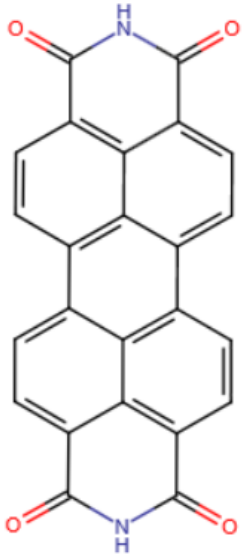
Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone)

CASRN: 81-33-4



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Docket

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

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
atm	atmosphere(s)
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
C.I.	Colour Index
cm^3	Cubic centimeters
CPMA	Color Pigments Manufacturing Association
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
g	Grams
g/mole	Grams per Unit-Molar Mass
hPa	Hectopascal
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
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
SACC	Science Advisory Committee on Chemicals
SAR	Structure-activity relationship
SDS	Safety Data Sheet
TSCA	Toxic Substances Control Act
U.S.	United States
µm	Micrometer

1 EXECUTIVE SUMMARY

This document presents the draft 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. All conclusions, findings, and determinations in this document are draft and subject to comment.

The EPA considered all reasonably available data for C.I. Pigment Violet 29 to make a determination of whether risk posed by a chemical substance is unreasonable. The EPA concludes that C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment, without considering costs or other non-risk factors, including no unreasonable risk to potentially exposed and susceptible subpopulations identified as relevant, under the conditions of use.

As part of this risk evaluation for C.I. Pigment Violet 29, the EPA conducted a qualitative assessment of potential environmental, consumer and general population exposures. This assessment is based on a consideration of the physical-chemical properties of C.I. Pigment Violet 29, which includes low solubility, low vapor pressure, low bioaccumulation potential, and poor absorption across all routes of exposure; as well as manufacturing information, which indicates that environmental releases from the conditions of use are limited. The EPA also conducted a quantitative screening-level assessment of occupational exposure using a high-end estimate of inhalation and dermal exposure. Qualitative and quantitative considerations of physical chemical data, environmental fate data, manufacturing, and use information indicates that exposures of C.I. Pigment Violet 29 are expected to be limited for the conditions of use of C.I. Pigment Violet 29.

Reasonably available data indicates that no effects were observed in environmental hazard testing with aquatic species up to the limit of solubility of the chemical and low hazard was reported for all routes of exposure in human health testing. The human health testing reported that no adverse effects were observed for all routes of exposure (oral, dermal, inhalation) and that C.I. Pigment Violet 29 is negative for genotoxicity. Structural activity relationships (SAR) considerations support the EPA's conclusion that C.I. Pigment Violet 29 is unlikely to be a carcinogen. Environmental hazard data available for fish, aquatic invertebrates and aquatic plants reported that no effects were observed up to the limit of solubility of the chemical. Based on the human health and environmental toxicity testing, the EPA concludes that C.I. Pigment Violet 29 presents a low hazard to human health and the environment.

The EPA uses reasonably available information, in a fit for purpose approach, to develop risk evaluations that rely on the best available science. The EPA obtained full study reports associated with the European Chemicals Agency (ECHA) robust summaries (some of which are also presented in summary format in an FDA Food Additive Petition (FAP) 8B4626 (BASF, 2013) and used them to make a preliminary determination of hazard during problem formulation (U.S. EPA, 2018b). There are supporting materials (24 individual scientific studies) that contain information protected as Confidential Business Information (CBI). Twenty of these studies have been submitted to and summarized by the European Chemicals Agency (ECHA) as part of their information on registered substances and these ECHA robust summaries are publicly available.[1] The EPA has reviewed these full study reports and confirmed that the results are consistent with the physical and chemical characteristics, environmental fate characteristics, and the determination of low environmental and human health hazards as presented in the ECHA robust summaries (presented in Appendices B-D). The EPA reviewed these full study

[1] https://echa.europa.eu/information-on-chemicals/registered-substances provides general information. Links to individual study summaries are provided in the attached table.

reports and assessed the quality of the methods and reporting of results of the individual studies using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and concluded that they are of high or medium quality. In addition, the EPA determined that the information presented in these full study reports is consistent with the robust summaries in the publicly available ECHA Database (ECHA, 2017).

In summary, based on reviewing the reasonably available information indicating a low hazard to human health and environmental receptors, low solubility, low vapor pressure, low bioaccumulation potential, low absorption, limited environmental releases and low potential for resulting exposures, the EPA concludes that C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment under the conditions of use. As per the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726), the EPA is taking comment on, and will also obtain peer review on, the draft risk evaluation for C.I. Pigment Violet 29.

2 INTRODUCTION

This document presents the draft 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, in June 2016.

The Agency published the Scope of the Risk Evaluation for C.I. Pigment Violet 29 (U.S. EPA, 2017b) in June 2017, and the problem formulation on June 1, 2018 (U.S. EPA, 2018b), which represented the analytical phase of risk evaluation in which "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" as described in Section 2.2 of the *Framework for Human Health Risk Assessment to Inform Decision Making*. The problem formulation presented three conceptual models and an analysis plan. The preliminary conclusions of the problem formulation were that no further analysis of any exposure pathway, i.e., to workers, consumers and the general population, was necessary. This was based on the EPA's analysis of the physical-chemical and fate properties, limited use volumes outside the manufacturing site, limited environmental releases, and low absorption by all routes of exposure.

The EPA indicated in the analysis plan of the problem formulation that it would review the 24 individual scientific study reports obtained from the data owners. These study reports characterized the physical and chemical properties, environmental fate properties, environmental hazard and human health hazards of C.I. Pigment Violet 29. These study reports contain information protected under statute as Confidential Business Information (CBI) by the Toxic Substances Control Act (TSCA). Twenty of these studies have been submitted to and summarized by the European Chemicals Agency (ECHA) as part of their information on registered substances and these ECHA robust summaries are publicly available. In certain cases, the same information is also presented in summary format in the Food Additive Petition (FAP) 8B4626 (ECHA, 2017) (BASF, 2013). The EPA indicated that if, upon review of the full study reports, the results were not scientifically sound or consistent with the robust summary reports, the EPA may conduct additional analysis to characterize the potential risks associated with this chemical, which could include changes to the exposure pathways analyzed. Following review of these studies, the EPA concluded that the results of these full study reports are consistent with the results presented in the ECHA robust summaries and the Food Additive Petition (FAP) 8B4626.

In this draft risk evaluation, the EPA presents the risk determination for C.I. Pigment Violet 29 based on the reasonably available information. The document is structured such that Section 2 presents the basic

physical-chemical characteristics of the chemical, as well as a background on uses, regulatory history, conditions of use, conceptual models, with particular emphasis on any changes since the publication of the problem formulation. This section also includes a discussion of the systematic review process utilized in this risk evaluation. Section 3 provides a discussion and analysis of the exposures, both human and environmental that can be expected based on the conditions of use for C.I. Pigment Violet 29. Section 4 discusses environmental and human health hazards of C.I. Pigment Violet 29 based on the full study reports received from the data owners. Risk characterization is presented in Section 5, which integrates and assesses reasonably available information on human health and environmental hazards and exposures, as required by TSCA 15 U.S.C 2605(b)(4)(F). This section also includes a discussion of any uncertainties and how they impact the risk evaluation. In Section 6, the agency presents the final determination of whether risk posed by a chemical substance is ''unreasonable'' as required under TSCA 15 U.S.C. 2605(b)(4). The EPA received comments on the published problem formulation for C.I. Pigment Violet 29. This document has considered the comments specific to C.I. Pigment Violet 29 as well as more general comments regarding the EPA's chemical risk evaluation approach for developing the draft risk evaluations for the first 10 chemicals the EPA is evaluating.

As per the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726), this draft risk evaluation will be subject to both public comment and peer review, which are distinct but related processes. The EPA is providing 60 days for public comment on this draft risk evaluation prior to the beginning of the meeting to inform the EPA Science Advisory Committee on Chemicals (SACC) peer review process. The purpose of this is to seek public comment on any and all aspects of this draft risk evaluation, including any conclusions, findings, and determinations, and the submission of any additional information that might be relevant to the science underlying the risk evaluation and the outcome of the systematic review associated with C.I. Pigment Violet 29. This satisfies TSCA section 6(b)(4)(H) which requires the EPA to provide public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

Peer review will be conducted in accordance with the EPA's regulatory procedures for chemical risk evaluations, including using the *EPA Peer Review Handbook* and other methods consistent with section 26 of TSCA (*See* 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Peer-review ensures scientific rigor and enhances transparency to the risk evaluation process.

As the EPA explained in the Risk Evaluation Rule (82 Fed. Reg. 33726; July 20, 2017), it is important for peer reviewers to consider how the underlying risk evaluation analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. The EPA believes peer reviewers will be most effective in this role if they receive the benefit of public comments on draft risk evaluations prior to peer review. For this reason, EPA is providing the opportunity for public comment before peer review on this draft risk evaluation. The final risk evaluation may change in response to public comments received on the draft risk evaluation and/or in response to peer review, which itself may be informed by public comments. The EPA will respond to public and peer review comments received on the draft risk evaluation and will explain changes made to the draft risk evaluation for C.I. Pigment Violet 29 in response to those comments in the final risk evaluation.

The EPA has asked for input at several stages of the process: on the use dossiers, the scopes, and the problem formulations. The EPA has received information and comments at each step specific to

individual risk evaluations, and information and comments of a more general nature relating to various aspects of the risk evaluation process, technical issues, and the regulatory and statutory requirements. The EPA has considered comments and information received at each step in the process and factored in the information and comments as the Agency deemed appropriate and relevant including comments on the published problem formulation of C.I. Pigment Violet 29. Thus, in addition to any new comments on the draft risk evaluation, the public should re-submit or clearly identify at this point any previously filed comments, modified as appropriate, that are relevant to this risk evaluation and that the submitter feels have not been responded to. The EPA does not intend to further respond to comments submitted prior to the publication of this draft risk evaluation unless they are clearly identified in comments on this draft risk evaluation.

2.1 Physical and Chemical Properties

C.I. Pigment Violet 29 is a Colour Index (C.I.) name used in sales of products containing anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone, CASRN 81-33-4. The name "C.I. Pigment Violet 29" is assigned, copyrighted and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists (EPA-HQ-OPPT-2016-0725-0039).

The EPA has received a full study report which contains two studies that characterize the physical and chemical properties of C.I. Pigment Violet 29 (BASF, 2013).

- OECD Guideline 102: Melting point
- OECD Guideline 105: Partition coefficient n-Octanol/Water (Pow)

As indicated in previous sections, a claim of business confidentiality by the data owners means that the EPA will not reproduce these full study reports in this risk evaluation. However, the EPA has confirmed that the results of these full study reports are consistent with the corresponding robust summaries available in ECHA, the results of which are presented in abbreviated format in Table 2-1. The EPA has reviewed these according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The results of this data quality evaluation can be found in the *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document*. As a result of this data quality evaluation, the EPA has verified the accuracy of the melting point data presented in the ECHA database and in the C.I. Pigment Violet 29 problem formulation.

The partition coefficient (Log K_{ow}) could not be determined from the study submitted to the EPA due to unacceptable methods which did not take into account the poor solubility in octanol and in water of C.I. Pigment Violet 29. The poor solubility in octanol and water means that the partitioning between the media cannot be determined. The solubility of C.I. Pigment Violet 29 was done in 8 percent ethanol and is reported as 0.0046 mg/L and 0.015 mg/L in 95 percent ethanol (BASF, 2013). The solubility of C.I. Pigment Violet 29 in octanol is reported in ECHA as <0.07 mg/L (ECHA, 2017). The EPA has utilized the data as presented in the ECHA database, which are summarized in Table 2-1. The water solubility of C.I. Pigment Violet 29 is 0.01 mg/L, as reported in the ECHA Database (ECHA, 2017), indicating that C.I. Pigment Violet 29 has low water solubility. As a result of these unacceptable methods, the measured Log K_{ow} was not used in this assessment and the EPI-estimated value of 3.76 for octanol/water partition coefficient was utilized, as described in the Table 2-1 below (U.S. EPA, 2018b).

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, 2017)
Molecular Weight	390.35 g/mol	(U.S. EPA, 2012b)
Physical Form	Solid	(ECHA, 2017)
Melting Point	No melting point found <400˚C	(ECHA, 2017) (BASF, 2013)
Density	1.584 g/cm^3 at 20 ˚C	(ECHA, 2017)
Vapor Pressure	<0 hPa at 20˚C	(ECHA, 2017)
Solubility in n-octanol	<0.07 mg/L	(ECHA, 2017)
Water Solubility	0.01 mg/L at 20˚C	(ECHA, 2017)
Log K_{OW}[1]	3.76 (estimated)	(U.S. EPA, 2012b)
Henry's Law Constant	1.84E-021 atm-m^3/mol (estimated)	(U.S. EPA, 2012b)

[1] The measured partition coefficient could not be determined due to poor solubility in octanol and water so the methods utilized in Log K_{OW} tests were unacceptable for characterizing this value; thus, the estimated Log K_{OW} of 3.76 is applicable for this evaluation.

2.2 Uses and Production Volume

Sun Chemical Corporation (Goose Creek, SC) is the only U.S. manufacturer of C.I. Pigment Violet 29 that reported to the Chemical Data Reporting (CDR) database in 2012 and 2016 (U.S. EPA, 2012a; U.S. EPA (2016)). Approximately 90 percent of the domestic production volume of C.I. Pigment Violet 29 in 2015(~530,000 lbs) was processed as a site-limited intermediate for the manufacture of other perylene pigments, while 10 percent of the production volume (~60,000 lbs) was processed and used in either commercial paints and coatings (~30,000 lbs) or commercial plastic and rubber products (~30,000 lbs). An unknown volume of C.I. Pigment Violet 29 is used in consumer watercolor and acrylic paints. This use of C.I. Pigment Violet 29 in artistic paint products, while unknown, is reported to comprise less than 1 percent of total sales (EPA-HQ-OPPT-2016-0725-0039). For C.I. Pigment Violet 29, CDR reporting is required for imports above 25,000 pounds per year per company per manufacturing site. C.I. Pigment Violet 29 has not been reported to be imported in the CDR 2012 and 2016 database, nor has evidence of current importation of C.I. Pigment Violet 29 been identified (U.S. EPA, 2012a; U.S. EPA (2016)). Due to no reported importation volumes in CDR, imported volumes of C.I. Pigment Violet 29 are expected to be lower than the reported production volume. Furthermore, according to a search of data from the U.S. Customs and Border Patrol Automated Manifest System (AMS), imports of C.I. Pigment Violet 29 have not been reported since 2011. As there are no data indicating current importation, import of C.I. Pigment Violet 29 is not included as a condition of use. In addition, even if it were imported, any potentially imported volumes of C.I. Pigment Violet 29 would be expected to be utilized for the same conditions of use as the domestically manufactured volumes.

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

The following are the four primary industrial and commercial uses and one consumer use identified for C.I. Pigment Violet 29:

- An intermediate to create or adjust color of other perylene pigments (~90 percent)
- Incorporation into paints and coatings used primarily in the automobile industry (~5 percent)
- Incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting (~5 percent)
- Merchant ink for commercial printing (<1 percent)
- Consumer watercolors and artistic color (<1 percent)

2.3 Regulatory and Assessment History

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

Federal Laws and Regulations

C.I. Pigment Violet 29 is regulated under several TSCA sections. Under TSCA Section 6(b) C.I. Pigment Violet 29 is on the initial list of chemicals to be evaluated for unreasonable risk (81 FR 91927, December 19, 2016). Under TSCA Section 8(a), manufacturing (including importing), processing and use information is reported under the CDR Rule (76 FR 50816, August 16, 2011). Under TSCA 8(b), C.I. Pigment Violet 29 is on the initial TSCA Inventory and therefore was not subject to the EPA's new chemicals review process under TSCA Section 5.

C.I. Pigment Violet 29 is subject to one additional federal statute or regulation, other than TSCA, that is implemented by the U.S. Food and Drug Administration (FDA). Chemicals that come in contact with food must first be reviewed by the FDA for safety. In 1998, BASF (Ludwigshafen, Germany) submitted a petition for C.I. Pigment Violet 29 to be a colorant in food-contact polymers. C.I. Pigment Violet 29 is approved by the FDA to be in finished articles that come in contact with food. It should not exceed 1 percent by weight of polymers and should follow specific conditions of use as described in the FDA regulations (21 CFR 178.3297). C.I. Pigment Violet 29 is not listed as an approved food additive.

The Safety Data Sheet (SDS) for C.I. Pigment Violet 29 lists recommended engineering controls to minimize workplace exposure to C.I. Pigment Violet 29. Engineering controls for C.I. Pigment Violet 29, as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017).

State Laws and Regulations

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

Laws and Regulations in Other Countries and International Treaties or Agreements

Multiple countries have C.I. Pigment Violet 29 on their chemical inventory list. (See Appendix A-3). C.I. Pigment Violet 29 is one of 23,000 chemicals on the Canadian Inventory's Domestic Substances List (DSL). However, the Canadian Ecological Risk Classification for C.I. Pigment Violet 29 did not meet the criteria for categorization as a prioritized substance for further evaluation. This determination 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 Canada's screening indicated that because of low toxicity and low solubility, C.I. Pigment Violet 29's hazard potential is low (Environment Canada, 2006).

2.4 Scope of the Evaluation

2.4.1 Conditions of Use Included in the Risk Evaluation

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." The conditions of use are described below in Table 2-2. There have been two modifications since the problem formulation (U.S. EPA, 2018b): the categories "other uses" and "import" have been removed due to the agency's inability to prove that they are actually conditions of use.[2] Besides these two modifications, no additional information was received by the EPA following the publication of the problem formulation that would update or otherwise require changes to the use document (EPA-HQ-OPPT-2016-0725-0004), conditions of use (Table 2-2) or the life cycle diagram as presented in the problem formulation (U.S. EPA, 2018b). The updated life cycle diagram is presented below in Figure 2-1.

[2] A list of "other uses" was compiled during EPA's initial searches. However, no further evidence was found during the problem formulation and risk evaluation to support the actual use of C.I. Pigment Violet 29 for these uses. This list of other uses included the following: Applications in odor agents, cleaning/washing agents, surface treatment, absorbents and adsorbents, laboratory chemicals, light-harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices, paper, architectural uses, polyester fibers, adhesion, motors, generators, vehicle components, sporting goods, appliances, agricultural equipment and oil and gas pipelines (EPA-HQ-OPPT-2016-0725-0004). As a result, these uses are not included in Table 2-2 and Figure 2-2.

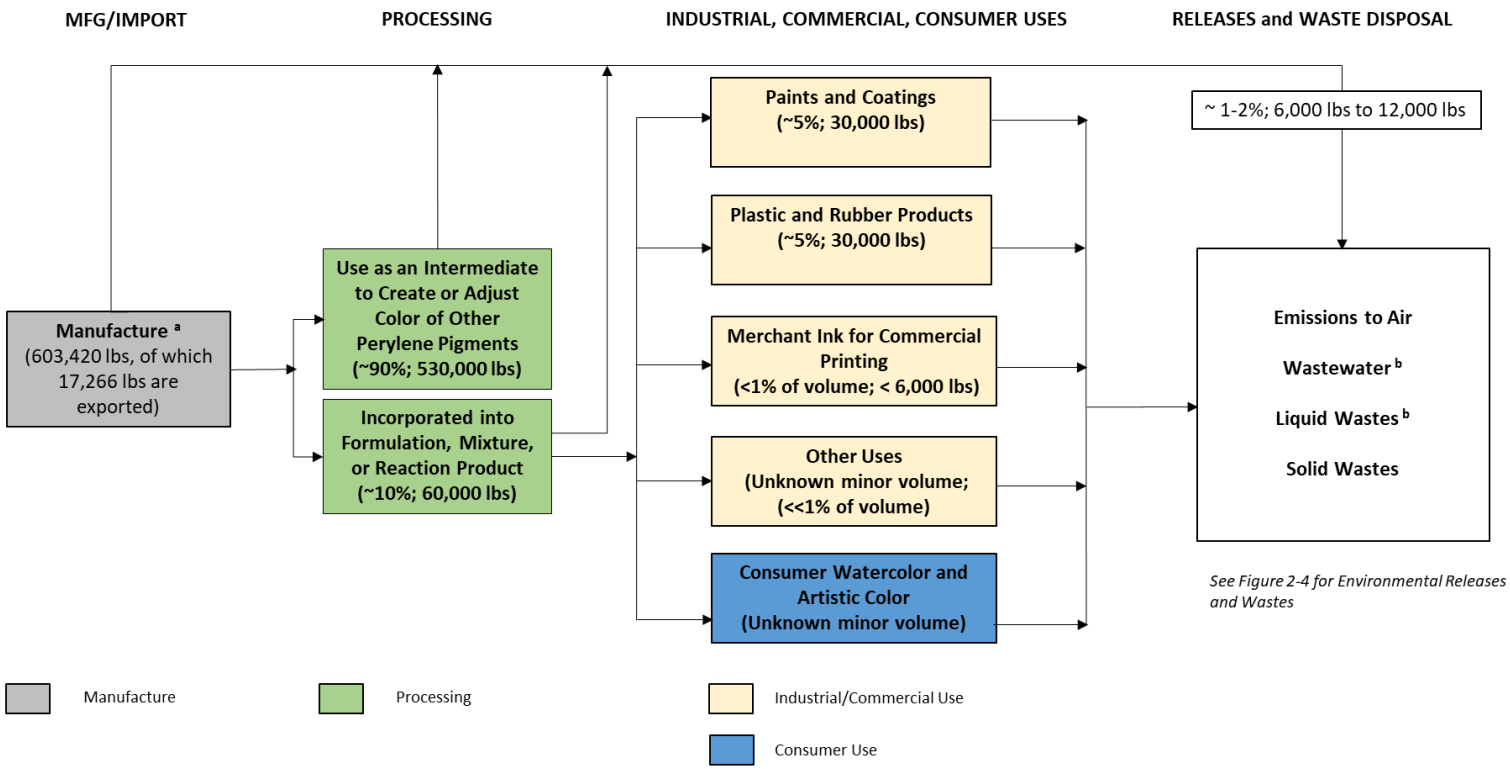

Figure 2-1. C.I. Pigment Violet 29 Life Cycle Diagram

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

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

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 (2016)
Processing	Processing - Incorporating into formulation, mixture, or reaction product	Paints and Coatings	U.S. EPA (2016); Public Comment, EPA-HQ-OPPT-2016-0725-0006
		Plastic and Rubber Products	U.S. EPA (2016); Public Comment, EPA-HQ-OPPT-2016-0725-0006
	Processing - Use as an Intermediate	Creation or adjustment to other perylene pigments	U.S. EPA (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; Public Comment, EPA-HQ-OPPT-2016-0725-0006
	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	

Life Cycle Stage	Category [a]	Subcategory [b]	References
	Wastewater	Industrial pre-treatment	Mott, 2017b; This reference applied only to manufacturing, no other sources specific to C.I. Pigment Violet 29 found.
		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 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.

2.4.2 Conceptual Models

The conceptual models for this risk evaluation are shown below in Figure 2-2, Figure 2-3, and Figure 2-4. The EPA considered the potential for hazards to human health and the environment resulting from exposure pathways outlined in the preliminary conceptual models of the C.I. Pigment Violet 29 scope document (U.S. EPA, 2017b). These conceptual models considered potential exposures resulting from consumer activities and uses, industrial and commercial activities, and environmental releases and wastes. The problem formulation documents refined the initial conceptual models and analysis plans that were provided in the scope documents (U.S. EPA, 2018b). Based on review and evaluation of reasonably available data for C.I. Pigment Violet 29, which indicated low hazard and limited exposures, the EPA determined in the problem formulation that no further analysis of any of the pathways outlined in the conceptual models was necessary due to low hazards and limited exposure for human health and the environment.

The EPA made two modifications to the conceptual models since the problem formulation. The first was the removal of the term "other uses" and "import" as no further evidence was found to support the actual use of C.I. Pigment Violet 29 in this category. The second change involved carrying out a quantitative screening-level analysis of risks to the population with the highest potential exposure. This was carried out by developing a screening-level analysis of sentinel exposure (dermal and inhalation) to workers (the population with the theoretical highest anticipated exposure) as described in Section 5.2.

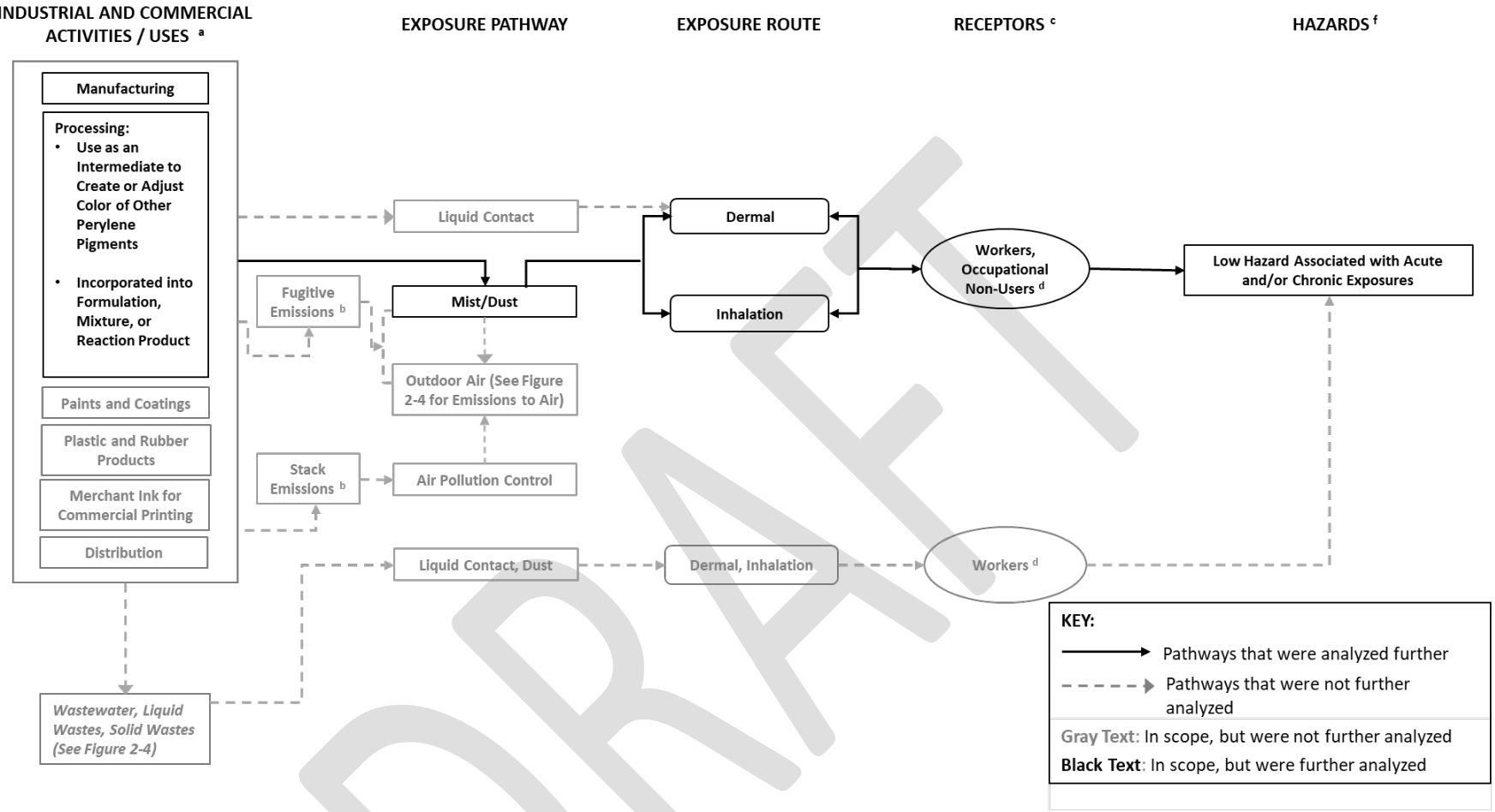

Figure 2-2. C.I. Pigment Violet 29 Final Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards. The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of C.I. Pigment Violet 29.

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

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

[c] Receptors include potentially exposed and susceptible subpopulations.

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

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

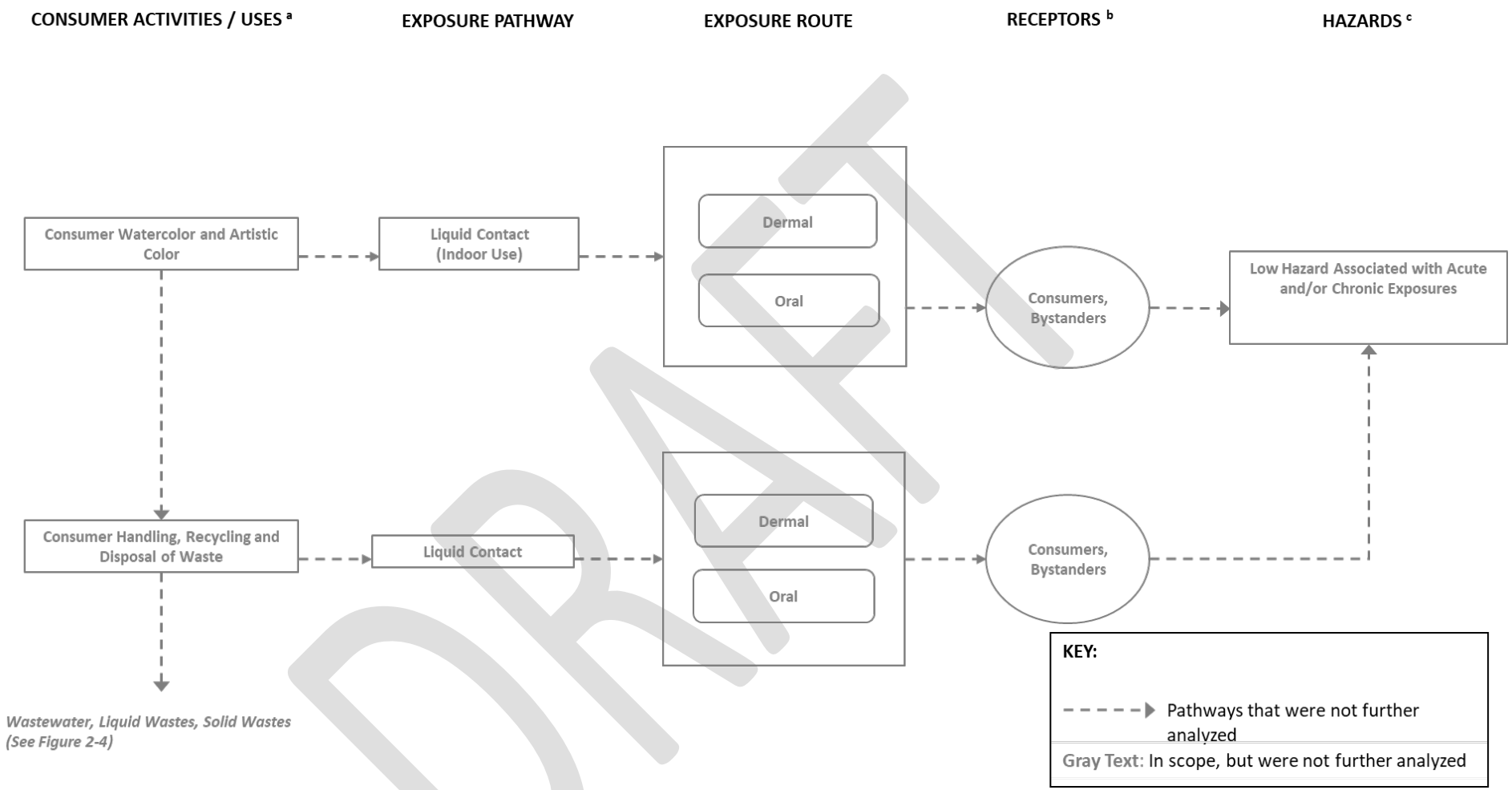

Figure 2-3. C.I. Pigment Violet 29 Final Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of C.I. Pigment Violet 29.

[a] Some products are used in both commercial and consumer applications.
[b] Receptors include potentially exposed or susceptible subpopulations.
[c] The EPA has reviewed the full study reports to confirm low hazard conclusions.

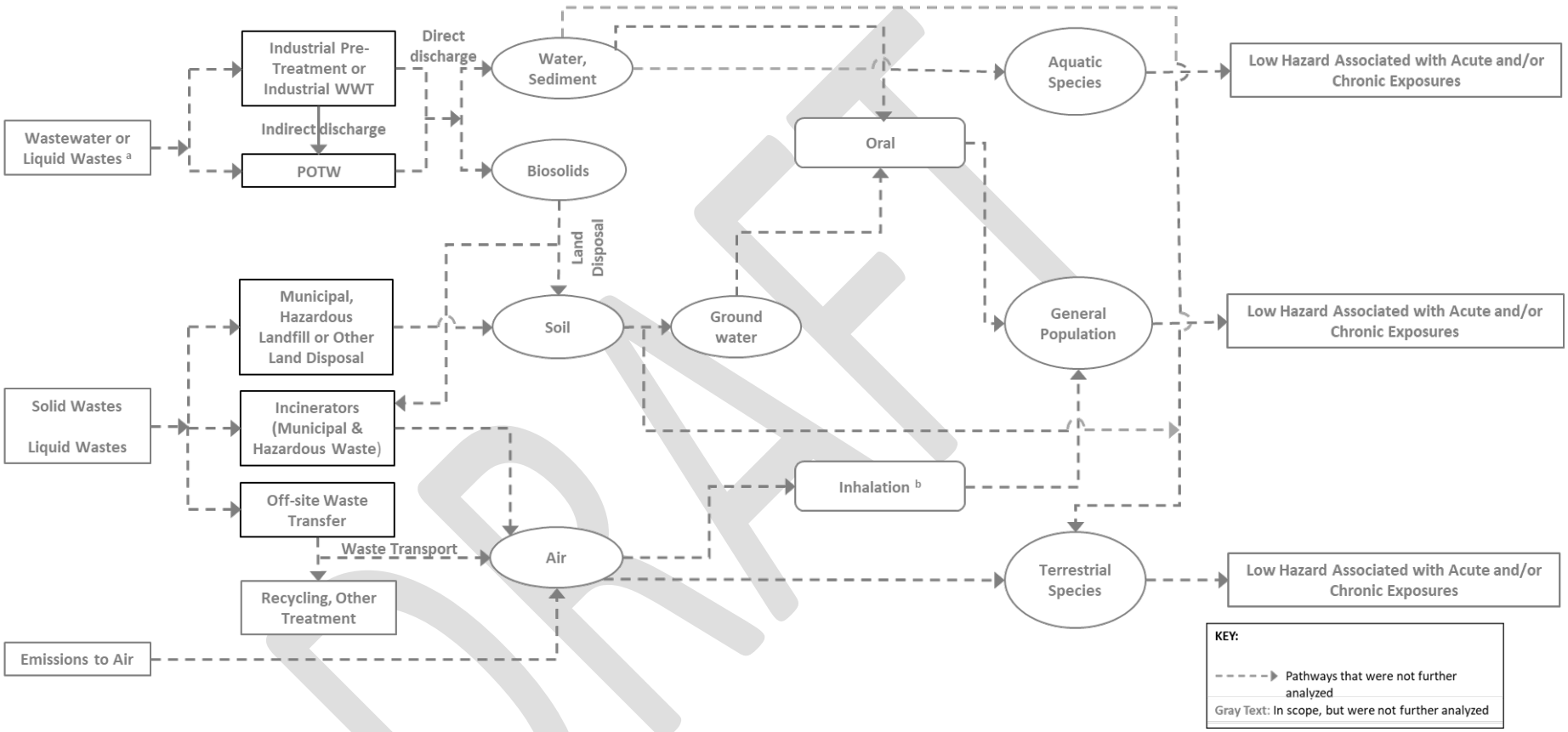

Figure 2-4. C.I. Pigment Violet 29 Final Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

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

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

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

2.5 Systematic Review

TSCA requires the EPA to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and base decisions under section 6 on the weight of scientific evidence. Within the TSCA risk evaluation context, the weight of the scientific evidence is defined as "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance". (40 C.F.R. 702.33). The EPA indicated in the analysis plan that it would review the full study reports obtained for all physical and chemical properties, environmental fate properties, environmental hazard and human health hazard data. The results of these studies were compared with the corresponding robust summaries, which presented in the ECHA Database (with the exception of four full studies; discussed below in Section 3.1 and Section 4.2), while some are also available in summary form in the Food Additive Petition (FAP) 8B4626 (ECHA, 2017) (BASF, 2013). The EPA received a total of 24 studies which were conducted to determine the physical-chemical properties (n=2), environmental fate properties (n=2), human health hazards (n=17) and environmental hazards (n=3). Of these 24 studies, 20 study reports are described in robust summary format in ECHA. Summaries of these studies as presented in the ECHA database are exhibited in Appendices B-D. Due to a claim of business confidentiality, the full study reports are not publicly available.[3] Three human health studies and one environmental fate study received from the data owners were not explicitly summarized in the ECHA Database, or the Food Additive Petition (FAP) 8B4626. A review of these four studies led the EPA to conclude that the conclusions are consistent with other robust summaries presented in ECHA that were conducted under the same guideline.

Several references initially identified as on-topic during a preliminary title and abstract screen were excluded after further screening based primarily on lack of information specific to C.I. Pigment Violet 29, due to the limited nature of these references, but were utilized in the assessment. This included exposure and engineering citations, i.e., correspondences with industry, considered to be on-topic and used to inform the likelihood of exposure. The nature of these documents is such that the current framework as outlined in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) is not well suited for the review of these types of references. And as such, these references were individually addressed, and as with all references utilized in the document are cited in the references section, and are publicly available in the EPA HERO database. As a result, formal data quality evaluation of these references according to the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) was not conducted.

2.5.1 Data Evaluation

During the data evaluation stage, the EPA typically assesses the quality of the methods and reporting of results of the individual studies identified during problem formulation using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The EPA evaluated the quality of the C.I. Pigment Violet 29 study reports to confirm the conclusions of the robust summaries available from the ECHA database. All studies were given either an overall high or medium confidence rating during data evaluation. The results of these data quality evaluations are summarized in Sections 2.1 (Physical and Chemical Properties), 3.1 (Fate and Transport) and 4 (Hazards (Effects)). Appendices B-D also present the overall confidence ratings for each study, and the *C.I. Pigment Violet*

[3] Due to a claim of confidentiality, the full reports are not publicly available. However, it is important to note that peer reviewers will have access to all information claimed business confidential to help inform their review.

29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document presents details of the data evaluations for each study, including scores for each metric and the overall study score.

2.5.2 Data Integration

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

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

3 EXPOSURES

3.1 Fate and Transport

Table 3-1 summarizes the environmental fate characteristics of C.I. Pigment Violet 29. The EPA used EPI Suite™ estimations and reasonably available fate data for C.I. Pigment Violet 29 to characterize the environmental fate and transport of the chemical.

Table 3-1. Environmental Fate Characteristics of C.I. Pigment Violet 29

Property or Endpoint	Value [a]	References
Indirect photodegradation	7.0 hours (estimated)	(U.S. EPA, 2012b)
Hydrolysis half-life	Stable (estimated)	(U.S. EPA, 2012b)
Biodegradation	Low biodegradability: 0-10 percent degradation in 28 days (OECD 301F)	(ECHA, 2017; BASF, 1999)
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 which is an uncertainty regarding the fate characterization. Despite the limitation in the dataset, similarities with other organic classes indicates that these predicted fate properties can be estimated by substructure fragments.

C.I. Pigment Violet 29 is highly persistent and has low bioaccumulation potential. Due to its physical properties, it is expected to bind strongly to soil organic matter and migration through soil to groundwater is likely to be minimal. If released to water, hydrolysis is expected to be negligible. Based on its estimated Henry's Law Constant, C.I. Pigment Violet 29 is not expected to volatilize from water. If released to air, it is unlikely to undergo direct photolysis and is expected to be in the solid phase (i.e.

particulates). Based on its estimated indirect photodegradation half-life of 7 hours, it is considered to degrade slowly to moderately by reacting with atmospheric hydroxyl radicals.

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

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

These full study reports contain information protected under statute as Confidential Business Information (CBI) by the Toxic Substances Control Act (TSCA) and therefore are not publicly available. The results of the OECD Guideline 301 F: Biodegradability: Manometric Respirometry Test as presented in the ECHA robust summary which are presented in Appendix B. The EPA reviewed these studies and concluded that C.I. Pigment Violet 29 is poorly biodegradable under normal environmental conditions. The activated sludge, respiration inhibition test study is not presented as robust summary in the ECHA database or the Food Additive Petition (FAP) 8B4626. Following review of these full study reports, the Agency has confirmed that the conclusions of the activated sludge, respiration inhibition test are consistent with the conclusions of the biodegradability test, as summarized in ECHA. Furthermore, the Agency has reviewed these full study reports according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and determined that these studies have received high confidence scores based on the evaluation metrics for environmental fate studies. The results of these evaluations can be found in *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document*.

3.2 Environmental Releases and Exposure

The EPA determined that 90 percent of the production volume is used on site as a chemical intermediate. As a result, only 10 percent of the total production volume (~60,000 lbs) is used in a way that could result in environmental releases and exposures (U.S. EPA, 2018b; Mott, 2017a; Mott, 2017b). Chemical manufactured and used as a site limited intermediate typically requires minimum handling, resulting in limited releases and exposure. During the use as a chemical intermediate, C.I. Pigment Violet 29 is consumed during the reaction. Releases and exposure as a result of this use is included in the releases and exposure during manufacturing. The majority of this volume is used in either commercial and consumer products. Specifically, paint products are for both commercial and consumer uses, while coatings, plastic and rubber products are for commercial uses only. C.I. Pigment Violet 29 is manufactured as a solid and in solution and has a low vapor pressure (<0 hPa at 20˚C) (U.S. EPA, 2012a; U.S. EPA (2016)). It is handled and processed as a dry powder and formulation during all conditions of use.

Physical-chemical (see Table 2-1) and fate (see Table 3-1) properties as well as engineering controls limiting manufacturing releases (as discussed below), are expected to result in limited exposure to air, water and sediment, groundwater via biosolids, and landfill leaching. The EPA concludes that approximately 1-2 percent of the volume is potentially released to air, landfill and surface water. Any potential surface water fraction is sent to an on-site waste water treatment during manufacturing (U.S. EPA, 2018b; Mott, 2017b). Sources of the loss include liquid solid separation, residues left in equipment, incidental spills, and dust emission.

Reasonably available information indicates that airborne exposures from both incineration and fugitive releases from manufacturing and/or processing are expected to be limited due to the low vapor pressure and volatility of C.I. Pigment Violet 29 (Henry's Law Constant $<1x10^{-10}$ atm-m^3/mol (U.S. EPA, 2017b)) and waste handling practices. Because the chemical is not volatile at process temperatures

during any conditions of use, evaporative losses (volatile fugitive air emissions) are not expected. Air releases directly to the environment from manufacturing are expected to be limited based on the use of dust handling systems by the manufacturer. (Mott, 2017b).

The remainder (1-2 percent of the volume) of C.I. Pigment Violet 29 that may enter the surface water via either direct discharge to a water of the U.S. or discharge after treatment at POTWs as a component of total suspended solids (TSS) from the sole U.S. manufacturer and from downstream users of C.I. Pigment Violet 29. Due to the low water solubility, solid physical state and high sorption of C.I. Pigment Violet 29, the vast majority of this chemical partitions to particulates and sediment where it is captured as sludge via an on-site above ground biological wastewater treatment system. This sludge is subsequently disposed of via incineration or landfill disposal (Mott, 2017b). Although there are no C.I. Pigment Violet 29-specific discharge limitations in National Pollutant Discharge Elimination System (NPDES) permits, discharges of C.I. Pigment Violet 29 could be subject to compliance with a NPDES discharge permit as a component of discharge limitations on TSS, thereby limiting potential discharges to water. Ultimately, of the NPDES-permitted TSS discharges for this sole domestic manufacturing facility, it is estimated that 0.6 lb/day of C.I. Pigment Violet 29 is being discharged (<0.1 percent of produced C.I. Pigment Violet 29) (Mott, 2017b).

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

Physical-chemical characteristics and manufacturing and use information was sufficient to determine that environmental exposures are likely to be limited for C.I. Pigment Violet 29. As a result, no further analysis was necessary for environmental releases and environmental exposure. Because per site volumes handled by downstream users are likely to be much less than the manufacturer (i.e., less than 5 percent each), it is expected that potential C.I. Pigment Violet 29 discharges per site to water and its related sediment, infiltration to groundwater via land application of biosolids, other landfill leaching, and air emissions will be proportionally lower.

3.3 Human Exposures

No additional information was received or identified by the EPA following the publication of the problem formulation that would alter the preliminary conclusions presented in the problem formulation that occupational, consumer and general population exposures to C.I. Pigment Violet 29 are limited (U.S. EPA, 2018b).

3.3.1 Occupational Exposures

Workers may be exposed via inhalation and dermal routes during handling of neat materials. However, absorption via inhalation pathways is expected to be poor 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, use of PPE, and due to poor absorption in solution based on low solubility. When C.I. Pigment Violet 29 is encapsulated in plastics or paint resins, it is not expected to leach out (21 CFR 178.3297; BASF, 1998). The sole manufacturer of C.I. Pigment Violet 29 reported an approximate maximum workplace air concentration of 0.5 mg/m^3 would be expected over a 12 hour shift (Mott, 2017a). It is not clear if the monitoring data were for C.I. Pigment Violet 29 or for total dust. If the data were for total dust, the actual air concentration of C.I. Pigment Violet 29 is likely to be lower than 0.5 mg/m^3 (Mott, 2017a).

Oral ingestion is not a relevant pathway for workers manufacturing C.I. Pigment Violet 29 since there is no forseeable route of exposure. Standard workplace practices prohibit eating and smoking in manufacturing facilities. In addition, minimal incidential oral exposures are avoided by the use of personal protective equipment (PPE) that are discussed below (Mott, 2017a). In addition, oral absorption is poor due to low water solubility.

Engineering controls for C.I. Pigment Violet 29, as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). Oral and inhalation exposures from downstream processors and users are possible; however, occupational exposures from these downstream users are likely to be limited due to the expected use of PPE (per Safety Data Sheet for C.I. Pigment Violet 29) and poor oral absorption due to low water solubility (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). Although oral and dermal exposure are expected to be limited due to poor adsorption and PPE utilized by workers, the EPA conducted a screening-level analysis to quantify a theoretical high-end scenario for workers, which assumes that PPE are not utilized.

3.3.1.1 Occupational Exposures Approach and Modeling

Inhalation Exposure:
Workers at the manufacturing site handle large volumes of C.I. Pigment Violet 29 at nearly 100 percent concentration. As a result, a high-end exposure analysis was performed to represent a theoretical high-end exposure of C.I. Pigment Violet 29 at a manufacturing site. This high-end estimate assumes that no particulate respirators are used. Using the air monitoring data from the one manufacturing site (0.5 mg/m^3 over 12 hours/day) and converting to an inhalation Potential Dose Rate (PDR) for workers is 7.5mg/day using the following equation:

$$(0.5\ \text{mg/m}^3 \times 1.25\ \text{m}^3/\text{hour} \times 12\ \text{hours/day}) = 7.5\text{mg/day}$$

Where:
- 0.5 mg/m^3= Manufacturer-provided workplace air monitoring results for total workplace dust (this conservatively assumes that 100 percent of the total dust is C.I. Pigment Violet 29) (Mott, 2017a)
- 1.25 m^3/hour= EPA default assumption of respiration rate[4]
- 12 hours/day= Assumed maximum shift length

[4] https://nepis.epa.gov/Exe/ZyPDF.cgi/P10000VS.PDF?Dockey=P10000VS.PDF

Dermal Exposure:
For the purposes of this screening-level assessment, the dermal potential dose rate for workers is assumed to be the theoretical maximum exposure of 3100 mg/day, which is the worst-case assumption used by the EPA for dermal exposure based on 2-hand dermal contact with solids without gloves.[5]

3.3.2 Consumer Exposures

Consumer exposures via oral and dermal routes are expected to be limited based on the uses and physical-chemical properties of C.I. Pigment Violet 29. Of the uses for C.I. Pigment Violet 29, the only consumer use is as a component of watercolor and artistic paint. Based on these uses, inhalation is not identified as a route of exposure for consumers since C.I. Pigment Violet 29 is not expected to volatilize from consumer watercolor and artistic color due to its low vapor pressure. Oral ingestion is expected to be limited due to the low water solubility (0.01 mg/L) and dermal and oral absorption are estimated to be poor for the neat material (because it is a solid with low solubility) and poor absorption in liquid (based on low solubility) (ECHA, 2017). As a result, the exposure scenarios calculated above for occupational exposure via inhalation and dermal are expected to greatly exceed any potential consumer exposure to paints. The only consumer exposure would be through artistic paints which are not directly marketed to infants or children. Even if there is incidental exposure as a result of oral consumption of paint, the exposure is not expected to exceed the high-end exposures of unprotected workers as calculated above. Based on the low potential for exposure through drinking water as discussed below in Section 3.3.3, or as a result of the consumer uses, it is not expected that the conditions of use for C.I. Pigment Violet 29 will exceed the exposure dose calculated for workers. As a result, no further analysis was conducted for consumer exposure.

3.3.3 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. Oral ingestion of C.I. Pigment Violet 29 is expected to be limited due to concentrations expected in surface and ground water. This limited concentration in water is due to high removal efficiency of C.I. Pigment Violet 29 during the waste water treatment process on site or at POTWs limiting releases to surface water and strong sorption to soil reducing migration to groundwater. Additionally, physical-chemical properties indicate that if ingested, absorption would be expected to be poor due to low water solubility. Inhalation of C.I. Pigment Violet 29 is expected to be low due to limited fugitive and incineration air releases. Low volatilization rates will limit fugitive air releases as vapor, while dust handling systems in place at the manufacturing facility are designed to capture dust in baghouses (Mott, 2017b). Any incidental exposures to the general population, in addition to being unlikely given the understanding of the uses and physical chemical properties of C.I. Pigment Violet 29, are not expected to be greater than the high-end exposure calculated for workers. As a result, no further analysis was conducted for exposure to the general population.

3.4 Other Exposure Considerations

3.4.1 Potentially Exposed or Susceptible Subpopulations

TSCA requires that a risk evaluation "determine whether at chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk factors, including an unreasonable risk to a *potentially exposed or susceptible subpopulation* identified as relevant to the risk evaluation by the Administrator, under the conditions of use." TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or

[5] ChemSTEER user guide (pg. 264) https://www.epa.gov/sites/production/files/2015-05/documents/user_guide.pdf

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 risk evaluation, the EPA analyzed the reasonably available information to ascertain whether some human receptor groups may have greater exposure or susceptibility than the general population to the hazard posed by a chemical. The results of the available human health data, which reported no effects for all routes of exposure (oral, dermal, and inhalation), indicating that there is no evidence of increased susceptibility for any single group relative to the general population. Exposures of C.I. Pigment Violet 29 would be expected to be higher amongst workers using C.I. Pigment Violet 29 as compared to the general population, so the exposure calculation for workers is based on full immersion and is therefore protective of all other subpopulations, such as children and pregnant women in the general population, which are not expected be exposed to C.I. Pigment Violet 29 at similarly high levels. Additionally, engineering controls during the manufacturing and processing of C.I. Pigment Violet 29 as outlined above would likely limit exposure to workers.

3.4.2 Aggregate and Sentinel Exposures

Section 2605(b)(4)(F)(ii) of TSCA requires the EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. The EPA has defined aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways." As a result of the limited nature of all routes of exposure resulting from the conditions of use of C.I. Pigment Violet 29, a consideration of aggregate exposures of C.I. Pigment Violet 29 was deemed not to be appropriate for this risk evaluation. The EPA defines sentinel exposure as "the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures." In terms of this risk evaluation, the EPA considered sentinel exposure in the form of a high-end screening level scenario for occupational exposure resulting from dermal and inhalation exposures, as these exposure routes are the most likely to result in the highest exposure given the details of the manufacturing process and the potential exposure scenarios discussed above. The calculation for dermal exposure is especially conservative given that it assumes full contact/immersion.

4 HAZARDS (EFFECTS)

4.1 Environmental Hazards

The only environmental hazard data identified for C.I. Pigment Violet 29 were three acute ecotoxicity studies presented in summary format in the ECHA Database (U.S. EPA, 2018b; ECHA, 2017). The EPA has received and reviewed full study reports corresponding to the ECHA robust summaries, which included the following study types:

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

As indicated in previous sections, a claim of business confidentiality by the data owners means that the EPA will not reproduce these full study reports in this risk evaluation. However, the EPA has confirmed that the results of these full study reports are consistent with the corresponding robust summaries

available in ECHA, which are presented in abbreviated format in Appendix C. The EPA has reviewed these full study reports according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The data quality evaluation indicated these studies are of high confidence and can be used to characterize the environmental hazards of C.I. Pigment Violet 29. The results of this data quality evaluation can be found in the *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document*.

These ECHA robust summaries indicate that toxicity effects were not observed for fish, daphnia and aquatic plants up to the limit of solubility of the chemical and that C.I. Pigment Violet 29 presents a low environmental hazard. This is consistent with the Canadian Ecological Risk Classification for C.I. Pigment Violet 29, which did not present additional information, where it was determined that C.I. Pigment Violet 29 did not meet the criteria for categorization as a prioritized substance for further evaluation and the potential hazard is low (Environment Canada, 2006)

4.2 Human Health Hazards

The EPA concludes that C.I. Pigment Violet 29 presents a low hazard to human health across all routes of exposure (U.S. EPA, 2018b). This conclusion is based on full study reports of the human health studies identified in the ECHA Database and Food Additive Petition (FAP) 8B4626 (ECHA, 2017; BASF, 1998). The full study reports received by the EPA included the following study types:

- OECD Guideline 401: Acute Oral Toxicity with Rats (two studies)
- OECD Guideline 404: Acute Dermal Irritation/Corrosion (two studies)
- OECD Guideline 405: Acute Eye Irritation/Corrosion (two studies)
- 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 (two studies)
- Non-Guideline Acute Toxicity: Acute Inhalation Toxicity with Rats (two studies)
- OECD Guideline 476: *In vitro* Mammalian Cell Gene Mutation Test
- Reverse mutation assay AMES test using *Salmonella typhimurium* and *Escherichia coli*

These full study reports concluded that no adverse effects were observed for all routes of exposure (oral, dermal, inhalation), nor were dermal or eye irritation effects reported. As a result, the EPA concludes that C.I. Pigment Violet 29 presents a low hazard to human health. Toxicity effects were observed in the intraperitoneal studies at high concentrations (LD_{50}= 7000-9000 mg/kg-bw). However, the nature of this route of exposure is not relevant for C.I. Pigment Violet 29 because the test material is injected directly into the intra-peritonium (body cavity) and C.I. Pigment Violet 29 is poorly absorbed by all routes due to its low solubility. The genotoxicity studies reported that C.I. Pigment Violet 29 is negative for genotoxicity. While no suitable analogs were identified for C.I. Pigment Violet 29 concerning genotoxicity, structural activity relationships (SAR) considerations and the expected poor absorption and uptake of C.I. Pigment Violet 29, support the EPA's conclusion that C.I. Pigment Violet 29 is unlikely to be a carcinogen. Hence, C.I. Pigment Violet 29 would not cause spatial or temporal perturbations to the DNA integrity. No data was found on the metabolism of C.I. Pigment Violet 29; hence the metabolic fate is unknown. However, C.I. Pigment Violet 29 is unlikely to be metabolized based on poor absorption.

In a reproduction/developmental toxicity screening test (as described in the ECHA robust summary), Wistar rats (10/sex/group) were administered C.I. Pigment Violet 29 in water via oral gavage at doses of 0, 100, 300, or 1000 mg/kg-bw/day. Males were dosed daily for 2 weeks prior to mating, during mating, and until the day prior to scheduled necropsy (study day 31). Females were dosed daily for two weeks

prior to mating, during mating, during gestation, and during lactation until the day prior to scheduled necropsy (study day 57). Litters were sacrificed on postnatal day 4. Males and females at 300 and 1000 mg/kg-bw/day showed black discoloration of feces throughout the study and of the contents of the glandular stomach, jejunum, and/or colon. The discoloration was considered to be the result of oral intake of the test substance, which is a pigment. There were no adverse, test substance-related effects on parental mortality, body weight, food consumption, macroscopic findings, organ weights (evaluated in males only), histopathology, spermatogenesis, mating or fertility indices, pre-coital interval, gestation index or length, number of implantation sites, post-implantation loss, live birth index, numbers of delivered pups, liveborn pups, and stillborn pups, pup viability index, pup sex ratio, pup clinical signs, pup body weights, or pup necropsy. Discoloration of the feces and contents of the glandular stomach, jejunum, and colon was considered non-adverse; therefore, the NOAEL for systemic toxicity in parental animals was 1000 mg/kg-bw/day. The NOAEL for reproductive/developmental toxicity in males and females was 1000 mg/kg-bw/day.

As indicated in previous sections, the EPA has reviewed these full study reports and determined that the results are consistent with the conclusions and information presented in the corresponding robust summaries in ECHA (Appendix D). Furthermore, the EPA has reviewed these according to the data quality evaluation criteria found in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and concludes that these studies are of high or medium confidence based on the evaluation metrics for human health hazard studies. The result of the data quality evaluation can be found in Appendix D, while the data quality evaluations are located in the *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document*.

Listed below are three additional studies submitted by one data owner; these were not available as robust summaries in the ECHA database or the Food Additive Petition (FAP) 8B4626:

- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion

The EPA reviewed these studies and concluded that the results of these three additional studies are consistent with the results of the full studies received that were conducted according to the same guideline that are publicly available in ECHA. Furthermore, following data evaluation of these three studies, the EPA concludes that these three studies are of high confidence based on the evaluation metrics for human health hazard studies.

5 RISK CHARACTERIZATION

5.1 Environmental Risk

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

discussed above, the EPA conducted a qualitative assessment of potential environmental exposures. This analysis considered reasonably available information including manufacture, use, and release information, and physical chemical characteristics. The EPA determines that environmental exposures of C.I. Pigment Violet 29, for the conditions of use of C.I. Pigment Violet 29, are expected to be limited as a result of a qualitative consideration of reasonably available physical-chemical, environmental fate, manufacturing and release, and exposure data. Considering the limited nature of the environmental exposures resulting from the conditions of use of C.I. Pigment Violet 29 and the lack of effects observed in the available environmental hazard studies, environmental concentrations of C.I. Pigment Violet are not expected to reach a concentration where adverse effects to environmental receptors could occur.

5.1.1 Assumptions and Key Sources of Uncertainty

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

In the previous sections, the EPA determined that expected releases and subsequent environmental exposures are limited as a result of a qualitative consideration of available physical-chemical, environmental fate, manufacturing and release, and exposure information. While the agency has determined that there are sufficient data available to make this determination, environmental monitoring data were not available to verify the conclusions of limited environmental exposures. This lack of monitoring data is unlikely to impact the conclusions, as the low solubility of the chemical and lack of environmental hazard means that it would be unlikely for environmental concentrations to reach a level where adverse effects could be observed in environmental receptors.

Strong sorption to sediment is indicated as a result of the EPI Suite™-estimated K_{OC} value (5.0), which suggests that potential aquatic releases could result in exposure to sediment-dwelling organisms. Data are not available to specifically characterize hazard to sediment-dwelling, aquatic invertebrates; however, based on the weight of evidence considering the limited potential for aquatic releases resulting from the conditions of use of C.I. Pigment Violet 29 and the lack of effects observed in all environmental hazard studies, particularly with *Daphnia magna,* (a sensitive surrogate species for aquatic invertebrates for which no adverse effects were observed) the EPA determines that sufficient data exist to make a determination of risk for these species. Due to a combination of low potential exposure and low hazard, the EPA concludes that C.I. Pigment Violet 29 is unlikely to present an unreasonable risk to sediment dwelling, aquatic invertebrates.

With regard to chronic exposure, there is uncertainty because, as mentioned above, chronic exposure environmental hazard testing with C.I. Pigment Violet 29 is not available. While data characterizing the potential hazards from chronic exposure are not available and there are uncertainties regarding the chronic hazard from exposure to C.I. Pigment Violet 29, the limited environmental releases and

exposure and low hazards reported across all hazard testing indicate that C.I. Pigment Violet 29 is unlikely to present an unreasonable risk to environmental receptors from chronic exposure.

As discussed above in Section 3.2, engineering controls and high capture efficiency of aquatic C.I. Pigment Violet 29 is expected to limit the potential for environmental releases and resulting exposures. These limited exposures across all routes and low hazard across all ecotoxicity and human health testing indicates that adverse effects are not expected for terrestrial species. Exposures to terrestrial species are not expected to reach levels where adverse effects could occur.

5.2 Human Health Risk

A total of 17 human health hazard studies were received and evaluated for C.I. Pigment Violet 29. All studies were given a high or medium overall confidence rating during data quality evaluation. The *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation Document* presents details of the data evaluations for each study, including scores for each metric and the overall study score. As discussed in Section 4.2, a review of the available human health data identified for C.I. Pigment Violet 29 indicates low hazard to human health across all routes of exposure (oral, dermal, inhalation). Available reproductive/developmental information did not report toxicity effects up to the highest concentration tested. Genotoxicity testing and structural considerations indicate that C.I. Pigment Violet 29 is unlikely to be a carcinogen. Based on physical chemical properties, C.I. Pigment Violet 29 is classified as poorly absorbed by all routes of exposure. In addition, the EPA conducted a quantitative assessment of the potential risk concerns resulting from occupational exposure. This approach involved a screening-level analysis to determine whether potential risks to workers exist from exposure to C.I. Pigment Violet 29 from the high-end workplace exposure. Using a qualitative analysis of potential consumer and environmental exposures, the EPA concludes that C.I. Pigment Violet 29 has a limited potential for exposure from these routes and is unlikely to exceed the worst-case exposure scenario calculated below for occupational exposure.

5.2.1 Risk Estimation for Acute, Non-Cancer Inhalation and Dermal

The EPA uses a Margin of Exposure (MOE) approach to assessing non-cancer risk. The MOE is the ratio of the point of departure (POD) dose divided by the human exposure dose. The MOE is compared to the benchmark MOE. If the MOE exceeds the benchmark MOE, this indicates that risks to human health are not expected.

The EPA calculated the MOE using the following equation[6]:

$$MOE = \left(\frac{(POD * POD\%Absorption)}{\left(\left(\frac{PDR}{BW}\right) * (ExposureRoute\%Absorption)\right)} \right) * \left(\frac{(DurationAnimal)}{(DurationHuman)} \right)$$

Breakdown of the equation:

- $POD * POD\%Absorption$ – An estimate of the internal dose in the animal study used for the NOAEL or LOAEL value.

[6] https://www.epa.gov/sites/production/files/2015-05/documents/13.pdf

- $\frac{PDR}{BW}$ - The engineering report exposure is in mg/day, not mg/kg. This term converts the total exposure to mg/kg. PDR calculated in Section 3.3.1 is 7.5 mg/day for inhalation to workers, and 3100 mg/day for dermal exposure.
- $\left(\frac{PDR}{BW}\right) * \%ExposureRouteAbsorption$ - This is a crude estimate of the internal dose in the human from the scenario exposure route. For C.I. Pigment Violet 29, due to poor absorption based on the low solubility, ExposureRoute%Absorption is presumed to be 10% from dermal and 100% from inhalation which are default values for chemical substances with poor absorption.
- $DurationAnimal/DurationHuman$ – Adjustment of POD for differences in days per week exposure between animal studies and the human exposure scenario. Repeated dose animal studies are typically conducted for 5 (subchronic, chronic) or 7 (developmental, reproduction) days. The POD dose used for the human must be adjusted if the animal and human days per week exposures differ. This is accomplished by utilizing a concentration-duration product constant (e.g., Haber's rule) to make the adjustment. If durations of exposure per week are unknown for the POD study or human exposure assume 5 days/week for each.

Where:

- DurationAnimal = Duration of the animal experiment in days/week (animals in the reproductive/developmental screening test were dosed for 7 days/week)
- DurationHuman = Duration of human exposure in days/week under the scenario being considered (workers are expected to work 5 days/week)
- ExposureRoute%Absorption = Percent absorption by the scenario exposure route
- MOE = Margin of Exposure
- PDR = Potential Dose Rate - worker exposure in mg/day. Even the inhalation route is presented this way.
- BW = Bodyweight of a worker (80kg)
- POD = Animal NOAEL or LOAEL POD in mg/kg
- POD%Absorption = Percent of the chemical absorbed in the animal POD study. In this case, absorption by the oral route

If the POD is based upon a No Observed Adverse Effect Level (NOAEL) then the acceptable Benchmark MOE[7] is typically ≥ 100. The value of 100 is used to account for variability between species (Interspecies Uncertainty factor (UF) = 10X) times the variability within the human population (Intraspecies Uncertainty Factor = 10).

For both dermal and inhalation exposure, the POD was set at the NOAEL of 1000 mg/kg/day, as no effects were observed up to the highest tested dose in the reproduction/developmental screening study available for the C.I. Pigment Violet 29 (Stark et al., 2013). The MOE of 14,933 was calculated for inhalation exposure was calculated using the following equation:

$$MOE\ (14{,}933) = \left(\frac{(1000 mg/kg/day * 100\%)}{\left(\left(\frac{7.5 mg/day}{80 kg}\right) * (100\% Absorption)\right)}\right) * \left(\frac{(7\ days/wk)}{(5\ days/wk)}\right)$$

[7] https://www.epa.gov/sites/production/files/2015-05/documents/13.pdf

The MOE of 361 was calculated for dermal exposure was calculated using the following equation:

$$MOE\ (361) = \left(\frac{(1000mg/kg/day * 100\%)}{\left(\left(\frac{3100mg/day}{80kg}\right) * (10\%Absorption)\right)} \right) * \left(\frac{(7\ days/wk)}{(5\ days/wk)}\right)$$

For C.I. Pigment Violet 29, the benchmark Margins of Exposures (MOE)[8] are set at 100. If the POD is based upon a No Observed Adverse Effect Level (NOAEL) then the acceptable Benchmark MOE is ≥ 100. The value of 100 is used to account for variability between species (Interspecies Uncertainty factor (UF) = 10X) times the variability within the human population (Intraspecies Uncertainty Factor = 10).

A comparison of the MOE for inhalation with the benchmark MOE (14,933/100) and the MOE for the worst-case dermal exposure with the benchmark MOE (361/100) indicated that risks were not identified for workers based on inhalation and dermal exposure, as the inhalation and dermal MOEs were greater than the benchmark MOE. The inhalation benchmark dose is >100x more than an exposure level that would trigger a risk concern. There is also no identified risk for the exposure scenario for dermal exposure (using high-end EPA occupational exposure estimate for two hand dermal contact[9]), even though it does not assume the use of gloves or other protective equipment described in Section 3.3.1. Hand to mouth exposure is not likely to result in exposures greater than these high-end screening-level exposure values, because as discussed above, eating, drinking and smoking are prohibited in manufacturing facilities. Based on the results of this screening-level analysis, risks are not expected for general population as exposure to the general population would be significantly lower than the exposures for workers. This suggests that the risk calculation is protective of general population exposures.

5.2.2 Assumptions and Key Sources of Uncertainty

All available human health data indicated that, regardless of the exposure route, C.I. Pigment Violet 29 presents a low hazard. While the EPA determines that the data available to characterize human health hazard of C.I. Pigment Violet 29 are sufficient to make a determination of risk, there are uncertainties (some may be significant, while others are minor). C.I. Pigment Violet 29 is presented with limited data sets and one of the factors that is missing is the absorption potential. Despite the lack of an absorption test, the EPA was able to describe potential absorption of C.I. Pigment Violet 29 based on physical-chemical properties, which indicate that C.I. Pigment Violet 29 is classified as poorly absorbed by all routes of exposure (low solubility, low vapor pressure), which led the EPA to consider a default assumption of 10 percent absorption from dermal exposure and 100 percent absorption from inhalation.[10]

The estimation of dermal exposure used in this evaluation was derived from the EPA/OPPT Direct 2-Hand Dermal Contact with Solids Model. This default value of 3100 mg/day is a high-end estimate of the total amount of solids remaining on hands as a result of the following worker activities:

[8] Margin of Exposure (MOE) = (Non-cancer hazard value, POD) ÷ (Human Exposure). The benchmark MOE is used to interpret the MOEs and consists of the total UF. (UF_S=1) x (UF_A=10) x (UF_H=10) x (UF_L=1) = Total UF=Benchmark MOE=100. UF_S=subchronic to chronic UF; UF_A=interspecies UF; UF_H=intraspecies UF; UF_L=LOAEL to NOAEL UF.
[9] ChemSTEER user guide (pg. 264) https://www.epa.gov/sites/production/files/2015-05/documents/user_guide.pdf
[10] ECHA Guidance on Information Requirements and Chemical Safety Assessment. Available online at http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

- Loading Solids into Transport Containers/Vessels (all activity types)
- Unloading Solids from Transport Containers/Vessels (all activity types)
- Cleaning Solid Residuals from Transport Containers/Vessels (all activity types)
- Sampling Solids (all activity type)
- Equipment Cleaning Losses of Solids
- Filter Media Changeout
- Grinding and Sanding
- Miscellaneous Activities Related to Solids Processing

Reproductive and health effects are based on one repeated dose study (reproductive/ developmental screening via gavage). This test does not provide complete information on all aspects of reproduction and development, but rather provides a limited means of detecting post-natal manifestations of pre-natal exposure, or effects that may be induced during post-natal exposure. A smaller number of animals and endpoints are utilized in the dose groups, and the duration of the study is shorter than a full chronic toxicity study. Moreover, in the absence of data from other reproduction/developmental toxicity tests, positive results are useful for initial hazard assessment and contribute to decisions with respect to the necessity and timing of additional testing. This screening test can be used to provide initial screening of possible effects on reproduction and/or development, either at an early stage of assessing the toxicological properties of chemicals, or on chemicals of concern. Uncertainties in the way that this reproductive/developmental screening test was conducted, which was the source of the POD, included the expression of test concentrations in terms of nominal concentrations, and a lack of reporting of the stages of spermatogenesis in the testes. In addition, this study was conducted as a screening-level test per OECD-421. These were minor uncertainties and the results were sufficiently robust to make a determination of low hazard. As no effects were observed up to the limit-dose, further chronic toxicity testing is not needed.

The absence of a chronic exposure carcinogenicity study resulted in some uncertainty regarding the carcinogenicity of C.I. Pigment Violet 29. Based on the available data, C.I. Pigment Violet 29 is not reported to be a developmental neurotoxin. Despite the lack of this study, the carcinogenic potential of C.I. Pigment Violet 29 was sufficiently assessed using available data, which included two short-term genotoxicity studies and a consideration of the structural activity of the compound, which determined that C.I. Pigment Violet 29 is not likely to be carcinogenic.

As noted in the previous sections, the EPA concludes that occupational, consumer, general population and environmental exposure is limited as a result of a qualitative and semi-quantitative consideration of available physical-chemical, environmental fate, manufacturing and release, and exposure information. While the EPA determined that there are sufficient data available to make this determination, there is some uncertainty as monitoring data were not identified to verify the conclusions of low exposure via water and air. Despite the lack of monitoring data, the low hazard and the low potential for exposure indicates that exposure concentrations are unlikely to reach a level that will result in adverse effects to human health. Based on the exposures scenarios for workers, the EPA concludes that C.I. Pigment Violet 29 presents no unreasonable risk from occupational exposure scenarios. As general population exposures are expected to be far less than occupational exposures, this determination applies to the general population as well.

6 RISK DETERMINATION

The EPA concludes that C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment, without considering costs or other non-risk factors, including no unreasonable risk to potentially exposed and susceptible subpopulations identified as relevant, under the conditions of use.

No effects were observed in environmental hazard testing with aquatic species up to the limit of solubility of the chemical, and it is not expected that aquatic exposures can reach concentrations where adverse effects can be seen. Low hazard was reported in all human health testing via all routes of exposure (oral, dermal and inhalation), nor were dermal or eye irritation effects reported. Risks were not identified based on a screening-level analysis, which calculated an MOEs based on the worst-case exposure scenario for routinely exposed population (workers at a manufacturing site operating without PPE) which were compared to theoretical worst-case MOEs in Section 5.2. As explained in Section 5.2, the inhalation MOE and the dermal MOE both exceeded the benchmark MOE indicating that risks were not identified for workers, or by extension consumers and the general population which are expected to be exposed at concentrations lower than worker exposures. The EPA expects limited environmental releases and resulting limited exposures from the conditions of use, based on low solubility, low vapor pressure, low bioaccumulation potential, poor absorption based on physical-chemical properties of the C.I. Pigment Violet 29, so exposures are likely to be less than these worst-case scenarios.

A determination in a risk evaluation that concludes a chemical does not present an unreasonable risk, as this draft risk evaluation does, must be issued by order. See TSCA section 6(i)(1). If finalized as proposed, the final version of this Risk Determination section would constitute the order required by TSCA section 6(i)(1).

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APPENDICES

Appendix A REGULATORY HISTORY

A-1 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)	The 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 the 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)	The 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 the EPA's new chemicals review process under TSCA section 5 (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 colorant in food-contact polymers.	C.I. Pigment Violet 29 is approved to be in finished articles that come in contact with food. It should not to exceed 1 percent by weight of polymers and should follow specific conditions of use (21 CFR

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		178.3297). C.I. Pigment Violet 29 is not listed as an approved food additive.

A-2 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 [11]
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.[12]
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.[13] There are no restrictions associated with being on the Chinese inventory.
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.[14] 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.

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

[12] 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.

[13] Chemical Inspection & Regulation Service. The Inventory of Existing Chemical Substance in China – IECSC (2013 and updates). April 20, 2016. Accessed October 11, 2017. http://www.cirs-reach.com/news-and-articles/the-inventory-of-existing-chemical-substance-in-china-iecsc-2013-and-updates.html.

[14] 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.

Country/Organization	Requirements and Restrictions
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.[15]
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.[16] 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.[17]
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.[18] There are no restrictions associated with being on the Philippine inventory.
Taiwan	C.I. Pigment Violet 29 in on the National Existing Chemical Inventory in Taiwan. There are no restrictions associated with being on the Taiwanese inventory.[19]
Vietnam	C.I. Pigment Violet 29 is on the draft (September 2018) Vietnam National Existing Chemical Inventory. There are no restrictions associated with being on the Vietnamese inventory.[20]

[15] NITE Chemical Risk Information Platform (NITE-CHRIP). Accessed March 14, 2017. https://www.nite.go.jp/en/chem/chrip/chrip_search/cmpInfDsp?cond=b98cea3dd3544a1a659f20644a00d99b0fce03568d4a8167a2c5b88e510e15f2_2

[16] 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.

[17] Environmental Protection Authority. Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone. Accessed October 11, 2017. https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/view/35898.

[18] 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.

[19] Occupational Safety and Health Administration, Ministry of Labor. TCSI Search. Accessed October 11, 2017. https://csnn.osha.gov.tw/content/home/Substance_Query_Q.aspx.

[20] ChemSafetyPRO. Vietnam National Existing Chemical Inventory. October 17, 2018. Accessed October 31, 2018. http://www.chemsafetypro.com/Topics/Vietnam/Vietnam_National_Existing_Chemical_Inventory.html.

Appendix B ENVIRONMENTAL FATE STUDY RESULTS[21]

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

Target System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration[2]	Endpoint	Effect[3]	Affiliated Reference[4]	Data Quality Evaluation results of full study report[5]
Biodegradation	OECD 301F - Biodegrad-ability: Manometric Respirometry Test)	Activated sludge, domestic, non-adapted (Concentration of sludge: 30 mg/I	Static renewal	100 mg/L	28 Days	Degradation degree of the test substance after 28 days (percent BOD/ThOD); 0-10	Poorly biodegradable	(BASF, 1999)	High

[1]Species/strain, sex of animals included in the study.
[2]Acute exposures defined as those occurring within a single day. Chronic exposures defined as 10 percent or more of a lifetime (U.S. EPA, 2011).
[3]The effect(s) listed were the most sensitive effects observed for that target organism in that study (i.e., the effect(s) upon which the POD was based).
[4]This column lists the primary reference of the full study report corresponding to the ECHA summary. [5]Information included in this column is the overall quality level resulting from the data quality evaluation – this also would include unacceptable studies for comparison with acceptable studies. Note that in addition to the final result for the study/endpoint, selected important quality considerations could also be included, such as low purity etc.
[5] One environmental fate study, OECD Guideline 209-Determination of the inhibition of oxygen consumption by activated sludge by Perylimid F in the Activated Sludge Respiration Inhibition Test according to GLP, EN 45001 and ICO 9002, was received by the data owner but is not reported in the ECHA database

[21] The data presented in these tables in Appendix B-D reflects the data summaries as presented in ECHA (ECHA, 2017). A claim of business confidentiality with the data owners of the full study reports prevents the publication of specific details from the full studies.

Appendix C ENVIRONMENTAL EFFECTS ENDPOINTS

Table_Apx C-1: Aquatic Plant Toxicity Study Summary for C.I. Pigment Violet 29 (ECHA, 2017)

Target System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration[2]	Endpoint	Effect[3]	Affiliated Reference[4]	Data Quality Evaluation results of full study report[5]
Mortality	OECD-201; Aquatic vascular plant: 7 days, static renewal	Duckweed (*Lemna gibba*)	static renewal	Nominal: 0 (control), 1, 3.2, 10, 32, 100 mg/L based on loading Measured Test Concentrations: 0.007 mg/L (highest)	7 Days	NES (based on growth [frond number and dry weight])	None reported	(BASF, 2012b)	High
	OECD-202; Acute freshwater invertebrate: 48 hours, static, limit	*Daphnia magna*	static	Measured test concentrations: - (control), 0.0065 mg/L	48 Hours	NES	None reported	(BASF, 2012a)	High
	OECD-203; Acute freshwater fish: 96 hours, static	Zebrafish (*Brachydanio rerio*)	static	Nominal test concentrations: 0 (control), 5000 mg/L	96 Hours	NES	None reported	(BASF, 1988)	High

[1]Species/strain, sex of animals included in the study.
[2]Acute exposures defined as those occurring within a single day. Chronic exposures defined as 10 percent or more of a lifetime (U.S. EPA, 2011).
[3]The effect(s) listed were the most sensitive effects observed for that target organ/system in that study (i.e., the effect(s) upon which the POD was based).
[4]This column lists the primary reference of the full study report corresponding to the ECHA summary.
[5]Information included in this column overall quality level resulting from the data quality evaluation – this also would include unacceptable studies for comparison with acceptable studies. Note that in addition to the final result for the study/endpoint, selected important quality considerations could also be included, such as low purity etc.

Appendix D HUMAN HEALTH EFFECTS ENDPOINTS

Table_Apx C-1: Toxicity Study Summaries for C.I. Pigment Violet 29 as Presented in the ECHA Database (ECHA, 2017)[22]

Target Organ/ System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration[2]	Endpoint	Effect[3]	Affiliated Reference[4]	Data Quality Evaluation results of full study report[5]
Mortality	OECD-401; Acute oral	Sprague-Dawley rat (5 animals/ sex/dose)	Oral	6810 and 10000 mg/kg bw	14 days	LD_{50} >10,000 mg/kg bw	None	(BASF, 1975b)	High
								(BASF, 1978c)	High
	OECD-401; Acute oral, single dose by gavage, limit	Sprague-Dawley rat (5 animals/ sex/dose)	Oral	10000 mg/kg bw	14 days	LD_{50} >10,000 mg/kg bw	None	(Rupprich and Weigand, 1984c)	High
	Acute Inhalation Toxicity	Wistar Rat (6 per sex)	Inhalation	0.31 mg/l air (calculated)	7 Hour	LC_{50}> 0.31 mg/L air	None	(BASF, 1978a)	Medium
		Rat (6 per sex)	Inhalation	14.74 mg/L	8 Hour	LC_{50}> 14.74 mg/L	None	(BASF, 1975a)	Medium
	Acute Intraperitone-al Toxicity - Conducted according to internal protocol	NMRI-Wiga Mouse	Intraperitoneal injection	10,000, 6,810, 4,640 mg/kg	14-day observation post injection	LD_{50}= 9000 mg/kg-bw	Mortality, Dyspnea, apathy, unsteady gait and ruffled fur	(BASF, 1978b)	High
		NMRI-Ivanovas Mouse (5 animals/ sex/ dose)	Intraperitoneal injection	2150, 4640 and 10000 mg/kg	14-day observation post injection	LD_{50}= 7000 mg/kg-bw	Mortality Dyspnoea, apathy, agitation, bad general health.	(BASF, 1975f)	High

[22] Listed below are three additional studies submitted by one data owner, they were not reported in the ECHA database.

- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion

Target Organ/ System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration[2]	Endpoint	Effect[3]	Affiliated Reference[4]	Data Quality Evaluation results of full study report[5]
Reproductive and Developmental	OECD-421 Reproduction and development toxicity	Wistar rat (10 males/ 10 females)	Gavage	100, 300, 1000 mg/kg bw/d	Exposure: premating period of 2 weeks and a mating period [max. of 2 weeks] in both sexes, approximately 1 week post-mating in males, and the entire gestation period as well as 4 days of lactation in females)	NOAEL= 1000 mg/kg bw/day	None reported[6]	(Stark et al., 2013)	High
Skin Irritation	OECD- 404; Skin irritation: occlusive	Weiber Wiener rabbit (3 animals)	Occlusive, applied to intact and damaged skin	Not specified, the test substance was given as a 50% aqueous preparation.	8 day observation period	Not irritating	None reported	(BASF, 1978d, 1975e)	Medium Medium
	OECD- 404; Skin irritation: in vivo	Weiber Wiener rabbit	Occlusive, applied to intact skin	Not specified, the test substance was given as a 50% aqueous preparation.	20 hour exposure, 8 day observation period	Not irritating	None reported	(Rupprich and Weigand, 1984a)	High
Eye irritation	OECD-405; Eye irritation / Corrosion	Weiber Wiener Rabbit (3 animals)	Single application	The substance was applied undiluted: 100 µl test material	72 hour observation period	Not irritating	None reported	(BASF, 1975c) (BASF, 1978e)	High High
	OECD-405; Eye irritation / Corrosion	Weiber Wiener Rabbit (2 animals)	The test substance was applied to the conjunctival sac of one eye in 2 animals	Single concentration: 50 µL	8-day observation period	Not irritating	None reported	(Rupprich and Weigand, 1984b)	High

Target Organ/ System	Study Type (year)	Species, Strain, Sex (Number/ group)[1]	Exposure Route	Doses/ Concentrations	Duration[2]	Endpoint	Effect[3]	Affiliated Reference[4]	Data Quality Evaluation results of full study report[5]
Skin sensitization	OECD-429; Skin sensitization: mouse local lymphocyte assay (LLNA)	Male CBA/Ca mouse (2 animals/ conc.)	The test substance in propylene glycol was applied, using a variable volume micro-pipette, to the dorsal surface of each ear	The test substance was applied as 3%, 10% or 30% w/v preparations in propylene glycol	3- day repeat exposure	Not irritating	None reported	(Johnson, 1999)	High
Genotoxicity	OECD-471; Genotoxicity – gene mutation (*in vitro*)	*Salmonella typhimurium* TA 100, TA 1535, TA 1537, TA 1538, TA 98 and *E. coli* WP2uvrA	In agar (plate incorporation)	4, 20, 100, 500, 2500 and 5000 µg/plate	Exposure duration: 48-72 hours at 37°C in the dark	Negative	The test compound proved to be not toxic.	(Jung and Weigand, 1983)	High
	OECD-476; Genotoxicity – gene mutation (*in vitro*)	Chinese hamster lung fibroblasts (V79) Target gene: HPRT	In-medium	Without metabolic activation system (S9 mix): 10.8; 21.5; 43.0; 86.0; 172.0; 344.0 µg/ml With S9 mix: 5.6; 10.8; 21.5; 43.0; 86.0; 172.0 µg/ml	7 days after treatment	Negative	The test item did not induce gene mutations at the HPRT locus in V79 cells.	(Wollny, 2012)	High

[1]Species/strain, sex of animals included in the study.
[2]Acute exposures defined as those occurring within a single day. Chronic exposures defined as 10 percent or more of a lifetime (U.S. EPA, 2011).
[3]The effect(s) listed were the most sensitive effects observed for that target organ/system in that study (i.e., the effect(s) upon which the POD was based).
[4]This column lists the primary reference of the full study report corresponding to the ECHA summary.
[5]Information included in this column is the overall quality level resulting from the data quality evaluation – this also would include unacceptable studies for comparison with acceptable studies. Note that in addition to the final result for the study/endpoint, selected important quality considerations could also be included, such as low purity etc.
[6] Effects observed were parental mortality, body weight, food consumption, macroscopic findings, organ weights (evaluated in males only), histopathology, spermatogenesis, mating or fertility indices, pre-coital interval, gestation index or length, number of implantation sites, postimplantation loss, live birth index, numbers of delivered pups, liveborn pups, and stillborn pups, pup viability index, pup sex ratio, pup clinical signs, pup body weights, or pup necropsy