

## **Environmental Justice Consultation Fact Sheet:**

### **Proposed Rulemaking Under TSCA Section 6(a) for C.I. Pigment Violet 29 (PV29)**

#### ***Background Information for this Consultation***

EPA is developing proposed regulations under section 6(a) of the Toxic Substances Control Act (TSCA) for C.I. Pigment Violet 29 (PV29) that EPA determined presents unreasonable risk. EPA made this determination in the final risk evaluation for PV29, completed in January 2021. EPA is initiating this action so that those conditions of use no longer present an unreasonable risk.

EPA is seeking input from communities during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation. Input from all stakeholders is critical to the risk management process. EPA is committed to developing risk management actions for chemicals in a way that is transparent and includes proactive and meaningful outreach with the public and other stakeholders.

While outreach and stakeholder engagement on risk management activities for this chemical will continue to move forward, EPA is actively reviewing the final risk evaluation to ensure it uses the best available science and protects human health and the environment, in accordance with the Executive Orders and other direction provided by the Biden-Harris Administration. The Agency will keep stakeholders updated as decisions are made, and next steps are determined.

#### ***C.I. Pigment Violet 29 and EPA's Risk Evaluation***

PV29 is used mainly as an intermediate to create or adjust color of other perylene pigments, incorporated into paints and coatings used primarily in the automobile industry, incorporated into plastic and rubber products used primarily in automobiles and industrial carpeting, used in merchant ink for commercial printing, and used in consumer watercolors and artistic color.

For the conditions of use found to present an unreasonable risk to health, EPA's determination is based on unreasonable risks to workers and occupational non-users when domestically manufacturing or importing the chemical, processing as a reactant or intermediate, incorporation into a formulation, recycling, various industrial and commercial uses, and disposal.

EPA found that there was unreasonable risk of alveolar hyperplasia (increased number of cells in the lungs where oxygen transfer occurs) inflammatory (swelling) and morphological changes (body cell structure changes) in the lower respiratory tract (lower portion of the lungs) from chronic (long-term) inhalation (breathing in) exposures.

The conditions of use that contribute to the unreasonable risks include domestic manufacturing and import; processing: incorporation into formulation, mixture, or reaction products in paints, coatings, plastic and rubber products; processing: use as an intermediate in the creation or adjustment of color of other perylene pigments; recycling; several industrial and commercial uses including in paints for automobiles (e.g., original equipment manufacturing and refinishing), coatings and basecoats; use in merchant ink for commercial printing; and disposal.

The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to evaluate the manufacture (including import), processing, distribution in commerce, use, and disposal of existing chemical substances and identify

unreasonable risks to health or the environment. Public comments on and external scientific peer review of the draft risk evaluation<sup>1</sup> informed the development of the final risk evaluation. The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2018-0604, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0725, on [www.regulations.gov](http://www.regulations.gov). More information about the final risk evaluation is at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-ci-pigment-violet-29>.

### ***Unreasonable Risks***

EPA’s unreasonable risk for PV29 is based on unreasonable risk of injury to the health of workers and occupational non-users during occupational exposures. EPA’s unreasonable risk determination is due to alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract from chronic inhalation exposures to PV29.

EPA determined PV29 presents an unreasonable risk of injury to human health based on the following conditions of use.

### **Conditions of Use of PV29 that Present an Unreasonable Risk**

<p><b>Manufacturing that Presents an Unreasonable Risk</b></p> <ul style="list-style-type: none"> <li>• Manufacturing (domestic manufacturing)</li> <li>• Manufacturing (import)</li> </ul>
<p><b>Processing that Presents an Unreasonable Risk</b></p> <ul style="list-style-type: none"> <li>• Incorporation into formulation, mixture or reaction products in paints and coatings</li> <li>• Incorporation into formulation, mixture or reaction products in plastic and rubber products</li> <li>• Intermediate in the creation or adjustment of color of other perylene pigments</li> <li>• Recycling</li> </ul>
<p><b>Industrial and Commercial Uses<sup>2</sup> that Present an Unreasonable Risk</b></p> <ul style="list-style-type: none"> <li>• Paints and coatings – Automobile (OEM and refinishing)</li> <li>• Paints and coatings – Coatings and basecoats</li> <li>• Merchant ink for commercial printing – Merchant ink</li> </ul>
<p><b>Disposal that Present an Unreasonable Risk</b></p>

<sup>1</sup> In 2016, the Office of Pollution Prevention and Toxics (OPPT) identified and selected PV29 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. EPA published the scope of the risk evaluation document in June 2017, the PV29 problem formulation document in June 2018, the PV29 draft risk evaluation in December 2018, and the PV29 revised draft risk evaluation in October 2020. EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of PV29 on June 18-21, 2019 and a letter peer review for the revised draft risk evaluation of PV29 in December 2020.

<sup>2</sup> Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this analysis, the Agency interprets the authority over “any manner or method of commercial use” under TSCA section 6(a)(5) to reach both.

- Disposal

### ***Risk Mitigation Approaches Under Section 6***

Under TSCA section 6(a), 15 U.S.C. § 2605(a), “If the Administrator determines ... that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.”

The table below summarizes regulatory options available under TSCA section 6(a).

The proposed regulation under development would address the unreasonable risk presented by the chemical. EPA is currently in the early stages of the rulemaking process and is interested in receiving information during this consultation to inform the development of regulatory options.

#### **Options under TSCA Section 6(a)**

<b>TSCA Section</b>	<b>Option</b>
<b>6(a)(1)</b>	A requirement <b>(A)</b> prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or <b>(B)</b> limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
<b>6(a)(2)</b>	A requirement <b>(A)</b> prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for <b>(i)</b> a particular use or <b>(ii)</b> a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or <b>(B)</b> limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for <b>(i)</b> a particular use or <b>(ii)</b> a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
<b>6(a)(3)</b>	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.
<b>6(a)(4)</b>	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.
<b>6(a)(5)</b>	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.
<b>6(a)(6)</b>	<b>(A)</b> A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes. <sup>3</sup>

<sup>3</sup> A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

TSCA Section	Option
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture <b>(A)</b> to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, <b>(B)</b> to give public notice of such risk of injury, and <b>(C)</b> to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

### ***Potential Environmental Justice Impacts***

EPA recognizes that decisions concerning TSCA section 6(a) regulations have consequences for stakeholders concerned about environmental justice issues. Environmental justice communities may be affected to the extent that individuals in these communities engage in the processing, industrial uses, commercial uses and disposal of PV29 that EPA determined present an unreasonable risk.

In addition to general comments, EPA requests input on any disproportionate public health or economic impacts that the unreasonable risks presented by PV29 may have in the context of environmental justice issues.

### ***Opportunity for Participation in Environmental Justice Consultation***

E.O. 12898 aims to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities. During this consultation process, EPA invites members of the public and national, local and non-governmental organizations, communities, and other interested stakeholders to participate in this process by attending the consultation sessions and providing written comments. After the conclusion of the Environmental Justice consultation process, all stakeholders are encouraged to also participate in the public comment process.

### ***Additional Outreach***

There are several opportunities for public and stakeholder engagement throughout the risk management process. This includes required consultations with certain groups, public meetings/webinars, one-on-one meetings with stakeholders, and public comment periods.

EPA is carrying out engagement opportunities in compliance with several executive orders. Some consultations will be open to the public, and in the interest of promoting transparency and encouraging participation, the dates and point of contacts for those consultation meetings will be listed on <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>.

Also, in support of EPA's commitment to implementing TSCA in an open and transparent manner, the Agency is organizing webinars on current risk management activities, including rulemaking such as this one. The purposes of these stakeholder engagement events are to educate stakeholders on various proposals, announcements, or policy decisions, as well as to provide a forum for the public to provide feedback or input during the risk management process.

EPA also holds meetings with stakeholders to educate them about TSCA implementation, listen to feedback, and obtain information that will benefit EPA's work. Finally, as part of the rulemaking process, EPA will solicit and obtain comments on proposed rules and other documents. To do this, the Agency will open public comment periods. These public comment periods relevant to TSCA implementation are announced by the Agency through press releases/listservs and by publication in the Federal Register.

### ***Additional Information***

For more information on this consultation or the rulemaking under TSCA section 6 for PV29 contact: Amanda Hauff, Office of Chemical Safety and Pollution Prevention's National Environmental Justice Program Manager, [hauff.amanda@epa.gov](mailto:hauff.amanda@epa.gov), 202-566-0603 or Todd Coleman, Office of Pollution Prevention and Toxics, [coleman.todd@epa.gov](mailto:coleman.todd@epa.gov), 202-564-1208.

Risk management and upcoming outreach for PV29: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-ci-pigment-violet-29>

PV29 Final Risk Evaluation: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-ci-pigment-violet-29>

US EPA Nontechnical Summary of the Risk Evaluation for PV29:  
[https://www.epa.gov/sites/production/files/2021-01/documents/pv29\\_non-technical\\_summary.pdf](https://www.epa.gov/sites/production/files/2021-01/documents/pv29_non-technical_summary.pdf)