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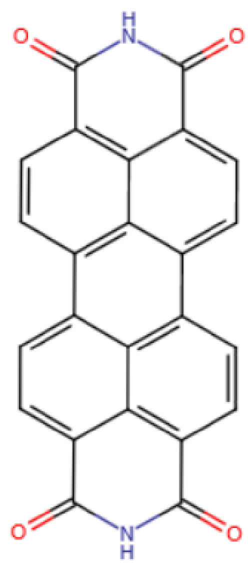
Scope of the Risk Evaluation for Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone)

CASRN: 81-33-4



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Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2016-0725.

Disclaimer

ABBREVIATIONS

°C	Degrees Celsius
°F	Degrees Fahrenheit
AICS	Australian Inventory for Chemical Substances
atm	atmosphere(s)
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
C.I.	Colour Index
cm^3	cubic centimeters
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPMA	Color Pigments Manufacturing Association
CPSC	Consumer Product Safety Commission
DEBITS	Degradation Effects Bioconcentration Information Testing Strategies
DNA	Deoxyribonucleic Acid
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission Scenario Documents
ETAD	Ecological and Toxicological Association of Dye and Organic Pigments Manufacturers
EU	European Union
FDA	Food and Drug Administration
g	Grams
HPV	High production volume
IBC	Intermediate Bulk Containers
IRIS	Integrated Risk Information System
ITC	Interagency Testing Committee
L	Liter(s)
K	Thousand
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)
mmHg	Millimeter(s) of Mercury
MSDS	Material Safety Data Sheet
NIH	National Institute of Health
NIOSH	National Institute of Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NTP	National Toxicology Program

OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturing
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
POD	Point of Departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PS	Polystyrene
PUR	Polyurethane
PVC	Polyvinyl chloride
RCRAInfo	Resource Conservation and Recovery Act Information
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAN	Styrene Acrylonitrile
SAR	Structure-activity relationship
SB	Styrene Butadiene
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
TCCR	Transparent, clear, consistent, and reasonable
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
U.S.	United States

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Pigment Violet 29 was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for Pigment Violet 29.

This document presents the scope of the risk evaluation to be conducted for Pigment Violet 29. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for Pigment Violet 29. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone is the TSCA inventory name and will be referred to as Pigment Violet 29 in this document (as indicated in 2014 TSCA Work Plan Update). Pigment Violet 29 is a trade 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 and should not be considered as an alternative technical or specific chemical name for Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone.

Pigment Violet 29 is an organic pigment used as a colorant, primarily in inks, paints and coatings and/or plastics.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to Pigment Violet 29 during a variety of conditions of use, such as paints and coatings, plastics and rubber products, merchant ink for commercial printing, and use as an intermediate to produce other perylene pigments. It also presents the consumer model that which indicates exposures occurring from Pigment Violet 29 containing products in either indoor or outdoor environments. For Pigment Violet 29, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have a greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Human health hazards of Pigment Violet 29 have been identified by EPA previously and include acute toxicity, eye irritation, skin irritation, skin sensitization, repeated-dose toxicity, and reproductive/developmental toxicity, all of which EPA expects to consider in the scope of the TSCA risk evaluation. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725). EPA expects to consider the hazards of Pigment Violet 29 to aquatic and terrestrial organisms potentially exposed under acute and chronic exposure conditions in the TSCA risk evaluation.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for Pigment Violet 29. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of Pigment Violet 29.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for Pigment Violet 29. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for Pigment Violet 29.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints and uncertainty associated with developing the risk evaluation process rule has resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to Pigment Violet 29. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. During risk evaluation, EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

Federal Laws and Regulations

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

State Laws and Regulations

Pigment Violet 29 is not subject to state statutes or regulations implemented by state agencies or departments.

Laws and Regulations in Other Countries and International Treaties or Agreements

Pigment Violet 29 is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A-2.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725) using the literature search strategy (see *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725) to ensure that EPA is considering information that has been made available since these assessments were conducted.

Table 1-1. Assessment History of Pigment Violet 29

Authoring Organization	Assessment
U.S.-Based Organizations	
BASF Corporation	Food Additive Petition for Safe Use of Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone, C.I. Pigment Violet 29, Paliogen Red Violet K 5011, as a Colorant in all Polymers (1998)
Interagency Testing Committee (ITC)	Forty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments (2002)
Color Pigments Manufacturers Association (CPMA)	Perylene Pigments including Pigment Violet 29 for the High Production Volume (HPV) Test Program, (2017)

On August 1998, BASF Corporation submitted summaries of acute oral toxicity, skin irritation and eye irritation studies to the U.S. Food and Drug Administration (FDA) as part of the food additive petition for safe use of Colour Index (C.I.) Pigment Violet 29 as a colorant in all polymers (Federal Register of October 6, 1998, (63 FR 53679)). Summaries of these studies indicated low acute toxicity (lethality), slight skin and eye irritation.

In 2002, Pigment Violet 29 was listed as a Degradation Effects Bioconcentration Information Testing Strategies (DEBITS) chemical for which information was solicited from manufacturers and trade associations by the ITC under TSCA. ITC reviewed information on 48 chemicals, including Pigment Violet 29, from the CPMA, Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), and the companies that were previously or are currently manufacturing these chemicals (FYI-0801-01413). Based on this information, ITC concluded there was limited production or use of Pigment Violet 29 at the time; therefore, did not request additional information on Pigment Violet 29 (Federal Register of March 6, 2002, (67 FR 10297)).

In March 2013, CPMA submitted study summaries for Perylene Pigments including Pigment Violet 29 for the High Production Volume (HPV) Test Program (CPMA, 2017). The tests specifically for Pigment Violet 29 were eye irritation and skin irritation (EPA-HQ-OPPT-2016-0725-0006). These summaries indicated no skin or eye irritation.

1.3 Data and Information Collection

EPA/Office of Pollution Prevention and Toxics (OPPT) generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk evaluations developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk assessments.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725) provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information - for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between Pigment Violet 29 and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of Pigment Violet 29. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

Table 2-1. Physical and Chemical Properties of Pigment Violet 29

Property	Value[a]	Reference
Molecular Formula	$C_{24}H_{10}N_2O_4$	
Molecular Weight	390.35 g/mole	
Physical Form	Solid	U.S. EPA (2012a)
Melting Point	350°C (estimated)	U.S. EPA (2012b)
Boiling Point	919°C at 760 mmHg (estimated)	U.S. EPA (2012b)
Density	1.68 g/cm^3 at 20˚C (estimated)	ACD (2011)
Vapor Pressure	3.3×10^{-23} mmHg (estimated)	U.S. EPA (2012b)
Vapor Density	Not available	
Water Solubility	0.169 mg/L (estimated)	U.S. EPA (2012b)
Octanol/Water Partition Coefficient	3.76 (for log K_{ow}; estimated)	U.S. EPA (2012b)
Henry's Law Constant	1.84E-021 atm-m^3/mole (estimated)	U.S. EPA (2012b)
Flash Point	314 ± 33 °C (estimated)	ACD (2011)
Auto Flammability	Not available	
Viscosity	Not available	
Refractive Index	Not available	
Dielectric Constant	Not available	

[a] Measured unless otherwise noted.

Pigments are colored, fluorescent or pearlescent particulate organic or inorganic finely divided solids that are usually insoluble in water. Pigments are essentially physically and chemically unaffected by the vehicle or medium in which they are incorporated. They alter appearance either by selective absorption, interference and/or scattering of light. They are usually incorporated by dispersion in paints, plastics, inks and fibers and retain their crystal or particulate nature throughout the pigmentation process (Jaffe, 2004). Pigment Violet 29 is a solid with low vapor pressure and low solubility in water.

There are no known by-products or degradation products resulting from the manufacture of Pigment Violet 29. There is a residual amount of naphthalimide, the starting material used in the fusion, at approximately 1% (Sun Chemical, 2017).

C.I. Pigment Violet 29 and C.I. Pigment Brown 26 are synonyms of CASRN 81-33-4. Pigment Brown 26 is a trade name and has the same chemical name and same CASRN as 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. The difference in color between Pigment Brown 26 and Pigment Violet 29 is related to particle size and not crystal form (Sun Chemical, 2017).

2.2 Conditions of Use

TSCA § 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.''

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for Pigment Violet 29,* EPA-HQ-OPPT-2016-0725). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Pigment Violet 29*, EPA-HQ-OPPT-2016-0004) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting 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; when distinguishable), distribution and disposal. The information 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.

For the purposes of CDR and this scope, CDR definitions were used. CDR 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, 2016b).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the volume information associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2016b). The 2016 CDR reporting data for Pigment Violet 29 are provided in Table 2-2 for Pigment Violet 29 from EPA's CDR database (U.S. EPA, 2016b).

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

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	520,916	CBI	CBI	CBI

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Figure 2-1 depicts the initial life cycle diagram of Pigment Violet 29 from manufacture to the point of disposal. The demand for pigments for use in automotive and powder coating due to their chemical resistance and light fastness properties is on the rise. Other key market trends include the increasing demand for high performance, special effect and heat management pigment solutions. These specialty pigments, including Pigment Violet 29, are used in the automotive, architecture, fiber, nylon, specialties and niche markets, and are expected to grow. Their use in the packaging market is also expected to grow as consumers continue to purchase more products globally. The demand for heat management pigments is expected to increase as well due to the need for solar management solutions within architectural and construction applications (Pianoforte, 2012).

Sun Chemical Corporation is the only U.S. manufacturer of Pigment Violet 29 that reported to CDR for Pigment Violet 29 in 2012 (U.S. EPA, 2012a). BASF SE, located in Germany, and Liaoning LianGang Pigment and Dyestuff Chemicals Company Ltd., located in China, are non-U.S. manufacturers of pigment products containing Pigment Violet 29 per C.I..

Four primary industrial and commercial uses and one consumer use have been identified from the manufacturing or importing of Pigment Violet 29:

- Use as an intermediate to create or adjust 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,
- Consumer watercolors and acrylic paint.

Figure 2-1 shows the production volume of Pigment Violet 29 that is associated with each life cycle stage. The 2016 CDR for production volume is claimed as CBI and is pending EPA approval of the substantiation. Public comments to the Pigment Violet 29 Use Document [EPA-HQ-OPPT-2016-0725-0004 (U.S. EPA, 2017b)] and CDR 2016 (U.S. EPA, 2016b), indicate 90% of the domestic production volume is processed as a site-limited intermediate in the formation of other perylene pigments or used to incorporate into formulation, mixture or reaction products. A commenter stated that Pigment Violet 29 is used to adjust the color of other perylene pigments. Approximately 10% of the production volume is processed and used in either commercial paints and coatings or commercial plastic and rubber products. Of the 10% of the total production volume used, approximately 50% is processed and used in commercial paints and coatings products and 50% in commercial plastic and rubber products. Pigment Violet 29 can be a component in a variety of plastics applications such as polyolefins, polyvinyl chloride (PVC), polyurethane (PUR), polystyrene (PS), styrene butadiene (SB), styrene acrylonitrile (SAN) and other polymers. Automotive and industrial coatings that include metallic finishes and textile printing are types of commercial paints and coatings described in comments submitted to the public docket (EPA-HQ-OPPT-2016-0725-0006). Less than 1 % of the production volume is processed into ink and then used in merchant ink for commercial printing. Pigment Violet 29 has other uses that are processed in an amount smaller than merchant ink for commercial printing (i.e., << 1%). Other uses of Pigment Violet 29 may include: applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, light-harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices, paper, architectural uses, polyester fibers, adhesion, motors, generators, vehicle components, sporting goods, appliances, agricultural equipment and oil and gas pipelines. EPA will further investigate the accuracy and significance of all identified Pigment Violet 29 uses in these products and applications in the risk evaluation process. An unknown minor volume of Pigment Violet 29 is used in consumer watercolor and acrylic paints. In the 2017 comments on Pigment Violet 29 Use Document [EPA-HQ-OPPT-2016-0725-0004 (U.S. EPA, 2017b)], commenters indicated they are not aware of Pigment Violet 29 being used for paints that are marketed to children.

The **"Use as an Intermediate to Other Perylene Pigments"** category includes Pigment Violet 29 as an intermediate for Pigment Red 179 (CASRN 5521-31-3) and Pigment Red 224 (CASRN 128-69-8) (EPA-HQ-OPPT-2016-0725-0006). Pigment Violet 29 can also be used to adjust the color of other perylene pigments (EPA-HQ-OPPT-2016-0725-0008).

The **"Incorporated into formulation, mixture, or reaction product"** category includes incorporation into paints and coatings products, and incorporation into plastic and rubber products. The paints and coatings are expected to primarily include commercial coatings used in automotive original equipment manufacturing (OEM) and refinishing operations. The plastic and rubber products are primarily expected to include commercial automotive parts and industrial carpets.

The **"Merchant ink for commercial printing"** category includes use of Pigment Violet 29 in commercial printing and packaging to impart lightfastness and color stability.

The **“Consumer Watercolor and Acrylic Paints”** category includes the use of Pigment Violet 29 as a pigment that is incorporated into professional quality watercolor and acrylic artist paint.

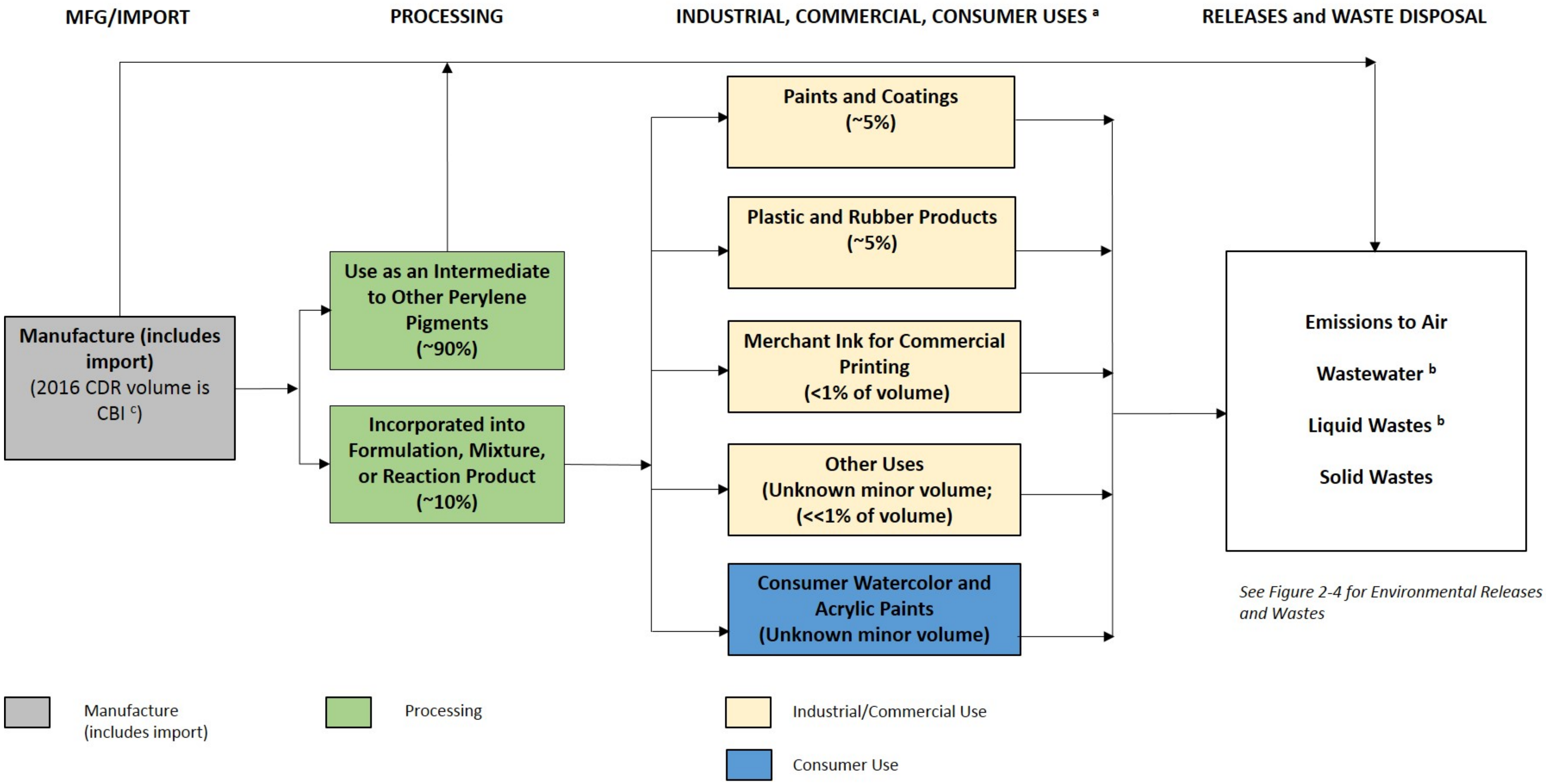

Figure 2-1. Initial Pigment Violet 29 Life Cycle Diagram

The initial life cycle diagram 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. Activities related to distribution (e.g., loading, unloading) will be considered throughout the Pigment Violet 29 life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

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

[c] 2012 CDR volume for Pigment Violet 29 is 520,916 lbs/year (U.S. EPA, 2012a).

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) as included in the life cycle diagram are summarized below. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR (U.S. EPA, 2016b) and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting (U.S. EPA, 2016a).

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for Pigment Violet 29 that EPA expects to consider in the risk assessment. Using the 2016 CDR (U.S. EPA, 2016b), EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

Table 2-3. Categories and Subcategories of Conditions of Use for Pigment Violet 29

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

Life Cycle Stage	Category [a]	Subcategory [b]	References
Distribution in commerce	Distribution	Distribution	Use Document, EPA-HQ-OPPT-2016-0725-0004; Public Comment, EPA-HQ-OPPT-2016-0725-0006
Industrial/commercial/ consumer use	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 (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
	Other uses	Applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, light-harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices, paper, architectural uses, polyester fibers, adhesion, motors, generators, vehicle	Use Document, EPA-HQ-OPPT-2016-0725-0004

Life Cycle Stage	Category [a]	Subcategory [b]	References
		components, sporting goods, appliances, agricultural equipment and oil and gas pipelines	
	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	Standard EPA approach, no sources specific to Pigment Violet 29 found
	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	

[a] These categories appear in the life cycle diagram (Figure 2-1), reflect CDR codes and broadly represent conditions of use of Pigment Violet 29 in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of Pigment Violet 29.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to Pigment Violet 29 identified in Table 2-3. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to the chemical substance.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for Pigment Violet 29.

Table 2-4. Environmental Fate Characteristics of Pigment Violet 29

Property or Endpoint	Value [a]	References
Indirect photodegradation	7.0 hours (estimated)	U.S. EPA (2012b)
Hydrolysis half-life	Stable	
Biodegradation	Poorly biodegradable: 0-10% degradation in 28 days (OECD 301F)	ECHA (2015)
Bioconcentration factor (BCF)	BCF=140 (estimated) [b]	U.S. EPA (2012b)
Bioaccumulation factor (BAF)	BAF = 50 (estimated)	U.S. EPA (2012b)
Soil organic carbon:water partition coefficient (Log K_{OC})	5.0 (estimated)	U.S. EPA (2012b)
[a] Measured unless otherwise noted [b] Limited pigment data in the EPI Suite training set		

Pigment Violet 29 is expected to bind to soil organic matter due to its soil organic carbon partition coefficient (1×10^5) and is not readily biodegraded. Migration of Pigment Violet 29 through soil to ground water is expected to be minimal due to the estimated Log K_{oc} value of 5.0. If released to water, hydrolysis is expected to be negligible. Pigment Violet 29 is not expected to enter the atmosphere via volatilization from water due to its estimated Henry's Law Constant of $<1\times10^{-10}$ atm-m^3/mole. If released to air, Pigment Violet 29 is expected to be in the particulate phase and is unlikely to undergo direct photolysis. The photodegradation of Pigment Violet 29 by atmospheric hydroxyl radicals is estimated to occur with a half-life of 7 hours.

Based on these fate properties, Pigment Violet 29 is expected to be highly persistent (environmental half-life (t ½) greater than 6 months) and have low bioaccumulation potential (BCF/BAF < 1,000).

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

Pigment Violet 29 is not a Toxics Release Inventory (TRI) chemical and no information is available in TRI.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

For scoping, EPA did not find environmental monitoring related to the presence of Pigment Violet 29 in the environment or biota in the United States. However, EPA expects to consider any environmental monitoring data that may result from the literature search.

2.3.4 Environmental Exposures

The manufacturing, processing distribution, use and disposal of Pigment Violet 29 can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for Pigment Violet 29.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personnel protective equipment have on occupational exposure levels.

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

Workers and occupational non-users may be exposed to Pigment Violet 29 when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Unloading and transferring Pigment Violet 29 to and from storage containers and to process vessels;
- Using Pigment Violet 29 in process equipment;
- Applying formulations and products containing Pigment Violet 29 onto substrates (e.g., spray applying coatings or adhesives containing Pigment Violet 29 during automotive refinishing operations);
- Cleaning and maintaining equipment;
- Sampling chemical, formulations or products containing Pigment Violet 29 for quality control;
- Repackaging chemical, formulations or products containing Pigment Violet 29;
- Handling, transporting and disposing waste containing Pigment Violet 29;
- Filter media change out;
- Compounding, converting, trimming and grinding plastics;

- Spray application and printing of coating/ink containing Pigment Violet 29; and,
- Performing other work activities in or near areas where Pigment Violet 29 is used.

For more detailed information on worker and occupational non-user exposures, refer to Appendices B-1-2 and B-1-3.

Based on these activities, EPA expects to consider inhalation exposure of particulate matter (dust) and dermal exposure, including skin contact with solids and liquid formulations containing Pigment Violet 29 for workers and occupational non-users. EPA also expects to consider potential worker exposure via oral route such as from incidental ingestion of Pigment Violet 29 residue on hand/body, or through particulates that deposit in the upper respiratory tract.

2.3.5.2 Consumer Exposures

Pigment Violet 29 can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers [EPA-HQ-OPPT-2016-0725, Sections 3 and 4, (U.S. EPA, 2017b)], and Table 2-3, and can therefore result in exposures to consumers.

Exposure routes for consumers using Pigment Violet 29-containing products may include dermal exposures through liquid contact and oral exposures.

EPA expects to consider dermal and oral exposures to consumers and bystanders associated with the consumer use in the home.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of Pigment Violet 29 could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA expects to consider each media, route and pathway to estimate general population exposures.

General population exposures to Pigment Violet 29 were identified in a variety of conditions of use pathways (Section 2.2, Figure 2-2 and Figure 2-4). Possible exposure pathways include inhalation of air from incineration or emissions and oral ingestion of drinking water.

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to air containing Pigment Violet 29 and oral exposures that may result from the conditions of use of Pigment Violet 29.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. 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 this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. Pigment Violet 29 has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006).

In summary, the risk evaluation for Pigment Violet 29, EPA expects to consider the following potentially exposed groups of human receptors including: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of Pigment Violet 29, as described in *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0725). Based on initial screening, EPA expects to consider the hazards of Pigment Violet 29 identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for Pigment Violet 29: European Chemicals Agency (ECHA) Database (ECHA, 2015). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for chemical name (*Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725).

EPA expects to consider the hazards of Pigment Violet 29 to aquatic and terrestrial organisms potentially exposed under acute and chronic exposure conditions. Toxicological data are available in ECHA, although no hazards have been identified in ECHA for Pigment Violet 29. ECHA provides ecotoxicology data for fish (acute), aquatic invertebrates (acute), aquatic plants/cyanobacteria and unidentified microorganisms. As noted in Section 2.3.1, Pigment Violet 29 is not expected to degrade in the environment and so at this time there are no aquatic concerns for environmental degradation products for Pigment Violet 29.

EPA expects to consider the hazards of Pigment Violet 29 to terrestrial organisms potentially exposed under acute and chronic exposure conditions. EPA has identified rat toxicity data for Pigment Violet 29 that may be used to characterize toxicity to terrestrial organisms.

2.4.2 Human Health Hazards

Pigment Violet 29 does not have an existing EPA IRIS Assessment. Information on health effects for non-cancer endpoints for Pigment Violet 29 is available in the ECHA Database (ECHA, 2015) and a HPV Test Plan for Perylene Pigments (CPMA, 2017). These sources provide robust summaries describing acute toxicity (oral/inhalation), skin and eye irritation, *in vivo* skin sensitization, *in vitro* genotoxicity, and reproductive/developmental toxicity. EPA does not possess the full study reports; therefore, EPA is actively pursuing acquisition of the full study reports for these endpoints in order to characterize health hazards of Pigment Violet 29. EPA also expects to consider studies identified in the literature search conducted by the Agency for Pigment Violet 29 (*Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725) to ensure that information that has been made available since those described above are taken into consideration. EPA expects to consider all potential hazards associated with Pigment Violet 29. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Study summaries of the animal toxicity data for Pigment Violet 29 acute toxicity, skin and eye irritation, skin sensitization, repeated-dose systemic toxicity and reproductive/developmental toxicity. EPA expects to consider all of these studies in the risk evaluation.

2.4.2.2 Genotoxicity and Cancer Hazards

Results of *in vitro* genotoxicity testing of Pigment Violet 29 (tested up to solubility) were negative with and without metabolic activation. Structure-activity evaluation of the unusual 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. Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely.

Consistent with the discussion in the preamble to the risk evaluation rule pertaining to conditions of use, EPA does not believe it makes sense to expend Agency resources evaluating hazards that EPA is confident are not presented by a chemical substance. Hence, unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29.

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to “a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation” by EPA. 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 hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical’s hazard(s).

2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for Pigment Violet 29, EPA developed three conceptual models, presented here.

2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial uses of Pigment Violet 29. EPA expects that workers and occupational non-users may be exposed to Pigment Violet 29 via inhalation, dermal and oral routes.

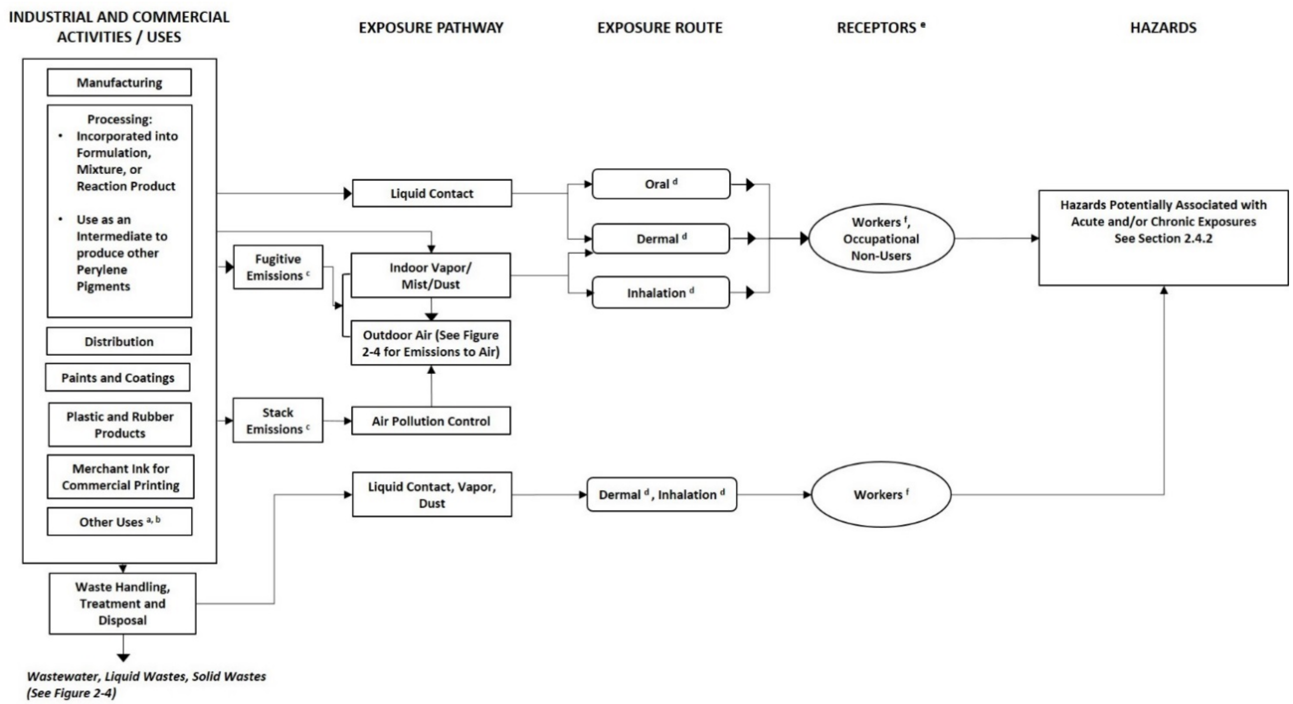

Figure 2-2. Initial Pigment Violet 29 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

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

[a] Other uses of Pigment Violet 29 include: applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, light-harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices, paper, architectural uses, polyester fibers, adhesion, motors, generators, vehicle components, sporting goods, appliances, agricultural equipment, and oil and gas pipelines.

[b] Some products are used in both commercial and consumer applications. Additional uses of Pigment Violet 29 are included in Table 2-3.

[c] 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.

[d] Dermal exposure may occur through skin contact with liquids, indoor vapors and dust; oral exposure may occur through incidental ingestion of Pigment Violet 29 residue on the hand/body, or through mists that deposit in the upper respiratory tract.

[e] Receptors include potentially exposed or susceptible subpopulations.

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

2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of Pigment Violet 29. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via dermal and oral routes, with dermal exposures being the most likely exposure route. It should be noted that some consumers may purchase and use products primarily intended, known or reasonably foreseen for commercial use. Dermal exposure from skin contact with liquids may also occur when performing certain activities associated with use of some consumer products, and oral exposure may occur through incidental ingestion of Pigment Violet 29 residue on hand/body (although this pathway is less likely).

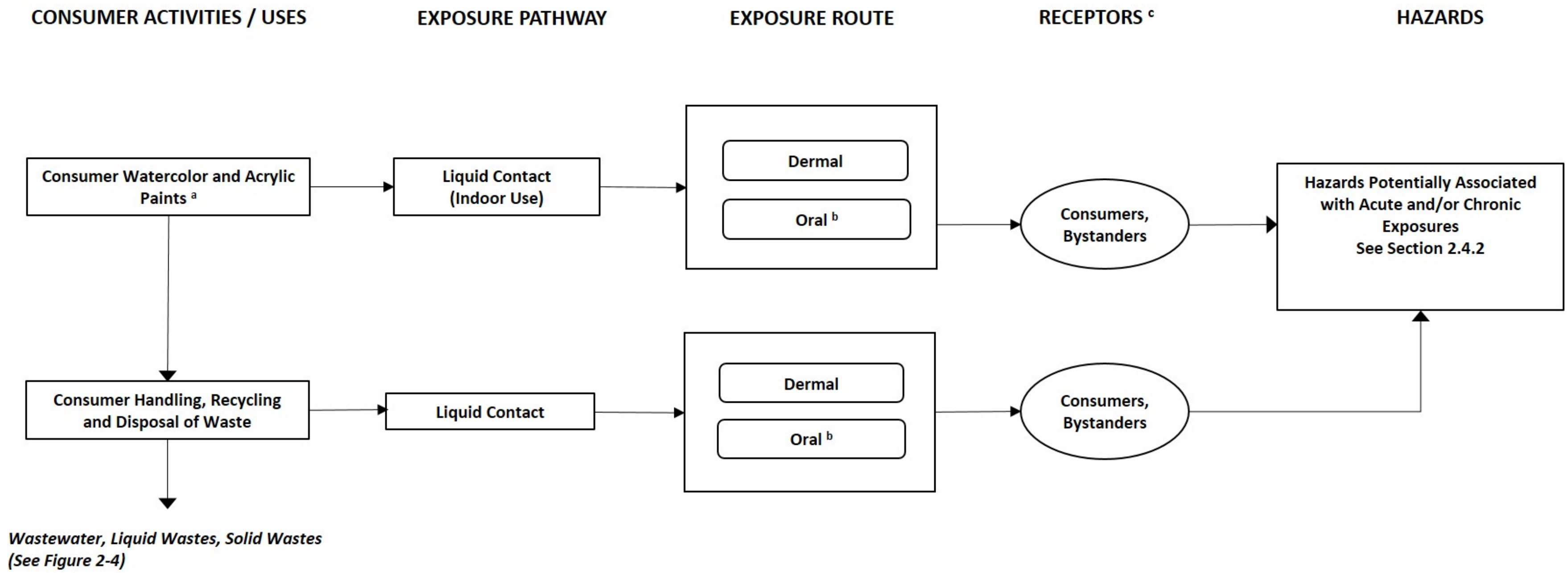

Figure 2-3. Initial Pigment Violet 29 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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

[a] Some products are used in both commercial and consumer applications. Additional uses of Pigment Violet 29 are included in Table 2-3.

[b] Dermal exposure may occur through skin contact with liquids; oral exposure may occur through incidental ingestion of liquids through consumer artist paint use.

[c] Receptors include potentially exposed or susceptible subpopulations.

2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

As shown in Figure 2-4, EPA anticipates that general populations living near industrial and commercial facilities using Pigment Violet 29 may be exposed via inhalation of outdoor air. In addition, aquatic and terrestrial life may be exposed to Pigment Violet 29 contaminated water, sediment, and soil.

Exposures to ecological species from releases of Pigment Violet 29 to environmental media and disposal of wastes containing Pigment Violet 29 are depicted in Figure 2-4.

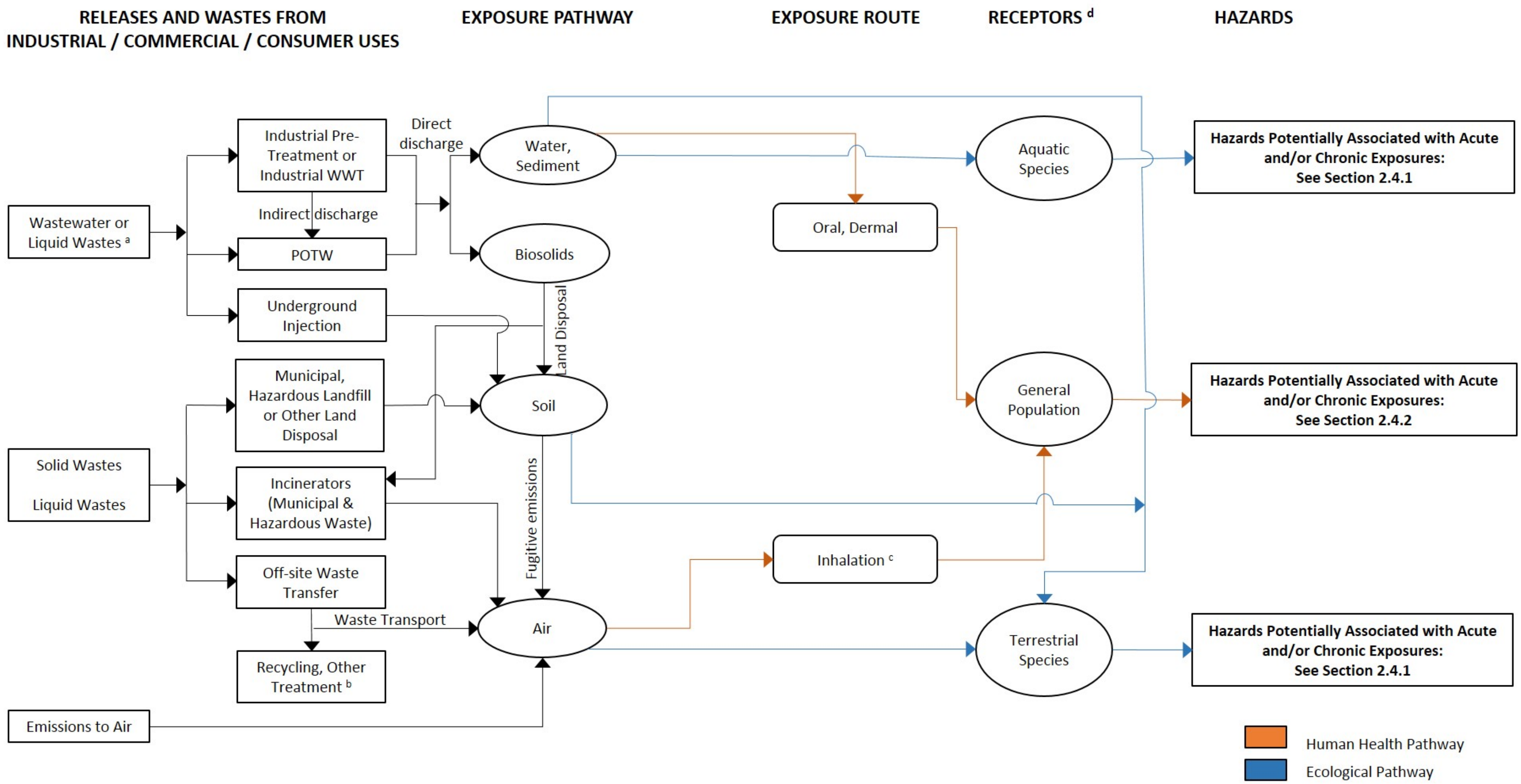

Figure 2-4. Initial Pigment Violet 29 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of 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. Groundwater may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Presence of mist is not expected. Dermal and oral exposure are negligible and therefore not included in the scope.

[d] Receptors include potentially exposed or susceptible subpopulations.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources (see *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725) as described in Section 1.3. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of Pigment Violet 29, as described in Section 2.2 of this scope. The analysis plan will be expanded if EPA identifies additional hazards, exposures, conditions of use or potentially exposed or susceptible subpopulations that are relevant to this risk evaluation. EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated (see *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0725).
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the EPA National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule, Resource Conservation and Recovery Act Information (RCRAInfo) database).
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of the evidence of environmental release data.
7) Map or group each condition(s) of use to a release assessment scenario.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.

2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its Environmental Exposure Assessment of Pigment Violet 29:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to extent data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
6) Map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements).
2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to Pigment Violet 29.
3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
6) Evaluate the weight of the evidence of occupational exposure data.
7) Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
2) Evaluate the weight of the evidence of consumer exposure data.
3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
7) Map or group each condition of use to consumer exposure assessment scenario(s).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
7) Evaluate the weight of the evidence of general population exposure data.
8) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an Environmental Hazard Assessment of Pigment Violet 29 as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.

4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of the evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000b). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000b). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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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		
TSCA – Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Pigment Violet 29 is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
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.	Pigment Violet 29 manufacturing (including importing), processing and use information is reported under the CDR Rule (76 FR 50816, August 16, 2011).
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.	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 (42 FR 64572, December 23, 1977).
Other Federal Regulations		
Consumer Product Safety Commission (CPSC)	Regulates art materials and requires that a products' formulation undergo a toxicological review for safety and adds labels if necessary.[1]	Applies to consumer products that may contain Pigment Violet 29. Whole formulation of product is tested.
Food and Drug Administration (FDA)	Pigment Violet 29 is approved to be in finished articles that come	Finished articles containing Pigment Violet 29 that come into

[1] CPSC. Art Material Business Guidance. Accessed March 14, 2017. https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Art-Materials.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	in contact with food. It should not to exceed 1% by weight of polymers and should follow specific conditions of use. Pigment Violet 29 is not listed as an approved food additive.	contact with food (21 CFR 178.3297).
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	Applies to consumer products that may contain Pigment Violet 29. Whole formulation of product is tested.

A.2 International Laws and Regulations

Table_Apx A-2. International Laws and Regulations

Country/Organization	Requirements and Restrictions
Australia	Pigment Violet 29 is on the Australian Inventory for Chemical Substances (AICS), a database of chemicals available for industrial use in Australia with no restrictions cited.[2]
Canada	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.[3]
European Union	Pigment Violet 29 is on the European Inventory of Existing Commercial Chemical Substances (EINECS) List, which includes chemical substances

[2] Australian Government. National Industrial Chemicals Notification and Assessment Scheme. Accessed March 14, 2017. https://www.nicnas.gov.au/search/chemical?id=1189.

[3] Government of Canada. Environment and Climate Change Canada. Search Engine for Chemicals and Polymers. Accessed March 14, 2017. http://www.ec.gc.ca/lcpe-cepa/eng/substance/chemicals_polymers.cfm.

Country/Organization	Requirements and Restrictions
	deemed to be on the European Community market between January 1, 1971 and September 18, 1981.[4] The Classification and Labelling list as no hazards classified and registered under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
Japan	Pigment Violet 29 has been notified in accordance with the provisions of Chemical Substances Control Law. They are exempt from the new chemical notification requirement and listed as Low Molecular Heterocyclic Organic Compounds on the existing chemical substances list.[5]

[4] ChemSafetyPRO. EU Chemical Inventory: EINECS, ELINCS and NLP. January 18, 2017. Accessed March 14, 2017. http://www.chemsafetypro.com/Topics/EU/EU_Chemical_Inventory_EINECS_ELINCS_NLP.html.

[5] NITE Chemical Risk Information Platform (NITE-CHRIP). Accessed March 14, 2017. http://www.nite.go.jp/en/chem/chrip/chrip_search/cmpInfDsp?cid=C010-529-04A&bcPtn=0&shMd=0&txNumSh=ODEtMzMtNA==&ltNumTp=1&txNmSh=&ltNmTp=&ltNmMh=1&txNmSh1=&ltNmTp1=&txNmSh2=&ltNmTp2=&txNmSh3=&ltNmTp3=&txMlSh=&ltMlMh=0&ltScDp=0&ltPgCtSt=100&rbDp=0&txScSML=&ltScTp=1&txUpScFl=null&hdUpScPh=&hdUpHash=&rbScMh=1&txScNyMh=&txMlWtSt=&txMlWtEd=&err

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for Pigment Violet 29.

B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

In general, pigments are colored, fluorescent, or pearlescent, organic or inorganic finely divided solids that are usually insoluble in, and essentially physically and chemically unaffected by, the vehicle or medium in which they are incorporated. They alter appearance either by selective absorption, interference and/or scattering of light. They are usually incorporated by dispersion in a variety of systems and retain their crystalline or particulate nature throughout the pigmentation process. The large number of systems vary widely from paints to plastics to inks and fibers (Jaffe, 2004).

The following subsections provide basic process descriptions for each life cycle stage of Pigment Violet 29 based on sources identified from the preliminary literature search.

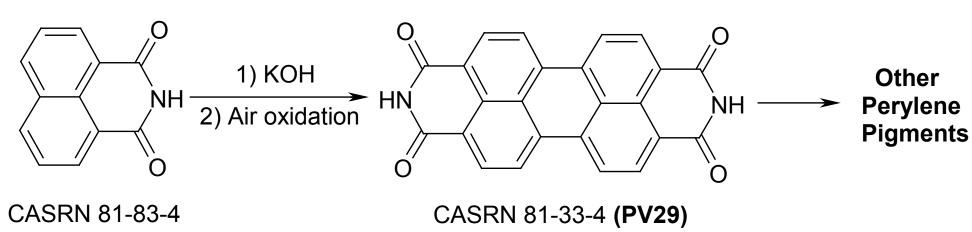
B.1.1 Manufacture and Import

B.1.1.1 Manufacturing

There is one domestic manufacture of Pigment Violet 29. EPA has not fully evaluated specific unit operations; however, the chemical reaction to produce Pigment Violet 29 and general process is presented below.

Ullmann's Encyclopedia of Industrial Chemistry (2012) describes the following chemical reaction to produce Pigment Violet 29:

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 as shown in Figure_Apx B- 1:



Figure_Apx B- 1. Chemical Reaction for Pigment Violet 29 [6]

The procedure for manufacturing has been well-established and has not changed in the last 80 years (U.S. EPA, 2017a).

[6] Industrial Organic Pigments 3rd ed. - W. Herbst, K. Hunger (Herbst and Hunger, 2004)

Potential release points include sources commonly evaluated by EPA from general chemical manufacturing operations:

- Equipment cleaning;
- Container residue (if 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.

B.1.1.2 Import

CDR information indicates there are no facilities importing Pigment Violet 29 above reporting threshold volume of 25,000 lbs per year.

B.1.2 Processing and Distribution

B.1.2.1 Paint and Coating Formulation (U.S. EPA, 2013)

Pigments are insoluble particles used to provide color, hide substrates, modify application properties, or improve final film properties. Pigments are supplied to the 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. Inert pigments often reduce or eliminate the need for the pigment dispersion steps, resulting in reduced production time, labor costs and waste. Functional pigments often modify final coating film properties such as corrosion resistance.

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;
- Product Sampling; and,
- Filtration and packaging.

Bulk solvents and resins are normally transported in road tankers and unloaded by pipes and pipelines into bulk storage tanks. Other liquid materials are delivered in 55-gallon drums or 1 tonne Intermediate Bulk Containers (IBCs). Powder pigments and extenders are delivered in 25 kilogram bags on 1 tonne pallets, in 1 tonne big bags, or occasionally in bulk road tankers from which they are unloaded by compressed air into bulk silos.

Pre-assembly or Pre-mixing of the Pigment Dispersion

In the pre-assembly and pre-mix step, liquid raw materials are assembled and then dispersed in containers to form a viscous material to which pigments are added. This step results in a consistently mixed intermediate product that is referred to as the base or mill base, which has the consistency of a paste. A formulation site may purchase a pigment dispersion containing the chemical of interest (that has already been pre-assembled and pre-mixed) as a raw material; in which case, this step may not be required. The type of equipment used in the pre-mix process is often dictated by the expected batch size. Materials may be mixed in large, high-speed dispersers, disc-type agitators, or variable-speed mixers. Drums equipped with portable mixers may be used for drum-sized batches. The most widely used dispersion method is the use of high-speed dispersers equipped with disk type impellers. The use of high-speed disperser can efficiently reduce the need for extensive grinding or milling.

Grinding or Milling of the Pigment Dispersion

Pigment grinding or milling is required when the size of the particles in the dispersion needs to be reduced. Solid raw materials loading into the mills may or may not include the use of air pollution control equipment, such as baghouse filters. It is common to dilute the pigment concentrate with resin or solvent prior to milling. Milling also occurs in an enclosed vessel. During pigment grinding, the pigment is incorporated into the liquid coating mixture to create a fine particle dispersion. Production mills grind the dry pigments and extenders within the liquid mixture (i.e., water, ammonia and dispersants). Each dry pigment particle is a cluster of many smaller particles. These mills separate pigment clusters into smaller particles and mix them into the liquid vehicle to produce a particle suspension.

Blending

After the grinding process is complete, the fine particle pigment dispersion is transferred to an agitated mix tank for blending. In the blending process, additional ingredients are added to the mixture to meet final product specifications. Final adjustments to color, viscosity, and other coating characteristics are achieved within a mixing tank.

Product Sampling

Samples are taken to check the color, viscosity and other characteristics of the mixture. These are normally taken by dipping a small container into the paint through the lid of a pan or hatchway of a tank. Emissions arise through the open hatch during sampling. To avoid such emissions, 'blind' sampling valves have been developed to assist the removal of samples. The samples are collected in a cup and the valve is cleaned from the outside. Alternatively, hatches can be used.

Filtration and Packaging

The filtration step removes undispersed particles or other contaminants that may have been introduced into the batch. The filtration process also removes any grinding media particles that might have exited the mixer along with the coating formulation. Filtration can be achieved through a variety of means. Filtration processes include the use of felt cloth bag filters and the use of strainers or sieves. One commonly used method includes the use of vibrating screens as strainers to separate unwanted material from the paint. Filter media are only replaced when they break, sometimes as often as 20 to 30 times a day. After filtration, the coating is transferred to a packaging station. Coatings may be transferred into pails, drums, totes, tank wagons, or other containers for shipment purposes. Transport container filling is highly automated but may occur manually depending on the container size and the facility in question.

Potential release sources include:

- Dust losses during unloading;
- Container residue losses during container cleaning and/or disposal;
- Product sampling losses;
- Equipment cleaning losses; and,
- Filter waste losses during filter media replacement.

B.1.2.2 Plastic Compounding (including recycling of used plastics) (U.S. EPA, 2014b)

The first step of the overall compounding process is the handling of the shipping containers. The type of shipping container used largely will depend on the physical properties of the additive chemical. Solid additives will be received as powders, pills, flakes or granules, which typically are shipped in boxes, bags, or fiber drums. Liquid additives are typically received in steel drums. Shipping containers are unloaded into mixing vessels. Environmental releases may result during this transfer activity, particularly for powdered solids 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. Two 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 die. The shape of the die 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.

Potential release sources include:

- Dust emissions from unloading solid powder;
- Container residue losses;
- Dust emissions from blending/compounding operations; and,
- Equipment cleaning residue.

B.1.2.3 Plastic Finishing/Converting (U.S. EPA, 2014b)

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, 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.

Potential release sources include:

- Container residue from plastic resin containing Pigment Violet 29 transport containers;
- Dust emissions from unloading compounded resins;
- Dust generation from forming processes;
- Equipment cleaning and cooling water from forming and molding processes; and,
- Solid waste from trimming operations.

B.1.2.4 Printing Ink (U.S. EPA, 1970)

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-roller or 5-roller horizontal or vertical mills.

Potential release sources include:

- Container residue losses during container cleaning and/or disposal;
- Dust emissions from unloading, grinding;
- Filter waste losses during filter media replacement; and,

- Equipment cleaning.

B.1.3 Uses

B.1.3.1 Commercial Use - Automobile OEM and Refinishing Painting (U.S. EPA, 2014a)

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.

Surface Preparation

Surface preparation involves removing residual wax, grease, or other contaminants from the surface to be painted to ensure adhesion of the new coating. The new coating may be applied over an existing coating if it is free of chips or cracks after it has been roughened through sanding. Alternatively, the previous coating may be removed using a mechanical method (e.g., sanding) or a paint-removing solvent. After the coating is roughened or removed, the surface is typically wiped down with a solvent- or water-based surface preparation product.

Paint Mixing

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.

Spray Application

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 to landfill or incineration. The coating mists/particulates that are not captured by the filter are emitted from the shop stacks into the surrounding environment.

Curing

Following application, each layer of coating is cured or dried. The coating may be allowed to dry at atmospheric conditions, or curing may be accelerated by using heated paint booth air or portable heat sources. Spray booths are typically equipped with fans that provide a flow of heated air to freshly painted vehicle parts. Air from outside of the shop is routed through a heat exchanger and a filter prior to entering the booth. Typical curing temperatures range from 49°C to 60°C (i.e., 120°F to 140°F). After leaving the heated paint booth, the coating will be dry, although the coating film may not be completely cured for days.

Potential release sources include:

- Container residue;
- Equipment cleaning residues (i.e., mixing cup, spray gun);
- Overspray dust/mist captured in spray booth and filters; and,
- Overspray dust/mist emitted to air from the shop.

B.1.3.2 Commercial Use - Incorporation into Industrial Textiles (OECD, 2017)

Pigments differ from dyes in that they:

- Remain insoluble during application;
- Have no affinity for the fibers;
- Require binders; and,
- Do not react with the fibers.

Little penetration of the color into the substrate occurs with pigments. Instead, pigments are usually mixed with a vehicle that hardens upon drying, forming an opaque coating.

Most manufactured textiles are shipped from textile mills to commission dyeing and finishing shops (for further processing in integrated mills) for final coloring or finishing. Alternatively, dyers and finishers may purchase gray goods from mills for conversion to finished textiles. The finisher then sells the finished piece to apparel, furnishing and industrial textile product manufacturers. A wide range of equipment is used for textile dyeing and finishing.

Liquid and solid dye formulations are typically unloaded from transport containers (e.g., drums) directly into the dyeing machine. Dye products may be supplied using feed lines or they may be poured or weighed manually.

Textiles are dyed using both continuous and batch processes, but is typically accomplished in batch processes. While the details of each type of batch process may be different, the basic steps include: a textile substrate is immersed in a bath in which dye is dispersed or dissolved; with agitation and heat, the dyestuff diffuses through the solution, is sorbed at the fiber surface and then diffuses into the fiber. This process can be used for fibers, yarns or fabrics.

Fibers may be dyed before they are spun into yarns or woven or knit into textile fabrics. Fiber dyeing is usually accomplished by pumping dye liquor through a stationary mass of fibers. Fiber is prepacked into some form of perforated basket, which is then loaded into the kettle or kier containing the dyebath. During dyeing the kettle is usually enclosed.

Potential release sources include:

- Dust emissions during unloading and transfer operations;
- Container residue losses;
- Disposal of spent dye bath; and,
- Equipment cleaning residue.

B.1.3.3 Commercial Use – Commercial printing and packaging (U.S. EPA, 2000a)

The fundamental steps in printing are referred to as imaging/film processing, image carrier preparation, printing and post-press operations. The printing industry can be 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. Brief summaries of each technology are presented below.

Lithography

Lithography is a planographic method of printing; in contrast to gravure, in which the image is etched or engraved below the surface of a plate or cylinder, or flexography, in which the image is raised above the surface of the plate. Where the image area and non-image area are in the same plane, the image area is ink receptive (water repellant) and the non-image area is water receptive (ink repellant). In offset lithographic printing, ink is transferred from the plate to a rubber blanket cylinder. The blanket cylinder is used to print the substrate.

Gravure

Gravure printing is a printing process in which an image (type and art) is etched or engraved below the surface of a plate or cylinder (rotogravure). On a gravure plate or cylinder, the printing image consists of millions of minute cells etched or engraved into copper cylinders that is subsequently plated with chrome. Gravure requires very fluid inks that flow from the cells to the substrate at high press speeds. In addition to inks, other materials including adhesives, primers, coatings and varnishes may be applied with gravure cylinders. These materials dry by evaporation as the substrate passes through hot air dryers. Solvent-borne or waterborne ink systems can be used but these ink systems are not interchangeable. Both the printing cylinders and the drying systems are specific to the solvent system in use. Rotogravure can be divided into the publication and product/packaging segments. Because of the expense and complexity of rotogravure cylinder engraving, it is particularly suited to long run printing jobs.

Flexography
Flexographic printing is an example of relief printing where the image area is raised relative to its non-image area. The pattern to be applied is raised above the printing plate and the image carrier is made of rubber or other elastomeric materials. The major applications of flexographic printing are flexible and rigid packaging; tags and labels; newspapers, magazines and directories; and consumer paper products such as paper towels and tissues. Because of the ease of plate making and press set up, flexographic printing is more suited to short production runs than gravure and accounts for the majority of package printing.

Flexographic inks must be very fluid to print properly and include both waterborne and solvent-based systems. The solvents must be compatible with the rubber or polymeric plates; thus, aromatic solvents are not used. Flexographic printing can be divided between publication and packaging/product printing. Additional distinctions can be made based on web versus sheet-fed press equipment.

Screen
In screen printing, ink is forced through a stencil placed over a porous screen. The screens are generally made of silk, nylon, or metal mesh. Screen printing is used for signs, displays, electronics, wall paper, greeting cards, ceramics, decals, banners and textiles. Ink systems used in screen printing include ultraviolet cure, waterborne, solvent borne and plastisol. Plastisol is mainly used in textile printing.

Both sheet-fed and web presses are used. Depending on the substrate printed, the substrate can be dried after each station or, for absorbent substrates, after all colors are printed. Solvent and waterborne inks are dried in hot air or infrared drying ovens. Dryer gasses are may be partially recycled and partially vented (either to the atmosphere or to an air pollution control system).

Letterpress
Letterpress printing uses a relief printing plate, as does flexography, and viscous inks similar to lithographic inks. Various types of letterpress plates are available. These plates differ from flexographic plates in that they have a metal backing. Sheet-fed, heatset web and non-heatset web presses can be used. Newspapers were traditionally printed by web non-heatset letterpress; however, flexographic and lithographic presses have gradually replaced this process. Letterpress is used to print newspapers, magazines, books, stationery and advertising.

Digital
Digital printing is any printing completed via digital files, not restricted to short runs and can provide variable printing such as incorporating data directly for a compact database and printing to a digital press not using traditional methods of film or printing plates.

Potential release sources include:
- Container residue;
- Equipment cleaning.

B.1.3.4 Other Uses
Pigment Violet 29 may also be used in a variety of other uses including: applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, light-

harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices, paper, architectural uses, polyester fibers, adhesion, motors, generators, vehicle components, sporting goods, appliances, agricultural equipment and oil and gas pipelines.

B.1.3.5 Non-TSCA Uses

EPA has identified one non-TSCA use for Pigment Violet 29 which is captured by the FDA. It is approved to be in articles that come in contact with food (21 CFR 178.3297). In addition, Pigment Violet 29 may be used in pharmaceuticals in Finland (EPA-HQ-OPPT-2016-0725-0004).