small business size standards for each industry sector. (13 CFR 121.201). For this final 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. Industrial sectors are identified by a NAICS code. In most cases, SBA has specified an employee size standard (100; 500; 750; 1,000; or 1,500 employees) or, in some cases, a sales-based, or other industry-specific indicator below which an entity in that particular NAICS code would be considered small (Ref. 76). The SBA employee size standards that apply to the companies that are potentially impacted (Ref. 75) by this final rule range from 500 to 1,500 employees.

Sales and employment data were obtained for the 52 UCEs that manufacture the 17 chemicals subject to this final rule to identify those UCEs that qualify for ''small business'' status, where data were available. Based on the SBA size standards for the NAICS codes that applied to those UCEs, 23 of the 52 UCEs (44%) were identified as small. The significance of this final rule's impact on these small businesses was analyzed by examining the number of small entities that experienced different levels of costs as a percentage of their sales. In such an analysis, small businesses are placed in the following categories on the basis of cost-to-sales ratios: less than 1.0%, 1.0% but less than 3.0%, and 3.0% or greater. Of the 23 companies that qualified for small business status according to the SBA size standards, none had a cost-to-sales ratio that exceeded 1.0%. Given these results, EPA concludes that there is not a significant economic impact on these small entities as a result of this final rule.

There were an additional two UCEs for which the NAICS code, sales, and employment data were not available. Because of this, EPA could not determine whether they are small businesses or assess the potential impacts of the test rule on them. However, it is very unlikely that both of these UCEs are small entities. Moreover, given the Agency's analysis for the identified small businesses, which concluded that there is not a significant economic impact on any of them, EPA believes it is reasonable to conclude that even if these two UCEs are small entities, they will not experience a significant economic impact. Consequently, EPA concludes that there will not be a significant economic impact on a substantial number of small entities as a result of the testing imposed in this final rule.

The estimated costs of the TSCA section 12(b) export notification, which, as a result of this final rule, would be required for the first export to a particular country of a chemical subject to the rule, is estimated to be $67.35 for the first time that an exporter must comply with TSCA section 12(b) export notification requirements, and $21.81 for each subsequent export notification submitted by that exporter to an additional country (Ref. 75). EPA has concluded that the costs of TSCA section 12(b) export notification would

have a negligible impact on exporters of the chemicals in this final rule, regardless of the size of the exporter.

Therefore, the Agency certifies that this final rule will not have a significant adverse economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this regulatory action 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 for the private sector in any 1 year. The analysis of the costs associated with this action are described in Unit VIII. In addition, since EPA does not have any information to indicate that any State, local, or tribal government manufactures or processes the chemicals covered by this action such that this final rule would apply directly to State, local, or tribal governments, EPA has determined that this final rule does not significantly or uniquely affect small governments. Accordingly, this final rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 13132

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that 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.''

This final rule does not have federalism implications. It 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 Executive Order 13132. This final rule establishes testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemicals. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by this action, this rule does not apply directly to States and localities and will not affect State and local governments. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), this final 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. As indicated in this unit, EPA has no information to indicate that any tribal government manufactures or processes the chemical substances covered by this action. Thus, Executive Order 13175 does not apply to this final rule. Although Executive Order 13175 was not yet in effect when EPA developed the proposed rule, its predecessor, Executive Order 13084, was and EPA's conclusions under Executive Order 13175 are consistent with EPA's considerations under Executive Order 13084.

G. Executive Order 13045

This final rule does not require special consideration pursuant to the terms of Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it is not likely to have an annual effect on the economy of $100 million or more and it does not have a potential effect or impact on children. This final rule establishes testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemicals, and will result in the production of information that will assist the Agency and others in determining whether the chemical substances in this final rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211

This final rule is not a ''significant energy action'' as defined in 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 likely to have a significant adverse effect on the supply, distribution, or use of energy. As such, the Agency has concluded that this final rule is not likely to have adverse energy effects.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C 272 note) 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.

Because this final rule involves technical standards, the Agency conducted a search to identify potentially applicable voluntary consensus standards. EPA identified 11 applicable voluntary consensus standards (Refs. 44–48, 52–56, and 64), listed in Table 4 of this unit, and is allowing their use in this final rule. Of the 11 voluntary consensus standards, 3 of those issued by ASTM evaluate the same type of toxicity as TSCA and OECD test guidelines, as shown in Table 4 of this unit.

TABLE 4.—APPLICABLE VOLUNTARY CONSENSUS STANDARDS

Voluntary Consensus Standard No./Year	Title of Voluntary Consensus Standard	TSCA Guideline/CFR Citation	OECD Test Method No.
ASTM E 324 (1999)	Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals		

TABLE 4.—APPLICABLE VOLUNTARY CONSENSUS STANDARDS—Continued

Voluntary Consensus Standard No./Year	Title of Voluntary Consensus Standard	TSCA Guideline/CFR Citation	OECD Test Method No.
ASTM E 729 (2002)	Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians		
ASTM E 1147 (1997)	Standard Test Method for Partition Coefficient (N-Octanol/Water) Estimation by Liquid Chromatography	799.6755, 799.6756	
ASTM. E1148 (2002)	Standard Test Method for Measurements of Aqueous Solubility	799.6784, 799.6786	
ASTM E 1163 (2002)	Standard Test Method for Estimating Acute Oral Toxicity in Rats	799.9130 (if gas at room temp.).	425
ASTM E 1193 (2004)	Standard Guide for Conducting Daphnia Magna Life-Cycle Toxicity Tests		
ASTM E 1218 (2004)	Standard Guide for Conducting Static Toxicity Tests with Microalgae		
ASTM E 1625 (2001)	Standard Test Method for Determining Biodegradability of Organic Chemicals in Semi-Continuous Activated Sludge (SCAS)		
ASTM E 1719 (1997)	Standard Test Method for Vapor Pressure of Liquids by Ebulliometry		
ASTM E 1782 (2003)	Standard Test Method for Determining Vapor Pressure by Thermal Analysis		
ISO 9888 (1999)	Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Static Test (Zahn-Wellens Method), Second Edition		

Copies of the ASTM and ISO standards referenced in this final rule have been placed in the public version of the official record for this final rule and are available to read, but not to copy, at the EPA Docket location described in **ADDRESSES**. You may obtain copies of the ASTM standards from the American Society for Testing and Materials, 100 Bar Harbor Dr., West Conshohocken, PA 19428–2959, and a copy of the ISO standard from the International Organization for Standardization, Case Postale, 56 CH-1211 Geneve 20 Switzerland. EPA received the required approval from the Director of the Federal Register for the incorporation by reference of the ASTM and ISO standards used in this final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

EPA is not aware of any potentially applicable n-octanol/water partition coefficient (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 guidelines published in 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 final rule are based.

J. Executive Order 12898

Pursuant to 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 has considered environmental justice-related issues with regard to the potential impacts of this action on the environmental and health conditions in minority and low-income populations. The Agency believes that the information collected under this final rule will assist EPA and others in determining the hazards and risks associated with the chemicals covered by the rule. Although not directly impacting environmental justice-related concerns, this information will better enable the Agency to protect human health and the environment.

XII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 799

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

Dated: March 1, 2006.

Susan B. Hazen,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241,

242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, the table is amended by adding an entry for § 799.5085 in numerical order under the indicated heading to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * .	* *
Identification of Specific Chemical Substance and Mixture Testing Requirements	
* * *	* *
799.5085	2070–0033
* * *	* *

* * * * *

PART 799—[AMENDED]

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

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

■ 4. By adding § 799.5085 to subpart D to read as follows:

§ 799.5085 Chemical testing requirements for certain high production volume 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'' substances in Table 2 in paragraph (j) of this section, the purity of each chemical substance must be 99% or greater, except for 1,3-propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester) (CAS No. 78–11–5), also known as pentaerythritol tetranitrate (PETN). PETN cannot be tested at 99% purity because of its explosive properties. It must be diluted in water or tested as a stabilized mixture with an appropriate stabilizer (e.g., D-lactose monohydrate is the stabilizer in PETN, NF which is a mixture of 20% by weight PETN and 80% by weight D-lactose monohydrate). The stabilizer used must be tested as a control. For the chemical substances identified as ''Class 2'' 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 April 17, 2006 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 an 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.	A. 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: —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 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 R & D (as described at 40 CFR 790.42(a)(5)). B. 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 specified in § 790.42(a)(2), (a)(4), and (a)(5) of this chapter, 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)(5) and (c)(8) 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 May 15, 2006.

(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) or (c)(8) 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 by May 15, 2006, EPA will publish a **Federal Register** document that will specify the test(s) and the chemical substance(s) for which no letter of intent has been

submitted, and notify manufacturers and processors in Tier 2 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 2 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you manufacture or process this chemical substance as of April 17, 2006, 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 document described in paragraph (c)(4) of this section.

(6) 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)(4) 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.

(7) 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)(6) 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.

(8) 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 § § 790.93 and 790.97 of this chapter, 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.

(9) If you are required to comply with this section, but your manufacturing or processing of 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)(8) 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 manufacturing 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 conduct of testing, and the submission of data; Part 792—Good Laboratory Practice Standards of this chapter; 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; paragraph (a)(2) and paragraph (b) of § § 790.80; 790.82(e)(1); 790.85; and 790.48.

(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 1 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 part 707, subpart D, of this chapter.

(h) *How must I conduct my testing*? (1) 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. Included in Table 3 in paragraph (j) of this section are the following 11 methods which are incorporated by reference:

(i) Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals, ASTM E 324–99.

(ii) Standard Test Method for Partition Coefficient (N-Octanol/Water) Estimation by Liquid Chromatography, ASTM E 1147–92. (Reapproved 1997)

(iii) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians, ASTM E 729–96. (Reapproved 2002)

(iv) Standard Test Method for Measurements of Aqueous Solubility, ASTM E 1148–02.

(v) Standard Test Method for Estimating Acute Oral Toxicity in Rats, ASTM E 1163–98. (Reapproved 2002)

(vi) Standard Guide for Conducting Daphnia Magna Life-Cycle Toxicity Tests, ASTM E 1193–97. (Reapproved 2004)

(vii) Standard Guide for Conducting Static Toxicity Tests with Microalgae, ASTM E 1218–04.

(viii) Standard Test Method for Determining Biodegradability of Organic Chemicals in Semi-Continuous Activated Sludge (SCAS), ASTM E 1625–94. (Reapproved 2001)

(ix) Standard Test Method for Vapor Pressure of Liquids by Ebulliometry, ASTM E 1719–97.

(x) Standard Test Method for Determining Vapor Pressure by Thermal Analysis, ASTM E 1782–03.

(xi) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Static Test (Zahn-Wellens Method), Second Edition, June 1, 1999, ISO 9888–99.

(2) The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the ASTM guidelines from the American Society for Testing and Materials, 100 Bar Harbor Dr., West Conshohocken, PA 19428–2959, and a copy of the ISO guideline from the International Organization for Standardization, Case Postale, 56 CH-1211 Geneve 20 Switzerland. You may inspect each test method at the EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(i) *Reporting requirements.* A final report for each specific test for each subject chemical substance must be received by EPA by May 17, 2007, unless an extension is granted in writing pursuant to 40 CFR 790.55. A robust summary of the final report for each specific test should be submitted 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 at: *http://www.epa.gov/chemrtk/robsumgd.htm*.

(j) *Designation of specific chemical substances and testing requirements.* The chemical substances identified by chemical name, Chemical Abstract Service Number (CAS No.), 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

CAS No.	Chemical name	Class	Required tests/(See Table 3 of this section)
74–95–3	Methane, dibromo-	1	A, C1, E2, F2
75–36–5	Acetyl chloride	1	A, B, C2, E2, F1
78–11–5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester)	1	A4, A5, B, C6, F2
84–65–1	9,10-Anthracenedione	1	A, F2
108–19–0	Imidodicarbonic diamide	1	A, B, C1, D, E1, E2, F1
110–44–1	2,4-Hexadienoic acid, (2E,4E)-	1	A, C4
112–52–7	Dodecane, 1-chloro	1	A, B, C3, D, E1, E2, F1
118–82–1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)]-	1	A, B, D, E1, E2, F2
149–44–0	Methanesulfinic acid, hydroxy-, monosodium salt	1	A, B, C1, E2, F1
409–02–9	Heptenone, methyl-	2	A, B, C1, D, E1, E2, F1
594–42–3	Methanesulfenyl chloride, trichloro-	1	A, B, C1, E1, E2, F2
624–83–9	Methane, isocyanato-	1	A, C1
1324–76–1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-	2	A, B, C1, D, E1, E2, F1
2941–64–2	Carbonochloridothioic acid, S-ethyl ester	1	A, B, C1, E2, F1
8005–02–5	C.I. Solvent Black 7	2	A, B, C1, D, E2, F1
65996–78–3	Light oil (coal), coke-oven	2	A, B, C1, D, E1, E2, F1
68611–64–3	Urea, reaction products with formaldehyde	2	A, B, C1, D, E1, E2, F1

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

Testing category	Test symbol	Test requirements and references	Special conditions
Physical/chemical properties	A	1. Melting Point: ASTM E 324 (capillary tube) 2. Boiling Point: ASTM E 1719 (ebulliometry) 3. Vapor Pressure: ASTM E 1782 (thermal analysis) 4. *n*-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 (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 (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)	*n*-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 are required to provide in the final study report the underlying rationale for the method 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 are required to provide in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted 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—Inherent biodegradation	B	For B, choose either of the methods listed in this column: 1. ASTM 1625 (semicontinuous activated sludge test) OR 2. ISO 9888 (Zahn-Wellens method)	None
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 2. Acute Toxicity to Daphnia: ASTM E 729 3. Toxicity to Plants (Algae): ASTM E 1218 *Test Group 2 for C1*: 1. Chronic Toxicity to Daphnia: ASTM E 1193 2. Toxicity to Plants (Algae): ASTM E 1218	The following are the special conditions for C1, C2, C3, C4, C5, and C7 testing; there are no special conditions for C6. If log K_{ow} <4.2: Test Group 1 is required If log K_{ow} ≥ 4.2: Test Group 2 is required Which test group is required is determined by the test substance's measured log K_{ow} as obtained under A[3].
	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 2. Toxicity to Plants (Algae): ASTM E 1218 *Test Group 2 for C2*: 1. Chronic Toxicity to Daphnia: ASTM E 1193 2. Toxicity to Plants (Algae): ASTM E 1218	

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

Testing category	Test symbol	Test requirements and references	Special conditions
	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 2. Toxicity to Plants (Algae): ASTM E 1218 Test Group 2 for C3: 1. Chronic Toxicity to Daphnia: ASTM E 1193 2. Toxicity to Plants (Algae): ASTM E 1218	
	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 2. Acute Toxicity to Daphnia: ASTM E 729 *Test Group 2 for C4*: 1. Chronic Toxicity to Daphnia: ASTM E 1193	
	C5	For C5, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C5*: 1. Acute Toxicity to Daphnia: ASTM E 729 *Test Group 2 for C5*: 1. Chronic Toxicity to Daphnia: ASTM E 1193	
	C6	Toxicity to Plants (Algae): ASTM E 1218	
	C7	For C7, Test Group 1 or Test Group 2 of 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 *Test Group 2 for C7*: 1. Chronic Toxicity to Daphnia: ASTM E 1193	
Mammalian toxicity—Acute	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 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—Genotoxicity	E1	Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510	None

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

Testing category	Test symbol	Test requirements and references	Special conditions
	E2	Conduct any one of the following three tests for chromosomal damage: *In vitro* Mammalian Chromosome Aberration Test: 40 CFR 799.9537 OR Mammalian Bone Marrow Chromosomal Aberration Test (*in vivo* in rodents: mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9538 OR Mammalian Erythrocyte Micronucleus Test [sampled in bone marrow] (*in vivo* 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 *in vitro* 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 *in vivo* methods instead of the *in vitro* method to address a chromosomal damage test requirement must submit to EPA a rationale for conducting that alternate test in the final study report.
Mammalian toxicity—Repeated dose/ reproduction/ developmental	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 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–2005–0033 at the EPA Docket Center, Rm. B102, 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–2005–0033 at the EPA Docket Center, Rm. B102, 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. EPA recommends, but does not require, that test sponsors who wish to conduct Test Group 1 studies on such chemicals to submit to EPA for approval a written request to conduct Test Group 1 studies 90 days prior to conducting such studies. The written request should include the rationale for conducting Test Group 1 studies.

[4] The OECD 425 Up/Down Procedure, revised by OECD in December 2001, is available under docket ID number EPA–HQ–OPPT–2005–0033 at the EPA Docket Center, Rm. B102, 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–2005–0033 at the EPA Docket Center, Rm. B102, 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 April 17, 2006.

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