United States
Environmental Protection Agency

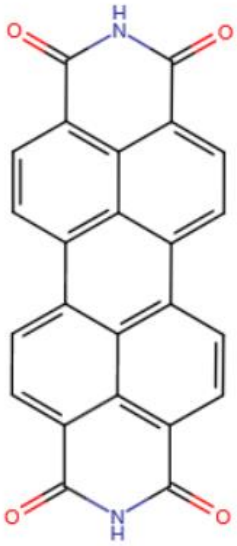
Office of Chemical Safety and
Pollution Prevention

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

Systematic Review Supplemental File:

Data Quality Evaluation of Environmental Release and Occupational Exposure Data

CASRN: 81-33-4



January 2021

This document is a compilation of tables for the data extraction and evaluation for PV-29. Each table shows the data point or set or information element that was extracted and evaluated from a data source in accordance with Appendix D of the Application of Systematic Review in TSCA Risk Evaluations. If the source contains more than one data set or information element, the review provides an overall confidence score for each data set or information element that is found in the source. Therefore, it is possible that a source may have more than one overall quality/confidence score.

Table of Contents

Explanatory Notes

These explanatory notes provide context to understand the short comments in the data evaluation tables.

Domain	Metric	Description of Comments Field
Reliability	Methodology	Indicates the sampling/analytical methodology, estimation method, or type of publication
Representativeness	Geographic Scope	Indicates the country of the study, publication, or underlying data
	Applicability	Indicates whether the data are for a condition of use within scope of the Risk Evaluation
	Temporal Representativeness	Provides the year of study, publication, or underlying data
	Sample Size	Describes the distribution of the sample or underlying data
Accessibility / Clarity	Metadata Completeness	Describes the completeness of the metadata
Variability and Uncertainty	Metadata Completeness	Indicates if study or publication addresses variability and uncertainty of the data or information

Releases to the Environment

Source Citation:	Sun Chemical. 2020. Environmental Release, occupational exposure and particle size of PV 29- Sun Chemical"s response".
Type of Data Source	Releases to the Environment; Environmental Release Data;
Hero ID	6662866

EXTRACTION

Parameter	Data
Life Cycle Stage:	Manufacturing
Life Cycle Description (Subcategory of Use):	Manufacturing
Release Source:	Violet 29 production
Disposal /Treatment Method:	WWTP
Environmental Media:	sludge
Daily Release Quantity (kg/day):	0.77 lb PV29/day to river, 21 lb/day to landfill
Annual Release Quantity (kg/yr):	7200 lbs PV29/yr to landfill from WWTP sludge, 300 lb/yr to river
Release Days per Year:	365.0
Number of Sites:	1.0
Waste Treatment Method:	WWTP

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	Medium	× 1	2	Data from Source, but no QA/QC or documentation
Domain 2: Representative						
	Metric 2:	Geographic Scope	High	× 1	1	US Facility data
	Metric 3:	Applicability	High	× 2	2	Data from applicable facility
	Metric 4:	Temporal Representativeness	High	× 2	2	2016.0
	Metric 5:	Sample Size	N/A		N/A	Not applicable; releases calculated as annual total and normalized by number of operating days; no samples taken
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	Medium	× 1	2	Metadata include most critical metadata: wastewater discharges with estimates of discharge frequency and treatment effectiveness; no information on specific activities or operations that generate wastewater
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Low	× 1	3	Not discussed

Continued on next page

– **continued from previous page**

Source Citation:	Sun Chemical. 2020. Environmental Release, occupational exposure and particle size of PV 29- Sun Chemical"s response".
Type of Data Source	Releases to the Environment; Environmental Release Data;
Hero ID	6662866

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments
	Overall Quality Determination†	High		1.5	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Occupational Exposure

Source Citation:	Mott, R. C.. 2017. Personal communication between Dr. Robert C. Mott (Sun Chemical Corporation) and Alie Muneer (EPA) regarding exposure questions.
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	4081896

EXTRACTION

Parameter	**Data**
Life Cycle Stage:	Manufacture
Life Cycle Description (Subcategory of Use):	Manufacture
Physical Form:	Dust
Route of Exposure:	inhalation
Exposure Concentration (Unit):	0.5 mg/m3 ("inhalation testing has shown exposure was 0.5mg/m3 over an 12 hour work shift.")
Number of Samples:	Not specified
Number of Sites:	1.0
Type of Measurement or Method:	Not specified
Worker Activity:	Not specified. Exposure concentration listed "over an 12 hour shift"
Number of Workers:	not specified
Type of Sampling:	Not specified
Sampling Location:	Not specified
Exposure Duration:	12 hours
Exposure Frequency:	Not specified
Bulk and Dust Particle Size Distribution:	Not specified
Engineering Control & percent Exposure Reduction:	Not specified
PPE:	not specified (for inhalation exposure - long sleeves and gloves for dermal)
Analytic Method:	Not specified

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments
Domain 1: Reliability					
	Metric 1: Methodology	Low	× 1	3	No discussion of sampling methodology provided. Only statement that "inhalation testing has shown 0.5 mg/m3 over an 12 hour work shift."
Domain 2: Representative					

Continued on next page

– continued from previous page

Source Citation:	Mott, R. C.. 2017. Personal communication between Dr. Robert C. Mott (Sun Chemical Corporation) and Alie Muneer (EPA) regarding exposure questions.
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	4081896

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
	Metric 2:	Geographic Scope	High	× 1	1	Source is the only known U.S. manufacturing facility
	Metric 3:	Applicability	High	× 2	2	Manufacturing is in scope.
	Metric 4:	Temporal Representativeness	High	× 2	2	2017; less than 10 years old
	Metric 5:	Sample Size	Low	× 1	3	Individual samples not provided and no characterization of sample distribution is provided.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	Low	× 1	3	Reference only states that measurements were of "inhalation testing", interpreted as breathing zone measurements. No other metadata provided.
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Low	× 1	3	No discussion of variability or uncertainty
Overall Quality Determination†			Medium		1.9	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	Sun Chemicals. 2020. Enclosure 1 - EPA request for additional information in response to SACC peer reveiwer and including public comments on the draft C.I. Pigment Violet 20 Risk Evaluation".
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	6656737

EXTRACTION

Parameter	Data
Life Cycle Stage:	Manufacture
Life Cycle Description (Subcategory of Use):	Manufacture
Physical Form:	Dust
Route of Exposure:	inhalation
Exposure Concentration (Unit):	Range: 0.22 mg/m3-1.2 mg/m3
Number of Samples:	5
Number of Sites:	1.0
Type of Measurement or Method:	Sample collection and analysis was performed in accordance with the National Institute for Occupational Safety and Health (NIOSH) Manual of Analytical Methods (NMAM) and OSHA Analytical Methods. Samples were submitted to an AIHA accredited laboratory. Personal samples for total dust were collected utilizing pre-weighed PVC cassettes. The samples were collected by utilizing a battery powered personal pump calibrated before and after use with a TSI 4100 primary calibrator.
Worker Activity:	Charging big bags to the blenders on elevation 70, Packing-out on level 14
Number of Workers:	4
Type of Sampling:	PBZ
Sampling Location:	Elevation 70 blender, miscellaneous places in building 82
Exposure Duration:	12 hours
Exposure Frequency:	Not specified
Bulk and Dust Particle Size Distribution:	Not specified
Engineering Control & percent Exposure Reduction:	Not specified
PPE:	Safety Glasses, Nitrile Gloves, Tyvek Coveralls, 3M 8511 Paper Dust Mask (95 percent efficiency) as specified in the detailed work instructions. Minimum PPE requirements for site-wide production areas include long-sleeve shirt, long-pants, steeled-toed safety shoes, safety glasses, and hard hat.
Analytic Method:	NIOSH 0500 method with working range between 1 to 20 mg/m3 for a 100L air sample

Continued on next page

– continued from previous page

Source Citation:	Sun Chemicals. 2020. Enclosure 1 - EPA request for additional information in response to SACC peer reveiwer and including public comments on the draft C.I. Pigment Violet 20 Risk Evaluation".
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	6656737

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments
Domain 1: Reliability					
	Metric 1: Methodology	Low	× 1	3	NIOSH method 500 was used but lacks the study detail.
Domain 2: Representative					
	Metric 2: Geographic Scope	High	× 1	1	Source is the only known U.S. manufacturing facility
	Metric 3: Applicability	High	× 2	2	Manufacturing is in scope.
	Metric 4: Temporal Representativeness	High	× 2	2	IH survey conducted in 2014; less than 10 years old
	Metric 5: Sample Size	High	× 1	1	Individual sample results provided; distribution can be fully characterized
Domain 3: Accessibility/Clarity					
	Metric 6: Metadata Completeness	High	× 1	1	Metadata include: samples are PBZ, 12-hr durations, and worker descriptions provided.
Domain 4: Variability and Uncertainty					
	Metric 7: Metadata Completeness	Medium	× 1	2	Uncertainty specified by NIOSH method; variability not addressed
Overall Quality Determination†		High		1.3	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	The EI Group Inc.. 2020. Industrial Hygiene Survey - Sun Chemical Corporation.
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	6656714

EXTRACTION

Parameter	Data
Life Cycle Stage:	Manufacture
Life Cycle Description (Subcategory of Use):	Manufacture
Physical Form:	Fine Dust, Crystalized solid
Route of Exposure:	inhalation
Exposure Concentration (Unit):	Below detection limit, Concentrations range from <0.65 - <1.15 (mg/m3)
Number of Samples:	10 SEG1 worker samples, 2 replicate, 2 blanks [Proposed 10 SEG1 worker samples]
Number of Sites:	1.0
Type of Measurement or Method:	Personal breathing samples at 2.0 L/min to calculate full-shift TWA
Worker Activity:	SEG1: spray dryer pack-out operators;SEG2: PV-29 bag transfer to IPCs for salt grinding operators;SEG3: tray dryer unloading operators and 3 employees working adjacent process tasks (loading wet press cake from super sacks onto drying trays/racks and into dryers);SEG4: G&B charging operators;SEG5: G&B pack-uot operators and adjacent worker moving boxed, closed super sacks;
Number of Workers:	16
Type of Sampling:	PBZ
Sampling Location:	SEG1: B9-2SEG2: C802 (Elevation 40)SEG3: Buildings B11-1 and B11-2 (open areas)SEG4: Building B11-1, 3rd floorSEG5: Buildings B11-1 and B11-2
Exposure Duration:	Range: 30-124 minutes
Exposure Frequency:	Not specified
Bulk and Dust Particle Size Distribution:	10 ”m to 0.043 ”m
Engineering Control & percent Exposure Reduction:	SEG1 & SEG3: No engineering controls, general dilution ventilation from fans and open bay doors;SEG2: Not specified;SEG4 & SEG5: Local exhaust ventilation system (LEV), baghouse
PPE:	’All SEG1-SEG5 and adjacent workers used tyvek coveralls, hard hats, safety glasses, nitrile gloves.SEG1 & SEG 3 also wore half-mask negative pressure air purifying respirators with N95 filters.
Analytic Method:	NIOSH 0600

Continued on next page

– continued from previous page

Source Citation:	The EI Group Inc.. 2020. Industrial Hygiene Survey - Sun Chemical Corporation.
Type of Data Source	Occupational Exposure; Monitoring Data;
Hero ID	6656714

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments

EVALUATION

Domain	Metric	Rating	MWF*	Score	Comments
Domain 1: Reliability					
	Metric 1: Methodology	Low	× 1	3	Study was conducted with a NIOSH method with approved modification but short sampling durations and low pump flow rate resulted in non-detect for most of the samples.
Domain 2: Representative					
	Metric 2: Geographic Scope	High	× 1	1	Source is the only known U.S. manufacturing facility
	Metric 3: Applicability	High	× 2	2	Manufacturing is in scope.
	Metric 4: Temporal Representativeness	High	× 2	2	Surveys conducted April-May 2020; less than 10 years old
	Metric 5: Sample Size	High	× 1	1	Individual sample results provided; distribution can be fully characterized
Domain 3: Accessibility/Clarity					
	Metric 6: Metadata Completeness	Low	× 1	3	Samples are PBZ, however, full shift is 10.5 hour but all measurements are 30 to 40 min.
Domain 4: Variability and Uncertainty					
	Metric 7: Metadata Completeness	High	× 1	1	Some variability discussion in Monitoring Sampling description; measurement uncertainty specified by analytical method
Overall Quality Determination†		High		1.4	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Facility

Source Citation:	Sun, Chemical. 2017. Safety Data Sheet: PERRINDO" Violet 29.
Type of Data Source	Facility; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	4121202

EXTRACTION

Parameter	**Data**
Life Cycle Stage:	Industrial/commercial/consumer use
Life Cycle Description (Subcategory of Use):	Merchant ink
Possible Physical Form:	Powder
Chemical Concentration:	90-95 percent

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Manufacturer Documentation
Domain 2: Representative						
	Metric 2:	Geographic Scope	High	× 1	1	US based manufacturer
	Metric 3:	Applicability	High	× 2	2	Physical characteristics of PV-29 applicable to scope
	Metric 4:	Temporal Representativeness	High	× 2	2	SDS dated 2017; less than 10 years old
	Metric 5:	Sample Size	N/A		N/A	No Comment.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	High	× 1	1	All concentration metadata provided
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Medium	× 1	2	Concentration provided as range; range addresses either the variability or uncertainty of concentration
Overall Quality Determination†			High		1.1	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	TCI America. 2017. Safety Data Sheet: 3,4,9,10-Perylenetetracarboxylic Diimide.
Type of Data Source	Facility; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	6571256

EXTRACTION

Parameter	**Data**
Life Cycle Stage:	Industrial/commercial/consumer use
Life Cycle Description (Subcategory of Use):	Laboratory Chemicals
Possible Physical Form:	Crystal-Powder
Chemical Concentration:	>95 percent

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Manufacturer Documentation
Domain 2: Representative						
	Metric 2:	Geographic Scope	High	× 1	1	US based manufacturer
	Metric 3:	Applicability	High	× 2	2	Physical characteristics of PV-29 applicable to scope
	Metric 4:	Temporal Representativeness	High	× 2	2	SDS dated 2017; less than 10 years old
	Metric 5:	Sample Size	N/A		N/A	No Comment.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	High	× 1	1	All concentration metadata provided
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Medium	× 1	2	Concentration provided as range; range addresses either the variability or uncertainty of concentration
Overall Quality Determination†			High		1.1	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	Sun, Chemical. 2017. Safety Data Sheet: Violet 29.
Type of Data Source	Facility; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	4121201

EXTRACTION

Parameter	Data
Life Cycle Stage:	Industrial/commercial/consumer use
Life Cycle Description (Subcategory of Use):	Coatings and basecoats, Merchant ink, Professional quality watercolor and acrylic artist paint
Possible Physical Form:	Solid
Chemical Concentration:	100 percent

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Manufacturer Documentation
Domain 2: Representative						
	Metric 2:	Geographic Scope	High	× 1	1	US based manufacturer
	Metric 3:	Applicability	High	× 2	2	Physical characteristics of PV-29 applicable to scope
	Metric 4:	Temporal Representativeness	High	× 2	2	SDS dated 2017; less than 10 years old
	Metric 5:	Sample Size	N/A		N/A	No Comment.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	High	× 1	1	All concentration metadata provided
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Low	× 1	3	No discussion of uncertainty or variability
Overall Quality Determination†			High		1.3	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	BASF. 2011. (NMP).
Type of Data Source	Facility; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	6656682

EXTRACTION

Parameter	Data
Life Cycle Stage:	Manufacture
Life Cycle Description (Subcategory of Use):	Manufacture
Process Description:	Bulk PV-29 Particle Size Distribution testing:<100 um=64.6 percent , <10 um=18.5 percent , <4 um=5.1 percent
Possible Physical Form:	Solid
Chemical Concentration:	%98-99 percent

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Certified analytical results
Domain 2: Representative						
	Metric 2:	Geographic Scope	Medium	× 1	2	Analysis of German-produced PV-29
	Metric 3:	Applicability	High	× 2	2	Physical characteristics of PV-29 applicable to scope
	Metric 4:	Temporal Representativeness	High	× 2	2	Particle size distribution test conducted in 2011; <10 years old
	Metric 5:	Sample Size	N/A		N/A	No Comment.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	High	× 1	1	All concentration and particle size distribution metadata provided
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Medium	× 1	2	Concentration provided as range; range addresses either the variability or uncertainty of concentration. Particle size distribution provided, which addresses variability
Overall Quality Determination†			High		1.3	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.

Source Citation:	Sun Chemical & U.S. EPA. 2020. PV-29 Particle size and EPA"s follow up questions- Sun Chemical"s response".
Type of Data Source	Facility; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	6662857

EXTRACTION

Parameter	**Data**
Life Cycle Stage:	Manufacture
Life Cycle Description (Subcategory of Use):	Manufacture
Process Description:	Mean weight Diameter= 53 nmMedian weight Diameter= 43 nm'Mean Diameter= 20 micronsMedian Diameter= 10.4 microns
Number of Sites:	1.0
Possible Physical Form:	Solid

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Manufacturer Documentation
Domain 2: Representative						
	Metric 2:	Geographic Scope	High	× 1	1	US based manufacturer
	Metric 3:	Applicability	High	× 2	2	Physical characteristics of PV-29 applicable to scope
	Metric 4:	Temporal Representativeness	Medium	× 2	4	Unknown date, though associated data shows date stamp suggesting >10 years
	Metric 5:	Sample Size	Medium	× 1	2	Characterized by a range with uncertain statistics
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	Medium	× 1	2	Some metadata included
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Low	× 1	3	No discussion, though some variability provided by statistics, but uncertainty not discussed
Overall Quality Determination†			Medium		1.7	

* MWF = Metric Weighting Factor

† If any individual metrics are deemed Unacceptable, then the overall rating is also unacceptable. Otherwise, the overall rating is based on the following scale: High: ≥ 1 to < 1.7; Medium: ≥ 1.7 to < 2.3; Low: ≥ 2.3 to ≤ 3.