United States
Environmental Protection Agency

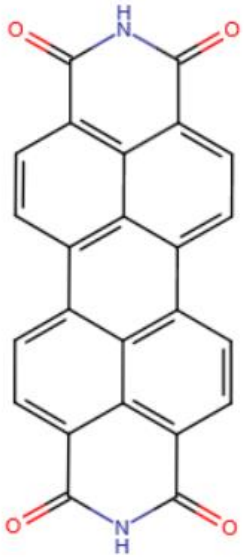
Office of Chemical Safety and
Pollution Prevention

Revised 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)

Systematic Review Supplemental File:

Data Quality Evaluation of Environmental Hazard Studies

CASRN: 81-33-4



October 2020

This document is a compilation of tables for the data extraction and evaluation for C.I. Pigment Violet 29 (CASRN 81-33-4). 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* U.S. EPA (2018). 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.

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Table 1. Fish Acute Toxicity Study with C.I. Pigment Violet 29, BASF (1988)

Study Reference:	BASF. 1988. Testing the acute toxicity in the fish model Zebra danio (*Brachydanio rerio*) over the course of 96 hours. Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. HERO ID: 4731539					
Note:	Conducted according to the OECD 203 Test Guideline (1984)					
Domain	**Metric**	**Qualitative Determination [*i.e.*, High, Medium, Low, Unacceptable, or Not rated]**	**Comments**	**Metric Score**	**Metric Weighting Factor**	**Weighted Score**
Test Substance	1. Test substance identity	High	Test substance was reported as perylimid, which is an European name for PV 29.	1	2	2
	2. Test substance source	Medium	Test substance source was not indicated. See note at the bottom of the table.	2	1	2
	3.Test substance purity	High	Purity was reported as > 95%.	1	1	1
Test setup	4. Negative controls	High[A]		1	2	2
	5. Negative control response	High	No mortality was reported in the controls.	1	1	1
	6. Randomized allocation	High	Section 4.7 indicated that individuals were randomly allocated among the test vessels.	1	1	1
Exposure characterization	7. Experimental System/Test Media Preparation	High[A]		1	2	2
	8. Consistency of Exposure administration	High[A]		1	1	1
	9. Exposure Duration and Frequency	High[A]		1	2	2
	10. Measurement of Test Substance Concentration	Medium	Test concentration was reported in terms of nominal test concentration and was not	2	1	2

Study Reference:	BASF. 1988. Testing the acute toxicity in the fish model Zebra danio (*Brachydanio rerio*) over the course of 96 hours. Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. HERO ID: 4731539					
			measured. This study was a limit test and the nominal concentration was far above the limit of solubility.			
	11. Number of exposure groups and dose spacing	High	This study was a limit test with one test concentration.	1	1	1
	12. Testing at or Below Solubility Limit	Medium	This study was conducted as a limit test. There was undissolved test material reported in the test vessel. The reported test material solubility was 670 mg/L. This was far higher than the 0.010 mg/L solubility limit the ECHA Database reported.	2	1	2
Test organisms	13. Test organism characteristics	High	Test organism description was available in Section 4.2 of the study.	1	2	2
	14. Acclimatization and Pretreatment Conditions	High	There was a 14-day conditioning period.	1	1	1
	15. Number of Organisms and Replicates per group	High	There were 10 fish/group.	1	1	1
	16. Adequacy of Housing Conditions	High	Aquaria size: 10 litres consisted of glass (length 30 cm, width 22 cm, height 24 cm) and stood in a water bath made from Hostalit ZR with a	1	1	1

Study Reference:	BASF. 1988. Testing the acute toxicity in the fish model Zebra danio (*Brachydanio rerio*) over the course of 96 hours. Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. HERO ID: 4731539					
			Plexiglas viewing window.			
Outcome Assessment	17. Outcome assessment methodology	Medium	Mortality was quantified, but discoloration of the test vessels prevented the observation of sublethal effects.	2	2	4
	18. Consistency of outcome assessment	High	The outcome assessment protocols and results were consistently reported for all test concentrations.	1	1	1
Confounding/ variable control	19. Confounding variables in test setup and procedures	High	There were no reported confounding variables in the experiments that could influence the outcome assessment.	1	2	2
	20. Outcomes unrelated to exposure	High	There were no reported differences among the test groups that could influence the outcome assessment.	1	1	1
Data presentation and analysis	21. Statistical methods	Not Rated	Given that no effects were observed for the one test concentration used in the experiment, no statistics were necessary.	NR	NR	NR
	22. Reporting of data	Medium	Mortality was quantified, but discoloration of the test vessels prevented the observation of sublethal effects.	2	2	4

Study Reference:	BASF. 1988. Testing the acute toxicity in the fish model Zebra danio (*Brachydanio rerio*) over the course of 96 hours. Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. HERO ID: 4731539					
	23. Explanation of Unexpected Outcomes	Not Rated	There were no unexplained outcomes and no effects observed up to the highest test concentration.	NR	NR	NR
			Sum of scores:	26	29	36
High	Medium	Low	**Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:**	1.241	**Overall Score (Rounded):**	1.2
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3			**Overall Quality Level:**	High
Footnote A: This metric met the criteria for high confidence as expected for this type of study.						

Table 2. Aquatic Plant with C.I. Pigment Violet 29, BASF (2012b)

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, *Lemna gibba* L. CPCC 310 Growth Inhibition Test according to OECD Guideline No. 221. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: October 2012), Pszczyna, Poland. HERO ID: 4731540					
Note:	Conducted according to OECD TG 221 (2006)					
Domain	**Metric**	**Qualitative Determination [*i.e.*, High, Medium, Low, Unacceptable, or Not rated]**	**Comments**	**Metric Score**	**Metric Weighting Factor**	**Weighted Score**
Test Substance	1. Test substance identity	High	Test substance was reported as Paliogen Violet 5011, which shares the same chemical name with PV29.	1	2	2
	2. Test substance source	High	Test material was provided by the study sponsor and reported.	1	1	1
	3.Test substance purity	Medium	Although the test substance purity was not reported in the study, the test concentrations were adequately quantified throughout the test.	2	1	2
Test setup	4. Negative controls	High[A]		1	2	2
	5. Negative control response	High	No effects were seen in the negative controls.	1	1	1
	6. Randomized allocation	High	Study report mentioned that replicates were arranged at random and rearranged repeatedly.	1	1	1
Exposure characterization	7. Experimental System/Test Media Preparation	High[A]		1	2	2
	8. Consistency of Exposure administration	High[A]		1	1	1

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, *Lemna gibba* L. CPCC 310 Growth Inhibition Test according to OECD Guideline No. 221. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: October 2012), Pszczyna, Poland. HERO ID: 4731540					
	9. Exposure Duration and Frequency	High[A]		1	2	2
	10. Measurement of Test Substance Concentration	High	Measured concentrations of all test concentrations reported.	1	1	1
	11. Number of exposure groups and dose spacing	High[A]		1	1	1
	12. Testing at or Below Solubility Limit	High	Study authors conducted the experiments above the solubility limit with no solvent and quantified the test concentrations.	1	1	1
Test organisms	13. Test organism characteristics	High	Test organism was *Lemna gibba* obtained from a laboratory.	1	2	2
	14. Acclimatization and Pretreatment Conditions	Medium	Although details about the acclimatization and pretreatment conditions were not reported, this is unlikely to affect the study results.	2	1	2
	15. Number of Organisms and Replicates per group	High[A]		1	1	1
	16. Adequacy of Housing Conditions	High[A]		1	1	1
Outcome Assessment	17. Outcome assessment methodology	High[A]		1	2	2
	18. Consistency of outcome assessment	High[A]		1	1	1

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, *Lemna gibba* L. CPCC 310 Growth Inhibition Test according to OECD Guideline No. 221. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: October 2012), Pszczyna, Poland. HERO ID: 4731540					
Confounding/ variable control	19. Confounding variables in test setup and procedures	High[A]		1	2	2
	20. Outcomes unrelated to exposure	Not Rated	No unexpected outcomes were reported.	NR	NR	NR
Data presentation and analysis	21. Statistical methods	High	Probit analysis was used to calculate slope of the dose response.	1	1	1
	22. Reporting of data	High[A]		1	2	2
	23. Explanation of Unexpected Outcomes	Not Rated	No unexplained outcomes were reported.	NR	NR	NR
			Sum of scores:	23	29	31
High	Medium	Low	**Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:**	1.069	**Overall Score (Rounded):**	1.0
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3			**Overall Quality Level:**	High
Footnote A: This metric met the criteria for high confidence as expected for this type of study.						

Table 3. Acute Aquatic Invertebrate Study with C.I. Pigment Violet 29, BASF (2012a)

Study Reference:	**BASF (2012). H-28548: Paliogen Violet 5011, *Daphnia magna,* Acute immobilization test. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May 2012), Pszczyna, Poland. HERO ID: 4731541**					
Note:	Conducted according to the OECD 202 Test Guideline (2004)					
Domain	**Metric**	**Qualitative Determination [*i.e.*, High, Medium, Low, Unacceptable, or Not rated]**	**Comments**	**Metric Score**	**Metric Weighting Factor**	**Weighted Score**
Test Substance	1. Test substance identity	High	Pages 37 and 46 indicated Paliogen Violet, the reported test substance, is comprised of PV 29 as indicated by the CASRN.	1	2	2
	2. Test substance source	High	Pages 37 and 46 indicated test material was sourced from the manufacturer.	1	1	1
	3.Test substance purity	Medium	Study report indicated that the Test material is PV 29, but does not specify the chemical purity. The test concentration of the definitive test was analytically verified by mass spectroscopy	2	1	2
Test setup	4. Negative controls	High	Negative controls and reference test were used.	1	2	2
	5. Negative control response	High	No immobilization/ mortality was observed.	1	1	1
	6. Randomized allocation	Low	There was only one test concentration, but it was not mentioned whether individuals were randomly allocated.	3	1	3
Exposure characterization	7. Experimental System/Test Media Preparation	High[A]		1	2	2

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, *Daphnia magna,* Acute immobilization test. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May 2012), Pszczyna, Poland. HERO ID: 4731541					
	8. Consistency of Exposure administration	High	Conducted as a limit test, concentrations were measured at start and termination of the test to quantify degradation.	1	1	1
	9. Exposure Duration and Frequency	High[A]		1	2	2
	10. Measurement of Test Substance Concentration	High[A]		1	1	1
	11. Number of exposure groups and dose spacing	High	Test was conducted as a limit test based on results of range-finding test.	1	1	1
	12. Testing at or Below Solubility Limit	High	Test was conducted as a limit test based on results of range-finding test. As a result, test was conducted as a limit test and test concentrations were analytically confirmed to match the reported limit of solubility for the test material.	1	1	1
Test organisms	13. Test organism characteristics	High[A]		1	2	2
	14. Acclimatization and Pretreatment Conditions	High[A]		1	1	1
	15. Number of Organisms and Replicates per group	High[A]		1	1	1
	16. Adequacy of Housing Conditions	High[A]		1	1	1
Outcome Assessment	17. Outcome assessment methodology	High[A]		1	2	2

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, *Daphnia magna,* Acute immobilization test. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May 2012), Pszczyna, Poland. HERO ID: 4731541					
	18. Consistency of outcome assessment	High[A]		1	1	1
Confounding/ variable control	19. Confounding variables in test setup and procedures	High	There were no reported confounding variables in the experiments that could influence the outcome assessment.	1	2	2
	20. Outcomes unrelated to exposure	High	There were no reported differences among the test groups that could influence the outcome assessment.	1	1	1
Data presentation and analysis	21. Statistical methods	Not Rated	No statistics necessary because the test was conducted as a limit test.	NR	NR	NR
	22. Reporting of data	High [A]		1	2	2
	23. Explanation of Unexpected Outcomes	Not Rated	No unexplained outcomes and no effects were observed up to the highest test concentration.	NR	NR	NR
			Sum of scores:	24	29	32
High	Medium	Low	**Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:**	1.103	**Overall Score (Rounded):**	1.1
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3			**Overall Quality Level:**	High
Footnote A: This metric met the criteria for high confidence as expected for this type of study.						

References

BASF. (1988). Testing the acute toxicity in the fish model Zebra danio (brachydanio rerio) over the course of 96 hours. Germany: Hoechst AG, Pharma Research Toxicology and Pathology.

BASF. (2012a). H-28548: Paliogen violet 5011, Daphnia magna, acute immobilization test. Pszczyna, Poland: Institute of Industrial Organic Chemistry, Branch Pszcyna Department of Ecotoxicology.

BASF. (2012b). H-28548: Paliogen violet 5011, Lemna gibba L., CPCC 310 growth inhibition test according to OECD guideline No. 221. Pszczyna, Poland: Institute of Industrial Organic Chemistry, Branch Pszcyna Department of Ecotoxicology.

U.S. EPA. (2018). Application of systematic review in TSCA risk evaluations. (740-P1-8001). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.