



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA-HQ-OPPT-2005-0033; FRL-9350-1]

RIN 2070-AD16

Revocation of TSCA Section 4 Testing Requirements for One High Production Volume Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing the revocation of certain testing requirements promulgated under the Toxic Substances Control Act (TSCA) for benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- (CAS No. 1324-76-1), also known as C.I. Pigment Blue 61. EPA is basing its decision to take this action on information received since publication of the final rule that established testing requirements for this chemical substance.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2005-0033, by one of the following methods:

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

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

12T-0714

• *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA-HQ-OPPT-2005-0033. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2005-0033. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding 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.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Catherine Roman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8157; email address: roman.catherine@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general and may be of particular interest to those persons who manufacture (defined by statute to include import), process, or export the chemical substance identified in this document. Because other persons may also be interested, the Agency has not attempted to describe all the specific persons that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

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

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

- i. Identify the document by docket ID number and other identifying information

(subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

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

II. Background

A. What Action is the Agency Taking?

EPA is proposing to amend the TSCA section 4(a) chemical testing requirements for one high production volume (HPV) chemical included in 40 CFR 799.5085.

Specifically, this amendment revokes some of the testing requirements for C.I. Pigment Blue 61. EPA is basing its decision to take this action on information (discussed in Unit III.) received since publication of the final rule (Ref. 1) that established testing requirements for this chemical substance.

In the **Federal Register** of March 16, 2012 (77 FR 15609) (FRL-9335-6), EPA issued a revocation of some or all of the testing requirements for 10 chemical substances by direct final rule. EPA received an adverse comment concerning the chemical substance C.I. Pigment Blue 61. Consequently, in accordance with the procedures described in the March 16, 2012 **Federal Register** document, EPA is withdrawing the revocation of certain testing requirements for C.I. Pigment Blue 61 in a separate document published elsewhere in today's **Federal Register**, and is now issuing this proposed rule.

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

Section 4(a) of TSCA authorizes EPA to require testing if certain findings are made. The TSCA section 4(a) findings include:

1. The chemical substance was produced in substantial quantities.
2. There are insufficient data upon which the effects of manufacture, distribution, processing, use, or disposal of a chemical substance on health or the environment can reasonably be determined or predicted.
3. Testing of the chemical substance with respect to such effects is necessary to develop such data. (See TSCA section 4(a)(1)(B)(i), (ii), and (iii); see also Ref. 1).

EPA is amending the testing requirements for C.I. Pigment Blue 61 because some of the findings that EPA made for this chemical substance are no longer supported.

III. Amendment to Chemical Testing Requirements

On July 17, 2006, the Color Pigments Manufacturers Association (CPMA) submitted a test plan for C.I. Pigment Blue 61. CPMA also submitted robust summaries of existing data which CPMA asked EPA to accept as satisfying some of the Agency's

data needs for C.I. Pigment Blue 61. Some of the existing data described in the summaries addressed C.I. Pigment Blue 56, a close analog of C.I. Pigment Blue 61, which CPMA requested EPA to accept as satisfying the Agency's data needs for C.I. Pigment Blue 61, providing a structure-activity relationship (SAR) argument in the test plan to justify that request (Refs. 2 and 3). CPMA also asked EPA to accept results for water solubility and octanol/water partition coefficient that were obtained by using an alternative method, due to the extremely low predicted solubility of C.I. Pigment Blue 61, instead of the methods specified by the test rule (Ref. 2). Finally, CPMA asked EPA to accept that determining a melting point for C.I. Pigment Blue 61 was not relevant because the pigment thermally decomposes before it melts (Ref. 2).

EPA reviewed the submitted information on physical/chemical properties and decided that melting point, boiling point, and vapor pressure determinations were not relevant because C.I. Pigment Blue 61 decomposes before it melts and the decomposition temperature had been reported (Ref. 4). EPA accepted the submitted data on water solubility as satisfying the Agency's data needs for that endpoint, but did not accept the calculated value submitted to satisfy the testing requirement for octanol/water partition coefficient (Ref. 4). EPA believes the calculated value would, most likely, underestimate the measured value (Ref. 4) required to be determined by the test rule.

EPA reviewed CPMA's SAR argument concerning C.I. Pigment Blue 61 and C.I. Pigment Blue 56 and agreed that C.I. Pigment Blue 56 is an acceptable surrogate for C.I. Pigment Blue 61, thereby allowing adequate data on C.I. Pigment Blue 56 to satisfy data needs for C.I. Pigment Blue 61 (Ref. 5). As a result, a biodegradation study of C.I. Pigment Blue 56, found adequate by an EPA review, satisfies the need for biodegradation

data on C.I. Pigment Blue 61 (Ref. 5). Likewise, a fish acute toxicity study and a chromosomal damage test of C.I. Pigment Blue 56, which EPA reviewed and found adequate, will satisfy the data need for those endpoints (Ref. 6) for C.I. Pigment Blue 61. EPA's review of the existing data on C.I. Pigment Blue 61 found the study on mammalian acute toxicity and the bacterial mutation assay to be adequate to satisfy the data needs for those endpoints (Ref. 6). The existing study on repeated-dose toxicity, however, did not satisfy the test requirement for that endpoint (Ref. 6).

Therefore, EPA is proposing to revoke the testing requirements for melting point, boiling point, vapor pressure, water solubility, biodegradation, fish acute toxicity, mammalian acute toxicity, bacterial reverse mutation, and chromosomal damage for C.I. Pigment Blue 61 by removing those requirements from those listed for that chemical substance in Table 2 in 40 CFR 799.5085(j). In order to clarify that test requirements for acute toxicity to *Daphnia* (an aquatic invertebrate) and toxicity to algae had not been satisfied by existing studies, and that the fish acute toxicity test requirement had been satisfied, the test symbol C2 replaces C1 for C.I. Pigment Blue 61 in Table 2 in 40 CFR 799.5085(j). The testing requirements for C.I. Pigment Blue 61 that are not proposed to be revoked include tests for octanol/water partition coefficient, acute toxicity to *Daphnia*, toxicity to algae, and combined 28-day repeated-dose toxicity with a reproduction/developmental toxicity screen. Studies responding to those test requirements were submitted to the Agency. The full studies and robust summaries (Ref. 7) are in the docket for this proposed rule, docket ID number EPA-HQ-OPPT-2005-0033.

IV. Public Comment

EPA received one adverse comment concerning the March 16, 2012 direct final

rule that revoked some of the testing requirements for C.I. Pigment Blue 61 and nine other chemical substances. The comment concerned the statement in the preamble of the direct final rule that certain full studies for C.I. Pigment Blue 61 had been claimed as CBI and were therefore not available to the public, although robust summaries were available in the docket. The commenter objected to EPA's placing the robust summaries in the docket rather than applying the disclosure requirements of TSCA section 14(b) to the full health and safety studies. The submitter of these studies has subsequently withdrawn the CBI claim on these studies. The full studies and the adverse comment are included in the docket for this proposed rule, docket ID number EPA-HQ-OPPT-2005-0033.

V. Economic Analysis

In the economic impact analysis for the final rule (Ref. 1) establishing testing requirements for C.I. Pigment Blue 61 and 16 other chemical substances, the Agency estimated the total testing cost to industry to be \$4.03 million for all 17 chemical substances included in that final rule, with an average of approximately \$237,000 per chemical substance (Ref. 8). This total included an additional 25% in administrative costs. An amendment to the final rule revoking testing requirements for coke-oven light oil (coal) reduced the total cost to industry to an estimated \$3.7 million for the remaining 16 chemical substances, with an average compliance cost of approximately \$232,000 per chemical substance. This proposed rule, combined with the direct final rule revoking all or some of the test rule requirements for 9 other chemical substances (see Ref. 1), would have the effect of further reducing the total testing cost by an estimated \$1.5 million (approximately 41%) (Ref. 9). In addition, the 25% administrative costs would be eliminated for these tests. The reduced total cost for the remaining 12 chemical

substances is estimated to be \$2.2 million (i.e., \$3.7 million—\$1.5 million), with an average compliance cost per chemical substance of approximately \$184,000 (Ref. 9).

VI. Export Notification

Persons who export or intend to export C.I. Pigment Blue 61 are and will remain subject to TSCA section 12(b) export notification requirements (See 40 CFR part 707, subpart D).

VII. References

The following documents are specifically referenced in the preamble for this proposed rule. In addition to these documents, other materials may be available in the docket established for this proposed rule under Docket ID number EPA-HQ-OPPT-2005-0033, which you can access through <http://www.regulations.gov>. Those interested in the information considered by EPA in developing this proposed rule should also consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether the other documents are physically located in the docket.

1. EPA. Testing of Certain High Production Volume Chemicals; Final Rule. **Federal Register** (71 FR 13708, March 16, 2006) (FRL-7335-2). Document ID number EPA-HQ-OPPT-2005-0033-0001.
2. CPMA. Letter to EPA from J. Lawrence Robinson concerning existing data and test plan. July 17, 2006. Document ID number EPA-HQ-OPPT-2005-0033-0185.
3. CPMA. Letter to EPA from J. Lawrence Robinson concerning existing data and test plan. May 9, 2007. Document ID EPA-HQ-OPPT-2005-0033-0246.
4. EPA. Memorandum from Diana Darling, Industrial Chemistry Branch (ICB), Economics, Exposure, and Technology Division (EETD), OPPT to Greg Schweer,

Chemical Information and Testing Branch (CITB), Chemical Control Division (CCD), OPPT. Testing requirements and existing data for physical/ chemical properties of the HPV test rule chemical, C.I. Pigment Blue 61 (CAS No. 1324-76-1). May 17, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0280.

5. EPA. Memorandum from Bob Boethling, Exposure Assessment Branch (EAB), OPPT to Greg Schweer, CITB, CCD, OPPT. Review of SAR argument and a biodegradation test concerning an HPV test rule chemical, C.I. Pigment Blue 61 (CAS No. 1324-76-1). May 15, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0279.

6. EPA. Email and attached review from David Brooks, Risk Assessment Division (RAD), OPPT to Greg Schweer and Catherine Roman, CITB, CCD, OPPT. Review of C.I. Pigment Blue (CAS No. 1324-76-1). August 22, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0286.

7. CPMA. Robust summaries submitted for C.I. Pigment Blue 61 on octanol/water partition coefficient, acute toxicity to Daphnia, toxicity to algae, and combined 28-day repeated-dose toxicity with a reproduction/developmental toxicity screen. Submitted on November 14, 2008. Document ID number EPA-HQ-OPPT-2005-0033-0318.

8. EPA. Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals. Prepared by Economic Policy and Analysis Branch (EPAB), EETD, OPPT. October 28, 2005. Document ID number EPA-HQ-OPPT-2005-0033-0131.

9. EPA. Email from Stephanie Suazo to Catherine Roman RE: "Revised Economic Analysis for Revocation of Testing Requirements" with attached economic

analysis. December 14, 2009. (Document ID number EPA-HQ-OPPT-2005-0033-0350).

VIII. Statutory and Executive Order Reviews

This proposed rule only eliminates existing requirements; it does not otherwise impose any new or revised requirements. As such, this action is not subject to review by the Office of Management and Budget (OMB) as a significant regulatory action under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Nor does it impose or change any information collection burden that requires additional review by OMB under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Because this proposed rule eliminates existing requirements without imposing any new or revised requirements, the Agency certifies pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that this action will not have a significant economic impact on a substantial number of small entities.

For the same reasons, it is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538), and does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in UMRA sections 203 and 204. This proposed rule does not have tribal implications, as specified in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), or federalism implications as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

Since this action is not economically significant under Executive Order 12866, it is not subject to Executive Order 13045, entitled “Protection of Children from

Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), and Executive Order 13211, entitled “Actions concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001).

This action does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

This proposed rule does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 799

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

Dated: May 8, 2012.

James J. Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is proposed to be amended as follows:

PART 799--[AMENDED]

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

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

2. In § 799.5085, revise the entry “CAS No. 1324-76-1” in Table 2 of paragraph

(j) to read as follows:

§ 799.5085 Chemical testing requirements for certain high production volume chemicals.

* * * * *

(j) * * *

TABLE 2.--CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

CAS No.	Chemical name	Class	Required tests/ (See Table 3 of this section)
* * *	* * *	*	*
1324-76-1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-	2	A4, C2, F1
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