

5. UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether 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 by EPA as relevant to this Risk Evaluation, under the conditions of use.

EPA has determined that C.I. Pigment Violet 29 presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in previous sections of this Risk Evaluation, the appendices and supporting documents of C.I. Pigment Violet 29, in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The full list of conditions of use evaluated for C.I. Pigment Violet 29 are listed in Table 1-3 of this Risk Evaluation: https://www.epa.gov/sites/default/files/2021-01/documents/1_final_risk_evaluation_for_c.i._pigment_violet_29.pdf. EPA's unreasonable risk determination for C.I. Pigment Violet 29 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 C.I. Pigment Violet 29:

- 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 C.I. Pigment Violet 29 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 C.I. Pigment Violet 29 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.

5.1 Background

5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for C.I. Pigment Violet 29 in January 2021. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (“Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis”) and other Administration priorities (Refs. 1, 2, 3, and 4), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science and weight of the scientific evidence.

As a result of this review, EPA announced plans to revise specific aspects of certain of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby can help ensure the protection of health and the environment (<https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>). To that end, EPA has reconsidered two key aspects of the risk determinations for C.I. Pigment Violet 29 published in January 2021. First, EPA has determined that the appropriate approach to these determinations is to make an unreasonable risk determination for C.I. Pigment Violet 29 as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA has determined that the risk determination explicitly state that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE will be considered during risk

management. Making unreasonable risk determinations based on the baseline scenario without assuming PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread noncompliance with applicable OSHA standards. EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health."¹, or because OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for C.I. Pigment Violet 29), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

Further discussion of the rationale for the whole chemical approach is found in the Federal Register Notice in the docket accompanying this revised C.I. Pigment Violet 29 unreasonable risk determination and further discussion of the proposed decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in section 5.2.4 below. With respect to the C.I. Pigment Violet 29 risk evaluation, EPA did not amend, nor does a whole chemical approach or change in assumptions regarding PPE require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

With regard to the specific circumstances of C.I. Pigment Violet 29, as further explained below, EPA has determined that a whole chemical approach is appropriate in order to protect health and the environment. The whole chemical approach is appropriate for C.I. Pigment Violet 29 because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (including import), processing, commercial and industrial use, and disposal) for health of workers and occupational non-users and severe health effects (specifically alveolar hyperplasia) associated with C.I. Pigment Violet 29 exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, and a substantial amount of the conditions of use drive the unreasonable risk, it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. In addition, as discussed below in Section 5.2.4, in making this risk determination, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising the assumption for C.I. Pigment Violet 29 that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents.

¹ As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 5).

As explained in the Federal Register Notice, the revisions to the unreasonable risk determination (Section 5 of this Risk Evaluation) follow the issuance of a draft revision to the TSCA C.I. Pigment Violet 29 unreasonable risk determination (87 FR 12690, March 7, 2022) (Ref. 6) and the receipt of public comment. A response to comments document is also being issued with this final revised unreasonable risk determination for C.I. Pigment Violet 29. As noted in the Federal Register Notice, the revisions to the unreasonable risk determination are based on the existing risk characterization section of this Risk Evaluation (Section 4), and do not involve additional technical or scientific analysis. The discussion of the issues in this revision to the risk determination supersedes any conflicting statements in the prior C.I. Pigment Violet 29 risk evaluation (January 2021) and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for C.I. Pigment Violet 29 (PV29) (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone*), January 2021). EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

5.1.2 Background on Unreasonable Risk Determination

In each risk evaluation under TSCA section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA also takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. This approach is in keeping with the Agency's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017).²

This section describes the revised unreasonable risk determination for C.I. Pigment Violet 29, under the conditions of use in the scope of the Risk Evaluation for C.I. Pigment Violet 29. This revised unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer review and public comments.

² This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's C.I. Pigment Violet 29 risk evaluation identified non-cancer adverse effects from acute and chronic inhalation exposures. The risk evaluation did not consider cancer effects because C.I. Pigment Violet 29 was not expected to be carcinogenic via genotoxic mechanisms. The health Risk Estimates for Occupational Inhalation Exposure Scenarios used to evaluate all conditions of use are in Table 4-4 of this Risk Evaluation.

In developing the exposure assessment for C.I. Pigment Violet 29, EPA analyzed reasonably available information to ascertain whether some human receptor groups may have greater exposure or susceptibility than the general population to the hazard posed by C.I. Pigment Violet 29. Exposures of C.I. Pigment Violet 29 would be expected to be higher amongst workers and occupational non-users (ONUs)³ who use C.I. Pigment Violet 29 as part of typical processes.

EPA evaluated exposures to workers and ONUs using reasonably available monitoring and modeling data for inhalation exposures given their greater exposure potential to C.I. Pigment Violet 29. It should be noted that although dermal exposure to workers using C.I. Pigment Violet 29 is possible, this was not quantitatively assessed because C.I. Pigment Violet 29 is expected to be poorly absorbed via oral and dermal exposure routes based on its physical and chemical properties. In addition, it should be noted that EPA used the analogue carbon black to estimate toxicity. EPA used an analogue because no data was reasonably available for C.I. Pigment Violet 29 for inhalation hazard. For each condition of use assessed, risks were estimated based on central tendency and high-end exposure estimates of C.I. Pigment Violet 29 particles in air based on workplace monitoring studies. The particle size distribution data used for risk characterization was based on the reported range of values for the workplace submitted by the manufacturer and importer of C.I. Pigment Violet 29. The description of the data used for human health exposure is in Section 2.3 of this Risk Evaluation. Uncertainties in the analysis are also discussed in Section 4.2 of this Risk Evaluation and considered in the unreasonable risk determination.

EPA also determined that expected exposures of C.I. Pigment Violet 29 in consumer products are negligible as a result of a qualitative consideration of available physical and chemical, environmental fate, and manufacturing release information as referenced in Section 2.3.4 of the Risk Evaluation.

EPA considered reasonably available information and environmental fate properties to characterize general population exposure from contaminated drinking water, surface water, or sediment via the oral and dermal routes. Based on that information, EPA does not expect general population exposure to C.I. Pigment Violet 29 from contaminated drinking water, surface water, or sediment via the oral and dermal routes. EPA evaluated risk to the general population from ambient air and disposal pathways for all conditions of use, including impacts to communities located next to facilities manufacturing or using C.I. Pigment Violet 29. Additional details regarding the general population are in Section 2.3.3 of this Risk Evaluation.

³ ONUs are workers who do not directly handle C.I. Pigment Violet 29 but perform work in an area where C.I. Pigment Violet 29 is present. (Executive Summary of this Risk Evaluation).

5.2.2 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as reproductive/developmental effects, cardiac and lung effects, and kidney and liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent concentration (HEC) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. Section 3.2.3.1 of this Risk Evaluation presents the PODs for non-cancer effects for C.I. Pigment Violet 29 and Section 4.2.3 of this Risk Evaluation presents the MOEs for non-cancer effects.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for chronic non-cancer risks for C.I. Pigment Violet 29 is 30. Additional information regarding the non-cancer hazard identification is in section 3.2.3.1 and the benchmark MOE is in Section 4.2 of this Risk Evaluation.

5.2.3 Cancer Risk Estimates

Usually, EPA determines cancer risk estimates to represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. The absence of a chronic carcinogenicity study for C.I. Pigment Violet 29 resulted in uncertainty regarding the carcinogenicity of C.I. Pigment Violet 29. Nonetheless, the carcinogenic potential of C.I. Pigment Violet 29 was assessed using reasonably available data. This data included two short-term C.I. Pigment Violet 29 genotoxicity studies (an AMES test and HPRT test; see Appendix E for a summary) as well as a consideration of the structural activity relationships (SAR) of the compound, which determined that C.I. Pigment Violet 29 is not likely to be carcinogenic by these mechanisms. The results of the sub-chronic genotoxicity testing indicate that C.I. Pigment Violet 29 does not demonstrate cytotoxicity or induce gene mutations at the HPRT locus. C.I. Pigment Violet 29 is expected to have poor absorption and uptake. SAR consideration of the seven fused rings suggests negligible potential for DNA intercalation due to its large size and inability to be metabolized to reactive ring epoxides because ring fusing impedes possibility for epoxidation. Overall, this information supports that C.I. Pigment Violet 29 is not likely to be carcinogenic via genotoxic mechanisms. Additional information regarding cancer risk assessments can be found in Section 3.2.3.2 of this Risk Evaluation.

Overall, tumor formation from C.I. Pigment Violet 29 is not expected at the rate No Observed Adverse Effect Concentration (NOAEC) HEC value of 0.28 mg/m³, a concentration that does not cause inflammation and hyperplasia precursor events in animal models. Therefore, a threshold RfC model is supported for risk assessment of C.I. Pigment Violet 29 rather than a linear model.

5.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of C.I. Pigment Violet 29 by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on noncancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. Whether EPA makes a determination of unreasonable risk for the chemical substance depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

In Section 3.2.3.1 of the C.I. Pigment Violet 29 risk characterization, alveolar hyperplasia was identified as the most sensitive endpoint for non-cancer adverse effect from acute and chronic inhalation for all conditions of use.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for characterizations is measured data or monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. This Risk Evaluation discusses major assumptions and key uncertainties according to steps of the risk assessment process including: exposure assessment, hazard assessment, and risk characterization. For the human health risk estimation, the assessment of assumptions and key sources of uncertainty focuses on the only route of exposure quantitatively evaluated for C.I. Pigment Violet 29 which is inhalation. Sources of uncertainty related to human health hazard include lack of quantitative monitoring data and lack of product specific information of C.I. Pigment Violet 29 within consumer products. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.2.4 of this Risk Evaluation.

When determining the unreasonable risk for a chemical substance, EPA considers the central tendency and high-end exposure levels in occupational settings, and low, moderate and high intensity of use for consumer uses. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure are generally estimates of average or typical exposure (Section 4.3 of this Risk Evaluation).

As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate

to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and ONUs) who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the C.I. Pigment Violet 29 risk evaluation (e.g., scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health."⁴, or because OSHA has not issued a permissible exposure limit (PEL) (as is the case for

⁴ As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 5).

C.I. Pigment Violet 29), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The revised unreasonable risk determination for C.I. Pigment Violet 29 is based on the peer reviewed risk characterization of the January 2021 Risk Evaluation, which was developed according to TSCA section 26(h) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation. Section 4.2.3 and Table 4-4 of this Risk Evaluation summarize the risk estimates with and without PPE, and informed the revised unreasonable risk determination.

5.3 Unreasonable Risk to the Environment

5.3.1 Environment

EPA typically calculates a Risk Quotient (RQ) to compare environmental concentrations against an effect level. However, RQs were not calculated for C.I. Pigment Violet 29, in consideration of the limited environmental exposures and low hazard to environmental receptors. Reasonably available data indicate that no effects were observed in three environmental hazard studies with toxicity testing with aquatic species up to the limit of solubility of C.I. Pigment Violet 29. Based on the environmental toxicity testing and qualitative assessment of potential environmental exposures, EPA concludes that C.I. Pigment Violet 29 presents a low hazard to the environment. Section 4.1 of this Risk Evaluation provides more detail regarding the environmental risk characterization for C.I. Pigment Violet 29.

5.3.2 Determining Unreasonable Risk of Injury to the Environment

EPA conducted a qualitative assessment of environmental risk of C.I. Pigment Violet 29. The sole U.S. manufacturing facility for C.I. Pigment Violet 29 reported low releases to the environment. This analysis considered reasonably available information including manufacture, use, and release information, and physical and chemical properties. EPA determines that environmental exposures of C.I. Pigment Violet 29 for the conditions of use of C.I. Pigment Violet 29 are expected to be limited as a result of a qualitative consideration of reasonably available physical and chemical, environmental fate, manufacturing and release, and exposure data. Considering the limited nature of the environmental exposures resulting from the conditions of use of C.I. Pigment Violet 29 and the lack of effects observed in the available environmental hazard studies, environmental concentrations of C.I. Pigment Violet are not expected to reach a level where adverse effects to environmental receptors could occur.

EPA further considered the effects on fish, aquatic invertebrates and aquatic plants. Based on concentrations of C.I. Pigment Violet 29 expected to be found in the environment, adverse effects are unlikely for aquatic species. Although hazard data are not available for sediment dwelling and terrestrial species, adverse effects are unlikely because of the low solubility of C.I. Pigment Violet 29 and low exposure to the environment.

Therefore, based on this Risk Evaluation, EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for C.I. Pigment Violet 29.

5.4 Additional Information regarding the Basis for the Unreasonable Risk Determination

Table 5-1 summarizes the basis for the revised determination of unreasonable risk of injury to health presented by C.I. Pigment Violet 29. In this table, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that drives the unreasonable risk determination. As explained in Section 5.2, for the revised unreasonable risk determination, EPA considered the effects on human health of exposure to C.I Pigment Violet 29 at the central tendency and high-end, the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.2.3 of the Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health⁵

Life Cycle Stage	Category ^a	Subcategory ^b	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer ^c	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Manufacture	Domestic manufacture	Domestic manufacture	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Manufacture	Import	Import	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Distribution in commerce ^d	Distribution in commerce	Distribution in commerce	Worker	Inhalation						
			ONU	Inhalation						
Processing	Processing – incorporation into formulation, mixture or reaction products	Paints and coatings	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Processing	Processing – incorporation into formulation, mixture or reaction products	Plastic and rubber products	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		

⁵ The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for C.I. Pigment Violet 29. This table is based on Table 4-4 of this Risk Evaluation.

Processing	Intermediate	Creation or adjustment to other perylene pigments	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Processing	Recycling	Recycling	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Industrial/ commercial use	Paints and coatings	Automobile (e.g., OEM and refinishing)	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
		Coatings and basecoats	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Industrial/ commercial use	Merchant ink for commercial printing	Merchant ink	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		
Industrial/ commercial use ^d	Plastic and rubber products	Automobile plastics	Worker	Inhalation						
			ONU	Inhalation						
Industrial/ commercial use ^d	Plastic and rubber products	Industrial carpeting	Worker	Inhalation						
			ONU	Inhalation						
Consumer Use ^d	Consumer watercolor and acrylic paints	Professional quality watercolor and acrylic artistic paint	Worker	Inhalation						
			ONU	Inhalation						

Disposal	Emissions to air, Wastewater, Solid wastes, and liquid wastes	Air, Industrial pre-treatment, Industrial wastewater treatment, Publicly owned treatment works (POTW), Underground injection, Municipal landfill, Hazardous landfill, Other landfill disposal, Municipal waste incinerator, Hazardous waste incinerator, Off-site waste transfer	Worker	Inhalation			✓	✓		
			ONU	Inhalation			✓	✓		

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

^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of C.I. Pigment Violet 29.

^b These subcategories reflect more specific information regarding the conditions of use of C.I. Pigment Violet 29.

^c EPA determined that C.I. Pigment Violet 29 is not likely to be carcinogenic and did not evaluate cancer effects from chronic exposure.

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

5.5 Order Withdrawing TSCA Section 6(i)(1) Order

The January 2021 risk evaluation for C.I. Pigment Violet 29 included individual risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present unreasonable risk were issued by order under TSCA section 6(i)(1). Section 5.4.1 of the January 2021 Risk Evaluation stated: “This subsection of the final Risk Evaluation... constitutes the order required under TSCA section 6(i)(1), and the ‘no unreasonable risk’ determinations in this subsection are considered to be final agency action effective on the date of issuance of this order.”

In this revised risk determination, EPA has determined that C.I. Pigment Violet 29 as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the January 2021 Risk Evaluation that were premised on a condition of use-specific approach to determining unreasonable risk. This subsection of the revised risk determination also constitutes an order withdrawing the TSCA section 6(i)(1) order in the January 2021 Risk Evaluation. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further explanation and justification for this action can be found in the Federal Register Notice announcing the availability of the draft revised risk determination for C.I. Pigment 29, 87 Fed. Reg. 12690 (March 7, 2022) (Ref. 6), and in the Federal Register Notice accompanying this revised risk determination.

5.6 References

1. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).
2. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, of January 25, 2021).
3. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).
4. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).
5. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. <https://www.osha.gov/annotated-pels>
6. Notice. Colour Index Pigment Violet 29 (PV29); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register* (87 FR 12690, March 7, 2022).