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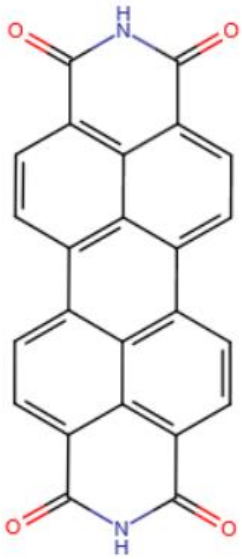
Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone)

CASRN: 81-33-4



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Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0604.

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ABBREVIATIONS

°C	Degrees Celsius
APF	Assigned Protection Factor
atm	Atmosphere(s)
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CFR	Code of Federal Regulations
CHRIP	Chemical Risk Information Platform
C.I.	Colour Index
cm^3	Cubic centimeters
COC	Concentration of Concern
CONC	Concentration
CSCL	Chemical Substances Control Law
CPMA	Color Pigments Manufacturers Association
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
ECOSAR	ECOlogical Structure-Activity Relationship Model
ECOTOX	ECOTOXicology Knowledgebase System
EPA	Environmental Protection Agency
EPI Suite™	Estimation Programs Interface suite of models
EU	European Union
FAP	Food Additive Petition
FDA	Food and Drug Administration
FR	Federal Register
FRC	Functional Residual Capacity
g	Grams
g/mole	Grams per Unit-Molar Mass
GSD	Geometric Standard Deviation
hPa	Hectopascal
ICRP	International Commission on Radiological Protection
K	Thousand
Kg	Kilogram(s)
L	Liter(s)
LADC	Lifetime Average Daily Concentration
LOD	Limit of Detection
lb	Pound
Log K_{oc}	Logarithmic Soil Organic Carbon: Water Partition Coefficient
Log K_{ow}	Logarithmic Octanol: Water Partition Coefficient
m^3	Cubic Meter(s)
mg	Milligram(s)
MAD	Median aerodynamic diameter
MMAD	Mass median aerodynamic diameter
MOE	Margin of Exposure
MSWLF	Municipal Solid Waste Landfills
N/A	Not Applicable

NES	No Effect at Saturation
NGO	Non-Governmental Organization
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OES	Occupational Exposure Scenario
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OU	Occupational User
PBZ	Personal Breathing Zone
PEL	Permissible Exposure Limit
PBPK	Physiologically based Pharmacokinetic
PF	Protection Factor
PM	Particulate Matter
PNOR	Particulates Not Otherwise Regulated
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PSD	Particle Size Distribution
PU	Pulmonary
RCRA	Resource Conservation and Recovery Act
RDDR	Regional Deposited Dose Ratio
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SACC	Science Advisory Committee on Chemicals
SAR	Structure-activity relationship
SCBA	Self-Contained Breathing Apparatus
SDS	Safety Data Sheet
SEG	Sample Exposure Group
TWA	Time-Weighted Average
TSCA	Toxic Substances Control Act
URT	Upper Respiratory Tract
U.S.	United States
U.S.C.	United States Code
µm	Micrometer
V_T	Tidal Volume

EXECUTIVE SUMMARY

This final risk evaluation for C.I. Pigment Violet 29 (CASRN 81-33-4) was performed in accordance with the Frank R. Lautenberg Chemical Safety for the 21st Century Act and is being issued following public comment and peer review. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, in June 2016. Under the amended statute, EPA is required under TSCA Section 6(b) to conduct risk evaluations to determine whether a chemical substance presents unreasonable risk of injury to health or the environment, under the conditions of use, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant to the risk evaluation. Also, as required by TSCA Section (6)(b), EPA established, by rule, a process to conduct these risk evaluations. *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726) (Risk Evaluation Rule). This final risk evaluation is in conformance with TSCA Section 6(b), and the Risk Evaluation Rule, and is to be used to inform risk management decisions. In accordance with TSCA Section 6(b), if EPA finds unreasonable risk from a chemical substance under its conditions of use in any final risk evaluation, the Agency will propose actions to address those risks within the timeframe required by TSCA. However, any proposed or final determination that a chemical substance presents unreasonable risk under TSCA Section 6(b) is not the same as a finding that a chemical substance is "imminently hazardous" under TSCA Section 7. The conclusions, findings, and determinations in this final risk evaluation are for the purpose of identifying whether the chemical substance presents unreasonable risk or no unreasonable risk under the conditions of use, in accordance with TSCA Section 6, and are not intended to represent any findings under TSCA Section 7.

TSCA Section 26(h) and Section 26(i) require EPA, when conducting risk evaluations, to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and to base its decisions on the weight of the scientific evidence.[1] To meet these TSCA Section 26 science standards, EPA used the TSCA systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). The data collection, evaluation, and integration stages of the systematic review process are used to develop the exposure, fate, and hazard assessments for risk evaluations.

C.I. Pigment Violet 29 is currently manufactured, processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. Leading applications for C.I. Pigment Violet 29 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. There were no changes to the conditions of use since the revised draft risk evaluation (EPA-HQ-OPPT-2018-0604-0091). EPA evaluated the following categories of conditions of use: manufacturing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal. The total production volume in 2015 was approximately 603,500 lbs (exclusive of imports) according to 2016 CDR (Section 1.2).

[1] "Weight of the scientific evidence" means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. (40 CFR 702.33)

Approach

EPA used reasonably available information (defined in 40 CFR 702.33 in part as "*information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines . . . for completing such evaluation"*), in a fit-for-purpose approach, to develop a risk evaluation that relies on the best available science and is based on the weight of the scientific evidence. EPA reviewed reasonably available information and evaluated the quality of the methods and reporting of results of the individual studies using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). To satisfy requirements in TSCA Section 26(j)(4) and 40 CFR 702.51(e), EPA has provided a list of studies considered in carrying out the risk evaluation and the results of those studies are summarized in Appendices C, D, E, and F.

In the *Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29* (U.S. EPA, 2018c) ("problem formulation"), EPA identified the conditions of use within the scope of the risk evaluation and presented three conceptual models and an analysis plan for this risk evaluation (U.S. EPA, 2018c). These have been carried into the final risk evaluation. The initial conceptual models were subsequently updated. Most notably, EPA has added to the final risk evaluation a quantitative assessment of the risks to human health from inhalation exposure from manufacturing, processing, industrial/commercial uses, and disposal using monitoring data submitted in response to a request for information and generated in response to a Section 4 Test Order for inhalation monitoring information. Consistent with the analysis plan of the problem formulation, EPA conducted a qualitative assessment of potential environmental, consumer and general population exposures for all conditions of use and exposure pathways other than inhalation exposure from manufacturing, processing, industrial/commercial uses and disposal. This qualitative assessment is based on a consideration of the physical and chemical properties of C.I. Pigment Violet 29, which includes low solubility, low vapor pressure, low bioaccumulation potential, and poor absorption across all routes of exposure; as well as manufacturing information, which indicates that environmental releases from the conditions of use are limited.

The final risk evaluation represents revisions to the published *Revised Draft Risk Evaluation for C.I. Pigment Violet* 29 (EPA-HQ-OPPT-2018-0604-0091) ("revised draft risk evaluation"). The revised draft risk evaluation represents revisions to the published *Draft Risk Evaluation for C.I. Pigment Violet* 29 (EPA-HQ-OPPT-2018-0604-0007) ("draft risk evaluation") that were made over the risk assessment development process. Significant changes to the draft risk evaluation include the addition of data from 24 full study reports and associated systematic review that were originally considered as Confidential Business Information (CBI); two sets of particle size distribution (PSD) data for C.I. Pigment Violet 29; two sets of data for breathing zone monitoring of dust in the Sun Chemical Corporation workplace; and solubility testing in water and octanol.

Some of the added data used in the revised draft risk evaluation was received by EPA under two Section 4(a)(2) TSCA Test Orders including solubility testing of C.I. Pigment Violet 29 in water and octanol, and dust monitoring study of Particulates Not Otherwise Regulated (PNOR) at the Sun Chemical Corporation workplace (the sole U.S. manufacturing site).

The additional data on PSD and dust monitoring was used to update the original methodology to assess the human health risks from inhalation of C.I. Pigment Violet 29. Critical changes included choice of a different surrogate chemical for assessing inhalation hazards based on the new PSD data and the revision of breathing zone dust exposures for occupational users (OUs) and occupational non-users (ONUs) in the Sun Chemical Corporation workplace.

Risk Characterization-Environmental Risks

Reasonably available environmental hazard data indicated that no adverse effects were observed in testing for acute exposure to fish, aquatic invertebrates and aquatic plants up to the limit of solubility of the chemical (0.003 mg/L; (Nicolaou, 2020)). While no chronic exposure testing was available for C.I. Pigment Violet 29, ECOSAR (v.2.0) modeling was used to predict the potential for effects following chronic exposure to C.I. Pigment Violet 29. The results of this modeling effort indicated that effects were predicted to occur at levels that were greater than 10x the limit of solubility. Physical and chemical properties and fate endpoints of C.I. Pigment Violet indicate that the chemical is persistent but is not expected to be bioaccumulative in the environment. In addition, the environmental release information from the sole U.S. manufacturing facility where the majority of the manufactured volume (90%) is consumed on-site as an intermediate to create other chemical substances, indicates that releases to surface water are low (0.8 lbs/day; (U.S. EPA, 2020a), with high capture efficiency of C.I. Pigment Violet 29 in biological wastewater treatment systems expected to further limit potential releases from downstream processors. As a result of the low hazard and low exposures to aquatic species, risk concerns were not identified for aquatic species, both sediment-dwelling and water column-dwelling. Based on the low vapor pressure and volatility of C.I. Pigment Violet 29 (Henry's Law Constant $<1x10^{-10}$ atm-m^3/mol (U.S. EPA, 2017c)), and low solubility, exposures to terrestrial species through air and water are not expected so risk concerns for terrestrial species are not identified.

Risk Characterization-Human Health Risks

For oral and dermal exposure, reasonably available hazard data indicates that C.I. Pigment Violet 29 presents a low hazard based on oral and dermal testing data. The human health testing reported that no adverse effects were observed for oral and dermal exposure and that C.I. Pigment Violet 29 is negative for genotoxicity. Based on the hazard information, EPA concludes that C.I. Pigment Violet 29 presents a low hazard to human health from oral and dermal exposure.

EPA concluded that unreasonable risks to the general population are not identified for C.I. Pigment Violet 29 under the conditions of use. The low solubility and limited releases of C.I. Pigment Violet 29 to surface water is expected to minimize potential exposures and risks of C.I. Pigment Violet 29 to the general population through drinking water. In addition, potential exposures to the general population through air releases are negligible due to the low vapor pressure and volatility of C.I. Pigment Violet 29.

EPA concluded that unreasonable risk to consumers are not identified as a result of the consumer use of C.I. Pigment Violet 29. Potential consumer exposure to C.I. Pigment Violet 29 includes use of consumer watercolor and artistic paint containing C.I. Pigment Violet 29. In the case of consumer products, the potential for chronic exposure to dust is unlikely.

EPA concluded that there are unreasonable risks associated with the manufacture, processing, industrial/commercial use and disposal of C.I. Pigment Violet 29. The risk concerns are associated with inhalation of C.I. Pigment Violet 29. For assessment of risks associated with inhalation exposures to workers for C.I. Pigment Violet 29, EPA used an analogue carbon black to estimate toxicity. EPA used an analog because no data was available for C.I. Pigment Violet 29 for inhalation exposure. For each condition of use, 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.

Chronic exposure to C.I. Pigment Violet 29 is expected to increase lung burden which may result in

kinetic lung overload, a pharmacokinetic phenomenon, which is not due to the overt toxicity of the chemical, but rather the possibility that C.I. Pigment Violet 29 dust overwhelms the lung clearance mechanisms over time. The inhalation toxicity data on the analogue carbon black demonstrated increased lung burden, alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract. However, inhaled particles may have systemic effects.

Section 6(b)(4)(F)(ii) of TSCA requires EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. EPA has defined aggregate exposure as "*the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways*" (40 CFR § 702.33). Exposures to C.I. Pigment Violet 29 were evaluated by inhalation and other routes of exposure (dermal, oral) separately. EPA chose not to employ simple additivity of exposure pathways within a condition of use because the only route of concern is chronic inhalation to C.I. Pigment Violet 29. As the absorption via dermal and oral routes is expected to be low, these exposure pathways are not expected to influence the toxicity in the respiratory tract. In this risk evaluation, EPA determined that aggregating exposure pathways would be inappropriate because the only route of concern is chronic inhalation to C.I. Pigment Violet 29, and the respiratory tract is the site of the adverse effects.

EPA defines sentinel exposure as "*the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures*" (40 CFR § 702.33). In this risk evaluation, EPA considered sentinel exposure the highest exposure given the details of the conditions of use and the potential exposure scenarios. In general, in cases where sentinel exposures result in MOEs greater than the benchmark, EPA did no further analysis because sentinel exposures represent the worst-case scenario. EPA's decisions for unreasonable risk are based on high-end exposure estimates to capture individuals with sentinel exposure.

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 determination does not consider costs or other non-risk factors. In making this 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 PESS, as determined by EPA); 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. The rationale for the unreasonable risk determination is discussed in Section 5. The Agency's risk determinations are supported by substantial evidence, as set forth in detail in this final risk evaluation.

Unreasonable Risk of Injury to the Environment: Given the low solubility of C.I. Pigment Violet 29 in water, limited environmental releases, and lack of environmental hazard, EPA determined that C.I. Pigment Violet 29 does not present an unreasonable risk to sediment-dwelling organisms, aquatic species, and terrestrial species. EPA determined that there is no unreasonable risk of injury to the environment from all conditions of use of C.I. Pigment Violet 29.

Unreasonable Risk of Injury to Health of the General Population: As part of the final risk evaluation for C.I. Pigment Violet 29, EPA found limited exposures to the general population from the conditions of use due to releases to air, water, or land. EPA considered reasonably available information and environmental properties to characterize general population exposure. EPA does not expect general population exposure from environmental exposure. Given limited exposure to C.I. Pigment Violet 29, EPA did not develop quantitative risk estimates for the general population in this risk evaluation, and EPA has determined that exposures from all conditions of use do not present an unreasonable risk to the general population.

Unreasonable Risk of Injury to Health: EPA's determination of unreasonable risk for specific conditions of use of C.I. Pigment Violet 29 listed below are based on health risks to workers, occupational non-users (ONUs), consumers, or bystanders from consumer use. As described below, EPA did not develop quantitative risk estimates for the general population in this risk evaluation. For chronic exposures, EPA evaluated toxicity in the lower respiratory tract. EPA estimated that the acute inhalation and acute and chronic oral and dermal exposure pathways for C.I. Pigment Violet 29 have low hazard; therefore, no quantitative risk estimates were developed. Additionally, EPA determined that C.I. Pigment Violet 29 is not likely to be carcinogenic and did not evaluate cancer effects from chronic exposure.

Unreasonable Risk of Injury to Health of Workers: EPA quantitatively evaluated non-cancer effects from chronic inhalation occupational exposures to determine if there was unreasonable risk to workers' health. Inhalation toxicity data on C.I. Pigment Violet 29 is not available, so low hazard via this route has not been demonstrated. Instead, the drivers for EPA's determination of unreasonable risk for workers are based on a read-across from an animal study of inhaled carbon black particles which evaluated the toxicity on the lower respiratory tract. Quantitative risk estimates were not developed for non-cancer effects and cancer from acute inhalation and acute and chronic dermal occupational exposures for any conditions of use because of low hazard.

EPA generally assumes compliance with OSHA requirements for protection of workers. In support of this assumption, EPA used reasonably available information, including public comments, indicating that some employers, particularly in the industrial setting, are providing appropriate engineering or administrative controls or PPE to their employees consistent with OSHA requirements. While OSHA has not issued a specific permissible exposure limit (PEL) for C.I. Pigment Violet 29, some level of respiratory PPE is assumed to be used due to the OSHA PEL for respirable dust particulates (particle sizes <10 μm) (29 CFR § 1910.1000). EPA also has information from the Sun Chemical Corporation manufacturer to support this assumption. However, information for each condition of use is not known. EPA does not believe that the Agency must presume, in the absence of such information, a lack of compliance with existing regulatory programs and practices. Rather, EPA assumes there is compliance with worker protection standards unless case-specific facts indicate otherwise; therefore, existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE in a manner that achieves the stated assigned protection factor (APF) or protection factor (PF). EPA's decisions for unreasonable risk to workers are based on high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE. EPA's approach for evaluating risk to workers and ONUs is to use the reasonably available information and professional judgement to construct exposure scenarios that reflect the workplace practices involved in the conditions of use of the chemicals and address uncertainties regarding availability and use of PPE.

For each condition of use of C.I. Pigment Violet 29 with an identified risk for workers, EPA evaluated the use of a respirator. However, EPA assumes that for some conditions of use, the use of appropriate respirators is not a standard industry practice, based on best professional judgement given the burden associated with the use of respirators, including the expense of the equipment and the necessity of fit-testing and training for proper use. For manufacturing, processing, recycling, and disposal conditions of use, air-purifying respirators (*e.g.* half face dust masks) with an APF of 10 were assumed. For one condition of use, paints and coatings for automobile (*e.g.*, Original Equipment Manufacturer (OEM) and refinishing), EPA assumed the use of a supplied-air respirator (continuous flow mode) with an APF of 25. For the remaining industrial, commercial, and consumer conditions of use, EPA assumed no use of a respirator because there is no C.I. Pigment Violet 29 OSHA requirement and there is a lack of reasonably available information on PPE use.

The unreasonable risk determinations reflect the severity of the effects associated with the occupational exposures to C.I. Pigment Violet 29 and incorporate consideration of the PPE that EPA assumes (respirator of APF 10 or 25) or in some scenarios the assumption of no PPE use. A full description of EPA's unreasonable risk determination for each condition of use is in Section 5.2.

Unreasonable Risk of Injury to Health of ONUs: 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. EPA evaluated non-cancer effects to ONUs from chronic inhalation occupational exposures to determine if there was unreasonable risk of injury to ONUs' health. The unreasonable risk determinations reflect the severity of the effects associated with the occupational exposures to C.I. Pigment Violet 29 and the assumed absence of PPE for ONUs, since ONUs do not directly handle the chemical and are instead doing other tasks in the vicinity of C.I. Pigment Violet 29 use. Additionally, ONUs are assumed not to be dermally exposed to the occupational use of a chemical substance. For inhalation exposures, EPA estimated ONUs' exposures and described the risks separately from workers' exposure A full description of EPA's unreasonable risk determination for each condition of use is in Section 5.2.

Unreasonable Risk of Injury to Health of Consumers: EPA did not develop quantitative risk estimates for non-cancer effects to consumers from acute inhalation, because EPA estimated that consumer exposures to C.I. Pigment Violet 29 in professional quality watercolor and acrylic artist paint are limited. EPA also did not develop quantitative risk estimates for oral and dermal exposures because C.I. Pigment Violet 29 is a solid with low solubility, thus eliminating or significantly reducing the potential for these routes of exposure. Due to the physical and chemical properties of C.I. Pigment Violet 29, EPA qualitatively found no or limited potential for exposure. A full description of EPA's unreasonable risk determination for the consumer condition of use is in Section 5.2.

Unreasonable Risk of Injury to Health of Bystanders (from Consumer Uses): EPA did not develop quantitative risk estimates for non-cancer effects to bystanders from acute inhalation exposures due to its low volatilization and no or limited exposures. Additionally, bystanders are assumed not to be dermally exposed to the consumer use of a chemical substance. A full description of EPA's unreasonable risk determination for the consumer condition of use is in Section 5.2.

Summary of Unreasonable Risk Determinations:
In conducting risk evaluations, "EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation…" 40 CFR 702.47. Pursuant to TSCA Section 6(i)(1), a determination of "no unreasonable risk" shall be issued by order and considered to be final agency action. Under EPA's implementing regulations, "[a] determination by EPA that the chemical substance, under one or more

of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order." 40 CFR 702.49(d).

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). The details of these determinations are in Section 5.2, and the TSCA Section 6(i)(1) order is contained in Section 5.4.1 of this revised draft risk evaluation.

Conditions of Use that Do Not Present an Unreasonable Risk
• 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 5.2.

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

1 INTRODUCTION

This document presents the final risk evaluation for C.I. Pigment Violet 29 under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended TSCA, the Nation's primary chemicals management law, in June 2016.

EPA published the *Scope of the Risk Evaluation for C.I. Pigment Violet 29* (U.S. EPA, 2017b) in June 2017, and the *Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29* (U.S. EPA, 2018c) on June 1, 2018, which represented the analytical phase of risk evaluation in which "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" as described in Section 2.2 of the *Framework for Human Health Risk Assessment to Inform Decision Making*. The problem formulation identified conditions of use and presented three conceptual models and an analysis plan. Based on EPA's analysis of the conditions of use, physical and chemical properties, fate endpoints, limited use volumes outside the manufacturing site, and low absorption by all routes of exposure, the problem formulation preliminarily concluded that further analysis of exposure pathways to workers, consumers, and the general population was necessary. EPA subsequently published the *Draft Risk Evaluation for C.I. Pigment Violet 29* (EPA-HQ-OPPT-2018-0604-0007) on December 11, 2018 and a *Revised Draft Risk Evaluation for C.I. Pigment Violet 29* (EPA-HQ-OPPT-2018-2018-0604) on October 13, 2020 and has taken public and peer review comments on both documents

The conclusions, findings, and determinations in this final risk evaluation are for the purpose of identifying whether the chemical substance presents unreasonable risk or no unreasonable risk under the conditions of use, in accordance with TSCA Section 6 and are not intended to represent any findings under TSCA Section 7.

As per EPA's final Risk Evaluation Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726), the draft and revised draft risk evaluations were subject to both public comments and peer review, which are distinct but related processes. EPA provided 60 days for public comment on all aspects of the draft risk evaluation and 50 days for the revised draft risk evaluation, including the submission of any additional information that might be relevant to the science underlying the risk evaluation. This satisfied TSCA Section 6(b)(4)(H), which requires EPA to provide public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

Following the publication of the draft risk evaluation, EPA released several updates to the draft that are reflected in this final risk evaluation. First, on March 21, 2019, EPA released 24 study reports that were originally claimed in full as confidential business information (CBI) by the data owners. Consistent with Agency regulations concerning the review of CBI claims located at 40 CFR Part 2, Subpart B, the Agency, in December 2018, requested substantiation of the CBI claims from the affected businesses. Subsequently, these entities provided responses to the substantiation request. The Agency made a final determination on the CBI claims, and this can be accessed at FOIA online at: https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2019-001853&type=request.

As a result, the 24 full study reports were made available in the public docket for C.I. Pigment Violet 29 (EPA-HQ-OPPT-2018-0604). Fifteen study reports were completely released without redactions, while nine study reports remain partially CBI with certain information redacted (*e.g.*, personal information relating to laboratory personnel, certain company-related information and, in one instance, individual test animal data tables).

On April 17, 2019, EPA released an updated systematic review supplemental file. Because the study reports were originally claimed as CBI, the EPA reviewers' comments were not included in the data evaluation scoring sheets in the original systematic review supplemental file. Several of the study reviews were also updated to correct technical errors and process inconsistencies in systematic review data evaluation scoring sheets and were released in an updated version of the *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation*. More information and a link to the updated systematic review scoring sheets can be found in the docket (EPA-HQ-OPPT-2018-0604-0039). The final data quality evaluation results for the data used in this final risk evaluation can be found in systematic review supplemental files released with this final risk evaluation (U.S. EPA, 2020b, c, d, e, f).

On June 6, 2019, EPA released a quantitative human health inhalation risk characterization approach. This approach used toxicity information for an analogue, barium sulfate, to estimate risks to workers from inhalation of C.I. Pigment Violet 29 dust in a manufacturing facility. This approach is described in a summary document released to the docket (EPA-HQ-OPPT-2018-0604-0052). This same general approach was used in the revised draft risk evaluation using new available data received for C.I. Pigment Violet 29 in Section 4.2.

Following the conclusion of the Scientific Advisory Committee on Chemicals (SACC) peer review meeting on June 18-21, 2019, EPA gathered additional data to address critical uncertainties identified in the draft risk evaluation indicated by the SACC and in public comments. All information received voluntarily through correspondence with manufacturing stakeholders of C.I. Pigment Violet 29 since the peer review meeting has been released to the docket with this final risk evaluation in a supplemental file entitled *Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a). Where data received from the manufacturing stakeholders was determined to be deficient, EPA utilized its information gathering authorities under TSCA Section 4. On February 28, 2020, EPA issued a TSCA Section 4(a)(2) Test Order for the generation and submission of solubility testing in water and octanol, as well as a respirable dust monitoring study. More information can be found in the TSCA Section 4 Test Order docket (EPA-HQ-OPPT-2020-0070).

Peer review was conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using the *EPA Peer Review Handbook* and other methods consistent with the science standards laid out in Section 26 of TSCA (see 40 CFR 702.45). As explained in the Risk Evaluation Rule (82 FR 33726 (July 20, 2017), the purpose of peer review is for the independent review of the science underlying the risk assessment. As such, peer review addressed aspects of the underlying science as outlined in the charge to the peer review panel including hazard assessment, assessment of dose-response, exposure assessment, and risk characterization.

As EPA explained in the Risk Evaluation Rule (82 FR 33726 (July 20, 2017), it is important for peer reviewers to consider how the underlying risk evaluation analyses fit together to produce an integrated risk characterization, which forms the basis of an unreasonable risk determination. EPA believes peer reviewers are most effective in this role if they received the benefit of public comments on draft risk evaluations prior to peer review. For this reason, and consistent with standard Agency practice, the public comment period coincided with public and peer review comments received on both the draft risk evaluation and the revised draft risk evaluation and explained changes made in response to those comments in this final risk evaluation and the associated response to comments document.

EPA also solicited input on the first 10 chemicals for risk evaluation under TSCA as it developed use documents, scope documents, and problem formulations. At each step, EPA has received information

and comments specific to individual chemicals and of a more general nature relating to various aspects of the risk evaluation process, technical issues, and the regulatory and statutory requirements. EPA has considered comments and information received at each step in the process and factored in the information and comments as the Agency deemed appropriate and relevant including comments on the published problem formulation of C.I. Pigment Violet 29 (EPA-HQ-OPPT-2016-0725-0048).

In this final risk evaluation, Section 1 presents the basic physical and chemical characteristics of C.I. Pigment Violet 29, as well as a background on uses, regulatory history, conditions of use, and conceptual models, with particular emphasis on any changes since the publication of the draft risk evaluation. This section also includes a discussion of the systematic review process utilized in this risk evaluation. Section 2 provides a discussion and analysis of the exposures, both human and environmental, that can be expected based on the conditions of use for C.I. Pigment Violet 29. Section 3 discusses environmental and human health hazards of C.I. Pigment Violet 29. Section 4 presents the risk characterization, which integrates and assesses reasonably available information on human health and environmental hazards and exposures, as required by TSCA (15 U.S.C. 2605(b)(4)(F)). This section also includes a discussion of any uncertainties and how they impact the risk evaluation. In Section 5, the agency presents the final determination of whether risk posed by a chemical substance is ''unreasonable'' as required under TSCA (15 U.S.C. 2605(b)(4)).

1.1 Physical and Chemical Properties

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 (EPA-HQ-OPPT-2016-0725-0039). Though C.I. Pigment Violet 29 was first produced in 1913, its commercialization did not occur until the late 1950s (Greene, 2001). It has been recognized for its high color strength, weather fastness and heat stability. The reasons for these high-performance characteristics have been attributed to the organizational structure of the molecule.

The ring structure of C.I. Pigment Violet 29 is a well-organized planer polycyclic aromatic ring system, and the intermolecular interactions play a major role in the chemical's behavior. The molecule is entirely planer, and the lack of substitution on ring system allows for close packing. Also, the molecule is symmetrical along many planes. It has two hydrogen bond donors (N-H) and four hydrogen bond acceptors (C=O). This leads to two-point recognition of the molecules via hydrogen bonding in a ladder-like arrangement. The unique structural components of this highly stable solid can, in part, explain the physical and chemical property information available for C.I. Pigment Violet 29. The complex hydrogen bonded system of C.I. Pigment Violet 29 would need to be disrupted for the chemical to melt or to dissolve. This is observed in the high melting point (>500 °C) and the low solubility of C.I. Pigment Violet 29 in water and in organic solvents. Due to its low solubility, determining various physical and chemical properties using conventional methods is difficult, if not impossible, to perform.

Prior to the publication of the draft risk evaluation, EPA received a full study report that contained characterization of the melting point, vapor pressure, density, particle size distribution and the partition coefficient in *n*-Octanol ($LogK_{ow}$) (BASF, 2013). All of this physical and chemical property information was evaluated for data quality, and the results are presented in abbreviated format in Table 1-1 Data quality evaluation results for the physical and chemical property studies are published in the "*Systematic Review Supplemental File: Data Quality Evaluation of Physical and Chemical Property Studies* (U.S. EPA, 2020f)."

The melting point, density and vapor pressure studies are of high quality, while the LogK $_{ow}$ study is unacceptable for use in risk assessment. In that study, the LogK $_{ow}$ was not measured directly, but instead, it was estimated based on the solubility of C.I. Pigment Violet 29 in water and octanol, respectively. The values provided for the water solubility (0.011 mg/L) and the octanol solubility (<0.07 mg/L, the Limit of Detection) were found to be unacceptable by EPA due to the fact that the limit of detection for the n-octanol solubility was higher than the measured water solubility. Also, due to the particle-like nature of the substance, EPA questioned whether the method of filtration completely removed undissolved material during the study.

To address uncertainties that resulted from the unacceptable rating of the LogK $_{ow}$ study (and solubility studies that constituted this study report), EPA utilized its TSCA Section 4 test order authorities to require the generation and submission of studies measuring solubility of C.I. Pigment Violet 29 in water (OECD 105, flask method) and n-octanol (ETAD method, 2005) (Nicolaou, 2020). The study report indicated no test material was observed in these matrices (water or octanol), and the Limit of Detection (LOD) was determined to be 0.0014 mg/L, and the Limit of Quantification (LOQ) was determined to be 0.003 mg/L. The results of the study are presented in abbreviated format in Table 1-1 The measured partition coefficient could not be determined due to poor solubility in octanol and water, so the methods utilized in LogK$_{OW}$ tests were unacceptable for characterizing this value. Due to low solubility of C.I. Pigment Violet 29, LogK$_{ow}$ was determined indeterminate property for C.I. Pigment Violet 29.

Table 1-1. Physical and Chemical Properties of C.I. Pigment Violet 29

Property	Value	Reference	Data Quality Rating
Molecular Formula	$C_{24}H_{10}N_2O_4$	(BASF, 2013)	N/A
Molecular Weight	390.35 g/mol	(U.S. EPA, 2012b)	N/A
Physical Form	Solid	(BASF, 2013)	N/A
Purity [1]	98% before purification; ≥ 99.6% after purification	(Nicolaou, 2020)	N/A
Melting Point	No melting point found <500˚C	(BASF, 2013)	High
Density	1.584 g/cm^3 at 20 ˚C	(BASF, 2013)	High
Vapor Pressure	<0.000001 hPa at 20˚C	(BASF, 2013)	High
Solubility in n-octanol	Not observed LOD: 0.0014 mg/L LOQ: 0.003 mg/L	(Nicolaou, 2020)	High
Water Solubility	Not observed LOD: 0.0014 mg/L LOQ: 0.003 mg/L	(Nicolaou, 2020)	High
Log K$_{OW}$ [2]	Not determined	(U.S. EPA, 2012b)	N/A
Henry's Law Constant [2]	1.84E-021 atm-m^3/mol (estimated)	(U.S. EPA, 2012b)	High [3]

[1] Impurities for the 98% pure substance were determined to be moisture (1.4%), ash (0.3%), naphthalimide (0.2%), and naphthalic acid/anhydride (0.02%).

Property	Value	Reference	Data Quality Rating
[2]Due to low solubility of C.I. Pigment Violet 29 in water and octanol, $LogK_{ow}$ was determined not to be a relevant property for C.I. Pigment Violet 29. Similarly, Henry's Law Constant should be interpreted with caution due to the low solubility of the compound, the predicted value may be questionable. [3]See data quality evaluation results for EPI Suite™ modeling in the *Systematic Review Supplemental File: Data Quality Evaluation of Environmental Fate and Transport Studies* available in the docket for C.I. Pigment Violet 29 (EPA-HQ-OPPT-2018-0604).			

1.2 Uses and Production Volume

The information on the conditions of use is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (*e.g.*, published literature and consultation with stakeholders), to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

Use categories include the following: "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016).

CDR and information received by EPA during the public comment periods show that C.I. Pigment Violet 29 is primarily processed as a site-limited intermediate for the creation or adjustment to other perylene pigments. The volume associated with processing as an intermediate is ~540,000 lbs/year or 90 percent of the total production volume reported in the 2016 CDR (U.S. EPA, 2016). Ten (10) percent of the total production volume (~60,000 lbs) was processed and used in either commercial paints and coatings (~30,000 pounds/year) or commercial plastic and rubber products (~30,000 lbs/year). An unknown volume of C.I. Pigment Violet 29 is used in consumer watercolor and acrylic paints. The volume of C.I. Pigment Violet 29 in artistic paint products is reported to comprise less than 1 percent of total sales (EPA-HQ-OPPT-2016-0725-0039).

EPA concludes that use of paints containing C.I. Pigment Violet 29 is a condition of use for this risk evaluation; however, the 2012 and 2016 CDR did not indicate use of C.I. Pigment Violet 29 in products intended for children (U.S. EPA, 2016, 2012a). Comments on C.I. Pigment Violet 29 Use Document (EPA-HQ-OPPT-2016-0725-0006), (CPMA, 2017a, c) in 2017 indicated that commenters are not aware of C.I. Pigment Violet 29 being used in paints that are marketed to children, although there are no explicit age-related restrictions on the purchase of professional artistic paints such as watercolors and acrylics. However, consumer products that are widely available, like watercolor and acrylic paints, could be reasonably foreseen to be used by children.

For C.I. Pigment Violet 29, CDR reporting is required for imports above 25,000 lbs per year per company per manufacturing site. C.I. Pigment Violet 29 has not been reported to be imported in the CDR 2012 and 2016 database (U.S. EPA, 2016, 2012a). However, following the publication of the draft risk evaluation, information was received from a group of NGOs indicating that BASF Corporation imports C.I. Pigment Violet 29 in volumes less than 25,000 lbs per year (EPA-HQ-OPPT-2018-0604-0016). BASF Corporation also confirmed their import of C.I. Pigment Violet 29 which is located in the *Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA,

2020a). Therefore, import of C.I. Pigment Violet 29 is included as a condition of use. However, imported volumes of C.I. Pigment Violet 29 would be expected to be less than 25,000 lbs and utilized for the same conditions of use as the domestically manufactured volumes as well as the consumer acrylic paints and watercolors.

The 2016 CDR reporting data on the production volume for C.I. Pigment Violet 29 are provided in Table 1-2 and come from EPA's CDR database (U.S. EPA, 2016). This information has not changed from that provided in the problem formulation (U.S. EPA, 2018c) and draft risk evaluation (EPA-HQ-OPPT-2018-0604-0007) and the revised draft risk evaluation (EPA-HQ-OPPT-2018-0604-0100).Total production volume of C.I. Pigment Violet 29 has increased from 2012 to 2015, as can be seen in Table 1-2.

Table 1-2. Production Volume of C.I. Pigment Violet 29 in CDR Reporting Period (2012 to 2015)[a]

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	517,980	474,890	535,139	603,420

[a] This CDR data is more specific and up to date than that currently available in ChemView. (https://chemview.epa.gov/chemview) (U.S. EPA, 2016).

According to data collected in EPA's 2016 Chemical Data Reporting (CDR) Rule, 603,420 lbs of C.I. Pigment Violet 29 were manufactured in the United States in 2015, of which ~17,000 lbs were exported (U.S. EPA, 2016). Import volume is estimated to be less than 25,000 lbs. EPA has identified data that indicates that there is one domestic manufacturer and one importer of C.I. Pigment Violet 29 in the United States.

1.3 Regulatory and Assessment History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to C.I. Pigment Violet 29. EPA compiled a regulatory summary from federal, state, international and other government sources, as cited in Appendix A.

Federal Laws and Regulations

C.I. Pigment Violet 29 is subject to federal statutes or regulations, in addition to TSCA, that are implemented by other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

State Laws and Regulations

EPA did not identify information indicating that C.I. Pigment Violet 29 is subject to state statutes or regulations implemented by state agencies or departments.

Laws and Regulations in Other Countries and International Treaties or Agreements

C.I. Pigment Violet 29 is on multiple countries' chemical inventories, but not subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these inventories is provided in Appendix A.2.

1.4 Scope of the Evaluation

1.4.1 Conditions of Use

TSCA Section 3(4) defines the conditions of use as ‘‘*the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of*.” Conditions of use are described below in Table 1-3. In the final risk evaluation, import was added as a condition of use, and consumer watercolor and acrylic paints are no longer listed as a commercial use. Water and acrylic paints are only a consumer use. EPA has not exercised its authority in TSCA Section 6(b)(4)(D) to exclude any C.I. Pigment Violet 29 conditions of use from the scope of the risk evaluation.

Table 1-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (2016); (U.S. EPA, 2020a); Public Comment, EPA-HQ-OPPT-2018-0604-0016
	Import	Import	
Processing	Processing - Incorporating into formulation, mixture, or reaction product	Paints and Coatings	U.S. EPA (2016); Public Comment, EPA-HQ-OPPT-2016-0725-0006
		Plastic and Rubber Products	U.S. EPA (2016); Public Comment, EPA-HQ-OPPT-2016-0725-0006
	Processing - Use as an Intermediate	Creation or adjustment to other perylene pigments	U.S. EPA (2016); Public Comment, EPA-HQ-OPPT-2016-0725-0006; Public Comment, EPA-HQ-OPPT-2016-0725-0008
	Recycling	Recycling	U.S. EPA (2016); Use Document, EPA-HQ-OPPT-2016-0725-0004
Distribution in commerce	Distribution	Distribution	Use Document, EPA-HQ-OPPT-2016-0725-0004; Public Comment, EPA-HQ-OPPT-2016-0725-0006

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial/commercial uses	Plastic and rubber products	Automobile plastics	Use Document, EPA-HQ-OPPT-2016-0725-0004; Public Comment, EPA-HQ-OPPT-2016-0725-0006
		Industrial carpeting	Public Comment, EPA-HQ-OPPT-2016-0725-0006
	Paints and coatings	Automobile (*e.g.*, OEM and refinishing)	Public Comment, EPA-HQ-OPPT-2016-0725-0006; Public Comment, EPA-HQ-OPPT-2016-0725-0013; Public Comment, EPA-HQ-OPPT-2016-0725-0009
		Coatings and basecoats	Public Comment, EPA-HQ-OPPT-2016-0725-0008; Public Comment, EPA-HQ-OPPT-2016-0725-0007
	Merchant ink for commercial printing	Merchant ink	Use Document, EPA-HQ-OPPT-2016-0725-0004; Public Comment, EPA-HQ-OPPT-2016-0725-0006
Consumer use	Consumer watercolor and acrylic paints	Professional quality watercolor and acrylic artist paint	Use Document, EPA-HQ-OPPT-2016-0725-0004
Disposal	Emissions to Air	Air	Mott, 2017b; (U.S. EPA, 2020a) This reference applied only to manufacturing, no other references specific to C.I. Pigment Violet 29 identified.
	Wastewater	Industrial pre-treatment	
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
	Solid wastes and liquid wastes	Municipal landfill	
		Hazardous landfill	

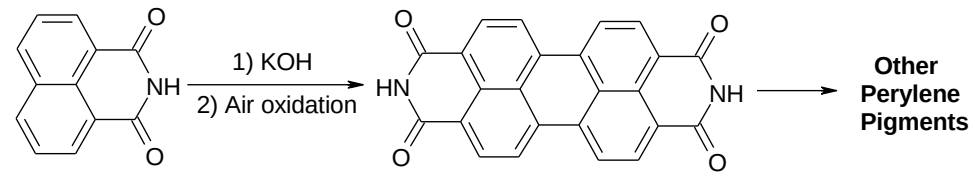
Life Cycle Stage	Category [a]	Subcategory [b]	References
		Other land disposal	
		Municipal waste incinerator	
		Hazardous waste incinerator	
		Off-site waste transfer	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of C.I. Pigment Violet 29 in industrial and/or commercial settings.
[b] These subcategories reflect more specific conditions of use of C.I. Pigment Violet 29.

1.4.1.1 Manufacturing

Manufacturing, Domestic Manufacture

There is one domestic manufacturer of C.I. Pigment Violet 29 in the U.S. Specific unit operations for the plant are not known; however, the chemical reaction to produce C.I. Pigment Violet 29 and general process are presented below. Ullmann's Encyclopedia of Industrial Chemistry (Hunger and Herbst, 2012) describes the following chemical reaction to produce C. I. Pigment Violet 29. C.I. Pigment Violet 29 is obtained by reacting naphthalimide (CASRN: 81-83-4) with molten potassium hydroxide (the potassium salt of the leuco form of perylenetetracarboxylic diimide is formed) and followed by atmosphere oxidation.



CASRN 81-83-4 CASRN 81-33-4 **(PV29)**

Figure 1-1. Chemical Reaction for Pigment Violet 29 (From (Hunger and Herbst, 2012))

The procedure for manufacturing has been well-established and has not changed in the last 80 years (U.S. EPA, 2017c). The domestic manufacturer of C.I. Pigment Violet 29 produces it as a solid (powder) that is used within its own plant to produce other pigments or is sold to other manufacturers and processers in bags as a powder. Potential release points include sources commonly evaluated by EPA from general chemical manufacturing operations:

- Equipment cleaning
- Container residue (if C.I. Pigment Violet 29 is temporarily stored prior to incorporation into on-site processing into a formulation, mixture, or reaction product)
- Fugitive dust emissions from container loading/unloading operations

Manufacturing, Import

Information provided by the one identified importer, BASF, indicates that C.I. Pigment Violet 29 is imported at volumes below CRD reporting thresholds of 25,000 lbs. Therefore, C.I. Pigment Violet is expected to be imported at unknown minor volumes under 25,000 lbs. EPA expects that C.I. Pigment Violet 29 and products containing C.I. Pigment Violet 29 are often stored in warehouses prior to

distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and quality control samples may be taken for analyses. According to information received from BASF regarding their importation practices, C.I. Pigment Violet 29 is imported as an "*industrial pigment product is 80% to 90% C.I. Pigment Violet 29. The concentration of the imported tint paste is <25% C.I. Pigment Violet 29. The concentration of paint/coating is <3% C.I. Pigment Violet 29. The primary function of this pigment is to tint the color of a paint and would generally be formulated at levels <1% but can be as high as 3%*.]" The information also indicates that the product is imported as a powder and a liquid (*Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a)).

1.4.1.2 Processing

Incorporation into Formulation, Mixture or Reaction Products – Paints and Coatings.
Sun Chemical Corporation provided information pertaining to sites that process C.I. Pigment Violet 29 for paint and coating manufacturing. Sun Chemical Corporation indicated that approximately 350 lbs are processed per batch and 8,800 lbs are processed per year at these processing facilities (EPA-HQ-OPPT-2018-0604). The market volume of C.I. Pigment Violet 29 reported in the 2016 CDR for all facilities in this sector was 30,000 lbs in 2015. EPA divided this market volume of 30,000 lbs by the estimated average annual volume used per facility of 8,800 lbs and, rounding up to the next whole number, estimated four sites that process C.I. Pigment Violet 29 for paint manufacturing.

Sun Chemical Corporation provided information to EPA indicating its direct customers that process C.I. Pigment Violet 29 for paint and coating manufacturing receive the chemical at 80% concentration in powder in bags that are manually opened and dumped into a mixer where it is milled and formulated into a tint paste. The paste is added to a wide variety of liquid base coats for the automobile industry (EPA-HQ-OPPT-2018-0604-0116). Pigments are typically supplied to the paint and coating formulator as dry powders, press cakes, or slurries. These materials may be classified in a variety of ways including white, inert extenders, color, and functional pigments. Traditional paint manufacturing processes consist of the following unit operations:

- Pre-assembly or pre-mixing (of the pigment dispersion);
- Grinding or milling (of the pigment dispersion);
- Blending of the final formulation; and
- Filtration and packaging.

Incorporation into Formulation, Mixture or Reaction Products – Plastic and Rubber Products
Sun Chemical Corporation provided information pertaining to sites that process C.I. Pigment Violet 29 for plastics manufacturing. Sun Chemical Corporation indicated "a few tons" are processed each day for "six to twelve" days per year at these processing facilities (EPA-HQ-OPPT-2018-0604). This equates to a minimum of 24,000 lbs per year. The use rate that was reported in the 2016 CDR for all facilities in this sector was 30,000 lbs in 2016. Therefore, EPA assumes one facility will process C.I. Pigment Violet 29 into plastics.

Sun Chemical Corporation provided information indicating its direct customer that processes C.I. Pigment Violet 29 for plastic manufacturing receives the chemical in bags that are manually opened and added to a vessel for weighing and dry blending with polymers and other additives. This preparation is then "extruded via a continuous and closed process involving encapsulation into pellets." (EPA-HQ-OPPT-2018-0604-0116).

The first step of a typical compounding process is the handling of the shipping containers. Pigments are received in bags or super sacs. Bags are unloaded into mixing vessels. Worker exposure and releases may result during this transfer activity due to the generation of airborne particulates. Once unloaded, blends of plastics additives, polymer resins and other raw materials are mixed to produce the compounded resin master batch. There are numerous methods used to blend resin master batches, including a variety of closed and partially open processes. Closed processes predominate in the plastics industry and comprise systems where the compounding process is almost completely enclosed. Open processes are those where compounding occurs in an open environment at ambient conditions. Tumble blenders, ball blenders, gravity mixers, paddle/double arm mixers, intensive vortex action mixers and banbury internal mixers are all closed systems and are considered to be blending processes. Roll mills and extruders are partially open systems and represent all-in-one processes that perform blending and forming of the final compounded plastic (*e.g.*, pellets, sheets).

Once resin compounding is completed, the solid master batch is transferred into an extruder where it is converted into pellets, sheets, films, or pipes. The extruder is a long, heated chamber that utilizes a continuously revolving screw to transfer the molten compounded resin through the extruder and into the dye. The shape of the dye determines the final form of the extrudate. The extruded plastic is then cooled in air or by direct immersion in water. Upon drying, the extrudate is packaged and shipped to downstream converting sites. Plastics converters receive the master batch of plastic resin from compounders and convert the plastic resin into a finished plastic product. The plastic resins, which contain the chemical additives, such as C.I. Pigment Violet 29, are received at the converting site as solid pellets, sheets, or films. They are then heated and are formed into the desired shape through a variety of converting methods, including extrusion, injection molding and thermoforming. The converted plastics may then undergo finishing operations, where secondary modifications yield the final, finished plastic product. Finishing operations include, but are not limited to filing, grinding, sanding, polishing, painting, bonding, coating and engraving.

In the first process step, plastics converters receive the thermoplastic resin from compounders, who blend resins and additives together into a master batch. The resins must be heated and melted to form the final product. In this regard, plastics converters use numerous methods to convert thermoplastics into final products. Conversion methods include:

- Extrusion: Plastic pellets or granules are heated, fluidized, homogenized and formed continuously as the extrusion machine feeds them through a die. Immediately after the die, the material is quenched, resulting in a very long plastic shape (*e.g.*, tube, pipe, sheet, or coated wire).
- Injection Molding: Plastic granules or pellets are heated and homogenized in a cylinder (usually by extrusion). The resin is injected via pressure into a cold mold where the plastic takes the shape of the mold as it solidifies.
- Blow Molding: A plastic forming process in which air is used to stretch and form plastic materials.
- Rotational Molding: Finely ground plastic powders are heated in a rotating mold to the point of melting and/or fusion. The melted resin evenly coats the inner surface of the rotating mold.
- Thermoforming: Heat and pressure are applied to plastic sheets that are placed over molds and formed into various shapes.

After heating and forming, finishing operations are performed to complete the finished plastic product. The plastic finishing operations will depend on the type of product produced. For example, most molded plastic articles require trimming to remove excess plastic. Trimming is performed via filing,

grinding and sanding. Other possible finishing operations include coating, polishing, bonding and engraving.

Use as an Intermediate in the Adjustment or Creation of Other Perylene Pigments
Information received from the Sun Chemical Corporation (the sole U.S. manufacturer) indicated that use C.I. Pigment Violet 29 as an intermediate for the adjustment or the creation of other perylene pigments occurs at their site concurrently with the manufacture of C.I. Pigment Violet 29 by the same workers. According to the process information received, "the production of C.I. Pigment Violet 29 is the starting point for the synthesis of all other perylene pigments at the facility. Other perylenes produced at the facility may contain an estimated 0-5% residual C.I. Pigment Violet 29 in the finished pigment. The remaining 10% of the finished C.I. Pigment Violet 29, which is not further processed or used as an intermediate, is sold into the Plastics and Coatings (P&C) industries" (*Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a)).

Processing - Recycling
EPA did not find C.I. Pigment Violet 29-specific information for recycling. However, this chemical has been identified in articles that are commonly recycled such as plastics which indicates that recycling may occur for waste plastics. The processes for recycling these materials may include grinding, washing, and rinsing the recycled material and incorporating it into new formulations and articles. EPA has not identified specific worker activities related to the recycling C.I. Pigment Violet 29 containing products. Based on EPA's knowledge, worker activities are anticipated to be exposed to C.I. Pigment Violet 29 from reclamation activities such as sorting, materials grinding steps and loading recovered materials into transport containers.

1.4.1.3 Industrial/Commercial Uses

Plastic and Rubber products – Automobile plastics and Industrial Carpeting
For these industrial/commercial uses, EPA is assuming that the industry does not handle C.I. Pigment Violet 29 as the pigment powder and is handling a product that already has C.I. Pigment Violet 29 incorporated into a plastic material or industrial carpeting fibers. There are no exposures to C.I. Pigment Violet 29 as a dust. After C.I. Pigment Violet 29 is encapsulated in plastics resins during processing and subsequently used as a plastic product, it is not expected to leach out as a result of the low solubility in water and octanol (21 CFR 178.3297; (BASF, 1998).

The automobile and industry carpeting process typically involves the following steps:

- Shaping plastic parts;
- Installing;

Paints and Coatings – Automobile (OEM Basecoats and Refinishing), Coatings and Refinishing
Automotive refinishing shops apply coatings to motor vehicles after the original manufacturing process. Refinishing operations occur in new car dealer repair/paint shops, fleet operator repair/paint shops, production auto-body paint shops and custom-made car fabrication facilities. Following structural preparation of the automobile, paint and/or coating mixtures are sprayed directly onto the automobile surface using a spray gun. The refinishing process typically involves the following steps:

- Structural repair;
- Surface preparation (cleaning and sanding);
- Mixing;
- Spray application of primer;
- Curing of the primer;

- Sanding;
- Solvent wipe-down;
- Topcoat (basecoat color and clearcoat) mixing;
- Spray application of topcoat; and,
- Final curing.

Most automotive refinishing shops have designated paint mixing rooms where most coating mixing occurs. Primers, clear coats and basecoats are usually mixed separately by hand in small containers to match the amount of coating needed for the job. Basecoat colors are often also mixed with mechanical agitators to ensure thorough mixing for color matching purposes.

Some shops will order a limited range of basecoat colors premixed from their supplier; however, most automotive refinishing shops mix their own colors. The coatings are metered or poured by hand into a mixing cup or other apparatus. The empty transport containers are either crushed for disposal or solvent-washed for future use, and their residue is disposed to landfill or incineration. The mixed coating is then transferred from the mixing cup to the spray gun cup. After the primer coating is applied, sanded, and wiped down, the basecoat color and clear coat are sprayed on and cured. Often, more than one coat of each type of coating (*i.e.*, primer, basecoat and clear coat) is applied.

Nearly all automotive refinishing spray coating processes are conducted in an enclosed or curtained area of the shop, equipped with ventilation systems and supply air filters to prevent contamination of the newly applied finish (*e.g.*, a spray booth). Often, these areas also incorporate a dry filter or other device to trap the oversprayed paint mists prior to their emission from the shop. Some of that oversprayed mist settles on the floor and walls of the area/booth and is subsequently swept or cleaned and disposed with other oversprayed coating wastes. The remaining mist is removed from the workspace via the ventilation system. This ventilated mist typically passes through a dry filter that is installed in the exhaust system. These filters are periodically changed out and disposed of in landfills or by incineration. The coating mists/particulates that are not captured by the filter are emitted from the shop stacks into the surrounding environment.

Merchant Ink for Commercial Printing

There are four major classes of printing ink: letterpress and lithographic inks, commonly called oil or paste inks; and flexographic and rotogravure inks, which are referred to as solvent inks. These inks vary considerably in physical appearance, composition, method of application and drying mechanism. Flexographic and rotogravure inks have many elements in common with the paste inks but differ in that they are of very low viscosity, and they almost always dry by evaporation of highly volatile solvents.

There are three general processes in the manufacture of printing inks: (1) cooking the vehicle and adding dyes, (2) grinding of a pigment into the vehicle using a roller mill and (3) replacing water in the wet pigment pulp by an ink vehicle (commonly known as the flushing process). The ink "varnish" or vehicle is generally cooked in large kettles at 200 to 600°F (93 to 315°C) for an average of 8 to 12 hours in much the same way that regular varnish is made. Mixing of the pigment and vehicle is done in dough mixers or in large agitated tanks. Grinding is most often carried out in 3 or 5 rollers horizontal or vertical mills.

The printing industry is organized by the type of printing technology used: lithography, rotogravure, flexography, screen, letterpress, and digital. Facilities tend to employ one type of printing process exclusively, although some of the larger facilities may use two or more types. The equipment, applications, and chemicals for each of these printing technologies differ; however, they all print an

image on a substrate following the same basic sequence. The fundamental steps include imaging/film processing, image carrier preparation, printing, and post-press operations.

After the manufacture and/or sale of C.I. Pigment Violet 29 containing products, there are possible inhalation exposures to workers associated with the use and handling of the C.I. Pigment Violet 29 products. Respirable dust and mist could be generated and inhaled by workers during commercial/industrial uses of C. I. Pigment Violet 29. These include spray painting of coatings containing C.I. Pigment Violet 29 and automobile body repair (removal of paints containing C.I. Pigment Violet 29.) Negligible inhalation exposure of C.I. Pigment Violet 29 is expected for the industrial and commercial uses in plastic and rubber products including automobile plastics and industrial carpeting.

These conditions of use may include the following worker activities with products or formulations containing C.I. Pigment Violet 29:

- cleaning and maintaining equipment;
- handling, transporting and disposing of waste;
- changing out filtering media;
- applying formulations (including spray application) and products to substrates; and,
- compounding, converting, trimming and grinding plastics.

1.4.1.4 Consumer Uses

Of the uses for C.I. Pigment Violet 29, the only potential consumer use is as a component of artistic watercolor and acrylic paint. Based on this use, inhalation is not identified as a route of exposure for consumers users or bystanders since C.I. Pigment Violet 29 is not expected to volatilize from these paints due to its low vapor pressure.

1.4.1.5 Disposal

Each of the conditions of use of C.I. Pigment Violet 29 may generate waste streams that are collected and transported to third-party sites for disposal, treatment, or recycling. Wastes containing C.I. Pigment Violet 29 that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include wastewater, solid wastes, and other wastes. Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA. C.I. Pigment Violet 29 is not considered a hazardous waste under Subtitle C of RCRA.

As indicated above in Section 2.2, Sun Chemical Corporation, the sole U.S. manufacturer of C.I. Pigment Violet 29 (and processor for the use as an intermediate to make other pigments, which uses 90% of the total manufactured volume) sends its non-hazardous wastewater treatment residuals (sludge) to the Oak Ridge Landfill in Dorchester County or the Berkeley County Landfill. Both landfills are RCRA Subtitle-D lined landfills permitted under the authority of South Carolina Regulation Number 61-107.19. Industrial wastes are sent to licensed industrial waste handlers where destruction removal efficiencies for incinerators are expected to be >99 percent (CPMA, 2017b). In

addition to design standards for Subtitle-D lined landfills, sorption to particulates and biosolids for C.I. Pigment Violet 29 are expected to be strong, and water solubility is low, so leaching of C.I. Pigment Violet 29 from landfills is expected to be negligible.

The life cycle diagram in Figure 1-2 depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016). EPA has evaluated activities resulting in exposures associated with the various lifecycle stages and conditions of use (*e.g.*, manufacturing, processing, distribution in commerce, industrial use, commercial use, consumer use, disposal).

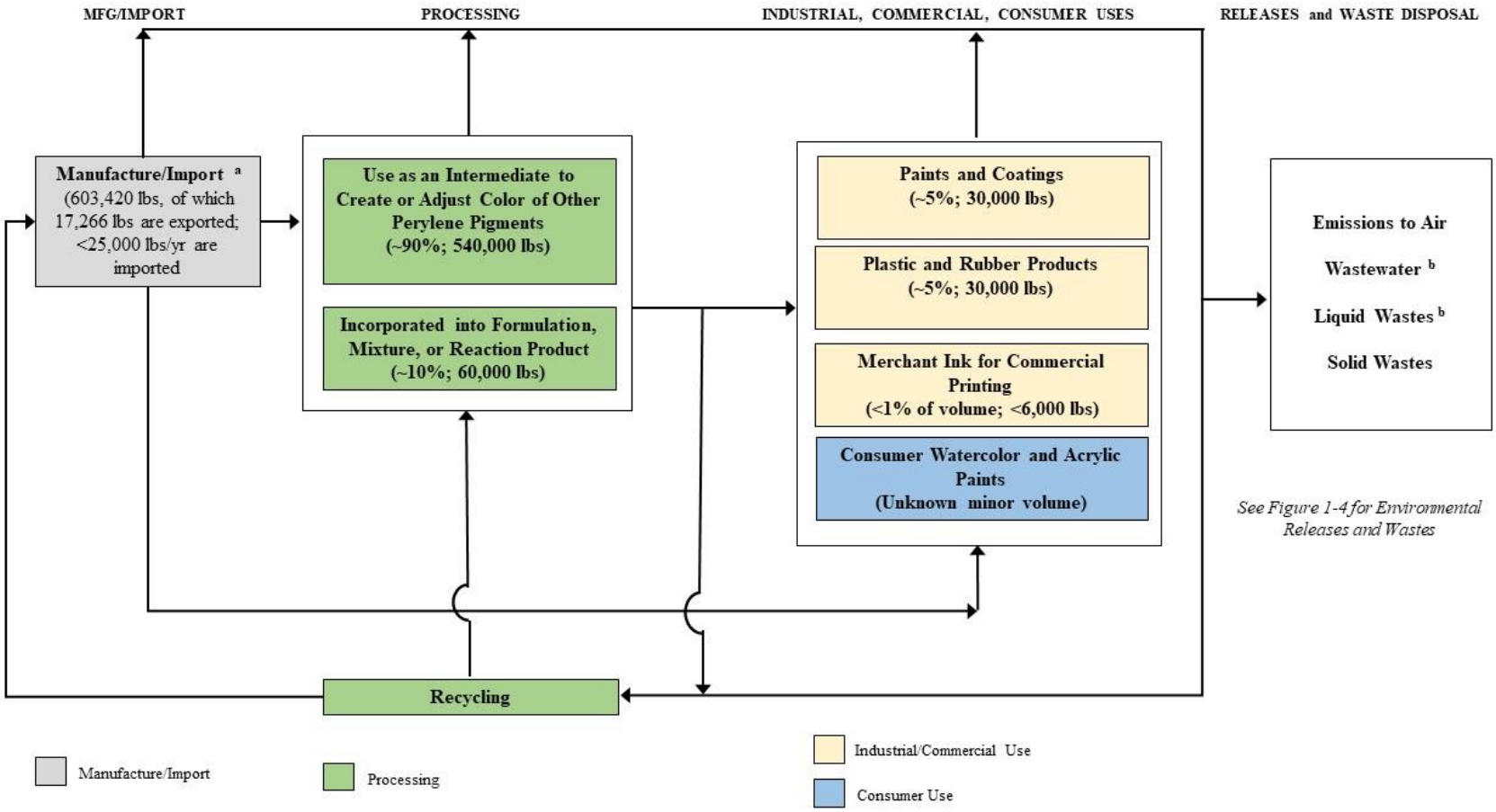


Figure 1-2. C.I. Pigment Violet 29 Life Cycle Diagram

[a] 603,420 lbs only includes volumes reported to CDR which does not include import volumes below the reporting threshold (U.S. EPA, 2012a; U.S. EPA, 2016).

[b] Wastewater: combination of water and organic liquid, where the organic content is < 50 percent. Liquid Wastes: combination of water and organic liquid, where the organic content is > 50 percent.

1.4.2 Conceptual Models

The conceptual models for this risk evaluation are shown below in Figure 1-3, Figure 1-4, and Figure 1-5. EPA considered the potential for hazards to human health and the environment resulting from exposure pathways outlined in the preliminary conceptual models of the C.I. Pigment Violet 29 scope document (U.S. EPA, 2017b). These conceptual models considered potential exposures resulting from consumer activities and uses, industrial and commercial activities, and environmental releases and wastes. The problem formulation document refined the initial conceptual models and analysis plans that were provided in the scope documents (U.S. EPA, 2018c). Based on review and evaluation of reasonably available data for C.I. Pigment Violet 29, which indicated low hazard and limited down-stream use volume, EPA determined in the problem formulation that no further analysis of any of the pathways outlined in the conceptual models was necessary.

EPA, however, did make two modifications to the conceptual models in the revised draft risk evaluation. The first was the addition of "import" as a condition of use. The second change involved carrying out a quantitative screening-level analysis of risks to the population with the highest potential exposure. This was carried out by developing a quantitative analysis of risks to workers (the population with the theoretical highest anticipated exposure) from inhalation exposure as described in Section 4.2.

In the revised draft risk evaluation, EPA further updated the life cycle diagram and conceptual models to include imports based on evidence provided in public comments and confirmed by the importer that BASF Corporation imports small volumes of C.I. Pigment Violet 29 (EPA-HQ-OPPT-2018-0604-0016). EPA has also updated the quantitative screening level analysis of risks to workers so that only risks to workers from inhalation are assessed quantitatively. Risks to workers from dermal exposure are assessed through a qualitative consideration of physical and chemical properties and is discussed further in Section 2.3.1.3.

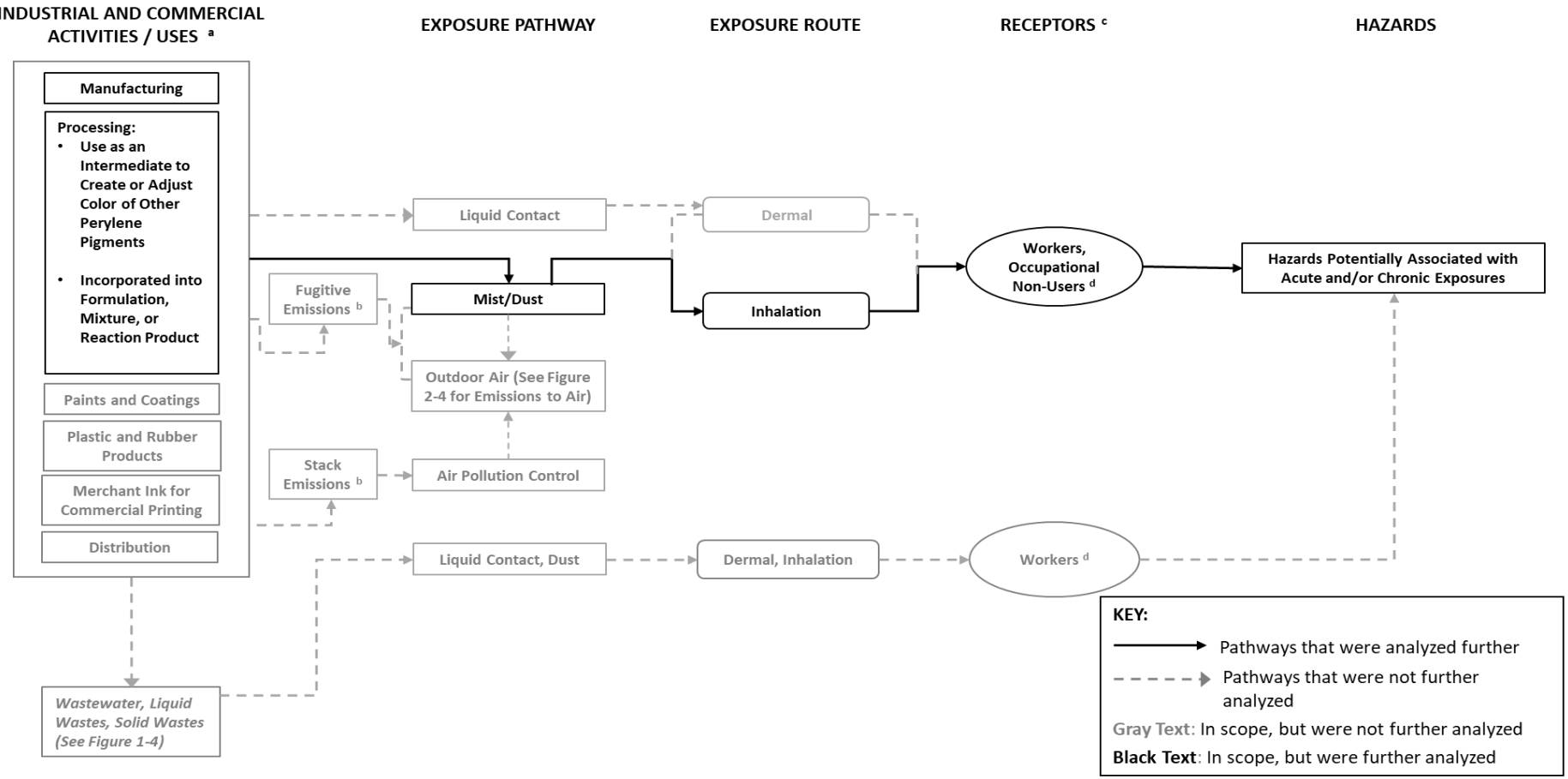


Figure 1-3. C.I. Pigment Violet 29 Final Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards. The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of C.I. Pigment Violet 29.

[a] Some products are used in both commercial and industrial applications.

[b] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[c] Receptors include PESS.

[d] When data and information are reasonably available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment (PPE) have on occupational exposure levels.

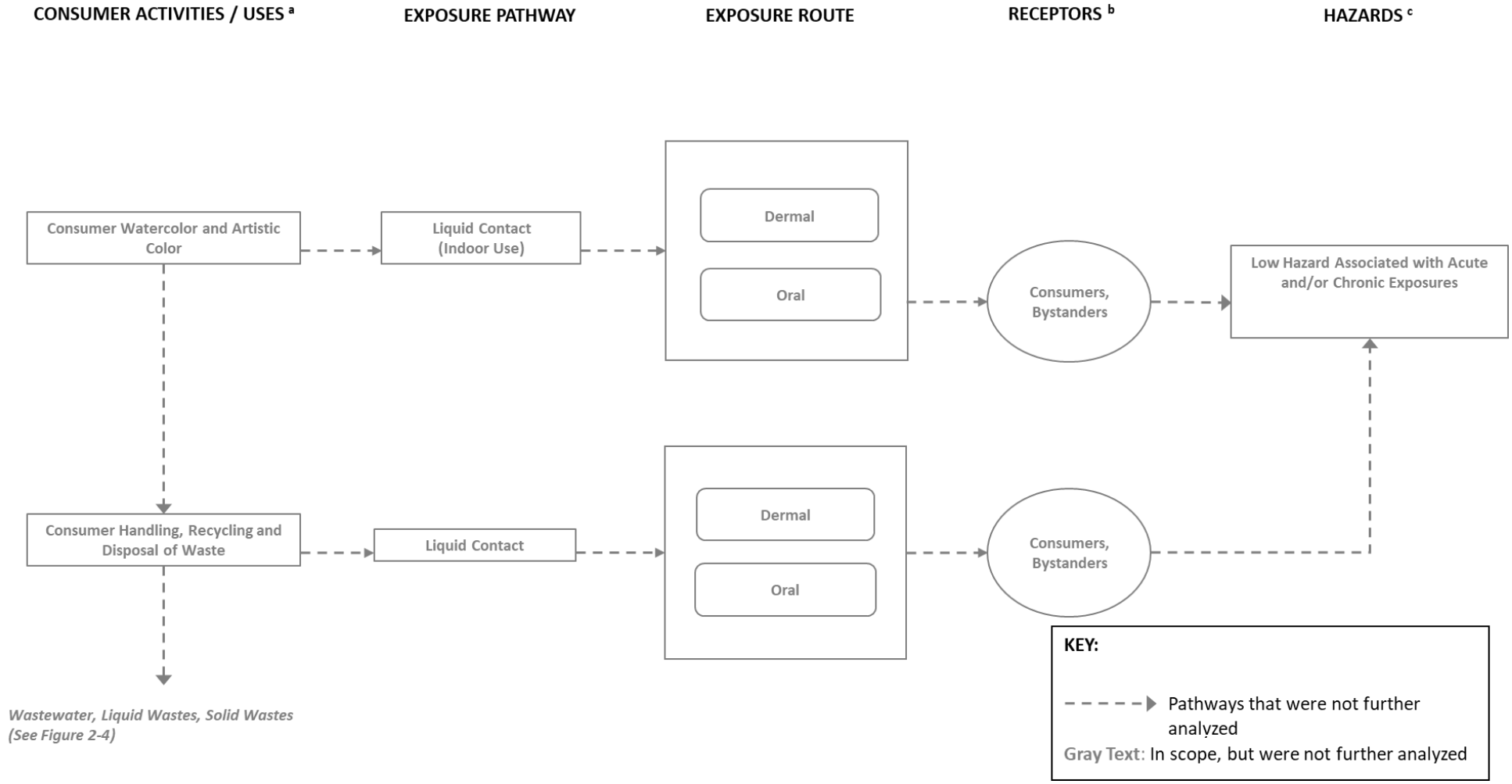


Figure 1-4. C.I. Pigment Violet 29 Final Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of C.I. Pigment Violet 29.

[a] Receptors include PESS.

[b] EPA has reviewed the full study reports to confirm low hazard conclusions.

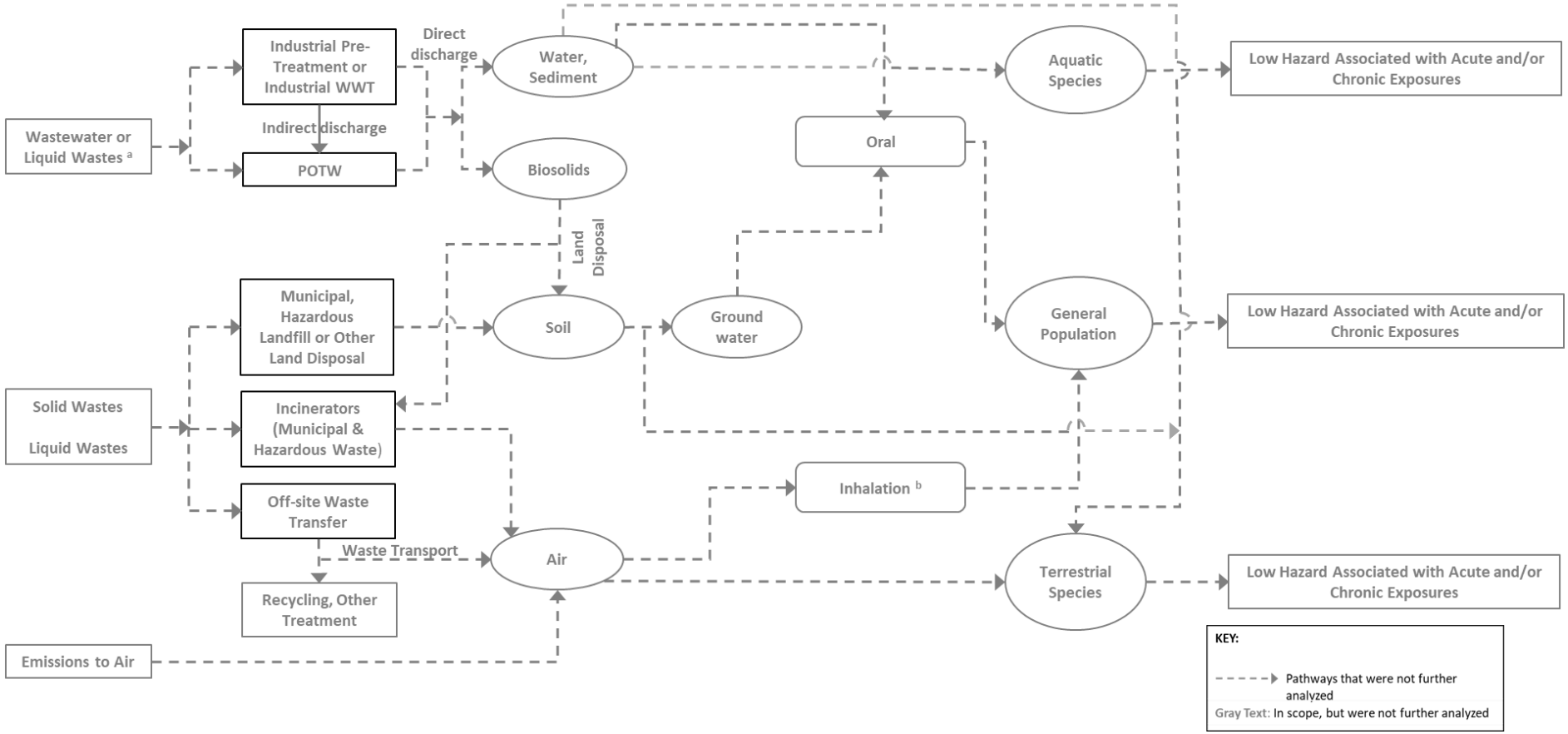


Figure 1-5. C.I. Pigment Violet 29 Final Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of C.I. Pigment Violet 29.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (*i.e.*, down the drain). Drinking water will undergo further treatment in drinking water treatment plant the effectiveness of the water treatment process on the removal of C.I. Pigment Violet 29 is unknown. Groundwater may also be a source of drinking water.

[b] Presence of mist to the environment is not expected.

[c] Receptors include PESS.

[d] EPA has reviewed the full study reports to confirm preliminary low hazard conclusions.

1.5 Systematic Review

TSCA requires EPA to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and base decisions under TSCA Section 6 on the weight of the scientific evidence. Within the TSCA risk evaluation context, the weight of the scientific evidence is defined as "*a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance*" (40 C.F.R. 702.33).

To meet the TSCA Section 26(h) science standards, EPA used the TSCA systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). The process complements the risk evaluation process in that the data collection, data evaluation and data integration stages of the systematic review process are used to develop the exposure and hazard assessments based on reasonably available information. EPA defines "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation (40 CFR 702.33).

EPA is implementing systematic review methods and approaches within the regulatory context of the amended TSCA. Although EPA adopted as many best practices as practicable from the systematic review community, EPA modified the process to ensure that the identification, screening, evaluation and integration of data and information can support timely regulatory decision making under the timelines of the statute.

1.5.1 Data and Information Collection

EPA planned and conducted a comprehensive literature search based on key words related to the different discipline-specific evidence supporting the risk evaluation (*e.g.*, environmental fate and transport; environmental releases and occupational exposure; exposure to general population, consumers and environmental exposure; and environmental and human health hazard). EPA then developed and applied inclusion and exclusion criteria during the title/abstract screening to identify information potentially relevant for the risk evaluation process. The literature and screening strategy as specifically applied to C.I. Pigment Violet 29 is described in S*trategy for conducting literature searches for Pigment Violet 29 (PV29): Supplemental document to the TSCA scope document. CASRN: 81-33-4* (U.S. EPA, 2017c) and the results of the title and abstract screening process were published in *Pigment Violet 29 (CASRN: 81-33-4) bibliography: Supplemental file for the TSCA scope document* (U.S. EPA, 2017a).

In addition to the literature search strategy, EPA used existing chemical assessments completed by other organizations to quickly identify relevant key and supporting information as a pragmatic approach to expedite the quality evaluation of the data sources, but many of those data sources were already captured in the comprehensive literature as explained above. In the case of C.I. Pigment Violet 29, EPA identified 24 studies through the ECHA (European Chemical Agency) Database entry for C.I. Pigment Violet 29 and a U.S. Food and Drug Administration (FDA) Food Additive Petition (FAP) 8B4626 (ECHA, 2017) (BASF, 2013). These 24 studies were conducted to determine the physical and chemical properties (n=6), environmental fate properties (n=2), human health hazards (n=17) and environmental hazards (n=3). EPA uploaded the 24 full study reports, which had initially been claimed in full as confidential business information (CBI) by the data owners, to the public docket in March 2019 (EPA-HQ-OPPT-2018-0604). Of these 24 studies, 15 study reports are completely released

without redactions, while nine study reports remain partially CBI with certain information redacted (*e.g.*, personal information relating to laboratory personnel, certain company-related information and, in one instance, individual test animal data tables are redacted). A full list of the studies and their redaction status can be found in the docket for C.I. Pigment Violet 29 (EPA-HQ-OPPT-2018-0604-0021).

Several references that were obtained by EPA and utilized in the draft risk evaluation were not initially subjected to a data quality evaluation because it was determined at the time that the data quality evaluation framework outlined in the *Application of Systematic Review in TSCA Risk Evaluations* was not applicable to these types of references (U.S. EPA, 2018a). This included physical and chemical property information (describing vapor pressure and density), as well as exposure and engineering information that was obtained through correspondences with industry considered to be on-topic and used to inform the likelihood of exposure. In the revised draft risk evaluation, EPA reviewed these references for data quality and the information has been made publicly available in the docket as a supplemental file concurrently with the release of the revised draft risk evaluation (U.S. EPA, 2020a). The results of the data quality evaluation of this information can be found in the supplemental file *Systematic Review Supplemental File: Data Quality Evaluation for Release and Occupational Exposure* and "*Systematic Review Supplemental File: Data Quality Evaluation of Physical and Chemical Property Studies* (U.S. EPA, 2020b);(U.S. EPA, 2020f)."

Additionally, EPA utilized its data gathering authorities for this chemical substance and a TSCA Section 4(a)(2) Test Order for C.I. Pigment Violet 29 was issued in February 2020 (EPA-HQ-OPPT-2020-0070). The Test Order required all manufacturers (including importers) to develop and submit solubility and occupational worker inhalation exposure information on C.I. Pigment Violet 29. The need for the Test Order was based on uncertainties identified in the reasonably available information by EPA and members of the Science Advisory Committee on Chemicals (SACC). The goal of the Test Order was to obtain additional information to decrease uncertainty in this risk evaluation. The sole U.S. manufacturer, Sun Chemical Corporation, developed the information and the known importer, BASF Corporation, claimed an exemption on the basis that the company would reimburse Sun Chemical Corporation for developing the information.

The Test Order required three tests: water solubility (OECD 105); octanol solubility (OECD 105); and the measurement of respirable particles in the Sun Chemical Corporation workplace according to NIOSH 0600. All three tests have been conducted and final reports submitted to EPA in June and July of 2020 and have been reviewed for data quality. More details and copies of the study reports can be found in the TSCA Section 4 Test Order docket (EPA-HQ-OPPT-2020-0070).

Figure 1-6 through Figure 1-10 depict literature flow diagrams illustrating the results of this process for each scientific discipline-specific evidence stream supporting the risk evaluation. Each diagram provides the total number of references at the start of each systematic review stage (*i.e.*, data search, data screening, data evaluation, data extraction/data integration) and those references excluded based on criteria guiding the screening and data quality evaluation decisions. Data sources identified as relevant to physical and chemical properties were not included in this literature flow diagram. The data quality evaluation of physical and chemical properties studies can be found in the supplemental document, *Data Quality Evaluation of Physical and Chemical Properties Studies* (U.S. EPA, 2020f), and the extracted data are presented in Table 1-1.

EPA made the decision to bypass the data screening step for data sources that were highly relevant to the risk evaluation as described above. These data sources are depicted as "key/supporting data

sources" in the literature flow diagrams. Note that the number of "key/supporting data sources" were excluded from the total count during the data screening stage and added, for the most part, to the data evaluation stage depending on the discipline-specific evidence. The number of publications considered in each step of the systematic review of C.I. Pigment Violet 29 for environmental fate and transport literature is summarized in Figure 1-6.

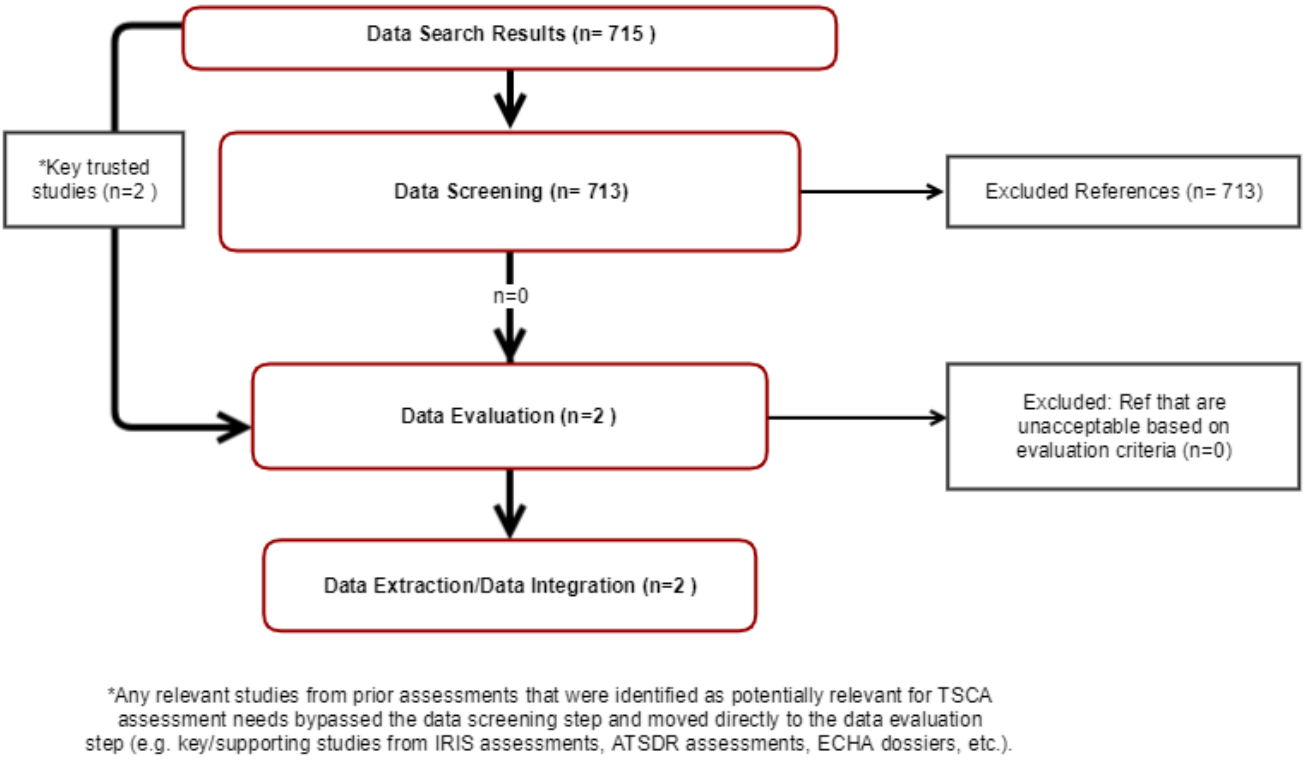


Figure 1-6. Literature Flow Diagram for Environmental Fate and Transport Data Sources for C.I. Pigment Violet 29

Literature search results for the environmental fate and transport of C.I. Pigment Violet 29 yielded 715 studies. This included two key and supporting studies initially identified in ECHA in summary format and then received in full study format by EPA. These two key studies entered data evaluation and were moved into data extraction and integration. Data quality evaluation was also carried out for the EPI Suite™ modeling program used to predict physical and chemical properties and environmental fate of C.I. Pigment Violet 29. The data quality evaluation results for the releases and occupational exposure data is available in the document titled *Revised Draft Risk Evaluation for C.I. Pigment Violet 29, Systematic Review Supplemental File: Data Quality Evaluation of Environmental Fate and Transport Studies* (U.S. EPA, 2020c).

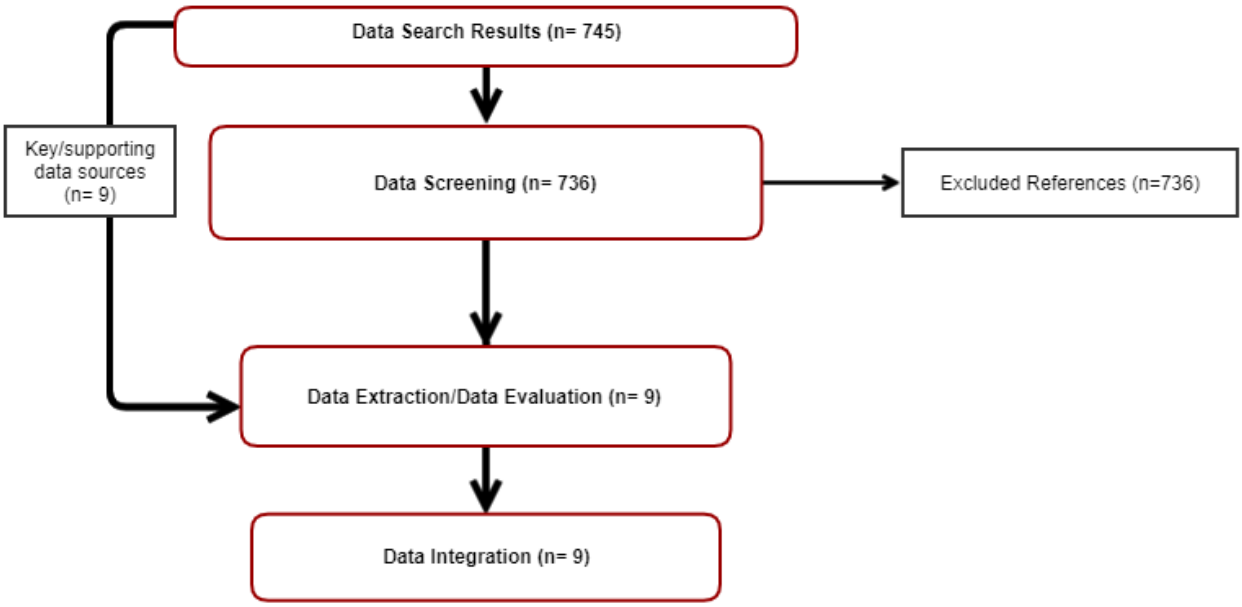


Figure 1-7. Releases and Occupational Exposures Literature Flow Diagram for C.I. Pigment Violet 29

Literature search results for environmental release and occupational exposure yielded 745 data sources. Of these data sources, nine were determined to be relevant for the risk evaluation. These nine information sources consisted of information EPA received directly from the manufacturing stakeholders describing the releases to the environment (1 description of the surface water releases), occupational exposure (2 workplace dust estimates received voluntarily and one workplace dust monitoring study generated in response to the TSCA Section 4 Test Order) and facility information (4 Safety Data Sheets) for the U.S. manufacturing stakeholders of C.I. Pigment Violet 29. These nine were considered key data sources and were entered directly into the data extraction/evaluation phase. This information was evaluated and extracted in accordance with Appendix D (*Data Quality Criteria for Occupational Exposure and Release Data*) of the *Application of Systematic Review for TSCA Risk Evaluations* document (U.S. EPA, 2018a). Of the nine sources from which data were extracted and evaluated, all were rated medium or high quality, and the results were integrated into the occupational exposure and environmental releases sections of the risk evaluation. The data quality evaluation results for the releases and occupational exposure data is available in the document titled *Systematic Review Supplemental File: Data Quality Evaluation of Environmental Release and Occupational Exposure Data* (U.S. EPA, 2020b).

The number of publications considered in each step of the systematic review of C.I. Pigment Violet 29 for non-occupational exposure literature is summarized in Figure 1-8.

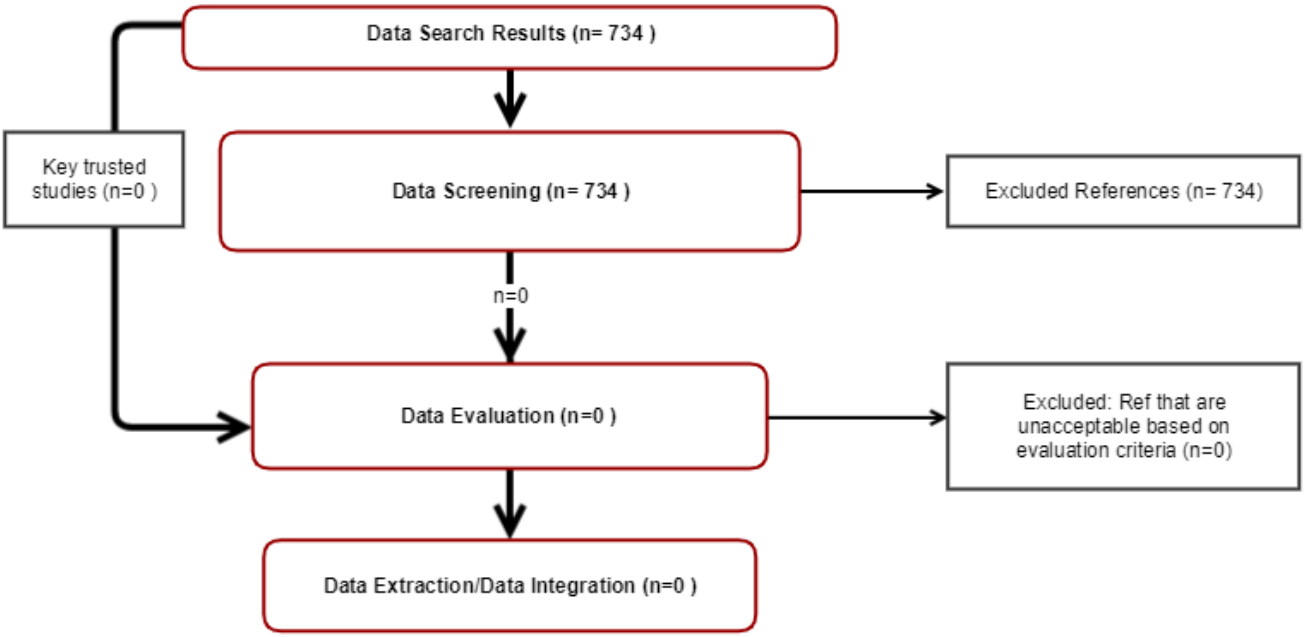


Figure 1-8. Literature Flow Diagram for General Population, Consumer and Environmental Exposure Data Sources for C.I. Pigment Violet 29

EPA conducted a literature search to determine relevant data sources for assessing exposures for C.I. Pigment Violet 29 within the scope of the risk evaluation. This search identified 734 data sources. Of these, 734 were excluded during the screening of the title, abstract, and/or full text, indicating no open literature sources were identified that were relevant to C.I. Pigment Violet 29. The information discussed in the environmental exposure section related to environmental releases was evaluated for data quality as part of the Releases and Occupational Exposures data quality evaluation criteria.

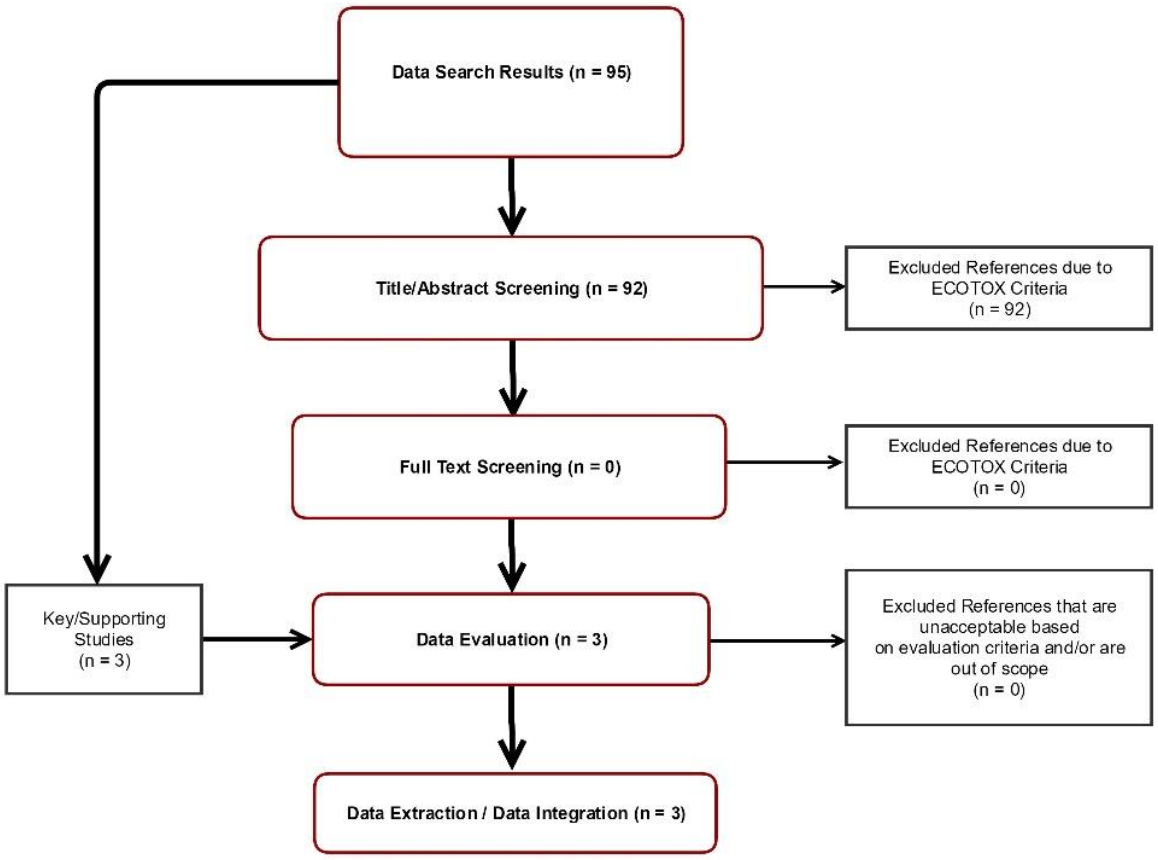


Figure 1-9. Key/Supporting Sources for Environmental Hazards for C.I. Pigment Violet 29
The environmental hazard data sources were identified through literature searches and screening strategies using the ECOTOX Standard Operating Procedures. For studies determined to be on-topic after title and abstract screening, EPA conducted a full text screening to further exclude references that were not relevant to the risk evaluation. Screening decisions were made based on eligibility criteria as documented in the ECOTOX User Guide (U.S. EPA, 2018b). Additional details can be found in the *Strategy for Conducting Literature Searches for Pigment Violet (PV29): Supplemental Document to the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725). The "Key/Supporting Studies" box represents data sources typically cited in existing assessments and considered highly relevant for the TSCA risk evaluation because they were used as key and supporting information by regulatory and non-regulatory organizations to support their chemical hazard and risk assessments. These citations were found independently from the ECOTOX process. These studies bypassed the data screening step and moved directly to the data evaluation step. The data quality evaluation results for the releases and occupational exposure data is available in the document titled "*Systematic Review Supplemental File: Data Quality Evaluation of Environmental Hazard Studies*"(U.S. EPA, 2020d).

The number of publications considered in each step of the systematic review of C.I. Pigment Violet 29 for human health hazard literature is summarized in Figure 1-10.

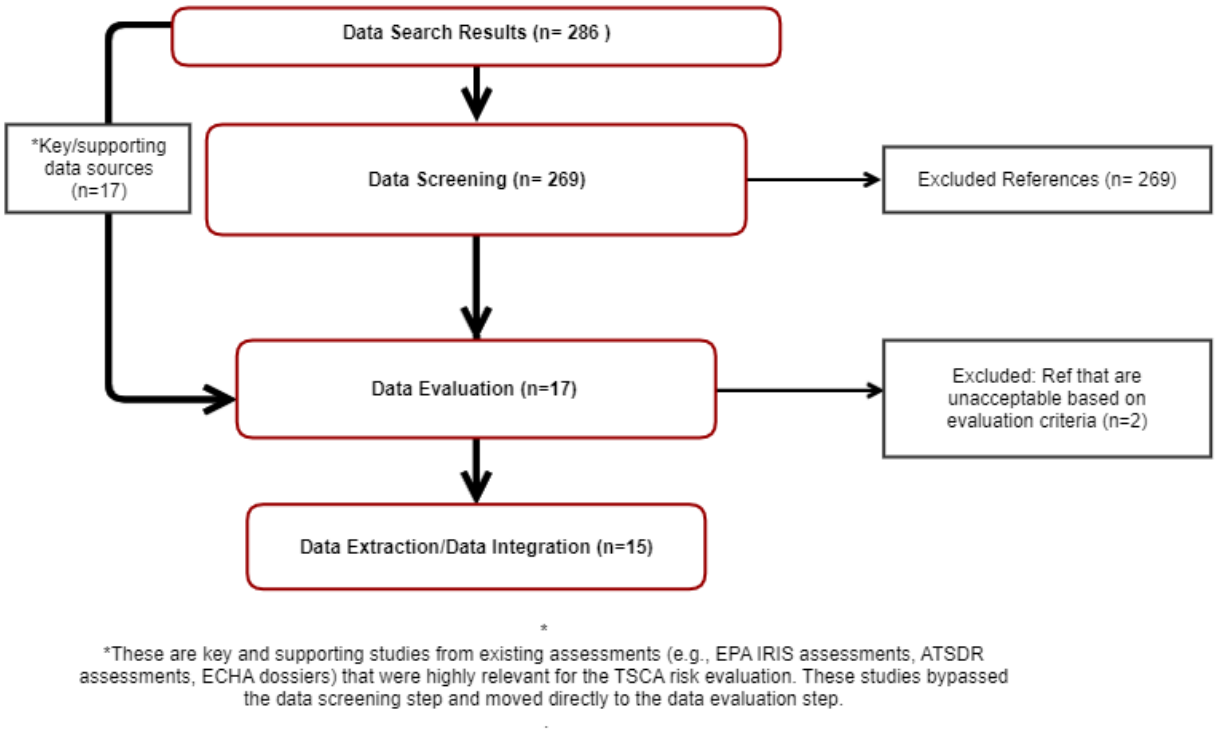


Figure 1-10. Literature Flow Diagram for Human Health Hazard Data Sources for C.I. Pigment Violet 29

Literature search results for human health hazard of C.I. Pigment Violet 29 yielded 286 studies. This included 17 key and supporting studies initially identified in ECHA in summary format and then received in full study format by EPA. Of the 269 remaining studies screened for relevance, all 269 were excluded as off topic. The 17 key/supporting studies were evaluated for data quality. Two studies were deemed unacceptable based on the evaluation criteria of human health hazard, and the remaining 15 studies were carried forward to data extraction/data integration. The data quality evaluation results for the releases and occupational exposure data is available in the document titled "*Systematic Review Supplemental File: Data Quality Evaluation of Human Health Hazard Studies*"(U.S. EPA, 2020e).

1.5.2 Data Evaluation

During the data evaluation stage, EPA typically assesses the quality of the methods and reporting of results of the individual studies identified during problem formulation using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). EPA evaluated the quality of the C.I. Pigment Violet 29 study reports to confirm the conclusions of the robust summaries available from the ECHA database. The results of these data quality evaluations are summarized in Section 1.1 (Physical and Chemical Properties), Section 2.1 (Fate and Transport) and Section 3 (Hazards (Effects)). Appendices C-D also present the overall confidence ratings for each study, and the *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document* (EPA-HQ-OPPT-2018-0604-0040) presents details of the data evaluations for each study, including scores for each metric and the overall study score.

In December 2018, EPA received public comments challenging the confidential treatment of the 24 study reports and the overall quality determinations of two acute inhalation toxicity studies (BASF, 1978b, 1975a). In response to these comments, EPA re-evaluated the study reports and updated the data evaluation scoring sheets based on public comments. The public input was valuable in that it led to further examination of the systematic review process which revealed both process and technical inconsistencies that led EPA to implement procedures for further refinement. For instance, EPA has made improvements in its quality assurance procedures and training of reviewers. EPA has also corrected technical errors in systematic review data evaluation scoring sheets of some specific studies where toxicological expertise was needed to evaluate specific criteria. The Updated Systematic Review (SR) Supplemental File (available in the docket for C.I. Pigment Violet 29 (EPA-HQ-OPPT-2018-0604-0040)) provides a more transparent approach than previously provided by including the metric scores, weighting, reviewers' comments and the study's overall score.

EPA initially released the SR Supplemental File without the EPA reviewers' comments due to concerns that the comments might contain information claimed CBI. The Updated SR Supplemental File now makes publicly available the EPA reviewers' comments related to the data quality evaluation of the physical and chemical characteristics, environmental fate, environmental hazard and human health studies. EPA also downgraded the confidence of two acute oral toxicity studies and two eye irritation studies from *High* to *Medium* confidence. Similarly, two intraperitoneal studies were downgraded from *High* to *Low* confidence. EPA determined that two acute inhalation studies (BASF, 1978b, 1975a) were *Unacceptable* primarily due to deficiencies in the exposure inhalation methods. Specifically, the studies were not designed for non-volatile substances, such as aerosols of respirable particles as would be expected for C.I. Pigment Violet 29. EPA determined that the Log K_{OW} determination described in the physical and chemical properties study report (BASF, 2013) was *Unacceptable* as a result of methodology which did not consider the poor solubility in octanol and in water of C.I. Pigment Violet 29, and this conclusion remains unchanged. However, the physical and chemical properties study report (BASF, 2013) describing the melting point was considered a separate study report by EPA where a quantification of the melting point was reviewed separately and found to be of *High* confidence. As a result, a total of three studies reviewed for C.I. Pigment Violet 29 were determined to be unacceptable- two acute inhalation studies (BASF, 1978b, 1975a) and a Log K_{ow} study (BASF, 2013).

All of these changes are reflected in the Updated SR Supplemental File (EPA-HQ-OPPT-2018-0604-0040) as well as the systematic review supplemental files released with this final risk evaluation. This final risk evaluation reflects the updated outcome of the data quality re-evaluation as well as any other changes resulting from the peer review process and additional public comment.

The data received from the TSCA Section 4(a)(2) Test Order for C.I. Pigment Violet 29 has been reviewed through the systematic review process. The solubility reports were determined to be high quality, according to the data quality evaluation results available in the docket in a supplemental file entitled *Systematic Review Supplemental File: Data Quality Evaluation of Physical and Chemical Property Studies* (U.S. EPA, 2020f). The occupational inhalation exposure report did not meet the terms set out in the approved study plan (EPA-HQ-OPPT-2020-0070-0006) but was given a high quality rating following a review for data quality. Despite this rating, EPA maintains that there are several critical deficiencies in the study that result in a determination of low confidence in the results. These deficiencies are explained in an EPA review of the monitoring study made available in the TSCA Section 4 Test Order docket (EPA-HQ-OPPT-2020-0070). As a result of the discrepancy between the data quality evaluation results for the study and EPA's confidence in the results, EPA will use this as an opportunity to update the data quality evaluation review criteria for occupational exposure studies. Given the uncertainties identified in the results of the monitoring study, the

occupational inhalation exposure risk characterization used several conservative assumptions when applying the results reported in this monitoring study.

1.5.3 Data Integration

During data integration and analysis, EPA considers quality, consistency, relevancy, coherence and biological plausibility to make final conclusions regarding the weight of the scientific evidence. As stated in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a), data integration involves transparently discussing the significant issues, strengths, and limitations as well as the uncertainties of the reasonably available information and the major points of interpretation (U.S. EPA, 2018d).

EPA analyzed and synthesized available lines of evidence regarding C.I. Pigment Violet 29's physical chemical properties, environmental fate and transport properties, potential for exposure and hazard. EPA also analyzed and synthesized available evidence for PESS. The sections below describe EPA's analysis of the relevant lines of evidence that were found acceptable for the risk evaluation based on the data quality reviews.

2 EXPOSURES

2.1 Fate and Transport

Table 2-1 summarizes the environmental fate characteristics of C.I. Pigment Violet 29. EPA used EPI Suite™ estimations and reasonably available fate data for C.I. Pigment Violet 29 to characterize the environmental fate and transport of the chemical.

Table 2-1 Environmental Fate Characteristics of C.I. Pigment Violet 29

Property or Endpoint	Value [a]	References
Indirect photodegradation	7.0 hours (estimated)	(U.S. EPA, 2012b)
Hydrolysis half-life	Stable (estimated)	(U.S. EPA, 2012b)
Biodegradation	Low biodegradability: 0-10 percent degradation in 28 days (OECD 301F)	(ECHA, 2017; BASF, 1999a)
Bioconcentration factor (BCF)	Low bioconcentration: BCF=140 (estimated) [b]	(U.S. EPA, 2012b)
Bioaccumulation factor (BAF)	BAF = 50 (estimated) [b]	(U.S. EPA, 2012b)
Soil organic carbon:water partition coefficient (Log K_{OC})	N/A [b]	

[a] Estimated unless otherwise noted.
[b] Due to the low solubility of C.I. Pigment Violet 29, the chemical was determined to be outside of the predictive methodology used by EPI Suite™ to predict LogKoc.

C.I. Pigment Violet 29 is highly persistent and has low bioaccumulation potential. Due to its physical properties, it is expected to bind strongly to soil organic matter, and migration through soil to groundwater is likely to be minimal. If released to water, hydrolysis is expected to be negligible. Based on its estimated Henry's Law Constant, C.I. Pigment Violet 29 is not expected to volatilize from water. If released to air, it is unlikely to undergo direct photolysis and is expected to be in the solid phase (*i.e.*, particulates). Based on its estimated indirect photodegradation half-life of 7 hours, it is considered to degrade slowly to moderately by reacting with atmospheric hydroxyl radicals.

EPA received the full study reports for the following environmental fate studies:

- OECD Guideline 301 F: Biodegradability: Manometric Respirometry Test
- OECD Guideline 209: Activated Sludge, Respiration Inhibition Test

The results of the OECD Guideline 301 F: Biodegradability: Manometric Respirometry Test and the activated sludge study are presented in Appendix C. EPA concluded that C.I. Pigment Violet 29 is poorly biodegradable under normal environmental conditions. The activated sludge test reported that no inhibition of respiration was observed following 30 minutes of exposure, and the EC 20 was determined to be >100 mg/L. The Agency evaluated two full study reports as well as the EPI Suite™ modeling program according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and assigned these studies high confidence scores based on the evaluation metrics for environmental fate studies. The results of these evaluations can be found in the supplemental file released with this revised draft risk evaluation entitled *Systematic Review Supplemental File: Data Quality Evaluation of Environmental Fate and Transport Studies* (U.S. EPA, 2020c).

Based on the solubility data submitted with the TSCA Section 4 Test Order, the concentration of C.I. Pigment Violet 29 dissolved in water or octanol was below the analytical quantitation limit of 0.003 mg/L in every sample tested (Nicolaou, 2020). These studies confirm that C.I. Pigment Violet 29 is an insoluble particulate substance; that there is no expectation that C.I. Pigment Violet 29 will be taken up by fat solubility; and confirms that C.I. Pigment Violet 29 is not expected to bioaccumulate. Due to the low solubility in water and octanol, the Log K_{ow} could not be included in the risk evaluation process for C.I. Pigment Violet 29. In addition, fugacity modeling is not relevant for C.I. Pigment Violet 29 because particulate substances like C.I. Pigment Violet 29 do not dissolve in water, air, or octanol like most organic substances. Instead, particulate substances will adsorb to solid surfaces and undergo particle transport rather than partition between air, water, and organic matter. It is also important to note that EPI Suite™ QSAR software does not predict chemical properties for substances with low solubility such as C.I. Pigment Violet 29. Therefore, there is low confidence in the results of EPI Suite™ modeling.

2.2 Environmental Releases and Exposure

EPA determined that 90 percent of the production volume is used on site as a chemical intermediate concurrently with the manufacturing process, so potential releases from this processing activity are subject to the same engineering controls and releases as described for the manufacture of C.I. Pigment Violet 29. The production of C.I. Pigment Violet 29 is the starting point for the synthesis of other perylene pigments, and this conversion to other pigments occurs at the manufacturing facility and C.I. Pigment Violet 29 is converted to other chemical substances. As a result, only 10 percent of the total production volume (~60,000 lbs) is used in a way that could result in downstream environmental releases and exposures (U.S. EPA, 2020a, 2018c). The remaining 90% of the chemical is consumed at the manufacturing facility as a site limited intermediate, where the chemical is consumed in a reaction to create other chemical substances, resulting in an extremely limited potential for releases of C.I. Pigment Violet 29 as a result of this process. The other 10% of the production volume is used in commercial products, specifically, paint and coating products and plastic and rubber products. The consumer use in acrylic paints and watercolors is not included in the downstream supply chain of the U.S. manufacturer, but believed to be imported as articles (CPMA, 2017b). C.I. Pigment Violet 29 is manufactured as a solid and in solution and has a low vapor pressure (<0.000001 hPa at 20˚C) (U.S. EPA, 2016, 2012a). It is shipped to paint formulators and plastic compounders as a dry powder.

Physical and chemical properties (see Table 1-1) and fate endpoints (see Table 2-1), as well as engineering controls limiting manufacturing (and processing as an intermediate) releases (as discussed below), are expected to result in limited exposure to air, water and sediment, groundwater via biosolids, and landfill leaching. EPA concludes that approximately 1-2 percent of the volume is potentially released to air, landfill and surface water. Any potential surface water fraction is sent to an on-site waste water treatment during manufacturing (U.S. EPA, 2020a, 2018c). Sources for environmental release include liquid solid separation, residues left in equipment, and dust emission.

Reasonably available information indicates that airborne exposures from both incineration and fugitive releases from manufacturing and/or processing are expected to be limited due to the low vapor pressure and volatility of C.I. Pigment Violet 29 (Henry's Law Constant $<1x10^{-10}$ atm-m^3/mol (U.S. EPA, 2017b)) and waste handling practices. Air releases directly to the environment from manufacturing are expected to be limited based on the use of dust handling systems by the manufacturer (U.S. EPA, 2020a).

The remainder (1-2 percent of the volume) of C.I. Pigment Violet 29 may enter the surface water via either direct discharge to water or discharge after treatment at POTWs as a component of total

suspended solids (TSS) from the sole U.S. manufacturer and from downstream processors and users of C.I. Pigment Violet 29. Due to the low water solubility, solid physical state and high sorption of C.I. Pigment Violet 29, the vast majority of this chemical partitions to particulates and sediment where it is captured as sludge via an on-site above ground biological wastewater treatment system. This sludge is subsequently disposed of via incineration or landfill disposal (U.S. EPA, 2020a). Although there are no C.I. Pigment Violet 29-specific discharge limitations in National Pollutant Discharge Elimination System (NPDES) permits, discharges of C.I. Pigment Violet 29 could be subject to compliance with a NPDES discharge permit as a component of discharge limitations on TSS, thereby limiting potential discharges to water. Ultimately, of the NPDES-permitted TSS discharges for this sole domestic manufacturing facility, it is estimated that 0.8 lb/day of C.I. Pigment Violet 29 is being discharged (<0.1 percent of produced C.I. Pigment Violet 29) (U.S. EPA, 2020a).

As indicated above, the sole U.S. manufacturer of C.I. Pigment Violet 29 sends its non-hazardous wastewater treatment residuals (sludge) to the Oak Ridge Landfill in Dorchester County or the Berkeley County Landfill. Both landfills are Resource Conservation and Recovery Act (RCRA) Subtitle D lined landfills permitted under the authority of South Carolina Regulation Number 61-107.19. While permitted and managed by the individual states, sites such as municipal solid waste landfills (MSWLFs) are required by federal regulations to implement many of the same requirements as Subtitle C landfills. MSWLFs must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSWLFs are also subject to closure and post-closure care requirements, as well as providing financial assurance for funding of any needed corrective actions. Industrial wastes are sent to licensed industrial waste handlers where destruction removal efficiencies for incinerators are expected to be >99 percent (CPMA, 2017b). In addition to design standards for Subtitle-D lined landfills, sorption to particulates and biosolids for C.I. Pigment Violet 29 are expected to be strong, and water solubility is low, so leaching of C.I. Pigment Violet 29 from landfills is expected to be negligible.

The information from the manufacturer was sufficient to adequately characterize releases from the manufacturing and 90% of the total processed volume, as the use as an intermediate in the creation of other pigments occurs concurrently with the manufacturing of C.I. Pigment Violet 29 and is subjected to the same engineering controls, as described in the *Supplemental File: Information Received from Manufacturing Stakeholders*(U.S. EPA, 2020c). Direct environmental releases are possible for the downstream processors and users who will handle 10% of the volume. Per site volumes handled annually by downstream users processing C.I. Pigment Violet 29 into formulations of paints and coatings and plastic and rubber products are expected to be limited (*i.e.*, less than 5 percent of the total production volume handled at each site); therefore, it is expected that potential C.I. Pigment Violet 29 discharges per site to water, sediment, infiltration to groundwater via land application of biosolids, landfill leaching, and air emissions will be limited.

2.3 Human Exposure Assessment

2.3.1 Occupational Exposures

EPA assessed occupational exposures following the analysis plan published in the June 2017 problem formulation (U.S. EPA, 2018c). Specific assessment methodology is described in further detail below for each type of assessment. Table 2-2 presents a crosswalk of the industrial and commercial conditions of use and the section of the risk evaluation in which occupational exposure for that use is assessed.

Table 2-2. Crosswalk of Subcategories of Use Listed in the Problem Formulation Document to Occupational Conditions of Use Assessed in the Risk Evaluation

Life Cycle Stage	Category	Assessed Condition of Use
Manufacture	Domestic manufacture	Section 1.4.1.1
	Import	
Processing	Intermediate in the creation or adjustment of color of other perylene pigments	Section 1.4.1.2
	Incorporation into formulation, mixture or reaction products in paints and coatings	
	Incorporation into formulation, mixture or reaction products in plastic and rubber products	
	Recycling	
Distribution in commerce	Distribution	Not assessed as a separate operation; exposures/releases from distribution are considered part of each condition of use.
Industrial/Commercial uses	Plastic and rubber products – Automobile plastics and industrial carpeting	Section 1.4.1.3
	Paints and coatings – Coatings, basecoats and automobile paints and coatings	
	Merchant ink for commercial printing	
Disposal	Disposal of solid and liquid wastes	Section 1.4.1.5

2.3.1.1 Number of Sites and Workers

Where available, EPA determined the number of sites and workers using data reported under the Chemical Data Reporting (CDR) Rule. The CDR Rule, issued under TSCA, requires manufacturers and importers to report certain information on the chemicals they produce domestically or import into the United States. For the 2016 CDR cycle, manufacturers and importers of chemicals listed on the TSCA inventory were required to report if their production volume exceeded 25,000 lbs at a single site during any of the calendar years 2012, 2013, 2014 or 2015. According to the Inhalation monitoring study provided by Sun Chemical Corporation, there are 22 workers directly handling C.I. Pigment Violet 29 and 56 ONUs who might be exposed to C.I. Pigment Violet 29 during manufacturing (The E.I. Group Inc., 2020).

EPA determined the number of workers using the related SOC codes from BLS analysis that are associated with primary NAICS code 325211 for plastics material and resin manufacturing and NAICS code 325510 for paint and coating manufacturing. The method for estimating the number of workers from these data is detailed in Appendix I. The resulting number of workers with potential direct exposure at the four paint and coating manufacturing sites combined is 56 (14 per site) and the total number of ONUs is 20 (5 per site). The number of workers at the plastic manufacturing site is 27 and the number of ONUs is 12.

2.3.1.2 Inhalation Exposures Approach and Methodology

To assess inhalation exposure, EPA reviewed reasonably available exposure monitoring data and mapped them to specific conditions of use. Monitoring data used in the occupational exposure assessment include workplace monitoring data from the manufacture of C.I. Pigment Violet 29. EPA assumes workers are those who directly handle C.I. Pigment Violet 29 at the facility. ONUs are workers who do not directly handle C.I. Pigment Violet 29 but perform work in an area where the chemical is present.

For exposure assessment, where reasonably available, personal breathing zone (PBZ) monitoring data were used to determine the exposure concentration. EPA evaluated two sets of monitoring data plus one measurement using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The data were then integrated based upon the strength of the evidence. All occupational inhalation exposure monitoring data integrated into this risk evaluation have either a high (<1.7 to >1) or medium (<2.3 to >1.7) confidence rating, as shown in Table 2-3. The data quality evaluation for the engineering and exposure data has been released with this final risk evaluation as a supplemental file entitled, *Systematic Review Supplemental File: Data Quality Evaluation of Environmental Release and Occupational Exposure Data* (U.S. EPA, 2020b).

Table 2-3. Data Evaluation of Sources Containing Occupational Exposure Data for Sun Chemical Corporation (Manufacturing and Use as a Chemical Intermediate)

Source Reference	Data Type	Confidence Rating	Conditions of Use
(The E.I. Group Inc., 2020) (HERO 6656714)	PBZ Monitoring	High (1.4)[A]	Manufacture: Domestic manufacture and import; Processing; Industrial/Commercial Uses
(U.S. EPA, 2020c) Pgs. 15-17 (HERO 6656737)	PBZ Monitoring	High (1.3)	Manufacture: Domestic Manufacture and import; Processing; Industrial/Commercial Uses
(Mott, RC., 2017a) (see (U.S. EPA, 2020c) Pg.3) (HERO 4081806)	Personal Communication	Medium (1.9)	Manufacture: Domestic Manufacture and import; Processing; Industrial/Commercial Uses

[A] There are 7 individual metrics. The overall rating is based on the following scale: High: greater than 1.7 to 1; Medium: greater than 2.3 to 1.7; Low: 3 to 2.3. PBZ = personal breathing zone.

In the draft risk evaluation, EPA used workplace dust exposure information provided by the sole manufacturer of C.I. Pigment Violet 29, Sun Chemical Corporation. Sun Chemical Corporation reported an approximate maximum workplace air concentration of 0.5 mg/m^3 would be expected over a 12 hour shift (Mott, 2017) at Sun's Bushy Park facility in South Carolina. EPA requested additional details about workplace air monitoring exposures based on SACC recommendations and later required occupational inhalation exposure air monitoring more specific to C.I. Pigment Violet 29 in the TSCA Section 4(a)(2) Test Order for C.I. Pigment Violet 29.

Two workplace air monitoring datasets were received. The first came in an email from Sun Chemical Corporation on October 25, 2019, in response to a request for clarification following the SACC meeting (Sun Chemicals, 2020) (available in (U.S. EPA, 2020c). The results of this study are reproduced below in Table 2-4. These measurements were collected from the employees' personal breathing zone (PBZ) and were analyzed for the total dust utilizing NIOSH 0500 method. Worker activities performed during the personal sampling included charging big bags to the blenders, packing out and other various solids handling.

Table 2-4 Total Dust Monitoring Results for Individual Operators at Sun Chemical Corporation Manufacturing Facility Reported in Enclosure 1 (EPA-HQ-OPPT-2018-0604)

Employee/Work Area	Sample ID	Air Volume (liter)	Total dust collected (mg)	Employee Exposure (mg/m^3)
Production Operator (B11)	14-0941902	175.5	0.21	1.2
Production Operator (B11)	14-0941898	266.5	0.11	0.4
Production Operator (C82)	14-0941899	852.6	0.57	0.67
Production Operator (B11)	14-0941900	826.8	0.47	0.57
Production Operator (C82)	14-0941904	854.1	0.19	0.22
Maximum (mg/m^3)		**1.2**		

To address critical uncertainties regarding the occupational exposure to workplace dust from the manufacture of C.I. Pigment Violet 29, EPA issued a TSCA Section 4(a)(2) Test order (signed on Feb 28, 2020) to compel the submission of a dust sampling study conducted according to National Institute for Safety and Health (NIOSH) 0600 test guideline. This study was identified as a critical data gap following the prior submission of particle size distribution data, which indicated that the mean weight diameter of the particles is 43 nanometers (nm), or 1000 times smaller than the particle size reported in the BASF study report upon which EPA had based its particle size estimate in the draft risk evaluation (BASF, 2013). This particle size data received from Sun Chemical are available in the supplemental file, *Revised draft Risk Evaluation for C.I. Pigment Violet 29, Systematic Review Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020c).

The second study, generated and submitted by Sun Chemical Corporation in response to the TSCA Section 4 Test Order is a respirable dust monitoring study submitted by Sun Chemical Corporation (The E.I. Group Inc., 2020). This study was reviewed, and EPA determined that the final report did not meet the terms of study plan set forth in the Test Order. This study plan and final report are available in the TSCA Section 4(a)(2) Test Order for C.I. Pigment Violet 29 docket (EPA-HQ-OPPT-2020-0070-0008). A review of the test order breathing zone study by EPA is provided as Appendix I. More information about the TSCA Section 4(a)(2) Test Order, as well as information about how to access the study reports, can be found on the TSCA Section 4 Test Order docket (EPA-HQ-OPPT-2020-0070).

The Sun Chemical Corporation respirable dust monitoring study provides respirable dust concentration for task-based samples collected during two production shifts of C.I. Pigment Violet 29 at the Sun Chemical Corporation Plant (The E.I. Group Inc., 2020). Workers at the Sun Chemical Corporation manufacturing site handle large volumes of C.I. Pigment Violet 29 at nearly 100 percent concentration. The employees described in the report worked directly with powdered C.I. Pigment Violet 29 as Operational Users (OUs) or were performing other work adjacent to a direct-handling activity as Operational Non-Users (ONUs). Monitoring data are grouped by individual employee exposure by work shift (day shift, night shift). The monitoring data are summarized in Table 2-5.

Table 2-5 Respirable Dust Monitoring Results for Individual Operators at Sun Chemical Corporation Manufacturing Facility Reported from June 2020 Report (The E.I. Group Inc., 2020)

Descriptions		Individual Samples			
Shift/ Operator Info	OU or ONU?	Sampled Minutes	Concentrations (Original Lab Results) (mg/m^3)	Concentrations used for determining average (mg/m^3)[1]	Average Conc. Monitored (mg/m^3)
Occupational Users (OUs) of C.I. Pigment Violet 29 – *SHIFT A*					
Operator #1 SEG 3 4/17/2020	OU	33 33	<0.75 <0.72	0.38 0.36	0.37
Operator #1 SEG 5 5/6/2020 (2nd date, diff. SEG)	OU	92 81 123	<0.27 <0.31 <0.21	0.14 0.16 0.11	0.13
Operator #5 SEG 4 5/5/2020	OU	40 29 31	<0.62 <0.86 <0.8	0.31 0.43 0.40	0.37
Operator #6 SEG 5 5/6/2020	OU	92 81 124	0.3 <0.31 **0.59**	0.30 0.16 0.59	0.38
Operator #7 SEG 1 5/26/2020	OU	23 25 28	<1.1 <1 <0.87	0.55 0.50 0.44	0.49
Operator #8 SEG 1 5/26/2020	OU	32 28 26	<0.77 <0.91 <0.96	0.39 0.46 0.48	0.44
Operator #11 SEG 2 5/26/2020	OU	35	<0.7	0.35	0.35
Occupational Users (OUs) of C.I. Pigment Violet 29 - *SHIFT B*					
Operator #9 SEG 1 5/26-27/2020	OU	28 33	<0.91 <0.77	0.46 0.39	0.42
Operator #10 SEG 1 5/26-27/2020	OU	39 27	<0.65 <0.95	0.33 0.48	0.39
Occupational Non-Users (ONUs) of C.I. Pigment Violet 29					
Operator #2 SEG 3 4/17/2020	ONU	39 40	<0.61 <0.59	0.31 0.30	0.30
Operator #3 SEG 3 4/17/2020	ONU	37 41	<0.67 <0.61	0.34 0.31	0.32
Operator #4 SEG 3 4/17/2020	ONU	34	<0.69	0.35	0.35
Operator #4	ONU	37	<0.92	0.46	0.46

Descriptions		Individual Samples			
SEG 5 5/6/2020 (2nd date, diff. SEG)					
Maximum Detected Concentration (ONU and OU)			0.59		
Average Concentration (OU)					0.37
Average Concentration (ONU)					0.36

[1] Values used for determining average respirable dust (mg/m^3) were calculated as the LOD/2 if the measurement was less than the limit of detection (LOD).

Using the information from the respirable dust monitoring study provided by Sun Chemical Corporation (The E.I. Group Inc., 2020), exposures were estimated for both workers directly handling C.I. Pigment Violet 29 and the workers who were performing other work adjacent to a direct-handling activity.

Strength, Limitations, and Uncertainties of the C.I. Pigment Violet 29 Inhalation Monitoring Information

Strengths:

The Sun Chemical Corporation respirable dust monitoring study describes employee C.I. Pigment Violet 29 handling activities for each of five similar exposure groups (SEG). Air samples were obtained during each task during which C.I. Pigment Violet 29 handling occurred. Industrial hygienists, supervised by a Certified Industrial Hygienist, monitored airborne respirable dust exposure to C.I. Pigment Violet 29 for OU employees and, when present in the SEG work area, for ONUs. On each shift during which air sampling was performed, the air sampling encompassed the entire time that C.I. Pigment Violet 29 was directly handled as part of a production task. An AIHA accredited laboratory analyzed the samples and the complete laboratory analytical report.

Limitations:

Although the Sun Chemical Corporation respirable dust monitoring study shows that respirable dust concentrations were well below the OSHA PEL, the short duration of the tasks involving C.I. Pigment Violet 29 meant that only modest volumes of air were collected during the task-based sampling periods, which in most cases was insufficient to reach the necessary air volume to reach the limit of quantitation of the sampling devices. Sampling larger volumes of air would have permitted the laboratory to accurately measure lower concentrations of airborne dust in the workplace, thereby likely causing fewer samples to be reported simply as a "less than" concentration based on the laboratory's limit of quantitation (LOQ). Larger sample air volumes would have been achieved if the air monitoring team had arranged longer sampling periods and/or used sampling equipment that operated at a higher air flow rate.

Uncertainties:

The modest air sampling volumes resulted in notable uncertainties.

Actual exposure levels unknown: Most significantly, because the vast majority of the sample results obtained at the Sun Chemical Corporation facility were obtained with modest sample volumes and had sample results described as less than the laboratory's reporting limit, it was not possible to determine

the employees' actual airborne exposure from those samples. The Agency only knows that the employee exposure was "less than" a calculated value (determined by the laboratory LOQ of 0.05 milligrams [mg] of dust on the filter, divided by the air volume sampled – measured in cubic meters [m^3]) (Reference: Sun Chemical Industrial Hygiene Survey, SGS Galson Laboratory Reports). The actual airborne concentration was somewhere between 0 (no airborne dust) and the reporting limit.

Estimated concentration based on LOQ/2: To avoid artificially inflating the estimated exposure level (which would have occurred if the Agency assumed that all exposures were equal to the reporting limit), the Agency instead assumed that the actual dust concentration was halfway between 0 and the reporting limit (calculated based on LOQ/2); however, this too is an estimate of the true exposure level.

Individual employee breaks and workflow were ambiguous
EPA estimated that each production operator spent 10.5 hours on the factory floor during a 12-hour shift, based on information in the Sun Chemical Industrial Hygiene Survey report which suggested that employees took a short break every two hours and presumably also had a lunch break. Since the report also indicates that the air sampling apparatus was removed from the employees after each C.I. Pigment Violet 29 task, sampling did not occur while employees were on break. For this reason, the Agency assumed that the sampled periods represented only the estimated 10.5 hours on the factory floor. If more detailed information had been reasonably available about typical employee workflow and breaks, the Agency may have made a different decision.

OUs have periods of exposure comparable to ONUs
The OU employees at the Sun Chemical Corporation facility only spent a fraction of their shift (approximately ½ hour to 2 hours) actually handling C.I. Pigment Violet 29. During periods of higher production rates, more operators could be engaged in producing the C.I. Pigment Violet 29 product (in each SEG and on each shift). Each of these OU employees would be exposed to respirable dust consisting of C.I. Pigment Violet 29 when they themselves intermittently handled C.I. Pigment Violet 29 material. They would also potentially experience additional C.I. Pigment Violet 29 exposure during the remaining portions of their work shift, due to C.I. Pigment Violet 29 released during the work of other operators in the area. During the air monitoring at the Sun Chemical Corporation facility, no OU employees were sampled while not directly handling PV-29, so their exposure levels during those periods were uncertain. To address this uncertainty, the Agency made an assumption that the average TWA exposure (for the period monitored) of ONU employees represented the exposure level experience by OU operators during those portions of their shift when they were not directly handling C.I. Pigment Violet 29 (*i.e.*, when they were working temporarily under ONU conditions). EPA calculated TWA exposures for OU employees using the estimated OU exposure levels for the period monitored and the average ONU exposure level during the unmonitored portions of the shift. EPA also calculated TWA exposures for ONU employees assuming full shift exposure and assuming the average ONU exposure level during the unmonitored portions of the shift.

As an additional uncertainty caused by the modest air sample volumes, all ONU exposures and most OU exposures were below the reporting level and are calculated based on LOQ/2. This means that the estimated amount of dust is fixed (1/2 x 0.05 mg) and that the estimated C.I. Pigment Violet 29 exposure levels vary inversely with the sampled air volume. A notable consequence is that OU and ONU employees, who had similar relatively brief sampling periods, also have similar estimated exposure levels.

Even with the deficiencies, the Sun Chemical Corporation Industrial Hygiene respirable dust monitoring study is still useful in understanding worker exposure during manufacturing. Unlike other general dust monitoring measurements previously submitted by the company, the Sun Chemical Corporation Industrial Hygiene respirable dust monitoring study was conducted while workers were handling C.I. Pigment Violet 29, and the samples taken were specifically analyzed for the respirable portion of dust.

As a result of these deficiencies, the monitoring data were used as an estimate of occupational exposure with the following assumptions:

- Workers were monitored while they were handling C.I. Pigment Violet 29 only. The sample collector was turned off when the worker stopped handling C.I. Pigment Violet 29 or left the work area for other tasks. For the exposure calculation, it was assumed that workers stayed near the work area throughout the entire shift and that they were continually exposed to C.I. Pigment Violet 29 at the average concentration measured across all Sample Exposure Groups for OUs.
- Samples were collected and analyzed for respirable dust particles. It was assumed that all the collected material is C.I. Pigment Violet 29. As the cut point for the collection of samples was 0.4 um it was assumed that the particle size diameter of the samples was less than or equal to 4 µm.
- Workers are exposed for 10.5 hours/day for 190 days/year. (Sun Chemical (2020)).

Particle Size Distribution (PSD) Data for C.I. Pigment 29

Initially, EPA received particle size information as part of a compilation of physical and chemical properties which indicated an average particle size diameter of 46.9 µm (BASF, 2013). Following the publication of the draft risk evaluation on C.I. Pigment Violet 29, EPA received additional particle size distribution (PSD) data from Sun Chemical Corporation. This data indicates that the median diameter of the particles is reported as 43 nanometers (nm), or 1000 times smaller than the particle size reported in the BASF study report upon which EPA had based its particle size estimate in the draft risk evaluation (BASF, 2013). In an additional characterization of the particle size diameter of C.I. Pigment Violet 29, the mean particle diameter was reported as 10.4 µm (U.S. EPA, 2020a). Due to the high degree of variability shown in the particle diameters of C.I. Pigment Violet 29, the risks from inhalation of C.I. Pigment Violet 29 dust were characterized using all reasonably available data to represent a range of potential particle diameters.

The particle size distribution information received from Sun Chemical Corporation following the SACC meeting is available in a supplemental file in the docket, *Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a). As the milling of C.I. Pigment Violet 29 to produce a powder of variable diameter is an aspect of the manufacturing process, these PSD data for C.I. Pigment Violet 29 were reviewed according to the data quality metrics for environmental release and occupational exposure data described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). The data quality evaluation results for this information can be found in *Systematic Review Supplemental File: Data Quality Evaluation for Release and Occupational Exposure* (U.S. EPA, 2020b).

In light of the additional available information on particle size provided to EPA, the Agency determined that the assumptions about particle size used to select the barium sulfate analogue in the Revised Inhalation Risk Characterization Summary were no longer appropriate to understand the inhalation potential of C.I. Pigment Violet 29. Specifically, the particle size of barium sulfate (MMAD 4.3 µm) is 100 times larger than the particle size data provided by Sun Chemical Corporation (0.043

µm). Therefore, EPA searched for a more appropriate analogue and selected carbon black, as an analogue to understand the risks from inhalation of C.I. Pigment Violet 29 dust in the risk characterization in Section 4.2. Elder et al., (2005) reported a particle size of 0.014 µm for high-surface area carbon black and a particle size of 0.070 µm for low-surface area carbon black; therefore, this range of particle sizes bracket the particle size of C.I. Pigment Violet 29 provided by Sun Chemical Corporation (0.043 µm). In addition to similar particle size, carbon black was considered an appropriate analogue for C.I. Pigment Violet 29 because of its similar physical and chemical properties, including insolubility and density (1.97 g/cm^3 for carbon black vs 1.69 g/cm^3 for C.I. Pigment Violet 29) and its similar chemical composition; both chemicals are used as pigments or inks and are predominantly comprised of a planar structure of multiple carbon rings.

Table 2-6 summarizes the particle size distribution (PSD) data EPA identified or subsequently received on C.I. Pigment Violet 29. The particle diameters range from nanometers to micrometers; it is unclear how these data correspond to the particle size of workplace dust. Therefore, EPA assumed that the range of PSD for C.I. Pigment Violet 29 reported by Sun Chemical represent the PSD of C.I. Pigment Violet 29 in the workplace breathing zone (ranging from a median of 0.043 to 10.4μm.

Table 2-6. Particle Size Distribution Data Available for C.I. Pigment Violet 29

Source of Particle Size Distribution	10th Percentile particle size (μm)	Median Particle Size (μm)	90th Percentile Particle Size (μm)	Sigma_g (GSD) [=exp[ln(median/ lower bound)/n]	Mass density
(BASF, 2013) (used in the draft risk evaluation)	5.9	46.9	806	2.82	1.58
Sun Chemical #1 (submitted after the publication of the draft risk evaluation; see pages 27-29 of the supplemental file (U.S. EPA, 2020a))	1.04	10.4	54.4	3.16	1.69
Sun Chemical #2 (submitted after the publication of the draft risk evaluation see pages 25-26 of the supplemental file (U.S. EPA, 2020a)	0.027	0.043	0.080	1.47	1.69 (assumed)

2.3.1.3 Dermal and Oral Exposures Approach and Methodology

EPA did not find any reasonably available information on oral exposure to workers. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict. Therefore, it can be difficult to quantitatively evaluate the oral route for occupational exposure scenarios. Dermal exposures to workers are possible but were not assessed quantitatively.

2.3.1.4 Consideration of Engineering Controls and PPE

Engineering controls for C.I. Pigment Violet 29 at the manufacturing site include wet scrubbers and dust collectors to control workplace indoor dust. Air pollution control devices include packed bed

scrubber systems with approximately 95% particulate matter (PM) removal efficiency and wet scrubber with approximately 90% PM removal efficiency and dust collectors with over 99.9 PM removal efficiency. PPE used at the manufacturing plant include safety glasses, nitrile gloves, Tyvek coveralls, 3M 8511 N95 filtering facepiece as specified in the detailed work instructions, long-sleeve shirt, long-pants, steeled-toed safety shoes, and hard hat (The E.I. Group Inc., 2020). Engineering controls for C.I. Pigment Violet 29, as stated directly in the Safety Data Sheet (SDS), include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls (Sun Chemical, 2017; TCI America, 2017; available in the docket at: U.S. EPA, 2020c). For downstream processors, SDS recommended PPE includes safety glasses with side-shields, "dust mask" and goggles under certain circumstances, chemical resistant impervious gloves, and particulate respirators (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017).

Information provided by the manufacturer of C.I. Pigment Violet 29 indicates that workers in the sole U.S. manufacturing facility wear N95 filtering facepieces or half mask elastomeric respirator with N95 filter during manufacturing activities, which corresponds to an APF of 10 (U.S. EPA, 2020c). Oral and inhalation exposures for downstream processors and industrial/commercial users are possible for both workers and ONUs; however, occupational exposures from these downstream users could be limited if the recommended PPE (per Safety Data Sheet for C.I. Pigment Violet 29) are used. Sun Chemical Corporation indicated that typical PPE at facilities that process C.I. Pigment Violet 29 into plastic includes Tyvek coverings, "goggles, and dust masks." Further, "a dust collection system" is used in the weight measuring areas at these facilities (Sun Chemical, 2020 6887861). Sun Chemical Corporation also indicated that typical PPE at facilities that process C.I. Pigment Violet 29 into coatings includes "protective clothing, a respirator, and chemical resistant gloves." Engineering controls used for unloading include local exhaust ventilation - mechanical exhaust fans with low level vents, a dust collection unit, and a supply air unit (EPA-HQ-OPPT-2018-0604).

OSHA requires and NIOSH recommends that employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. The hierarchy of controls prioritizes the most effective measures first which is to eliminate or substitute the harmful chemical (*e.g.*, use a different process, substitute with a less hazardous material), thereby preventing or reducing exposure potential. Following elimination and substitution, the hierarchy recommends engineering controls to isolate employees from the hazard, followed by administrative controls, or changes in work practices to reduce exposure potential (*e.g.*, source enclosure, local exhaust ventilation (LEV) systems). Administrative controls are policies and procedures instituted and overseen by the employer to protect worker exposures. As the last means of control, the use of PPE (*e.g.*, respirators, gloves) is recommended, when the other control measures cannot reduce workplace exposure to an acceptable level.

EPA generally assumes compliance with OSHA requirements for protection of workers, including the implementation of the hierarchy of controls. In support of this assumption, EPA used reasonably available information indicating that some employers, particularly in the industrial setting, are providing appropriate engineering, or administrative controls, or PPE to their employees consistent with OSHA requirements. EPA does not have reasonably available information to support this assumption for each condition of use; however, EPA does not believe that the Agency must presume, in the absence of such information, a lack of compliance with existing regulatory programs and practices. Rather, EPA assumes there is compliance with worker protection standards unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE in a manner that achieves the stated APF

or PF. EPA's decisions for unreasonable risk to workers are based on high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE. EPA believes this is a reasonable and appropriate approach that accounts for reasonably available information and professional judgement related to worker protection practices, and addresses uncertainties regarding availability and use of PPE.

OSHA's Respiratory Protection Standard (29 CFR 1910.134) provides a summary of respirator types by their assigned protection factor (APF). OSHA defines APF to mean: the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program according to the requirements of OSHA's Respiratory Protection Standard. If respirators are necessary in atmospheres that are not immediately dangerous to life or health, workers must use NIOSH-certified air-purifying respirators or NIOSH-approved supplied-air respirators with the appropriate APF. Respirators that meet these criteria include air-purifying respirators with N95 filter. Respirators must meet or exceed the required level of protection listed in Table 2-7. Based on the APF, inhalation exposures may be reduced by a factor of 5 to 10,000 if respirators are properly worn and fitted. The impact of respirator use on worker exposure is addressed in Human Health Risk Section 4.2.

Table 2-7. Assigned Protection Factors for Respirators in OSHA Standard 29 CFR 1910.134

Type of Respirator	Quarter Mask	Half Mask	Full Facepiece	Helmet/ Hood	Loose-fitting Facepiece
1. Air-Purifying Respirator	5	10	50	-	-
2. Power Air-Purifying Respirator (PAPR)	-	50	1,000	25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator	-	-	-	-	-
• Demand mode	-	10	50	-	-
• Continuous flow mode	-	50	1,000	25/1,000	25
• Pressure-demand or other positive-pressure mode	-	50	1,000	-	-
4. Self-Contained Breathing Apparatus (SCBA)	-	-	-	-	-
• Demand mode	-	10	50	50	-
• Pressure-demand or other positive-pressure mode (*e.g.*, open/closed circuit)	-	-	10,000	10,000	-

Source: 29 CFR 1910.134(d)(3)(i)(A)

2.3.2 Consumer Uses and Bystander Exposure

Consumer user and bystander exposures via oral and dermal routes are expected to be limited based on the uses and physical and chemical properties of C.I. Pigment Violet 29. Of the uses for C.I. Pigment Violet 29, the only potential consumer use is as a component of artistic watercolor and acrylic paint. Based on this use, inhalation is not identified as a route of exposure for consumers users or bystanders since C.I. Pigment Violet 29 is not expected to volatilize from these paints due to its low vapor pressure. Absorption of C.I. Pigment Violet 29 after oral ingestion is expected to be limited due to the low water solubility (0.003 mg/L) and dermal and oral absorption are estimated to be poor for the neat

material (because it is a solid with low solubility) (Nicolaou, 2020). As a result, no further analysis was conducted, and risk estimates were not developed for consumer and bystander exposure.

2.3.3 General Population Exposures

General population exposures to C.I. Pigment Violet 29 are expected to be minimal due to the limited releases of C.I. Pigment Violet 29 to the environment as a result of engineering controls on manufacturing releases. Additionally, physical and chemical properties (Table 1-1) and fate endpoints (Table 2-1) would also result in minimal exposure to air, water, sediment, and groundwater via biosolids and landfill leaching. Inhalation of C.I. Pigment Violet 29 is expected to be low due to limited fugitive and incineration air releases. Low volatilization rates will limit fugitive air releases as vapor, while dust handling systems in place at the manufacturing facility are designed to capture dust in baghouses (U.S. EPA, 2020a). Oral ingestion of C.I. Pigment Violet 29 is expected to be negligible due to limited concentrations expected in surface and ground water. Negligible surface water concentrations are due to high removal efficiency of C.I. Pigment Violet 29 during the wastewater treatment process on site or at POTWs limiting releases to surface water. Further, C.I. Pigment Violet 29 exhibits strong sorption to soil which would reduce migration to groundwater from biosolids application or leaching from landfill disposal. Additionally, physical and chemical properties indicate that, if found in these media and ingested, absorption would be expected to be poor due to low water solubility. As a result, no further analysis was conducted for exposure to the general population.

2.3.4 Key Assumptions and Uncertainties- Consumer and General Population Exposures

In the previous sections, EPA 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 and release information. C.I. Pigment Violet 29 is present in formulations of consumer paint products, where it is not present in a dust form and therefore not respirable. C.I. Pigment Violet 29 present in dried paint and plastic products is expected to be encapsulated and available physical and chemical property information indicates that due to a low solubility in water and octanol, it is not expected to leach out. A lack of monitoring information or modeling diminishes the confidence in these conclusions. The submission of updated solubility data, however, supports EPA's medium confidence in the strength of these conclusions as they relate to consumer exposure (Nicolaou, 2020).

EPA determined that expected releases and subsequent environmental exposures are limited as a result of a qualitative consideration of available physical and chemical, environmental fate, and manufacturing and release information. While the agency has determined that there are sufficient data available to make this determination, quantitative environmental monitoring data of air, groundwater, and surface water were not available to verify the conclusions of negligible environmental exposures. To better identify possible releases to the environment, information was submitted by the Sun Chemical Corporation manufacturing facility estimating these releases and deemed to be of high data quality. The data quality evaluation for the environmental release information received from the sole U.S. manufacturer has been released with this final risk evaluation as a supplemental file entitled, *Systematic Review Supplemental File: Data Quality Evaluation of Environmental Release and Occupational Exposure Data* (U.S. EPA, 2020b).While this lack of quantitative monitoring data represents a source of uncertainty, it is unlikely to impact the conclusions, as the low solubility of the chemical, low environmental releases (<1 lb/day) and lack of environmental hazard means that it would be unlikely for environmental concentrations to reach a level where adverse effects could be observed in environmental receptors. Overall, EPA has a medium to high confidence in characterizing releases to the environment and subsequent exposure to the general population.

2.4 Other Exposure Considerations

2.4.1 Potentially Exposed or Susceptible Subpopulations (PESS)

TSCA Section 6(b)(4)(A) requires that a risk evaluation "determine whether at 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 as relevant to the risk evaluation by the Administrator, under the conditions of use." TSCA Section 3(12) states that "[t]he term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

For occupational exposures, EPA assessed exposures to workers and ONUs from all conditions of use. Table 2-8 and Table 2-9 present the percentage of employed workers and ONUs who may be susceptible subpopulations within select industry sectors relevant to C.I. Pigment Violet 29 conditions of use. The percentages were calculated using Current Population Survey (CPS) data for 2017. CPS is a monthly survey of households conducted by the Bureau of Census for the Bureau of Labor Statistics (BLS) and provides a comprehensive body of data on the labor force characteristics. Statistics for the following subpopulations of workers and ONUs are provided: individuals age 16 to 19, men and women of reproductive age,[2] and the elderly. For the purpose of this risk evaluation, EPA considers "reproductive age" as age 16 to 54. As shown in Table 2-8, men make up the majority of the workforce in manufacturing sectors. In other sectors, women (including those of reproductive age and elderly women) make up nearly half of the workforce.

Adolescents (16 to <21 years old) appear to be generally a small part of the total workforce based on CPS data for employed individuals between 16 and 19 years of age. Table 2-9 presents further breakdown on this subset of adolescents employed by industry subsectors. As shown in the table, they comprise less than two percent of the manufacturing workforce.

Table 2-8 Percentage of Employed Persons by Age, Sex, and Industry Sector

Age group	Sex	Manufacturing	Professional and business services
16-19 years	Male	0.8%	0.7%
	Female	0.4%	0.5%
Reproductive age (16-54 years)	Male	52.9%	44.4%
	Female	22.2%	32.8%
Elderly (55+)	Male	17.5%	13.4%
	Female	7.3%	9.4%

Source: (U.S. BLS, 2017). Percentage calculated using CPS table 14, "Employed persons in nonagricultural industries by age, sex, race, and Hispanic or Latino ethnicity."

[2] While statistics on pregnant women are not available, CPS provides data on the number of employed female workers by age group, which allows for determination of the number of employed women of reproductive age.

Table 2-9. Percentage of Employed Persons Age 16-19 Years by Detailed Industry Sector

Sector	Subsector	Age: 16-19 years
Manufacturing	All	1.2%
Professional and business services	Waste management and remediation services	0.9%

Source: (U.S. BLS, 2017). Percentage calculated using CPS table 18b, "Employed persons by detailed industry and age."

The CPS uses 2012 Census industry classification, which was derived from the 2012 NAICS. The Census classification uses the same basic structure as NAICS but is generally less detailed. C.I. Pigment Violet 29 conditions of use fall under the following Census industry sectors:

- Manufacturing – The Manufacturing sector comprises establishments engaged in the mechanical, physical, or chemical transformation of materials, substances, or components into new products. Establishments in the sector are often described as plants, factories, or mills. For C.I. Pigment Violet 29, this sector covers most conditions of use that occur in an industrial setting, including Manufacturing and Import.
- Processing – The sector comprises downstream processors engaged in activities where C.I. Pigment Violet 29 is incorporated into products such as paints and coatings and rubber and plastics. These downstream processors normally operate in a facility similar to the manufacturing facility. This sector likely covers facilities that are engaged in the importation of C.I. Pigment Violet 29 or products and formulations containing C.I. Pigment Violet 29. This sector covers waste management and remediation services, which includes establishments that may handle, dispose, treat, and recycle wastes containing C.I. Pigment Violet 29.
- Industrial/Commercial uses – This sector comprises establishments that utilize products created by downstream processors. This includes automotive manufacturers that handle plastics and rubber products as well as paints and coatings containing C.I. Pigment Violet 29. Carpeting containing C.I. Pigment Violet 29 is also covered by these uses.

2.4.2 Aggregate and Sentinel Exposures

Section 6(b)(4)(F)(ii) of TSCA requires EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. EPA has defined aggregate exposure as "*the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways*" (40 CFR § 702.33). Exposures to C.I. Pigment Violet 29 were evaluated by inhalation and other routes of exposure (dermal, oral) separately. EPA chose not to employ simple additivity of exposure pathways within a condition of use because the only route of concern is chronic inhalation to C.I. Pigment Violet 29. Chronic exposure to C.I. Pigment Violet 29 is expected to increase lung burden which may result in kinetic lung overload, a pharmacokinetic phenomenon, which is not due to the overt toxicity of the chemical, but rather the possibility that C.I. Pigment Violet 29 dust overwhelms the lung clearance mechanisms over time and ultimately result in adverse effects. The inhalation toxicity data on the analogue carbon black demonstrated increased lung burden, alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract. However, inhaled particles may have systemic effects. As the absorption via dermal and oral routes is expected to be low, these exposure pathways are not expected to influence the toxicity in the respiratory tract. Therefore, aggregating these exposure pathways would be inappropriate. Chronic exposure to C.I. Pigment Violet 29 is expected to increase lung burden, overwhelm the lung clearance mechanisms over time, and ultimately result in adverse effects. Exposure via dermal and oral routes is expected to be low due to workplace practices,

including use of PPE such as gloves; and any absorption from dermal or oral exposure is expected to be negligible based on the insolubility of C.I. Pigment Violet 29. Therefore, these exposure pathways are not expected to influence the toxicity in the respiratory tract." Therefore, EPA determined that sentinel exposure via inhalation was the most appropriate approach for risk characterization.

EPA defines sentinel exposure as "*the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures*" (40 CFR § 702.33). In this risk evaluation, EPA considered sentinel exposure the highest exposure given the details of the conditions of use and the potential exposure scenarios. In cases where sentinel exposures result in MOEs greater than the benchmark or cancer risk lower than the benchmark, EPA did no further analysis because sentinel exposures represent the worst-case scenario. EPA's decisions for unreasonable risk are based on high-end exposure estimates to capture individuals with sentinel exposure.

3 HAZARDS (EFFECTS)

3.1 Environmental Hazards

The environmental hazard data identified for C.I. Pigment Violet 29 were three acute ecotoxicity studies as well as an activated sludge respiration inhibition test. EPA has received and reviewed full study reports, which included the following study types:

- OECD Guideline 203: Fish Acute Toxicity Test (BASF, 1988)
- OECD Guideline 202: *Daphnia* sp., Acute Immobilization Test (BASF, 2012a)
- OECD Guideline 221: *Lemna* sp., Growth Inhibition test (BASF, 2012b)
- OECD Guideline 209: Activated Sludge Respiration Inhibition Test (BASF, 1999b)

EPA has reviewed these full study reports (non CBI version are available in the public docket, EPA-HQ-OPPT-2018-0604) according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The data quality evaluation indicated these studies are of high confidence and can be used to characterize the environmental hazards of C.I. Pigment Violet 29. The results of this data quality evaluation can be found in the *Supplemental File: Data Quality Evaluation of Environmental Hazard Studies (*U.S. EPA, 2020d*)*.

A 96-hour study (BASF, 1988), conducted with zebrafish (referred to by the scientific name *Brachydanio rerio* in the study) was submitted to EPA. This study report indicates that the test was conducted as a limit test with a single exposure concentration corresponding to a nominal loading rate of 5000 mg/L. The test medium did not appear to be filtered due to a reported presence of test material in the medium. No mortality or changes in the exposure group relative to the control group were observed or reported in the test. The study authors reported a limit of solubility of 670 mg/L that was inconsistent with the limit of solubility reported in the other ecotoxicity tests and with the measured limit of solubility of 0.003 mg/L as reported in the water solubility testing (Nicolaou, 2020). As no explanation for the study authors' determination of the solubility limit was provided and no effects were observed in the test organisms, this was not determined to critically impact the utility of the study, as it likely represented the loading rate and not the actual limit of solubility.

A 48-hour acute study with aquatic invertebrates (*Daphnia magna*) was conducted with C.I. Pigment Violet 29 (referred to as Paliogen Violet 5011 in the study report) (BASF, 2012a). Similar to the acute study with fish, this study was conducted as a limit test, where a control and a single test concentration represented by a nominal loading rate of 100 mg/L were used. The study authors allowed the stock solution to mix for 3 days before filtering with a 0.20 µm membrane disc. Analytical confirmation of the concentrations of C.I. Pigment Violet 29 in the test medium indicated that the concentration of the test item ranged from 0.0065 µg/L- 0.0078 µg/L. This concentration is slightly higher than the reported limit of solubility in the test submitted by Sun Chemical Corporation (Nicolaou, 2020). This is likely due to the larger diameter filter membrane that was used (0.20 µm vs. 0.02 µm used in the solubility test) that resulted in undissolved particulate matter present in the test medium. As part of the test, the authors conducted three preliminary range finding tests and one definitive test to test for immobilization as a result of exposure to the test material. The study authors defined immobility as the inability to swim after gentle agitation of the test vessel. 45% immobilization was observed in individuals at the highest concentration of one of the three non-GLP range finding tests, but this was not observed in the other two range-finding tests or the definitive tests, so it was not determined to impact the validity of the test. No immobilization was observed in the definitive test, so the reported the EC_{50} for aquatic invertebrates was >100 mg/L indicating that no effects were observed up to the limit of solubility. The data quality evaluation for this study determined that it is of high confidence.

A 7-day toxicity study with aquatic plants (*Lemna gibba*) was conducted with C.I. Pigment Violet 29. The test was conducted with a range of loading rates: 1.0, 3.2, 10, 32 and 100 mg/L. These test concentrations were analytically verified, and the measured test concentrations were found not to be correlated with the loading rate. The test concentrations were found to vary between 0.0067-0.0071 mg/L, which is similar to the range observed in the test with *Daphnia magna*. Growth effects were estimated based on effects on yield inhibition and inhibition of mean growth rate as manifested in effects on frond number and dry weight of the individuals in the test. The authors concluded that no statistically significant effects were observed on yield or growth rate up to the limit of solubility of C.I. Pigment Violet 29.

All three environmental hazard studies indicate that adverse effects were not observed for fish, daphnia and aquatic plants up to the limit of solubility of the chemical following acute exposure. The activated sludge respiration inhibition test also reported no inhibition of microbial respiration up to the highest tested concentration of 1000 mg/L. Because chronic toxicity studies were not available, EPA used ECOSAR (v.2.0) predictive modeling to characterize potential hazards following chronic exposure to C.I. Pigment Violet 29. ECOSAR (v.2.0) predictive modeling outputs, presented in Table 3-1. below, indicate that chronic toxicity effects are only expected at levels that are greater than 10 times the measured limit of solubility of C.I. Pigment Violet 29 (0.003 mg/L). ECOSAR relies on a linear mathematical relationship between the physical and chemical properties of a chemical and the corresponding log of the measured toxicity values within the training set of chemicals for each class of interest (in the case of C.I. Pigment Violet 29, this class is imides). The results of the acute ecotoxicity studies as well as ECOSAR predictions for chronic exposures indicate that C.I. Pigment Violet 29 presents a low environmental hazard. Please see Appendix H for the full ECOSAR output.

Table 3-1. Ecological Hazard Characterization of C.I. Pigment Violet 29

Duration	Test organism	Endpoint	Hazard value (mg/L)	Effect Endpoint	ECOSAR-predicted hazard value (mg/L)[1]	Citation
Acute	Fish	72 hr LC_{50}	> Reported loading rate (5000 mg/L)	Mortality	2.80	(BASF, 1988)
	Aquatic invertebrates	48 hr EC_{50}	> Reported limit of solubility (0.0065 mg/L)	Immobilization	2.59	(BASF, 2012a)
	Microorganism	EC_{20}	> Reported loading rate (100 mg/L)	Respiration	N/A	(BASF, 1999b)
Chronic	Fish	ChV	N/A	N/A	0.245	N/A
	Aquatic invertebrates	ChV	N/A	N/A	0.459	N/A
Other	Aquatic Plants	EC_{50}	> Reported limit of solubility (0.0069 mg/L)	Based on growth [frond number and dry weight	0.410	(BASF, 2012b)
		LOEC	> Reported limit of solubility (0.0069 mg/L)		0.062	
		NOEC	Reported limit of solubility (0.0069 mg/L)			

[1] Predictions were made with ECOSAR v2.0. More information on the use of this tool is available at: https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model. Model inputs and outputs are available in Appendix H.

3.2 Human Health Hazards

3.2.1 Approach and Methodology

EPA identified human health hazard data for C.I. Pigment Violet 29 through an extensive literature search as described in Section 1.5 and shown in Figure 1-10. Literature search results for human health hazard of C.I. Pigment Violet 29 yielded 286 studies. Of the 286 studies, 17 key and supporting studies were initially identified in ECHA in summary format and then received in full study format by EPA. The 17 key/supporting studies were evaluated for data quality. The 269 remaining studies were screened for relevance, and all 269 were excluded as off topic. The *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document* (EPA-HQ-OPPT-2018-0604-0040) presents details of the data evaluations for each study, including scores for each metric and the overall study score. Two inhalation studies were deemed unacceptable based on the evaluation criteria of human health hazard, and the remaining 15 studies were carried forward to data extraction/data integration. The data quality evaluation results for the releases and occupational exposure data are available in the document titled "*Systematic Review Supplemental File: Data Quality Evaluation of Human Health Hazard Studies*" (U.S. EPA, 2020e). The results reported in these studies, as well as their data quality evaluation scores, are reported in Appendix E.

3.2.2 Toxicokinetics

There is little information available on the toxicokinetics of C.I. Pigment Violet 29. Absorption of C.I. Pigment Violet 29 in the neat form by oral, dermal and inhalation exposures are expected to be negligible as the pigment is produced as a neat solid material. C.I. Pigment Violet 29 either as a neat material or encapsulated in plastics or paint resins is not expected to be reactive or leachable (21 CFR 178.3297; (BASF, 1998)). No information was found on the metabolism of C.I. Pigment Violet 29; hence the metabolic fate is unknown. However, C.I. Pigment Violet 29 is unlikely to be metabolized based on poor absorption.

3.2.3 Hazard Identification

3.2.3.1 Non-Cancer

Oral and Dermal Exposures

The reviewed human hazard studies for C.I. Pigment Violet 29 (as summarized in the Appendix E tables) show that no adverse effects are observed for oral and dermal exposures at doses at or above the limit dose of 1000 mg/kg body weight (bw)/day, nor are dermal or eye irritation effects reported. Available oral and reproductive/developmental information did not report toxicity effects up to the highest dose tested (1000 mg/kg-bw/day, the limit dose). Also, C.I. Pigment Violet 29 is expected to be poorly absorbed by the oral and dermal exposure routes based on its physical and chemical properties and the skin pigmentation finding reported in the oral LD_{50} study. Based on these results, EPA concludes that C.I. Pigment Violet 29 presents a limited hazard to human health via oral and dermal exposure pathways. Therefore, the risk characterization (Section 4) does not include these exposure pathways for quantitative analysis. The REACH SDS for C.I. Pigment Violet 29 indicates the presence of an anhydride residual compound which would have concerns for dermal and respiratory sensitization (3,4,9,10-perylenetetracarboxylic dianhydride).

Intraperitoneal Injection Studies

Two acute (one injection) intraperitoneal injection studies are available for C.I. Pigment Violet 29. Toxicity effects were observed in the intraperitoneal injection studies only at high concentrations (LD_{50}= 7000-9000 mg/kg- bw). However, EPA does not consider injection of C.I. Pigment Violet 29

directly into the intra-peritoneum (body cavity) a relevant route of exposure. These studies are summarized in Appendix E.

Inhalation Studies

EPA determined that two acute inhalation studies (BASF, 1978b, 1975a) were *Unacceptable* primarily due to deficiencies in the exposure inhalation methods. Specifically, the studies were not designed for non-volatile substances, such as aerosols of respirable particles as would be expected for C.I. Pigment Violet 29. As a result, no acceptable inhalation toxicity studies were identified for C.I. Pigment Violet 29. These studies are summarized in Appendix E.

As C.I. Pigment Violet 29 is manufactured as a conglomerate solid that is a collection of particles that may be milled to certain particle sizes, humans may be exposed to these particles by inhalation. EPA assumes that human may be exposed when opening the bags of conglomerate, during milling, and during any other mechanical processing. However, inhaled particles may have systemic effects. The respiratory tract has myriad responses to inhaled particles, including neurogenic, cardiovascular, and metabolic dysfunction in addition to inflammation, remodeling leading to asthma, and a host of other respiratory diseases (U.S. EPA, 2019). One such effect is kinetic lung overload, defined as when the exposure concentration is sufficiently high or the duration sufficiently long that the particle deposition rate exceeds the clearance rate. Chronic exposure to C.I. Pigment Violet 29 may increase lung burden which may result in kinetic lung overload, a pharmacokinetic phenomenon, which is not due to the overt toxicity of the chemical, but rather the possibility that C.I. Pigment Violet 29 dust overwhelms the lung clearance mechanisms over time. The inhalation toxicity data on the analogue carbon black demonstrated increased lung burden, alveolar hyperplasia and inflammatory and morphological changes in the lower respiratory tract. Inhalation of poorly soluble particles like C.I. Pigment Violet 29 is associated with adverse effects in the respiratory tract of test animals.

Inhalation Analogue

EPA decided to re-evaluate the analogue used in the Revised Inhalation Risk Characterization Summary document (EPA-HQ-OPPT-2018-0604-0052) due to the greater range of particle sizes reported by Sun Chemical Corporation including much smaller, more respirable particle sizes. Three PSD data sets are available for C.I. Pigment Violet 29 and are described in 2.3.1. The initial set of PSD, used in the Supplemental Inhalation Assessment to the draft risk evaluation, used a median particle size of 46.9 µm (BASF, 2013). This quantity is a much larger particle size compared to the two other sets of data provided by Sun Chemical Corporation with medians of reported PSDs ranging from 0.04 to 10.4 µm). The PSD information received from Sun Chemical Corporation following the SACC meeting is available in a supplemental file in the docket, *Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a).

Based on the smaller (and more respirable) particle size reported by Sun Chemical Corporation (up to 1000 times smaller) compared to the original assessment (which used barium sulfate as an analogue), EPA searched for a more appropriate analogue. Carbon black (CASRN 1333-86-4) was selected as an analogue for C.I. Pigment Violet 29, in part because it has a similar particle size distribution. Elder et al., (2005), reported a particle size of 0.014 µm for high-surface area carbon black and a particle size of 0.070 µm for low-surface area carbon black; therefore, this range of particle sizes bracket the particle size of C.I. Pigment Violet 29 provided by Sun Chemical Corporation (0.043 µm). In addition, carbon black was determined to be an appropriate analogue for evaluating potential lung toxicity from C.I. Pigment Violet 29 due to the similarities in other physical and chemical properties (density, insolubility), limited absorption and metabolism, similar chemical uses and composition (both chemicals are used as pigments or inks and are predominantly comprised of a planar structure of

multiple carbon rings), and carbon black is a well-studied chemical. Table 2-6 summarizes the particle size distribution (PSD) data EPA identified or subsequently received on C.I. Pigment Violet 29.

Carbon black is a suitable analogue for C.I. Pigment Violet 29 because both compounds are pigments and are respirable, poorly soluble particulate matter that are expected to cause increased lung burden via inhalation exposures and potentially kinetic lung overload at higher exposure concentrations or longer exposure durations. Both compounds are expected to cause adverse effects to the respiratory tract such as irritation, inflammation, and proliferation. Carbon black also is structurally similar to C.I. Pigment Violet 29 with respect that both compounds contain conjugated polyaromatic ring structures.

Carbon Black Analogue Studies

Sub-chronic or chronic inhalation toxicity data is not available for C.I. Pigment Violet 29, thus analogue data must be considered to inform potential human health hazards. A 13-week inhalation toxicity study of carbon black for three species by Elder et al., (2005), was identified by EPA to assess the inhalation toxicity of C.I. Pigment Violet 29. Carbon black and C.I. Pigment Violet 29 are both respirable, poorly soluble particulate matter pigments with conjugated aromatic rings that are expected to cause increased lung burden and associated adverse effects on the respiratory tract. Elder et al., (2005) examined particle retention kinetics, inflammation, and histopathology of the lungs in female rats, mice, and hamsters exposed for 13 weeks to high surface area carbon black (HSCb) at concentrations chosen to span a no observable adverse effects concentration (NOAEC) up to an exposure concentration to likely produce adverse effects on the lungs (0, 1, 7 and 50 mg/m^3 nominal concentrations). Rats were also exposed to low surface area carbon black (50 mg/m^3, nominal; LSCb). The study did not assess the upper respiratory tract or systemic effects. The overall study LOAEC was established at 7.6 mg/m^3 based on alveolar hyperplasia, inflammatory and morphological changes in the lungs in rats such as histopathology and adverse bronchoalveolar lavage (BAL) parameters (*i.e.* polymorphonuclear leukocyte numbers). The LOAEC values were 7.6, 13.9 and 11.1 mg/m^3 for rats, mice and hamsters, respectively, based on similar responses in all species. Based on the Lowest Observed Adverse Effect Concentrations (LOAEC) values and endpoints in all three species, the study indicated that rats were the most sensitive species for risk assessment. In all species, there was a concentration-responsive increase in the lung burden of carbon black and increased half-times for particle clearance. Increased lung burden can lead to lung overload, which is a kinetic phenomenon when the lung particle deposition rate exceeds the particle clearance rate. The clearance of particles in rats is 10 times faster in than humans. Based on the lung retained dose data, the study concluded that lung particle kinetic overload was observed in hamsters exposed to the high concentration of HSCb, in mice exposed to the mid dose and the high concentrations and in rats exposed to mid- and high-concentration HSCb and high-concentration LSCb. Decreased lung particle clearance caused by xenobiotic particulate matter can impede the clearance of background dust and pathogens. The resulting adverse effects of carbon black exposure were not observed for any species at 1.1 mg/m^3 exposure, the lowest concentration tested for all three species. Therefore, the No-Observed Adverse Effect Concentration (NOAEC) reported for ultrafine carbon black at 1.1 mg/m^3 following exposure to HsCb was utilized as the point of departure (POD) to estimate inhalation risks in Section 4.2.1. The particle characteristics (mass median aerodynamic diameter or MMAD and geometric standard deviation or GSD), HEC values and endpoints are listed separately for each species below.

The Regional Deposited Dose Ratio (RDDR) is the ratio of the deposited dose in a respiratory tract region of interest for humans relative to the deposited dose in laboratory animal species. The RDDR is utilized to adjust the measured or nominal particulate matter exposure level in the various regions of the respiratory tract from animal studies to the corresponding human exposure level. The Dosimetric Adjustment Factor (DAF) across species for carbon black was derived by the RDDR program

described in EPA's "*Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*". The DAF values in various regions of the respiratory tract for humans versus animals are calculated by the RDDR software (*i.e.*, extra-thoracic, thoracic, total respiratory tract, pulmonary, tracheobronchial, and extra-respiratory regions). The RDDR software was utilized for dosimetric adjustment across species instead of the multi-path particle dosimetry (MPPD) model because the MPPD software cannot calculate the DAF for hamsters tested in the Elder et al., (2005) study. The RDDR results are based on the inhalation study aerosol characteristics (Geometric Standard Deviation or GSD, median mass aerodynamic diameter or MMAD), animal species, animal mass (which varies by gender), human body mass, etc. To clarify, the RDDR software calculates the deposited dose ratio, not the retained dose ratio, in various regions of the respiratory tract between animals and humans. The weight of the scientific evidence from the effects observed in the animal toxicity study (clinical signs, tissue effects, biochemical changes) and the aerosol characteristics in the inhalation study inform the selection of the respiratory tract region of interest and RDDR value selected as the DAF. The duration-adjusted concentration is calculated as the inhalation study point of departure (POD or NOAEC or LOAEC) multiplied by the inhalation study exposure duration per week divided by the worker exposure duration per week (Kuempel et al., 2015). The Human Equivalent Concentration (HEC) is the concentration in humans that elicits the same effects as the corresponding animal study concentration. The HEC is the product of the duration-adjusted concentration and the RDDR value. The utilization of the HEC value allows the reduction of the inter-species pharmacokinetic (PK) factor from 3X to 1X. The RDDR values, endpoint table, lung images and software outputs for carbon black are listed in Appendix F.

In a sub-chronic inhalation toxicity study carbon black (Cb) was administered to female F-344 rats by dynamic whole-body exposure at nominal concentrations of 0, 1, 7, and 50 mg/m^3 Printex-90 high surface area Cb [HSCb] and 50 mg/m^3 Sterling V, low surface area Cb [LSCb] for 6 hours per day, 5 days/week for a total of 13 weeks. Control groups received filtered air. Groups of six animals were used for the histopathological and particle dosimetry analyses while groups of five animals were used for all other end points. The LOAEC in rats is the mid dose of 7.6 mg/m^3 based on increased clearance half-times ($T_{1/2}$), the slow rate in decrease of post-exposure % Cb lung retention, adverse BAL parameters (*i.e.*, increased BAL cell numbers, increased BAL polymorphonuclear leukocytes or PMN numbers, etc), increased alveolar Type II cell density, increased number of alveolar Type II cells in S phase in the alveolar parenchyma, alveolar hyperplasia and increased Cb-laden macrophages. Increased BAL PMN numbers and BAL cell numbers are an indication of inflammation. At 50.3 mg/m^3, there was additionally increased lung weights, alveolar fibrosis and thickened alveolar septa. The NOAEC is 1.1 mg/m^3.

Table 3-2. Carbon Black Sub-Chronic Inhalation Study in Rats: Particle Characteristics Elder et al., (2005)

Test group	Nominal Concentration (mg/m^3)	Analytical Concentration (mg/m^3)	MMAD µm	GSD
Control	0	--	--	--
Low Dose HSCb	1	1.1 ± 0.2	1.4	2.5
Mid Dose HSCb	7	7.6 ± 1.9	1.6	2.7
High Dose HSCb	50	50.3 ± 5.6	1.5	2.5
High Dose LSCb	50	48.2 ± 5.0	0.8	3.2

In a sub-chronic inhalation toxicity study, carbon black (Cb) was administered to female B6C3F1 mice by dynamic whole body exposure at nominal concentrations of 0, 1, 7, and 50 mg/m^3 Printex-90 high surface area Cb [HSCb] for 6 hours per day, 5 days/week for a total of 13 weeks (Elder et al., 2005). Control groups received filtered air. Groups of six animals were used for the histopathological and particle dosimetry analyses while groups of five animals were used for all other end points. The LOAEC in mice is the mid dose of 13.9 mg/m^3 based on increased clearance half-times ($T_{1/2}$) and adverse BAL parameters (*i.e.*, increased BAL cell numbers, increased BAL polymorphonuclear leukocytes (PMN) numbers, etc). Increased BAL PMN numbers and BAL cell numbers are an indication of inflammation. At 64.4 mg/m^3, there was additionally increased lung weights and increased BAL lactate dehydrogenase levels (LDH). The NOAEC is 1.1 mg/m^3.

Table 3-3. Carbon Black Sub-chronic Inhalation Study in Mice: Particle Characteristics (Elder et al., 2005)

Test group	Nominal Concentration (mg/m^3)	Analytical Concentration (mg/m^3)	MMAD µm	GSD
Control	0	--	--	--
Low Dose HSCb	1	1.1 ± 0.2	2.0	2.8
Mid Dose HSCb	7	13.9 ± 7.1	1.6	2.3
High Dose HSCb	50	64.4 ± 15.6	2.0	2.5

In a sub-chronic inhalation toxicity study carbon black (Cb) was administered to F1B Syrian golden female hamsters by dynamic whole body exposure at nominal concentrations of 0, 1, 7, and 50 mg/m^3 Printex-90 high surface area Cb [HSCb] for 6 hours per day, 5 days/week for a total of 13 weeks. Control groups received filtered air. Groups of six animals were used for the histopathological and particle dosimetry analyses while groups of five animals were used for all other end points. The LOAEC in hamsters is the mid dose of 11.1 mg/m^3 based on adverse BAL parameters such as increased BAL cell numbers, increased BAL polymorphonuclear leukocytes (PMN) numbers, increased BAL LDH levels, etc. At 63.0 mg/m^3, there were also increased lung weights, increased clearance half-times ($T_{1/2}$), increased alveolar Type II cell density and increased Cb laden macrophages. Increased BAL PMN numbers and BAL cell numbers are an indication of inflammation. The NOAEC is 1.1 mg/m^3. Based on the endpoints at the LOAEC, the Elder et al., (2005) study indicated that hamsters were the least sensitive species tested and did not achieve kinetic lung overload until the high concentration, thus did not provide a suitable POD for risk assessment. Rats provided more robust endpoints at a lower LOAEC value than hamsters. Although hamsters had a slightly lower NOAEC HEC value than rats, this result is simply due to poor dose selection for the lowest concentration in the hamster study (*i.e.*, >10 fold spacing between the low and mid doses).

Table 3-4. Carbon Black Sub-chronic Inhalation Study in Hamsters: Particle Characteristics (Elder et al., 2005)

Test group	Nominal Concentration (mg/m^3)	Analytical Concentration (mg/m^3)	MMAD µm	GSD
Control	0	--	--	--
Low Dose HSCb	1	1.1 ± 0.2	1.5	2.5
Mid Dose HSCb	7	11.1 ± 4.3	1.4	2.6

Test group	Nominal Concentration (mg/m^3)	Analytical Concentration (mg/m^3)	MMAD µm	GSD
High Dose HSCb	50	63.0 ± 14.0	1.4	2.4

Table 3-5. Human Equivalent Concentrations for Sub-chronic Carbon Black Inhalation Study (Elder et al., 2005)

Species	NOAEC (mg/m^3)	Duration Adjusted NOAEC* (mg/m^3)	Pulmonary Region RDDR	Human Equivalent Concentration (HEC in mg/m^3)
Rats	1.1	0.63	0.450	0.28
Mice	1.1	0.63	0.695	0.44
Hamsters	1.1	0.63	0.253	0.16

*Worker exposure is 10.5 hours/day and 5 days/week. Inhalation study exposure was 6 hours/day and 5 days/week.
The duration-adjusted NOAEC = NOAEC x (6 hours/10.5 hours) x (5 days/5 days).
HEC is the product of the duration-adjusted NOAEC and the Regional Deposited Dose Ratio (RDDR).
The RDDR model utilized the default human body weight of 80.0 kg for adults. Using the body weight of 71.6 kg for age 16-21 humans also produced a pulmonary region RDDR value of 0.450 for female rats.

A chronic inhalation toxicity study of carbon black for rats by Nikula et al., (1995) was identified by EPA to assess the chronic inhalation toxicity of C.I. Pigment Violet 29. Carbon black and C.I. Pigment Violet 29 are both respirable, poorly soluble particulate matter pigments with conjugated aromatic rings that are expected to cause increased lung burden at elevated exposure levels or chronic durations and associated adverse effects on the respiratory tract. In a chronic inhalation toxicity study, carbon black (Cb) was administered to male and female F-344 rats by dynamic whole-body exposure at nominal concentrations of 0, 2.5 and 6.5 mg/m^3 for 16 hours/day for 5 days/week for 24 months. The study was particularly conservative with exposures lasting 16 hours/day for the entire lifetime of rats, in comparison to human worker exposure durations (*i.e.*, 10.5 hours/day and the worker exposure is a fraction of their lifetime). Control groups received filtered air exposure. Nikula et al., (1995) examined lung particle burden, survival, body mass, tumor formation and histopathology of the lungs in rats chronically exposed to carbon black. The study did not evaluate the upper respiratory tract or systemic effects. There was a concentration-responsive and time-responsive increase in the lung burden of carbon black, and male rats had a higher lung burden than female rats. Increased lung burden can lead to lung overload, which is a kinetic phenomenon when the lung particle deposition rate exceeds the particle clearance rate. Based on the retained lung dose data, the study indicated that lung particle kinetic overload was observed at the low dose of 2.46 mg/m^3 after three months. Decreased lung particle clearance caused by xenobiotic particulate matter can impede the clearance of background dust and pathogens. The study LOAEC was established at the lowest concentration of 2.46 mg/m^3 based on decreased body weight, decreased survival, increased lung burden, increased lung weights, alveolar macrophage hyperplasia, alveolar epithelial hyperplasia, chronic lung inflammation, lung septal fibrosis, bronchiolar-alveolar metaplasia, lung squamous cyst formation, increased lung tumor incidence and focal lung fibrosis with epithelial hyperplasia. A study NOAEC was not determined. In comparison, the Elder study female rat NOAEC HEC is 0.28 mg/m^3 or 8 times lower than the Nikula et al., (1995) study female rat LOAEC HEC of 2.23 mg/m^3. The Elder et al., (2005) study LOAEC HEC in female rats is a lower value of 1.96 mg/m^3. Lung cancer hazard is not anticipated at concentrations in which chronic active inflammation and cell proliferation are not present. The particle

characteristics (mass median aerodynamic diameter or MMAD and geometric standard deviation or GSD) and HEC values of the Nikula et al., (1995) study are listed below.

Table 3-6. Carbon Black Chronic Inhalation Study in Rats: Particle Characteristics (Nikula et al., 1995)

Test group	Nominal Concentration (mg/m^3)	Analytical Concentration (mg/m^3)	MMAD µm	GSD
Control	0	--	--	--
Low Dose	2.5	2.46 ± 0.03	0.10	2.16
High Dose	6.5	6.55 ± 0.06	1.95	1.84

Table 3-7. Human Equivalent Concentrations for the Carbon Black Chronic Inhalation Study (Nikula et al., 1995)

Rat Gender	LOAEC (mg/m^3)	Duration Adjusted LOAEC* (mg/m^3)	Pulmonary Region RDDR	Human Equivalent Concentration (HEC in mg/m^3)
Female	2.46	3.75	0.594	2.23
Male	2.46	3.75	0.524	1.96

*Worker exposure is 10.5 hours/day and 5 days/week. Inhalation study exposure was 16 hours/day and 5 days/week
The duration adjusted LOAEC = LOAEC x (16 hours/10.5 hours) x (5 days/5 days)
The HEC is the product of the duration adjusted LOAEC and the Regional Deposited Dose Ratio (RDDR)

Point of Departure (POD) Selection Rationale

The subchronic inhalation study by Elder et al., (2005) demonstrated that rats were the most sensitive species to carbon black exposure based on a LOAEC value of 7.6 mg/m^3 for female rats compared to a LOAEC of 13.9 mg/m^3 for female mice and 11.1 mg/m^3 for female hamsters. Elder (2005) concluded that hamsters were the least sensitive species, thus the hamster POD was not appropriate for risk assessment. Converting the concentrations for female rats in this study to Human Equivalent Concentration (HEC) results in a LOAEC HEC 1.96 mg/m^3 and a NOAEC HEC of 0.28 mg/m^3. The chronic inhalation study by Nikula et al., (1995) resulted in a LOAEC HEC of 2.23 mg/m^3 for female rats, which is comparable to the LOAEC HEC in the subchronic study by Elder et al., (2005); however, this was the lowest concentration tested in the chronic study, and a NOAEC was not established. Therefore, NOAEC HEC value of 0.28 mg/m^3 for female rats in the Elder et al., (2005) study provides the POD from the most sensitive species with the lowest rat LOAEC HEC value that has an experimentally determined NOAEC value, thus an appropriate POD for risk assessment.

A special case for consideration when evaluating the toxicity of inhaled particles is the kinetic phenomenon of particle overload. This phenomenon is defined as the overwhelming of clearance in the pulmonary (PU) region leading to a reduction in the ability of the lung to remove particles, and a resultant accumulation or “overload” occurs which results in a retained mass burden in the lung greater than that which would occur with normal physiological clearance rates (Driscoll and Borm, 2020) (Miller, 2000). Numerous other reviews have discussed this phenomenon of particle overload and the difficulties it poses for the extrapolation of chronic effects in rats to humans (Warheit et al., 2016) (Oberdorster, 2002; ILSI, 2000; Miller, 2000; Oberdorster, 1995); (Morrow, 1994).

The relevance of particle overload to humans and non-rodent species is not clear. Long-term experimental exposure data in animal studies is difficult to interpret for humans given that these kinds of exposures are unlikely to occur under ambient conditions. These types of exposure may however, be of concern to humans occupationally exposed to some particle types (Mohr et al., 1994), since overload may involve all insoluble materials and affect all species if the particles are deposited at a sufficient rate (Pritchard, 1989), *i.e.*, if the deposition rate exceeds the clearance rate. In addition, the suggestion that macrophage-mediated clearance is normally slower and perhaps less important in humans than in rats (Morrow, 1994), suggests significant differences in macrophage loading between the two species, further putting into question the relevance of this effect in humans.

A key issue when considering if overload occurred is whether increased particle retention due to large lung burdens needs to be differentiated from that due to inherently high cytotoxicity (e.g., quartz). Thus, consideration of the hazard or risk posed by a particle exposure requires characterization of both possible particle overload and some knowledge of the inherent toxicity of the particle under consideration, especially as many key events associated with "overload" are also embedded in pathways leading to various other adverse outcomes. Despite the frequent use of the term poorly soluble, low toxicity (PSLT) particles in scientific and regulatory literature, a clear consensus definition has not been published, although a recent expert workshop offered guidance on a tiered testing strategy to define critical characteristics (Driscoll and Borm, 2020). The strategy suggested by experts at this workshop was to first define poorly soluble particles (PSPs) and then Low Toxicity (LT) as a subgroup of PSP.

While EPA considers the noncancer effects of lung overload such as inflammation and hyperplasia observed in the carbon black inhalation studies to be relevant to C.I. Pigment Violet 29, EPA did not conclude the same for lung tumor formation. As discussed in Section 3.2.3.2 of the final risk evaluation, the NOAEC value of 1.1 mg/m^3 from Elder et al., (2005), used to calculate the HEC of 0.28 mg/m3 is below the LOAEC HEC of 2.23 mg/m^3 where tumor formation and precursor events such as lung hyperplasia, fibrosis were observed.

Consideration of kinetic overload thus merely creates context for the evaluation of toxicity data on an inhaled particle. If overload is demonstrated to occur, especially when considering rat tumors, then these effects may be less relevant for human risk assessment. However, as noted, several other "noncancer" events such as inflammation and hyperplasia are related to other adverse outcome pathways and should be evaluated as relevant (U.S. EPA, 2019).

3.2.3.2 Cancer

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 is not likely to be carcinogenic via genotoxic mechanisms.

There are other mechanisms of carcinogenicity beyond those arising from genotoxicity. Of particular relevance to C.I. Pigment Violet 29 is the importance to evaluate the potential for effects of lung inflammation and hyperplasia in response to the presence of particles in the lungs (in this case of the analogue carbon black) that, at high enough concentration over long enough time, can result in metaplasia in rats. In examining carbon black as an analogue for C.I. Pigment Violet 29, it is important to note that the Elder et al., (2005) carbon black inhalation study did not demonstrate inflammation nor hyperplasia nor lung overload conditions at the NOAEC of 1.1 mg/m^3 (rat HEC is 0.28 mg/m^3). Inflammation and hyperplasia are precursor events to tumor formation at later timeframes. The TSCA New Chemicals Program Chemical Categories document contains a category for "respirable, poorly soluble particulates" such as C.I. Pigment Violet 29 (OPPT EPA, 2010). This document states "the rat model at overload is dependent on coexistent chronic active inflammation and cell proliferation, at lower lung doses in which chronic active inflammation and cell proliferation are not present, no lung cancer hazard is anticipated. The Elder et al., (2005) carbon black sub-chronic inhalation study female rat NOAEC HEC is 0.28 mg/m^3 or 8 times lower than the Nikula et al., (1995) carbon black chronic inhalation study female rat LOAEC HEC of 2.23 mg/m^3 based on lung hyperplasia, fibrosis and tumors in this 24-month study (a major duration of the lifetime of a rat) (Nikula et al., 1995). If overload is demonstrated to occur, especially when considering rat tumors, then these effects may be less relevant for human risk assessment. However, as noted, several other "noncancer" events such as inflammation and hyperplasia are related to other adverse outcome pathways and should be evaluated as relevant (U.S. EPA, 2019).

Overall, tumor formation from C.I. Pigment Violet 29 is not expected at the rat NOAEC HEC value of 0.28 mg/m^3, 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.

4 RISK CHARACTERIZATION

4.1 Environmental Risk

Based on the results of toxicity testing with aquatic species, EPA concludes that C.I. Pigment Violet 29 demonstrates a low hazard to environmental receptors. A total of three environmental hazard studies were identified for C.I. Pigment Violet 29 and were given high overall confidence ratings during data evaluation. The *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document* presents details of the data evaluations for each study, including scores for each metric and the overall study score. No effects were observed in acute toxicity testing with fish, aquatic invertebrates, and aquatic plants up to the limit of solubility of C.I. Pigment Violet 29. As a result, no concentrations of concern (COC) can be calculated for this chemical, as it is not possible to dissolve enough quantities of C.I. Pigment Violet in water to elicit a response in aquatic organisms. As discussed above, EPA conducted a qualitative assessment of potential environmental exposures. 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.

4.1.1 Assumptions and Key Sources of Uncertainty

All available environmental hazard data indicated that C.I. Pigment Violet 29 presents a low hazard, as no effects were observed to fish, aquatic invertebrates and aquatic plants following acute exposure up to the highest concentrations tested (limit of solubility). While EPA determined that sufficient data are available to characterize environmental hazards of C.I. Pigment Violet 29, there are uncertainties. EPA has determined there is low hazard to environmental receptors based on an ecotoxicity dataset that is comprised of acute testing with three aquatic species. As a result, there are no data that characterize the hazard of C.I. Pigment Violet 29 to aquatic species following chronic exposure, nor are there data available from toxicity testing with terrestrial species to characterize the hazards of C.I. Pigment Violet 29. Therefore, there is some uncertainty regarding the environmental risk following acute exposure to sediment-dwelling invertebrates, chronic exposure to aquatic species, and exposure to terrestrial species. In addition, the lack of environmental monitoring data means that the limited predicted environmental concentrations cannot be verified empirically.

In the previous sections, EPA determined that expected releases and subsequent environmental exposures are limited as a result of a qualitative consideration of available physical and chemical, environmental fate, manufacturing and release, and exposure information. While the agency has determined that there are sufficient data available to make this determination, quantitative environmental monitoring data of air, groundwater, and surface water were not reasonably available to verify the conclusions of negligible environmental exposures. To better identify possible releases to the environment, information was submitted by the sole domestic manufacturing facility estimating these releases and deemed to have a high data quality determination. While this lack of quantitative monitoring data represents a source of uncertainty, it is unlikely to impact the conclusions, as the low solubility of the chemical, low environmental releases (<1 lb/day) and lack of environmental hazard means that it would be unlikely for environmental concentrations to reach a level where adverse

effects could be observed in environmental receptors. Overall, EPA has a medium to high confidence in characterizing releases to the environment and subsequent environmental exposure.

Data are not reasonably available to specifically characterize hazard to sediment-dwelling aquatic invertebrates; however, based on the weight of the scientific evidence considering the limited potential for aquatic releases resulting from the conditions of use of C.I. Pigment Violet 29 and the lack of effects observed in all environmental hazard studies, particularly with *Daphnia magna* (a sensitive surrogate species for aquatic invertebrates for which no adverse effects were observed), EPA determined that sufficient data exist to make a determination of risk for these species. Due to a combination of low potential exposure and low hazard, EPA concludes that no risk concerns for C.I. Pigment Violet 29 were identified for sediment-dwelling aquatic invertebrates.

With regard to chronic exposure, there is uncertainty because, as mentioned above, chronic exposure environmental hazard testing with C.I. Pigment Violet 29 is not reasonably available. While data characterizing the potential hazards from chronic exposure are not reasonably available and there are uncertainties regarding the chronic hazard from exposure to C.I. Pigment Violet 29, the limited environmental releases and exposure and low hazards reported across all hazard testing indicate that risk concerns for environmental receptors from chronic exposure to C.I. Pigment Violet 29 were not identified.

As discussed above in Section 2.2, engineering controls and low releases of C.I. Pigment Violet 29 to surface water are expected to minimize the potential for environmental releases and resulting exposures. These limited exposures across all routes and low hazard across all ecotoxicity testing indicate that adverse effects are not expected for terrestrial species.

4.2 Human Health Risk

4.2.1 Risk Characterization Approach

In the risk evaluation for C.I. Pigment Violet 29, EPA uses an MOE approach to characterize non-cancer risk for human health. The MOE is the ratio of the Human Equivalent Concentration (HEC) concentration divided by the human exposure concentration. Chronic non-cancer estimates for inhalation exposures to C.I. Pigment Violet 29 were derived for occupational scenarios using estimated inhalation average daily concentrations (ADCs). The central and high-end ADC exposure estimates were compared to the chronic inhalation hazard HEC of 0.28 mg/m^3 using a benchmark MOE of 30. Table 4-2 shows the calculated MOEs for central and high-end exposures.

As described in Section 2.3, the risk characterization of C.I. Pigment Violet 29 focuses on occupational chronic inhalation exposures as a dust. Table 4-1 shows the occupational use scenarios, populations of interest and toxicological endpoints identified for chronic inhalation exposures to C.I. Pigment Violet 29. As described in Section 3.2.3.1, carbon black was identified as an analogue for C.I. Pigment Violet 29.

MOE estimates allow for the presentation of a range of risk estimates. The occupational exposure scenarios considered risks to workers from manufacturing and processing associated with chronic inhalation exposure. Inhalation was the only relevant route of exposure to workers as described in the human exposure assessment (Section 2.3). For non-cancer effects, risks for effects were evaluated for chronic exposures (based on lung effects). All consumer uses were considered qualitatively.

The benchmark MOE used to evaluate risks for represents the product of all uncertainty factors (UFs) used for the non-cancer POD for inhalation exposures. These UFs accounted for various uncertainties including:

1. **Animal-to-human extrapolation (UF_A):** The UF_A accounts for the uncertainties in extrapolating from rodents to humans. In the absence of data, the default UF_A of 10 is adopted which breaks down to a factor of 3 for toxicokinetic variability and a factor of 3 for toxicodynamic variability. There is no PBPK model for C.I. Pigment Violet 29 to account for the interspecies extrapolation using rodent toxicokinetic data in order to estimate internal doses. In this assessment, a portion of the interspecies uncertainty is accounted for by use of the RDDR model for estimating the deposited particle fraction in the alveolar region of the lung (internal dose) which accounts for toxicokinetics, so the factor of 3 for toxicokinetic variability is reduced to a factor of 1. A UF_A of 1 is assigned for toxicokinetic and UF of 3 is retained to account for toxicodynamic differences between the test species and humans. Several non-carcinogenic effects associated with the inhalation exposure of carbon black (the analogue for C.I. Pigment Violet 29) observed in the Elder et al., (2005) study including alveolar hyperplasia, inflammation and morphological changes in the lungs of rats, mice and hamsters are adverse effects considered by EPA to be relevant to humans ((U.S. EPA, 2019); *Integrated Science Assessment for Particulate Matter*) and require the retention of the UF_A of 3 for toxicodynamics for use in this final risk evaluation.
2. **Inter-individual variation (UF_H):** The UF_H accounts for the variation in sensitivity within the human population. In the absence of data, the default UF_H of 10 is adopted which breaks down to a factor of 3 for toxicokinetic variability and a factor of 3 for toxicodynamic variability. Since there is no PBPK model for C.I. Pigment Violet 29 to reduce the human toxicokinetic/ toxicodynamic variability, the total UF_H of 10 was retained for use in this final risk evaluation.
3. **Extrapolation from subchronic to chronic (UF_S):** The UF_S accounts for the uncertainty in extrapolating from a subchronic to a chronic POD. Typically, a UF_S of 10 is used to extrapolate a POD from a less-than-chronic study to a chronic exposure, except for reproductive/developmental endpoints where a study may cover the full duration of relevant developmental or reproductive processes. The available information in animal studies support pulmonary system effects at similar concentrations following chronic exposures to carbon black particles (the analogue for C.I. Pigment Violet 29) compared to sub-chronic exposures. Specifically, the rat NOAEC HEC of 0.28 mg/m^3 for C.I. Pigment Violet 29 risk calculations are based on the no-effect concentrations for precursor events such as inflammation and hyperplasia in the Elder et al., (2005) study, thus, a POD for downstream events in a longer duration study is not warranted, and a UF_S of 1 was utilized by EPA in this final risk evaluation.
4. **Extrapolation from a LOAEC to a NOAEC (UF_L):** The UF_L accounts for the uncertainty in extrapolating from a POD based on a LOAEC to a NOAEC. The noncancer POD for the carbon black analogue for C.I. Pigment Violet 29, is a NOAEC. Therefore, a UF_L of 1 is used by EPA in this final risk evaluation.

Table 4-1. Use Scenarios, Populations of Interest and Toxicological Endpoints for Assessing Occupational Risks Following Chronic Exposures to C.I. Pigment Violet 29

Populations and Toxicological	Occupational Use Scenarios of C.I. Pigment Violet 29
Population of Interest and Exposure Scenario	**Occupational User (OU):** Adult male and female[1] (>16 years old) workers who directly handle C.I. Pigment Violet 29 as part of their job function (10.5-hour workday). **Occupational Non-user (ONU):** Adult male and female[1] (>16 years old) workers who do not directly handle C.I. Pigment Violet 29, but who are potentially exposed by being present in the surrounding work area of the manufacturing workplace (10.5-hour workday).
Health Effects of Concern, Concentration and Time Duration	**Non-Cancer Health Effects:** *Point of Departure (POD):* Reported No Observed Adverse Effect Concentration (NOAEC) of 1.1 mg/m^3 (measured) for the carbon black analogue in air from Elder et al., (2005) an inhalation study conducted on rats, mice and hamsters. The associated lowest observed adverse effect concentration (LOAEC) was of 7.6 mg/m^3 (measured) for alveolar hyperplasia, inflammatory and morphological changes in the lungs of rats, the most sensitive species. The proliferative effects were associated with increased particle burden observed in the pulmonary region of the lungs. The human equivalent concentration (HEC) associated with the POD NOAEC from Elder et al., (2005) for alveolar hyperplasia, inflammatory and morphological changes in the lungs of rats, mice and hamsters is equal to 0.28 mg/m^3
Uncertainty Factors (UF) used in Non-Cancer Margin of Exposure (MOE) calculations	Animal-to-human extrapolation (UF_A)=3 Inter-individual variation (UF_H)=10 Extrapolation from subchronic to chronic (UF_S)=1 Extrapolation from a LOAEC to a NOAEC (UF_L)=1 Benchmark MOE=30
[1]Includes pregnant women and adults of reproductive age.	

Table 4-2. Calculation of Margins of Exposure (MOEs for Manufacturing Workers and Processors)

Worker	Exposure	CONC in Air	Exposure Duration	Exposure Frequency	Work Years	Averaging Time	Average Daily CONC	Human Equivalent CONC	Margin of Exposure	Application Factor		
		C_{air}	ET	EF	ED	AT	ADC	HEC	MOE	APF		
		mg/m^3	hours/day	days/year	years	days	mg/m^3	mg/m^3		10	25	50
Occupational Users (OU)	High-End	1.2	10.5	190	40	350400	0.273	0.28	1.02	10.2	26	51
Occupational Users (OU)	Central Tendency	0.37	10.5	190	40	350400	0.084	0.28	3.3	33	83	166
Occupational Non Users (ONU)	High-End	0.59	10.5	190	40	350400	0.134	0.28	2.1	NC	NC	NC
Occupational Non Users (ONU)	Central Tendency	0.36	10.5	190	40	350400	0.082	0.28	3.4	NC	NC	NC
Occupational Downstream Processors and Users	High-End	1.2	8	250	40	350400	0.274	0.28	1.02	10.2	26	51
Occupational Downstream Processors and Users	Central Tendency	0.37	8	250	40	350400	0.084	0.28	3.3	33	83	166

ADC (mg/m^3) = (C_{air} * ET * EF * ED) / AT
Averaging time (AT in hours) = ED * 365 days/year * 24 hours/day
Based on information specific to the Sun Chemical Plant
NC = Not Calculated
Calculated MOE values in bold are less than the benchmark MOE and indicate risk
CONC = Concentration

All endpoints evaluated for dose-response modeling and their associated UFs are provided in Table 4-1.

4.2.2 Occupational Exposure Summary

Two air monitoring study data sets are available for dust exposures in the Sun Chemical Corporation workplace as described in Section 2.3.1.1 and summarized in Section 2.3.1.2. Inhalation risk associated with C.I. Pigment Violet 29 is evaluated for central tendency and high-end air concentrations (Table 4-3) for OUs and ONUs.

Table 4-3. Exposure Estimates for Occupational Workers at the Sun Chemical Corporation Manufacturing Facility.

Occupational Worker	Central Tendency Concentration in air mg/m^3	High End Concentration in air mg/m^3
Workers directly handling C.I. Pigment Violet 29 (OU)	0.37 Average of concentrations for OUs from Table 2-5	1.2 Maximum detected concentration from Table 2-4
Occupational Non-Users (ONUs)	0.36 Average of concentrations for ONUs from Table 2-5	0.59 Maximum detected concentrations for OUs and ONUs from Table 2-4

4.2.3 Risk Estimation for Chronic Non-Cancer Inhalation Risks

Table 4-4. Risk Estimations for Occupational Inhalation Exposure Scenarios

Life Cycle Stage/Category	Exposure Level (Table 4-2)	Margins of Exposure (MOE)					Benchmark MOE (= Total UF)
		Occupational User (OU) No respirator	Occupational Non-User (ONU) No respirator	Worker APF 10	Worker APF 25	Worker APF 50	
Manufacture – Domestic manufacture	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	
Manufacture – Import	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	
Processing- Use as an Intermediate	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	30
	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30

Life Cycle Stage/Category	Exposure Level (Table 4-2)	Margins of Exposure (MOE)					Benchmark MOE (= Total UF)
		Occupational User (OU) No respirator	Occupational Non-User (ONU) No respirator	Worker APF 10	Worker APF 25	Worker APF 50	
Processing-incorporation into formulation, mixture or reaction products in plastic and rubber products	Central Tendency	**3.3**	**3.3**	33	83	166	
Processing – Recycling	High-End	**1.02**	**2.1**	10.2	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	
Industrial/ Commercial Use: Plastic, Rubber Products, Industrial Carpeting	Not Quantitatively Evaluated						
Industrial/ Commercial Use: Automobile coatings, and merchant ink	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	
Consumer Use: Consumer watercolor and acrylic paints	Not Quantitatively Evaluated						
Disposal of solid wastes	High-End	**1.02**	**2.1**	**10.2**	**26**	51	30
	Central Tendency	**3.3**	**3.3**	33	83	166	

EPA made OES-specific determinations of assumed respirator use. Risk estimates are shown based on assumed PPE in Table 4-5 as a "what-if" scenario, even if those limits are not used for risk determination.

Table 4-5 Assumed PPE Protection Considered for Risk Determination by COU

COU	APF
Manufacturing: Domestic	10
Import	10
Processing: Use as an Intermediate	10
Processing: Paints and Coatings	10
Processing: Plastic and Rubber products	10

COU	APF
Processing: Recycling	10
Disposal	10
Industrial/Commercial Uses	0-25
Consumer Use	None

4.2.4 Assumptions and Key Sources of Uncertainty

While EPA determines that the data available to characterize human health hazard of C.I. Pigment Violet 29 are sufficient to make a determination of risk, there are uncertainties. Assumptions and sources of uncertainty in the risk estimates for human health associated with inhalation of C.I. Pigment Violet 29 are discussed according to steps of the risk assessment process including: exposure assessment, hazard assessment and risk characterization. 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.

In the previous sections, EPA determined that expected releases and subsequent general population exposures are limited as a result of a qualitative consideration of available physical and chemical, environmental fate, manufacturing and release, and exposure information. While the agency has determined that there are sufficient data available to make this determination, quantitative monitoring data of air, groundwater, and surface water were not reasonably available to verify the conclusions of limited general population exposures. To better identify possible releases to the environment that could affect the general population, information was submitted by the sole domestic manufacturing facility estimating these releases and deemed to have a high data quality determination. While this lack of quantitative monitoring data represents a source of uncertainty, it is unlikely to impact the conclusions, as the low solubility of the chemical and low environmental releases (<1 lb/day) means that it would be unlikely for environmental concentrations to reach a level where adverse effects could be observed in the general population. Overall, based on the physical and chemical properties associated with C.I. Pigment Violet 29, environmental fate characteristics, and available information concerning releases to the environment as supplied by the sole U.S. manufacturer (Section 1.1 and Section 1.2), EPA has a medium to high confidence in characterizing releases to the environment and subsequent general population exposure.

Similarly, EPA determined that expected consumer population exposures are limited as a result of a qualitative consideration of reasonably available information on physical and chemical properties and fate endpoints. Consumer exposures were unable to be quantitatively modeled due to lack of product specific information of C.I. Pigment Violet 29 within consumer products representing a key uncertainty. Nevertheless, physical and chemical properties such as expected low volatilization, low water solubility and poor absorption lead to expected low exposures. Overall, EPA has medium confidence in characterizing consumer exposure.

Human Health Hazard Assessment - Inhalation

There is not an acceptable inhalation study available for C.I. Pigment Violet 29. Therefore, the agency selected carbon black (CASRN 1333-86-4) as an analogue. Carbon black was selected as an analogue for C.I. Pigment Violet 29 because it has a similar particle size distribution and other physical and chemical properties (density, insolubility), limited absorption and metabolism, similar chemical uses and composition (both chemicals are used as pigments or inks and are predominantly comprised of a

planar structure of multiple carbon rings), and carbon black is a well-studied chemical. Both C.I. Pigment Violet 29 and carbon black are respirable, poorly soluble particulates that are expected to cause increased lung burden and potentially kinetic lung overload at sufficient exposure levels or durations. Therefore, a carbon black 13-week inhalation toxicity study examining effects on the lower respiratory tract was used to estimate inhalation risks for C.I. Pigment Violet 29. The assumption is that carbon black and the toxicity study using carbon black are good approximations of C.I. Pigment Violet 29 particles retained in the lower respiratory tract and toxicity. At the nanoscale, C.I. Pigment Violet 29 and carbon black are very different substances with potentially different physical and chemical properties. Given the structural complexity of C.I. Pigment Violet 29, it is acknowledged that finding a suitable surrogate is difficult.

As C.I. Pigment Violet 29 is manufactured as a conglomerate solid that is a collection of particles that may be milled to certain particle sizes, humans may be exposed to these particles by inhalation. EPA assumes that human may be exposed when opening the bags of conglomerate, during milling, and during any other mechanical processing. However, inhaled particles may have systemic effects. The respiratory tract has myriad responses to inhaled particles, including neurogenic, cardiovascular, and metabolic dysfunction in addition to inflammation, remodeling leading to asthma, and a host of other respiratory diseases (U.S. EPA, 2019b). The possible systemic effects associated with the inhalation of C.I. Pigment Violet 29 and the analogue carbon black are unknown and are a potential source of uncertainty in the final risk evaluation.

The particle size distribution in the workplace has been reported by Sun Chemical Corporation, but the results show a range of sizes. The assumption is that the particle sizes reported by Sun Chemical Corporation reflect the range of values in the workplace. As the particle size of C.I. Pigment Violet 29 for different conditions of use is unknown and only a range is reported for the manufacturing facility, the uncertainty in the hazard assessment is high, and the results are considered to be of low confidence. Based on these assumptions and data availability, the confidence in the inhalation hazard assessment is low.

Risk Characterization – Inhalation

Because the exposure estimates and hazard assessment for inhalation exposures to C.I. Pigment Violet 29 are considered to be of high uncertainty and low confidence, the confidence in the risk estimation is considered to be low.

4.3 Other Risk Related Considerations

4.3.1 Potentially Exposed or Susceptible Subpopulations (PESS)

TSCA requires that a risk evaluation "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

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 who use C.I. Pigment Violet 29 as part of typical processes.

Of the human receptors identified in the previous sections, EPA identifies the following groups as PESS due to their greater exposure and considered them in the risk evaluation:

- *Workers and ONUs*. EPA assessed exposure to these subpopulations using personal exposure monitoring data (measured data) and modeling approaches. The exposure estimates were applicable to both male and female workers of reproductive age, including adolescents.
- *Consumer users and bystanders associated with consumer use*. C.I. Pigment Violet 29 has been identified as being present in products available to consumers for purchase and use; however, only some individuals within the general population are expected to use these products. Therefore, those who do use these products are a PESS due to greater exposure. Consumer bystanders, although they do not use a product containing C.I. Pigment Violet 29, are also a PESS due to the possibility that bystanders can be any age group (including infants, toddlers, children, and elderly) with greater exposure when in a residence where products containing C.I. Pigment Violet 29 are used. A description of the exposure assessment for consumers is available in Section 2.3.2.

There are some exposure scenarios where greater exposure from multiple sources may occur and individuals who may have greater potential for exposure to C.I. Pigment Violet 29. For example, some workers and ONUs may also use consumer products containing C.I. Pigment Violet 29 and have additional exposure outside of the workplace. In developing the risk evaluation, EPA analyzed the 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 a chemical. The results of the available human health data, reported no effects of C.I. Pigment Violet 29 at doses up to and including a limit dose of 1000 mg/kg/day, and no evidence of increased susceptibility in the developmental/reproductive toxicity screening test, indicating that there is no evidence of increased susceptibility for any single group relative to the general population (Stark et al., 2013).

4.3.2 Aggregate and Sentinel Exposures

Section 6(b)(4)(F)(ii) of TSCA requires EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. EPA has defined aggregate exposure as "*the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways*" (40 CFR § 702.33).

In this risk evaluation, EPA decided not to aggregate exposure pathways because the only route of concern is chronic inhalation to C.I. Pigment Violet 29, and the lungs are the site of the adverse effects. Chronic exposure to C.I. Pigment Violet 29 is expected to increase lung particulate burden, overwhelm the lung clearance mechanisms over time, and ultimately result in adverse effects. Exposure via dermal and oral routes is expected to be low due to workplace practices, including use of PPE such as gloves; and any absorption from dermal or oral exposure is expected to be negligible based on the insolubility of C.I. Pigment Violet 29. Therefore, these exposure pathways are not expected to influence the toxicity in the respiratory tract.

EPA defines sentinel exposure as "the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures" (40 CFR 702.33). In this risk evaluation, EPA considered sentinel exposures by considering exposures to populations who may have upper bound exposures,– for example, workers who perform activities with higher exposure potential, including occupational users who work directly

with C.I. Pigment Violet 29 and occupational non-users working in the vicinity. Where statistical data are available, EPA typically uses the 95th percentile value of the available dataset to characterize high-end exposure for a given condition of use. In this risk evaluation, EPA considered exposure to particles the median of the smaller particle size distribution to represent sentinel exposure.

5 UNREASONABLE RISK DETERMINATION

5.1 Overview

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. These determinations do not consider costs or other non-risk factors. In making these determinations, 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 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).[3]

This section describes the final unreasonable risk determinations for the conditions of use in the scope of the risk evaluation. The final unreasonable risk determinations are based on the risk estimates in the final risk evaluation, which may differ from the risk estimates in the revised draft risk evaluation due to letter peer review and public comments. Therefore, the final unreasonable risk determinations of some conditions of use may differ from those in the revised draft risk evaluation.

5.1.1 Human Health

EPA's risk evaluation identified non-cancer adverse effects from chronic inhalation exposures to C.I. Pigment Violet 29. The health risk estimates for all conditions of use are in Section 4.2.3.

For the C.I. Pigment Violet 29 risk evaluation, EPA did not find any evidence of increased susceptibility for any single group relative to the general population. EPA identified workers and ONUs who use or are exposed to C.I. Pigment Violet 29 as part of typical processes and consumers and bystanders as PESS for this risk evaluation.

EPA evaluated exposures to workers and ONUs using reasonably available monitoring and modeling data for inhalation exposures, as applicable. EPA conducted a qualitative assessment for industrial and commercial plastic and rubber product uses exposure and consumer exposure and concluded that exposures are expected to be limited.

The description of the data used for human health exposure is in Section 2.3. Uncertainties in the analysis are discussed in Section 4.1 and considered in the unreasonable risk determination for each condition of use presented below.

EPA considered reasonably available information and environmental fate properties to characterize general population exposure. General population exposures to C.I. Pigment Violet 29 are expected to be minimal due to the limited environmental releases of C.I. Pigment Violet 29 and the insolubility in water and low volatility. Similarly, oral ingestion of C.I. Pigment Violet 29 is expected to be negligible

[3] 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 statutes have different authorities and mandates and may involve risk considerations other than those discussed here.

due to limited concentrations expected in surface and ground water based on minimal environmental releases and insolubility in water. Inhalation of C.I. Pigment Violet 29 by the general population is expected to be low due to limited fugitive and incineration air releases from manufacturing and processing. As a result, no further analysis was conducted for exposure to the general population. For each condition of use, EPA found that there was no unreasonable risk to the general population from exposure via surface water, ground water and air. Additional details regarding the general population are in Section 2.3.1.2.

5.1.1.1 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (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) for a specific health endpoint) divided by the exposure concentration for the specific scenario of concern. Section 3.2.3.1 presents the PODs for non-cancer effects for C.I. Pigment Violet 29 and Section 3.2.3.2 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 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 benchmark MOE is in Section 4.2.

5.1.1.2 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs) can provide a risk profile 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 non-cancer effects. Whether EPA makes a determination of unreasonable risk 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. A calculated MOE greater than the benchmark MOE alone does not support a determination of no unreasonable risk, since EPA may consider other risk-based factors when making an unreasonable risk determination.

When making an unreasonable risk determination based on injury to health of workers (who are one example of PESS), EPA also makes assumptions regarding workplace practices and the implementation of the required hierarchy of controls from OSHA. EPA assumes that feasible exposure controls, including engineering controls, administrative controls, or use of PPE are implemented in the workplace. While OSHA has not issued a specific PEL for C.I. Pigment Violet 29, some level of respiratory PPE is assumed to be used due to the OSHA PEL for respirable dust particulates (29 CFR § 1910.1000). EPA has information from the manufactures to support this assumption. However, information for each condition of use is not known. EPA's decisions for unreasonable risk to workers

are based on high-end exposure estimates in order to capture not only exposures for PESS but also to account for the uncertainties related to whether or not workers are using PPE. EPA does not assume that ONUs use PPE. For each condition of use, depending on the reasonably available information and professional judgement, EPA assumes workers use of respirators with APFs ranging from 10 to 25. However, EPA assumes that for some conditions of use, the use of respirators is not a standard industry practice, based on professional judgement given the burden associated with the use of respirators, including the expense of the equipment and the necessity of fit-testing and training for proper use. Once EPA has applied the appropriate PPE assumption for a particular condition of use in each unreasonable risk determination, in those instances when EPA assumes PPE is used, EPA also assumes that the PPE is used in a manner that achieves the stated APF.

In the C.I. Pigment Violet 29 risk characterization, EPA considered non-cancer risk estimates from chronic inhalation exposures in the unreasonable risk determination. Quantitative risk estimates were not developed for the acute inhalation, oral and dermal exposure pathways for C.I. Pigment Violet 29 because of low hazard, as described in Section 4.2.1. Additionally, EPA determined that C.I. Pigment Violet 29 is not likely to be carcinogenic. Lastly, since there is no high-quality test data for inhalation toxicity available for C.I. Pigment Violet 29, EPA used carbon black as an analogue. Based on the carbon black inhalation study, those adverse effects were used to estimate inhalation risks for C.I. Pigment Violet 29 (alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract).

The C.I. Pigment Violet 29 risk determination considers the uncertainties associated with the reasonably available information to justify the use of a high-end exposure concentration of 1.2 mg/m^3 in air for downstream processers and users. EPA only has low quality monitoring data available for the manufacturing of C.I. Pigment Violet 29. In the absence of monitoring data for downstream processers and users, EPA assumes that downstream processers and users of C.I. Pigment Violet 29 are not exposed to air concentrations exceeding the occupational exposure analysis as described in Section 2.3.1.

When making a determination of unreasonable risk, the Agency has a higher degree of confidence where uncertainty is low. Similarly, EPA has high confidence in the hazard and exposure characterizations when, for example, the basis for characterizations is measured data, monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. Where EPA has made assumptions in the scientific evaluation, whether or not those assumptions are protective is also a consideration. Additionally, when available, EPA considers the central tendency and high-end exposure levels when determining the unreasonable risk. High-end risk estimates (*e.g.*, 95^{th} percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and central tendency risk estimates are generally estimates of average or typical exposure.

EPA may make a determination of no unreasonable risk for conditions of use where the substance's hazard and exposure potential, or where the risk-related factors described previously, lead the Agency to determine that the risks are not unreasonable.

5.1.2 Environment

To assess environmental risk, EPA typically calculates a risk quotient (RQ) to compare environmental concentrations against an effect level. The environmental concentration is determined based on the levels of the chemical released to the environment (*e.g.*, surface water, sediment, soil, biota) under the conditions of use, based on the fate properties, release potential, and reasonably available

environmental monitoring data. The effect level is calculated using concentrations of concern that represent hazard data for aquatic, sediment-dwelling, and terrestrial organisms. However, RQs were not calculated for C.I. Pigment Violet 29, in consideration of the limited environmental exposures and low hazard.

Reasonably available data indicate that no effects were observed in environmental hazard testing with aquatic species up to the limit of solubility of C.I. Pigment Violet 29. Environmental hazard data available for fish, aquatic invertebrates and aquatic plants reported that no effects were observed up to the limit of solubility of the chemical. Based on the environmental toxicity testing, EPA concludes that C.I. Pigment Violet 29 presents a low hazard to the environment. Additionally, based on the known releases from manufacturing; the physical and chemical properties; and environmental fate endpoints of C.I. Pigment Violet 29, EPA conducted a qualitative assessment of the presence of C.I. Pigment Violet 29 in the environment. Section 4.1 provides more detail regarding the environmental risk for C.I. Pigment Violet 29.

5.1.2.1 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. Engineering controls, aquatic high capture efficiency at the site as well as physical and chemical properties support EPA's conclusion of limited environmental release to air, water and sediment, groundwater via biosolids, and landfill leaching.

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 in the environment. There are no environmental risk estimates for C.I. Pigment Violet 29; the qualitative assessment is in Section 4.2.

5.2 Detailed Unreasonable Risk Determinations by Condition of Use

Table 5-1. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	Unreasonable Risk	Detailed Risk Determination
Manufacture	Domestic manufacture	Domestic manufacture	Yes	Section 5.2.1.1
	Import	Import	Yes	Section 5.2.1.2
Processing	Incorporation into formulation, mixture or reaction products	Paints and Coatings	Yes	Sections 5.2.1.3
		Plastic and Rubber Products	Yes	Section 5.2.1.4
Processing	Use as an intermediate	Creation or adjustment to other perylene pigments	Yes	Section 5.2.1.5
Processing	Recycling	Recycling	Yes	Section 5.2.1.6

Life Cycle Stage	Category [a]	Subcategory [b]	Unreasonable Risk	Detailed Risk Determination
Distribution in commerce	Distribution	Distribution	No	Section 5.2.1.7
Industrial/ commercial use	Plastic and rubber products	Automobile plastics	No	Section 5.2.1.8
		Industrial carpeting	No	Section 5.2.1.9
	Paints and coatings	Automobile (*e.g.*, OEM and refinishing)	Yes	Section 5.2.1.10
		Coatings and basecoats	Yes	Section 5.2.1.11
	Merchant ink for commercial printing	Merchant ink	Yes	Section 5.2.1.12
Consumer uses	Consumer watercolor and acrylic paints	Professional quality watercolor and acrylic artist paint	No	Section 5.2.1.13
Disposal	Emissions to Air	Air	Yes	Section 5.2.1.14
	Wastewater	Industrial pre-treatment		
		Industrial wastewater treatment		
		Publicly owned treatment works (POTW)		
		Underground injection		
	Solid wastes and liquid wastes	Municipal landfill		
		Hazardous landfill		
		Other land disposal		
		Municipal waste incinerator		
		Hazardous waste incinerator		
		Off-site waste transfer		

Life Cycle Stage	Category [a]	Subcategory [b]	Unreasonable Risk	Detailed Risk Determination
[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. 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.				

5.2.1 Human Health

5.2.1.1 Manufacture – Domestic Manufacture

Section 6(b)(4)(A) unreasonable risk determination for domestic manufacture of C.I. Pigment Violet 29: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that the domestic manufacture of C.I. Pigment Violet 29 presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures at the high-end support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from domestic manufacture of C.I. Pigment Violet 29.

5.2.1.2 Manufacture – Import

Section 6(b)(4)(A) unreasonable risk determination for import of C.I. Pigment Violet 29: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that import of C.I. Pigment Violet 29 presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from import of C.I. Pigment Violet 29.

5.2.1.3 Processing – Incorporation into formulation, mixture or reaction products in paints and coatings

Section 6(b)(4)(A) unreasonable risk determination for the processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in paints and coatings: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in paints and coatings presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.

- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in paints and coatings.

5.2.1.4 Processing – Incorporation into formulation, mixture or reaction products in plastic and rubber products

Section 6(b)(4)(A) unreasonable risk determination for the processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in plastic and rubber products: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in plastic and rubber products presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
  Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from processing of C.I. Pigment Violet 29 in the incorporation into formulation, mixture or reaction products in plastic and rubber products.

5.2.1.5 Processing – Intermediate in the creation or adjustment of color of other perylene pigments

Section 6(b)(4)(A) unreasonable risk determination for the processing of C.I. Pigment Violet 29 as an intermediate in the creation or adjustment of color of other perylene pigments: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that processing of C.I. Pigment Violet 29 as an intermediate in the creation or adjustment of color of other perylene pigments presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from processing of C.I. Pigment Violet 29 as an intermediate in the creation or adjustment of color of other perylene pigments.

5.2.1.6 Processing – Recycling

Section 6(b)(4)(A) unreasonable risk determination for the processing by recycling of C.I. Pigment Violet 29: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that processing by recycling of C.I. Pigment Violet 29 presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from processing by recycling of C.I. Pigment Violet 29.

5.2.1.7 Distribution in Commerce

Section 6(b)(4)(A) unreasonable risk determination for distribution in commerce of C.I. Pigment Violet 29: Does not present an unreasonable risk of injury to health (workers and ONUs).

For the purposes of the unreasonable risk determination, distribution in commerce of C.I. Pigment Violet 29 is the transportation associated with the moving of C.I. Pigment Violet 29 in commerce. The loading and unloading activities are associated with other conditions of use. EPA assumes transportation of C.I. Pigment Violet 29 is done taking similar measures as to the transportation of hazardous materials, and emissions are therefore minimal (with the exception of spills and leaks, which are outside the scope of the risk evaluation). Based on the limited emissions from the transportation of chemicals, EPA determines there is no unreasonable risk of injury to health (workers and ONUs) from the distribution in commerce of C.I. Pigment Violet 29.

5.2.1.8 Industrial/Commercial Use – Plastic and rubber products – Automobile plastics

Section 6(b)(4)(A) unreasonable risk determination for the industrial and commercial use of C.I. Pigment Violet 29 in plastic and rubber products in automobile plastics: Does not present an unreasonable risk of injury to health (workers and ONUs).

A quantitative evaluation of the worker and ONU exposures attributable to this condition of use is not included in the risk evaluation because EPA estimates that worker and ONU exposures to C.I. Pigment Violet 29 in plastic and rubber products in automobiles are negligible. Due to its low solubility in water and octanol, C.I. Pigment Violet 29 is not expected to leach out of automobile plastics for industry and commercial use. Inhalation exposure to C.I. Pigment Violet 29 is expected to be limited, thus eliminating or significantly reducing the potential for exposures (Section 1.4.1.3).

5.2.1.9 Industrial/Commercial Use – Plastic and rubber products – Industrial carpeting

Section 6(b)(4)(A) unreasonable risk determination for the industrial and commercial use of C.I. Pigment Violet 29 in plastic and rubber products in industrial carpeting: Does not present an unreasonable risk of injury to health (workers and ONUs).

A quantitative evaluation of the worker and ONU exposures attributable to this condition of use is not included in the risk evaluation because EPA estimates that worker and ONU exposures to C.I. Pigment Violet 29 in plastic and rubber products in industrial carpeting are negligible. Due to its low solubility in water and octanol, C.I. Pigment Violet 29 is not expected to leach out of industry carpets for industry and commercial use. Inhalation exposure to C.I. Pigment Violet 29 is expected to be limited, thus eliminating or significantly reducing the potential for exposures (Section 1.4.1.3).

5.2.1.10 Industrial/Commercial Use – Paints and coatings – Automobile (OEM and refinishing)

Section 6(b)(4)(A) unreasonable risk determination for the industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in automobile OEM and refinishing: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in automobile OEM and refinishing does present an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 25, which is the highest APF assumed across all the conditions of use, the risk estimates of non-cancer effects from chronic inhalation exposures do support an unreasonable risk determination. The high-end risk estimates of non-cancer effects from chronic inhalation exposures when assuming use of respirators with APF of 25 approximate the benchmark and do support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in automobile OEM and refinishing.

5.2.1.11 Industrial/Commercial Use – Paints and coatings – Coatings and basecoats

Section 6(b)(4)(A) unreasonable risk determination for the industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in coatings and basecoats: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, without assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in coatings and basecoats presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- EPA does not assume workers use any type of respirator during industrial and commercial use of paints and coatings in coatings and basecoats.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from industrial and commercial use of C.I. Pigment Violet 29 in paints and coatings in coatings and basecoats.

5.2.1.12 Industrial/Commercial Use – Merchant ink for commercial printing – Merchant ink

Section 6(b)(4)(A) unreasonable risk determination for the industrial and commercial use of C.I. Pigment Violet 29 in merchant ink for commercial printing: Presents an unreasonable risk of injury to health (workers).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, without assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that industrial and commercial use of C.I. Pigment Violet 29 in merchant ink for commercial printing presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in

Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- EPA does not assume workers use any type of respirator during industrial and commercial use of merchant ink in commercial printing.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from industrial and commercial use of C.I. Pigment Violet 29 in merchant ink for commercial printing.

5.2.1.13 Consumer Use – Consumer watercolor and acrylic paints – Professional quality watercolor and acrylic artist paint

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of C.I. Pigment Violet 29 in professional quality watercolor and acrylic artist paint: Does not present an unreasonable risk of injury to health (consumers and bystanders).

A quantitative evaluation of the consumer and bystander exposures attributable to this condition of use is not included in the risk evaluation because EPA estimates that consumer and bystander exposures to C.I. Pigment Violet 29 in professional quality watercolor and acrylic artist paint are limited. Due to its low vapor pressure, C.I. Pigment Violet 29 is not expected to volatilize from consumer watercolor and artistic color and inhalation is not identified as a route of exposure for consumers and bystanders. Because it is a solid with low solubility, oral ingestion and dermal and oral absorption are expected to be limited, thus eliminating or significantly reducing the potential for exposures (Section 2.3.2).

5.2.1.14 Disposal

Section 6(b)(4)(A) unreasonable risk determination for disposal of C.I. Pigment Violet 29: Presents an unreasonable risk of injury to health (workers and ONUs).

For workers, EPA found that there was unreasonable risk of non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of PPE. For ONUs, EPA found that there was unreasonable risk of non-cancer effects from chronic inhalation exposures at the high-end.

EPA's determination that disposal of C.I. Pigment Violet 29 presents an unreasonable risk is based on the comparison of the risk estimates for chronic non-cancer effects to the benchmarks (Table 4-4) and other considerations. As explained in Section 5.1, EPA considered the health effects of C.I. Pigment Violet 29, the exposures from the condition of use, and the uncertainties in the analysis (Section 4.1.1):

- For workers, when assuming the use of respirators with APF of 10, the risk estimates of non-cancer effects from chronic inhalation exposures support an unreasonable risk determination.
- For ONUs, the risk estimates of non-cancer effects at the central tendency and high-end support an unreasonable risk determination.
- Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.
- Inhalation exposures for ONUs were assessed using the maximum concentration of C.I. Pigment Violet 29 measured during the Section 4 Test Order monitoring at the manufacturing site as a high-end exposure estimate.
- Dermal exposures were determined to have low hazard; therefore, no quantitative risk estimates were developed. The qualitative analysis does not support an unreasonable risk determination.

In summary, the risk estimates, the health effects of C.I. Pigment Violet 29, the exposures, and consideration of uncertainties support EPA's determination that there is unreasonable risk of injury to health (workers and ONUs) from disposal of C.I. Pigment Violet 29.

5.2.1.15 Environment

6(b)(4)(A) unreasonable risk determination for all conditions of use of C.I. Pigment Violet 29: Does not present an unreasonable risk of injury to the environment (aquatic, sediment-dwelling, and terrestrial organisms.

For all conditions of use, EPA found that no effects were observed for each high-quality environmental hazard study and environmental exposures are expected to be limited. Low solubility of C.I. Pigment Violet 29 in water (<0.0014 mg/L), low environmental releases (<1 lb/day) from the sole U.S. manufacturing facility, and lack of environmental hazard means that it would be unlikely for environmental concentrations to reach a level where adverse effects could be observed in environmental receptors. Further, due to a combination of low potential exposure across all routes and low hazard for ecotoxicity and human health, EPA concludes that C.I. Pigment Violet 29 does not present an unreasonable risk to sediment dwelling organisms, aquatic species, and terrestrial species.

In summary, the environmental effects of C.I. Pigment Violet 29, the exposures, physical and chemical properties of C.I. Pigment Violet 29 and consideration of uncertainties support EPA's determination that there is no unreasonable risk to the environment from all conditions of use of C.I. Pigment Violet 29.

5.3 Changes to the Unreasonable Risk Determination from Revised Draft Risk Evaluation to Final Risk Evaluation

In this final risk evaluation, EPA made changes to the unreasonable risk determinations for C.I. Pigment Violet 29 following the publication of the revised draft risk evaluation, as a result of the analysis following letter peer review and public comment. There are four types of changes: changes to the model used to evaluate risk; therefore, changes in determinations for certain conditions of use; clarification of the descriptions of the conditions of use; the removal of a quantitative analysis for two conditions of use; and the clarification to the health endpoint.

In the revised draft risk evaluation, a MPPD model was used to calculate the occupational inhalation exposure risks; however, in this final risk evaluation the RDDR model is used. The MPPD model was not thought to be appropriate because the particle size data was not robust enough and the MPPD model cannot calculate HECs for the hamster data in the Elder et al., (2005) study, while the RDDR

model can accept hamster data input. The RDDR model requires MMAD and GSD data inputs, therefore the particle size data from the Elder et al., (2005) study was utilized to correspond with the adverse effects in the study. Therefore, the RDDR model did not use any of the three particle size data previously evaluated in the revised risk evaluation. The RDDR is utilized to adjust the measured or nominal particulate matter exposure level in the various regions of the respiratory tract from animal studies to the corresponding human exposure level. The change in model resulted in unreasonable risk determinations for all ONUs and industrial and commercial use in automobile paint OEM and refinishing condition of use.

In this final risk evaluation, EPA has clarified the description of the conditions of use that appeared in the draft risk evaluation. Specifically:

- The process description for plastic and rubber products (automobile plastics) in the revised risk evaluation is added. It includes the shaping and installing of plastic parts into the automobile.
- Any mention of processing is removed from all industrial and commercial conditions of use process descriptions. These uses are meant to capture use of products that already incorporate C.I. Pigment Violet 29. Further, no direct exposure with solid C.I. Pigment Violet 29 is observed in any industrial or commercial conditions of use.
- Any mention of industrial and commercial uses was removed from all processing conditions of use process descriptions to reduce any overlap in conditions of use.

The quantitative analysis for industrial and commercial plastic and rubber products (automobile plastics and industrial carpeting) conditions of use has been removed from this final risk evaluation. Previously, EPA evaluated the risk of these two conditions of use based on inhalation of C.I. Pigment Violet 29 particles; however, the Agency determined that under these conditions of use, C.I. Pigment Violet 29 is trapped in the plastic matrix of these finished products and any inhalation exposure to C.I. Pigment Violet 29 is negligible. This change results in a no unreasonable risk determination.

In the revised draft risk evaluation, the potential health endpoint was described as lung overload. However, lung overload and increased lung burden are not necessarily health effects rather, they are kinetic phenomenon that could lead to adverse effects in the lungs. The final risk evaluation has the potential health effects described as alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract lungs, based on inhalation study data on the analogue carbon black.

5.4 Unreasonable Risk Determination Conclusion

5.4.1 No Unreasonable Risk Determinations

TSCA Section 6(b)(4) requires EPA to conduct risk evaluations to determine whether chemical substances present unreasonable risk under their conditions of use. In conducting risk evaluations, "EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation…" 40 CFR 702.47. Pursuant to TSCA Section 6(i)(1), a determination of "no unreasonable risk" shall be issued by order and considered to be final agency action. Under EPA's implementing regulations, "[a] determination made by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluations, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order." 40 CFR 702.49(d).

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:

- Distribution in commerce;
- Industrial and commercial use in plastic and rubber products for automobile plastics (Section 5.2.1.10, Section 5.1.1, Section 5.1.2, Section 4);
- Industrial and commercial use in plastic and rubber products for industrial carpeting (Section 5.2.1.10, Section 5.1.1, Section 5.1.2, Section 4);
- Consumer use in professional quality watercolor and acrylic artist paint (Section 5.2.1.13, Section 5.1.1, Section 5.1.2, Section 4).

This subsection of the final risk evaluation therefore 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. All assumptions that went into reaching the determinations of no unreasonable risk for these conditions of use, including any considerations excluded for these conditions of use, are incorporated into this order.

The support for each determination of "no unreasonable risk" is set forth in Section 5.2 of the final risk evaluation, "Detailed Unreasonable Risk Determinations by Condition of Use." This subsection also constitutes the statement of basis and purpose required by TSCA Section 26(f).

5.4.2 Unreasonable Risk Determinations

EPA has determined that the following conditions of use of C.I. Pigment Violet 29 present an unreasonable risk of injury:

- Manufacture: domestic manufacturing;
- Manufacture: 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: use as an intermediate in the creation or adjustment of color of other perylene pigments;
- Processing: recycling;
- Industrial and commercial use in paints and coatings for automobiles (*e.g.*, OEM and refinishing)
- Industrial and commercial use in paints and coatings for coatings and basecoats;
- Industrial and commercial use in merchant ink for commercial printing; and
- Disposal.

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.

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APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substance Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	3 chemical data submissions from an order received for C.I. Pigment Violet 29: solubility in water, solubility in n-octanol and particulates not otherwise regulated, respirable (2020). Accessed in the public docket EPA-HQ-OPPT-2020-0070.
Toxic Substance Control Act (TSCA) – Section 6(b)	EPA is directed to identify and conduct risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	C.I. Pigment Violet 29 is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
Toxic Substance Control Act (TSCA) – Section 8(a)	The TSCA § 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	C.I. Pigment Violet 29 manufacturing (including importing), processing and use information is reported under the CDR Rule (85 FR 20122, April 9, 2020).
Toxic Substance Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, (including imported) or processed, in the United States.	C.I. Pigment Violet 29 was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA Section 5 (60 FR 16309, March 29, 1995).
Other Federal Regulations		
Food and Drug Administration (FDA)	Chemicals that come in contact with food must first be reviewed by the FDA for safety. In 1998 BASF submitted a petition for C.I. Pigment Violet 29 to be a colorant in food-contact polymers.	C.I. Pigment Violet 29 is approved to be in finished articles that come in contact with food. It should not to exceed 1 percent by weight of polymers and should follow specific conditions of use (21 CFR 178.3297). C.I. Pigment Violet 29 is not listed as an approved food additive.

A.2 International Laws and Regulations

Table_Apx A-2. Regulatory Actions by other Governments and Tribes

Country/Organization	Requirements and Restrictions
Australia	C.I. Pigment Violet 29 is on the Australian Inventory for Chemical Substances (AICS), a database of chemicals available for industrial use in Australia. There are no regulatory obligations or conditions cited for C.I. Pigment Violet 29.
Canada	C.I. Pigment Violet 29 is on the public portion of the Domestic Substances List (DSL). The DSL is an inventory of approximately 23,000 substances manufactured, imported or used in Canada on a commercial scale. Substances not appearing on the DSL are considered to be new to Canada and are subject to notification.
China	C.I. Pigment Violet 29 is on the non-confidential Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). The inventory was last updated on May 1, 2020. There are no restrictions associated with being on the Chinese inventory.
European Union	C.I. Pigment Violet 29 is registered for use in the EU. (European Chemicals Agency (ECHA) database. August 21, 2020). C.I. Pigment Violet 29 was evaluated under the 2019 Community rolling action plan (CoRAP) under regulation (European Commission [EC]) No1907/2006 – REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) (European Chemicals Agency (ECHA) database. Accessed August 21, 2020).
Japan	In accordance with the provisions of Chemical Substances Control Law (CSCL), C.I. Pigment Violet 29 is exempt from the new chemical notification requirement and listed as Low Molecular Heterocyclic Organic Compound on the existing chemical substances list (NITE Chemical Risk Information Platform (NITE-CHRIP).
Korea	C.I. Pigment Violet 29 is on the Korea Existing Chemicals Inventory because it is a chemical that was domestically commercialized prior to February 2, 1991 and was designated and published by the Minister of Environment in consultation with the Minister of Labor. There are no restrictions associated with being on the Korean inventory.
New Zealand	C.I. Pigment Violet 29 was added to the New Zealand Inventory (NZloC) on January 12, 2006 with the approval status that it may be used as a component in a product covered by a group standard, but it is not approved for use as a chemical in its own right. There are no restrictions or exclusions associated with C.I. Pigment Violet 29.
Philippines	C.I. Pigment Violet 29 is on the Philippines Inventory of Chemicals and Chemical Substances (PICCS). PICCS was developed to provide government, industry and the public with a core inventory of all existing chemicals and chemical substances in the country and is updated

Country/Organization	Requirements and Restrictions
	annually. There are no restrictions associated with being on the Philippine inventory.
Taiwan	C.I. Pigment Violet 29 in on the National Existing Chemical Inventory in Taiwan. There are no restrictions associated with being on the Taiwanese inventory.
Vietnam	C.I. Pigment Violet 29 is on the draft (September 2018) Vietnam National Existing Chemical Inventory. There are no restrictions associated with being on the Vietnamese inventory.

Appendix B LIST OF SUPPLEMENTAL DOCUMENTS

List of supplemental documents:

a. Associated systematic review data quality evaluation and data extraction documents that provide additional detail and information on individual study evaluations and data extraction including criteria and scoring results.

    a. *Final 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), Systematic Review Supplemental File: Data Quality Evaluation of Physical and Chemical Property Studies* (U.S. EPA, 2020f)

    b. *Final 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), Systematic Review Supplemental File: Data Quality Evaluation of Environmental Fate and Transport Studies* (U.S. EPA, 2020c)

    c. *Final 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), Systematic Review Supplemental File: Data Quality Evaluation of Human Health Hazard Studies* (U.S. EPA, 2020e)

    d. *Final 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), Systematic Review Supplemental File: Data Quality Evaluation of Environmental Hazard Studies* (U.S. EPA, 2020d)

    e. *Final 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), Systematic Review Supplemental File: Data Quality Evaluation of Environmental Release and Occupational Exposure Studies* (EPA-HQ-OPPT-2018-0604)

b. Other supplemental files

    a. *Final 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) Supplemental File: Information Received from Manufacturing Stakeholders* (U.S. EPA, 2020a)

Appendix C ENVIRONMENTAL FATE STUDY RESULTS

Table_Apx C-1. Environmental Fate Study Summary for C.I. Pigment Violet 29 (ECHA, 2017)

Target System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect	Affiliated Reference	Data Quality Evaluation results of full study report
Biodegradation	OECD 301F - Biodegrad-ability: Manometric Respirometry Test)	Activated sludge, domestic, non-adapted (Concentration of sludge: 30 mg/L)	Static renewal	100 mg/L	28 Days	Degradation degree of the test substance after 28 days (percent BOD/ThOD); 0-10	Poorly biodegradable	(BASF, 1999a)	High
Activated sludge inhibition	EN 45001/ ISO 9002	Activated sludge from laboratory wastewater plants treating municipal and synthetic sewage	Static	1 g/L test substance was added to the inoculum	30 min	EC20 >100 mg/L	No Significant inhibition of respiration was measured	(BASF, 1999b)	High

[1]Species/strain, sex of animals included in the study.

Appendix D ENVIRONMENTAL EFFECTS ENDPOINTS

Table_Apx D-1. Aquatic Plant Toxicity Study Summary for C.I. Pigment Violet 29

Target Effect	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[3]
Mortality	OECD-201; Aquatic vascular plant: 7 days, static renewal	Duckweed (*Lemna gibba*)	Static renewal	Nominal: 0 (control), 1, 3.2, 10, 32, 100 mg/L based on loading Measured Test Concentrations: 0.007 mg/L (highest)	7 Days	NES[4] (based on growth [frond number and dry weight])	None reported	(**BASF, 2012b**)	High
	OECD-202; Acute freshwater invertebrate: 48 hours, static, limit	*Daphnia magna*	Static	Measured test concentrations: - (control), 0.0065 mg/L	48 Hours	NES	None reported	(**BASF, 2012a**)	High
	OECD-203; Acute freshwater fish: 96 hours, static	Zebrafish (*Brachydanio rerio*)	Static	Nominal test concentrations: 0 (control), 5000 mg/L	96 Hours	NES	None reported	(**BASF, 1988**)	High

[1]Species/strain, sex of animals included in the study.
[2]The effect(s) listed were the most sensitive effects observed for that target organ/system in that study (*i.e.*, the effect(s) upon which the POD was based).
[3]Information included in this column overall quality level resulting from the data quality evaluation – this also would include unacceptable studies for comparison with acceptable studies. Note that in addition to the final result for the study/endpoint, selected important quality considerations could also be included, such as low purity etc.
[4]NES means no effect at saturation.

Appendix E HUMAN HEALTH EFFECTS ENDPOINTS

Table_Apx E-1. Toxicity Study Summaries for C.I. Pigment Violet 29

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
Mortality	OECD-401; Acute oral	Sprague-Dawley rat (5 animals/ sex/dose)	Oral	6810 and 10000 mg/kg bw	14 days	LD_{50} >10,000 mg/kg bw	No mortality or macroscopic abnormalities were observed at necropsy; dark red coloring of the skin and dark red coloring of the feces were observed. No effects were reported regarding body weight.	(Kim et al., 1999; BASF, 1975b)	Medium
	OECD-401; Acute oral	Sprague-Dawley rat (5 animals/ sex/dose)	Oral	10000 mg/kg bw	14 days	LD_{50} > 10,000 mg/kg-bw	No mortality, effects on body weight, or macroscopic abnormalities at necropsy were observed. Dyspnea was observed at the beginning of the test (specific time-point not provided) and red-colored feces were observed on day 1.	(BASF, 1978d)	Medium
	OECD-401; Acute oral, single dose by gavage, limit	Wistar rat	Oral			LD_{50} > 5,000 mg/kg-bw	No mortality, clinical signs of toxicity, or effects on body weight were observed. No macroscopic findings were observed at necropsy.	(Rupprich and Weigand, 1984c)	High

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
	Acute Inhalation Toxicity	Wistar Rat (6 per sex)	Inhalation	0.31 mg/l air (calculated)	7 Hour	LC_{50}> 0.31 mg/L air	None of the animals died during the exposure period. There were no abnormal observations during clinical investigations. No effects on body weight were reported. There were no abnormal observations during gross pathology. Average concentration of substance in the atmosphere as stated in the report: 0.31 mg/L (no analytical monitoring conducted).	(BASF, 1978b)	Unacceptable
		Rat (6 per sex)	Inhalation	14.74 mg/L	8 Hour	LC_{50}> 14.74 mg/L	None of the animals died during the exposure period. Slight irritation of the mucous membrane was observed. No effects on body weight were reported. No abnormal observations during gross pathology. Average concentration of substance in the atmosphere as stated in the report: 14.74 mg/L (no analytical monitoring conducted).	(BASF, 1975a)	Unacceptable

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
	Acute Intraperitone-al Toxicity - Conducted according to internal protocol	NMRI-Wiga Mouse	Intraperitoneal injection	10,000, 6,810, 4,640 mg/kg	14-day observation post injection	LD_{50}= 9000 mg/kg-bw	2/5 males and 5/5 females treated with 10,000 mg/kg-bw, and 1/5 females treated with 6,810 mg/kg-bw died. Dyspnea, apathy, unsteady gait, and ruffled fur were reported until day 4 in mice given 10,000 and 6,810 mg/kg-bw. Death occurred on days 2 and 3, with bad general health observed until and including day 4. Mice given 4,640 mg/kg-bw showed dyspnea and ruffled fur only on the first day of treatment. Intra-abdominal precipitation of the test substance and coloration were observed in mice that died on study and in mice euthanized at study termination; thickening of the edges of the liver was also noted in mice at study termination.	(Anderson et al., 2010; BASF, 1978c)	Low

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
		NMRI-Ivanovas Mouse (5 animals/ sex/ dose)	Intraperitoneal injection	2150, 4640 and 10000 mg/kg	14-day observation post injection	LD_{50}= 7000 mg/kg-bw	At 10,000 mg/kg-bw, all animals died within 7 days. At 4,640 mg/kg-bw, 2/5 males and 1/5 females died; 1/5 males died when treated with 2,150 mg/kg-bw. Dyspnea, apathy, agitation, lying on the stomach, tumbling, bradykinesia, paresis of the hind extremities, spastic walk, shivering, tremors, roll cramps, flexing cramps, tonic cramps, tonic-clonic cramps, systemic red coloration of the skin and bad general health were observed. Body weight gain was normal. Intra-abdominal precipitation of the substance and isolated agglutination were recorded at gross necropsy.	(BASF, 1975f)	Low

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
Reproductive and Developmental	OECD-421 Reproduction and development toxicity	Wistar rat (10 males/ 10 females)	Gavage	100, 300, 1000 mg/kg bw/d	Exposure: premating period of 2 weeks and a mating period [max. of 2 weeks] in both sexes, approximately 1-week post-mating in males, and the entire gestation period as well as 4 days of lactation in females)	NOAEL= 1000 mg/kg bw/day	Test substance-related but non-adverse findings included: black-discolored feces from study day 1 until the end of the study in all male and female F_0 animals at 300 and 1000 mg/kg-bw/day; black discoloration of the contents of the digestive tract (jejunum, colon, and/or glandular stomach) in all male and female F_0 animals at 300 and 1000 mg/kg-bw/day at necropsy. No test substance-related, adverse effects were noted on parental mortality, clinical signs, body weight, food consumption, macroscopic findings, organ weights (evaluated in males only), histopathology, spermatogenesis, mating or fertility indices, pre-coital interval, gestation index or length, number of implantation sites, post-implantation loss, live birth index, numbers of delivered pups, live-born pups, and stillborn pups, pup viability index, pup sex ratio, pup clinical signs, pup body weights, or pup necropsy up to the highest dose tested (1000 mg/kg-bw/day).	(Stark et al., 2013)	High

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
Skin Irritation	OECD-404; Skin irritation: occlusive	White Vienna rabbits (2 females)	Occlusive, applied to intact skin	Not specified, the test substance was given as a 50% aqueous preparation.	The report describes findings after 24 hours and at the end of the observation period (8 days)	Not irritating	The authors concluded no irritation potential; however, exact determination of erythema scores at 24, 72, and 96 hours was not possible due to coloring by the test substance which persisted until day 4. Erythema scores were 0 on days 7 and 8. Edema scores were 0 throughout the entire study	(BASF, 1975e)	Medium
	OECD-404; Skin irritation: occlusive	Weiber Wiener rabbit (3 animals)	Occlusive, applied to intact and damaged skin	Not specified, the test substance was given as a 50% aqueous preparation.	8-day observation period	Not irritating	None reported; The authors concluded no irritation potential; however, exact determination of erythema scores at 24, 48, and 72 hours was not possible due to coloring by the test substance. All other erythema scores were 0. All edema scores for intact skin were 0. Edema scores for damaged/scarified skin ranged from 0-2 at 24 hours and 0-1 at 48 hours and were 0 for the remainder of the study.	(BASF, 1978e, 1975e)	Medium
	OECD-404; Skin irritation: *in vivo*	Weiber Wiener rabbit	Occlusive, applied to intact skin	Not specified, the test substance was given as a 50% aqueous preparation.	20-hour exposure, 8-day observation period	Not irritating	None reported; Very slight, barely visible erythema (score of 1) was noted up to 48 hours; no erythema was observed at 72 hours post-exposure. Edema scores were 0 throughout the entire study. Two of three rabbits exhibited small, reddish-brown skin discoloration.	(Rupprich and Weigand, 1984a)	High

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
Eye irritation	OECD-405; Eye irritation / Corrosion	Weiber Wiener Rabbit (3 animals)	Single application	The substance was applied undiluted: 100 µl test material	72-hour observation period	Not irritating	None reported; Secretion and substance residues were observed at 1 hour. Remaining substance and smear were observed after 24 hours. The irritation caused by the test substance was not different from the control substance (talcum powder). Scores for iris and cornea were all 0. Chemosis (score of 1) was noted up to 24 hours. Conjunctival redness (score of 1) was noted up to and including day 8 (findings were similar for the talcum treated control eyes). Substance residues were observed in both animals until day 7.	(BASF, 1975c, d)	Medium
	OECD-405; Eye irritation / Corrosion	Weiber Wiener Rabbit (2 animals)	The test substance was applied to the conjunctival sac of one eye in 2 animals	Single concentration: 50 µL	8-day observation period	Not irritating	None reported; Minimal redness of the conjunctivae (scores of 1-2) was observed in all animals at 1, 24, and 48 hours. Redness (score of 1) was still noted in 1/3 rabbits at 72 hours (end of observation period) but was expected to be reversible upon longer observation. Chemosis (score of 1) was noted in 2/3 rabbits at 1 hour; chemosis scores were 0 thereafter. Scores for iris and cornea were all 0. Substance residues were observed in all animals after 1 hour.	(BASF, 1978a)	Medium

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
	OECD-405; Eye irritation / Corrosion	New Zealand albino rabbits (3 animals)	Test substance and carrier solution were dripped once into the conjunctiva of the left eye.	100 mg of the test substance added to 0.05 ml 0.9% NaCl solution	24-hour observation intervals for 72 hours followed by single observation after 7 days	Not irritating	Slight swelling and redness of the conjunctiva as well as hyperemia of the iris after 24 hours. Distinctive inflammation and a diffuse, carmine redness of the conjunctiva. No effects remained after 7 days.	(Rupprich and Weigand, 1984b)	High
Skin sensitization	OECD-429; Skin sensitization: mouse local lymphocyte assay (LLNA)	Male CBA/Ca mouse (2 animals/ conc.)	The test substance in propylene glycol was applied, using a variable volume micro-pipette, to the dorsal surface of each ear	The test substance was applied as 3%, 10% or 30% w/v preparations in propylene glycol	3- day repeat exposure	Not irritating	None reported; The test substance did not cause skin sensitization when applied at concentrations up to 30% w/v.	(Johnson, 1999)	High

Target Organ/ System	Study Type	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration	Endpoint	Effect[2]	Affiliated Reference[3]	Data Quality Evaluation results of full study report[4]
Genotoxicity	OECD-471; Genotoxicity – gene mutation (*in vitro*)	*Salmonella typhimurium* TA 100, TA 1535, TA 1537, TA 1538, TA 98 and *E. coli* WP2uvrA	In agar (plate incorporation)	4, 20, 100, 500, 2500 and 5000 µg/plate	Exposure duration: 48-72 hours at 37°C in the dark	Negative	The test compound proved to be not toxic; In the cytotoxicity test, the test compound was tested at concentrations of 4 to 10,000 µg/plate and did not show any toxicity to the bacteria. In the mutagenicity test, the test compound was tested at concentrations of 4 to 5,000 µg/plate with and without metabolic activation and was concluded to be non-mutagenic	(Jung and Weigand, 1983)	High
	OECD-476; Genotoxicity – gene mutation (*in vitro*)	Chinese hamster lung fibroblasts (V79) Target gene: HPRT	In-medium	Without metabolic activation system (S9 mix): 10.8; 21.5; 43.0; 86.0; 172.0; 344.0 µg/ml With S9 mix: 5.6; 10.8; 21.5; 43.0; 86.0; 172.0 µg/ml	7 days after treatment	Negative	The test item did not induce gene mutations at the HPRT locus in V79 cells; Under the experimental conditions, the test item did not induce gene mutations at the HPRT locus in V79 cells when tested up to a concentration of 172 µg/mL with and without metabolic activation.	(Wollny, 2012)	High

[1]Species/strain, sex of animals included in the study.
[2]The effect(s) listed were the most sensitive effects observed for that target organ/system in that study (*i.e.*, the effect(s) upon which the POD was based).
[3]This column lists the primary reference of the full study report corresponding to the ECHA summary.
[4]Information included in this column is the overall quality level resulting from the data quality evaluation – this also would include unacceptable studies for comparison with acceptable studies. Note that in addition to the final result for the study/endpoint, selected important quality considerations could also be included, such as low purity etc.
[5]Effects evaluated by the study authors were parental mortality, body weight, food consumption, macroscopic findings, organ weights (evaluated in males only), histopathology, spermatogenesis, mating or fertility indices, pre-coital interval, gestation index or length, number of implantation sites, post-implantation loss, live birth index, numbers of delivered pups, liveborn pups, and stillborn pups, pup viability index, pup sex ratio, pup clinical signs, pup body weights, or pup necropsy

Appendix F CARBON BLACK INHALATION STUDIES, ENDPOINTS AND RDDR MODEL OUTPUTS

A special case for consideration when evaluating the toxicity of inhaled particles is the kinetic phenomenon of particle overload. This phenomenon is defined as the overwhelming of clearance in the pulmonary (PU) region leading to a reduction in the ability of the lung to remove particles, and a resultant accumulation or "overload" occurs which results in a retained mass burden in the lung greater than that which would occur with normal physiological clearance rates (Driscoll and Borm, 2020; Miller, 2000). Numerous other reviews have discussed this phenomenon of particle overload and the difficulties it poses for the extrapolation of chronic effects in rats to humans (Warheit et al., 2016; Oberdorster, 2002; ILSI, 2000; Miller, 2000; Oberdorster, 1995; Morrow, 1994).

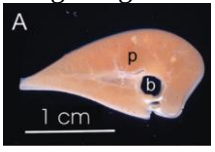
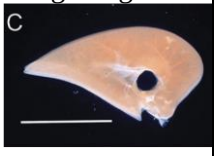
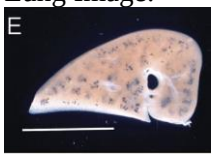
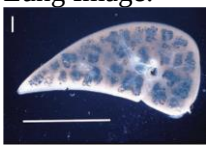
The relevance of particle overload to humans, and even to species other than laboratory rats and mice, is not clear. While it likely to be of little relevance for most "real world" ambient exposures of humans, it is of concern in interpreting some long-term experimental exposure data. And it may be of concern to humans occupationally exposed to some particle types (Mohr et al., 1994), since overload may involve all insoluble materials and affect all species if the particles are deposited at a sufficient rate (Pritchard, 1989), *i.e.*, if the deposition rate exceeds the clearance rate. In addition, the relevance to humans is also clouded by the suggestion that macrophage-mediated clearance is normally slower and perhaps less important in humans than in rats (Morrow, 1994), and that there will be significant differences in macrophage loading between the two species.

A key issue when considering whether overload occurred is that increased particle retention due to large lung burdens needs to be differentiated from that due to inherently high cytotoxicity (*e.g.*, quartz). Thus, consideration of the hazard or risk posed by a particle exposure requires characterization of both possible particle overload and some knowledge of the inherent toxicity of the particle under consideration, especially as many key events associated with "overload" are also embedded in pathways leading to various other adverse outcomes. Despite the frequent use of the term poorly soluble, low toxicity (PSLT) particles in scientific and regulatory literature, a clear consensus definition has not been published, although a recent expert workshop offered guidance on a tiered testing strategy to define critical characteristics (Driscoll and Borm, 2020). The strategy suggested by experts at this workshop was to first define poorly soluble particles (PSPs) and then Low Toxicity (LT) as a subgroup of PSP.

Consideration of kinetic overload thus merely creates context for the evaluation of toxicity data on an inhaled particle. If overload is demonstrated to occur, especially when considering rat tumors, then these effects may be less relevant for human risk assessment. However, as noted, several other "noncancer" events such as inflammation and hyperplasia are related to other adverse outcome pathways and should be evaluated as relevant (U.S. EPA, 2019).

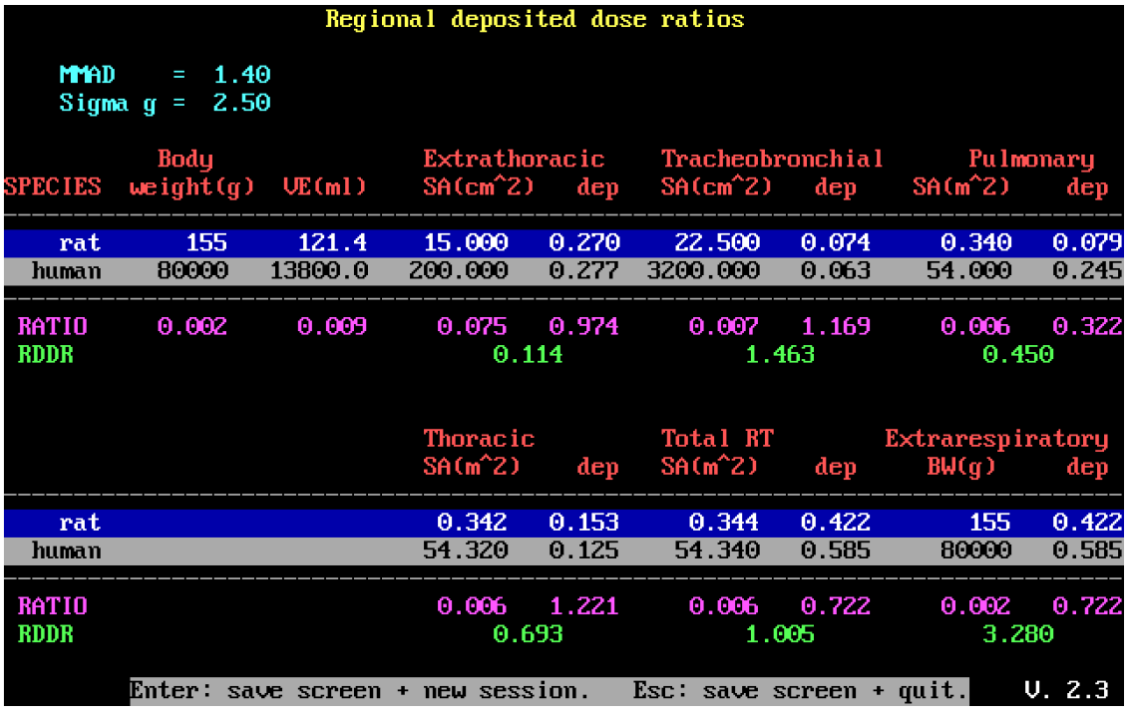
The Regional Deposited Dose Ratio (RDDR) model can be utilized to refine the assessment of inhalation studies. The endpoint table for the Elder et al., (2005) carbon black inhalation study and the RDDR program outputs are listed below (nominal concentrations of 0, 1, 7 and 50 mg/m^3).

Table_Apx F-1. Carbon Black Sub-chronic Inhalation Study Endpoints

Species	Study Effects				
	Control Group	**Low Dose HSCb**	**Mid Dose HSCb**	**High Dose HSCb**	**High Dose LSCb**
Rats	No Adverse Effects Identified Lung Image: 	No Adverse Effects Identified Lung Image: 	Increased clearance $T_{1/2}$, Slow rate in decrease of Cb post-exposure % lung retention, Increased alveolar Type II Cell Density & Increased alveolar parenchyma cells in S phase, Alveolar hyperplasia, Cb laden macrophages, Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes, Increased BAL protein, Increased BAL LDH, Increased BAL beta-glucuronidase Lung Image: 	Increased lung weights, Slow rate in decrease of Cb post-exposure % lung retention, No significant Cb lung clearance, Increased alveolar Type II cell density & Increased alveolar parenchyma cells in S phase, Alveolar fibrosis, Alveolar hyperplasia, Vacuolated macrophages, Cb laden macrophages, Thickened alveolar septa, Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes, Increased BAL protein, Increased BAL LDH, Increased BAL beta-glucuronidase Lung Image: 	Increased clearance $T_{1/2,}$ Slow rate in decrease of Cb post-exposure % lung retention, , Increased Alveolar Cell Density & Increased alveolar parenchyma Cells in S phase, Alveolar hyperplasia, Alveolar fibrosis, Cb laden macrophages, Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes, Increased BAL protein, Increased BAL LDH, Increased BAL beta-glucuronidase Lung Image: 

Species	Study Effects				
	Control Group	**Low Dose HSCb**	**Mid Dose HSCb**	**High Dose HSCb**	**High Dose LSCb**
Mice	No Adverse Effects Identified	No Adverse Effects Identified	Increased clearance $T_{1/2,}$ Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes, Increased BAL protein, Increased BAL beta-glucuronidase, Decreased % cell viability	Increased lung weights, Increased clearance $T_{1/2,}$, Increased alveolar Type II cell density & Increased alveolar parenchyma Cells in S phase, Alveolar hyperplasia, Cb laden macrophages, , Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL protein, Increased BAL LDH, Increased BAL beta-glucuronidase, Decreased % cell viability	--
Hamsters	No Adverse Effects Identified	No Adverse Effects Identified	Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes, Increased BAL LDH, Increased BAL beta-glucuronidase	Increased lung weights, Increased clearance $T_{1/2,}$ Increased alveolar Type II cell density, Cb laden macrophages, Increased BAL cell numbers, Decreased % BAL macrophages, Increased BAL % PMNs, Increased BAL % lymphocytes,	--

Species	Study Effects				
	Control Group	Low Dose HSCb	Mid Dose HSCb	High Dose HSCb	High Dose LSCb
				Increased BAL LDH, Increased BAL beta-glucuronidase	



Regional deposited dose ratios

MMAD = 1.40
Sigma g = 2.50

SPECIES	Body weight(g)	VE(ml)	Extrathoracic SA(cm^2)	dep	Tracheobronchial SA(cm^2)	dep	Pulmonary SA(m^2)	dep
rat	155	121.4	15.000	0.270	22.500	0.074	0.340	0.079
human	80000	13800.0	200.000	0.277	3200.000	0.063	54.000	0.245
RATIO	0.002	0.009	0.075	0.974	0.007	1.169	0.006	0.322
RDDR			0.114		1.463		0.450	

	Thoracic SA(m^2)	dep	Total RT SA(m^2)	dep	Extrarespiratory BW(g)	dep
rat	0.342	0.153	0.344	0.422	155	0.422
human	54.320	0.125	54.340	0.585	80000	0.585
RATIO	0.006	1.221	0.006	0.722	0.002	0.722
RDDR		0.693		1.005		3.280

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Figure_Apx F-1. Elder et al., (2005) Carbon Black Sub-chronic Inhalation Study: RDDR Outputs in Female Rats, Low Dose

Regional deposited dose ratios

MMAD = 2.00
Sigma g = 2.80

SPECIES	Body weight(g)	VE(ml)	Extrathoracic SA(cm^2)	dep	Tracheobronchial SA(cm^2)	dep	Pulmonary SA(m^2)	dep
mouse	22	25.6	3.000	0.409	3.500	0.072	0.050	0.074
human	80000	13800.0	200.000	0.368	3200.000	0.076	54.000	0.213
RATIO	0.000	0.002	0.015	1.111	0.001	0.947	0.001	0.347
RDDR			0.137		1.605		0.695	

	Thoracic SA(m^2)	dep	Total RT SA(m^2)	dep	Extrarespiratory BW(g)	dep
mouse	0.050	0.146	0.051	0.555	22	0.555
human	54.320	0.125	54.340	0.657	80000	0.657
RATIO	0.001	1.165	0.001	0.844	0.000	0.844
RDDR	1.009		1.679		5.614	

Enter: save screen + new session. Esc: save screen + quit. V. 2.3

Figure_Apx F-2. Elder et al., (2005) Carbon Black Sub-chronic Inhalation Study: RDDR Outputs in Female Mice, Low Dose

Regional deposited dose ratios

MMAD = 1.50
Sigma g = 2.50

SPECIES	Body weight(g)	VE(ml)	Extrathoracic SA(cm^2)	dep	Tracheobronchial SA(cm^2)	dep	Pulmonary SA(m^2)	dep
hamster	162	67.5	14.000	0.434	20.000	0.047	0.300	0.069
human	80000	13800.0	200.000	0.293	3200.000	0.066	54.000	0.241
RATIO	0.002	0.005	0.070	1.480	0.006	0.714	0.006	0.287
RDDR			0.103		0.558		0.253	

	Thoracic SA(m^2)	dep	Total RT SA(m^2)	dep	Extrarespiratory BW(g)	dep
hamster	0.302	0.117	0.303	0.551	162	0.551
human	54.320	0.125	54.340	0.601	80000	0.601
RATIO	0.006	0.933	0.006	0.916	0.002	0.916
RDDR	0.334		0.802		2.215	

Enter: save screen + new session. Esc: save screen + quit. V. 2.3

Figure_Apx F-3. Elder et al., (2005) Carbon Black Sub-chronic Inhalation Study: RDDR Outputs in Female Hamsters, Low Dose

Regional deposited dose ratios

MMAD = 1.95
Sigma g = 1.84

SPECIES	Body weight(g)	VE(ml)	Extrathoracic SA(cm^2)	dep	Tracheobronchial SA(cm^2)	dep	Pulmonary SA(m^2)	dep
rat	229	167.3	15.000	0.458	22.500	0.058	0.340	0.077
human	80000	13800.0	200.000	0.343	3200.000	0.084	54.000	0.248
RATIO	0.003	0.012	0.075	1.334	0.007	0.695	0.006	0.309
RDDR			0.216		1.198		0.594	

	Thoracic SA(m^2)	dep	Total RT SA(m^2)	dep	Extrarespiratory BW(g)	dep
rat	0.342	0.135	0.344	0.593	229	0.593
human	54.320	0.125	54.340	0.675	80000	0.675
RATIO	0.006	1.077	0.006	0.878	0.003	0.878
RDDR	0.781		1.682		3.717	

Enter: save screen + new session. Esc: save screen + quit. V. 2.3

Figure_Apx F-4. Nikula et al., (1995) Carbon Black Chronic Inhalation Study: RDDR Outputs in Female Rats, Low Dose

Regional deposited dose ratios

MMAD = 1.95
Sigma g = 1.84

SPECIES	Body weight(g)	VE(ml)	Extrathoracic SA(cm^2)	dep	Tracheobronchial SA(cm^2)	dep	Pulmonary SA(m^2)	dep
rat	380	253.5	15.000	0.553	22.500	0.040	0.340	0.045
human	80000	13800.0	200.000	0.343	3200.000	0.084	54.000	0.248
RATIO	0.005	0.018	0.075	1.610	0.007	0.477	0.006	0.180
RDDR			0.394		1.247		0.524	

	Thoracic SA(m^2)	dep	Total RT SA(m^2)	dep	Extrarespiratory BW(g)	dep
rat	0.342	0.085	0.344	0.638	380	0.638
human	54.320	0.125	54.340	0.675	80000	0.675
RATIO	0.006	0.676	0.006	0.944	0.005	0.944
RDDR	0.743		2.741		3.650	

Enter: save screen + new session. Esc: save screen + quit. V. 2.3

Figure_Apx F-5. Nikula et al., (1995) Carbon Black Chronic Inhalation Study: RDDR Outputs in Male Rats, Low Dose

Appendix G APPROACHES FOR ESTIMATING NUMBER OF WORKERS IN AN OCCUPATIONAL SETTING

1. This appendix summarizes the methods that EPA used to estimate the number of workers who are potentially exposed to C.I. Pigment Violet 29 at paint and coating manufacturing sites and plastic manufacturing sites that incorporate the pigment into pellets ultimately used to dye nylon fibers. The method consists of the following steps: Identify the North American Industry Classification System (NAICS) codes for the industry sectors associated with each scenario.
2. Estimate total employment by industry/occupation combination using the Bureau of Labor Statistics' Occupational Employment Statistics (OES) data (U.S. BLS, 2016).
3. Refine the OES estimates where they are not sufficiently granular by using the U.S. Census' Statistics of U.S. Businesses (SUSB) data on total employment by 6-digit NAICS (U.S. Census Bureau, 2015)
4. Estimate the percentage of employees likely to be using C.I. Pigment Violet 29 instead of other chemicals (*i.e.*, the market penetration of C.I. Pigment Violet 29 in the scenario).
5. Estimate the number of sites and number of potentially exposed employees per site.
6. Estimate the number of potentially exposed employees within the scenario.

Step 1: Identifying Affected NAICS Codes
As a first step, EPA identified NAICS industry codes associated with each scenario. EPA generally identified NAICS industry codes for a scenario by:

- Querying the U.S. Census Bureau's *NAICS Search* tool using keywords associated with each scenario to identify NAICS codes with descriptions that match the scenario.
- Referencing EPA Generic Scenarios (GS's) and Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents (ESDs) for a scenario to identify NAICS codes cited by the GS or ESD.

Section 2.3.2 in the main body of this report presents the NAICS codes EPA identified for the respective scenarios:

- 325211 for Plastics Material and Resin Manufacturing; and
- 325510 for Paint and Coating Manufacturing.

Step 2: Estimating Total Employment by Industry and Occupation
BLS's OES data provide employment data for workers in specific industries and occupations (U.S. BLS, 2016). The industries are classified by NAICS codes (identified previously), and occupations are classified by Standard Occupational Classification (SOC) codes.

Among the relevant NAICS codes, EPA reviewed the occupation description and identified those occupations (SOC codes) where workers are potentially exposed to C.I. Pigment Violet 29. Table_Apx G-1 shows the SOC codes EPA classified as occupations potentially exposed to C.I. Pigment Violet 29 during Plastic Manufacturing. These occupations are classified into workers (W) and occupational non-users (O). All other SOC codes are assumed to represent occupations where exposure is unlikely.

Table_Apx G-1. SOCs with Worker and ONU Designations for Plastic Manufacturing Sites

SOC	Occupation	Designation
17-2000	Engineers	O
17-3000	Drafters, Engineering Technicians, and Mapping Technicians	O
19-2031	Chemists	O
19-4000	Life, Physical, and Social Science Technicians	O
47-2000	Construction Trades Workers	W
49-1000	Supervisors of Installation, Maintenance, and Repair Workers	O
49-2000	Electrical and Electronic Equipment Mechanics, Installers, and Repairers	W
49-9040	Industrial Machinery Installation, Repair, and Maintenance Workers	W
49-9060	Precision Instrument and Equipment Repairers	W
49-9070	Maintenance and Repair Workers, General	W
49-9090	Miscellaneous Installation, Maintenance, and Repair Workers	W
51-1000	Supervisors of Production Workers	O
51-2000	Assemblers and Fabricators	W
51-4020	Forming Machine Setters, Operators, and Tenders, Metal and Plastic	W
51-6090	Miscellaneous Textile, Apparel, and Furnishings Workers	O
51-8020	Stationary Engineers and Boiler Operators	W
51-8090	Miscellaneous Plant and System Operators	W
51-9000	Other Production Occupations	W

W = worker designation
O = ONU designation

After identifying relevant NAICS and SOC codes, EPA used BLS data to determine total employment by industry and by occupation based on the NAICS and SOC combinations. For example, there are 1,360 employees associated with 4-digit NAICS 3252 (*Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing*) and SOC 51-2000 (*Assemblers and Fabricators*).

Using a combination of NAICS and SOC codes to estimate total employment provides more accurate estimates for the number of workers than using NAICS codes alone. Using only NAICS codes to estimate number of workers typically result in an overestimate, because not all workers employed in that industry sector will be exposed. However, in some cases, BLS only provide employment data at the 4-digit or 5-digit NAICS level; therefore, further refinement of this approach may be needed (see next step).

Step 3: Refining Employment Estimates to Account for lack of NAICS Granularity
The third step in EPA's methodology was to further refine the employment estimates by using total employment data in the U.S. Census Bureau's (U.S. Census Bureau, 2015) SUSB. In some cases, BLS OES's occupation-specific data are only available at the 4-digit or 5-digit NAICS level, whereas the

SUSB data are available at the 6-digit level (but are not occupation-specific). Identifying specific 6-digit NAICS will ensure that only industries with potential C.I. Pigment Violet 29 exposure are included. As an example, OES data are available for the 4-digit NAICS 3252 *Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing*, which includes the following 6-digit NAICS:

- NAICS 325211 Plastics Material and Resin Manufacturing;
- NAICS 325212 Synthetic Rubber Manufacturing; and,
- NAICS 325220 Artificial and Synthetic Fibers and Filaments Manufacturing.

In this example, NAICS 325211 is of interest. The Census data allow EPA to calculate employment in the specific 6-digit NAICS of interest as a percentage of employment in the BLS 4-digit NAICS.

The 6-digit NAICS 325211 comprises 76.2 percent of total employment under the 4-digit NAICS 3252. This percentage can be multiplied by the occupation-specific employment estimates given in the BLS OES data to further refine estimates of the number of employees with potential exposure.

Table_Apx G-2 illustrates this granularity adjustment for NAICS 325211.

Table_Apx G-2. Estimated Number of Potentially Exposed Workers and ONUs under NAICS 325211

NAICS	SOC	Occupation	Designation	Employment by SOC at 4-digit NAICS level	% of Total Employment	Estimated Employment by SOC at 6-digit NAICS level
3252	17-2000	Engineers	O	6,960	76.2%	5,304
3252	17-3000	Drafters, Engineering Technicians, and Mapping Technicians	O	1,710	76.2%	1,303
3252	19-2031	Chemists	O	1,600	76.2%	1,219
3252	19-4000	Life, Physical, and Social Science Technicians	O	2,740	76.2%	2,088
3252	47-2000	Construction Trades Workers	W	910	76.2%	693
3252	49-1000	Supervisors of Installation, Maintenance, and Repair Workers	O	910	76.2%	693
3252	49-2000	Electrical and Electronic Equipment Mechanics, Installers, and Repairers	W	740	76.2%	564
3252	49-9040	Industrial Machinery Installation, Repair, and Maintenance Workers	W	3,900	76.2%	2,972
3252	49-9060	Precision Instrument and Equipment Repairers	W	110	76.2%	84
3252	49-9070	Maintenance and Repair Workers, General	W	2,710	76.2%	2,065

NAICS	SOC	Occupation	Designation	Employment by SOC at 4-digit NAICS level	% of Total Employment	Estimated Employment by SOC at 6-digit NAICS level
3252	49-9090	Miscellaneous Installation, Maintenance, and Repair Workers	W	30	76.2%	23
3252	51-1000	Supervisors of Production Workers	O	4,060	76.2%	3,094
3252	51-2000	Assemblers and Fabricators	W	1,360	76.2%	1,036
3252	51-4020	Forming Machine Setters, Operators, and Tenders, Metal and Plastic	W	1,170	76.2%	892
3252	51-6090	Miscellaneous Textile, Apparel, and Furnishings Workers	O	**	76.2%	0
3252	51-8020	Stationary Engineers and Boiler Operators	W	190	76.2%	145
3252	51-8090	Miscellaneous Plant and System Operators	W	6,210	76.2%	4,732
3252	51-9000	Other Production Occupations	W	23,590	76.2%	17,977

numbers may not sum exactly due to rounding.
W = worker
O = occupational non-user
** No data for this SOC
Source: (U.S. BLS, 2016; U.S. Census Bureau, 2015)

Step 4: Estimating the Percentage of Workers Using C.I. Pigment Violet 29 Instead of Other Chemicals

In the final step, EPA typically accounts for the market share by applying a factor to the number of workers determined in Step 3. This accounts for the fact that the chemical being evaluated may be only one of multiple chemicals used for the applications of interest. EPA did not identify market penetration data for any conditions of use for C.I. Pigment Violet 29. In the absence of market penetration data for a given scenario, EPA assumed C.I. Pigment Violet 29 may be used at up to all sites and by up to all workers calculated in this method as a bounding estimate. This assumes a market penetration of 100%.

Step 5: Estimating the Number of Workers per Site

EPA calculated the number of workers and occupational non-users in each industry/occupation combination using the formula below:

Number of Workers or ONUs in NAICS/SOC (Step 2) × Granularity Adjustment Percentage (Step 3) = Number of Workers or ONUs in the Industry/Occupation Combination

EPA then estimated the total number of establishments by obtaining the number of establishments reported in the U.S. Census Bureau's SUSB (2015) data at the 6-digit NAICS level.

EPA then summed the number of workers and occupational non-users over all occupations within the applicable NAICS code and divided these sums by the number of establishments in the NAICS code to calculate the average number of workers and occupational non-users per site.

Step 6: Estimating the Number of Workers and Sites for each Occupational Exposure Scenario
EPA estimated the number of workers and occupational non-users potentially exposed to C.I. Pigment Violet 29 and the number of sites that use C.I. Pigment Violet 29 in a given scenario through the following steps:

6.A. Obtaining the total number of establishments by:
   i. Dividing the total yearly production volume by the yearly use rate per facility as reported by the sole U.S. manufacturer (Sun Chemical, 2020).

6.B. Estimating the total number of workers and occupational non-users potentially exposed to C.I. Pigment Violet 29 for each NAICS by taking the number of establishments in Step 6.A and multiplying it by the average number of workers and occupational non-users per site from Step 5.

Appendix H RISK EVALUATION CALCULATIONS FOR C.I. PIGMENT VIOLET 29 ECOSAR (v.2.0) OUTPUT

Table_Apx H-1. ECOSAR (v.2.0) Output

Class Results: Imides					
Organism	**Duration**	**End Point**	**Concentration (mg/L)**	**Max Log Kow**	**Flags**
Fish	96h	LC_{50}	2.8	5	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Daphnid	48h	LC_{50}	2.59	5	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Green Algae	96h	EC_{50}	0.41	6.4	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Fish		ChV	0.25	8	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Daphnid		ChV	0.46	8	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Green Algae		ChV	0.06	8	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported
Mysid	96h	LC50	0.82	5	Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported

Appendix I EPA REVIEW OF DUST MONITORING STUDY CONDUCTED BY SUN CHEMICAL CORPORATION IN RESPONSE TO SECTION 4 TEST ORDER

The Risk Assessment Division (RAD) has reviewed the final industrial hygiene report of PV-29 exposures at Sun Chemical Corporation dated June 23, 2020, in reference to the test order requirements for occupational monitoring data. RAD finds that the study performed by Sun Chemical Corporation (Sun) does not meet the requirements of the Order, for the following reasons:

1. The approved study plan included a total of 43 samples, 30 worker Occupational User (OU) samples and 13 Occupational Non-User (ONU) samples. Instead, 23 OU samples and six ONU samples were collected. The submitted monitoring report did not meet the number of samples specified in the test order and study plan, Specific deficiencies are described further below. During the call with Sun on July 21, 2020, they reported that there were challenges getting their sample numbers up to what they planned to do per the test order study plan due to their production schedule because of COVID-19 and that they lost three OU samples to pumps turning off when the sample tubing became kinked while the employee being sampled was seated on a fork-lift truck.
2. The samples were collected in a sub-optimal manner such that results are not representative of OU exposures and ONU exposures.
    a. Samples were collected for short periods of time back to back instead of collecting each sample for a longer period of time to better represent the full duration of the C.I. Pigment Violet 29 tasks performed. Sun stated that they did this to achieve a higher number of samples and to not contaminate the C.I. Pigment Violet 29 samples with other particulates that were also being handled by the same workers.
    b. EPA approved the Sun-requested modification to use a Parallel Particle Impactor (PPI), although the flow rate was not specified. The lowest flow rate PPI was used for the sampling, which resulted in most samples being below the limit of detection. Based on the low measured concentrations; a higher flow PPI should have been used to collect a higher volume of sample and result in a better characterization of the worker and ONU exposures. Sun stated that they thought they would not have an issue being below the Limit of Detection (LOD) of 0.05 mg using the lower flow rate and acknowledged in hindsight that a higher flow rate PPI should have been used. Additionally, if Sun had reviewed the results in the April 17th and May 5th sampling and noted that the results were below the LOD, they may have been able to make a course correction of using a PPI with a higher flow rate for the next sampling period at the end of May.
    c. Area samples were collected right next to open bay doors, which was not representative of exposures to ONUs. One would not expect ONUs to be paid for standing next to open bay doors for a full shift; also, bay doors might not always be open in less optimal weather conditions. Sun stated that they monitored in that area with bay doors open because that was the best representation of ONU exposures.
    d. There were three instances of pump failures which resulted in samples being

lost. Standard industrial hygiene practice is to have extra pumps and replace failed pumps with working pumps to complete the sample collection. Sun stated that the pumps did not fail but automatically turned off when the sample tubing became kinked for the worker who was seated on the fork-lift truck. It is unclear whether the failed pump alarm went off.

e. One ONU was incorrectly sampled/identified based on the sampling report; it appeared that this person was handling C.I. Pigment Violet 29 and wearing a respirator. Based on the Sun call, this ONU worker was not handling C.I. Pigment Violet 29 and wore the respirator while handling a different chemical in the area.

As shown in Table_Apx I-1, there are several instances where the results did not include the number of samples specified in the study plan (see highlighted cells in Table_Apx I-1 below). In addition, the sampling results indicated sub-optimal approaches for measuring OU and ONU exposures to C.I. Pigment Violet 29, as described below.

Table_Apx I-1. Sampling in Study Plan and Final Report

Similar Exposure Group	Date Sampled	Occupational User # Samples - Study Plan	Occupational User # Samples - Final Report	Occupational Non-User # Samples - Study Plan	Occupational Non-User # Samples - Final Report	Number of Duplicate Samples Collected	Number of Blanks Analyzed	Sampling Notes
1	26-27 May-20	10	11	0	0	1	2	Visible dust emissions, OU wore respirators
2	26-May-20	10	1	0	0	0	2	1 sample pump failure, visible dust, OU wore respirator
3	17-Apr-20	4	2	6	5	1	2	2 ONU sample pump failures. OU wore respirators
4	5-May-20	1	3	1	0	1	2	Local exhaust ventilation
5	6-May-20	5	6	6	1	1	2	Visible dust emissions, OU and ONU wore respirators

Grey cells indicate sampling events which did not meet study plan requirements.

The sample results contained in the report are based on sub-optimal sampling with almost every sample result being below the limit of detection (LOD) of 0.05 mg of respirable particulate. Only two of the 29 OU and ONU (columns 4 + 6) personal breathing zone results (7%) were above the limit of detection. The remaining breathing zone samples were below the LOD. Overall, the results are quite limited for characterizing exposures to OU and ONU workers. The Sun study plan, which was approved by EPA, stated that they would collect more breathing zone samples than was provided in the final report. The approved study plan included 30 OU samples, of which 23 were provided. Only one of 10 required samples were provided for SEG 2. The approved study plan included 13 ONU samples; six were provided. Only one of six samples were provided for one ONU, and one ONU was not sampled (see above table).

Upon assessment of the sampling for the five similar exposure groups (SEGs), RAD has the following findings (these are in chronological order):

SEG 3 (April 17, 2020): One occupational user (OU) worker was sampled twice for short periods of time back-to-back. These samples could have been combined into one longer term sample; Sun reported that these workers were handling other chemicals in addition to C.I. Pigment Violet 29 and sampled only during handling of C.I. Pigment Violet 29. Three occupational non-user (ONU) workers were sampled for a total of five results. They also lost two sample results due to a pump failure. The ONU samples could have been combined into longer duration samples. Sun reported that these workers were handling other chemicals in addition to C.I. Pigment Violet 29 and sampled only during handling of C.I. Pigment Violet 29. RAD also had concerns with calling these workers ONUs because they appeared to be handling C.I. Pigment Violet 29 wet press cake; Sun reported the wet press cake was for a different chemical. Workers also did housekeeping activities but the report it is not clear if Sun sampled those workers while doing this housekeeping work. One duplicate and two-blank results are also reported per the study plan. All of the breathing zone results for SEG 3 were below the LOD.

SEG 4 (May 5, 2020): One OU worker was sampled for three short periods of time in close succession. The three short-term samples could have been combined into one longer duration sample. Sun reported that these workers were handling other chemicals in addition to C.I. Pigment Violet 29 and sampled only during handling of C.I. Pigment Violet 29. The results were all below the LOD. One ONU worker was in the area but was not sampled as was stated in the EPA-approved study plan. One duplicate and two blanks were also reported as required by the study plan.

SEG 5 (May 6, 2020): Two OU workers were sampled three times for short periods back-to-back. These samples could have been combined into one longer sample. Sun reported that these workers were handling other chemicals in addition to C.I. Pigment Violet 29 and sampled only during handling of C.I. Pigment Violet 29. Two of the six results were above the LOD. One ONU was sampled one time although the study plan stated that there would be six samples taken. RAD has concern that this worker is not an ONU because the worker was handling C.I. Pigment Violet 29 and was wearing a respirator. Sun stated that this worker is an ONU and was wearing the respirator to protect against exposure to a different chemical in the area.

Three area samples were taken for SEG 5. The samplers were located right next to open bay doors which is not an optimal place for locating area sampling devices per standard industrial hygiene practices which promote collecting samples which are representative of likely exposures. In addition, bay doors may not always be open during inclement weather.

SEG 1 (May 26 & 27, 2020): OU workers were sampled two or three times for short periods of time in close succession. These samples could have been combined into one longer duration sample for each of these four workers. Sun reported that these workers were handling other chemicals in addition to C.I. Pigment Violet 29 and Sun sampled only during handling of C.I. Pigment Violet 29. All results are below the LOD. One duplicate and two blanks are reported per the study plan.

SEG 2 (May 26, 2020): One OU worker was sampled one time. A second sample had a pump failure and was excluded from the report. The EPA-approved study plan stated that 10 samples would be collected for this SEG. One result is not representative of this SEG. Two blanks were analyzed. Zero duplicates were taken for SEG 2.

The greatest concern RAD has from the breathing zone results is that monitored workers were sampled for very short periods of time. It appears that workers were in the C.I. Pigment Violet 29 areas over multiple samples. The sample results are for such short periods of time and do not appear to represent the full duration of the C.I. Pigment Violet 29 tasks performed. Sun reported that the production of C.I. Pigment Violet 29 was reduced due to COVID-19, and these workers were handling other chemicals in addition to C.I. Pigment Violet 29. Sun reported that they sampled workers only while handling of C.I. Pigment Violet 29.

The Parallel Particle Impactor (PPI) was used by Sun Chemical Corporation. This is a modified NIOSH method for the 0600 respirable dust method, and the use of a PPI for this monitoring was approved by the EPA. The flow rates for the PPI of 2, 4, or 8 liters per minute (lpm) are recommended by the PPI manufacturer based on the amount of sampling time and anticipated air concentrations as referenced in two (one peer-reviewed and the other not) SKC studies included at the end of the report. Sun utilized a modified NIOSH 0600 method by using the PPI, for a 2 lpm flow rate. This PPI was likely not adequate for the very short sample durations and the potentially low PV-29 air concentrations. The PPI at the higher air flow should have been considered by Sun to address this issue and provide results which are representative of actual exposures to workers and ONUs. Sun acknowledged that a higher flow rate PPI should have been used.

The purpose of the test order is to reduce uncertainties in assessing C.I. Pigment Violet 29 occupational inhalation exposures. Based on the Employee Shift Activity tables, Sun chose to collect many short- duration samples instead of combining them into longer duration, full shift samples. Although longer sampling could result in the inclusion of other dust sources, C.I. Pigment Violet 29 could persist in the workplace air even after the handling of C.I. Pigment Violet 29 stops. The employee activity tables indicate that

the workers do not necessarily leave C.I. Pigment Violet 29 work areas and thus, the sample collection device would not have been exposed to other respirable dust sources. The samples should have been combined over the full shift as a single sampling event in most cases.

Several pump failures occurred during sampling which created gaps in results for certain workers. This was especially critical for SEG 2 where there is only one other breathing zone result for one OU worker. Good industrial hygiene practice dictates to have back-up pumps to ensure that sampling is not compromised due to pump failure.

Finally, it is very difficult to interpret Sun Chemical Corporation's breathing zone sampling results because different pieces of information were spread across several different final report tables and other documents instead of being combined into one table or spreadsheet. Additionally, some sample results which are duplicates were not clearly labeled as such and are included in some tables as actual sample results. Duplicate samples are collected for QA purposes, and should not be used for estimating exposures. In reporting the results, Sun did not clearly label the four duplicates, the ten blanks, the twenty-nine breathing zone results and the three area samples. It is also important to remove the names of employees from report tables as personal information need not be provided to the Agency.

In summary, the sampling conducted by Sun Chemical Corporation did not meet the terms of the test order. The sampling was conducted in a sub-optimal manner such that only 29 of the 43 required samples were collected, and almost every sampling result was below the LOD. In addition, the samples that were collected are not representative of OU and ONU full shift exposures due to the manner in which the samples were collected.