

**Supporting Statement for a Request for OMB Review under
the Paperwork Reduction Act**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Voluntary Cover Sheet for TSCA Submissions

EPA ICR No.: 1780.04 OMB Control No.: 2070-0156

1(b) Short Characterization

This Information Collection Request (ICR) pertains to the voluntary use of a cover sheet that has been developed by industry and EPA to facilitate the processing of information that is submitted to the Agency under sections 4 and 8 of the Toxic Substances Control Act (TSCA), or under the Voluntary Children's Chemical Evaluation Program (VCCEP). The cost and burdens related to the submissions under TSCA sections 4 and 8 and VCCEP have already been approved the Office of Management and Budget (OMB) and are contained in the following ICRs:

- (1) TSCA section 4 submissions are addressed in "Section 4 Test Rules and Consent Orders," OMB Control No. 2070-0033, EPA ICR No. 1139.
- (2) TSCA section 8(d) submissions are addressed in "TSCA Section 8(d) Health and Safety Data Reporting Rule," OMB Control No. 2070-0004, EPA ICR No. 0575.
- (3) TSCA section 8(e) reporting requirements are addressed in "Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)," OMB Control No. 2070-0046, EPA ICR No. 0794.
- (4) Certain voluntary reporting requirements are addressed in "Voluntary Children's Chemical Evaluation Program (VCCEP)," OMB Control No. 2070-0165, EPA ICR No. 2055.

This ICR, therefore, only applies to the burden and costs associated with the use of the voluntary cover sheet for those submissions.

Under TSCA sections 4 and 8, industry is required to submit certain information and studies for existing chemical substances. VCCEP is a voluntary reporting program. EPA typically receives several thousand submissions each year, with each submission consisting of three studies, on average. In addition, EPA may impose specific data call-ins on industry.

The submissions EPA receives can be numerous, lengthy and complex. For example, EPA received 10,000 submissions in FY 1992 in response to the TSCA Section 8(e) Compliance Audit Program. Processing of these submissions was not completed until FY 1995. In June 1994, EPA received 900 submissions, representing approximately 3,500 studies, under a TSCA section 8(d) data call-in for siloxanes by the Interagency Testing Committee (ITC).

Submissions/studies are received, logged, internally tracked, duplicated, distributed to government scientists for review and analysis, indexed, microfiched and made publicly available through the TSCA Test Submissions (TSCATS) database. However, TSCATS is only an online index of, and pointer system to, the large volume of unpublished studies; the full texts are available only in paper or on microfiche.

Under the auspices and funding of the Silicone Environmental Health and Safety Council (SEHSC), industry, EPA, and the ITC developed a model software application for submitting summary data for the section 8(d) siloxane data call-in. This model was designed around the TSCATS data structure but expanded to include additional data elements deemed valuable by industry. The objective was to capture comprehensively all submissions and studies from the ten SEHSC member companies for EPA's more efficient and effective receipt, tracking, processing, identification, internal and external search and retrieval, and upload to TSCATS for public availability. In addition, discussions were initiated and are ongoing for the electronic transfer by electronic medium or EDI of full submissions.

OPPT initiated a voluntary pilot program to accept certain Health and Safety Data submissions in an electronic format. Participating companies submit TSCA Health and Safety Study Cover Sheet(s) with attached electronic copies of the studies over the Internet. The studies are submitted in Portable Document Format (PDF) and digitally signed using the Public Key Infrastructure (PKI) standard. Allowing industry to submit TSCA Health and Safety Studies over the Web will reduce burden on Industry as well as the Agency by incorporating standardization and indexing of data, on-line help and automatic processing. This will also assist EPA in meeting goals established in the Paperwork Reduction Act (PRA) and the Government Paperwork Elimination Act (GPEA).

As a follow-up to the experience with the TSCA section 8(d) siloxane data call-in, the Chemical Manufacturers Association (CMA, now known as the American Chemical Council [ACC] and so referred to in the rest of this document), the Specialty Organics Chemical Manufacturers Association (SOCMA), and the Chemical Industry Data Exchange (CIDX), are actively and cooperatively pursuing summary data transfer by software application and EDI. In particular, ACC led the effort to develop the standardized cover sheet for voluntary use by industry as a first step to an electronic future and to begin familiarizing companies with standard requirements and concepts of electronic commerce. This form, entitled "TSCA Health and Safety Study Cover Sheet," was designed by ACC for voluntary use as a cover sheet for submissions of information under TSCA sections 4, 8(d) and 8(e), and now under VCCEP as well.

The voluntary use of a cover sheet facilitates the submission of information by displaying certain basic data elements, permitting EPA more easily to identify, log, track, distribute, review and index submissions, and makes information publicly available more rapidly and at reduced cost via TSCATS, to the mutual benefit of both industry and EPA. It is this form/cover sheet that is addressed in this information collection request.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

The standardized cover sheet discussed in this ICR is used in conjunction with submissions of information as required under TSCA sections 4, 8(d), 8(e) and VCCEP. The need and authority for these reporting requirements are discussed in detail in the information collection requests associated with these requirements and are not themselves relevant to the discussion of the use of the standardized cover sheet form that follows.

ACC and member companies actively utilize electronic commerce in their daily business operations. They recognize the future importance of electronic commerce for all their operations. This TSCA Cover Sheet is a first step in standardizing data and terms to promote the acceptance and implementation of electronic TSCA submissions to and communications with the Agency. ACC has determined that this TSCA Cover Sheet, as a paper and near term electronic version, will achieve efficiencies through industry-industry and industry-EPA cooperation, will engender more efficient systems, and will result in significant money and time savings.

2(b) Use/Users of the Data

EPA staff members in the Office of Pollution Prevention and Toxics (OPPT) are the primary users of the data found on the standardized cover sheet. OPPT employees use the information displayed on the cover sheet to identify the submission when it reaches EPA without having to examine portions of a submission that may be very lengthy and complex. OPPT staff members subsequently use information from the cover sheet to distribute, locate and track the submission as the submission moves through Agency reviews and decision points, to index the data, and to identify the data within the TSCATS database in making the data publicly available.

OPPT and ACC expect that the use of the TSCA Cover Sheet by industry will provide EPA the following benefits: expedited processing; reduced errors; improved data quality; more timely EPA access and scientific review; improved communication between EPA and industry submitters; quicker public availability; and overall time and money savings.

In addition, ACC and OPPT expect that the use of the TSCA Cover Sheet by industry will provide industry the following benefits: improved internal company storage; more efficient preparation and submission; standardized keywords; improved data quality; quicker decisions; improved understanding of EPA's needs; quicker access through TSCATS to relevant studies by industry toxicologists; and significant potential cost savings from non-initiation/non-duplication of studies through rapid TSCATS availability.

3. NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

The use of the Voluntary TSCA Cover Sheet is not a separate collection activity; rather it simply offers a cover form that may be used in conjunction with other submissions. These submissions still occur only once. As such, there is no duplicative collection.

3(b) Public Notice Required Prior to ICR Submission to OMB

Prior to submission to OMB, this ICR will be made available to the public for comment through a Federal Register notice. The public will have 60 days to provide comments. Any comments received will be given consideration when completing the supporting statement that is submitted to OMB.

3(c) Consultations

This effort developed from the cooperative effort among the Silicone Environmental Health and Safety Council (SEHSC), the Interagency Testing Committee (ITC), and EPA for the SEHSC-developed data base effort in response to the 30th ITC list/TSCA section 8(d) reporting. Out of this effort, ACC and SOCMA initiated subsequent discussions with EPA for their design and pilot of the Voluntary TSCA Cover Sheet. ACC and SOCMA are committed to encouraging member companies to use the cover sheet when submitting TSCA studies under sections 4, 8(d), 8(e) and VCCEP to EPA.

EPA will pursue additional consultations with interested parties during the development of the renewal of this collection.

3(d) Effects of Less Frequent Collection

Since the use of this cover sheet is strictly voluntary on the part of respondents, this is not applicable.

3(e) General Guidelines

The use of this cover sheet does not exceed any of the PRA guidelines at 5 CFR 1320.6.

3(f) Confidentiality

Any information included on the cover sheet may be claimed as confidential by the respondent. Claims of confidentiality are handled according to EPA procedures described in 40 CFR Part 2 and in the TSCA Confidential Business Information Security Manual, which call for careful protection of confidential, trade secret or proprietary information.

3(g) Sensitive Questions

This information collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents and NAICS Codes

Respondents affected by this activity are found mainly under NAICS codes 324 - Petroleum and Coal Products Manufacturing, and 325 - Chemical Manufacturing.

4(b) Information Requested

(i) Data Items

The Voluntary Cover Sheet simply captures certain information that is being submitted under another approved ICR. The data items included on the Cover Sheet are already contained in the submission to which the cover sheet is attached, and include the following:

Data Element	Description
1. Submission Type	Identifies the submission, including the type of submission and whether it is the initial submission, a follow-up or a final report.
2. Summary of Attachment	Allows the respondent to provide a summary or abstract of the attached study or report, any internal company tracking number, an EPA tracking number, and an indication of the number of studies submitted.
3. Chemical Identification	Identifies the chemical(s) addressed in the submission.
4. Title of Attachment	Identifies the title of the attached study or report.
5. Indexing Terms	Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.
6. Study/Report Information	Provides specific information regarding the attached study or report, including the source, date of the study or report, sponsor(s), and the length of the document.

7. Submitter Information	Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.
8. Comments	Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.
9. Signature	A signature is required for submissions under section 8(e); the cover form provides a place for the submitter's signature, thereby avoiding the need for or use of a separate cover letter.
10. Continuation	Allows the submitter to expand the response to any of the previous items, if needed, without the need to use a separate cover letter or additional forms.

A copy of the sample Voluntary Cover Sheet for TSCA Submissions is attached to this ICR, along with the instructions provided to users. ACC designed the form to capture all data and information required under “Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e),” and determined there was significant value for standardized data presentation under TSCA sections 4, 8(d) and 8(e). Additionally, TSCATS index codes to identify study type, subject organism (if appropriate), and route of exposure (if appropriate) are included.

(ii) Respondent Activities

After making the determination to submit information to EPA under TSCA sections 4 or 8, VCCEP, or to otherwise submit TSCA-related chemical information to EPA, the submission of which is covered under separate ICRs, the respondent will decide whether or not to use the TSCA Cover Sheet for that submission. The use of the TSCA Cover Sheet for submissions under TSCA is completely voluntary. However, ACC and SOCMA explicitly solicit and encourage their members to use it for all such submissions.

Once the respondent has decided to use the Voluntary TSCA Cover Sheet, the respondent simply completes the form by transferring or summarizing the information that the respondent has already assembled as part of its submission. In many cases the use of this cover sheet takes the place of a cover or transmittal letter to EPA that the respondent might otherwise routinely prepare, containing much of the same information as is found on the cover sheet. Respondents are not obliged to prepare or develop additional data or information in order to use the cover sheet.

The completed cover sheet is then included as part of the submission to EPA. Please note, this ICR does not include any burden or costs associated with the actual transmittal of the information to EPA, or that associated with maintaining a copy of the submission in their records. The existing ICRs that address the underlying submission already include the burden and costs

associated with copying and mailing the submission to the Agency, and with keeping a copy of the submission in their records.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

OPPT staff use the information found on the cover sheet to identify the type of submission or the type of information contained in a submission, to route a submission to other EPA staff for review, evaluation or action, to file or retrieve a submission, and to conduct other routine information-management tasks associated with the receipt and processing of a submission. Since the information appears in a consistent, standardized format, OPPT staff members are able to complete these tasks in a highly efficient manner.

OPPT staff members review and take action upon the submissions themselves in accordance with procedures that are described in greater detail in the information collection requests associated with the specific reporting requirements previously referenced.

5(b) Collection Methodology and Management

Since this is a standardized cover sheet attached to a more detailed and lengthy submission, the collection methodology and management of this cover sheet necessarily follow the collection methodology and management associated with the specific information collections for which this cover sheet will be utilized. These collections are described in greater detail in the information collection requests associated with the specific reporting requirements previously referenced.

In general EPA enters the information found on the cover sheet into Agency information management systems so as to identify, locate and track the submission as the submission moves through appropriate Agency reviews and actions. EPA anticipates that the use of the cover sheet by respondents will result in cost and time savings, greater data accuracy and quality, and more timely public availability of data.

5(c) Small Entity Flexibility

The use of this voluntary cover sheet does not directly affect any existing small entity flexibility applicable to respondents to the reporting requirements under TSCA sections 4, 8(d), 8(e) or VCCEP. Any small entity flexibility associated with these collections is described in greater detail in the information collection requests associated with these reporting requirements. (In general, reporting requirements under TSCA sections 8(d) and 8(e) apply to all respondents, regardless of size. Small entities required to report under TSCA section 4 have certain options available to them in responding to those requirements. Under VCCEP, no company is required to

participate.) For those respondents, whether large or small, that respond to these information collections, the use of this cover sheet should provide a more efficient means of submitting required information. However, since the use of this cover sheet is strictly voluntary (although the underlying reporting requirement may be mandatory), a respondent may choose not to use the form at all.

5(d) Collection Schedule

Since this is a standardized cover sheet attached to a more detailed and lengthy submission, the collection schedule associated with this cover sheet necessarily follows the collection schedules associated with the specific information collections for which this cover sheet will be utilized. In general, responses to reporting requirements under TSCA sections 4, 8(d), 8(e) and VCCEP are “on-occasion” responses for which a strict collection schedule does not apply.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

In using this Voluntary TSCA Cover Sheet effort, respondents are not required to generate any new data; rather they simply transfer information from the underlying submission to the cover sheet. Although the information included in the cover sheet is often included in a cover letter, the Agency has not attempted to estimate any burden adjustment to the underlying ICRs to reflect the use of the Voluntary TSCA Cover Sheet, rather than a cover letter to the Agency. This ICR only estimates the burden and costs associated with the use of the Voluntary TSCA Cover Sheet. As such, it estimates the burden and costs related to the respondent’s review of the instructions, completion of the form, and the identification of the appropriate TSCATS study index terms.

6(a) Estimating Respondent Burden

Based on the industry estimates provided during the ACC-initiated pilot of the cover sheet in the spring of 1996, which ranged from 15 minutes to an hour, EPA estimates that the average burden associated with the use of the cover sheet is approximately 30 minutes (0.5 hour).

Using recent estimates of the yearly average number of potential submissions expected under the other ICRs for submissions related to TSCA sections 4, 8(d), 8(e) and VCCEP, and assuming that respondents used the Voluntary TSCA Cover Sheet for every submission, Table 1 illustrates the total potential burden related to this ICR. This assumption effectively results in an overstatement of the total burden associated with the use of the Voluntary TSCA Cover Sheet since not all respondents will choose to use the cover sheet. However, there are no reliable data available to suggest a lesser level of use of the form that EPA could use to calculate the burden associated with its use. The burden identified below should be considered the maximum upward bound for the total burden rather than a precise estimate of the burden based on the actual real-life use of the form.

Table 1 – Total Potential Burden					
Submission Type	Total Average Annual Submissions	Burden Hours and Cost per Submission Burden Costs ¹		Total Burden Hours and Cost	
TSCA Sec. 4 ²	1,425	0.5	\$24.86	712.5	\$35,426
TSCA Sec. 8(d) ³	36	0.5	\$24.86	18.0	\$895
TSCA Sec. 8(e) - initial ⁴	345	0.5	\$24.86	172.5	\$8,577
TSCA Sec. 8(e) - follow-up ⁴	108	0.5	\$24.86	54.0	\$2,685
VCCEP ⁴	209	0.5	\$24.86	104.5	\$5,196
Total Potential Burden	2,123	0.5	\$24.86	1,061.5	\$52,779

Since the Voluntary TSCA Cover Sheet is expected to be used in lieu of the letter that has been used in the past to transmit submission to the Agency, this burden should not be considered additive to the existing burden estimates provided in the underlying ICRs. Accounting for this separately in this ICR may also result in the double counting of this particular burden. However, the Agency wishes to continue the voluntary use of this cover sheet and will account for its burden separately until the form is more widely used.

6(b) Estimating Respondent Cost

Based on information provided by ACC, a technical level employee is expected to complete the Voluntary TSCA Cover Sheet. For purposes of estimating the cost associated with completing this form, EPA used the most current average industry labor costs for technical employees of \$49.72 per hour (Source: Labor rates are unpublished December 2004 data from BLS for all manufacturing industries, the most recent available. The estimates include fringe benefits and 17% overhead). As shown in Table 1, the total potential cost associated with

¹ This is based on an estimated labor cost of \$49.72/hour, as discussed in section 6(b).

² Section 4 Test Rules and Consent Orders, including HPV Challenge Program Submissions; OMB No. 2070-0033; EPA ICR No. 1139.06; February 2005.

³ TSCA Section 8(d) Health and Safety Data Reporting Rule; OMB No. 2070-0004; EPA ICR No. 0575.09; April 2005.

⁴ Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e); OMB No. 2070-0046; EPA ICR No. 0794.10; September 2005.

⁵ Data Submissions for the Voluntary Children’s Chemical Evaluation Program (VCCEP); OMB No. 2070-0165; EPA ICR No. 2055.02; December 2005.

completing the cover form is \$52,779.

6(c) Estimating Agency Burden and Cost

Industry use of the cover sheet does not increase Agency burden and cost over that currently associated with these information collections. It is anticipated, in fact, that the Agency's costs for data processing, system support and storage and distribution may decrease. Currently EPA staff must extract cover sheet information from the submission itself and any accompanying cover letter; this task will be eased by EPA staff being able to obtain necessary information directly from the standardized form.

Current Agency burden and costs are:

Section 4: 5,911 hours / \$327,883

(Source: Section 4 Test Rules and Consent Orders; OMB No. 2070-0033; EPA ICR No. 1139.07; June 2005)

Section 8(d): 5,720 hours / \$233,908

(Source: TSCA Section 8(d) Health and Safety Data Reporting Rule; OMB No. 2070-0004; EPA ICR No. 0575.09; February 2003)

Section 8(e): \$50,685

(Source: Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e); OMB No. 2070-0046; EPA ICR No. 0794.10; June 2003)

VCCEP: 1,100 hours / \$575,242

(Source: Data Submissions for the Voluntary Children's Chemical Evaluation Program (VCCEP); OMB No. 2070-0165; EPA ICR No. 2055.01; September 2003)

In addition, it should be noted that the time and costs for making publicly available TSCA data and information in TSCATS is estimated to be reduced by approximately 25-33% for studies/submissions utilizing the voluntary cover sheet.

6(d) Bottom Line Burden Hours and Costs

(i) Respondent Tally

Each use of the cover sheet is estimated to result in a burden of 0.5 hours, at a cost of \$24.86. The Agency estimates a total of 2,123 submissions each year, so the total potential burden associated with this ICR is estimated to be 1,061.5 hours, at an estimated cost of \$52,779.

(ii) Agency Tally

Industry use of the cover sheet does not increase Agency burden and cost over that currently associated with the underlying information collections with which the cover sheet is used, which are covered by other ICRs.

6(e) Reasons for Change in Burden

There is a decrease of 8,074.5 hours (from 9,136 hours to 1,061.5 hours) in the total estimated respondent burden compared with that identified in the information collection most recently approved by OMB. This decrease reflects a decrease in the estimated number of submissions under TSCA sections 4, 8(d) and 8(e), offset by the estimated number of submissions under VCCEP, for which the Voluntary TSCA Cover Sheet could be used, in particular a substantial decrease in the estimated number of TSCA section 4 submissions. (As discussed in the TSCA section 4 ICR identified elsewhere in this document, this decrease results from a reduction in the estimated number of section 4 test rules and Enforceable Consent Agreements EPA expects to issue, as well as a reduction in the estimated testing remaining for the HPV Challenge Program. EPA also now estimates the VCCEP submissions in a separate ICR.) Since the use of the Voluntary TSCA Cover Sheet is a direct reflection of the number of submissions received under TSCA sections 4, 8(d), 8(e) and VCCEP, any change in the estimated numbers of submissions under those requirements will result in a parallel change in the burden hours associated with this information collection. The potential number of annual submissions may change from year to year, but the Agency believes that the estimated number of submissions used in this ICR is reasonable. In addition, EPA now uses more accurate BLS data for labor rates, resulting in lowered respondent costs. This decrease represents an adjustment.

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0156, is estimated to average 0.5 hours per response. According to the Paperwork Reduction Act, "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. For this collection it includes the time needed to review instructions; train personnel to be able to respond to the collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above and on the form. In addition, the OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use

of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2006-0499, which is available for public viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1544 and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. An electronic version of the public docket is available through the Federal Docket Management System (FDMS) at www.regulations.gov. Use FDMS to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OPPT-2006-0499 and OMB control number 2070-0156 in any correspondence.