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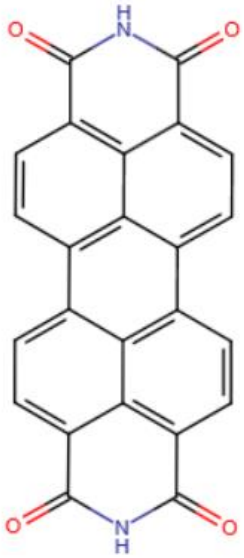
Pollution Prevention

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

CASRN: 81-33-4



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

Disclaimer
Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

ABBREVIATIONS

°C	Degrees Celsius
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
CCL	Contaminant Candidate List
cm^3	Cubic centimeters
CPMA	Color Pigments Manufacturing Association
CWA	Clean Water Act
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
ETAD	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
EU	European Union
FDA	Food and Drug Administration
g	Grams
g/mole	Grams per Unit-Molar Mass
hPa	Hectopascal
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
IRIS	Integrated Risk Information System
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)
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NZloC	New Zealand Inventory
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
PICCS	Philippines Inventory of Chemicals and Chemical Substances
POTW	Publicly owned treatment works
PS	Polystyrene
PUR	Polyurethane
PVC	Polyvinyl chloride
RegDet	Regulatory Determination
SAN	Styrene Acrylonitrile
SAR	Structure-activity relationship
SB	Styrene Butadiene
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
TSCA	Toxic Substances Control Act
U.S.	United States
µm	Micrometer

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). C.I. 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. In June 2017, EPA published the Scope of the Risk Evaluation for C.I. Pigment Violet 29 (U.S. EPA, 2017c). As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for C.I. Pigment Violet 29. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for C.I. Pigment Violet 29 and presents refined conceptual models and analysis plans that describe how EPA expects to evaluate the risk for C.I. Pigment Violet 29. EPA also identifies any conditions of use, hazards, or exposure pathways which were included in the scope document but which EPA does not plan to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards, or exposure pathways without further analysis and therefore plans to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. 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, and consequently merit a risk evaluation. EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise greatest potential for risk. 82 FR 33726, 33728 (July 20, 2017).

C.I. Pigment Violet 29 is an organic pigment found in the following uses: (1) colorant primarily in paints and coatings, plastics and rubber products, merchant ink for commercial printing; (2) intermediate to create or adjust the color of other perylene pigments; (3) formulation, mixture, or reaction product; and (4) consumer watercolor and artistic color. EPA has received public comments specific to the C.I. Pigment Violet 29 Scope Document (U.S. EPA, 2017c; available in the public docket: EPA-HQ-OPPT-2016-0725), which have been reviewed and addressed within the relevant text of this document.

Environmental and human health hazard studies characterizing the physical/chemical properties, environmental fate, human health, and environmental hazards of C.I. Pigment Violet 29 were identified in the European Chemicals Agency (ECHA) Database (ECHA, 2017b) and FDA's Food Additive Petition (FAP) 8B4626 for C.I. Pigment Violet 29 (BASF, 1998a), the results of which were consistent

with the ECHA studies. EPA has reviewed the robust study summaries of physical/chemical properties, environmental fate, human health hazard and environmental hazard studies in these databases, (summarized in Appendix C- Appendix F) and obtained the full study reports from the data owners for in-depth review. In addition, EPA has reviewed the *on-topic* literature from the Pigment Violet 29 (81-33-4) Bibliography: Supplemental File for the TSCA Scope Document (U.S. EPA, 2017a). No *on-topic* references were identified in the literature search for environmental fate, exposure (i.e., general population and consumers), environmental and human health hazards of C.I. Pigment Violet 29 (U.S. EPA, 2017a). A review of the three engineering/occupational exposure citations identified as *on-topic* revealed that these references are not relevant to the risk evaluation of C.I. Pigment Violet 29. Twenty other *on-topic* references previously identified were examined and found to be about pigments other than C.I. Pigment Violet 29 and will be excluded from further consideration. A preliminary review of these study summaries indicates that C.I. Pigment Violet 29 presents a low hazard to human health and environmental receptors.

Analysis of manufacturing conditions, uses and engineering controls of C.I. Pigment Violet 29 indicates that releases from manufacturing, processing, distribution, use and disposal are expected to be limited. Physical-chemical characteristics (i.e., low vapor pressure, low water solubility, high sorption to organic matter, high molecular weight, high Log K_{ow}) indicate exposures would be limited if C.I. Pigment Violet 29 is released to the environment.

All potential exposure pathways to workers, consumers, general population and the environmental receptors resulting from the manufacturing and use of C.I. Pigment violet 29 are included in the risk evaluation. However, based on limited releases, low potential for environmental and human exposures, and low toxicity profile for mammals and aquatic species, EPA concludes that further analysis of these exposure pathways to workers, consumers, general population and environmental receptors is not warranted for C.I. Pigment Violet 29.

The analysis plan for C.I. Pigment Violet 29 therefore consists of evaluating the study reports received by the Agency to ensure that the studies are scientifically sound and the results are consistent with EPA's preliminary review of the robust summaries in the ECHA database and the FDA Food Additive Petition (FAP) 8B4626 for C.I. Pigment Violet 29 (BASF, 1998a). If the review of these study reports indicates that the results are not scientifically sound or consistent with the robust summary reports, EPA may conduct additional analysis in developing the Draft Risk Evaluation for C.I. Pigment Violet 29, which may include changes to the pathways analyzed.

EPA is soliciting public comment on this problem formulation document for C.I. Pigment Violet 29, as an additional interim step, prior to publication of the Draft Risk Evaluation. EPA will carefully consider comments and additional data/information received as it develops the Draft Risk Evaluation. As per EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, EPA will also take comment and peer review the Draft Risk Evaluation for C.I. Pigment Violet 29.

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation for C.I. Pigment Violet 29 under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act, the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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). Additional background information and rationale for C.I. Pigment Violet 29's inclusion list of the first 10 chemicals is provided in Appendix A-1.

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, within 6 months after the initiation of a risk evaluation. The Scope Documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for C.I. Pigment Violet 29. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" (see Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making) (U.S. EPA, 2014). The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in the EPA Human Health Risk Assessment Framework (U.S. EPA,

2014). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

During problem formulation, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore plans to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for C.I. Pigment Violet 29 and has considered the comments specific to C.I. Pigment Violet 29 in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulations, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to C.I. Pigment Violet 29. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA evaluated and considered the impact of existing laws and regulations (e.g., regulations on landfill disposal, design, and operations) in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA uses may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase of the risk evaluation. This is discussed in detail in Section 2.5.2. As part of the problem formulation, background information on the inclusion of C.I. Pigment Violet 29 in 2012 and 2014 TSCA Work Plans was added to Appendix A-1.

Federal Laws and Regulations

C.I. Pigment Violet 29 is subject to one federal statute or regulation, other than TSCA, that is implemented by the U.S. Food and Drug Administration. A summary of federal laws, regulations and implementing authorities, including the U.S. Food and Drug Administration, is provided in Appendix A-2. In response to comments from the Color Pigments Manufactures Association (CPMA) (EPA-HQ-OPPT-2016-0725-0039), (CPMA, 2017b), EPA has clarified that C.I. Pigment Violet 29 does not have any regulatory restrictions under Federal Hazardous Substance Act (FHSA) and Consumer Product Safety Commission (CPSC) as had been indicated in the scope. Therefore, these regulations were removed from Appendix A-2.

State Laws and Regulations

C.I. 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
In response to a comment (EPA-HQ-OPPT-2016-0725-0039) indicating that additional countries have C.I. Pigment Violet 29 on their chemical inventory list, EPA has added chemical inventories for China, Korea, New Zealand, the Philippines, Taiwan and Vietnam to Appendix A-3 . C.I. Pigment Violet 29 is listed on the Canadian Inventory of the 23,000 substances on the Domestic Substances List (DSL) but the Ecological Risk Classification for C.I. Pigment Violet 29 did not meet the criteria for categorisation as a prioritized substance for further evaluation. These determinations for C.I. Pigment Violet 29 and seven other similar pigments were made using a combination of QSAR modeling and hazard data for analogous pigments with low solubility (Pigment Red 149; CAS RN 4948-15-6). The conclusion of this screening was consistent with EPA's findings and indicated that because of low toxicity and low solubility, C.I. Pigment Violet 29 did not meet the criteria for further evaluation and the potential hazard is low (Environment Canada, 2006).

1.2 Data and Information Collection

EPA/Office of Pollution Prevention and Toxics (OPPT) generally applies a systematic review 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 evaluation. Additional information that may be considered and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for C.I. Pigment Violet 29.

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; environmental 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 information potentially relevant to the risk evaluation. For most disciplines, 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. EPA/OPPT also searched for 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* provides details about the data sources and search terms that were used in the initial search (U.S. EPA, 2017d).

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* (U.S. EPA, 2017d). 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 environmental hazard). 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* discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic* (U.S. EPA, 2017d).

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* and were 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* (U.S. EPA, 2017a). 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.

1.3 Data Screening During Problem Formulation

The *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* did not identify any *on-topic* literature search results for environmental fate, exposure (general population and consumers), environmental and human health hazards of C.I. Pigment Violet 29 (U.S. EPA, 2017a) with the exception of the study summaries in the ECHA Database, three engineering/occupational exposure literature search results and the two studies from Food Additive Petition (FAP) 8B4626 (BASF, 1998a): (1) Solubility of C.I. Pigment Violet 29 in ethanol and; (2) Reverse mutation assay AMES test using *Salmonella typhimurium* and *Escherichia coli*. Further review of the three engineering/occupational exposure citations identified as *on-topic* revealed that these references are not relevant to the C.I. Pigment Violet 29 risk evaluation. The full study report for the solubility of C.I. Pigment Violet 29 in ethanol has been reviewed by EPA and summarized in Section 2.1. The full study report for the Reverse mutation assay AMES test using *Salmonella typhimurium* and *Escherichia coli* has been received by the agency and will be reviewed according to the evaluation strategy discussed below.

The *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* also identified twenty other references previously cited in OPPT's documents. Based on a comment received [(EPA-HQ-2016-0725-0039) (CPMA, 2017b)], EPA conducted a second title/abstract screening and determined that some of these references were not relevant to C.I. Pigment Violet 29. As such, these references were excluded from further consideration for C.I. Pigment Violet 29. EPA also identified a number of EPA guidance documents and previous OPPT documents and plans to consider them during the development of the draft risk evaluation for C.I. Pigment Violet 29. Appendix B contains a list of the *on-topic* references that were excluded from further consideration for C.I. Pigment Violet 29.

EPA plans to review the full study reports related to physical/chemical characteristics, environmental fate, human health and environmental hazard of C.I. Pigment Violet 29 using the evaluation strategies as described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). These studies correspond to robust summaries in the ECHA Database as well as a full study report for the Ames assay from the Food Additive Petition (FAP) 8B4626. The study quality evaluation of the study reports is intended to confirm or update the conclusions of the robust summaries available from the ECHA Database that were used to support the preliminary findings discussed in this problem formulation document.

2 PROBLEM FORMULATION

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 included in the scope document a life cycle diagram and conceptual models that describe the actual or potential relationships between C.I. Pigment Violet 29 and human and environmental receptors. For this problem formulation, EPA conducted a preliminary data review of reasonably available fate, exposure and hazard data and determined its suitability for analysis and to identify exposure pathways, receptors and health endpoints for analysis. EPA summarized the outcome of this evaluation in conceptual models that illustrate the exposure pathways, receptor populations and effects that will be subject to further analysis in the risk evaluation (Section 2.5). EPA also prepared an analysis plan to convey the proposed approach to conducting the risk evaluation (Section 2.6).

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. The C.I. Pigment Violet 29 scope document had physical and chemical properties based on estimated values (U.S. EPA, 2017c). During problem formulation, the physical and chemical properties have been updated, where possible, to reflect measured values from the ECHA Database and are provided in Table 2-1. An estimated value for the octanol/water partition coefficient (Log K_{OW}) is presented in Table 2-1. The measured partition coefficient could not be determined due to poor solubility in octanol and water; thus, the estimated Log K_{OW} of 3.76 is applicable for this evaluation. EPA plans to review the full study reports identified in Table_Apx C-1, which the Agency has received from the data owner(s), using the evaluation strategies as described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

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

Property	Value	Reference
Molecular Formula	$C_{24}H_{10}N_2O_4$	(ECHA, 2017b)
Molecular Weight	390.35 g/mole	(U.S. EPA, 2012b)
Physical Form	Solid	(ECHA, 2017b)
Melting Point	No melting point found < 400˚C	(ECHA, 2017b)
Boiling Point	Not available	
Density	1.584 g/cm^3 at 20 ℃	(ECHA, 2017b)
Vapor Pressure	< 0 hPa at 20˚C	(ECHA, 2017b)
Vapor Density	Not available	
Water Solubility	0.01 mg/L at 20˚C	(ECHA, 2017b)
Log K_{OW}	3.76 (estimated)	(U.S. EPA, 2012b)
Henry's Law Constant	1.84E-021 atm-m^3/mole (estimated)	(U.S. EPA, 2012b)
Flash Point	Not available	
Auto Flammability	Not available	
Viscosity	Not available	
Refractive Index	Not available	
Dielectric Constant	Not available	

C.I. Pigment Violet 29 is a Colour Index name used in sales of products containing anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,2,8,10(2H,9H)-tetrone, CASRN 81-33-4. The name "C.I. Pigment Violet 29" is assigned, copyrighted and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists (EPA-HQ-OPPT-2016-0725-0039). The Colour Index is an international standard and classification system describing essential colorants which comprise commercial dyes and pigments.

Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,2,8,10(2H,9H)-tetrone identified by CASRN 81-33-4, is a violet or red-brown pigment and called by the following Colour Index names: C.I. Pigment Violet 29 and C.I. Pigment Brown 26. The difference in color between C.I. Pigment Brown 26 and C.I. Pigment Violet 29 is related to particle size and not crystal form (Sun Chemical, 2017a).

EPA preliminarily reviewed a full study report of the solubility of C.I. Pigment Violet 29 in ethanol from the Food and Drug Administration's Food Additive Petition (FAP) 8B4626 (BASF, 1998a). According to FAP 8B4626, solubility of various pigments including C.I. Pigment Violet 29 was done in 8% and 95% ethanol. In the study, the solubility in 8% ethanol is reported as 0.0046 mg/L and 0.015 mg/L in 95% ethanol. Based on these results, C.I. Pigment Violet 29 has very low solubility in ethanol. Solubility of C.I. Pigment Violet 29 was also assessed in octanol. The solubility in octanol is reported as 0.07 mg/L. The water solubility of C.I. Pigment Violet 29 is 0.01 mg/L per ECHA Database. Based on all solubility test results, C.I. Pigment Violet 29 has low solubility.

There are no known by-products or degradation products resulting from the manufacture of C.I. Pigment Violet 29. There is a residual amount of naphthalimide, the starting material used in the fusion, at approximately 1% (Sun Chemical, 2017a). Per robust study summary reports from the ECHA Database, the hazard profile of naphthalimide is low for human health and environmental receptors (ECHA, 2017a). Based on the minimal amount of naphthalimide released from manufacturing and low hazard,

EPA will not conduct any further analysis of the naphthalimide residual associated with C.I. Pigment Violet 29 production.

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.”

Pigments are widely used and found in a wide range of products that are colored. Below is specific use information for C.I. Pigment Violet 29.

2.2.1 Data and Information Sources

Since conditions of use has not changed since the issuance of the C.I. Pigment Violet 29 scope document (U.S. EPA, 2017c) on June 22, 2017, the conditions of use remain the same for problem formulation.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of C.I. Pigment Violet 29 and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA’s review of published literature and online databases including the most recent data available from EPA’s Chemical Data Reporting program (CDR) and Safety Data Sheets (SDSs). EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of C.I. Pigment Violet 29 and queried government and commercial trade databases. EPA also received comments on the *Scope of the Risk Evaluation for Pigment Violet 29* (U.S. EPA, 2017c) that were used to determine the current conditions of use. In addition, EPA convened meetings with companies, industry groups, chemical users, states, environmental groups, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities and a September 15, 2017 meeting with several representatives from trade associations.

As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider” in a risk evaluation, suggesting that EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis. (82 FR 33736, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or use as an intermediate) or that have been adequately assessed by another regulatory agency.

The activities that EPA no longer believes are conditions of use or that were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation

No conditions of use were excluded during problem formulation; thus, Table 2-3 from the C.I. Pigment Violet 29 Scope Document (U.S. EPA, 2017c) remains the same and is presented in Table 2-2 below.

2.2.2.2 Categories and Subcategories of Conditions of Use in Scope of the Risk Evaluation

Because no conditions of use were excluded during problem formulation, Table 2-2 below remains the same as presented in the C.I. Pigment Violet 29 Scope Document [Table 2-3 in (U.S. EPA, 2017c)] and in Section 2.2.2.1.

Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (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
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;

Life Cycle Stage	Category [a]	Subcategory [b]	References
			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 components, sporting goods, appliances, agricultural equipment and oil and gas pipelines	Use Document, EPA-HQ-OPPT-2016-0725-0004
	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 C.I. 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 C.I. Pigment Violet 29 in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of C.I. Pigment Violet 29.

2.2.2.3 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer; when distinguishable) and disposal. Additions or changes to conditions of use based on additional information gathered or analyzed during problem formulation are described further in Sections 2.2.2.1 and 2.2.2.2. The activities that EPA determined are out of scope during problem formulation are not included in the life cycle diagram. 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, peer reviewed 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 (Appendix D in Instructions for Reporting 2016 TSCA Chemical Data Reporting), (U.S. EPA, 2016a).

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 C.I. Pigment Violet 29 are provided in Table 2-3 (U.S. EPA, 2016b). The 2016 CDR reporting period encompasses production and import volumes for 2012 to 2015. The C.I. Pigment Violet 29 scope document 2012 production volume data was the aggregate production volume for the 2012 CDR reporting cycle and the 2016 CDR data was not presented due to CBI claims. During problem formulation, EPA worked with the CDR reporter to remove CBI claims, such that Table 2-3 now shows 2016 CDR data including the final production volume for 2012; therefore, the production volumes for 2012 differed slightly between the C.I. Pigment Violet 29 scope document and this problem formulation document.

Table 2-3. Production Volume of C.I. Pigment Violet 29 in Chemical Data Reporting (CDR) Reporting Period (2012 to 2015) [a, b]

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

[a] Sun Chemical has waived all claims of CBI for C.I. Pigment Violet 29 in the 2016 CDR (Sun Chemical, 2017b).
[b] 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 problem formulation document is more specific and up-to-date than currently in ChemView.
[c] Final production volume for 2012 reported in 2016 CDR reporting cycle.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram are summarized below (U.S. EPA, 2016b).

Sun Chemical Corporation is the only U.S. manufacturer of C.I. Pigment Violet 29 that reported to CDR in 2012 and 2016 (U.S. EPA, 2012a). EPA is also aware of C.I. Pigment Violet 29 being imported into the United States below the reporting threshold of 25,000 lbs per year from a confidential source per comments from CPMA [EPA-HQ-OPPT-2016-0725-0006, (CPMA, 2017a).

Figure 2-1 shows the production volume of C.I. Pigment Violet 29 that is associated with each life cycle stage. The imported material is used for merchant ink for commercial printing, other uses, and consumer watercolor and artistic color (Figure 2-1, (CPMA, 2017a)). This information also indicates that import volume is considerably less than the manufacturing volume.

Four primary industrial and commercial uses and one consumer use have been identified for C.I. Pigment Violet 29:

- Use as an intermediate to create or adjust color of other perylene pigments (~90%)
- Incorporation into paints and coatings used primarily in the automobile industry (~5%)
- Incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting (~5%)
- Use in merchant ink for commercial printing (< 1%)
- Consumer watercolors and artistic color (unknown minor volume)

Public comments on the C.I. Pigment Violet 29 Use Document [EPA-HQ-OPPT-2016-0725-0004, (U.S. EPA, 2017b)] and 2016 CDR (U.S. EPA, 2016b), indicate 90% of the 2015 domestic production volume (540,000 lbs) is processed as a site-limited intermediate in the manufacture of other perylene pigments. This use is corroborated by the American Coatings Association statement that C.I. Pigment Violet 29 is used to adjust the color of other perylene pigments [(EPA-HQ-OPPT-2016-0725-0008), (ACA, 2017)].

Approximately 10% of the production volume (~60,000 lbs) is processed and used in either commercial paints and coatings (~30,000 lbs) or commercial plastic and rubber products (~30,000 lbs). The 2012 CDR did not indicate these products were intended for or specifically marketed to children (U.S. EPA, 2012a). Automotive and industrial coatings that include metallic finishes and textile printing are types of commercial paints and coatings [(EPA-HQ-OPPT-2016-0725-0006), (CPMA, 2017a)]. C.I. 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 (BASF, 1998b), (COLORS, 2011). Less than 1% of the production volume (~6,000 lbs) is processed into ink and then used in merchant ink for commercial printing.

An unknown minor volume of C.I. Pigment Violet 29 is used in consumer watercolor and acrylic paints. Furthermore, C.I. Pigment Violet 29 used in professional artistic paint products is less than 1% of total sales [(EPA-HQ-OPPT-2016-0725-0039), (CPMA, 2017b)]. The 2012 CDR did not indicate use of C.I. Pigment Violet 29 in products intended for children (U.S. EPA, 2012a). In the 2017 comments on C.I. Pigment Violet 29 Use Document [(EPA-HQ-OPPT-2016-0725-0006), (CPMA, 2017a)], commenters indicated they are not aware of C.I. Pigment Violet 29 being used for paints that are marketed to children, although there are no explicit age-related restrictions on the purchase of professional artistic paints such as watercolors and acrylics. However, consumer products that are widely available, like watercolor and acrylic paints, could be reasonably foreseen to be used by children.

The changes in life cycle diagram since June 22, 2017 include showing the estimated releases from manufacturing and updated production volume values where applicable, as a result of CBI claims being removed.

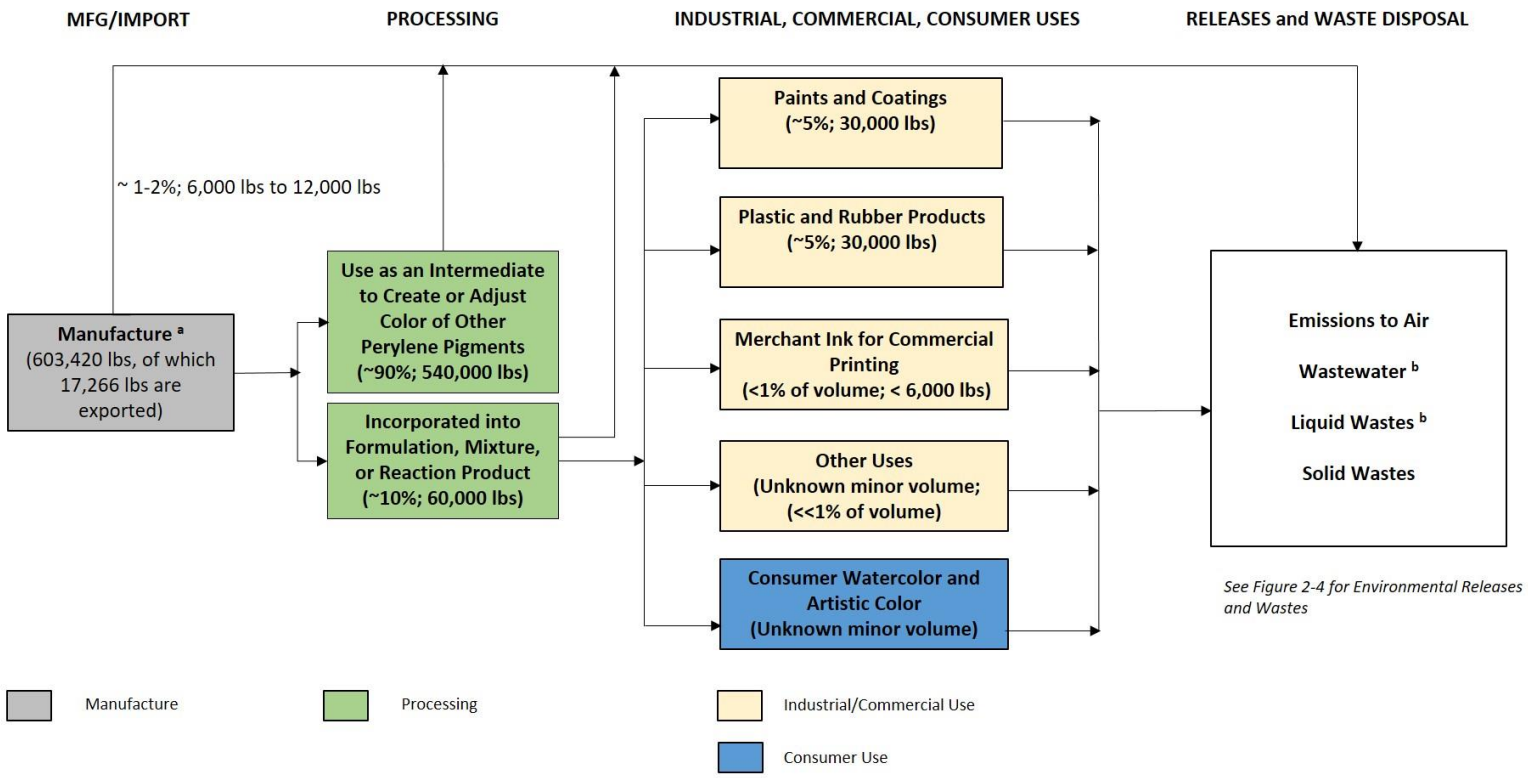

Figure 2-1. C.I. Pigment Violet 29 Life Cycle Diagram

The life cycle diagram depicts the conditions of use 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 C.I. Pigment Violet 29 life cycle, rather than using a single distribution scenario.

[a] 603,420 lbs does not include import volumes since it is below the CDR reporting threshold of 25,000 lbs (CPMA, 2017a); however, uses of imported C.I. Pigment Violet 29 are represented in the LCD.

[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%.

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 C.I. Pigment Violet 29. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use for C.I. Pigment Violet 29 and the exposure to human receptors, including potentially exposed or susceptible subpopulations and environmental receptors. EPA will consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to C.I. Pigment Violet 29.

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.

During problem formulation, EPA considered volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates, and organic carbon:water partition coefficient (log K_{OC}) and bioaccumulation potential when making changes, as described in Section 2.5, to the conceptual models. Systematic literature review is currently underway, so model results, robust study summaries from ECHA, and basic principles were used to support the fate data used in problem formulation.

The C.I. Pigment Violet 29 (U.S. EPA, 2017c) fate properties described here are based on review of ECHA robust study summaries (ECHA, 2017b) and EPA EPI Suite estimated values (U.S. EPA, 2017c) as summarized in Table 2-4. As indicated previously, EPA's literature search (U.S. EPA, 2017a) did not identify any other *on-topic* references pertinent to fate and transport of C.I. Pigment Violet 29.

C.I. Pigment Violet 29 is expected to be highly persistent and has low bioaccumulation potential. Preliminary review of robust summaries for studies related to biodegradation indicates that it is not readily biodegradable. Due to its physical properties, it is expected to bind strongly to soil organic matter and migration through soil to groundwater is likely to be minimal. If released to water, hydrolysis is expected to be negligible. Based on its estimated Henry's Law Constant, C.I. Pigment Violet 29 is not expected to volatilize from environmental waters. If released to air, it is unlikely to undergo direct photolysis and expected to be in the particulate phase. Based on its estimated indirect photodegradation half-life of 7 hours, it is considered to degrade moderately to slowly by reaction with atmospheric hydroxyl radicals.

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

Property or Endpoint	Value [a]	References
Indirect photodegradation	7.0 hours (estimated) [b]	U.S. EPA (2012b)
Hydrolysis half-life	Stable	
Biodegradation	Low biodegradability: 010% degradation in 28 days (OECD 301F)	ECHA (2017b)
Bioconcentration factor (BCF)	Low bioconcentration: BCF=140 (estimated) [b]	U.S. EPA (2012b)
Bioaccumulation factor (BAF)	BAF = 50 (estimated) [b]	U.S. EPA (2012b)
Soil organic carbon:water partition coefficient (Log K_{OC})	5.0 (estimated) [b]	U.S. EPA (2012b)

[a] Measured unless otherwise noted.
[b] There are limited pigment data in the EPI Suite training set, therefore values should be used with caution.

Fate test data EPA identified in the ECHA Database for this chemical includes biodegradation and activated sludge respiration inhibition testing (ECHA, 2017b). During problem formulation, EPA requested and received these studies from the data owner(s):

1. OECD Guideline 301 F: Biodegradability: Manometric Respirometry Test
2. OECD Guideline 209: Activated Sludge, Respiration Inhibition Test

EPA plans to review the full study reports for these tests using the evaluation strategies as described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

However, pigments commonly exist as aggregates in particles sizes of approximately 0.1 µm and exhibit low affinity for water and octanol. The bioaccumulation of such aggregates is likely limited by their molecular weight and size.

2.3.2 Releases to the Environment

C.I. Pigment Violet 29 is manufactured and imported as a solid and in solution and has a low vapor pressure (<0 hPa at 20˚C). It is handled and processed as a dry powder and formulation during all conditions of use. Because the chemical is not volatile at process temperatures during any conditions of use, evaporative losses (volatile fugitive air emissions) are not expected.

The sole domestic manufacturer of C.I. Pigment Violet 29 has estimated standard yield loss of 1-2% of the volume during the manufacturing (6,000- 12,000 lbs for 2015) (Mott, 2017b). Most of the lost C.I. Pigment Violet 29 is captured and disposed such that a very minimal amount is released. Potential release sources at this site and sites that process and use C.I. Pigment Violet 29 include, but are not limited to: residual material in storage and transfer containers that are subsequently cleaned or disposed of, pigment that is spilled during the handling of the dry powder during transfer operations, equipment cleaning, and overspray of coatings.

Air and water releases directly to the environment from manufacturing are expected to be limited based on information provided from the domestic manufacturer. Dust handling systems are in place at the manufacturing facility that capture dust in baghouses. The efficiency rate is greater than 99.5% (Mott, 2017b; Sun Chemical, 2017b). Spilled pigment from handling of the dry powder is collected and placed in contaminated industrial waste bins. The bags and waste bins are subsequently sent to a licensed industrial waste handler for disposal (CPMA, 2017a). One to two percent of produced C.I. Pigment

Violet 29 is lost during handling and most are channeled to an on-site aboveground biological wastewater treatment system that captures C.I. Pigment Violet 29 (Mott, 2017b). Of this material that is captured during the wastewater treatment process, greater than 95% of the wastewater treatment residue is disposed of at either the Oak Ridge Landfill in Dorchester County or the Berkeley County Landfill, RCRA Subtitle-D lined landfills permitted under the authority of South Carolina Regulation Number 61-107.19 Solid Waste Management (Mott, 2017a), (RCRAInfo Facility Information). Less than 0.1% of produced C.I. Pigment Violet 29 is released to surface waters (0.6 lb/day, as reported by the manufacturer).

C.I. Pigment Violet 29 is supplied to formulator as dry powders, press cakes, or slurries. Pigments grinding or milling is required when the size of the particles in the dispersion needs to be reduced. After grinding and/or milling, C.I. Pigment Violet 29 is blended with other additives and solvents. Formulated paint and coatings (5% of total production volume) are filtered prior to packaging. For plastics and rubber (5% of total production volume), pigments and other additives are mixed with polymer resins and other raw materials to produce compound resin master batch. It is then transferred into an extruder where it is converted into pellets, sheets, films, or pipes. The extruded plastics are shipped to downstream converting sites where they are formed into the desired shape through a variety of converting methods, including extrusion, injection molding and thermoforming.

No data pertaining to environmental releases from the twenty downstream industrial facilities that process C.I. Pigment Violet 29 into plastics, paints and coatings were identified. These uses account for 10% of the total production volume. However, CPMA indicated that all of these facilities are subject to EPA and state regulations resulting in limiting releases to air, water, and land of materials to the environment.

Exposure and releases are possible when handling concentrated C.I. Pigment Violet 29 but once it is encapsulated in plastics or paint resins, it is not expected to leach out [21 CFR 178.3297, (BASF, 1998a)].

No specific release information for C.I. Pigment Violet 29 was found in the references identified during the full-text screening of the *on-topic* references under the Engineering section of *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017a). However, releases to the environment from the conditions of use are possible (e.g., from manufacturing and use as a site-limited intermediate which is ~1-2%; incorporation into plastics, paints and coatings; application of coatings).

Based on information provided by the domestic manufacturer that is summarized above, releases from the manufacturing site are expected to be limited. Based on the information from industries, use information, and the physical properties of C.I. Pigment Violet 29, most of the waste from manufacturing as well as the various processing and uses are expected to be sent to landfills or incineration for disposal and only limited quantities are expected to be released to surface water.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable biomonitoring 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. EPA did not find environmental monitoring data (e.g., presence in air, soil, sediment, surface water, or biota) indicating the presence of C.I. Pigment Violet 29 in the U.S. or internationally (U.S. EPA, 2017a). EPA also did not find biomonitoring data for C.I. Pigment Violet 29 (U.S. EPA, 2017a). Although the

persistence and tendency to sorb to sediment means that there is the potential for entry into the aquatic food web, available data indicate that the BAF is low so uptake and bioaccumulation is likely to be limited.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of C.I. Pigment Violet 29 can result in releases to the environment. In this section, EPA presents exposures to aquatic and terrestrial organisms.

As outlined above, physical-chemical and fate properties as well as engineering controls limiting manufacturing (the largest use) releases are expected to result in limited exposure to water and sediment, groundwater via biosolids, landfill leaching, and air. It is estimated that less than one pound per day of C.I. Pigment Violet 29 is being released as the overall total of the National Pollutant Discharge Elimination System (NPDES)-permitted total suspended solids (TSS) discharges from the sole US manufacturer (Mott, 2017b). Because volumes used by downstream users are markedly less than the manufacturer (less than 5% each), it is expected that there will be minimal releases to water and sediment, groundwater via biosolids, landfill leaching, and air.

Where releases do occur, they are expected to result in limited environmental exposures. Specifically, releases of C.I. Pigment Violet 29 to water and sediment could occur during the wastewater treatment process following manufacturing/processing through possible releases of TSS, but these releases and corresponding aquatic exposures are expected to be limited since the high sorption of this chemical to organic matter (Log K_{oc} = 5.0; see Table 2-4) will result in the vast majority of C.I. Pigment Violet 29 being captured as sludge in wastewater treatment facilities which is subsequently disposed of via incineration or landfill disposal. Similarly, the strong sorption properties would be expected to limit exposure via migration to groundwater from C.I. Pigment Violet 29 disposed of in landfills or applied via biosolids.

Air exposures from both incineration and fugitive releases from manufacturing and/or processing are expected to be low due to described fate properties and waste handling practices. Specifically, due to the low vapor pressure and volatility of C.I. Pigment Violet 29 (Henry's Law Constant $<1x10^{-10}$ atm-m^3/mole; Section 2.3.1 (U.S. EPA, 2017c)). Industrial wastes are sent to licensed industrial waste handlers where destruction removal efficiencies for incinerators are expected to be >99% (CPMA, 2017a).

2.3.5 Human Exposures

Human exposure to C.I. Pigment Violet 29 through occupational (Figure 2-2), consumer (Figure 2-3) or general population (Figure 2-4) activities and uses is possible, but exposures via all routes (oral, dermal, and inhalation) are expected to be low when physical-chemical properties are considered.

2.3.5.1 Occupational Exposures

Workers may be exposed via inhalation and dermal routes. However, absorption via inhalation pathways is expected to be low due to low water solubility and dermal absorption is estimated to be negligible for the neat material (because it is a solid of high molecular weight), and poor absorption in solution (based on high molecular weight and low solubility). EPA received inhalation exposure monitoring information from the domestic manufacturer of C.I. Pigment Violet 29. The information indicates a workplace air concentration of 0.5 mg/m^3 over a 12-hour shift (Mott, 2017a). It is not clear if the monitoring result was for C.I. Pigment Violet 29 or for total dust. If the level was for total dust, the actual air concentration of C.I. Pigment Violet 29 is likely to be lower than 0.5 mg/m^3 (i.e., lower exposure).

Oral contact is not a relevant pathway for workers manufacturing C.I. Pigment Violet 29 since eating is not allowed in the production and laboratory work areas and proper personal protective equipment (PPE) are expected to be worn at the sole C.I. Pigment Violet 29 US manufacturing facility (Mott, 2017a). In addition, oral absorption is negligible due to low water solubility.

For downstream processors and users, worker exposure via inhalation through particulates that deposit in the upper respiratory tract or oral routes such as incidental ingestion of C.I. Pigment Violet 29 residue on hands is possible. These exposures are possible during handling solids and spray application of coatings containing C.I. Pigment Violet 29. However, oral and inhalation exposures to downstream processors and users are likely to be limited due to the use of PPEs and negligible oral absorption due to low water solubility [(BASF, 2017), (Sun Chemical, 2017d), (CPMA, 2017a)].

EPA reviewed available Safety Data Sheets (SDSs) for C.I. Pigment Violet 29. The SDSs recommend the use of personal protective equipment to minimize exposure, including the use of chemical-resistant protective gloves and safety glasses with side-shields or a face shield if a splashing hazard exists. It also recommends adequate ventilation when handling C.I. Pigment Violet 29 [(BASF, 2017), (Sun Chemical, 2017d), (Sun Chemical, 2017c)].

The domestic manufacturer of C.I. Pigment Violet 29 also indicates that workers in production and laboratory areas at their facility wear long sleeves and gloves to prevent dermal exposure (Mott, 2017a). Furthermore, while limited exposures are deemed possible, and as mentioned above, absorption via dermal and inhalation routes is expected to be low (see Section 2.4.2.1).

2.3.5.2 Consumer Exposures

Possible exposure pathways/routes for C.I Pigment Violet 29 in consumer products are through liquid contact with paint and subsequent dermal absorption or oral ingestion (Figure 2-3). Inhalation is not identified as a route of exposure for consumers since C.I. Pigment Violet 29 is not expected to be released from consumer watercolor and artistic color as a vapor due to its low vapor pressure. Consumer exposures via oral and dermal routes are expected to be limited based on physical-chemical properties of C.I. Pigment Violet 29. Oral ingestion is expected to be negligible due to the low water solubility (see Table 2-1; 0.01 mg/L) and dermal absorption is estimated to be negligible for the neat material (because it is a solid of high molecular weight) and poor absorption in liquid (based on high molecular weight and low solubility). Further, C.I. Pigment Violet 29 was approved as a colorant for food packaging and is expected to remain within plastics (Appendix A-2). Therefore, consumer exposures associated with identified consumer uses are expected to be limited.

2.3.5.3 General Population Exposures

General population exposures to C.I. Pigment Violet 29 are expected to be limited due to the limited releases of C.I Pigment Violet 29 outlined above (Section 2.3.4). Possible exposure routes for the general population include oral ingestion of water or groundwater and inhalation of air associated with releases of C.I. Pigment Violet 29 (Figure 2-4). Oral ingestion of C.I. Pigment Violet 29 is expected to be negligible due to low concentrations expected in surface and ground water. This low concentration in water is due to high capture efficiency of C.I. Pigment Violet 29 during the waste water treatment process limiting releases to surface water and strong sorption to soil reducing migration to groundwater (Section 2.3.4). Additionally, physical-chemical properties indicate that even if ingested, absorption would be expected to be limited due to low water solubility. Inhalation of C.I. Pigment Violet 29 is expected to be limited due to limited fugitive and incineration air releases (Figure 2-4, Section 2.3.2). Low volatilization rates will limit fugitive air releases as vapor (Section 2.3.1), while engineering

controls during manufacturing capture the majority of any C.I. Pigment Violet 29 that would be released (see Section 2.3.1). Downstream industrial facilities are subject to EPA and state regulations that would be expected to similarly limit air releases (Section 2.3.2). Furthermore, absorption via inhalation is expected to be low due to low water solubility. Dermal exposures, should they occur, are expected to be limited because dermal absorption is estimated to be negligible because it is a solid of high molecular weight and solubility.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an 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." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. 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.

Exposures of C.I. Pigment Violet 29 would be expected to be higher amongst workers and consumers using C.I. Pigment Violet 29 as compared to the general population. However, these potential exposures are likely to be limited due to physical-chemical and fate properties resulting in limited absorption and engineering controls during the manufacturing, processing and use of C.I. Pigment Violet 29 as outlined above.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of C.I. Pigment Violet 29, as described *in* *Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017d). No specific human health or environmental hazard information for C.I. Pigment Violet 29 was identified during the full-text screening of the *on-topic* references under the human health hazard or environmental hazard sections of *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017a). Based on initial screening of the robust summaries available in the ECHA and FAP databases the hazards to human and environmental receptors are expected to be low. EPA plans to confirm the low hazards of C.I. Pigment Violet 29 by reviewing the study reports that were used to formulate the robust summaries. When conducting the risk evaluation, the relevance of any hazard within the context of a specific exposure scenario will be judged for appropriateness. For C.I. Pigment Violet 29, exposures are expected to be low. This means that it is unlikely that exposure scenarios will be further analyzed in the risk evaluation.

2.4.1 Environmental Hazards

As indicated previously, the environmental hazard data identified for C.I. Pigment Violet 29 were the studies described in the robust summaries in ECHA Database (ECHA, 2017b).

Aquatic toxicity data were available, which measured the acute toxicity of C.I. Pigment Violet to a fish, aquatic invertebrate, and aquatic plant species. Appendix E presents the robust summaries available from the ECHA Database that EPA used to preliminarily characterize the environmental hazard of C.I. Pigment Violet 29.

The Agency is currently in possession of full study reports for the following studies:

- OECD Guideline 203: Fish Acute Toxicity Test
- OECD Guideline 202: *Daphnia* sp., Acute Immobilization Test
- OECD Guideline 221: *Lemna* sp., Growth Inhibition test

EPA will review all full study reports during risk evaluation using the data quality review evaluation metrics and the rating criteria described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

Review of the robust summaries indicates that no adverse effects were observed in fish (acute), aquatic invertebrate (acute), and aquatic plants at the limit of solubility for C.I. Pigment Violet 29. Based on the lack of adverse effects observed, EPA preliminarily concludes that the aquatic hazard is low for C.I. Pigment Violet 29. This is consistent with the Canadian Ecological Risk Classification for C.I. Pigment Violet 29, discussed in Appendix A-1, where it was determined that C.I. Pigment Violet 29 did not meet the criteria for categorisation as a prioritized substance for further evaluation and the potential hazard is low.

As noted in Section 2.3.1, C.I. Pigment Violet 29 is not expected to degrade in the environment, so EPA has no concerns for environmental degradation products for C.I. Pigment Violet 29.

No studies were identified that characterized the effects of chronic exposure of C.I. Pigment Violet 29 to aquatic species, or the effects to terrestrial species. As a result of uncertainties inherent in extrapolating between acute and chronic exposure regimes and dissimilar environmental receptors, multiple lines of evidence were considered to evaluate the potential for hazards under chronic aquatic exposure conditions and to terrestrial organisms. The combination of low hazard of C.I. Pigment Violet 29 to aquatic species, low hazard in mammalian tests (see Section 2.4.2), the low limit of solubility, low vapor pressure, low bioaccumulation potential, low environmental releases and resulting exposures from manufacturing, use, and disposal, as well as low absorption (see Section 2.4.2) indicate that hazard to terrestrial and aquatic receptors from acute and chronic exposures to C.I. Pigment Violet 29 is expected to be low.

2.4.2 Human Health Hazards

C.I. Pigment Violet 29 does not have an existing EPA IRIS Assessment; however there is available toxicity data on C.I. Pigment Violet 29 from ECHA (ECHA, 2017b) and the Food Additive Petition (FAP) 8B4626 (BASF, 1998a). EPA plans to review these studies using the approaches and/or methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) to ensure that EPA is considering information that has been made available. Based on the reasonably available information, the following sections describe the hazards EPA expects to further analyze.

2.4.2.1 Non-Cancer Hazards

As indicated previously, the human health hazard data identified for C.I. Pigment Violet 29 were those described in the robust summaries in ECHA Database (ECHA, 2017b). Several of the studies were

referenced in the Food Additive Petition (FAP) 8B4626 (BASF, 1998a). The results of the studies referenced in the FAP were compared against the results of the summaries in the ECHA database and were found to be consistent. No additional information was available in the FAP to define the non-cancer hazards of C.I Pigment Violet 29.

The Agency is currently in possession of the full study reports for the human health studies summarized in Appendix F:

- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion
- OECD Guideline 429: Skin Sensitisation: Local Lymph Node Assay
- OECD Guideline 421: Reproduction / Developmental Toxicity Screening Test
- Non-Guideline Acute Toxicity: Acute Intraperitoneal Toxicity with Rats
- Non-Guideline Acute Toxicity: Acute Inhalation Toxicity with Rats

Together, these full study reports represent all the human health data on C.I. Pigment Violet 29 found in the ECHA Database. Additional study summaries were identified in the ECHA database, but these were found to be conducted on analogous chemicals, so these studies were not requested at this time. EPA will review all full study reports and the expanded summary documents during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

Preliminary review of the robust summaries indicates lack of effects in any standard toxicity test. These findings are consistent with the expectation that C.I. Pigment Violet 29 is poorly absorbed by all routes (oral, dermal, and inhalation) due to its physical-chemical properties.

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

2.4.2.2 Genotoxicity and Cancer Hazards

Genotoxicity data are available for C.I. Pigment Violet 29, including those summarized in the ECHA Database (ECHA, 2017b) and the Food Additive Petition (FAP) 8B4626 (BASF, 1998a).

The Agency is currently in possession of the following full study reports of genotoxicity tests summarized in Appendix F:

- OECD Guideline 476: *In vitro* Mammalian Cell Gene Mutation Test
- Reverse mutation assay AMES test using *Salmonella typhimurium* and *Escherichia coli* from Food Additive Petition (FAP) 8B4626 (BASF, 1998a).

EPA will review all full study reports during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

EPA also considered potential carcinogenicity during problem formulation. Perylene, the 5-ring polycyclic hydrocarbon moiety in the center of C.I. Pigment Violet 29, has been shown to be a negative or marginal carcinogen in limited studies (IARC, 2010). This low carcinogenicity potential is supported by structure-activity relationship (SAR) analysis and EPA's OncoLogic cancer expert system (available at https://www.epa.gov/tsca-screening-tools/oncologictm-computer-system-evaluate-carcinogenic-potential-chemicals) because the arrangement of the five benzene rings in perylene does not favor metabolic activation to epoxides. The addition of the imides groups to perylene to form C.I. Pigment Violet 29 is expected to decrease solubility, increase bulkiness and thereby further reduce the likelihood of carcinogenic potential. Testing for carcinogenicity of C.I. Pigment Violet 29 has not been conducted. However, negative genotoxicity results, SAR considerations and the expected negligible absorption and uptake of C.I. Pigment Violet 29, support EPA's conclusion that C.I. Pigment Violet 29 is unlikely to be a carcinogen.

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 analyze 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 Conceptual Models

EPA risk evaluation guidance (U.S. EPA, 1998; U.S. EPA, 2014), defines Problem Formulation as the part of the risk evaluation framework that identifies the major factors to be considered in the evaluation. It draws from the regulatory, decision-making and policy context of the risk evaluation and informs the evaluation's technical approach.

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. The initial conceptual models describing the scope of the risk evaluation for C.I. Pigment Violet 29, have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section EPA outlines whether pathways will be included and further analyzed in the risk evaluation; will be included but will not be further analyzed in risk evaluation; and will not be included in the TSCA risk evaluation and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on the exposure pathways that were identified in the C.I. Pigment Violet 29 scope document (U.S. EPA, 2017c) and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017). EPA expects to be able to reach conclusions about particular hazards or exposure pathways without extensive evaluation and plans to conduct no further analysis on those hazards or exposure pathways in order to allow EPA to focus the Agency's resources on more extensive or quantitative

analyses. As discussed below, EPA preliminarily determined that there are no environmental release and waste pathways for the environment or general populations that EPA plans to further analyze in the risk evaluation.

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. The initial conceptual models describing the scope of the risk evaluation for C.I. Pigment Violet 29, have been refined during problem formulation, where no exposure pathways are expected to be assessed further. The changes to the conceptual models in this problem formulation are described along with the rationales. Figure 2-2 and Figure 2-3 illustrate the flow of C.I. Pigment Violet 29 from chemical manufacture and processing through potential exposure pathways to effects to human receptors (e.g., workers, consumers, general population). Figure 2-4 illustrates the flow of C.I. Pigment Violet 29 from chemical manufacture and processing through potential exposure pathways to effects to environmental receptors (e.g., terrestrial and aquatic wildlife).

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

The revised conceptual model for Industrial and Commercial Activities and Uses (Figure 2-2) describes the pathways of exposure from industrial and commercial activities and uses of C.I. Pigment Violet 29 that EPA plans to include in the risk evaluation. The C.I. Pigment Violet 29 Scope Document presented possible exposure pathways and exposure routes to human and environmental receptors associated with environmental releases and waste handling, treatment and disposal of C.I. Pigment Violet 29 for industrial and commercial activities (U.S. EPA, 2017c). During problem formulation, EPA further analyzed the potential exposures and hazards to workers and has refined the conceptual models accordingly with releases, pathways and routes of exposure that EPA has concluded do not warrant further analysis indicated in Figure 2-2.

Inhalation

Mist and dust emissions from fugitive and stack emissions are expected to be limited. Air emissions are typically relevant for volatile and/or dusty materials and since C.I. Pigment Violet 29 is not volatile, the vapor pathway is not relevant. Since the vapor pressure of C.I. Pigment Violet 29 is nil, the vapor release during uses of paint is not a concern. Also, dust handling systems are in place at the manufacturing facility where the dried powder is added or discharged from the equipment and 99.5% of dust is captured in baghouses. The resulting dust and bags are handled as contaminated industrial waste and sent to a licensed waste handler for disposal. Absorption of C.I. Pigment Violet 29 via inhalation is also expected to be negligible based on low water solubility. Inhalation monitoring has shown that exposure was about 0.5 mg/m^3 over a 12-hr work shift (Mott, 2017a). Due to the low potential for inhalation exposure and low potential absorption and low inhalation toxicity, this pathway will not be further analyzed in the risk evaluation.

Oral

Oral contact is not a relevant pathway for workers manufacturing C.I. Pigment Violet 29 since eating is not allowed in the production and laboratory work areas and proper personal protective equipment are expected to be worn at the sole C.I. Pigment Violet 29 US manufacturing facility (Mott, 2017a). In addition, oral absorption is negligible due to low water solubility. EPA plans no further analysis of this pathway for workers or occupational non-users in the risk evaluation.

Dermal

Dermal absorption is estimated to be negligible when C.I. Pigment Violet 29 is a solid, and low if it is in solution based on the low water solubility and high molecular weight. Dermal exposure is possible if C.I. Pigment Violet 29 is formulated in solvent. However, based on the review of the robust summaries of human health data in the ECHA Database (ECHA, 2017b), hazards to human health are expected to be low. Dermal absorption of C.I. Pigment Violet 29 is estimated to be negligible for the neat material since it is a solid, and poor dermal absorption if it is in solution based on the low water solubility and high molecular weight. EPA plans no further analysis of this pathway for workers or occupational non-users in the risk evaluation.

Waste handling, treatment and disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same low hazard conclusion as other industrial and commercial activities and uses. During problem formulation, EPA further analyzed the potential exposures and hazards to consumers and bystanders and has refined the conceptual models accordingly. Releases of C.I. Pigment Violet 29 from recycling of used papers and plastic articles containing C.I. Pigment Violet 29 is possible. However, due to its low water solubility and high sorption to particulates and biosolids, most C.I. Pigment Violet 29 in aqueous waste streams is expected to be captured in the waste water treatment systems. As a result of the lack of exposure expected to result from this pathway, EPA plans no further analysis of this pathway for workers or occupational non-users in the risk evaluation. Figure 2-3 in the C.I. Pigment Violet 29 Scope Document presented the possible exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of C.I. Pigment Violet 29 (U.S. EPA, 2017c). Due to these releases, pathways and routes of exposure, EPA has concluded no further analysis of these pathways is warranted, as indicated in Figure 2-3.

Consumer Handling and Recycling and Disposal of Waste

Releases of C.I. Pigment Violet 29 from recycling of used papers and plastic articles containing C.I. Pigment Violet 29 is possible. However, due to its low water solubility, any C.I. Pigment Violet 29 in aqueous waste stream is expected to be captured in the waste water treatment systems. As the majority of C.I. Pigment Violet 29-containing consumer waste consists of consumer products that are expected to enter the consumer waste streams for landfill disposal or recycling, consumer exposure to these products is low, as these activities take place in licensed waste management facilities. Similarly, C.I. Pigment Violet 29 in paints and plastics is expected to remain embedded in these materials, thereby limiting exposure. Due to the low potential for exposure resulting from consumer activities and low toxicity to human receptors, EPA plans no further analysis of these pathways for consumer activities in the risk evaluation.

2.5.2 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The revised conceptual model (Figure 2-4) in the C.I. Pigment Violet 29 Scope Document presents possible exposure pathways, exposure routes, and hazards to human and environmental receptors from environmental releases and wastes of C.I. Pigment Violet 29 (U.S. EPA, 2017c). During problem formulation, EPA further analyzed the potential exposures and hazards to the general population and environmental receptors and has refined the conceptual models accordingly with releases, pathways and routes of exposure that EPA has concluded do not warrant further analysis indicated in Figure 2-4.

2.5.2.1 Pathways That EPA Plans to Include and Further Analyze in the Risk Evaluation

There are no environmental release and waste pathways for the environment or general populations that EPA plans to further analyze in the risk evaluation.

2.5.2.2 Pathways that EPA Plans to Include in the Risk Evaluation but Not Further Analyze

Ambient Water and Drinking Water Pathways

Currently, no states or tribes include criteria for C.I. Pigment Violet 29 in water quality standards and values are not available for use in NPDES permits. Thus, EPA cannot conclude that risk to human health and aquatic life from exposure to C.I. Pigment Violet 29 in ambient waters has been effectively managed. As a result, this pathway is included in the Risk Evaluation. EPA may publish CWA section 304(a) human health or aquatic life criteria for Pigment Violet 29 in the future if it is identified as a priority under the CWA.

As described in Section 2.3.2, releases to water are expected to be limited from the sole U.S. manufacturer and downstream users. Chemicals may enter surface water via either direct release to water or release after treatment at POTWs, in compliance with an NPDES discharge permit. Due to low water solubility and its solid physical state, direct releases of C.I. Pigment Violet 29 to water are expected to partition into particulates and sediment; but the amounts are expected to be limited due to minimal releases to surface water. Likewise, C.I. Pigment Violet 29 releases from downstream users to POTWs would be expected to separate during settling in primary treatment due to low water solubility and to partition largely to the biosolids and particulates during secondary treatment. Sorption to particulates and biosolids are expected to be strong and water solubility is low; therefore, biosolids that contain C.I. Pigment Violet 29 are expected to lead to negligible migration to ground water. Hence, C.I. Pigment Violet 29 concentrations in surface water and groundwater are expected to be low based on limited releases and physical-chemical properties (low water solubility).

Based on the environmental fate described, C.I. Pigment Violet 29 is also not expected to be present in drinking water (surface or ground water) at significant levels and hence, oral ingestion of water is deemed an insignificant exposure pathway for C.I. Pigment Violet 29. Furthermore, as described previously, even if oral ingestion occurs, absorption of C.I. Pigment Violet 29 is expected to be limited due to its very low water solubility. This conclusion is supported by available experimental human health hazard data showing no adverse effects as a result of exposure to C.I. Pigment Violet 29 in both acute and repeated-dose studies. Hence, EPA concludes that further analysis for risk to the general population from oral exposures is not warranted.

Environmental hazard data reported in the ECHA Database indicate no effects were observed at the solubility limit for C.I. Pigment Violet 29 in toxicity tests with an aquatic plant, an aquatic invertebrate and a fish. Taken together with the limited releases expected to water (wastewater (direct/indirect) and groundwater), EPA concludes that further analysis of exposures to aquatic species from exposure to C.I. Pigment Violet 29 is not warranted. Similarly, as a result of the low potential for exposure to terrestrial environmental receptors and low acute toxicity to the surrogate species (aquatic and mammalian), further risk analysis to terrestrial environmental receptors is not warranted. As indicated above, this is consistent with the Canadian Ecological Risk Classification for C.I. Pigment Violet 29, discussed in Appendix A-1.

Air Pathway

As indicated in Sections 2.3.1 and 2.3.2, low volatilization rates will limit fugitive air releases as vapor, while engineering controls capture the majority of any C.I. Pigment Violet 29 that would be released during incineration. Dust handling systems are in place at the manufacturing facility that capture C.I. Pigment Violet 29 lost as dust during manufacturing. The efficiency rate is greater than 99.5% (Mott, 2017b; Sun Chemical, 2017b). Furthermore, absorption via inhalation is expected to be low due to low water solubility. Due to the low potential for inhalation exposure and low potential absorption and low inhalation toxicity, this pathway will not be further evaluated in the risk evaluation.

Disposal Pathways

The sole domestic manufacturer of C.I. Pigment Violet 29 has estimated standard yield loss of 1-2% of the volume during the manufacturing (6,000- 12,000 pounds for 2015) (Mott, 2017b). Greater than 95% of this loss is estimated to be captured via on-site above ground biological wastewater treatment system that captures C.I. Pigment Violet 29 as well as dust handling systems in place at the manufacturing facility, which capture dust in baghouses (Mott, 2017b).

As indicated above, and in Section 2.3.2, the sole U.S. manufacturer of C.I. Pigment Violet 29 sends its non-hazardous wastewater treatment residuals (sludge) to the Oak Ridge Landfill in Dorchester County or the Berkeley County Landfill. Both landfills are RCRA Subtitle-D lined landfills permitted under the authority of South Carolina Regulation Number 61-107.19.

In addition to design standards for Subtitle-D lined landfills which are intended to limit the potential for leachate, sorption to particulates and biosolids for C.I. Pigment Violet 29 are expected to be strong and water solubility is low, so leaching of C.I. Pigment Violet 29 from landfills is expected to be negligible. C.I. Pigment Violet 29 contained in consumer products is expected to be encapsulated in plastics or paint resins, which further limits the potential for leaching from disposal of these products. Due to the low potential for exposure, low hazards to human health and low hazard to environmental receptors, EPA concludes further evaluation of exposures resulting from disposal to landfills is not warranted.

As indicated in Section 2.3.2, the sole U.S. manufacturer of C.I. Pigment Violet 29 sends its non-hazardous wastewater treatment residuals (sludge) to the Oak Ridge Landfill in Dorchester County or the Berkeley County Landfill. Both of these landfills are RCRA Subtitle-D lined landfills permitted under the authority of South Carolina Regulation Number 61-107.19, so land application of biosolids is not expected to be a release pathway for the manufacturer, so this pathway is outside of scope of this assessment. Similarly, EPA does not plan to include on-site releases to land that go to underground injection. There are no current underground injection sites for C.I. Pigment Violet 29 and none are expected; so this disposal pathway is also outside the scope of this evaluation.

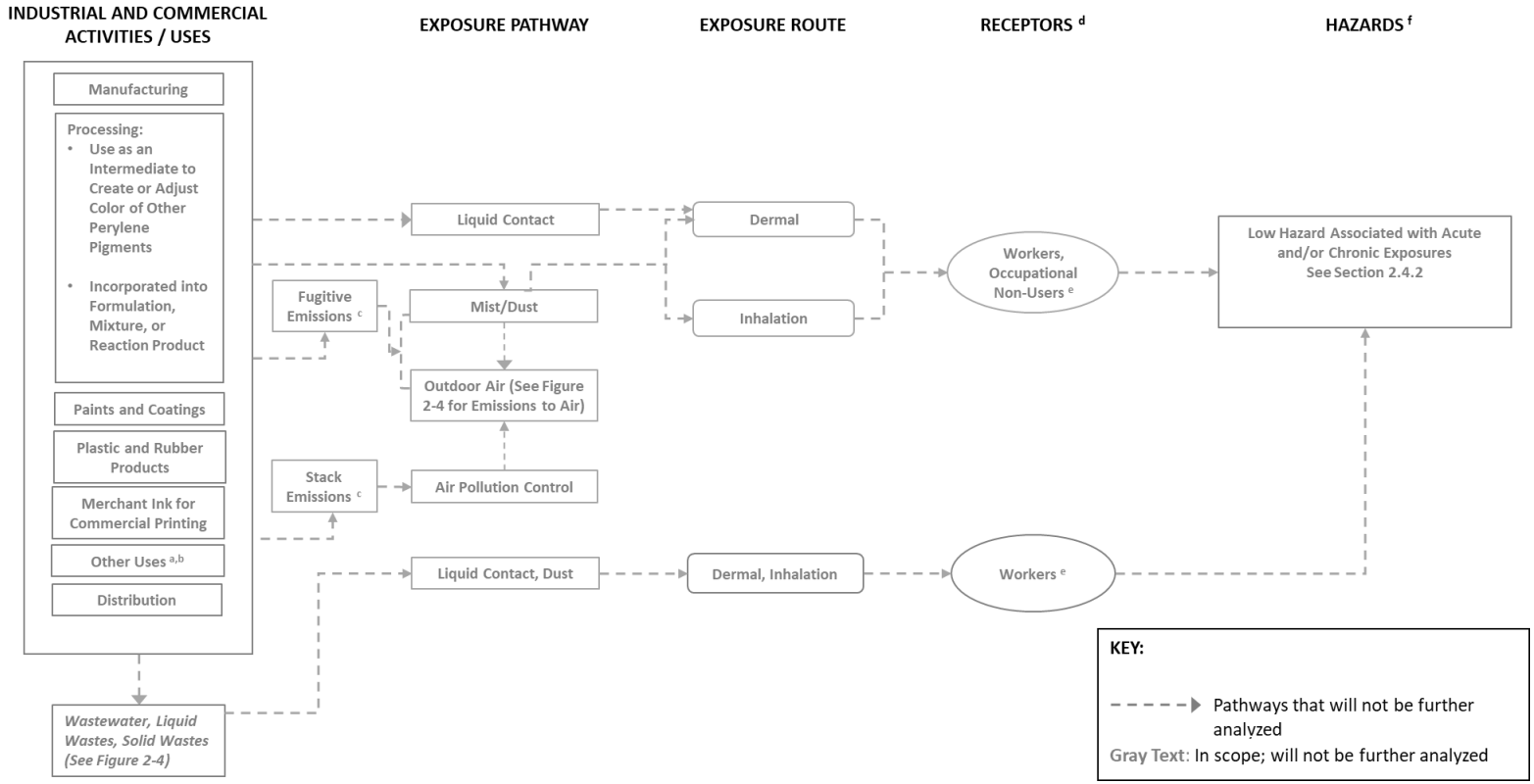

Figure 2-2. C.I. Pigment Violet 29 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

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

[a] Other uses of C.I. Pigment Violet 29 may include: applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, pharmaceuticals, 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.

[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] Receptors include potentially exposed and susceptible subpopulations.

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

[f] EPA will review full study reports to confirm preliminary low hazard conclusions.

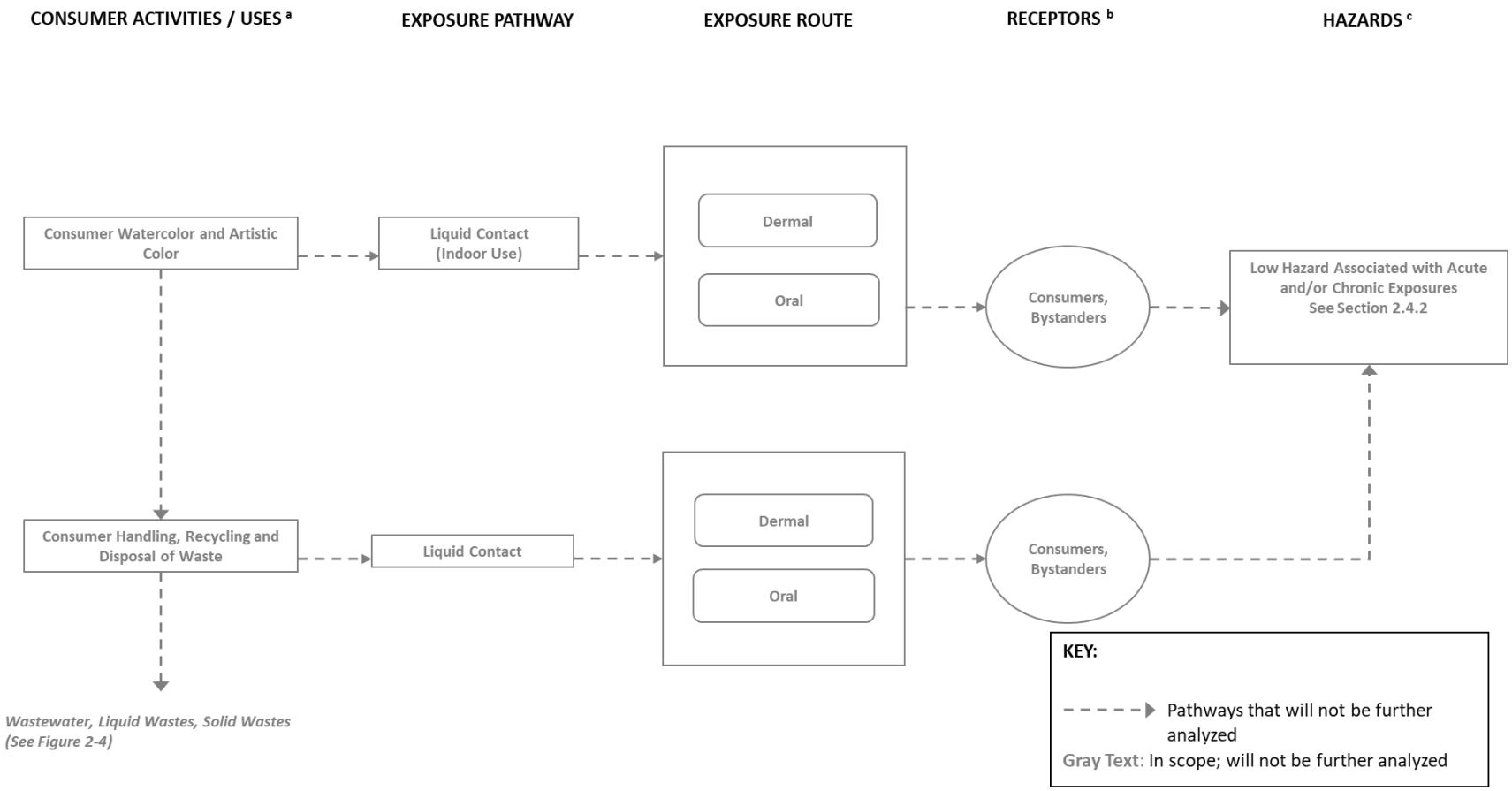

Figure 2-3. C.I. Pigment Violet 29 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors form consumer activities and uses of C.I. Pigment Violet 29.

[a] Some products are used in both commercial and consumer applications.
[b] Receptors include potentially exposed or susceptible populations.
[c] EPA will review full study reports to confirm preliminary low hazard conclusions.

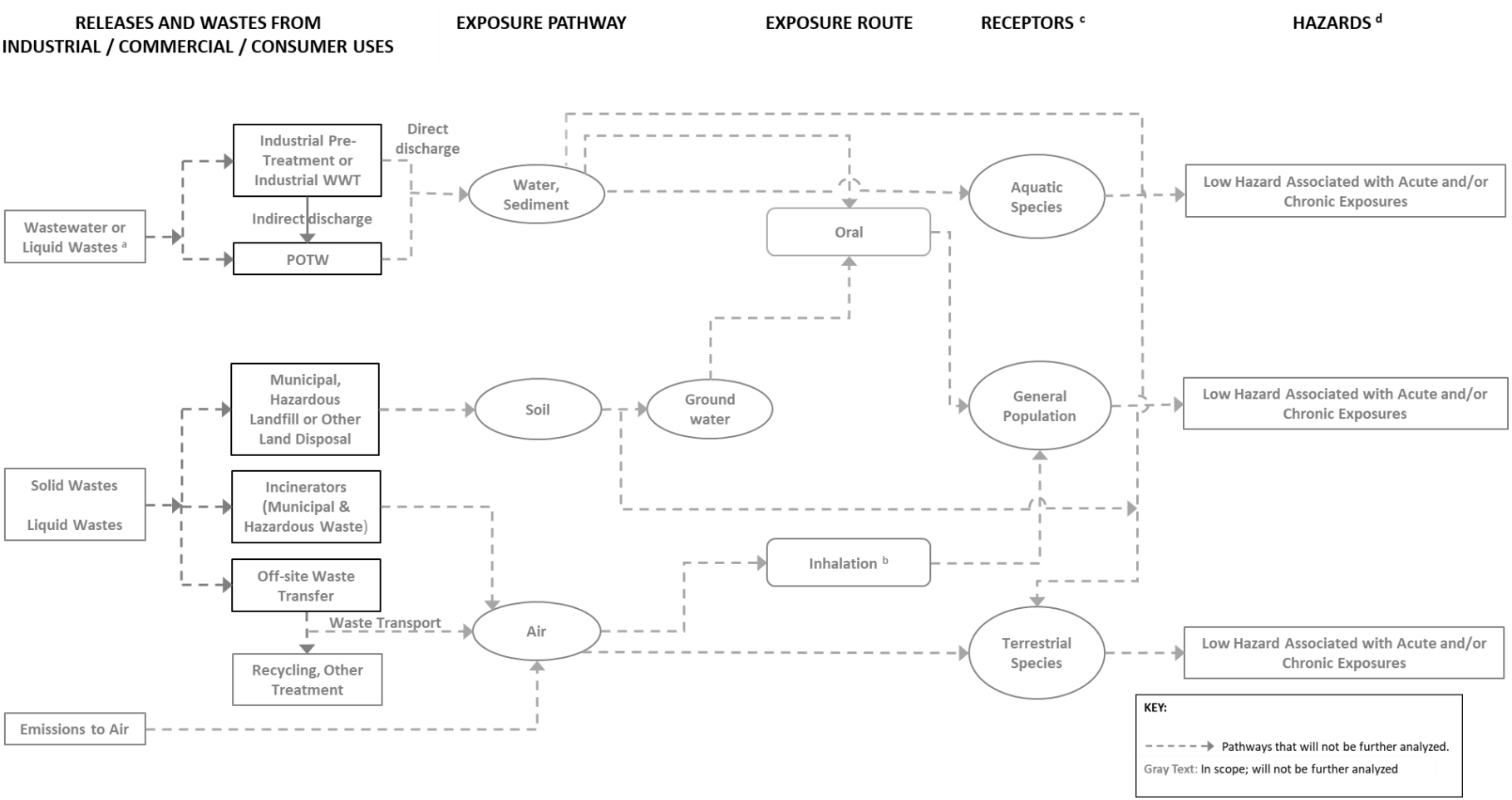

Figure 2-4. C.I. Pigment Violet 29 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

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

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

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

[c] Receptors include potentially exposed or susceptible populations.

[d] EPA will review full study reports to confirm preliminary low hazard conclusions.

2.6 Analysis Plan

As described in Section 2.5, due to physical-chemical and fate properties, limited use volumes outside the manufacturing site, limited environmental releases, and low absorption by all routes of exposure, it is concluded further analysis of exposure pathways to workers, consumers and the general population is not warranted. As noted, EPA has obtained full study reports for all physical and chemical properties, environmental fate, environmental hazard and human health hazard data from the ECHA Database (ECHA, 2017b) and the Food Additive Petition (FAP) 8B4626 (BASF, 1998a). The full study reports will be reviewed by EPA as it develops the Draft Risk Evaluation. The low environmental and human health hazards reported in these robust study summaries led the EPA to preliminarily conclude that C.I. Pigment Violet 29 presents a low hazard to human health and environmental receptors. The aquatic study summaries indicated that no effects were observed up to the solubility limit of C.I. Pigment Violet 29, while the acute and repeated-dose study summaries for human health reported no adverse effects. If, upon review of the full study reports, the results are not scientifically sound or consistent with the robust summary reports, EPA may conduct additional analysis to characterize the potential risks of this chemical, which could include changes to the pathways analyzed.

Based on all currently available information, including robust study summaries indicating low hazard, EPA preliminarily proposes no further analysis of environmental releases and exposure pathways. EPA will review any public comments and additional data/information prior to the publication of the Draft Risk Evaluation and incorporate these responses in the Draft Risk Evaluation. As per EPA's final rule, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, EPA will also take comment and peer review the Draft Risk Evaluation for C.I. Pigment Violet 29.

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APPENDICES

Appendix A. REGULATORY HISTORY

A-1 Background Information on the Inclusion of C.I. Pigment Violet 29 in TSCA 2012 and 2014 Work Plans

C.I. Pigment Violet 29 was added to the TSCA Work Plan in 2012. As described in detail in the Methodology (U.S. EPA, 2012c), all chemicals on the Work Plan were scored by 3 criteria: hazard, exposure and persistence and bioaccumulation. The criteria were scored from 1-3, where 3 is the highest concern and 1 is the lowest concern. See Table_Apx A-1 for scoring of C.I. Pigment Violet 29. The purpose of the Work Plan was not to evaluate risk, but used as a tool for screening chemicals.

Table_Apx A-1: 2014 TSCA Work Plan

Chemical Name	When was the chemical added?	Hazard Criteria Met	Hazard Score	Exposure Criteria Met	Exposure Score	Persistence & Bioaccumulation Criteria Met	Persistence & Bioaccumulation Score	Use	Risk Assessment Status and Other Actions	CASRN
Anthra[2,1,9-def:6,5,10-d'e'f'] diisoquinoline-1,3,8,10(2H,9H)-tetrone (Pigment Violet 29)	Added 2012	Aquatic toxicity	3*	Widely used in consumer products Estimated to have moderate releases to the environment	3	High environmental persistence Low bioaccumulation potential	2	Consumer Industrial	Not yet initiated	81-33-4

The hazard criteria used for the 2012 TSCA Work Plan Chemicals is described in the Methodology (U.S. EPA, 2012c). Chemicals were scored on the basis of readily available data, and no judgment was made concerning completeness or robustness of the available data set for a given chemical.

In 2012, C.I. Pigment Violet 29 was given the highest hazard score of 3 based on aquatic toxicity. The score was based on a predicted, modeled fish acute LC_{50} value of 4.6 mg/l reported in Ecological Categorization Results, Canadian Domestic Substances List (DSL) (Environment Canada, 2006).

Prior to the 2014 TSCA Work Plan update, Canada had updated their Ecological Categorization Results (OECD, 2017) indicating that C.I. Pigment Violet 29 is not categorized as inherently toxic to aquatic organisms. However, EPA's updates for the 2014 Work Plan were based only on newer data for exposure, i.e., 2016 TRI and 2016 CDR data. EPA did not update the hazard ratings for any chemicals for the 2014 Work Plan update; therefore, C.I. Pigment Violet 29 remained with a high hazard score.

C.I. Pigment Violet 29 is listed on the Canadian Inventory of the 23,000 substances on the Domestic Substances List (DSL) but the Ecological Risk Classification for C.I. Pigment Violet 29 did not meet the

criteria for categorisation as a prioritized substance for further assessment. The determination for C.I. Pigment Violet 29 and seven other similar pigments was made using a combination of QSAR modeling and hazard data for analogous pigments with low solubility (Pigment Red 149; CAS RNs 4948-15-6). The conclusion of this screening was consistent with EPA's findings and indicated that because of low toxicity and low solubility, C.I. Pigment Violet 29 did not meet the criteria for further assessment and the potential hazard is low (Environment Canada, 2006).

In 2012, C.I. Pigment Violet 29 was given the highest exposure score of 3 based on findings in consumer products and moderate release to the environment. Data weighed to determine the score were the production volume in CDR 2012's reporting year (520,916 pounds per year), number of use sites (1), the Industrial Function Category (pigments) and the reported commercial uses and use in consumer products. Expert judgment, generic scenarios, experience with new and existing chemical assessments and exposure scenarios were drawn on to derive the final exposure score of 3. Updated data from the 2016 CDR had no effect on the exposure score. The current Problem Formulation for C.I. Pigment Violet 29 uses more specific exposure data and should be regarded as more accurate compared to the scores created in the 2012 and 2014 Work Plan process.

A-2 Federal Laws and Regulations

Table_Apx A-4. 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.	C.I. Pigment Violet 29 is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA – Section 8(a)	The TSCA § 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	C.I. Pigment Violet 29 manufacturing (including importing), processing and use information is reported under the CDR Rule (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.	C.I. Pigment Violet 29 was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		(42 FR 64572, December 23, 1977).
Other Federal Regulations		
Food and Drug Administration (FDA)	Chemicals that come in contact with food must first be reviewed by the FDA for safety. In 1998 BASF submitted a petition for C.I. Pigment Violet 29 to be a food additive.	C.I. Pigment Violet 29 is approved to be in finished articles that come in contact with food. It should not to exceed 1% by weight of polymers and should follow specific conditions of use (21 CFR 178.3297). C.I. Pigment Violet 29 is not listed as an approved food additive.

A-3 International Laws and Regulations

Table_Apx A-5. International Laws and Regulations

Country/Organization	Requirements and Restrictions
Australia	C.I. Pigment Violet 29 is on the Australian Inventory for Chemical Substances (AICS), a database of chemicals available for industrial use in Australia. There are no regulatory obligations or conditions cited for C.I. Pigment Violet 29 [1]
Canada	C.I. Pigment Violet 29 is on the public portion of the Domestic Substances List (DSL). The DSL is an inventory of approximately 23,000 substances manufactured, imported or used in Canada on a commercial scale. Substances not appearing on the DSL are considered to be new to Canada and are subject to notification.[2]
China	C.I. Pigment Violet 29 is on the non-confidential Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). The inventory was last updated on January 31, 2013.[3] There are no restrictions associated with being on the Chinese inventory.

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

[2] 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.

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Country/Organization	Requirements and Restrictions
European Union	C.I. Pigment Violet 29 is on the European Inventory of Existing Commercial Chemical Substances (EINECS) List, which includes chemical substances deemed to be on the European Community market between January 1, 1971 and September 18, 1981.[4] Based on information provided in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier, C.I. Pigment Violet 29 is not classified as a hazard on the Classification and Labelling list.
Japan	In accordance with the provisions of Chemical Substances Control Law, C.I. Pigment Violet 29 is exempt from the new chemical notification requirement and listed as Low Molecular Heterocyclic Organic Compound on the existing chemical substances list.[5]
Korea	C.I. Pigment Violet 29 is on the Korea Existing Chemicals Inventory because it is a chemical that was domestically commercialized prior to February 2, 1991 and was designated and published by the Minister of Environment in consultation with the Minister of Labor.[6] There are no restrictions associated with being on the Korean inventory.
New Zealand	C.I. Pigment Violet 29 was added to the New Zealand Inventory (NZloC) on January 12, 2006 with the approval status that it may be used as a component in a product covered by a group standard, but it is not approved for use as a chemical in its own right. There are no restrictions or exclusions associated with C.I. Pigment Violet 29.[7]
Philippines	C.I. Pigment is on the Philippines Inventory of Chemicals and Chemical Substances (PICCS). PICCS was developed to provide government, industry and the public with a core inventory of all existing chemicals and chemical substances in the country and is updated annually.[8] There are no restrictions associated with being on the Philipino inventory.

[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.

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[6] Chemical Inspection & Regulation Service. Korea Existing Chemicals Inventory. December 20, 2016. Accessed October 11, 2017. http://www.cirs-reach.com/KoreaTCCA/Korea_Existing_Chemicals_Inventory_KECI.html.

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[8] Republic of the Philippines Chemical Management Section. Philippine Inventory of Chemicals and Chemical Substances. Accessed October 11, 2017. http://chemical.emb.gov.ph/?page_id=138.

Country/Organization	Requirements and Restrictions
Taiwan	C.I. Pigment Violet 29 in on the National Existing Chemical Inventory in Taiwan. There are no restrictions associated with being on the Taiwanese inventory.[9]
Vietnam	C.I. Pigment Violet 29 is on the draft (March 2017) Vietnam National Existing Chemical Inventory. There are no restrictions associated with being on the Vietnamese inventory.[10]

[9] Occupational Safety and Health Administration, Ministry of Labor. TCSI Search. Accessed October 11, 2017. https://csnn.osha.gov.tw/content/home/Substance_Result.aspx?enc=XpkoFr9qGvTvISX6V8jgsQ==.
[10] ChemSafetyPRO. Vietnam National Existing Chemical Inventory. October 28, 2016. Accessed October 11, 2017. http://www.chemsafetypro.com/Topics/Vietnam/Vietnam_National_Existing_Chemical_Inventory.html.

Appendix B. LIST OF ON-TOPIC REFERENCES EXCLUDED FROM FURTHER CONSIDERATION

The following references were listed in their pertinent sections in the C.I. Pigment Violet 29 Bibliography document.

Engineering/Occupational Exposure

The following *on-topic* references were excluded from further consideration during a second title/abstract screening:

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Kozma, E; Catellani, M. (2013). Perylene diimides based materials for organic solar cells. Dyes and Pigments. 98: 160-179. http://www.sciencedirect.com/science/article/pii/S014372081300034X.

Ling, MM; Erk, P; Gomez, M; Koenemann, M; Locklin, J; Bao, Z. (2007). Air-stable n-channel organic semiconductors based on perylene diimide derivatives without strong electron withdrawing groups. Adv Mater Deerfield. 19: 1123-1127. http://onlinelibrary.wiley.com/doi/10.1002/adma.200601705/abstract.

OPPT Risk Assessment, Problem Formulation or Scope Document

The following *on-topic* references were excluded from further consideration during a second title/abstract screening because they pertain to pigments other than C.I. Pigment Violet 29:

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Appendix C. PHYSICAL AND CHEMICAL PROPERTIES

Table_Apx C-1: Physical and Chemical Properties for C.I. Pigment Violet 29

Test substance	Endpoint	Results	Name of test material/Analytical purity	Test Guideline/comments	Source
C.I. Pigment Violet 29	Melting point	>400 °C	Paliogen Violet 5011 [a]/ >98-99%	OECD Guideline 102/No melting point found below 400 °C	(ECHA, 2017b)
C.I. Pigment Violet 29	Vapor Pressure	<0 hPa at 20 °C	Paliogen Violet 5011/ >98-99%	OECD Guideline 104	(ECHA, 2017b)
C.I. Pigment Violet 29	Water Solubility	0.01 mg/L at 20 °C	Paliogen Violet 5011/ >98-99%	OECD Guideline 105	(ECHA, 2017b)
C.I. Pigment Violet 29	Density	1.584 g/cm^3 at 20 °C	Paliogen Violet 5011/ >98-99%	OECD Guideline 109/ relative density	(ECHA, 2017b)
C.I. Pigment Violet 29	Octanol/water Partition Coefficient	<0.85 at 23 °C (measured) 3.76 (estimated)	Paliogen Violet 5011/ >98-99%	Calculated on the basis of the solubility in water and octanol determined experimentally	(ECHA, 2017b) (U.S. EPA, 2012b)
C.I. Pigment Violet 29	Solubility in n-octanol	<0.07 mg/L at at 20 °C	Paliogen Violet 5011/ >98-99%	Not stated	(ECHA, 2017b), (BASF, 1998a)

[a] BASF's trade name for C.I. Pigment Violet 29.

Appendix D. ENVIRONMENTAL FATE STUDY SUMMARIES

Table_Apx D-1: Environmental Fate Studies for C.I. Pigment Violet 29

Test substance	Study type	Endpoint	Description of test result/comments	Source
C.I. Pigment Violet 29	OECD 301F -Biodegradability: Manometric Respirometry Test)	% Biodegradation	0-10% (%BOD/ThOD) biodegradation after 28 days.	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review
C.I. Pigment Violet 29	OECD 305; Bioaccumulation; 8-weeks bioaccumulation study	Bioaccumulation factor (BCF and BAF)	No bioaccumulation from the 8-weeks bioaccumulation study. EPA EPI Suite estimate has similar result: low bioaccumulation (BCF=140; BAF=50)	Private data owner(s) EPA has received the full study report from the data owner(s) and this report is under review
C.I. Pigment Violet 29	OECD 209; Activated Sludge, Respiration inhibition test study	EC_{20} and EC_{50}	Has low toxicity to the activated sludge process in the receiving wastewater treatment plant (EC_{20} ca.1.8 mg/L, EC50 ca. 6.5 mg/L).	Private data owner(s) EPA has received the full study report from the data owner(s) and this report is under review

Appendix E. ENVIRONMENTAL HAZARD STUDY SUMMARIES

E-1 Toxicity to Aquatic Organisms

E-1-1 Aquatic Plant Toxicity

Table_Apx E-1: Aquatic Plant Toxicity Study for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Comments	Source
C.I. Pigment Violet 29	OECD-201; Aquatic vascular plant: 7 days, static renewal	Duckweed (*Lemna gibba*)	NES (based on growth [frond number and dry weight])	Nominal test concentrations: 0 (control), 1, 3.2, 10, 32, 100 mg/L based on loading Measured test concentration: 0.007 mg/L (highest) Test solution preparation: "The control and each test concentration was filtrated through a conditioned cellulose acetate membrane (Filter Sartorius, 0.20 µm pores). The concentrations 1.0 and 3.2 mg/L were prepared by dilution from the concentration 10.0 mg/L before the filtration. Before the dilution was made, the 10 mg/L concentration was checked carefully for homogeneous distribution of the test substance and for presence of precipitated test material. The test solution was clear and without precipitates. The test solution for the control was treated in the same way as the mixtures for the test concentrations: it was stirred for 72 hours, conditioned at 20 °C and was filtrated in the same way as the test concentrations to exclude any influences from the preparation of the test solutions. The preparation of the test solutions as described resulted in homogeneous solution, *i.e.*, Water	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review

Test substance	Study type	Species	Endpoint	Comments	Source
				Accommodated Fraction (WAF) which were used for exposure." (ECHA, 2017b) Analytical measurements: "In fresh solutions the measured concentrations of test item were between 0.06 – 0.07 mg/L. The measured values did not correlate with the loading, which demonstrates that the measured concentrations were at the solubility limit in the test medium under test conditions. In 48 and 72 hour old solutions the concentration of test item was between 0.067 – 0.071 mg/L." (ECHA, 2017b)	
Abbreviation: NES = no effects at saturation					

E-1-2 Aquatic Invertebrate Toxicity

Table_Apx E-2: Aquatic Invertebrate Toxicity Study for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Comments	Source
C.I. Pigment Violet 29	OECD-202; Acute freshwater invertebrate: 48 hours, static, limit	*Daphnia magna*	NES	Nominal test concentration: 0 (control), 100 mg/L Measured test concentration: - (control), 0.0065 mg/L Test solution preparation: "100.3 mg of test item was weighed into a glass flask and mixed with Elendt medium up to 1L. The stock solution was mixed thoroughly in an incubator at a temperature of 40 °C for 3 days with stirring resulting in a homogeneous, intensive grey mixture with a concentration of 100 mg/L. The stock solution was conditioned at a temperature of 20°C with continuous stirring. Next the control and the test concentration were filtered over a 0.20 µm membrane disc. After the filtration a clear and transparent solution was observed in the concentration of 100.0 mg/L. The filter was previously saturated with the test mixture." (ECHA, 2017b)	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review
Abbreviation: NES = no effects at saturation					

E-1-3 Fish Toxicity

Table_Apx E-3: Fish Toxicity Study for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Comments	Source
C.I. Pigment Violet 29	OECD-203; Acute freshwater fish: 96 hours, static	Zebrafish (*Brachydanio rerio*)	NES	Purity: >95% Nominal test concentrations: 0 (control), 5000 mg/L Test solution preparation: "The test substance was mixed with the test medium and homogenized using an ultra turrax. Evidence of undissolved material (e.g. precipitate, surface film, etc): floating particles of test substance were visible." (ECHA, 2017b)	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review
Abbreviation: NES = no effects at saturation					

Appendix F. HUMAN HEALTH HAZARD STUDY SUMMARIES

F-1 Acute Toxicity Studies

Table_Apx F-1: Acute Toxicity Studies for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Description of effects/comments	Source
C.I. Pigment Violet 29	OECD-401; Acute oral, single dose by gavage, limit	Sprague-Dawley rat	LD_{50} > 10,000 mg/kg-bw	No mortality or macroscopic abnormalities at necropsy; systemic dark red coloring of the skin and dark red coloring of the feces	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review
C.I. Pigment Violet 29	OECD 403-Acute Inhalation Toxicity	Wistar Rat	LC_{50}> 5.2 mg/L air	No mortality observed. Sublethal effects were irregular, accelerated and/or intermittent respiration, flight behaviour and discoloured fur. From day 7 of the observation period onward, no abnormalities, except discoloured fur, were detected in the animal	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review
C.I. Pigment Violet 29	OECD 402-Acute Dermal Toxicity	Sprague-Dawley Rat	LD_{50} > 2,500 mg/kg-bw	No mortality, no abnormal findings, red-brown staining at the application site observed.	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review

F-2 Repeated-Dose Toxicity Studies

There were no repeated-dose toxicity studies found for C.I. Pigment Violet 29.

F-3 Reproductive and Developmental Toxicity Studies

Table_Apx F-2: Reproductive and Developmental Study for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Description of effects/comments	Source
C.I. Pigment Violet 29	OECD-421; Reproductive/ developmental screening via gavage (exposure: premating period of 2 weeks and a mating period [max. of 2 weeks] in both sexes, approximately 1 week post-mating in males, and the entire gestation period as well as 4 days of lactation in females)	Wistar rat	NOAEL = 1000 mg/kg-bw/day (highest dose tested)	No test substance-related, adverse findings were noted; black discolored feces from study day 1 until the end of the study in all male and female animals at 300 mg/kg-bw/day and 1000 mg/kg-bw/day; macroscopically black discoloration of the content of the digestive tract in numerous animals	(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review

F-4 Skin Irritation and Sensitization Studies

Table_Apx F-3: Skin Irritation and Sensitization Studies for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Description of effects/comments	Source
C.I. Pigment Violet 29	OECD- 404; Skin irritation: occlusive	Weiber Wiener rabbit	Not irritating		(ECHA, 2017b) EPA has received the full study reports from the data owner(s) and these reports are under review
C.I. Pigment Violet 29	OECD-405; Eye irritation	Rabbit	Not irritating		
C.I. Pigment Violet 29	OECD- 404; Skin irritation: occlusive	Weiber Wiener rabbit	Not irritating		
C.I. Pigment Violet 29	OECD-405; Eye irritation	Weiber Wiener rabbit	Not irritating		
C.I. Pigment Violet 29	OECD-429; Skin sensitization: mouse local lymphocyte assay	Male CBA/Ca mouse	Negative		

F-5 Genotoxicity and Cancer Studies

Table_Apx F-4: Genotoxicity Studies for C.I. Pigment Violet 29

Test substance	Study type	Species	Endpoint	Description of effects/comments	Source
C.I. Pigment Violet 29	OECD-471; Genotoxicity – gene mutation (*in vitro*)	*Salmonella typhimurium* TA 100, TA 1535, TA 1537, TA 1538, TA 98 and *E. coli* WP2uvrA	Negative		(ECHA, 2017b), (BASF, 1998a) EPA has received the full study report from the data owner(s) and this report is under review
C.I. Pigment Violet 29	OECD-476; Genotoxicity – gene mutation (*in vitro*)	Chinese hamster lung fibroblasts (V79) Target gene: HPRT	Negative		(ECHA, 2017b) EPA has received the full study report from the data owner(s) and this report is under review

APPENDIX G. INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

As indicated in Section 1.2, the *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* did not identify *on-topic* literature search results for C.I. Pigment Violet 29 (U.S. EPA, 2017a). The exceptions are those relevant studies on C.I. Pigment Violet 29 that were identified in the ECHA Database and the two studies from Food Additive Petition (FAP) 8B4626 (BASF, 1998a). The *Pigment Violet 29 (CASRN: 81-33-4) Bibliography: Supplemental File for the TSCA Scope Document* also identified twenty other references previously cited in OPPT's documents. Based on a comment received [(EPA-HQ-2016-0725-0039) (CPMA, 2017b)], EPA conducted a second title/abstract screening and determined that some of these references were not relevant to C.I. Pigment Violet 29. As such, with the exception of the ECHA and FAP studies, these references were excluded from further consideration for C.I. Pigment Violet 29.

As no new *on topic references* were identified during problem formulation, EPA did not develop additional inclusion/exclusion criteria for C.I. Pigment Violet 29 to guide full text screening activities. EPA/OPPT's initial methods, approaches and procedures for identifying, compiling, and screening publicly available information supporting the TSCA risk evaluation for C.I. Pigment Violet 29 can be found in the *Strategy for Conducting Literature Searches for Pigment Violet 29 (PV29): Supplemental Document to the TSCA Scope Document*. If new information is received by the Agency after the publication of the TSCA Problem Formulation, EPA plans to use the initial eligibility criteria already published in the *Strategy for Conducting Literature Searches for Pigment Violet 29 (PV29): Supplemental Document to the TSCA Scope Document* to conduct the title and abstract screening. If necessary, EPA will make refinements to the inclusion and exclusion criteria and include them in the Risk Evaluation.