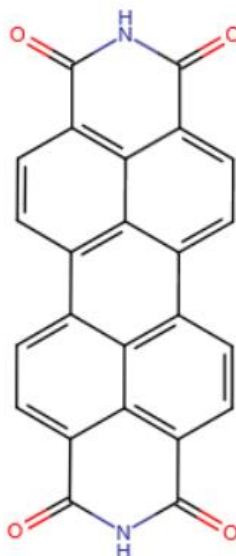




**Non-Technical Summary for
C.I. Pigment Violet 29
(Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-
1,3,8,10(2H,9H)-tetrone)**

CASRN: 81-33-4



January 2021

ACTION

- EPA is releasing the final risk evaluation on C.I. Pigment Violet 29 (PV29). After evaluating 14 conditions of use of PV29, EPA has determined that PV29 presents an unreasonable risk under 10 conditions of use. This includes an unreasonable risk to workers and occupational non-users when domestically manufacturing or importing the chemical, processing the chemical for a variety of uses, and when used in a variety of industrial and commercial conditions of use. PV29 does not pose an unreasonable risk under distribution in commerce or in a variety of industrial and commercial and consumer applications. EPA also determined that PV29 does not present an unreasonable risk to the environment and general population.
- This final risk evaluation is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st 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 final risk evaluation and supplemental materials can be found in docket EPA-HQ-OPPT-2018-0604 on 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 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

- After evaluating 14 conditions of use, EPA determined that PV29 presents an unreasonable risk under 10 conditions of use. This includes an unreasonable risk of injury to health of workers and occupational non-users (ONUs).
- Between the revised draft and the final risk evaluation, industrial/commercial use in automobile paint changed from no unreasonable risk to unreasonable risk and risk to all ONUs changed from no unreasonable risk to unreasonable risk. This change is due to a different model being used and the margin of exposure (MOE) changing from 30 to 100 with the new model. The APF assumed for industrial/commercial use in automobile paint of 25, was no longer protective. Also, two conditions of use were changed from unreasonable risk to no unreasonable risk because PV29 in 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 PV29 from these conditions of use is negligible.
- These unreasonable risks of injury to health include alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract for chronic inhalation exposures.
- The conditions of use with 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 conditions of use that EPA determined do not present an unreasonable risk include distribution in commerce; industrial and commercial uses including in finished plastic and rubber products for automobile plastics and industrial carpeting; and consumer use in professional quality watercolor and acrylic artist paint.
- 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 the 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 on 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. Along with the final risk evaluation, EPA is releasing a document that provides a response to public and peer review comments.

BACKGROUND

- Leading applications 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 aggregate production volume reported under the Chemical Data Reporting rule for the 2016 period indicates over 600,000 pounds of PV29 were manufactured (including imports) in the United States.
- Evaluation and risk management steps for the PV29 final risk evaluation:
 - EPA has issued the final risk evaluation for PV29, meeting the requirements set forth in TSCA section 6. EPA is now initiating the process to address the unreasonable risks identified in the final risk evaluation. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risks identified.

NEXT STEPS

- EPA has issued the final risk evaluation for PV29, meeting the requirements set forth in TSCA section 6(b). EPA is now initiating the process to address the unreasonable risks identified. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risks identified.

SUMMARY OF UNREASONABLE RISK DETERMINATIONS

EPA has determined that the following conditions of use of C.I. Pigment Violet 29 do not present an unreasonable risk of injury to health or the environment. These determinations are considered final agency action and are being issued by order pursuant to TSCA Section 6(i)(1).

Conditions of Use that Do Not Present an Unreasonable Risk
<ul style="list-style-type: none">• Distribution in Commerce• Plastic and rubber products – Automobile plastics

- Plastic and rubber products – Industrial carpeting
- Consumer Use – Consumer watercolor and acrylic paints – Professional quality watercolor and acrylic artist paint

EPA has determined that the following conditions of use of C.I. Pigment Violet 29 present an unreasonable risk of injury. EPA will initiate TSCA Section 6(a) risk management actions on these conditions of use as required under TSCA Section 6(c)(1). Pursuant to TSCA Section 6(i)(2), the unreasonable risk determinations for these conditions of use are not considered final agency action. The details of these determinations are in Section **Error! Reference source not found.**

Manufacturing that Presents an Unreasonable Risk

- Domestic Manufacture
- Import

Processing that Presents an Unreasonable Risk

- Incorporation into formulation, mixture or reaction products in paints and coatings
- Incorporation into formulation, mixture or reaction products in plastic and rubber products
- Intermediate in the creation or adjustment of color of other perylene pigments
- Recycling

Industrial and Commercial Uses that Present an Unreasonable Risk

- Paints and coatings – Automobile (OEM and refinishing)
- Paints and coatings – Coatings and basecoats
- Merchant ink for commercial printing – Merchant ink

Disposal that Presents an Unreasonable Risk

- Disposal