# C.I. Pigment Violet 29 (PV29): Risk Evaluation and Risk Management under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
February 23, 2021

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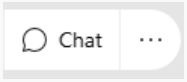
  - Use the chat in the lower right corner of your screen 

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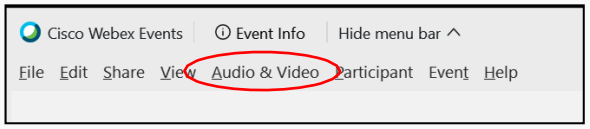


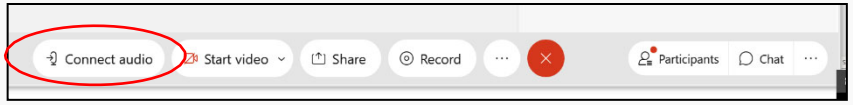

# Agenda

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| **1:00 – 1:05 pm** | Introductory Remarks<br><br>*Tanya Mottley – Division Director, Existing Chemicals Risk Management Division* |
| **1:05 – 1:45 pm** | Background on Risk Evaluation and Unreasonable Risk Findings for C.I. Pigment Violet (PV-29)<br><br>Risk Management Requirements under TSCA; Types of Information to Inform Risk Management; and Principles for Transparency during Risk Management<br><br>*Todd Coleman – Environmental Protection Specialist, Risk Management Branch 3, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics* |
| **1:45 – 3:00 pm** | Public comments |

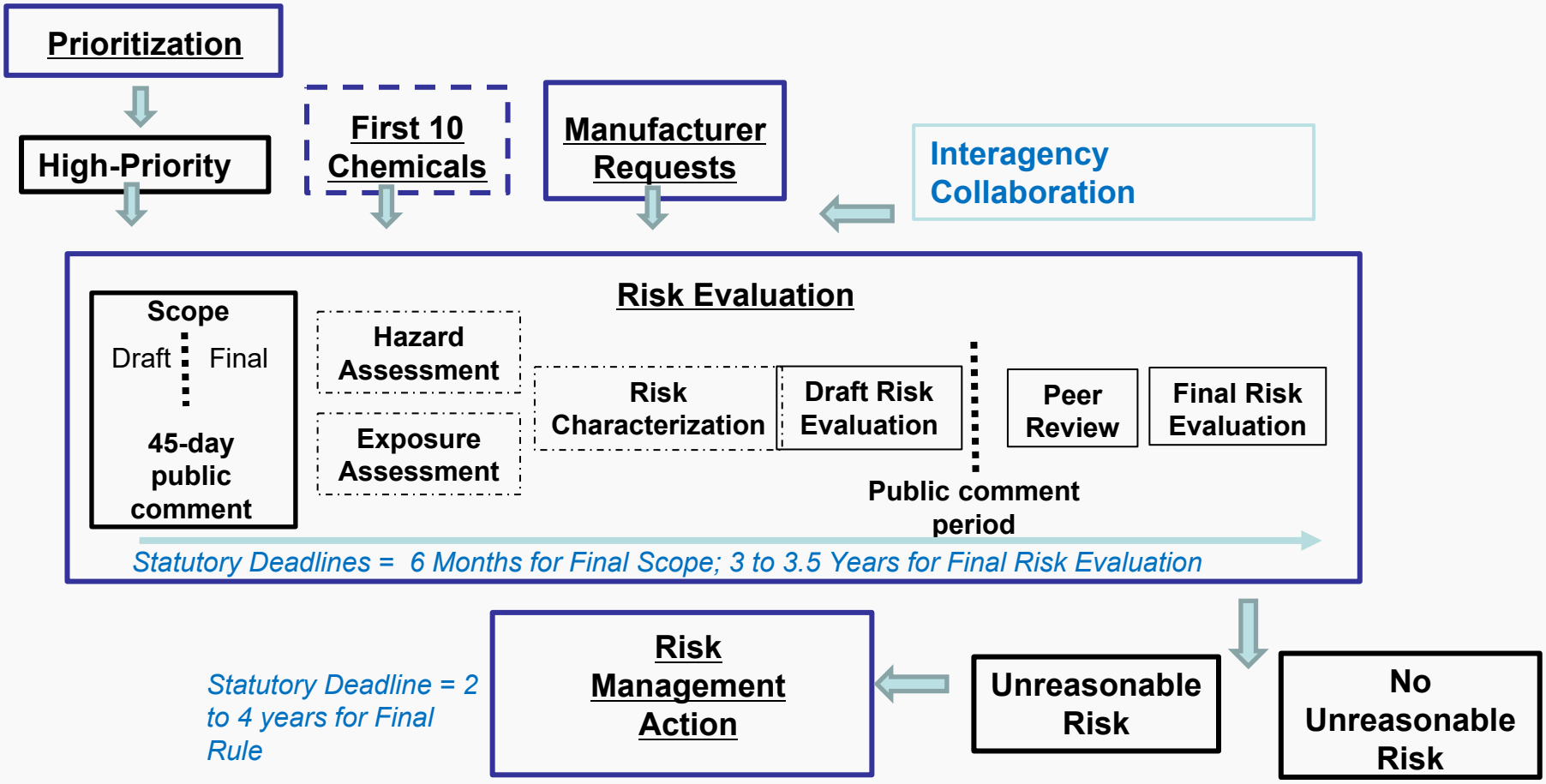
# Outline of Presentation

- Background on Risk Evaluations
- Findings from Risk Evaluation for PV29
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

# Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years

# Risk Evaluation Process and Timeline



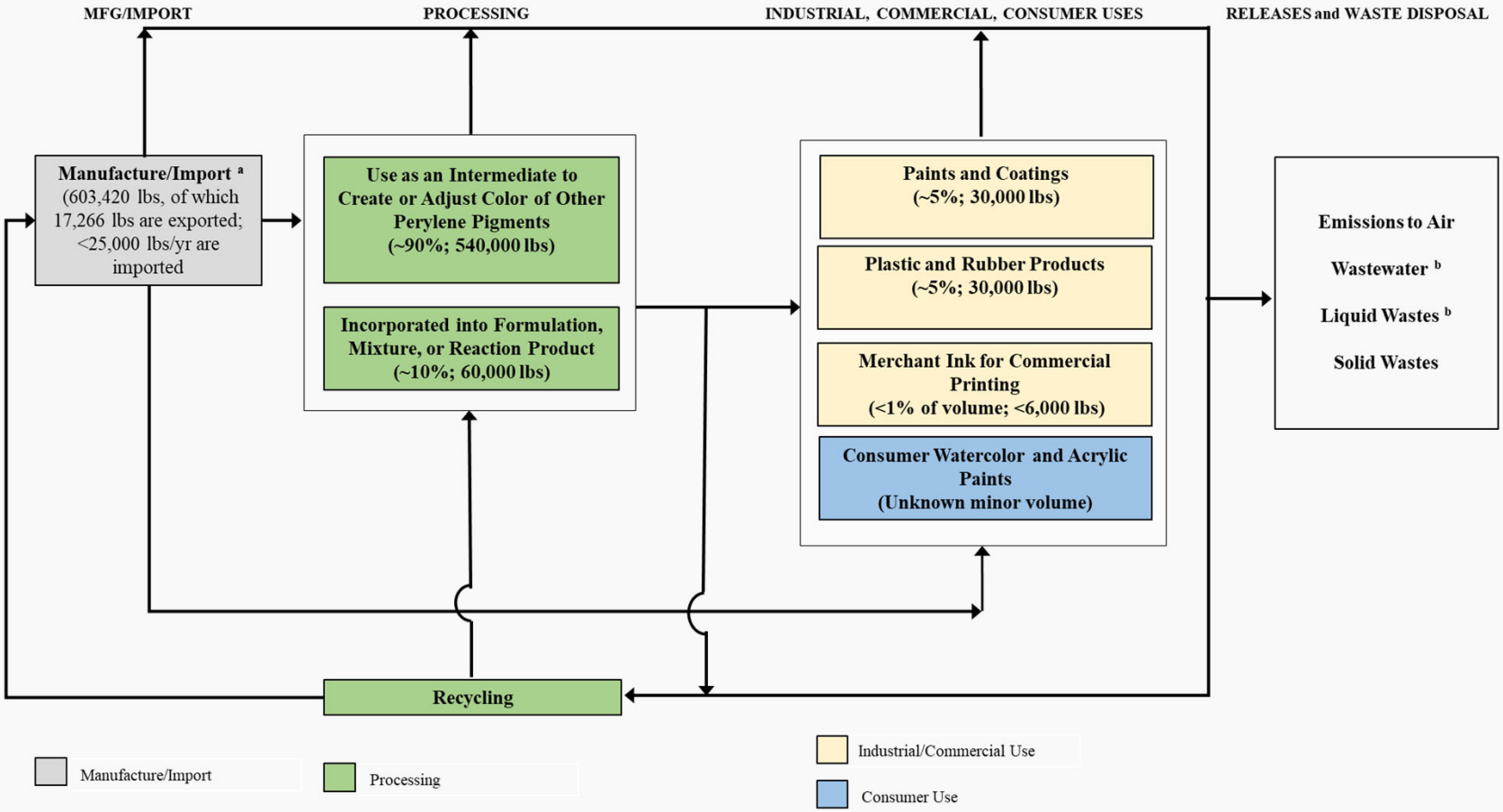
# Overview of Risk Evaluation for PV29

- Final risk evaluation published January 2021
  - 14 conditions of use were evaluated
  - Final risk evaluation follows a series of risk evaluation activities
  - PV29 draft risk evaluation: December 2018; PV29 revised draft risk evaluation October 2020; PV29 problem formulation: June 2018; PV29 scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 49 public comments received on the draft and revised draft risk evaluation (revised draft comment period closed December 19, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft risk evaluation (June 2019) and participated in a letter peer review for the revised draft risk evaluation (December 2020)
- 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

# General Information on PV29

- C.I. Pigment Violet 29 is a Colour Index (C.I.) name used in sales of products containing anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone, CASRN 81-33-4
- The name "C.I. Pigment Violet 29" is assigned, copyrighted and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists
- It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of PV29, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial and consumer), recycling, and disposal
- PV29 has a wide range of uses, including processing into paints, coatings, plastic, and rubber products; use as an intermediate in perylene pigments, and use in inks and consumer acrylic/watercolor paints
- The total aggregate production volume was between 603,420 pounds in 2015

# PV29 Life Cycle Diagram



# Determinations of No Unreasonable Risk

- EPA determined that PV29 does not present an unreasonable risk to the environment under all the conditions of use
- EPA found no unreasonable risk to consumers, bystanders, or the general population
- EPA found no unreasonable risk to industrial and commercial users of plastic and rubber products for automobile plastics and industrial carpeting
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)

# Unreasonable Risk Determinations

- EPA found unreasonable risk to workers and occupational non-users from 10 out of 14 conditions of use
  - These include domestic manufacturing or import of the chemical; incorporation into formulation, mixture or reaction products in paints, coatings, plastic and rubber products; use as an intermediate for other perlyene pigments; use in paintings and coatings in the automobile sector, and merchant ink for commercial printing; recycling; and disposal
  - Risks to workers and occupational non-users can come from long-term inhalation exposure
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
- EPA's risk evaluation evaluated alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract from chronic inhalation exposures
- EPA did not evaluate cancer effects from chronic exposure because PV29 is not likely to be carcinogenic via genotoxic mechanisms.

# Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Processing: incorporation into formulation, mixture or reaction products in paints and coatings
- Processing: incorporation into a 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 and commercial use: paints and coatings – automobile (OEM and refinishing)
- Industrial and commercial use: paints and coatings – coatings and basecoats
- Industrial and commercial use: merchant ink for commercial printing
- Disposal

# Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of PV29:
  - Long term inhalation exposure which would cause alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract
- Personal Protective Equipment (PPE):
  - OSHA has not set a PEL for PV29
  - EPA assumes PPE for respirable dust particulates will be used by manufacturing and processing workers (half face dust mask with APF of 10); furthermore, industrial and commercial worker in painting and coating of automobiles are also expected to wear PPE (air-supplied respirator with APF 25)
  - EPA does not assume the remaining industrial, commercial and consumer use any PPE
  - EPA does not assume ONUs use PPE because they do not handle the chemical

# Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process
- Substantial increase in regulatory activities expected due to unreasonable risk findings across diverse conditions of use

# TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes

# TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

# Examples of Regulatory Options

- Provide a prominent label securely attached to import container or product with specific directions, limitations, and precautions, or that describes the health endpoints
- Prohibit importing, processing, and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls and PPE at occupational sites
- Require importers, processors, and distributors to maintain ordinary business records
- Require importers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)

# Examples of Regulatory Options

- Require monitoring of exposures in occupational settings
- Mandate administrative controls and system requirements at occupational sites
- Mandate a training program at occupational sites and measures to limit access to the chemical
- Require a hazard communication program to educate workers on label directions, warnings, etc.

# TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health;
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives; and
  - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives

# Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs

# Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent

# Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective

# Coordination and Engagement

- In developing risk management approaches EPA:
  - Consults with stakeholders to learn about condition of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
  - Conducts site visits to obtain detailed information on existing practices in chemical manufacturing, processing, and use
  - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions

# Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
  - Other chemicals following their final risk evaluations
- Consultations seeking targeted feedback, with:
  - States and local governments
  - Tribes
  - Small businesses
  - Environmental justice organizations and communities

# Impact of Biden-Harris Executive Order on Protecting Public Health and the Environment

- EPA is actively reviewing final risk evaluations to ensure they use the best available science and protect human health and the environment
- The agency will keep stakeholders updated as decisions are made, and next steps are determined

# Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- PV29: Todd Coleman (Coleman.todd@epa.gov, 202-564-1208)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)

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- Commenters will be unmuted in alphabetical order by their first name.
  - If you have your phone on mute, remember to unmute it before speaking.
- You have five minutes to provide your comment.