

**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: C.I. Pigment Violet 29 (PV29); Regulation under the Toxic Substances Control Act (TSCA)

EPA ICR No.: 7797.01

OMB Control No.: 2070-NEW

Docket ID No.: EPA-HQ-OPPT-2021-0277

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 C.I. Pigment Violet 29 (PV29) under its conditions of use. The proposed rule would:

- Require prescriptive controls for certain occupational conditions of use of PV29; and
- 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 labels,
- Prescriptive controls information generation, recordkeeping, and notification requirements, including:
 - Development of documentation for appropriate respiratory protection and related recordkeeping;
 - Development and notification to potentially exposed persons (employees and others in the workplace) about appropriate respiratory protection and usage and related recordkeeping; and
 - Development and notification to potential exposed persons (employees and other in the workplace) about an equipment and area cleaning plan, and related recordkeeping, including but not limited to implementation records and documentation.

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

Summary of Three-Year Average Incremental Burden Hours and Costs (2023\$)

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 Non-Labor Costs	Average Annual Total Costs
Agency Burden	-	-	-	-	-	-	-
Rule Familiarization	49,670	0.33	0.33	16,557	\$1,619,063	-	\$1,619,063
Downstream Notification	1	0.33	0.67	1	\$62	-	\$62
Labeling	1	0.33	0.54	1	\$50	\$200	\$250
PPE Program	22	1.00	4.67	103	\$7,610	-	\$7,610
Equipment and Area Cleaning Recordkeeping	22	1.00	14.33	315	\$19,600	-	\$19,600
Total	49,670	0.33	0.34	16,977	\$1,646,384	\$200	\$1,646,584

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)) (Ref. 1), 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. 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 proposes to:

- 1) Require the use of prescriptive workplace controls for certain occupational conditions of use of PV29, including (as applicable) APF 50 respirators, and area and equipment cleaning.

2) 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 PV29 under the conditions of use.

Downstream Notification. Without the downstream notification requirement, there is a greater likelihood 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 risk that EPA has determined to be unreasonable. Downstream notification would be carried out by updates to the SDS and labels 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 PV29, who would provide notice to companies downstream upon shipment of PV29 about the restrictions. The information submitted to downstream companies through the SDS and labels would provide knowledge and awareness of the restrictions to these companies.

Prescriptive controls 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 for use of prescriptive controls would provide potentially exposed persons in a workplace with clear and necessary information and would provide EPA with a necessary evidence mechanism for effective enforcement. The regulated entities would develop, compile, and retain records that are necessary for implementing use of prescriptive controls, providing workplace notification to potentially exposed persons, and serve as a reference for EPA or authorized entities. These records include general business records such as area and equipment cleaning related records and respiratory protection related records. These recordkeeping requirements are also necessary to permit the EPA to conduct its enforcement activities to ensure compliance within the regulated community.

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, and unique to, the January 2021 PV29 Risk Evaluation and risk determination revised in September 2022. Because there are no existing statutes that have established precedence in the regulation of PV29 with criteria similar to the authorities granted under TSCA, the information collection activity is not a duplication. Lastly, while this collection activity required by EPA is similar to those of other Federal agencies such as OSHA, OSHA has not established area and equipment cleaning requirements for PV29; in this way, some entities who were not previously required to maintain certain records under the OSHA standard may be subject to recordkeeping requirements in order to demonstrate they have addressed unreasonable risk under TSCA. The requirements of this rulemaking also include regulated entities where OSHA requirements are not applicable (e.g., public sector workers not covered by an OSHA State plan, and self-employed workers). Thus, these are unprecedented and EPA-specific collection activity guidelines for the regulation of PV29 under TSCA and therefore has no duplicative requirements.

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

EPA requests comment regarding the number of small businesses subject to the rule and the potential impacts of the rule on these small businesses. EPA is soliciting comment on whether six months is a reasonable timeframe to implement respiratory protection requirements or if a different timeframe is needed. EPA will consider compliance timeframes that may be substantially longer or shorter than the proposed timeframes for owners or operators for procedural adjustments needed to comply with the proposed requirements outlined Unit IV of the proposed rule and is requesting comment on the feasibility of the proposed compliance timeframes, as well as longer or shorter timeframes. Per the Small Business Advocacy Review (SBAR) Panel's recommendation, EPA is requesting comment on this approach, specifically how to mitigate the exposure to dry powder PV29, by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate inhalation exposure to PV29 to address the unreasonable risk. Per the SBAR Panel's recommendation, EPA requests comment on reasonable compliance timeframes for small businesses, with emphasis on comment about how to provide longer compliance timeframes for transitioning to uses requiring reformulation. Per the SBAR Panel's recommendation, EPA requests comment on a regulatory approach for those conditions of use where the EPA has confidence that exposures to PV29 can be effectively controlled, and what flexibility could be provided to regulated entities to incorporate the hierarchy of controls to reduce exposures so that the unreasonable risk is no longer present. Per the SBAR Panel's recommendation, EPA requests comment on state-of-the-art equipment, engineering and administrative controls, and monitoring for inhalation exposures.

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 PV29. Due to EPA's determination that PV29 presents an unreasonable risk, the proposed risk management rule involves information collection activities that are intended to ensure that PV29 does not present an unreasonable risk, 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 respiratory protection equipment usage, area cleaning, and equipment cleaning would be compromised. EPA would not be able to determine if unreasonable risk is mitigated, leading to the possibility of injury and hinderance of investigative efforts by the regulated entity and by EPA.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

- 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 would require that regulated entities retain records for a duration of five 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 respiratory protection usage, area cleaning, and equipment cleaning 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 by the Agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the Agency 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 three 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-2021-0277 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 in September 2023; presentations to small business stakeholders and the general public in February 2021; and discussions with representatives from different industries, non-governmental organizations, technical experts and

users of PV29. 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, and users about uses of PV29; identify workplace practices, engineering controls, administrative controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to PV29 under the conditions of use; generate potential risk reduction strategies; and understand the type of recordkeeping, notifications, and reporting already ongoing (**Attachment 3**).

9. Explain any decisions to provide payments or gifts 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. 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 the 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 as O&M costs under non-labor costs covered under question 13.**

Respondent Burden Hours and Labor Costs

EPA's *Economic Analysis of the Proposed Regulation of PV29 Under TSCA* (U.S. EPA, 2024) provides the detailed methodology for estimating the number of respondents.

The paperwork burden and associated costs include the activity types listed below.

1. Rule Familiarization

49,670 entities are assumed to have rule familiarization costs. Note that this includes entities that only have a rule familiarization burden associated with determining that they need not take action to comply with any of the rule's requirements (they do not manufacture, process or use regulated PV29). These entities are estimated to have a one-time labor burden of one hour, with a weighted average wage rate of \$97.79 (reflecting a mix of managerial wage rates for the manufacturing sector (\$93.07), the trade, transportation and utilities sector (\$94.70), and service sector (\$99.58).

2. Downstream Notification

One entity is estimated to have downstream notification costs associated with a one-time one-hour labor burden at the manufacturing managerial wage rate of \$93.07.

3. Labeling

The economic analysis includes an estimated a one-time labor cost of \$100 to \$200 for one entity for labeling. For the paperwork reduction act analysis, it is assumed that this reflects a labor burden of 1.61 hours at the manufacturing managerial wage rate of \$93.07 (i.e., a one-time labor cost of \$150). There is also a one-time materials cost of \$600.

4. PPE Program

There are eight respondents with an 8-hour initial labor burden for establishing a PPE program and a 2-hour annually recurring labor burden. The labor cost is estimated using the industrial hygienist wage rate of \$74.12 (Abt Global 2024).

5. Equipment and Area Cleaning Recordkeeping

There are 22 respondents with an initial managerial labor burden of four hours and a production worker annual labor burden of 15 minutes per week (or 13 hours per year). The weighted average wage reflecting a mix of manufacturing managerial and production worker labor is \$62.16.

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

Fully Loaded Hourly Labor Rates for Relevant Occupations (2023\$)

Industry	Use Categories	Occupation	Total Compensation ^a	Overhead ^b	Loaded hourly rate ^c
Manufacturing	PV29 manufacturing and intermediate processing PV29 importing Processing into automotive paints and coatings Processing into plastics and rubber products Automotive painting (new vehicles)	Management, business, and financial	\$77.56	\$15.51	\$93.07
		Installation, maintenance, and repair	\$49.17	\$9.83	\$59.00
		Production	\$35.15	\$7.03	\$42.18
		Certified Industrial Hygienist	\$61.76	\$12.35	\$74.12
Trade, transportation, and utilities	Recycling Disposal	Management, business, and financial	\$78.92	\$15.78	\$94.70
		Production, transportation, and material moving	\$36.60	\$7.32	\$43.92
Service providing	Automotive refinishing	Management, business, and financial	\$82.98	\$16.60	\$99.58
		Production	\$29.88	\$5.98	\$35.86
a. Source: Bureau of Labor Statistics 2024b b. Total compensation times assumed overhead rate of 20%. c. Sum of total compensation and overhead					

The table below presents the summary of the average annual burden hours and costs per facility over the first three years, as well as the three-year total burden hours and costs associated with the primary option. See Chapter 4 of the Economic Analysis for a more detailed description of how the time burden and wage rates were estimated.

Summary of Three Year Average Incremental Burden Hours and Costs for Primary Option (2023\$)

Activity	No. of Respondents	Avg Annual Responses Per Respondent	Avg Annual Burden Per Respondent	Avg Annual Total Labor Burden	Avg Annual Total Labor Costs	Avg Annual Total Non-Labor Costs	Avg Annual Total Costs
Agency Burden	-	-	-	-	-	-	-
Rule Familiarization	49,670	0.33	0.33	16,557	\$1,619,063	-	\$1,619,063
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PPE Program	22	1.00	4.67	103	\$7,610	-	\$7,610
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Total	49,670	0.33	0.34	16,976	\$1,646,384	\$200	\$1,646,584

13. Provide an estimate for the total annual cost burden to respondents or record keepers 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 consider 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 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.

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.

EPA estimates that there is a one-time cost to engrave and change labeling plates to design new labels under the proposed rule. This non-labor cost is presented in the following table.

Table 4-1: Paperwork Non-Labor Cost Associated with Labeling

Number of Respondents	One-Time Cost Per Respondent for a Labeling Plate Change	One-Time Cost Per Respondent for a Labeling Plate Change	Average Annual Total Cost
1	\$600	\$200	\$200

14. Provide estimates of annualized costs 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.

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 the burden or capital/O&M cost estimates.

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

16. For collections of information whose results will be published, outline 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 that display would be inappropriate.

Not applicable.

18. Explain each exception to the topics of 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

PRA Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-NEW). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR Part(s) 751. 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 public reporting and recordkeeping burden for this collection of information is estimated to be 0.33 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Information Engagement Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence.

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-2021-0277, which is available at <https://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.

List of Attachments

The attachments listed below can be found in the docket for this ICR. The docket for this ICR is accessible electronically through regulations.gov using Docket ID Number: EPA-HQ-OPPT-2021-0277.

- | | Title |
|----|---------------------------|
| 1. | Proposed Rule |
| 2. | Economic Analysis |
| 3. | Stakeholder Meeting Index |

References

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