

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

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title: n-Methylpyrrolidone (NMP); Regulation under the Toxic Substances Control Act (TSCA) (Proposed Rule; RIN 2070-AK85)

EPA ICR No.: 2786.01

OMB Control No.: 2070-NEW

Docket ID No.: EPA-HQ-OPPT-2020-0744

Abstract

The Environmental Protection Agency (EPA) proposed a rule under section 6 of the Toxic Substances Control Act (TSCA) to address the unreasonable risk to human health presented by n-methylpyrrolidone (NMP) under its conditions of use. The proposed rule would:

- Prohibit the manufacture (including import), processing, distribution in commerce, and use of NMP for five occupational conditions of use;
- Require container size limits and labeling requirements for the manufacture (including import), processing, and distribution in commerce for seven consumer uses;
- Require prescriptive workplace controls, including concentration limits and personal protective equipment (PPE), for seven occupational conditions of use;
- Require strict workplace controls, including an NMP workplace chemical protection program (WCPP), that would include requirements to prevent direct dermal contact with NMP, for all other occupational conditions of use, including the commercial use of paints and coatings and paint, coating, and adhesive removers containing high concentrations of NMP in uses essential to the missions of the Department of Defense (DOD) and National Aeronautics and Space Administration (NASA);
- Require a concentration limit on NMP for the import, processing, and distribution in commerce of one consumer use;
- Establish recordkeeping and downstream notification requirements.

The information collection activities contained in the proposed rule are:

- Downstream notification requirements through Safety Data Sheets (SDS); and

- WCPP-related information generation, recordkeeping, and notification requirements, including:
 - Development of exposure control plans;
 - Related recordkeeping;
 - Development of documentation for a PPE program and related recordkeeping;
 - Development of documentation for a respiratory protection program and related recordkeeping;
 - Development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans and PPE program implementation documentation, and respirator program documentation; and
 - Development of documentation demonstrating eligibility for the WCPP if relevant for use of high concentrations of NMP and self-certification-related information generation, recordkeeping, and notification requirements, including:
 - Self-certification statement documenting the facility has implemented and complies with the WCPP, including:
 - All documentation requirements associated with the WCPP
 - Name, title, email address, and phone number of person signing the statement
 - Notification and distribution of self-certification statement to sellers or distributors from whom the facility is purchasing NMP.

The proposed rule would require that records be retained for 5 years from the date of generation.

Summary Annual Burden and Costs

Activity	Number of Respondents	Average Annual Responses Per Respondent	Average Annual Burden Per Respondent	Average Annual Total Labor Burden	Average Annual Total Labor Costs	Average Annual Total Labor Burden	Average Annual Total Costs
Agency Burden	-	-	-	-	-	-	-
Rule Familiarization ¹	63,749	0.33	0.70	\$71	-	44,438	\$3,315,307
Downstream Notification (SDS) ¹	81	0.33	0.67	\$63	-	54	\$5,116
Glove testing ¹	34,782	0.33	-	-	\$5,925	-	\$206,079,628
Glove testing - Recordkeeping ¹	34,782	0.33	0.08	\$8	-	2,898	\$275,213
Exposure control plan ¹	7,017	0.33	13.33	\$951	-	93,566	\$6,673,151
Regular inspections	7,017	4	4.00	\$285	-	28,070	\$2,001,945
WCPP Recordkeeping	7,017	1	2.92	\$208	-	20,507	\$1,462,588
All Activities	63,749	-	2.97			189,534	\$219,812,949

Note: columns may not sum due to rounding

¹This activity is assumed to be a one-time initial cost. Thus, the three-year average annual costs in this table will be higher than the annualized costs for these activities as presented in Chapter 7 of the Economic Analysis because the latter are annualized over a longer 20-year analytical timeframe.

Legal authority: The Toxic Substances Control Act (TSCA), 15 U.S.C. § 2605(a).

Respondents/affected entities: Persons that manufacture, process, use, distribute in commerce, or dispose of NMP or products containing NMP.

Respondent's obligation to respond: Mandatory. 15 U.S.C. 2605(a) and 40 CFR part 751.

Confidentiality of responses: Not applicable.

Total Burden and Costs

Estimated total number of potential respondents: 63,749.

Frequency of response: On occasion

Estimated total annual burden: 189,534 hours. Burden is defined at 5 CFR 1320.3(b).

Estimated total annual costs: \$219,812,949 includes \$206,079,628 annualized capital or operation and maintenance costs, including required glove testing and documentation of testing results, as presented under Q13.

Changes in the estimates: Not applicable. This is a request for a new OMB Control Number.

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. TSCA Section 6(a) authorizes EPA to:

- (1) Prohibit or restrict manufacture, processing, or distribution in commerce,
- (2) Prohibit or restrict the manufacture, processing, or distribution in commerce of the chemical substance above a specified concentration,
- (3) Require minimum warnings or instructions with respect to use, distribution, or disposal,
- (4) Require manufacturers or processors to make and retain records,
- (5) Prohibit or regulate any manner of commercial use,
- (6) Prohibit or regulate any manner of disposal, and/or
- (7) Require manufacturers or processors to give notice of the unreasonable risk of injury, and to recall products if required.

EPA proposed to:

- 1) Prohibit the manufacture (including import), processing, distribution in commerce, and use of NMP for five occupational conditions of use.
- 2) Require container size limits and labeling requirements for the manufacture (including import), processing, and distribution in commerce for seven consumer uses.
- 3) Require prescriptive workplace controls, including concentration limits and PPE requirements, for seven occupational conditions of use.
- 4) Require strict workplace controls, including an NMP WCPP, that would include requirements to prevent direct dermal contact with NMP, for all other occupational conditions of use including the commercial use of paints and coatings and paint, coating, and adhesive removers containing high concentrations of NMP in uses essential to the missions of the Department of Defense (DOD) and National Aeronautics and Space Administration (NASA);
- 5) Require a concentration limit on NMP for the import, processing, and distribution in commerce of one consumer use;
- 6) Establish recordkeeping and downstream notification requirements.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.

The information collection activities covered by this ICR are necessary to mitigate the unreasonable risk from NMP under the conditions of use.

Downstream Notification. Without the downstream notification requirement, there is a greater likelihood that non-prohibited uses of NMP could be diverted to prohibited uses, or that users would buy or use materials that they do not realize are subject to the restrictions in the final rule. This would result in continuation of the risks that EPA has determined to be unreasonable. Downstream notification would be carried out by updates to the relevant SDS and is necessary for effective implementation and enforcement of the rule as it provides a record of notification on use restrictions throughout the supply chain. Downstream notification would be required for manufacturers, processors, and distributors in commerce of NMP, who would provide notice to companies downstream upon shipment of NMP about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies.

WCPP-related information generation, recordkeeping, and notification requirements. EPA has authority under section 6 of TSCA to require recordkeeping related to the regulatory requirements imposed by EPA. This is especially important where, as here, such records are needed for effective implementation and enforcement of the TSCA section 6 rule to eliminate unreasonable risk. Information collection activities for such records required by a WCPP would provide potentially exposed persons in a workplace with clear and necessary information and would provide EPA with a necessary evidential mechanism for effective enforcement. The regulated entities would develop, compile, and retain records that are necessary for implementing the exposure controls of the WCPP, provide workplace notification to potentially exposed persons, and serve as a reference for EPA or authorized entities. These records include WCPP records, general business records such as invoices or bills-of-lading, exposure monitoring records, exposure control plan records, and records related to exemptions. These records demonstrate that regulated entities are in compliance with the requirements in this rule. Compliance with the rule is required to mitigate the unreasonable risk to human health identified by EPA for NMP. These recordkeeping requirements are also necessary to permit the EPA to conduct its enforcement activities and to ensure compliance within the regulated community.

EPA. This information collection activity will ensure the availability of information to EPA upon inspection. The proposed rule would not establish requirements that result in the submission of information to EPA.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The proposed rule would not establish reporting requirements, so no information would be

submitted to EPA. Therefore, there is no need for any technology facilitation under the proposed rule related to the information collection activities. The recordkeeping requirement does not specify a particular technology or method of retaining the required information.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

EPA's collection pursuant to the TSCA section 6(a) regulations for this rulemaking do not duplicate any other information collection activity. EPA is requiring information to ensure the elimination of unreasonable risk that was identified in December 2022 following the December 2020 NMP Risk Evaluation. Because there are no existing statutes that have established precedence in the regulation of NMP with criteria similar to the authorities granted under TSCA, the information collection activity is not a duplication. While this collection activity required by EPA is similar to those of other Federal agencies such as OSHA, there is no chemical-specific PEL or OSHA standard for NMP. These are unprecedented and EPA-specific collection activity guidelines for the regulation of NMP under TSCA and therefore has no duplicative requirements.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

At the recommendation of the Small Business Review Panel, EPA is requesting comment on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements. In addition, EPA is requesting comment on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing NMP; implementation of new engineering or administrative controls; changes to labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management challenges. EPA also requests comment on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements, (see #1 above) to the extent necessary so that the chemical substance or mixture no longer presents such risk. EPA has authority under section 6 of TSCA to require recordkeeping related to the regulatory requirements imposed by EPA. This is important where, as here, such records and reports are necessary for effective implementation and enforcement of the section 6 rule.

Due to the nature of the triggering events that initiate information collection activities under the proposed rule (i.e., the exposure of potentially exposed persons, consumers, and bystanders to

unreasonable risk) a shorter timeframe for record retention is not feasible. The information collection activities covered by this ICR are necessary in order to ensure the effective mitigation of unreasonable risk from NMP. Due to EPA's determination that NMP presents an unreasonable health risk, the proposed risk management rule involves information collection activities that are intended to ensure that NMP does not present unreasonable risks, thus any associated burdens to the regulated entities are necessary for the implementation of a TSCA section 6(a) rulemaking. Should the records in this information collection activity not be maintained nor be made accessible in accordance with the proposed rulemaking, effective implementation of the WCPP would be compromised and EPA would not be able to determine if unreasonable risk is mitigated, leading to the possibility of injury or death and will hinder investigative efforts by the regulated entity and by EPA.

- 7. Explain any special circumstances that require the collection to be conducted in a manner:**
- a) requiring respondents to report information to the agency more often than quarterly;**
 - b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
 - c) requiring respondents to submit more than an original and two copies of any document;**
 - d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
 - e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
 - f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
 - g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
 - h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

This proposed rulemaking and information collection activity will require that regulated entities retain records for a duration of 5 years from the date of its inception such as downstream notification. EPA has tailored this timeframe to coincide with the statute of limitations for civil penalty enforcement (28 U.S.C. 2842). EPA expects that 5-year retention of records for a WCPP is necessary for effective implementation and enforcement of this rulemaking.

- 8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.**

Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The proposed rulemaking serves as the public notice for this ICR. Interested parties should submit comments referencing Docket ID No. EPA-HQ-OPPT-2020-0744 to the address listed at the end of this document. EPA will address any comments received from OMB or the public concerning the information collection activities contained in the rule, and the agency's response, when developing the final rule.

EPA has engaged in significant consultation and outreach with the regulated community and other affected entities during development of the proposed rulemaking. Key opportunities to obtain public input on the availability and type of data that should be required, frequency of monitoring, and methods for carrying out downstream notification include the outreach meetings with small entity representatives held as part of the Small Business Advocacy Review (SBAR) Panel, where submitted comments indicated an ability to achieve a WCPP for certain uses; presentations to small business stakeholders in May 2023; and discussions with representatives from different industries, non-governmental organizations, technical experts and users of NMP. A list of external meetings held during the development of this proposed rule is in the docket. The purpose of these discussions was to create awareness and educate stakeholders and regulated entities on the provisions for risk management required under section 6(a) of TSCA; obtain input from manufacturers, processors, distributors, users, academics, advisory councils, and members of the public health community about uses of NMP; identify workplace practices, engineering controls, administrative controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to NMP under the conditions of use; generate potential risk reduction strategies; and understand the type of recordkeeping, notifications, and reporting already ongoing.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This collection does not provide any payment or gift to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

EPA will not be collecting any information. Therefore, confidential information will not be submitted to EPA.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The information collection activities do not include questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under ‘Annual Cost to Federal Government’.**

EPA’s *Economic Analysis of the Proposed Regulation of n-Methylpyrrolidone (NMP)* (U.S. EPA, 2023) provides the detailed methodology for estimating the number of respondents.

The paperwork burden and associated costs include the activity types listed below. Note that not all entities would incur burden or costs from these activities because they may already be meeting the requirements as part of their usual business practices.

- Rule familiarization
 - The 63,749 facilities with associated PRA burdens and costs are assumed to incur an average initial cost of \$156 for an average initial 2.09-hour burden (Managerial and Certified Industrial Hygienist labor) associated with rule familiarization.
- Downstream notification
 - Each person who manufactures (including imports), processes, or distributes in commerce NMP or NMP-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the

restrictions on its use. It is assumed that 81 respondents (manufacturers, import, and repackage facilities) accomplish this by modifying the SDS to note the restrictions, and the burden associated with the downstream notification requirements, including the related recordkeeping, is 2 hours (Manufacturing/Managerial labor), with an associated labor cost of \$189.48. Shipment records are assumed to be kept as part of ordinary business practices, and therefore no incremental burden is estimated for this requirement.

- Glove Testing
 - Firms would be required to select dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the tasks to be performed, conditions present, and the duration of use. It is assumed that the 34,782 respondents using dermal PPE will incur a one-time non-labor glove testing cost of \$17,775. It is also assumed that firms would incur a one-time burden of 15 minutes to document test results (Managerial labor).

- WCPP
 - Under the proposed rule primary option, the 7,017 facilities complying with the rule through a WCPP would be required to develop exposure control plans, maintain records, and conduct regular inspections. The estimated costs and burdens are as follows:
 - Each respondent is assumed to spend a one-time burden of 40 hours with an associated labor cost of \$2,853 (certified industrial hygienist labor). Respondents are also estimated to inspect facilities four times per year, spending 4 hours and \$285 annually on inspections (certified industrial hygienist labor).
 - Recordkeeping associated with the PPE program and any dermal exposures are estimated to require 2.92 burden hours and an average of \$208 in associated labor costs annually (certified industrial hygienist labor).

The table below presents the labor rates used to estimate the costs of the labor burdens under the ICR.

Industry Wage Rates (2022\$)

Labor Category	Data Series ¹	Date	Wage (\$/hour)	Fringe Benefit	Total Compensation	Overhead as % of Total Compensation ₂	Overhead	Hourly Loaded Wages
			(a)	(b)	(c) =(b)+(a)	(d)	(e)=(c)*(d)	(f)=(c)+(e)
Manufacturing								
Managerial	BLS ECEC, Private Manufacturing industries, “Mgt, Business, and Financial”	22-Dec	\$54.29	\$24.66	\$78.95	20%	\$15.79	\$94.74
Professional / Technical	BLS ECEC, Private Manufacturing industries, “Professional and related“	22-Dec	\$46.01	\$23.27	\$69.28	20%	\$13.86	\$83.14
Clerical	BLS ECEC, Private Manufacturing industries, “Office and Administrative Support”	22-Dec	\$23.11	\$10.33	\$33.44	20%	\$6.69	\$40.13
Production Worker	BLS ECEC, Private Manufacturing Industries, “Production occupations”	22-Dec	\$21.79	\$11.63	\$33.42	20%	\$6.68	\$40.10
Services								
Managerial	BLS ECEC, Service-providing Industries, Management, professional, and related occupations, “Mgt, Business, and Financial”	22-Dec	\$54.77	\$24.99	\$79.76	20%	\$15.95	\$95.71
Maintenance and Repair Worker	BLS ECEC, Service-providing Industries, Natural resources, construction, and maintenance occupations, “Installation, maintenance, and repair”	22-Dec	\$28.39	\$13.15	\$41.54	20%	\$8.31	\$49.85
Transportation and Public Utilities								
Managerial	BLS ECEC, Trade, Transportation, and Utilities Industries, “Mgt, Business, and Financial”	22-Dec	\$54.12	\$21.82	\$75.94	20%	\$15.19	\$91.13
Maintenance and Repair Worker	BLS ECEC, Trade, Transportation, and Utilities Industries, “Installation,	22-Dec	\$31.08	\$15.29	\$46.37	20%	\$9.27	\$55.64

Industry Wage Rates (2022\$)

Labor Category	Data Series ¹	Date	Wage (\$/hour)	Fringe Benefit	Total Compensation	Overhead as % of Total Compensation ²	Overhead	Hourly Loaded Wages
			(a)	(b)	(c) =(b)+(a)	(d)	(e)=(c)*(d)	(f)=(c)+(e)
	maintenance, and repair"							
Agriculture								
Managerial	BLS ECEC, Goods-producing Industries, "Management, professional, and related occupations"	22-Dec	\$48.82	\$22.42	\$71.24	20%	\$14.25	\$85.49
Farm Worker	BLS ECEC, Goods-producing industries, "Construction, extraction, farming, fishing, and forestry occupations"	22-Dec	\$28.68	\$13.71	\$42.39	20%	\$8.48	\$50.87
Other								
Certified Industrial Hygienist	Wage: BLS OEWS Occupational Health & Safety Specialists (19-5011) Fringes as percent of wage: BLS ECEC, Private Manufacturing industries, "Professional and related occupations" ³	22-May	\$39.47	\$19.96	\$59.43	20%	\$11.89	\$71.32

¹ Source: *Employer Costs for Employee Compensation: December 2022* (BLS 2023b).

² An overhead rate of 20% is used based on assumptions in *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions* (EPA 2020b)

³ BLS 2023c

The table below presents the summary of the average annual burden hours and costs per facility associated with the proposed option. See Chapter 7 of the Economic Analysis for a more detailed description of how the time burden and wage rates were estimated. The burden and cost estimates provided reflect the figures provided in the accompanying ICR for the rule.

Summary of Three Year Average Incremental Burden Hours and Costs for Primary Option

Activity	Number of Respondents	Average Annual Responses per Respondent	Average Annual Burden per Respondent	Average Annual Labor Cost per Respondent	Average Annual Non-Labor Cost per Respondent	Average Annual Total Labor Burden	Average Annual Total Labor Costs	Average Annual Total Non-Labor Costs
Rule Familiarization ¹	63,749	0.33	0.70	\$52	-	44,438	\$3,315,307	-
Downstream Notification (SDS) ¹	81	0.33	0.67	\$63	-	54	\$5,116	-
Glove testing ¹	34,782	0.33	-	-	\$5,925	-	-	\$206,079,628
Glove testing - Recordkeeping ¹	34,782	0.33	0.08	\$8	-	2,898	\$275,213	-
Exposure control plan ¹	7,017	0.33	13.33	\$951	-	93,566	\$6,673,151	-
Regular inspections	7,017	4	4.00	\$285	-	28,070	\$2,001,945	-
WCPP Recordkeeping	7,017	1	2.92	\$208	-	20,507	\$1,462,588	-
All Activities	63,749	-	2.97			189,534	\$13,733,320	\$206,079,628

¹This activity is assumed to be a one-time initial cost. Thus, the three-year average annual costs in this table will be higher than the annualized costs for these activities as presented in Chapter 7 of the Economic Analysis because the latter are annualized over a longer 20-year analytical timeframe.

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- a) The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- b) If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

Firms are required to select dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the tasks to be performed, conditions present, and the duration of use, such as in accordance with ASTM F739-91 *Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact*. It is assumed that the 34,782 respondents using dermal PPE will incur a one-time non-labor glove testing cost of \$17,775. The total annual non-labor costs are estimated to be \$206,079,628. EPA's *Economic Analysis of the Proposed Regulation of n-Methylpyrrolidone (NMP)* (U.S. EPA, 2023) describes these cost estimates in detail.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

There will be no agency collection activities under the proposed rule. There will only be third-party notification and recordkeeping requirements.

15. Explain the reasons for any program changes or adjustments reported in hour or cost burden.

This is a new, rule-related information collection. Therefore, the reported burden reflects a program change.

16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Not applicable.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in “Certification for Paperwork Reduction Act Submissions.”

EPA does not request an exception to the certification of this information collection.

SUPPLEMENTAL INFORMATION

The annual public burden for this collection of information is estimated to average approximately 2.97 hours annually per respondent over the three-year period. 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 and understand instructions; prepare and submit reports (including searching data sources); complete and review the collection of information; transmit the information; and keep records.

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 Number EPA-HQ-OPPT-2020-0744, which is available at <http://www.regulations.gov>. This site can be used 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. When in the system, select “search,” then key in the Docket ID Number identified above.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via <http://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under 30-day Review— Open for Public Comments” or by using the search function.

All comments received by EPA will be included in the docket without change, including any

personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

LIST OF ATTACHMENTS

The docket for this ICR is accessible electronically through [regulations.gov](https://www.regulations.gov) using Docket ID Number: EPA-HQ-OPPT-2020-0744.

Ref.	Title
1.	Proposed Rule

REFERENCES

Economic Analysis

Stakeholder Meeting Index

TSCA section 6 ([15 U.S.C. 2605](#))