

appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

**Abstract:** The New Source Performance Standards (NSPS) for the Graphic Arts Industry (40 CFR part 60, subpart QQ) were proposed on October 28, 1980, and promulgated on November 8, 1982. The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart QQ.

Owners or operators of the affected facilities must make an initial notification, performance tests, periodic reports, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semiannually.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 37 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

**Respondents/Affected Entities:** Graphic arts facilities.

**Estimated Number of Respondents:** 19.

**Frequency of Response:** Initially, occasionally, and semiannually.

**Estimated Total Annual Hour Burden:** 1,718.

**Estimated Total Annual Cost:** \$163,005, which includes \$163,005 in labor costs exclusively. There are no annualized capital/startup costs or O&M costs associated with this ICR.

**Changes in the Estimates:** There is no change in the number of hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens.

Dated: May 21, 2010.

**John Moses,**

*Director, Collection Strategies Division.*

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**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2010-0446; FRL-8827-3]

### Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA will begin a general practice of reviewing confidentiality claims for chemical identities in health and safety studies, and in data from health and safety studies, submitted under the Toxic Substances Control Act (TSCA) in accordance with Agency regulations at 40 CFR part 2, subpart B. Section 14(b) of TSCA does not extend confidential treatment to health and safety studies, or data from health and safety studies, which, if made public, would not disclose processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture. Where a chemical identity does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment. This builds on similar efforts regarding confidentiality of chemical identities listed on the public version of the TSCA Chemical Substances Inventory (TSCA Inventory) and submitted in notifications pursuant to TSCA section 8(e), discussed in the **Federal Register** of January 21, 2010.

**DATES:** EPA expects to begin reviews of confidentiality claims — both newly submitted and existing claims — in accordance with this guidance on August 25, 2010. Though EPA is not required to solicit comment for this action, comments received before this date will inform these reviews.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0446, by one of the following methods:

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

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

- **Hand Delivery:** OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2010-0446. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to docket ID number EPA-HQ-OPPT-2010-0446. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.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 e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at

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

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Scott M. Sherlock, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8257; e-mail address: [sherlock.scott@epa.gov](mailto:sherlock.scott@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](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This document is directed to the public in general, though it does not directly impose any binding requirements on parties outside the Agency. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process chemical substances and mixtures subject to TSCA (15 U.S.C. 2601 *et seq.*). You may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this document is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in 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](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM 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. What Action is the Agency Taking?

The Agency expects to respond to certain confidentiality claims regarding chemical identities in health and safety studies and in data from health and safety studies with a determination letter under 40 CFR 2.306(d), 40 CFR 2.204(d)(2), and 40 CFR 2.205(f) that such information is clearly not entitled to confidential treatment. This **Federal Register** document only serves to announce an impending general Agency practice, and this document does not

constitute a final Agency action; rather, any determination letter issued by EPA will constitute the Agency's final determination that the chemical identity at issue is not entitled to confidential treatment under TSCA section 14 (15 U.S.C. 2613), and the recipient of such a determination letter may seek judicial review under 5 U.S.C. 701 *et seq.*

At this time, EPA expects to issue these determination letters when the chemical identity claimed as confidential:

1. Was submitted as part of a health and safety study, or of data from a health and safety study, submitted under TSCA that is subject to TSCA section 14(b)(1).
2. Does not explicitly contain process information.
3. Does not reveal data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

Each determination letter will provide a contact person within the Agency whom the recipient of the letter can contact with any questions or concerns about the determination related to the submission.

The TSCA Inventory is a list of chemical substances subject to TSCA that are in commerce in the United States, and the fact that a chemical substance is on the TSCA Inventory may be claimed as confidential. Release of a chemical identity under TSCA section 14(b) may correspondingly affect the validity of a confidentiality claim for presence on the TSCA Inventory. EPA expects to examine TSCA Inventory confidentiality claims for chemical identity at the time it makes determinations under TSCA section 14(b). EPA will issue determinations on confidential inventory status when appropriate.

This action is part of a broader effort to increase transparency and provide more valuable information to the public by identifying data collections where information may have been claimed and treated as confidential in the past but is not in fact entitled to confidentiality under TSCA. For such information, EPA is considering what actions might be appropriate in accordance with its confidentiality regulations at 40 CFR part 2, subpart B. EPA believes these actions will make more health and safety information available to the public and support an important mission of the Agency to promote public understanding of the potential risks posed by chemical substances in commerce.

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

Under TSCA section 3(6) (15 U.S.C. 2602(6)):

The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.

Health and safety studies may be submitted under various sections of TSCA, such as TSCA section 8(d) rules explicitly requiring submission of health and safety studies, notices of substantial risk under TSCA section 8(e), and TSCA section 4 rules requiring persons to perform testing. (15 U.S.C. 2603, 2607(d), and 2607(e)) Premanufacture notices submitted under TSCA section 5 must include test data in the possession or control of the person submitting the notice. (15 U.S.C. 2605(d)(1)(B)) Chemical identity is part of a health and safety study. See, e.g., 40 CFR 716.3 and 40 CFR 720.3(k).

Section 14(b)(1) of TSCA provides that health and safety studies and data from health and safety studies are not entitled to confidential treatment unless such information, if made public, would disclose processes used in the manufacturing or processing of a chemical substance or mixture or in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture. (15 U.S.C. 2613(b)(1)) This document discusses the disclosure of process information element only, and does not deal with the portion of a mixture information element, which pertains to the concentrations of the components of a mixture.

Section 14(b)(1) of TSCA is limited to health and safety studies and data submitted with respect to chemical substances or mixtures that have been offered for commercial distribution and those for which testing is required under TSCA section 4 or for which notification is required under TSCA section 5.

Until recently, EPA has not announced the Agency's views regarding when disclosure of chemical identities may in turn disclose process information. In the **Federal Register** issue of January 21, 2010 (75 FR 3462) (FRL-8807-9), EPA announced that "[w]here a health and safety study submitted under section 8(e) of TSCA involves a chemical identity that is already listed on the public portion of the TSCA Chemical Substances

Inventory, EPA expects to find that the chemical identity clearly is not entitled to confidential treatment."

In that January 21, 2010 **Federal Register** document the Agency stated that:

"Where the identity of a chemical substance is already contained on the public portion of the TSCA Chemical Substances Inventory, which is publicly available from the National Technical Information Service and other sources, EPA believes that the identity itself, even assuming it might otherwise be CBI, as well as any information that might be derived from it about processes or portions, has already been disclosed."  
*Id.*

The January 21, 2010 **Federal Register** document did not, however, address chemical substances not on the public TSCA Inventory. With respect to such chemical substances, EPA is aware that some companies believe their competitors are sufficiently knowledgeable that if EPA were to disclose the chemical identity, the competitors would be capable of ascertaining on their own how the chemical substance might be manufactured or processed, and therefore this would in effect disclose process information.

EPA, however, questions the assertion that when disclosing a chemical identity of a chemical substance inspires a competitor to ascertain a process for manufacturing the chemical substance, such disclosure is equivalent to disclosing the process itself. Disclosing the end product of a process (i.e., a chemical identity) is not the same thing as disclosing the process to make that end product. The process information would come from the competitor's expertise, research, or publicly available sources, not from EPA. Although some companies might find such use of a chemical identity undesirable, EPA does not believe that TSCA section 14(b) was intended to limit the uses of information from a health and safety study.

Interpreting TSCA section 14(b)(1) otherwise might for all intents and purposes exclude chemical identities in health and safety studies from the disclosure provisions of TSCA section 14(b). Carried to its logical conclusion, the argument that the manufacturing process for chemical substances can be figured out by someone knowledgeable in the area and for that reason disclosure of chemical identities is considered equivalent to disclosing process information, would yield the perverse result that chemical identities would rarely, if ever be subject to TSCA section 14(b) disclosure.

Chemical identity has been claimed as confidential in a significant number of

health and safety submissions. The result, in the context of substantial risk notices under TSCA section 8(e) for example, has been that the public is able to see that some unidentified chemical substance might present a substantial risk of injury to health or the environment. EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted. Congress did not specifically exempt chemical identities from TSCA section 14(b), and EPA believes that interpreting TSCA section 14(b) in such a manner would be inconsistent with the intent of Congress in enacting the provision.

It is EPA's view that as a general matter disclosure of a chemical identity does not disclose process information except where the identity explicitly contains process information. For example, a name such as "formaldehyde" (Chemical Abstracts Service (CAS) No. 50-00-0) reveals nothing about the process to make the chemical substance, even if any chemist could figure out independently that formaldehyde can be generated by oxidizing methanol.

In contrast, the names of some chemical substances — especially polymers and chemical substances of unknown or variable composition, complex reaction products and biological materials (known as UVCB substances) — do explicitly contain process information. An illustrative UVCB example is CAS No. 64742-28-5, specific chemical substance's name "Distillates (petroleum), chemically neutralized light paraffinic." A polymer example is CAS No. 68474-52-2, safflower oil, polymer with adipic acid, glycerol and phthalic anhydride. The monomers adipic acid, glycerol and phthalic anhydride are reactants, information pertaining to manufacture of the polymer. EPA expects that such names would not be subject to TSCA section 14(b) disclosure in those instances where the chemical substances' name were claimed as confidential in a study.

EPA intends to begin review of confidentiality claims for identities of chemical substances in health and safety studies, and data from health and safety studies, as described in this guidance, on August 18, 2010. The Agency solicits comments prior to that date regarding classes of chemical substances and attributes of chemical identities that do or do not disclose process information. Such comments will inform the Agency's reviews. Where process information in the chemical identity is unnecessary to

characterize the chemical substance or mixture, EPA may release a version of the chemical identity with the process information removed.

EPA premanufacture notification regulations at 40 CFR 720.90(c) state that EPA will deny a confidentiality claim for chemical identity in a health and safety study submitted as part of a premanufacture notice unless:

1. The information in turn discloses process information,
2. The information discloses portions of a mixture, or
3. “[t]he specific chemical identity is not necessary to interpret a health and safety study” (see also 40 CFR 725.92(c) regarding microbial commercial activity notices). Consistent with the intent of TSCA section 14(b) to allow broad public availability of health and safety data, with limited exceptions, EPA intends to interpret paragraph 3. narrowly.

#### IV. Why is EPA Taking this Action?

Part of the Agency’s mission is to promote public understanding of potential risks by providing understandable, accessible, and complete information on potential chemical risks to the broadest audience possible. In support of this mission, EPA posts useful information about chemical substances regulated under TSCA for the public on its website (<http://www.epa.gov/oppt/index.htm>). One important source of this information is health and safety studies submitted to the Agency. The TSCA section 14(b) exclusion from confidential protection for information from health and safety studies indicates the importance attributed by Congress to making such information available to the public. Chemical identities in particular constitute basic information that helps the public to place risk information in context. Making public chemical identities in health and safety studies whose confidentiality is precluded by TSCA will support the Agency’s mission.

#### List of Subjects

Environmental protection, Chemicals, Confidential Business Information, Health and safety, Reporting and recordkeeping.

Dated: May 20, 2010.

**Stephen A. Owens,**

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

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**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9155-2]

### New York State Prohibition of Discharges of Vessel Sewage; Final Affirmative Determination

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of determination.

**SUMMARY:** Notice is hereby given that the Regional Administrator of the Environmental Protection Agency—Region 2, has determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the waters of the New York State (NYS) Canal System, including the 524 linear miles of navigable waterways within the Erie, Oswego, Champlain, and Cayuga-Seneca canal segments, and including Onondaga, Oneida, and Cross Lakes.

**SUPPLEMENTARY INFORMATION:** On April 30, 2009, the State of New York petitioned the Regional Administrator, EPA—Region 2, pursuant to Section 312(f)(3) of Public Law 92-500 as amended by Public Law 95-217 and Public Law 100-4, for a determination that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the NYS Canal System.

The NYS Department of Environmental Conservation (NYSDEC), in collaboration with the New York State Canal Corporation, the New York Department of State, and the New York State Environmental Facilities Corporation, prepared and submitted the petition, and NYSDEC certified the need for greater protection of the water quality in the NYS Canal System.

The waters of the proposed No Discharge Zone fall within the jurisdictions of the NYS Thruway Authority and NYS Canal Recreationway Commission, and include four distinct segments of the NYS Canal System. Adequate pumpout facilities are defined as one pumpout station for every 300 to 600 boats, pursuant to the Clean Vessel Act: Pumpout Station and Dump Station Technical Guidelines (59 FR 11290-02).

*Findings:* Potential vessel population in the NYS Canal System was determined using three sources of information: slips (6,896), boater registrations (21,201), and lockings (23,278). Based on the numbers determined through these sources and the number of pumpouts available (87), the following ratios were determined: using number of slips: 1:80, using NYS

Boater Registrations 1:243, and using number of lockings: 1:267, respectively. Thus adequate pumpouts are available for all boaters using the NYS Canal System. For all vessel waste disposal from pumpouts, there are 87 NYS Clean Vessel Assistance Program (CVAP) completed projects, 4 dispose of wastes to an on-site septic system, 21 dispose to a holding tank and 62 dispose to a municipal wastewater treatment plant. Thus all vessel sewage will be either discharge into State approved and regulated septic tanks or holding tanks for transport to a sewage treatment plant. Online maps are provided at <http://www.nysefc.org/maps> and include Google maps of pumpout locations and marina sheets that provide boaters with detailed availability information. Based on the above, EPA Region 2, has determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the waters of the New York State (NYS) Canal System. The following is a summary of EPA’s findings regarding the adequacy of pumpout facilities for the four Canal System segments at issue:

#### Champlain Canal

The Champlain Canal encompasses an area from the Federal lock in Troy, NY, to Whitehall, NY. The Champlain Canal leads north to Lake Champlain. Lake Champlain is a large waterbody that is already designated as a No Discharge Zone (NDZ) for vessel sewage, and the direct disposal of greywater into the lake is also prohibited. The total travel distance of the canal area is 60 miles, and to travel the entire length takes approximately 7 hours. There are 276 slips available and 7 operating pumpouts on the Champlain Canal. The 1:300 ratio would only require one pumpout, if the calculation were based solely on the number of slips. The availability of seven pumpouts for this canal meets the criteria for sufficient pumpout access, even accounting for some additional demand from transient traffic. The NYS side of Lake Champlain has an additional 1,014 slips available and 8 additional pumpouts.

#### Erie Canal

The Erie Canal stretches from Waterford (at the confluence of the Mohawk and Hudson Rivers) to the Tonawandas (at the Niagara River), traveling through Oneida Lake and Cross Lake, and connecting to Onondaga Lake along the way. This portion of the Canal is 338 miles long and has 44 pumpouts available for 2,555 slips. Achieving a 1:300 ratio would require a minimum of nine pumpouts for the