EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule involves a technical standard. EPA is adopting an ASTM standard as described in Unit II.A of the **SUPPLEMENTARY INFORMATION** section of this document. The technical standard included in today's rule is a standard developed by ASTM, a voluntary consensus standards body, and thus raises no issues under the NTTAA. The ASTM standard in today's action may be obtained from ASTM International at 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959, 610–832–9585 (phone), 610–832–9555 (fax), or *service@astm.org* (e-mail); or through the ASTM Web site (*http://www.astm.org*).

J. Executive Order 12898: Federal Actions To Address Environmental Justice and Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The allowance of ASTM D6500–05 will provide additional flexibility to the regulated community in meeting olefins in gasoline testing requirements. This final rule amendment does not relax control measures on sources regulated by the rule and therefore will not cause emission increases from these sources.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective November 21, 2011.

IV. Statutory Provisions and Legal Authority

Statutory authority for today's final rule comes from sections 211(c) and 211(k) of the CAA (42 U.S.C. 7545(c) and (k)). Section 211(c) allows EPA to regulate fuels that contribute to air pollution which endangers public health or welfare, or which impairs emission control equipment. Section 211(k) prescribes requirements for RFG and CG and requires EPA to promulgate regulations establishing these requirements. Additional support for the fuels controls in today's final rule comes from sections 114(a) and 301(a) of the CAA.

List of Subjects in 40 CFR Part 80

Environmental protection, Air pollution control, Fuel additives, Gasoline, Diesel, Imports, Incorporation by reference, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: October 13, 2011.

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble, part 80 of title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to reads as follows:

Authority: 42 U.S.C. 7414, 7521(l), 7545 and 7601(a).

Subpart D—[Amended]

■ 2. Section 80.46 is amended by adding paragraphs (b)(2) and (h)(1)(iii) to read as follows:

§ 80.46 Measurement of reformulated gasoline fuel parameters.

* * * * *

(b) * * *

(2)(i) Any refiner or importer may determine olefin content using ASTM standard method ASTM D6550 (incorporated by reference, see paragraph (h) of this section) for purposes of meeting any testing requirement involving olefin content; provided that

(ii) The refiner or importer test result is correlated with the method specified in paragraph (b)(1) of this section on a site-specific basis, in order to achieve an unbiased prediction of the result in volume percent, for the method specified in paragraph (b)(1) of this section.

* * * * *

(h) * * *

(1) * * *

(iii) ASTM standard method D6550–05 (''ASTM D6550''), Standard Test Method for Determination of Olefin Content of Gasolines by Supercritical-Fluid Chromatography, approved November 1, 2005.

* * * * *

[FR Doc. 2011–27219 Filed 10–20–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2009–0112; FRL–8885–5]

RIN 2070–AJ86

Testing of Certain High Production Volume Chemicals; Third Group of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating this final rule under section 4(a)(1)(B) of the Toxic Substances Control Act (TSCA) to require manufacturers, importers, and processors to conduct testing to obtain screening level data for health and environmental effects and chemical fate for 15 high production volume (HPV) chemical substances listed in this final rule. This test data is needed in order to help EPA to determine whether these 15 HPV chemical substances pose a risk to human health and/or environmental safety. Based on comments received by EPA on the proposed rule for this final rule, EPA has determined that only 15 of the 29 HPV chemical substances proposed for testing meet the criteria for testing at this time.

DATES: This final rule is effective November 21, 2011.

The incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of November 21, 2011.

For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on November 7, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2009–0112. 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 in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the Office of Pollution Prevention and Toxics (OPPT) Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

Submission of Information: See Unit V.E.3. of the **SUPPLEMENTARY INFORMATION** for additional instructions for submission of information (*e.g.,* letters-of-intent-to-test, exemption requests, study plans, final study reports).

Submission of information containing CBI and/or non-CBI material may be submitted by one of the following methods:

- *Mail:* Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, *Attn:* 40 CFR 799.5089; Docket ID Number EPA–HQ–OPPT–2009–0112.
- *Hand delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. E6428 ((202) 564–8930), Environmental Protection Agency, 1201 Constitution Ave., NW., Washington, DC 20004, *Attn:* 40 CFR 799.5089; Docket ID Number EPA–HQ–OPPT–2009–0112.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Paul Campanella or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone numbers:* (202) 564–8091 or (202) 564–8173; *e-mail addresses: campanella.paul@epa.gov* or *schaeffer.john@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. 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 § 799.5089(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 included in this final rule will be 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 15 HPV chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.
- Processors of one or more of the 15 HPV chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit V.E. and consult § 799.5089(b) of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult either of the technical persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What action is the agency taking?

EPA is promulgating this final rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)) that requires manufacturers and processors of 15 HPV chemical substances to conduct testing for environmental fate (including 5 tests for physical/chemical properties and biodegradation), ecotoxicity (in fish, *Daphnia,* and algae), acute toxicity, genetic toxicity (gene mutations and chromosomal aberrations), repeat dose toxicity, and developmental and reproductive toxicity. The chemical substances are HPV chemicals (*i.e.,* chemical substances with a production/import volume equal to or greater than 1 million pounds (lb) per year). A detailed discussion regarding efforts to enhance the availability of screening level hazard and environmental fate information about HPV chemical substances can be found in a **Federal Register** notice which published on December 26, 2000 (Ref. 1).

In the proposed rule for this final rule, published in the **Federal Register** issue of February 25, 2010, EPA proposed Screening Information Data Set (SIDS) testing for 29 HPV chemical substances (Ref. 2). EPA received comments on the proposed rule. In consideration of those comments, EPA changed some testing requirements for certain HPV chemical substances and is not including certain other HPV chemical substances in this final rule, as explained in Unit III. On the basis that adequate data are available for certain proposed testing endpoints, EPA reduced the number of tests required for two chemical substances; for another chemical substance, EPA dropped all testing requirements and is not including that chemical substance in this final rule. In addition, EPA is not including 12 of the proposed chemical substances in this final rule because data provided to EPA after the proposed rule was published indicate that these chemical substances are no longer HPV, no longer have substantial human exposure, or no longer have substantial environmental release. Furthermore, EPA is deferring final action for one chemical substance, as explained in Unit VIII. This final rule requires testing for 15 of the 29 HPV chemical substances originally proposed for testing in 2010.

This action follows earlier testing actions for certain HPV chemical substances (see the proposed and final rules entitled: ''Testing of Certain High Production Volume Chemicals; Proposed Rule'' (Ref. 3); ''Testing of Certain High Production Volume Chemicals; Final Rule'' (Ref. 4);

''Testing of Certain High Production Volume Chemicals; Second Group of Chemicals; Proposed Rule'' (Ref. 5); and ''Testing of Certain High Production Volume Chemicals; Second Group of Chemicals; Final Rule'' (Ref. 6)).

EPA also intends to propose testing for additional HPV chemical substances in a proposed rule scheduled for publication in 2011.

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. This is the policy of the United States, which is articulated in TSCA section 2(b)(1) (15 U.S.C. 2603(b)(1)), which states:

> * * * 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, EPA is promulgating this final rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)). Section 4(a) of TSCA mandates EPA require by rule that manufacturers and/or processors of chemical substances and mixtures conduct testing, if the EPA Administrator finds that:

> (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 EPA Administrator shall require by rule that testing be conducted on that chemical substance or mixture to develop data about 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 (TSCA section 4(a)(1)).

Once the EPA Administrator has made a finding under TSCA section 4(a)(1)(A) or TSCA section 4(a)(1)(B), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance or mixture that are relevant to whether the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or any combination of such activities, presents 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 TSCA section 4(a)(1)(B)(i) findings. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy published in the **Federal Register** issue of May 14, 1993 (B Policy) (Ref. 7, p. 28738).

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'' hazard and risk characterizations for 15 HPV chemical substances specified in Table 2 in § 799.5089(j) of the regulatory text. Following consideration of the public comments on the proposed rule (Ref. 2), EPA is making the following findings for the 15 HPV 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?

In April 1998, EPA initiated a national effort to make available to the public certain basic information about the environmental fate and potential health and environmental hazards associated with the most widespread chemical substances in commerce. Mechanisms to collect or, where necessary, develop needed data on U.S. HPV chemical substances include the HPV Challenge Program, certain international efforts (the Organization for Economic Cooperation and Development (OECD) HPV SIDS Program, the International Council of Chemical Associations (ICCA) HPV Initiative), and TSCA section 4 test rules. HPV chemical substances are manufactured or imported in amounts equal to or greater than 1 million lb per year and were first identified for the HPV Challenge Program through data reported under the 1990 Inventory Update Reporting (IUR) rule. The HPV Challenge Program is a voluntary testing program created by the United States to ensure that a baseline set of data on approximately 2,800 HPV chemical substances would be made available to EPA and the public. The SIDS data set sought by the HPV Challenge Program was developed by OECD, of which the United States is a member. The SIDS provides an internationally agreed-upon set of test data for screening HPV chemical substances for human and environmental hazards, and assists the Agency and others in making an informed, preliminary judgment about the hazards of HPV chemical substances.

The HPV Challenge Program was designed to make maximum use of scientifically adequate existing test data and to avoid unnecessary and duplicative testing of U.S. HPV chemical substances. Therefore, EPA continues to participate in the voluntary international efforts, complementary to the HPV Challenge Program, that OECD is coordinating to secure basic hazard information on HPV chemical substances in use worldwide, including some of those on the 1990 U.S. HPV chemical substances list (Ref. 8). This includes agreements to sponsor a U.S. HPV chemical substance under either the OECD HPV SIDS Program (Ref. 9), including sponsorship by OECD member countries beyond the United States, or the international HPV Initiative that is being organized by ICCA (Ref. 10).

As EPA stated in the first TSCA section 4 HPV test rule, U.S. data needs that remained unmet in the HPV Challenge Program or through international efforts could be addressed through TSCA section 4 rulemakings, such as the final rule promulgated by EPA on March 16, 2006 (Ref. 4) and the final rule promulgated by EPA on January 7, 2011 (Ref. 6). This is the third TSCA section 4 HPV test rule; it addresses unmet data needs for 15 HPV chemical substances.

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 Web site (*http://www.epa.gov/chemrtk*) and in the docket for this final rule identified under **ADDRESSES**. As appropriate, this information will be used to ensure a scientifically sound basis for risk assessments and risk management actions.

D. Why is EPA focusing on HPV chemical substances and SIDS testing?

This final rule pertains to HPV chemical substances, which EPA has determined account for 95% of total chemical production in the United States (Ref. 11, p. 32296). Based on 1990 IUR reports, EPA found that only 7% of non-polymeric organic HPV chemical substances had a full set of publicly available and internationally recognized basic screening test data for health and environmental effects (Ref. 12). Of the over 2,800 U.S. HPV chemical substances, 43% had no publicly available basic hazard data. For the remaining chemical substances, limited amounts of the data were available. This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemical substances pose risks to human health or the environment, as well as the public's ability to know about the hazards of chemical substances that may be found in their environment, their homes, their workplaces, and the products they buy.

SIDS testing evaluates the following six testing endpoints (Ref. 9):

- 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).

Data on the six SIDS endpoints provide a consistent minimum set of information that can help to assess the relative risks of chemical substances and whether additional testing or assessment is necessary.

E. How will the data developed under this final rule be used?

EPA will use the data obtained from this final rule to support development of preliminary hazard and risk assessments for the 15 HPV chemical substances subject to this final rule. The data will also be used by EPA to set priorities for further testing that may produce hazard information which may be needed by EPA, other Federal agencies, the public, industry, and others, to support adequate risk assessments. EPA uses data from TSCA section 4 test rules to support such actions as the risk management decisions and activities under TSCA, development of water quality criteria, Toxics Release Inventory (TRI) listings, and reduction of workplace exposures.

As appropriate, this information will be used to ensure a scientifically sound basis for risk assessments 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 addition, a key goal of the HPV Challenge Program was making basic health and environmental effects data for HPV chemical substances available to the public as part of EPA's ''Right to Know'' Initiative. A basic premise of the HPV Challenge Program was that the public has a right to know about the hazards associated with chemical substances in their environment. Everyone—including industry, environmental protection groups, animal welfare organizations, government groups, and the general public—can use the data provided through the HPV Challenge Program, and also data collected on HPV chemical substances through other means, including TSCA section 4 testing, to make informed decisions related to the human and the environmental hazards of chemical substances that they encounter in their daily lives.

III. Response to Public Comments

EPA received a number of comments, which are available in the docket, in response to the proposed rule (Ref. 2). A summary of those comments and EPA's response to each comment are presented in the document entitled ''Response to public comments regarding testing of certain high production volume chemicals'' (Response to Public Comments) (Ref. 13). The comments on the proposed rule were submitted by the American Coke and Coal Chemicals Institute; Dover Chemical Corporation; the Society of Chemical Manufacturers and Affiliates on behalf of Bimax, Inc. and Rhodia, Inc.; Eastman Chemical Company; Nease Corporation; the International Imaging Industry Association; Special Materials Company; BASF Corporation; the American Chemistry Council; Sasol North America, Inc.; the Chlorinated Paraffins Industry Association; INVISTA S.à.r.l.; Greenwich Chemical Consulting, Inc., on behalf of Brenntag North America, Inc.; Kowa American Corporation, Miami Chemical, Inc., and Univar U.S.A., Inc.; GE Water and Process Technologies; and Special Materials Company. Comments were also submitted by People for the Ethical Treatment of Animals (PETA); the Physicians Committee for Responsible Medicine; the Alternatives Research Development Foundation; and the American Anti-Vivisection Society. EPA also received comments from a private citizen. In response to these comments, EPA made the following changes to the regulatory text in this final rule:

1. EPA is no longer requiring testing for the following 13 chemical substances:

- Benzene, 1,2-dimethyl-3-nitro- (Chemical Abstract Service Registry Number (CASRN) 83–41–0).
- 3-Pentanone (CASRN 96–22–0).
- 1-Tetracosanol (CASRN 506–51–4).
- 1-Hexacosanol (CASRN 506–52–5).
- 2-Propenoic acid, 2-carboxyethyl ester (CASRN 24615–84–7).
- Methanesulfonamide, *N*-[2-[(4-amino-3-methylphenyl)ethylamino]ethyl]-, sulfate (2:3) (CASRN 25646–71–3).
- Solvent naphtha (coal) (CASRN 65996–79–4).
- Tar oils, coal (CASRN 65996–82–9).
- Tar, coal, high temperature (CASRN 65996–89–6).
- Distillates (coal tar) (CASRN 65996–92–1).
- Pitch, coal tar-petroleum (CASRN 68187–57–5).
- 1,4-Benzenedicarboxylic acid, 1,4-dimethyl ester, manuf. of, by-products from (CASRN 68988–22–7).
- Extract residues (coal), tar oil alk., naphthalene distn. residues (CASRN 73665–18–6).

These changes are further discussed in Unit VII.A. and in the ''Response to Public Comments'' document (Ref. 13).

2. *N*-octanol/water partition coefficient, log 10 basis (log K_{ow}); and reproductive/developmental toxicity testing are not required for benzene, 1-chloro-4-(trifluoromethyl)- (CASRN 98–56–6). The aquatic toxicity testing requirement for this chemical substance has also been reduced. These changes are further discussed in Unit VII.B. and in the ''Response to Public Comments'' document (Ref. 13).

3. Water solubility, ready biodegradation, aquatic toxicity, acute mammalian toxicity, combined repeated-dose/reproductive/developmental toxicity, and *in vitro* mutagenicity tests are not required for benzenesulfonic acid, dimethyl (CASRN 25321–41–9). These changes are further discussed in Unit VII.B. and in the ''Response to Public Comments'' document (Ref. 13).

IV. Findings

A. What is the basis for EPA's final rule to test these chemical substances?

As described in Unit II.B., in order to promulgate a rule under TSCA section 4(a) requiring the testing of chemical substances or mixtures, EPA must make certain findings of either risk (TSCA section 4(a)(1)(A)(i)) or production combined with either chemical release or human exposure (TSCA section 4(a)(1)(B)(i)), in addition to findings (discussed in this unit) regarding the sufficiency of existing data (TSCA section 4(a)(l)(A)(ii) or TSCA section 4(a)(1)(B)(ii)) and the need for testing (TSCA section 4(a)(1)(A)(iii) or TSCA section 4(a)(1)(B)(iii)). 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 section 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 § 799.5089(j) of the regulatory text, along with their CASRNs.

EPA generally considers ''substantial production'' and ''substantial exposure'' of a chemical substance or mixture under TSCA section 4(a)(1)(B)(i) to be aggregate production (including import) volume equaling or exceeding 1 million lb per year of that chemical substance or mixture, and exposure of 1,000 workers or more, or 10,000 consumers or more, or 100,000 members of the general population or more to a chemical substance or mixture. See EPA's B Policy (Ref. 7) for further discussion on how EPA generally evaluates chemical substances or mixtures under TSCA section 4(a)(1)(B)(i).

EPA finds that, under TSCA section 4(a)(1)(B)(i), each of the 15 HPV chemical substances included in this final rule is produced in substantial quantities and that there is or may be substantial human exposure to each chemical substance (Ref. 14). 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 the 15 HPV chemical substances identified in this final rule is necessary to develop such data (TSCA section 4(a)(1)(B)(iii)) (see Unit IV.F.). EPA has not identified any additional factors as discussed in the B Policy (Ref. 7) to cause the Agency to use decisionmaking criteria other than the general thresholds described in the B Policy with respect to the chemical substances included in this final rule.

The chemical substances included in this final rule are listed in § 799.5089(j) of the regulatory text along with their CASRNs. For a chemical-by-chemical summary of each of the findings, see Table 1 of this unit. Table 1 of this unit summarizes EPA's findings with respect to worker and consumer exposure, and includes the production volume, number of workers and broad use categories reported under IUR and Preliminary Assessment Information Reporting (PAIR) rules, and from the National Occupational Exposure Survey (NOES). For more details, see the discussion which follows the table and also the Exposure Findings Supporting Information document (Ref. 14).

TABLE 1—EXPOSURE BASED FINDINGS

CASRN	2006 IUR production (million lb)	2006 IUR substantial human exposure met (≥ 1,000 workers)	NOES (number of workers)	2006 IUR or PAIR commercial/consumer use	Meet exposure based criteria for commercial workers	Meet exposure based criteria for consumers
98–09–9	1 to <10			X	X	X
98–56–6	10 to <50			X	X	X
111–44–4	1 to <10			X	X	X
127–68–4	1 to <10		9,386		X	
515–40–2	1 to <10			X	X	X
2494–89–5	1 to <10			X	X	X
5026–74–4	1 to <10	X			X	
22527–63–5	1 to <10			X	X	X
25321–41–9	1 to <10		2,843		X	
52556–42–0	1 to <10	X		X	X	X
68082–78–0	1 to <10		41,153		X	
68442–60–4	1 to <10			X	X	X
68610–90–2	1 to <10			X		X
70693–50–4	1 to <10			X	X	X
72162–15–3	1 to <10		64,227		X	

Note: CASRN—Chemical Abstract Service Registry Number, IUR—Inventory Update Reporting, PAIR—Preliminary Assessment Information Reporting, NOES—National Occupational Exposure Survey.

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 or imported in an amount equal to or greater than 1 million lb per year (Ref. 14); this finding is based on information gathered pursuant to the 2006 IUR submissions (see 2006 CFR edition for 40 CFR part 710), which is the most recently available compilation of TSCA Chemical Substance Inventory data. EPA believes that these annual production and/or importation volumes are ''substantial'' as that term is used with reference to production in TSCA section 4(a)(1)(B)(i) (see Ref. 7, p. 28746). A discussion of EPA's ''substantial production'' finding for each chemical substance included in this final rule is contained in a separate document (Ref. 14).

C. Are a substantial number of workers exposed to these chemical substances?

EPA finds that the manufacture, processing, and use of 14 of the 15 HPV chemical substances included in this action results or may result in exposure of a substantial number of workers to the chemical substances. 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. 14). (*Note:* For the single chemical substance for which EPA has not found substantial worker exposure, EPA finds that there is substantial consumer exposure; see Table 1 and Ref. 14.)

This finding is based, in large part, on information submitted in accordance with the 2006 IUR submissions (see 2006 CFR edition for 40 CFR part 710) and the 2006 PAIR (Ref. 15). For chemical substances whose total production volume (manufactured and imported) exceeded 300,000 lb at a site during calendar year 2005, manufacturers and importers were required to report the number of potentially exposed workers during industrial processing and use to the extent the information was readily obtainable. In addition, submitters were required to provide information regarding the commercial and consumer uses of the chemical substance.

In accordance with the Agency's B Policy (Ref. 7), EPA believes, as a general matter, that an exposure of 1,000 workers or more to a chemical substance is ''substantial'' as that term is used with reference to ''human exposure'' in TSCA section 4(a)(1)(B)(i) (Ref. 7). EPA is not aware of any facts in this case that warrant departure from that policy and finds that there is or may be substantial human exposure (workers) to 14 of these 15 HPV chemical substances.

Besides the 2006 IUR and 2006 PAIR data, EPA also reviewed NOES data developed by the National Institute for Occupational Safety and Health (NIOSH). NOES was a nationwide data gathering project conducted by NIOSH, which was designed to develop national estimates for the number of workers potentially exposed to various chemical, physical, and biological agents and describe the distribution of these potential exposures. Begun in 1980 and completed in 1983, the survey involved a walk-through investigation by trained surveyors of 4,490 facilities in 523 different types of industries. Surveyors recorded potential exposures when a chemical agent was likely to enter or contact the worker's body for a minimum duration. These potential exposures could be observed or inferred. Information from these representative facilities was extrapolated to generate national estimates of potentially exposed workers for more than 10,000 different chemical substances (Refs. 16–18). For 4 of the 15 HPV chemical substances, the NOES data also supports EPA's finding that 1,000 or more workers are exposed to these chemical substances.

EPA also compared production volumes from the 1986 IUR data to the production volumes for the 2006 IUR data. For the 15 HPV chemical substances in this final rule, there was no decrease in production volume from 1986 to 2006 (Ref. 14). For the chemical substances for which EPA has NOES data, the 2006 IUR production volume data are consistent with NOES results, as the production volumes for these seven chemical substances either stayed the same or increased since 1986, thereby indicating that the usage of these chemical substances is no less than when NOES data were gathered, and, by inference (without contradictory data) that worker exposure is also likely to have stayed the same or increased.

EPA carefully considered the industrial and commercial processing and use information reported for each of these 15 HPV chemical substances in 2006 IUR and PAIR submissions. Commercial uses are defined as, ''The use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (*e.g.,* dry cleaning establishment, painting contractor)'' (see 2006 edition of the CFR for 40 CFR 710.43). Detailed information from the 2006 IUR submissions can be found in: ''Testing of Certain High Production Volume Chemicals-3 (Exposure Findings Supporting Information)'' (Ref. 14). Based on the nature of the reported IUR uses, EPA considers that chemical substances with reported commercial uses may result in potential exposure to 1,000 workers or more. The total number of workers reported under the 2006 IUR data is the sum of information on industrial workers plus commercial use workers.

D. Are a substantial number of consumers exposed to these chemical substances?

Based on 2006 IUR data, EPA finds that the uses of 9 of the 15 HPV chemical substances included in this action result or may result in exposure to a substantial number of consumers (Ref. 14). EPA reviewed the consumer use information reported for the 2006 IUR data and carefully considered the nature of those uses. Upon completion of the review, EPA concluded that the reported consumer uses for these chemical substances may result in at least 10,000 potentially exposed consumers, thus meeting the exposure based finding for consumers.

In addition to findings made based on the 2006 IUR data, EPA has also made consumer exposure-based findings for one additional chemical substance based on the National Library of Medicine (NLM) Household Products Database (HPD) (see Ref. 13). The chemical substances reported in the HPD are present in multiple household products including hobby/craft products, personal care products, home cleaning products, home maintenance products, and automotive products. The HPD provides information on the chemical ingredients and their percentage in specific brands of household products. Information in the HPD is from a variety of publicly available sources including brand-specific labels and Material Safety Data Sheets, when available from manufacturers and manufacturers' Web sites.

EPA finds that consumers' use of the products identified in the HPD may expose a substantial number of consumers (*i.e.,* 10,000 or more) to the chemical substances in those products. EPA believes that an exposure of 10,000 or more consumers to a chemical substance is ''substantial'' as that term is used with reference to ''human exposure'' in TSCA section 4(a)(1)(B)(i) (Ref. 7). Therefore, EPA finds that there is or may be substantial human exposure (consumers) to 10 of these 15 HPV chemical substances.

A discussion of EPA's ''substantial exposure'' finding for consumers is contained in a separate document (Ref. 14).

E. Does sufficient data exist for these chemical substances?

EPA has determined that for the 15 HPV chemical substances for which testing is required under this final rule, there are either no data available on SIDS testing endpoints or these data are insufficient to reasonably determine or predict the effects on human health or the environment that may result from exposures during the manufacturing, processing, distribution in commerce, use, or disposal of the subject chemical substances.

The finding of insufficient data is based on the results of searches for data on SIDS endpoints by EPA, including available data as summarized on its High Production Volume Information System (HPVIS) (Refs. 1, 19, and 20). This finding is also based on the results of EPA's review of studies/data identified by commenters in response to the proposed rule or identified by EPA after the publication of the proposed rule to this final rule. The studies and data submitted or identified subsequent to the proposed rule were found to be sufficient for some proposed tests of certain chemical substances and those tests are not required for those chemical substances in this final rule (see Unit VII.).

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

F. Is testing necessary 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 to ascertain the health and environmental effects of the 15 HPV chemical substances in this final rule. EPA knows of no other means to generate the SIDS data other than the testing described in this final rule, and therefore believes that conducting the SIDS testing identified for the 15 HPV chemical substances is necessary to provide data relevant to a determination of whether the manufacture, processing, and use of the chemical substances does or does not present an unreasonable risk of injury to human health and the environment. EPA also believes it is important to make these data available to satisfy the ''Right-to-Know'' principles included in the HPV Challenge Program goals.

V. Final Rule

A. What testing is required by this final rule?

EPA is requiring specific testing and reporting requirements for the chemical substances specified in § 799.5089(j) of the regulatory text. The testing requirements for each chemical are denoted by alphanumeric symbols in Table 2 in § 799.5089(j) of the regulatory text. Table 3 in § 799.5089(j) of the regulatory text provides the key to identify the tests denoted by the alphanumeric symbols and also lists special conditions that might apply when conducting some of those tests. Test methods listed in Table 3 in § 799.5089(j) of the regulatory text are grouped according to the endpoint that they address. The endpoints and test standards required under this final rule are listed in this unit. Also discussed in this unit are the special conditions which EPA has identified and is requiring for several of the required test standards.

1. *Physical/Chemical Properties*—a. Melting Point: ASTM International (ASTM) E 324–99 (capillary tube) (Ref. 21) (or, for substances liquid at room temperature, Freezing Point: OECD102 (melting point/melting range) (Ref. 22)).

b. *Boiling Point:* ASTM E 1719–05 (ebulliometry) (Ref. 23).

c. *Vapor Pressure:* ASTM E 1782–08 (thermal analysis) (Ref. 24).

d. *n-Octanol/Water Partition Coefficient:* Method A (40 CFR 799.6755—shake flask).

e. Method B (ASTM E 1147–92 (Reapproved 2005)—liquid chromatography) (Ref. 25).

f. Method C (40 CFR 799.6756—generator column).

g. *Water Solubility:* Method A (ASTM E 1148–02 (Reapproved 2008)—shake flask) (Ref. 26).

h. Method B (40 CFR 799.6784—shake flask).

i. Method C (40 CFR 799.6784—column elution).

j. Method D (40 CFR 799.6786—generator column).

EPA is requiring, for those chemical substances for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324–99. Though ASTM has withdrawn this method, ASTM still makes the method available for informational purposes and it can still be purchased from ASTM at the address listed in § 799.5089(h) of the regulatory text. ASTM has explained that ASTM E 324–99 was withdrawn because:

> The standard utilizes old, well-developed technology; it is highly unlikely that any additional [changes] and/or modifications will ever be pursued by the E15 [committee]. The time and effort needed to maintain these documents detract from the time available to develop new standards which use modern technology. (Ref. 27)

EPA concludes, therefore, that ASTM's withdrawal of ASTM E 324–99 does not have negative implications on the validity of the method.

However, where the chemical substance is a liquid at room temperature a measured freezing point would meet the obligation to report the melting point. However, ASTM E 324–99 (capillary tube) does not specifically include instructions for determining freezing point. Therefore, EPA is instead requiring OECD 102 (melting point/melting range), which includes guidance for determining freezing point for substances that are liquid at room temperature.

ASTM has updated and revised its test method for vapor pressure (ASTM E 1782–08—thermal analysis) since the proposed rule was published. Some material related to alternative test methods and some unnecessary descriptive material was omitted in the revision, but the test method itself is unchanged. The updated and revised method (ASTM E 1782–08—thermal analysis) is the required test method for the vapor pressure endpoint in this final rule. Note: ASTM issues its test methods under a fixed designation (*e.g.,* E 1719): ''the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (e) indicates an editorial change since the last revision or reapproval'' (Ref. 23).

In addition, ASTM has updated its test method for Measurement of Aqueous Solubility (ASTM E 1148–02). The test method was reapproved in 2008. There was a minor change in ''Referenced Documents,'' but the test method itself is unchanged. When required, the updated method (ASTM E 1148–02 (Reapproved 2008)) is listed as the required test method for the ''Water Solubility'' endpoint in this final rule (Ref. 26).

For the log K_{ow} 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 § 799.5089(j) of the regulatory text.

For the log K_{ow} endpoint, EPA is requiring that an appropriate selection be made from among three alternative

methods for measuring the chemical substance's log K_{ow}. Prior to determining the appropriate standard to use to measure the *n*-octanol/water partition coefficient, EPA is recommending that the log K_{ow} be quantitatively estimated. EPA recommends that the method described in ''Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients'' (Ref. 28) be used in making such estimation. EPA is requiring that test sponsors must submit with the final study report the underlying rationale for the test standard selected for this endpoint. EPA is requiring this approach in recognition of the fact that, depending on the chemical substance's log $K_{ow,}$ one or more test methods may provide adequate information for determining the log $K_{ow,}$ but that in some instances one particular test method may be more appropriate. In general, EPA believes that the more hydrophobic a subject chemical substance is the more suitable Method B (ASTM E 1147–92 (Reapproved 2005)), and especially Method C (40 CFR 799.6756—generator column), and the less suitable Method A (40 CFR 799.6755—shake flask), become. The required test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA highly recommends that all required *n*-octanol/water partition coefficient tests be conducted at pH 7 to ensure environmental relevance. The required test standards and log K_{ow} ranges that would determine which tests must be conducted for this endpoint are shown in Table 2 of this unit.

TABLE 2—TEST REQUIREMENTS FOR THE PHYSICAL/CHEMICAL PROPERTIES

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	*n*-Octanol/water partition coefficient (log 10 basis) or log K_{ow}: Select 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 1147–92 (Reapproved 2005) (liquid chromatography) Method C: 40 CFR 799.6756 (generator column)	*n*-Octanol/water partition coefficient (log 10 basis) 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, B, or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.

Note: ASTM—ASTM International.

For the ''Water Solubility'' endpoint, EPA is requiring that the appropriate selection be made from among four alternative methods for measuring that endpoint. The test method used would be determined by first quantitatively estimating the test substance's water solubility. One recommended method for estimating water solubility is described in, ''Improved Method for Estimating Water Solubility from Octanol/Water Partition Coefficient'' (Ref. 29). EPA is also requiring that test sponsors submit in the final study report the underlying rationale for the test standard selected for this endpoint. EPA also highly recommends that all required water solubility tests be conducted starting at pH 7 to ensure environmental relevance. Table 3 of this unit shows the estimated water solubility ranges that EPA is requiring for use in this final rule to select the appropriate test standard.

TABLE 3—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 would be selected from those listed in this column—see Special Conditions in the adjacent column. Method A: ASTM E 1148–02 (Reapproved 2008) (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 would be determined by the test substance's estimated water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 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.

Note: ASTM—ASTM International, mg/L—milligram/liter.

2. *Environmental Fate and Pathways*—a. Ready Biodegradation: Method A: ASTM E 1720–01 (Reapproved 2008) (sealed vessel CO_2 production test) (Ref. 30).

b. *Method B:* International Organization for Standardization (ISO)

14593:1999(E) (CO_2 headspace test) (Ref. 31).

c. *Method C:* ISO 7827:1994(E) (method by analysis of dissolved organic carbon (DOC)) (Ref. 32).

d. *Method D:* ISO 9408:1999(E) (determination of oxygen demand in a closed respirometer) (Ref. 33).

e. *Method E:* ISO 9439:1999(E) (carbon dioxide evolution test) (Ref. 34).

f. *Method F:* ISO 10707:1994(E) (closed bottle test) (Ref. 35).

g. *Method G:* ISO 10708:1997(E) (two-phase closed bottle test) (Ref. 36).

ASTM has updated its test method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test (ASTM E 1720–01). The test method was reapproved in 2008. There were minor changes, including the deletion of mention of specific apparatus brands in the ''Apparatus'' section; however the test method itself is unchanged. When required, the reapproved method (ASTM E 1720–01 (Reapproved 2008)) is listed as the required test method for the ''Ready Biodegradation'' endpoint in this final rule (Ref. 30).

For the ''Ready Biodegradation'' endpoint, EPA is requiring that the appropriate selection be made from among seven alternative methods for measuring the test substance's ready biodegradability. For most test substances, EPA considers Method A (ASTM E 1720–01 (Reapproved 2008)) and Method B (ISO 14593:1999(E)) to be generally applicable, cost effective, and widely accepted internationally. However, the test method used will depend on the physical and chemical properties of the test substance, including its water solubility. An additional document, ISO 10634:1995(E) (Ref. 37), provides guidance for selection of the appropriate test method for a given test substance considering the test substance's physical and chemical properties. EPA is also requiring that test sponsors submit in the final study report the underlying rationale for the test standard selected for this endpoint.

3. *Aquatic Toxicity*—a. *Test Group 1:*

i. Acute toxicity to fish (ASTM E 729–96 (Reapproved 2007)) (Ref. 38).

ii. Acute toxicity to *Daphnia* (ASTM E 729–96 (Reapproved 2007)) (Ref. 38).

iii. Toxicity to plants (algae) (ASTM E 1218–04 $^{\varepsilon 1}$) (Ref. 39).

b. *Test Group 2:*

i. Chronic toxicity to *Daphnia* (ASTM E 1193–97 (Reapproved 2004)) (Ref. 40).

ii. Toxicity to plants (algae) (ASTM E 1218–04 $^{\varepsilon 1}$) (Ref. 39).

ASTM has updated ASTM E 729–96 (Reapproved 2002), its test method for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians. ASTM reapproved this test method in 2007. There were minor changes (for example, reference to the ASTM Web site in place of the ''Annual Book of ASTM Standards,'' minor changes in references and dates, titles of ASTM documents changed to correspond to new titles, *etc.*) but the test method itself is unchanged. The updated method (ASTM E 729–96 (Reapproved 2007)) is listed as the required test method for the ''Aquatic Toxicity'' endpoints in this final rule (Ref. 38).

For the ''Aquatic Toxicity'' endpoint, the OECD HPV SIDS Program recognizes that, for certain chemical substances, acute toxicity studies are of limited value in assessing the chemical substances' aquatic toxicity. This issue arises when considering chemical substances with high log K_{ow} values. In such cases, toxicity is unlikely to be observed over the duration of acute toxicity studies because of reduced uptake and the extended amount of time required for such chemical substances to reach steady state or toxic concentrations in the test organism. For such situations, the OECD HPV SIDS Program recommends use of chronic toxicity testing in *Daphnia* in place of acute toxicity testing in fish and *Daphnia.*

EPA is 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 Coefficient,'' and in Table 3 in § 799.5089(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 § 799.5089(j) of the regulatory text) are required: Acute toxicity to fish (ASTM E 729–96 (Reapproved 2007)), Acute toxicity to *Daphnia* (ASTM E 729–96 (Reapproved 2007)), and Toxicity to plants (algae) (ASTM E 1218–04 $^{\varepsilon 1}$).

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 § 799.5089(j) of the regulatory text) are required: Chronic toxicity to *Daphnia* (ASTM E 1193–97 (Reapproved 2004)) and/or Toxicity to plants (algae) (ASTM E 1218–04 $^{\varepsilon 1}$). As outlined in Table 3 in § 799.5089(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.

For the purposes of this final rule, EPA's use of a log K_{ow} equal to or greater than 4.2 is consistent with the approach taken in the Agency's final policy statement under TSCA section 5, ''Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances'' (Ref. 41). Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 29, 42, and 43). A chemical substance with a fish BCF value of 1,000 or more is characterized as having a tendency to accumulate in living organisms relative to the concentration of the chemical substance in the surrounding environment (Ref. 43). EPA has also used a measured BCF that is equal to or greater than 1,000 or, in the absence of bioconcentration data, a log P [same as log K_{ow}] value equal to or greater than 4.3 to help define the potential of a new chemical substance to cause significant adverse environmental effects (Ref. 44). EPA considers the difference between the log K_{ow} of 4.3 cited in the 1989 **Federal Register** document (Ref. 46) and the log K_{ow} value of 4.2 cited in this final TSCA section 4 test rule to be negligible.

EPA recognizes that in some circumstances, acute aquatic toxicity testing (Test Group 1) may be relevant for certain chemical substances having a log K_{ow} equal to or greater than 4.2. Chemical substances that are dispersible in water (*e.g.,* surfactants, detergents, aliphatic amines, and cationic dyes) may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. For any chemical substance listed in Table 3 in § 799.5089(j) of the regulatory text for which a test sponsor believes that an alternative to the log K_{ow} threshold of 4.2 is appropriate, the test sponsor may request a modification of the test standard in this final rule as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method to be used for determining whether acute or chronic aquatic toxicity testing must be performed for a specific substance.

4. *Mammalian Toxicity—Acute*—a. Acute Inhalation Toxicity (rat): Method A (40 CFR 799.9130).

b. Acute Oral Toxicity (rat): Method B (ASTM E 1163–98 (Reapproved 2002) (Ref. 45) or 40 CFR 799.9110(d)(1)(i)(A)).

For the ''Mammalian Toxicity—Acute'' endpoint, EPA is requiring that certain ''special conditions,'' such as the chemical substance's physical/chemical properties or physical state, be considered in determining the appropriate test method from among

those included for this endpoint in Table 3 in § 799.5089(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 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 § 799.5089(j) of the regulatory text). In the case of a potentially explosive test substance, care must be taken to avoid the generation of explosive concentrations. For all other chemical substances (*i.e.,* those that are either liquids or solids at room temperature), EPA is requiring that acute toxicity testing be conducted via oral administration using an ''Up/Down'' test method (described as Method B (ASTM E 1163–98 (Reapproved 2002) or 40 CFR 799.9110(d)(1)(i)(A)) in Table 3 in § 799.5089(j) of the regulatory text). Consistent with the HPV Challenge Program, EPA is allowing the use of the Neutral Red Uptake (NRU) basal cytotoxicity assay to select the starting dose for the acute oral toxicity test. This test is included as a special condition in Table 3 in § 799.5089(j) of the regulatory text. The National Institutes of Environmental Health Sciences (NIEHS) provides guidance on how to use the NRU assay to estimate a starting dose for an acute oral toxicity test (Ref. 46). Recent versions of the standardized protocols for the NRU assay are available at the NIEHS/Interagency Coordination Committee on the Validation of Alternative Methods Web site (Refs. 47–49).

5. *Mammalian Toxicity—Genotoxicity*—a. Gene Mutations: Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510.

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

Persons 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 test sponsor who uses one of the *in vivo* methods instead of the *in vitro* method to address this endpoint would be required to submit to EPA in the final study report a rationale for conducting that alternate test.

6. *Mammalian Toxicity—Repeated Dose/Reproduction/Developmental*—a. Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365.

b. *Reproduction/Developmental Toxicity Screening Test:* 40 CFR 799.9355.

c. *Repeated Dose 28-Day Oral Toxicity Study:* 40 CFR 799.9305.

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

In the proposed rule (Ref. 2) to this final rule, EPA stated that certain of the chemical substances for which mammalian toxicity—repeated dose/reproduction/developmental toxicity testing is required may be used solely as ''closed system intermediates'' (*e.g.,* stored in controlled on-site facilities; or with controlled transport, *i.e.,* to a limited number of locations within the same company or second parties which use the chemical in a controlled way as an intermediate with a well-known technology). A chemical substance that is intended to undergo a further deliberate reaction to produce another industrial substance is considered an intermediate. Intermediates which are contained in closed systems and therefore have a limited potential for exposure may be eligible for a reduced testing battery. In these situations, such chemical substances may be eligible for a reduced testing battery that substitutes a developmental toxicity study for the SIDS requirement to address repeated dose, reproduction, and developmental toxicity. EPA requested that commenters who believe their chemical substance is used solely as a closed system intermediate submit appropriate information along with their comments which substantiate this belief, but EPA did not receive any comments from potential test sponsors that their chemical substance was a closed system intermediate.

B. When will the testing imposed by this final rule begin?

This final rule is effective 30 days after its publication in the **Federal Register**. Once it is effective, the required testing must be initiated in time to allow the required final report to be submitted within 13 months of the effective date of this final rule (see § 799.5089(i) of the regulatory text).

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 § 799.5089(j) of the regulatory text, the reporting requirements described in § 799.5089(i) of the regulatory text, and with Good Laboratory Practice Standards (GLPS) at 40 CFR part 792.

D. What form of test substances will be tested under this final rule?

EPA is specifying two distinct approaches for identifying the specific chemical substances that would be tested under this final rule, the application of which would depend on whether the chemical substance is considered to be a ''Class 1'' or a ''Class 2'' chemical substance. First introduced when EPA compiled the TSCA Chemical Substance Inventory, the term Class 1 chemical substance refers to a chemical substance having a chemical composition that consists of a single-chemical species (not including impurities) that can be represented by a specific, complete structure diagram. By contrast, a Class 2 chemical substance has a composition that cannot be represented by a specific, complete chemical structure diagram, because such a chemical substance generally contains two or more different chemical species (not including impurities). A ''Class 2'' designation most frequently represents a group of chemical

substances that have similar combinations of different chemical species and/or that were prepared from similar feedstocks using similar production methods. By contrast, Class 1 chemical substances generally represent a much narrower group of chemical substances for which the only variables are their impurities. Table 2 in § 799.5089(j) of the regulatory text identifies the listed chemical substances as either Class 1 or Class 2 chemical substances.

The ''Class 1'' chemical substances listed in Table 2 in § 799.5089(j) of the regulatory text (*i.e.,* 11 of the 15 HPV chemical substances included in this final rule) must be tested at a purity of at least 99%. In instances in which the test sponsor(s) believes that a 99% level of purity is unattainable for a given chemical substance, 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 § 799.5089(j) of the regulatory text (*i.e.,* 4 of the 15 HPV chemical substances included in this final rule), EPA is requiring that the chemical substance tested be any representative form of the chemical substance.

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

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

- Well-characterized in terms of molecular formulae, structural diagrams, and compositional percentages of all species present (for example, methyl phenol);
- Less well-characterized, for example, characterized only by molecular formulae, 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 of manufacture used to manufacture the substance (for example, nut shell liquor of cashew).

Secondly, the composition of some Class 2 chemical 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.

EPA believes that, for purposes of this final rule, the testing of any representative form of a subject Class 2 chemical substance would provide the data necessary to support the development of preliminary or screening level hazard and risk characterizations for the subject Class 2 chemical substance. However, EPA encourages the selection of representative forms of 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 would be required to include test substance identification information, including name, CASRN, strength, purity, and composition, or other appropriate characteristics (see 40 CFR 792.185).

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 (including import) or process, or intend to manufacture or process, one or more chemical substances listed in this final rule during the time period described in Unit V.E.2. However, if you do not know or cannot reasonably ascertain that you manufacture or process a chemical substance listed in this final rule (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you are not subject to this final rule for that listed chemical substance (See § 799.5089(b)(2) of the regulatory text).

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 chemical substance listed in Table 2 in § 799.5089(j) of the regulatory text at any time from the effective date of this final rule to the end of the test cost reimbursement period.

3. *Will I be required to test if I am subject to this final rule?* It depends on the nature of your activities. All persons who are subject to this final 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 must initially comply with this final rule. To comply, they 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.

See 40 CFR 790.5 (''Submission of information'') and 40 CFR 790.45 (''Submission of letter-of-intent-to-conduct-testing or exemption application'') for details. (Note: In addition to the identifying information specified in § 790.5, EPA also requests that the docket ID number EPA–HQ–OPPT–2009–0112 be included on the submission). For all submissions under this part, six copies must be provided to EPA. All submissions for this final rule, except those containing CBI, will be entered into the docket under ''Supporting and Related Material.'' Addresses of the OPPT Document Control Office, where this information should be sent, are found in this final rule under ''*Submission of Information.''*

Persons in Tier 2:

- Do not have to initially comply with this final rule.
- Are not required to take any action unless EPA notifies them to the contrary (because, for example, no person in Tier 1 had submitted a letter-of-intent-to-conduct-testing), as described in Unit V.E.3.f.

a. *Who is in Tier 1 and Tier 2*? Table 4 of this unit describes who is in Tier 1 and Tier 2.

TABLE 4—PERSONS SUBJECT TO THIS FINAL RULE: TIER 1 AND TIER 2

Tier 1 (persons initially required to comply)	Tier 2 (persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule 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 kgs (1,100 lb) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for research and development (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)).

Note: kgs—kilograms, TSCA—Toxic Substances Control Act.

Under 40 CFR 790.2, EPA may establish procedures for specific test rules that differ from the generic procedures governing TSCA section 4(a) test rules in 40 CFR part 790. For purposes of this final rule, EPA has established 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. The Agency took administrative burden and complexity into account in determining who was to be in Tier 1 in this final rule.

Tier 1 includes: Chemical manufacturers who, in the experience of the Agency, have traditionally conducted testing or participated in testing consortia under previous TSCA section 4(a) test rules.

Tier 2 includes:

- Processors, manufacturers of less than 500 kilograms (kgs) (1,100 lb) per year (small-volume manufacturers).
- Manufacturers of small quantities for research and development (R&D).
- Byproduct manufacturers.
- Impurity manufacturers.
- Manufacturers of naturally occurring substances.
- Manufacturers of non-isolated intermediates.
- Manufacturers of components of Class 2 chemical substances.

Byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring chemical substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 chemical substances historically have not participated in testing or contributed to reimbursement of those persons who have conducted testing. EPA is not aware of any circumstances in which test rule Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791.

EPA understands that for some manufacturers the marginal transaction costs involved in negotiating and administering testing arrangements may raise the expense and burden of testing to a level that is disproportional to the additional benefits of including these persons in Tier 1. Therefore, EPA does not believe that the likelihood of the persons included in Tier 2 actually conducting the testing is sufficiently high to justify burdening these persons with Tier 1 requirements (*e.g.,* submitting requests for exemptions). Nevertheless, these persons, along with all other persons in Tier 2, would be subject to reimbursement obligations to persons who actually conduct the testing, as described in Unit V.E.4.

b. *Subdivision of Tier 2 entities.* In this final rule the Agency has further subdivided which persons in Tier 2 would be required to perform testing, if needed.

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

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

If the Agency needs testing from persons in Tier 2, EPA would seek testing from persons in Tier 2A before proceeding to persons in Tier 2B. It is appropriate to call upon manufacturers before processors because the Agency believes that testing costs are traditionally passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 50). In addition, ''[t]here are [typically] so many processors [of a given test rule chemical substance] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs'' (Ref. 51).

c. *When is it appropriate for a person required to comply with this final rule to apply for an exemption rather than to submit a letter-of-intent-to-conduct-testing?* You may apply for an exemption if you believe that the required testing will be performed by another person (or a consortium of persons formed under TSCA section 4(b)(3)(A)). Procedures relating to exemptions are in 40 CFR 790.80 through 790.99, and § 799.5089(c)(2), (c)(5), (c)(7), and (c)(11) of the regulatory text. In this final rule, EPA will not require the submission of equivalence data (*i.e.,* data demonstrating that the chemical substance is equivalent to the chemical substance actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 790.85 do not apply to this final rule.

d. *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 has

received a letter-of-intent-to-test from another source or has received (or expects to receive) the test data that would be required under this final rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate conditional exemptions if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA. EPA may then require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5089(c)(8) of the regulatory text for details on submitting this notice. In addition, the Agency will terminate a conditional exemption if no letter-of-intent-to-test has been received from persons required to comply with this final rule. See, *e.g.,* § 799.5089(c)(6) of the regulatory text. Note that persons who obtain exemptions or receive them automatically would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit V.E.4.

e. *What are my obligations if I am in Tier 2?* If you are in Tier 2, you are subject to this final 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.

The Agency may require you to submit a notice-of-intent-to-test or an exemption application if no manufacturer in Tier 1 has notified EPA of its intent to conduct testing and EPA has published a **Federal Register** document directing persons in Tier 2 to make the required submissions (see § 799.5089(c)(4), (c)(5), (c)(6), and (c)(7) of the regulatory text), or if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA (see 40 CFR 790.93 and § 799.5089(c)(10) of the regulatory text).

f. *What will happen if no one submits a letter-of-intent-to-conduct-testing?* If no one in Tier 1 submits a letter-of-intent-to-test within 30 days of the effective date of this final rule, EPA will notify in a separate **Federal Register** document persons in Tier 2A first, and then persons in Tier 2B of their obligation to submit a letter-of-intent-to-test, or an exemption application (see § 799.5089(c)(4) and (6) of the regulatory text). Persons in Tier 2A will have 30 days from the date the document published in the **Federal Register** to submit the required notice or exemption application. If no one in Tier 2A makes the required notification, EPA will follow the same procedure to notify persons in Tier 2B.

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

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

F. What are the reporting requirements under this final rule?

Study plans must be submitted for each test for each chemical substance 90 days after the effective date of this final rule, unless an extension is granted in writing pursuant to 40 CFR 790.55. See 40 CFR 790.50 (submission of study plans) for what information the study plan must contain. A final report must be submitted for each test for each chemical substance 13 months after the effective date of this final rule; *i.e.,* by the deadline indicated in § 799.5089(i) of the regulatory text. Addresses of the OPPT Document Control Office, where this information should be sent, are found in this final rule under ''*Submission of Information.*''

EPA also requests that a robust summary of the final report for each specific test 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'' (Ref. 19). Persons who submit a robust summary are also encouraged to submit it electronically via HPVIS to allow for its ready incorporation into HPVIS. Directions for electronic submission of robust summary information into HPVIS are provided at *https://iaspub.epa.gov/oppthpv/metadata.html.* This link will direct you to the ''HPVIS Quick Start and User's Guide.''

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

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 set forth in the final rule may submit a modification request to the Agency, pursuant to 40 CFR 790.55. EPA will determine whether modification of the test schedule is appropriate, and may first seek public comment on the modification.

H. Will there be sufficient test facilities and personnel to undertake the testing required under this final rule?

EPA's most recent analysis of laboratory capacity (Ref. 52) indicates

that available test facilities and personnel would adequately accommodate the testing specified in this final rule.

I. Might EPA seek further testing of the chemical substances 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 would seek further health and/or environmental effects testing for these chemical substances. Should the Agency decide to seek such additional testing via a test rule, EPA would initiate a separate action for that purpose.

VI. Export Notification

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

VII. Decision Not To Require Testing for Certain Chemical Substances

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

Based on comments received on the proposed rule and findings, the information before EPA at this point does not provide a basis to make the findings of substantial production, release to the environment in substantial quantities, and/or substantial human exposure for 12 of the chemical substances included in the proposed rule. Comments indicated that 11 of the chemical substances were not or are no longer produced or imported in amounts equal to or greater than 1 million lb per year. Comments also indicated that the proposed finding of ''enters or can be reasonably anticipated to enter the environment in substantial quantities'' cannot be made for an additional chemical substance. Because the data provided show manufacture, human exposure, and/or environmental release are below the B Policy thresholds (discussed in Unit IV.A.) under TSCA section 4(a)(1)(B)(i), and because EPA has not identified any additional factors as discussed in the B Policy (Ref. 7) to cause the Agency to use decisionmaking criteria other than the general thresholds described in the B Policy for these chemical substances, EPA is not including these chemical substances in this final rule. In the event new Chemical Data Reporting (CDR) data or other data provide new or additional support for the TSCA section 4(a)(1)(B)(i) finding for any of these chemical substances, EPA will take appropriate steps to proceed with a test rule for the chemical substance(s).

Based on public comment, EPA no longer has the basis to find that six chemical substances are produced or imported in amounts equal to or greater than 1 million pounds per year. Therefore, these six chemical substances are no longer included in this final rule: Benzene, 1,2-dimethyl-3-nitro- (CASRN 83–41–0); 1-tetracosanol (CASRN 506–51–4); 1-hexacosanol (CASRN 506–52–5); 2-propenoic acid, 2-carboxyethyl ester (CASRN 24615–84–7); methanesulfonamide, *N*-[2-[(4-amino-3-methylphenyl)ethylamino]ethyl]-, sulfate (2:3) (CASRN 25646–71–3); and tar, coal, high-temp. (CASRN 65996–89–6).

Based on public comment, EPA no longer has the basis to find for an additional six chemical substances that they have substantial human exposure or substantial environmental release and so are also not included in this final rule. These chemical substances are: Solvent naphtha (coal) (CASRN 65996–79–4); tar oils, coal (CASRN 65996–82–9); distillates (coal tar) (CASRN 65996–92–1); pitch, coal tar-petroleum (CASRN 68187–57–5); 1,4-benzenedicarboxylic acid, 1,4-dimethyl ester, manuf. of, by-products from (CARN 68988–22–7); and extract residues (coal), tar oil alk., naphthalene distn. residues (CASRN 73665–18–6).

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

For certain testing endpoints for certain chemical substances listed in the proposed rule, EPA is not making the TSCA section 4(a)(1)(B)(ii) finding 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 * * *'' and is not finalizing the proposed testing. Table 2 in § 799.5089(j) of the regulatory text, which lists the chemical substances and testing requirements, has been revised to reflect this. For one chemical substance no testing is required; for two others, a more limited set of testing is being required than was originally proposed. Further discussion follows in Units VII.B.1.–3.

1. *Mutagenicity endpoints and screening reproduction/developmental toxicity of 3-pentanone (CASRN 96–22–0).* As discussed in Unit E.2. of the ''Response to Public Comments'' document (Ref. 13), EPA reviewed additional data, including studies submitted by PETA (PETA submitted these data on behalf of themselves and other Animal Welfare Organizations (AWOs)) for 3-pentanone (CASRN 96–22–0). After reviewing these data, EPA finds existing studies are adequate to evaluate mutagenicity and reproduction/developmental toxicity and is not finalizing the proposed testing for mutagenicity and reproduction/developmental toxicity. Therefore, 3-pentanone is not included in this final rule.

2. *Log K_{ow}, ready biodegradation, aquatic toxicity, and screening reproduction/developmental toxicity of benzene, 1-chloro-4-(trifluoromethyl)-(CASRN 98–56–6).* As discussed in Unit E.3. of the ''Response to Public Comments'' document (Ref. 13), EPA reviewed additional data, including studies submitted by the Greenwich Chemical Consulting, Inc. (GCC) for benzene, 1-chloro-4-(trifluoromethyl)-. After reviewing these data, EPA finds existing studies are adequate to evaluate log K_{ow} and screening reproduction/developmental toxicity and is not finalizing the proposed testing for these endpoints. In addition, EPA has reviewed the biodegradation studies and aquatic toxicity studies. EPA considers the biodegradation studies to be inadequate, so that test is required. While EPA considers the acute fish and invertebrate testing to no longer be necessary, EPA is still requiring an algal toxicity study.

3. *Physical/chemical properties, ready biodegradation, aquatic toxicity, acute mammalian toxicity, combined repeated-dose/screening reproduction/developmental toxicity, and mutagenicity endpoints of benzenesulfonic acid, dimethyl (CASRN 25321–41–9).* As discussed in Unit E.7. of the ''Response to Public Comments'' document (Ref. 13), EPA reviewed additional data, including studies submitted by Nease Corporation providing data for several analogue chemical substances for benzenesulfonic acid, dimethyl. EPA finds these data acceptable to fulfill all of the proposed testing endpoints with

the exception of these three physical/chemical (p-chem) properties: Boiling point, vapor pressure and log K_{ow}.

VIII. Decision to Defer Final Action for Chloroalkanes

EPA is deferring final action for chlorinated paraffins: Alkanes, chloro (CASRN 61788–76–9). In addition to the proposed test rule (Ref. 2), EPA published an Action Plan for Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins (Ref. 53). There is currently an unresolved issue regarding whether all the production previously reported to the Agency under CASRN 61788–76–9 should in fact be covered by that listing. Pending resolution of this issue, EPA will defer making a final decision regarding test rule requirements for CASRN 61788–76–9, and will reevaluate the testing needs for CASRN 61788–76–9 based on future CDR reports.

IX. Economic Impacts

EPA has prepared an economic assessment entitled ''Economic Impact Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals; Third Group of Chemicals'' (Ref. 53), a copy of which has been placed in the docket for this final rule. This economic assessment evaluates the potential for significant economic impacts as a result of the testing required by this final rule. The analysis covers 15 HPV chemical substances. The total cost of providing test data on the 15 HPV chemical substances that were evaluated in this economic analysis is estimated to be $5.13 million (Ref. 54).

While legally subject to this final rule, processors of a subject chemical substance would be required to comply with the requirements of this final rule only if they are directed to do so by EPA as described in § 799.5089(c)(5) and (c)(6) of the regulatory text. EPA would only require processors to test if no person in Tier 1 has submitted a notice of its intent to conduct testing, or if, under 40 CFR 790.93, a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data to EPA. Because EPA has identified at least one manufacturer in Tier 1 for each subject chemical substance, the Agency assumes that, for each chemical substance in this 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. Because EPA does not expect that processors will need to comply with this final rule, the economic assessment does not address processors.

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 substance's sale price. This measure compares annual revenues from the sale of a chemical substance to the annualized compliance cost for that chemical substance to assess the percentage of testing costs that can be accommodated by the revenue stream generated by that chemical substance over a number of years. Compliance costs include costs of testing and administering the testing, as well as reporting costs. Annualized compliance 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 substance to derive the cost-to-sales ratio.

EPA estimates the total annualized compliance cost of testing for the 15 HPV chemical substances evaluated in the economic analysis to be $0.56 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 this final rule are expected to have a negligible impact on exporters. The estimated cost of the TSCA section 12(b) export notification requirements, which, under this final rule, would be required for the first export to a particular country of a chemical substance subject to this final rule, is estimated to range from $27.49 per notice to $86.99 per notice (Ref. 54). The Agency's estimated total costs of testing (including both laboratory and administrative costs), annualized testing cost, and public reporting burden hours for this final rule are presented in the economic assessment.

Under a least cost scenario, 7 out of the 15 HPV chemical substances (47%) would have a price impact at less than the 1% level. Similarly, 5 out of the 15 HPV chemical substances (33%) would be impacted at less than the 1% level under an average cost scenario. Thus, the potential for adverse economic impact due to this final rule is low for at least 33% of the chemical substances in this final rule. Approximately 10 chemical substances (67%) of the 15 HPV chemical substances for which price data are available would have a price impact at a level greater than or equal to 1% under the average cost scenario.

EPA believes that the testing of the chemical substances in this final rule presents a low potential for adverse economic impact for a reasonable number of the chemical substances. 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 nearly half of the chemical substances. There are, however, some chemical substances for which the price impact is expected to exceed 1% of the revenue from that chemical substance. The potential for adverse economic impact is expected to be higher for these chemical substances. In these cases, companies may choose to use revenue sources other than the profits from the individual chemical substances to pay for testing. Smaller businesses are less likely to have additional revenue sources to cover the compliance costs in this situation. Therefore, the Agency also compared the costs of compliance to company sales for small businesses. In that analysis, EPA found that the costs of testing requirements in this final rule for chemical substances produced by a specific company exceed 1% of company revenues for only one of the affected companies.

EPA does not provide quantitative estimates of the benefits from these tests. Ideally, a discussion of benefits would focus on the additional benefits to be gained from new information relative to information that already exists. Such an approach could examine the value of new information provided as a result of this final rule where such information has not been publicly available. Because of constraints on information on the value of information, EPA's evaluation of benefits is qualitative and does not address incremental benefits. EPA believes, however, that the net benefits of the new information are positive.

X. Materials in the Docket

As indicated under **ADDRESSES**, a docket was established for this final rule under docket ID number EPA–HQ–OPPT–2009–0112. The following is a listing of the documents that have been placed in the docket for this final rule. The docket includes information considered by EPA in developing this final rule, including the documents listed in this unit, which are physically located in the docket. In addition,

interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, consult either of the technical persons listed under **FOR FURTHER INFORMATION CONTACT**. The docket is available for review as specified under **ADDRESSES**.

1. EPA. Data Collection and Development on High Production Volume (HPV) Chemicals. Notice. **Federal Register** (65 FR 81686, December 26, 2000) (FRL–6754–6).
2. EPA. Testing of Certain High Production Volume Chemicals; Third Group of Chemicals. Proposed Rule. **Federal Register** (75 FR 8575, February 25, 2010) (FRL–8805–8).
3. EPA. Testing of Certain High Production Volume Chemicals. Proposed Rule. **Federal Register** (65 FR 81658, December 26, 2000) (FRL–6758–4).
4. EPA. Testing of Certain High Production Volume Chemicals. Final Rule. **Federal Register** (71 FR 13708, March 16, 2006) (FRL–7335–2).
5. EPA. Testing of Certain High Production Volume Chemicals; Second Group of Chemicals. Proposed Rule. **Federal Register** (73 FR 43314, July 24, 2008) (FRL–8373–9).
6. EPA. Testing of Certain High Production Volume Chemicals; Second Group of Chemicals. Final Rule. **Federal Register** (76 FR 1067, January 7, 2011) (FRL–8846–9).
7. EPA. TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, Substantial or Significant Human Exposure. Notice. **Federal Register** (58 FR 28736, May 14, 1993).
8. EPA, OPPT. HPV Challenge Program Chemical List. Available online at: *http://www.epa./oppt/chemrtk/pubs/update/hpvchmlt.htm.*
9. OECD Secretariat. OECD Programme on the Co-Operative Investigation of High Production Volume Chemicals. *Manual for the Assessment of Chemicals.* Paris, France. September 2004. Available online at: *http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.htm.*
10. ICCA. ICCA HPV Working List of Chemicals. October 2005. Available online at: *http://www.icca-chem.org/Home/ICCA-initiatives/High-production-volume-chemicals-initiative-HPV.*
11. EPA. TSCA Section 4(a)(1)(B) Proposed Statement of Policy. Notice. **Federal Register** (56 FR 32294, July 15, 1991).
12. EPA, OPPT. Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? April 1998. Available online at: *http://www.epa.gov/chemrtk/pubs/general/hazchem.htm.*
13. EPA, OPPT, Chemical Information and Testing Branch (CITB). Response to public comments regarding testing of certain high production volume chemicals. August 2010.
14. EPA, OPPT, Economics, Exposure and Technology Division (EETD). Testing of Certain High Production Volume Chemicals-3 (Exposure Findings Supporting Information). March 2011.
15. EPA. Preliminary Assessment Information Reporting; Addition of Certain Chemicals. Final Rule and Technical Corrections. **Federal Register** (71 FR 47122, August 16, 2006) (FRL–7764–9).
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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), this final rule is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, because it does not 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, EPA did not submit this final rule to OMB for review under Executive Order 12866.

EPA has prepared an economic analysis of this action, which is contained in a document entitled ''Economic Impact Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals; Third Group of Chemicals'' (Ref. 54). A copy of the economic analysis is available in the docket for this final rule and is summarized in Unit IX.

B. Paperwork Reduction Act

This final rule does not impose any new or amended paperwork collection requirements that would require additional review and/or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under PRA, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). In the context of developing a new test rule, the Agency must determine whether the total annual burden covered by the approved ICR needs to be amended to accommodate the burden associated with the new test rule. If so the Agency must submit an Information Correction Worksheet (ICW) to OMB and obtain OMB approval of an increase in the total approved annual burden in the approved EPA ICR No. 0795. The Agency's estimated burden for this final rule is provided in the economic analysis (Ref. 54).

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 impose any new requirements or changes to the export notification requirements, and is not expected to result in any substantive changes in the burden estimates for EPA ICR No. 0795 that would require additional review and/or approval by OMB. Under 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. The standard chemical testing program involves the submission of letters-of-intent-to-test (or exemption applications), study plans, semi-annual progress reports, test results, and some administrative costs. For this final rule, EPA estimates the public reporting burden for all 15 HPV chemical substances is 25,226 hours, with an estimated burden per chemical substance of 1,682 hours (Ref. 54). The estimated burden of the information collection activities related to export notification is estimated to average 1 burden hour for each chemical substance/country combination for an initial notification and 0.5 hours for each subsequent notification (Ref. 54). 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 test rules for chemical substances. As such, EPA does not expect to need to request an increase in the total burden hours approved by OMB for export notifications.

As defined by PRA and 5 CFR 1320.3(b), ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining

information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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 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 factual basis for this determination is presented in the small entity impact analysis prepared as part of the economic analysis for this final rule (Ref. 54), which is summarized in Unit IX., 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 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 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 that EPA prepared as part of the economic analysis for this final rule (Ref. 54), EPA has determined that this final rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency's analysis presents only the estimated potential impacts on small business.

Two factors are examined in EPA's small entity impact analysis (Ref. 54) in order to characterize the potential small entity impacts of this final rule on small business:

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

Section 601(3) of RFA establishes as the default definition of ''small business'' the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which SBA establishes small business size standards (13 CFR 121.201). For this 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. In analyzing potential impacts, RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of RFA provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. Even though the Agency has used the default SBA definition of small business to conduct its analysis of potential small business impacts for this final rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the chemical manufacturing industrial sector (*i.e.,* NAICS code 325 and NAICS code 324110), approximately 98% of the firms would be classified as small businesses under the default SBA definition. The SBA size standard for 75% of this industry sector is 500 employees, and the size standard for 23% of this industry sector is 750, 1,000, or 1,500 employees. When assessing the potential impacts of test rules on chemical manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means to judge the ability of a chemical manufacturing firm to support chemical testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated previously, therefore, the factual basis for the RFA determination for this final rule is based on an analysis using the default SBA size standards. Although EPA is not currently proposing to establish an alternate definition for use in the analysis conducted for this final rule, the analysis for this final rule also presents the results of calculations using a standard based on total annual sales (40 CFR 704.3).

The SBA has developed 6 digit NAICS code-specific size standards based on employment thresholds. These size standards range from 500 to 1,500 employees for the various 6 digit NAICS codes that are potentially impacted (Ref. 54). For a conservative estimate of the number of small businesses affected by this final rule, the Agency chose an employment threshold of less than 1,500 employees for all businesses regardless of the NAIC-specific threshold to determine small business status.

For each manufacturer of the 15 HPV chemical substances covered by this final rule, the parent company (ultimate corporate entity (UCE)) was identified and sales and employment data were obtained for companies where data was publicly available. The search determined that there were 31 affected UCEs. Sales and employment data could be found for 30 of these UCEs (97%).

Parent company sales data were collected to identify companies that qualified as a ''small business'' for purposes of RFA analysis. Based on the SBA size standard applied (1,500 employees or less), 13 companies (38%) were identified as small.

The potential significance of this final rule's impact on small businesses was analyzed by examining the number of small entities that experienced different levels of costs as a percentage of their sales. Small businesses were placed in the following categories on the basis of cost-to-sales ratios: Less than 1%, greater than 1%, and greater than 3%. This analysis was conducted under both a least and average cost scenario.

Of the 13 small businesses included in the analysis, 1 company (8%) had cost-to-sales ratios of greater than 1% under both the least and average cost scenarios. For the single business where sales and employment data were unavailable, EPA conducted an analysis to evaluate the potential impact on this company using the median sales value sales of all other small businesses equal to $24.3 million. The costs for the company were estimated to be well below 1% of this sales level. Given these results, the Agency has determined that there is not a significant economic impact on a substantial number of small entities as a result of this final rule.

The estimated cost of the TSCA section 12(b)(1) export notification, which, as a result of this final rule, would be required for the first export to a particular country of a chemical substance subject to this final rule, is estimated to be $86.99 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $27.49 for each subsequent export notification submitted by that exporter (Refs. 54–56). EPA has concluded that the costs of TSCA section 12(b)(1) export notification would have a negligible impact on exporters of the chemical substances in this final rule, regardless of the size of the exporter.

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 final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any 1 year. It is estimated that the total aggregate costs of this final rule, which are summarized in Unit IX., would be $5.08 million. The total annualized costs of this final rule are estimated to be $1.81 million. In addition, since EPA does not have any information to indicate that any State, local, or Tribal government manufactures or processes the chemical substances covered by this action such that this final rule would apply directly to State, local, or Tribal governments, EPA has determined that this final rule would 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

Under Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), EPA has determined that this final rule does not have ''federalism implications'' because 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 the Executive Order. This final rule establishes testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by this action, this final 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 9, 2000), EPA has determined that this final rule does not have Tribal implications because it will not have any effect 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 Order. As indicated previously, 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.

G. Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it does not establish an environmental standard intended to mitigate health or safety risks, will not have an annual effect on the economy of $100 million or more, nor does it otherwise have a disproportionate effect on children. This final rule establishes testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances, and that will result in the development of data about those chemical substances that can subsequently be used to 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 subject to Executive Order 13211, entitled ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is unlikely to have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

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.

This final rule involves technical standards that require the use of particular test methods. When the Agency makes findings under TSCA section 4(a), EPA is required by TSCA section 4(b) to include specific standards or test methods that are to be used for the development of the data required in the test rules issued under TSCA section 4. For some of the testing that is required by this final rule, EPA is requiring the use of voluntary consensus standards issued by ASTM and ISO, and a OECD guideline, which evaluate the same type of toxicity as the TSCA and OECD test methods, where applicable. Copies of the 17 ASTM and ISO standards and 1 OECD guideline, referenced in § 799.5089(h) of the regulatory text, have been placed in the docket for this final rule and may also be obtained by contacting the organizations that produced these materials. The addresses for these organizations are listed in the regulatory text of § 799.5089(h). EPA received the required approval from the Director of the Federal Register for the incorporation by reference of the ASTM and ISO standards and OECD guideline 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 voluntary consensus standards which evaluate partition coefficient (*n*-octanol/water) generator column, water solubility (column elution and generator column), acute inhalation toxicity, bacterial reverse mutations, *in vivo* mammalian bone marrow chromosomal aberrations, combined repeated dose with reproductive/developmental toxicity screen, repeated dose 28-day oral toxicity screen, or the reproductive developmental toxicity screen which could be considered in lieu of TSCA test methods, 40 CFR 799.6756, 799.6784, 799.6786, 799.9130, 799.9510, 799.9538, 799.9365, 799.9305, and 799.9355.

J. Executive Order 12898

This final rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994). The Agency believes that the information collected under this final rule will assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by this final rule. Although not directly impacting environmental justice-related concerns, this information will better enable the Agency to better protect human health and the environment, including in low-income and minority communities.

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 in 40 CFR Part 799

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

Dated: October 13, 2011.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 799—[AMENDED]

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

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

■ 4. Add new § 799.5089 to subpart D to read as follows:

§ 799.5089 Chemical testing requirements for third group of high production volume chemicals (HPV3).

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

(b) *Am I subject to this section?* (1) If you manufacture (including import) or intend to manufacture, or process or intend to process, any chemical substance listed in Table 2 in paragraph (j) of this section at any time from November 21, 2011 to the end of the test data reimbursement period as defined in 40 CFR 791.3(h), you are subject to this section with respect to that chemical substance.

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

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

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

Persons initially required to comply with this section (Tier 1)	Persons not initially required to comply with this section (Tier 2)
Persons not otherwise specified in column 2 of this table that manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section.	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 lb) annually (as described at 40 CFR 790.42(a)(4)); or —For research and development (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)).

Note: kgs—kilograms, TSCA—Toxic Substances Control Act.

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

(2) If you are in Tier 1 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, you

must, for each test required under this section for that chemical substance, either submit to EPA a letter-of-intent-to-test or apply to EPA for an exemption from testing. The letter-of-intent-to-test or the exemption application must be received by EPA no later than December 20, 2011.

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

(4) If no person in Tier 1 has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section on or before December 20, 2011, EPA will publish a **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter-of-intent has been submitted and notify manufacturers in Tier 2A of their obligation to submit a letter-of-intent-to-test or to apply for an exemption from testing.

(5) If you are in Tier 2A (as specified in Table 1 in paragraph (c) of this section) with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you manufacture, or intend to manufacture, this chemical substance as of November 21, 2011, 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 in Tier 1 or Tier 2A has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(4) of this section, EPA will publish another **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter-of-intent has been submitted, and notify processors in Tier 2B of their obligation to submit a letter-of-intent-to-test or to apply for an exemption from testing.

(7) If you are in Tier 2B (as specified in Table 1 in paragraph (c) of this section) with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you process, or intend to process, this chemical substance as of November 21, 2011, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(6) of this section, either submit to EPA a letter-of-intent-to-test or apply to EPA for an exemption from testing. The letter-of-intent-to-test or the exemption application must be received by EPA no later than 30 days after publication of the document described in paragraph (c)(6) of this section.

(8) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(6) of this section, EPA will notify all manufacturers and processors of those chemical substances of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter-of-intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give the manufacturers and processors of the chemical substance(s) an opportunity to take corrective action.

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

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

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

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

(2) For each test with respect to which you submit to EPA a letter-of-intent-to-test, you must submit a study plan and 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 40 CFR part 790 (except for those requirements listed in this paragraph as not applicable to this section), including the submission of letters-of-intent-to-test or exemption applications, submission of study plans, the conduct of testing, and the submission of data; 40 CFR part 792—Good Laboratory Practice Standards; and this section. The following provisions of 40 CFR part 790 do not apply to this section: Paragraphs (a), (d), (e), and (f) of § 790.45; § 790.48; paragraphs (a)(2) and (b) of § 790.80; paragraph (e)(1) of § 790.82; and § 790.85.

(e) *If I do not comply with this section, when will I be considered in violation of it?* You will be considered in violation of this section as of 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 40 CFR part 707, subpart D.

(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 18 test 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, approved September 10, 1999.

(ii) Standard Test Method for Partition Coefficient (*N*-Octanol/Water) Estimation by Liquid Chromatography, ASTM E 1147–92 (Reapproved 2005), approved August 1, 2005.

(iii) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians, ASTM E 729–96 (Reapproved 2007), approved October 1, 2007.

(iv) Standard Test Method for Measurements of Aqueous Solubility, ASTM E 1148–02 (Reapproved 2008), approved February 1, 2008.

(v) Standard Test Method for Estimating Acute Oral Toxicity in Rats, ASTM E 1163–98 (Reapproved 2002), approved October 10, 2002.

(vi) Standard Guide for Conducting *Daphnia magna* Life-Cycle Toxicity Tests, ASTM E 1193–97 (Reapproved 2004), approved April 1, 2004.

(vii) Standard Guide for Conducting Static Toxicity Tests with Microalgae, ASTM E 1218–04^{e1}, approved April 1, 2004.

(viii) Standard Test Method for Vapor Pressure of Liquids by Ebulliometry, ASTM E 1719–05, approved March 1, 2005.

(ix) Standard Test Method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test. ASTM E 1720–01 (Reapproved 2008), approved February 1, 2008.

(x) Standard Test Method for Determining Vapor Pressure by Thermal Analysis, ASTM E 1782–08, approved March 1, 2008.

(xi) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Method by Analysis of Inorganic Carbon in Sealed Vessels (CO_2 Headspace Test). First Edition, March 15, 1999. ISO 14593:1999(E).

(xii) Water Quality—Evaluation in an Aqueous Medium of the ''Ultimate'' Aerobic Biodegradability of Organic Compounds—Method by Analysis of Dissolved Organic Carbon (DOC). Second Edition, September 15, 1994. ISO 7827:1994(E).

(xiii) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium by Determination of Oxygen Demand in a Closed Respirometer. Second Edition, August 1, 1999. ISO 9408:1999(E).

(xiv) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Carbon Dioxide Evolution Test. Second Edition, March 1, 1999. ISO 9439:1999(E).

(xv) Water Quality—Evaluation in an Aqueous Medium of The ''Ultimate'' Aerobic Biodegradability of Organic Compounds—Method by Analysis of Biochemical Oxygen Demand (Closed Bottle Test). First Edition, October 15, 1994. ISO 10707:1994(E).

(xvi) Water Quality—Evaluation in an Aqueous Medium of the Ultimate Aerobic Biodegradability of Organic Compounds—Determination of Biochemical Oxygen Demand in a Two-Phase Closed Bottle Test. First Edition, February 1, 1997. ISO 10708:1997(E).

(xvii) Water Quality—Guidance for the Preparation and Treatment of Poorly Water-Soluble Organic Compounds for the Subsequent Evaluation of Their Biodegradability in an Aqueous Medium. First Edition, August 15, 1995. ISO 10634:1995(E).

(xviii) Guideline for the Testing of Chemicals: Melting Point/Melting Range. OECD 102. July 27, 1995.

(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 standards from ASTM International, 100 Bar Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, *telephone number:* (610) 832–9585, *Web address: http://www.astm.org;* copies of the ISO standards from the International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH–1211 Geneve 20, Switzerland, telephone number: +41–22–749–01–11, *Web address: http://www.iso.org;* and copies of the OECD guideline from the Organization for Economic Cooperation and Development, 2, rue André Pascal, 75775 Paris Cedex 16, France, telephone number: +33–1–45–24–82–00, *Web address: http://www.oecd.org.* You may inspect each standard and guideline at the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. The materials are also available for inspection 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/cfr/ibr-locations.html.*

(i) *Reporting requirements.* A study plan for each specific test for each subject chemical substance must be received by EPA by February 20, 2012 unless an extension is granted in writing pursuant to 40 CFR 790.55. A final report for each specific test for each subject chemical substance must be received by EPA by December 21, 2012 unless an extension is granted in writing pursuant to 40 CFR 790.55. EPA is also requesting that a robust summary of the final report for each specific test 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 online at *http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm.*

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

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

CASRN	Chemical name	Class	Required tests (see Table 3 of this section)
98–09–9	Benzenesulfonyl chloride	1	C2, E1, E2, F1
98–56–6	Benzene, 1-chloro-4-(trifluoromethyl)-	1	B, C6

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS—Continued

CASRN	Chemical name	Class	Required tests (see Table 3 of this section)
111–44–4	Ethane, 1,1′-oxybis[2-chloro-	1	C6, F1
127–68–4	Benzenesulfonic acid, 3-nitro-, sodium salt (1:1)	1	A3, F2
515–40–2	Benzene, (2-chloro-1,1-dimethylethyl)-	1	A1, A3, A4, A5, B, C1, D, E1, E2, F1
2494–89–5	Ethanol, 2-[(4-aminophenyl)sulfonyl]-, 1-(hydrogen sulfate)	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
5026–74–4	2-Oxiranemethanamine, N-[4-(2-oxiranylmethoxy)phenyl]-N-(2-oxiranylmethyl)-	1	A1, A2, A3, A4, A5, B, C2, F1
22527–63–5	Propanoic acid, 2-methyl-, 3-(benzoyloxy)-2,2,4-trimethylpentyl ester	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
25321–41–9	Benzenesulfonic acid, dimethyl-	1	A2, A3, A4
52556–42–0	1-Propanesulfonic acid, 2-hydroxy-3-(2-propen-1-yloxy)-, sodium salt (1:1).	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68082–78–0	Lard, oil, Me esters	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68442–60–4	Acetaldehyde, reaction products with formaldehyde, by-products from	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68610–90–2	2-Butenedioic acid (2E)-, di-C8-18-alkyl esters	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
70693–50–4	Phenol, 2,4-bis(1-methyl-1-phenylethyl)-6-[2-(2-nitrophenyl)diazenyl]-	1	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
72162–15–3	1-Decene, sulfurized	2	A2, A3, A4, A5, B, C1, D, E1, E2, F1

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

[**Note:** The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section]

Testing category	Test symbol	Test requirements and references	Special conditions
Physical/chemical properties.	A	1. Melting Point: ASTM International (ASTM) E 324–99 (capillary tube), if a Freezing Point: Organization for Economic Cooperation and Development (OECD) 102 (melting point/melting range). 2. Boiling Point: ASTM E 1719–05 (ebulliometry). 3. Vapor Pressure: ASTM E 1782–08 (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 1147–92 (Reapproved 2005) (liquid chromatography). Method C: 40 CFR 799.6756 (generator column). 5. Water Solubility: (See Special Conditions for the water solubility test requirement and select the appropriate method to use, if any, from those listed in this column.) Method A: ASTM E 1148–02 (Reapproved 2008) (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 (log 10 basis) or log K_{ow}: Which method is required, if any, is determined by the test substance's estimated[i] 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, B, or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. Water Solubility: Which method is required, if any, is determined by the test substance's estimated[ii] water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 milligram/Liter (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.

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

[**Note:** The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section]

Testing category	Test symbol	Test requirements and references	Special conditions
Environmental fate and pathways—ready biodegradation.	B	For B, consult International Organization for Standardization (ISO) 10634:1995(E) for guidance, and choose one of the methods listed in this column: 1. ASTM E 1720–01 (Reapproved 2008) (sealed vessel CO_2 production test) OR 2. ISO 14593:1999(E) (CO_2 headspace test) OR 3. ISO 7827:1994(E) (analysis of DOC) OR 4. ISO 9408:1999(E) (determination of oxygen demand in a closed respirometer) OR 5. ISO 9439:1999(E) (CO_2 evolution test) OR 6. ISO 10707:1994(E) (closed bottle test) OR 7. ISO 10708:1997(E) (two-phase closed bottle test).	Which method is required, if any, is determined by the test substance's physical and chemical properties, including its water solubility. ISO 10634:1995(E) provides guidance for selection of an appropriate test method for a given test substance. Test sponsors must provide in the final study report the underlying rationale for the method selected.
Aquatic toxicity	C1	For C1, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C1:* 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Acute Toxicity to *Daphnia:* ASTM E 729–96 (Reapproved 2007). 3. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$. *Test Group 2 for C1:* 1. Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$.	The following are the special conditions for C1, C2, C3, C4, C5, and C7 testing; there are no special conditions for C6. Which test group is required is determined by the test substance's measured log K_{ow} as obtained under Test Category A, or using an existing measured log K_{ow}.[iii] If log $K_{ow} < 4.2$: Test Group 1 is required. If log $K_{ow} \geq 4.2$: Test Group 2 is required.
	C2	For C2, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C2:* 1. Acute Toxicity to *Daphnia:* ASTM E 729–96 (Reapproved 2007). 2. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$. *Test Group 2 for C2:* 1. Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$.	
	C3	For C3, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C3:* 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$. *Test Group 2 for C3:* 1. Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$.	
		For C4, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C4:* 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Acute Toxicity to *Daphnia:* ASTM E 729–96 (Reapproved 2007). *Test Group 2 for C4:* Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004).	

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

[**Note:** The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section]

Testing category	Test symbol	Test requirements and references	Special conditions
	C5	For C5, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C5:* Acute Toxicity to *Daphnia:* ASTM E 729–96 (Reapproved 2007). *Test Group 2 for C5:* Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004).	
	C6	Toxicity to Plants (Algae): ASTM E 1218–04$^{\varepsilon 1}$.	
	C7	For C7, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C7:* Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). *Test Group 2 for C7:* Chronic Toxicity to *Daphnia:* ASTM E 1193–97 (Reapproved 2004).	
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 1163–98 (Reapproved 2002) OR 2. Acute (Up/Down) Oral Toxicity (rat): 40 CFR 799.9110(d)(1)(i)(A).	Which testing method is required is determined by the test substance's physical state at room temperature (25 °C). For those test substances that are gases at room temperature, Method A is required; otherwise, use either of the two methods listed under Method B. In Method B, 40 CFR 799.9110(d)(1)(i)(A) refers to the OECD 425 Up/Down Procedure.[iv] Estimating starting dose for Method B: Data from the neutral red uptake basal cytotoxicity assay[v] 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.
	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.	

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

[**Note:** The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section]

Testing category	Test symbol	Test requirements and references	Special conditions
	F3	Repeated Dose 28-Day Oral Toxicity Study in rodents: 40 CFR 799.9305.	

[i] 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. 1995. This reference is available in docket ID number EPA–HQ–OPPT–2009–0112 at the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

[ii] 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 in docket ID number EPA–HQ–OPPT–2009–0112 at the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

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

[iv] The OECD 425 Up/Down Procedure, revised by OECD in December 2001, is available in docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

[v] The neutral red uptake basal cytotoxicity assay, which may be used to estimate the starting dose for the mammalian toxicity-acute endpoint, is available in docket ID number EPA–HQ–OPPT–2009–0112 at the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

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