

Supporting Statement for a Request for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

This document quantifies burden issues associated with the proposed rule, which is a companion rule to the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive Rule”). This supporting statement for a new ICR captures the incremental burdens due to the proposed rule.

1(a) Title of the Information Collection(s)

TITLE: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

EPA ICR No.: 2594.01 OMB Control No.: 2070-NEW

Docket ID No.: EPA-HQ-OPPT-2018-0320

Reference ICR: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications (EPA ICR No. 2565.03; OMB Control No. 2070-0201)

1(b) Short Characterization/Abstract

The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, required EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, EPA finalized a rule, the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive Rule”) requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016. This reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the prioritization of chemicals for risk evaluation. The reporting period for manufacturers (includes importers) ended on February 7, 2018, and the reporting period for processors ended on October 5, 2018. 82 FR 37520 (8/11/17) <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0070> Included in the Active-Inactive Rule were provisions for the submission of confidential business information (CBI). Submitters were required to substantiate all CBI claims made in that collection, except for chemical substance identity—which they had an option to voluntarily substantiate.

This regulatory action, the Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (RIN 2070-AK21), is a companion rule to the Active-Inactive Rule. TSCA section 8(b)(4)(C) requires that “(n)ot later than 1 year after the date on which the Administrator compiles the initial list of active substances, the Administrator

shall promulgate a rule that establishes a plan to review all CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the list.” The statute at 8(b)(4)(D) prescribes the requirements of the plan. TSCA section 8(b)(4)(E) provides the timeframe for the reviews of the specific chemical identities claimed as confidential, extension possibilities and process, and requirements for providing updates on the Agency’s progress.

The data elements covered under the proposed rule are chemical substance identities claimed as CBI in the Active-Inactive Rule collection. In many instances the chemical substance identities were voluntarily substantiated through the Active-Inactive Rule collection.

This ICR covers the burden for those who submitted a NOA Form A, but did not voluntarily substantiated CBI claims for chemical substance identity in the Active-Inactive Rule submission who are required to submit substantiation under the proposed rule.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, required EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016. This reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the prioritization of chemicals for risk evaluation. The reporting period for manufacturers (includes importers) ended on February 7, 2018, and the reporting period for processors ended on October 5, 2018. 82 FR 37520 (8/11/17)

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0070>

As noted above, this regulatory action, is a companion rule to the Active-Inactive Rule. TSCA section 8(b)(4)(C) requires that “(n)ot later than 1 year after the date on which the Administrator compiles the initial list of active substances, the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list.” The statute at 8(b)(4)(D) prescribes the requirements of the plan. TSCA section 8(b)(4)(E) provides the timeframe for the reviews of the specific chemical identities claimed as confidential, extension possibilities and process, and requirements for providing updates on the Agency’s progress.

This ICR covers the burden for those who have not voluntarily substantiated CBI claims for chemical substance identity in the Active-Inactive Rule Collection who are required to submit substantiation under the proposed rule.

2(b) Practical Utility/Users of the Data

The collection of information is mandated by TSCA section 8(b)(4)(C) and (D). The primary users of the data will be Federal staff who will use the information to inform the mandated confidentiality review process. This in turn will facilitate an updating of the TSCA Inventory, culling from the confidential portion of the active list those CBI listed chemicals that do not meet the criteria.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

The collection of the information is mandated by TSCA section 8(b)(4)(C) and (D). The information sought is necessary to address this requirement. While information could have been provided voluntarily pursuant the Active-Inactive Rule, persons who were required to substantiate claims, and did not do so through the voluntary collection, will need to comply with this collection.

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

The proposed rulemaking serves as the public notice for this ICR. Interested parties should submit comments referencing Docket ID No. EPA-HQ-OPPT-2016-0426 to the address listed at the end of this document. Responses will be taken into account in developing the final rulemaking.

3(c) Consultations

There have been no additional consultations to those noted in the reference ICR.

This collection does not exceed any of the Paperwork Reduction Act (PRA) guidelines at 5 CFR 1320.6.

3(d) General Guidelines

This collection does not exceed any of the Paperwork Reduction Act (PRA) guidelines at 5 CFR 1320.6, with the exceptions listed below.

The record retention period of this collection is five years, as specified in 40 CFR 711.25, exceeding the PRA maximum of three years. EPA is not proposing changes to the record retention period.

3(e) Confidentiality

No changes from reference ICR.

The required information may be considered by the submitter to be a trade secret, proprietary, or confidential business information (CBI). However, TSCA mandates that EPA require the submission of such information because it is essential for maintaining the individual chemical substance listings on the TSCA Inventory. Because unique, individual chemical substances are listed on the Inventory, the Agency requires specific chemical identity information for each listing to properly maintain on the TSCA Inventory. Additionally, the Agency is required by TSCA section 8(b) to routinely publish non-confidential data on each chemical substance on the TSCA Inventory. Congress included this provision to provide the public with information on chemical substances in U.S. commerce.

The Agency's policies allow public involvement while preserving confidentiality. TSCA section 14(a) prohibits, except in limited circumstances, the disclosure of trade secret information. Under 40 CFR part 2, when the specific chemical identity data are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in Federal Register notices and the publications of the TSCA Inventory. Persons will be reporting chemical identity information in NOAs based on a list of TSCA Inventory chemical substances posted in EPA's Substance Registry System. This list does not contain confidential chemical identity information. In reporting a non-CBI substance, persons will select a substance listed with a Chemical Abstracts Service Registry Number (CASRN) and a Chemical Abstracts (CA) Index name. In reporting a confidential substance, persons will select a substance listed with a generic chemical name and an EPA-assigned accession number. Although no confidential chemical identity information will be included in NOAs, persons are required to reassert claims to maintain the confidentiality of chemical substances as listed on the confidential portion of the TSCA Inventory.

The 2016 amendments to TSCA include new provisions that impact procedures for how confidential business information claims can be made and the Agency's obligations to review and make determinations concerning the validity of the claims. Persons submitting NOAs that claim reported information CBI must follow the general requirements of TSCA section 14 for making such claims, as modified by the specific provisions under to TSCA section 8(b). TSCA section 14(c) requires that submitters claiming CBI must provide a specific statement attesting to the basis for the CBI claims. TSCA also requires that all submissions containing information claimed as CBI must also include substantiations in support of the CBI claims. With the exception of existing claims on chemical identity (as stated in TSCA section 8(b)), substantiations are required at the time of notification.

Based on its experience, EPA expects that information included in NOAs, specifically submitter information (company name and contact information), will likely be claimed CBI. The Agency has developed an elaborate system to prevent unauthorized disclosure of CBI. This system includes procedures for logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters, procedures for photocopying and transmitting CBI, and a stand-alone CBI local area computer network. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need

the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures have been instituted to restrict access to computerized CBI. These procedures are detailed in the “TSCA CBI Protection Manual,” October 2003. EPA believes these procedures protect confidential business information while providing the public with as much information as possible.

Any information being sent via CDX is transmitted using secure technologies to protect CBI. EPA-provided reporting application, termed e-NOA, encrypts submissions using a Federal Information Processing Standards (FIPS)-compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is downloaded from CDX to the e-NOA software, and the corresponding private key is sent to EPA’s New Chemical System (NCS). The encryption remains while the submission is transmitted via CDX to NCS. The file can be decrypted only with the NCS's private key when it has reached its final destination. The NCS is the only party that possesses the private key, which converts the encrypted text back into readable text.

The same protection will occur for all correspondence going back to the submitter. The NCS and e-NOA software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the e-NOA software.

3(f) Sensitive Questions

No changes from reference ICR.

This collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

No changes from reference ICR. Impacted respondents would include entities that reported a confidential chemical substance in the TSCA Inventory Notification (Active-Inactive) Requirements reporting rule (82 FR 37520, August 11, 2017, codified at 40 CFR Part 710) through a Notice of Activity (NOA) Form A and did not provide an upfront (voluntary) confidentiality substantiation at that time. This action may be of particular interest to entities that are regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 324 and 325, among others).

4(b) Information Requested

(i) Data elements, including recordkeeping requirements

Persons subject to this Request are persons subject to the Active-Inactive Rule who chose not to voluntarily substantiate the claims for confidential chemical substance identity when addressing other requirements of the Rule.

Persons who voluntarily submitted substantiations for chemical substance identities claimed as confidential in that collection are exempt from any requirement under this Rule

Persons who substantiated the claim for specific chemical identity less than five years before the substantiation deadline set forth in this proposed rule are exempt from the substantiation requirements if they identify the submission containing the substantiation by form number, submission type, and date or equivalent identifier.

Persons who claimed chemical substance identity as confidential in the Active-Inactive Rule collection must substantiate the claims by addressing the questions set forth in 40 CFR 710.37.

Under 40 CFR 710, submitters must keep documentation of information in a TSCA section 8(b) notice for five years from the date of submitting the notice.

(ii) Submitter Activities/Information Collections (ICs)

- Rule familiarization.
- Compliance determination.
- CBI substantiation or identify previous substantiation.
- Date and time stamps.

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

5(a) Agency Activities

The Agency develops and maintains the electronic tool used to collect and verify data and routinely conducts other activities related to the processing, analysis and storage of the information collected under this rule. In this ICR, Agency activities related to the changes created by the proposed rule are considered including:

- Submission receipt and tracking
- Data Review (CBI review, recommendations and determinations, including identifying and recovering previously submitted substantiations as authorized under TSCA section 8(b)(4)(D) and referenced above in 4(b)(i))
- Quality Control.

5(b) Information Requested.

Persons subject to this Rule will be required to complete the substantiation portion of the Form A used in the Active-Inactive Reporting. Those persons who wish to rely on the previously submitted substantiations as authorized under TSCA section 8(b)(4)(D) and referenced above in 4(b)(i)), will need to identify the substantiation in this form. There will be no other changes to the reference ICR. Submission of information will rely on the existing e-NOA software and be submitted electronically using CDX.

5(c) Collection Methodology and Management

- All forms must be generated using the e-NOA software and submitted electronically via CDX. The data being transmitted electronically via CDX are encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for efficient data transmittal to Agency data systems. The Agency requires all section 8(b) notices to be submitted electronically via CDX.
- An electronic signature is required for TSCA section 8(b) notices submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process.
- All software users need to perform the “finalization” step in generating a document. During the “finalization” step, the software checks that all legally required information is included, provides warnings where necessary, and saves data in a read-only format acceptable to the Agency. Section 8(b) notices in which data have not undergone the “finalization” step are determined incomplete. This step is necessary to allow for an accurate and efficient transfer of data to EPA data systems. The word, “finalized,” is in the file name and the name ends with “tsca.” The “finalized” file (folder) contains the CBI and non-CBI data in XML format that are non-editable. The CBI and non-CBI attachments are also in this folder in their native format. Attachments must be submitted in one of EPA’s approved formats for the Agency to be able to open the files.
- All information sent via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The software facilitates the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also allows submitters to share a draft notice within their company during the creation of a notice and to save a copy of the final file for future use. A “Profiler,” available in the software, also allows for certain information to be kept on file by the submitter to avoid the burden associated with re-entering the same information into a new form.
- The Agency also benefits from receiving electronic submissions. Data systems are populated electronically, minimizing the potential for human error. Agency personnel are also able to communicate efficiently with submitters electronically. Because companies register with EPA to submit their data electronically to the Agency via CDX, the Agency in turn communicates electronically with submitters

via CDX. The electronic means of communication provides significant time and resource efficiencies for both parties.

- Additionally, to aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA regulatory requirements. When TSCA Hotline staff members are unable to answer questions regarding TSCA section 8(b), the questions are referred to OPPT staff for appropriate resolution.

5(d) Small Business Flexibility

The reporting and recordkeeping requirements associated with TSCA section 8(b) are applicable to all affected entities, regardless of size of business. However, EPA provides specialized assistance to respondents, particularly to small entities. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers and processors of chemical substances. This office has established a TSCA Hotline to assist small businesses complying with TSCA rules. It provides material such as copies of Federal Register notices, advisories, and other information on request.

Moreover, EPA has taken certain steps to minimize for all respondents the reporting burden associated with complying with this collection. For example, the information technology used by EPA includes chemical substances on the TSCA Inventory in EPA Substance Registry System. This list allows submitters to select their reportable chemical substances from the list rather than manually entering each substance. Additionally, submitters are able to report multiple chemical substances in one session; upon completion of a session, each chemical substance will be transmitted in one NOA submission.

Finally, EPA provides the services of TSCA Inventory and other personnel to assist persons with reporting questions and notice preparation prior to submission. TSCA Inventory personnel routinely respond to TSCA section 8(b) inquiries that pertain to the full scope of TSCA section 8(b) regulations.

5(e) Collection Schedule.

Does not apply. Submission of information under this collection is on an as-needed basis, initiated by the submitters.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This analysis presents the burden and cost estimates for affected entities, and covers submission of substantiations for CBI chemID claims from the Active-Inactive rule reporting period from August 12, 2017 through October 5, 2018 for which (voluntary) upfront substantiations were not provided (EPA, 2018).¹ Table 1 provides a list of general activities required for compliance with the proposed rule. Table 1 also provides a cross-walk of the related Information Collection category that corresponds to each activity. The NOA Form A is a company-based multi-chemical submission. For the proposed rule’s burden and cost estimates, information is considered according to the submission unit of analysis and also according to another key unit of analysis: the “chemical-specific amendment” to a NOA Form A. Burden and cost calculations are based EPA’s estimates that substantiations will be received for 2,849 chemical-specific amendments to NOA Form As, submitted by 126 companies. EPA estimates reporting according to two groups of reporters: (1) reporters who cite a previous reference for substantiation claims, with the average company reporting on four chemicals per NOA Form A; and (2) reporters who provide full substantiation, with the average company reporting on 27 chemicals per NOA Form A. For full derivation of universe estimates, see the *Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory* .

Table 1. Cross-Walk between Industry Activities and Related Information Collections (ICs)

Activity	Description	Related IC(s) included in this ICR
Preparation and Submission of Reports	Staff must collect all of the information, required by submissions. This ICR covers amendments to the NOAs submitted during Active-Inactive rule reporting to provide substantiation for claims of confidentiality for chemical substance identity. The information must be gathered, reviewed, and submitted to EPA. This activity involves any research necessary to identify the correct information and the act of completing the submission review.	Prepare and Submit Report, and Maintain Records
Recordkeeping	Respondents must keep records supporting their submissions.	Prepare and Submit Report, and Maintain Records

6(a) Estimating Respondent Burden

This section presents the burden of this information collection activity to respondents in terms of the time required by companies to perform the activities as outlined in Section 3 of this document. The overall unit burden experienced by companies is estimated by combining activity-level unit burdens at the appropriate scale (e.g. per company or per chemical) to produce estimates for unit burden per submission, by company. This section details the activity-level unit burdens grouped by type of activity. For additional details see *Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory* .

The required activities are described below. Table 3 provides the detailed estimates.

¹ The NOA Form A information collection was conducted from August 12, 2017 to February 8, 2018 for manufactures (including importers) and from February 9, 2018– October 5, 2018 for processors.

Rule Familiarization. The burden associated with rule familiarization involves becoming familiar with the full requirements of the rule, which includes reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which reporting requirements will be met. This level of activity applies to those companies that submitted NOAs under the Active-Inactive rule, included a CBI chemID claim, but did not provide upfront substantiation for the claim.

Compliance Determination. The burden associated with compliance determination involves determining whether or not substantiation is required. Since reporters already know whether or not they submitted substantiation for CBI chemID claims as part of the Active-Inactive rule, there is no burden for compliance determination under this rule.

Form Completion/Submission. A chemical-specific NOA amendment includes substantiation for one CBI chemID for a company. Submitters citing a previous reference must include identification for a previous submission by case number/transaction ID (or some other equivalent identifier), submission type, and date of submission.

Submitters providing full substantiation must answer the CBI chemID substantiation questions, and provide certification as follows:

A. APPLICABLE TO ANY CBI CLAIM

(1) Substantiation questions for any confidentiality claim. For any information with a confidentiality claim that you assert is exempt from substantiation pursuant to TSCA section 14(c)(2), answer only the question in paragraph (c)(1)(i) of this section. For all other information with a confidentiality claim, answer the questions in paragraphs (c)(1)(ii) through (vi) of this section. If more than one data element on Form A or Form B is claimed as confidential, you must answer the applicable questions individually for each data element. If the answer to a question applies for all confidentiality claims on the form, indicate this in your substantiation response.

(i) Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

(ii) Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.

(iii) To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Identify the measures or internal controls your business has taken to protect the information claimed as confidential: Non-disclosure agreement required prior to access; access is limited to individuals with a need-to-know; information is physically secured; other internal control measure(s). If yes, explain.

(iv) Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.

(v) Is the claim of confidentiality intended to last less than 10 years? If so, indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

(vi) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If you answered yes, explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

B. APPLICABLE ONLY TO CHEMICAL IDENTITY CBI CLAIMS

(2) *Substantiation for confidentiality claims for chemical identity.* Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

C. CERTIFICATION

Certification statement for claims. An authorized official of a person submitting or substantiating a claim of confidentiality or a request to maintain an existing claim of confidentiality for specific chemical identity must certify that the submission complies with the requirements of this part by signing and dating the following certification statement: “I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.” I further certify that it is true and correct that:

(1) My company has taken reasonable measures to protect the confidentiality of the information;

(2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Recordkeeping. Submitters must keep records supporting their submissions for five years. Recordkeeping requirements for NOAs are necessary for EPA compliance and enforcement purposes.

A summary of activity-level unit burdens is included in Table 2.

Table 2. Activity-Level Unit Burdens

Description	Activity-Level Unit Burden (hours)	Unit of Analysis	Source(s)
Rule familiarization	3.000	Per company	<ul style="list-style-type: none"> • Active-Inactive Rule EA (EPA, 2017) • Agency estimate
Compliance determination	Estimated at zero	Per company	Agency estimate
Nominal Single-Chemical Submission			
Substantiation via Previous Reference --OR--	0.500	Per chemical	Agency estimate
Full CBI Substantiation for Chemical Identity	1.150	Per chemical	Active-Inactive Rule EA (EPA, 2017)
Date and Time Stamps	System-generated	Per submission	N/A
Miscellaneous			
Recordkeeping	0.063	Per company	<ul style="list-style-type: none"> • Active-Inactive Rule EA (EPA, 2017) • Agency estimate

In Table 3, activity-level burdens are combined to produce unit burdens for the average company associated with submissions for the two groups of reporters affected by the proposed rule.

For reporters citing a reference to a previous substantiation, EPA estimates that the average company reports on four chemicals. For reporters submitting full substantiation, EPA estimates that the average company reports on 27 chemicals .

For total industry burden and cost by activity and reporting group, see Table 8 of this document in Section 6(d).

Table 3. Incremental Unit Burden per Average Company, by Reporting Group

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
RULE FAMILIARIZATION	Company	0.000	1.500	1.500	3.000
COMPLIANCE DETERMINATION	Chemical	0.000	0.000	0.000	0.000
FORM COMPLETION					
Substantiation using Previous Reference --OR-- Full Substantiation for Chemical Identity	Chemical	0.000	0.500	0.000	0.500
	Chemical	0.000	0.770	0.380	1.150
Date and Time Stamps	Submission				System-Generated
RECORDKEEPING					
Per Submission	Company	0.063	0.000	0.000	0.063
COMPANY-LEVEL UNIT BURDEN FOR SUBSTANTIATION USING PREVIOUS REFERENCE (4 CHEMICALS) ¹					
Rule Familiarization					3.000
Compliance Determination					0.000
Form Completion					2.000
Average Burden per Company without Recordkeeping					5.000
Recordkeeping					0.063
TOTAL, Company-Level Unit Burden using Previous Reference to Substantiation					5.063
COMPANY-LEVEL UNIT BURDEN FOR FULL SUBSTANTIATION (27 CHEMICALS) ²					
Rule Familiarization					3.000
Compliance Determination					0.000
Form Completion					31.050
Average Burden per Company without Recordkeeping					34.050
Recordkeeping					0.063
TOTAL, Company-Level Unit Burden with Full Submission of Substantiation					34.113
General Note Derivation of unit burden estimates are detailed in Table 3 in EPA .					
Footnotes					
¹ An average company is expected to report four chemicals, as derived from NOA submissions .					
² An average company is expected to report 27 chemicals, as derived from NOA submissions .					

6(b) Estimating Respondent Cost

Estimation of industry unit cost per submission involves combining the activity-level unit burdens identified in Section 6(a) with wage data (for December 2017) from the Bureau of Labor Statistics (BLS) , as converted from raw wage rate and benefit data to loaded wage rates. Table 4 presents the resultant loaded wage rates for managerial, professional/technical, and clerical staff.

Table 4. Industry Wage Rates (2017 Dollars)

Labor Category	Data Series ^a	Date	Wage (a)	Fringe Benefit (b)	Fringes as % Wage (c) = (b)/(a)	Overhead % wage ^b (d)	Fringe + Overhead Factor ^c (e) = (c)+(d)+1	Hourly Loaded Wages (f) = (a) × (e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-17	\$46.59	\$22.16	49%	17%	1.66	\$76.67
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-17	\$45.82	\$24.33	55%	17%	1.72	\$77.94
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-17	\$20.49	\$11.02	52%	17%	1.69	\$34.99

Footnotes
^a Source: *Employer Costs for Employee Compensation Historical Supplementary Tables: December 2006 – June 2018*. All rates are rounded to the nearest cent.
^b An overhead rate of 17% is used based on assumptions in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002).
^c The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

Industry company-level unit costs are presented below in Table 5, in similar fashion to the company-level unit burdens provided in Table 3.

For total industry burden and cost by activity and reporting group, see Table 8 of this document in Section 6(d).

Table 5. Incremental Unit Costs per Average Company, by Reporting Group

Activity	Unit of Analysis	Clerical Cost (2017\$) (a)	Technical Cost (2017\$) (b)	Managerial Cost (2017\$) (c)	Total Cost (2017\$) (d) = (a) + (b) + (c)
RULE FAMILIARIZATION	Company	\$0.00	\$116.91	\$115.01	\$231.92
COMPLIANCE DETERMINATION	Chemical	\$0.00	\$0.00	\$0.00	\$0.00
FORM COMPLETION					
Substantiation via Previous Reference --OR--	Chemical	\$0.00	\$38.97	\$0.00	\$38.97
CBI Substantiation for Chemical Identity	Chemical	\$0.00	\$60.01	\$29.13	\$89.14
Date and Time Stamps	Submission				System-Generated
RECORDKEEPING					
Per Submission	Company	\$2.19	\$0.00	\$0.00	\$2.19
COMPANY-LEVEL UNIT COST FOR SUBSTANTIATION USING PREVIOUS REFERENCE (4 CHEMICALS) ¹					
Rule Familiarization					\$231.92
Compliance Determination					\$0.00
Form Completion					\$155.88
Typical Average Cost per Company without Recordkeeping					\$387.80
<i>Recordkeeping</i>					\$2.19
TOTAL, Company-Level Unit Cost using Previous Reference to Substantiation					\$389.99
AVERAGE UNIT COST FOR FULL SUBSTANTIATION (27 CHEMICALS) ²					
Rule Familiarization					\$231.92
Compliance Determination					\$0.00
Form Completion					\$2,406.78
Average Cost per Company without Recordkeeping					\$2,638.70
<i>Recordkeeping</i>					\$2.19
TOTAL, Company-Level Unit Cost with Full Submission of Substantiation					\$2,640.89
General Notes					
See Table 2 for unit burden estimate information; See Table 4 for Wage Rates. Additionally Agency best professional judgement is employed to finalize results. See details in Table 2. Industry wage rates are provided in Table 4. Derivation of unit cost estimates are detailed in Table 5 in EPA .					
Footnotes					
¹ An average company is expected to report four chemicals, as derived from NOA submissions .					
² An average company is expected to report 27 chemicals, as derived from NOA submissions .					

6(c) Estimating Agency Burden and Cost

The implementation of EPA capacity to receive and process substantiations for CBI chemID claims will involve additional costs during the 90-day reporting period to collect information, and for about five years thereafter to review claims, as well as to update the TSCA Inventory based as

needed. EPA IT systems and related maintenance for facilitating form submission and processing are also required.

Estimates of Agency labor required to complete substantiation review are discussed in Section 4.6 of the *Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory*. Agency burden is combined with wage data in Table 6 to estimate Agency cost, as shown in Table 7.

Table 6. Agency Wage Rate (2017 Dollars)

Labor Category	Data Source for Wage Information ^a	Wage (\$/hour) (a)	Fringe Benefit (b)	Fringes as % wage (c) = (b) / (a)	Overhead as % wage ^b (d)	Fringe + Overhead Factor ^c (e) = (c) + (d) + 1	Loaded Wage (\$/hour) (f) = (a) × (e)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Arlington, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates	\$51.48	Included in 60% overhead	N/A	60%	1.6	\$82.37
Footnotes							
^a Source: Salaries & Wages for the locality of Washington-Baltimore-Arlington (Office of Personnel Management (OPM), 2017). All rates are rounded to the nearest cent.							
^b The 60 percent fringes-and-overhead rate is from <i>Instructions for Preparing ICRs</i> (EPA, 2009).							
^c The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.							

Table 7. Agency Burden and Costs for IT and Substantiation Review

Activity	Number of chemical-specific NOA claims Requiring Review	Burden (Hours)	Labor Cost (2017\$)	Non-Labor Cost (2017\$)	Total Cost (2017\$)
CDX and CISS	N/A	73	\$6,013	\$10,000	\$16,013
Management of NOA Submissions	5,986	1.5 hours x 5,986 claims	\$739,600	\$0	\$739,600
		8,979			
TSCA Inventory Maintenance	N/A	73	\$6,013	\$10,000	\$16,013
TOTAL Annual Ongoing Costs					\$771,626
General Notes					
1. Sources: Estimates used in the Active-Inactive rule ((Williamson, 2016); Agency best professional judgement) and wage rates in Table 6.					
2. All FTE hours are associated with a labor cost based on wage rate for GS-13 Step 5 of \$82.37 per hour and assumes 2,080 working hours per year (see Table 6); 0.5 FTE from Active-Inactive rule is factored down (to 7%) based on the percent of total chemicals in NOA Form As with CBI chemID claims that are reflected in counts for chemical-specific NOA Form A claims (EPA, 2018).					

6(d) **Bottom Line Burden Hours and Costs**

Total industry burden and cost are estimated by combining industry unit burdens from Table 3 and industry unit costs from Table 5 with affected universe counts, as derived in the *Economic*

Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory.

In Table 3, activity burdens are combined to produce unit burdens associated with submissions for the two groups of reporters affected by the proposed rule. For reporters citing a reference to a previous substantiation, EPA estimates that the average company reports on four chemicals. For reporters submitting full substantiation, EPA estimates that the average company reports on 27 chemicals. Similar unit costs are produced in Table 5.

Total burden and total costs are then aggregated for all companies in the affected universe. Total industry burden and cost are presented in Table 8.

Table 8. Overall Incremental Industry Burden and Costs, by Reporting Group

IC: Prepare and Submit Report, and Maintain Records	Unit Burden (Hours per Company)	Unit Costs (2017\$)	Number of Respondents / Responses (Companies)	Total Burden (Hours)	Total Costs (2017\$)
REPORTERS USING REFERENCE TO PREVIOUS SUBSTANTIATION					
Rule Familiarization	3.000	\$231.92	23	69	\$5,334
Compliance Determination	0.000	\$0.00	23	0	\$0
Form Completion (4 Chemicals)	2.000	\$155.88	23	46	\$3,585
Recordkeeping	0.063	\$2.19	23	1	\$50
Subtotal				116	\$8,969
REPORTERS WITH FULL SUBSTANTIATION					
Rule Familiarization	3.000	\$231.92	103	2309	\$23,888
Compliance Determination	0.000	\$0.00	103	0	\$0
Form Completion (27 Chemicals)	31.050	\$2,406.78	103	3,198	\$247,898
Recordkeeping	0.063	\$2.19	103	6	\$226
Subtotal				3,513	\$272,012
ALL REPORTERS					
Total			126	3,629	\$280,981
General Note					
Total industry burden and costs are estimated by combining company-level unit burdens (Table 3) and costs (Table 5) with estimates of the potentially affected universe .					

The following tables display the annual burden and costs borne by respondents and EPA associated with submitting and processing substantiation for claims of confidentiality for chemical substance identity as part of an amended NOA as a result of this information collection for the period of this ICR.

Table 9. Annual Incremental Burden, Proposed Rule

Burden Category	Burden Hours				
	Year 1	Year 2	Year 3	Total ICR Period	Average Annual ICR Period
Industry Burden					
REPORTERS USING REFERENCE TO PREVIOUS SUBSTANTIATION	116	0	0	116	39
REPORTERS WITH FULL SUBSTANTIATION	3,513	0	0	3,513	1,171
Industry Burden, Total	3,629	0	0	3,629	1,210

6(e) Reasons for Change in Burden

This is a new data collection activity resulting from the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires additional responsibilities of EPA in maintaining the TSCA Inventory, and imposes reporting requirements on regulated entities wishing to maintain claims of confidentiality for chemical substance identity. As such, the change being implemented in this ICR period is the addition of new burden and cost for these activities, as presented in Table 9. The total burden to industry for this ICR period is 3,629 hours, all occurring in during a 90-day reporting period after the rule is enacted.

6(f) Burden Statement

The industry burden for this collection of information annually is estimated to average 1.688 hours per average response for referencing a previous substantiation (for an average of four chemicals per company) and 11.371 hours per average response for providing full substantiation (for an average of 27 chemicals per company). An Agency may not conduct or sponsor such a request and a person or facility is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in title 40 of the CDR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument of form, if applicable.

The Agency has established a public docket for the rulemaking that includes this ICR under Docket ID No. EPA-HQ-OPPT-2018-0320 which is available for online viewing at <http://www.regulations.gov>, or in-person viewing at the Pollution Prevention and Toxics Docket in EPA Docket Center (EPA/DC). EPA/DC Public Reading Room is located in the William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Ave., N.W., Washington, DC. EPA/DC 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 EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

You may submit comments regarding 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. Submit your comments, referencing EPA ICR No. 2594.01 and OMB Control No. 2070-NEW, to both (1) EPA online using <http://www.regulations.gov> (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

7. REFERENCES

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