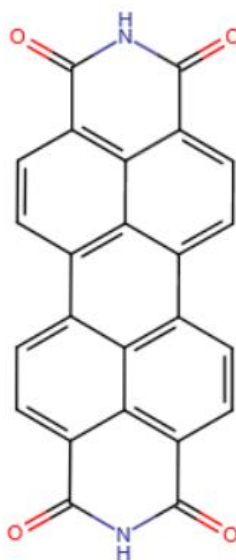




**Non-Technical Summary of the Risk Evaluation for  
C.I. Pigment Violet 29  
(Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-  
1,3,8,10(2H,9H)-tetrone)**

**CASRN: 81-33-4**



*August 2022*

## **BACKGROUND**

- The TSCA risk evaluation for C.I. Pigment Violet 29 (PV29) was issued in January 2021.
- Uses for PV29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic color.
- The total annual production volume reported under the Chemical Data Reporting (CDR) rule for the 2015 period (per the 2016 CDR reporting cycle) indicates slightly above 600,000 pounds of PV29 were manufactured (including imported) in the United States.

## **ACTION**

- EPA is releasing a final revision to the risk determination on PV29 with an order withdrawing the TSCA section 6(i)(1) order previously included in the January 2021 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in March 2022 (87 FR 12690). EPA has determined that PV29 presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2021 risk evaluation and a 2022 final revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, which requires EPA to prioritize and evaluate the safety of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA must regulate the substance to address the unreasonable risk.
- The 2021 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2018-0604 and EPA-HQ-OPPT-2016-0725 on [www.regulations.gov](http://www.regulations.gov).
- PV29 was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.
- Public comments and external scientific peer review informed the development of the PV29 final risk evaluation. EPA published the PV29 final revised unreasonable risk determination in August 2022, the PV29 draft revised unreasonable risk determination in March 2022, the PV29 risk evaluation in January 2021, the PV29 revised draft risk evaluation in October 2020, the PV29 draft risk evaluation in November 2018, the PV29 problem formulation document in June 2018, and the scope document in June 2017.

## **KEY POINTS**

- Risk conclusions from human health were based on the most robust acute and chronic non-cancer endpoints. Alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract for chronic inhalation exposures are the primary effects from PV29 exposure.
- In the revised unreasonable risk determination for PV29, EPA is making an unreasonable risk determination for PV29 as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate for PV29 because there are benchmark exceedances for substantial number of conditions of use for human health, and the severity of the health effects associated with PV29 exposures.

- After evaluating 14 conditions of use, EPA determined that PV29 presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers and occupational non-users (ONUs).
- In addition, EPA is revising the assumption that workers always or properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE did not alter the conditions of use that drive the unreasonable risk.
- Overall, 10 conditions of use of the 14 evaluated drive the PV29 whole chemical unreasonable risk determination due to risks identified for human health. These COUs include domestic manufacturing and import; processing: incorporation into formulation, mixture, or reaction products in paints and coatings, and in plastic and rubber products; processing: use as an intermediate in the creation or adjustment of color of other perylene pigments; recycling; industrial and commercial uses in paints for automobiles (e.g., original equipment manufacturing and refinishing), in coatings and basecoats, and in merchant ink for commercial printing; and disposal.
- The conditions of use that do not drive EPA's unreasonable risk determination for PV29 include distribution in commerce; industrial and commercial uses in finished plastic and rubber products for automobile plastics and industrial carpeting; and consumer use in professional quality watercolor and acrylic artist paint. Use of consumer articles and products containing PV29 or where these items were distributed in commerce do not drive the unreasonable risk determination for PV29. EPA did not identify risk of injury to the general population that drives the unreasonable risk determination for PV29.
- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for PV29.
- EPA released the draft risk evaluation for PV29 in November 2018 for a 60-day public comment period. Additionally, 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.
- EPA released a revised draft risk evaluation for PV29 in October 2020 for a 30-day public comment period, which was extended for an additional 20 days. Additionally, a letter peer review was conducted for members of the SACC during the 30-day public comment period. Both reports are in the TSCA SACC docket (EPA-HQ-OPPT-2018-0604) on [www.regulations.gov](http://www.regulations.gov).
- Between the November 2018 draft and the January 2021 risk evaluation, a different model and analogue was used resulting in the benchmark margin of exposure (MOE) changing from 100 to 30. Also, EPA determined that PV29 in finished plastic and rubber products is encapsulated in the plastic matrix and not expected to leach out. These conditions of use were not quantitatively evaluated in the final risk evaluation because exposure to PV29 from these conditions of use was determined to be negligible. Along with the January 2021 risk evaluation, EPA released a document that provides a response to public and peer review comments.
- EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the January 2021 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for PV29 published in March 2022.

## **NEXT STEPS**

- EPA has issued the final risk evaluation (2021 risk evaluation and 2022 revised risk determination) for PV29, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified.

## **SUMMARY OF UNREASONABLE RISK DETERMINATION**

EPA has determined that PV29 presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for PV29 is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing - Domestic Manufacture
- Manufacturing - Import
- Processing: Incorporation into Formulation, Mixture or Reaction Products in Paints and Coatings
- Processing: Incorporation into Formulation, Mixture or Reaction Products in Plastic and Rubber Products
- Processing: Intermediate in the Creation or Adjustment of Color of Other Perylene Pigments
- Processing: Recycling
- Industrial/Commercial Use: Paints and Coatings – Automobile (OEM and Refinishing)
- Industrial/Commercial Use: Paints and Coatings – Coatings and Basecoats
- Industrial/Commercial Use: Merchant Ink for Commercial Printing
- Disposal

The following conditions of use do not drive EPA's unreasonable risk determination for PV29:

- Distribution in commerce;
- Industrial/commercial use in plastic and rubber products – automobile plastics;
- Industrial/commercial use in plastic and rubber products – industrial carpeting; and
- Consumer use in professional quality watercolor and acrylic artist paint.

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use, and does not consider the revised risk determination for PV29 to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that PV29 no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate

upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.