

**C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the  
TSCA Risk Evaluation**

Data Evaluation Scoring Sheets

<b>Study Reference:</b>	BASF. 2013. Physical-Chemical properties of “Paliogen Violet 5011”. BASF Study No. 11L00105. Competence Center Analytics, BASF SE, D-67056 Ludwigshafen. Test Completion Date: November, 28, 2011.	
<b>Note:</b>	The characteristic evaluated in this form is Log Kow (octanol/water partition coefficient)	
<b>Domain</b>	<b>Description/ Definition</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>
<b>Representativeness</b>	The information or data reflects the data and chemical substance type.	High
<b>Appropriateness</b>	The information or data reflects anticipated results based on chemical structural features or behaviors.	Not Rated
<b>Evaluation/ Review</b>	The information or data reported has reliable review.	Not Rated
<b>Reliability/ Unbiased (Method Objectivity)</b>	The method for producing the data/information is not biased towards a particular product or outcome.	Not Rated
<b>Reliability/ Analytic Method</b>	The information or data reported is from a reliable method.	Unacceptable

<b>Study Reference:</b>	BASF. 2013. Physical-Chemical properties of “Paliogen Violet 5011”. BASF Study No. 11L00105. Competence Center Analytics, BASF SE, D-67056 Ludwigshafen. Test Completion Date: November, 28, 2011.	
<b>Note:</b>	The characteristic evaluated in this form is melting point	
<b>Domain</b>	<b>Description/ Definition</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>
<b>Representativeness</b>	The information or data reflects the data and chemical substance type.	High
<b>Appropriateness</b>	The information or data reflects anticipated results based on chemical structural features or behaviors.	High
<b>Evaluation/ Review</b>	The information or data reported has reliable review.	Medium
<b>Reliability/ Unbiased (Method Objectivity)</b>	The method for producing the data/information is not biased towards a particular product or outcome.	High
<b>Reliability/ Analytic Method</b>	The information or data reported is from a reliable method.	High

Study Reference:	BASF. 1999. Determination of the Biodegradability of Perylimid F in the Manometric Respirometry Test according to GLP, EN 45001 and ISO 9002. Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (Study Completion Date: July, 1999).					
Domain	Metric	Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]	Metric Score	Metric Weighting Factor	Weighted Score (Metric Score x Metric Wt. Factor) <sup>1</sup>	
Test Substance	1. Test Substance Identity	High	1	2	2	
	2. Test Substance Purity	High	1	1	1	
Test Design	3. Study Controls	High	1	2	2	
	4. Test Substance Stability	High	1	1	1	
Test Conditions	5. Test Method Suitability	High	1	1	1	
	6. Testing Conditions	High	1	2	2	
	7. Testing Consistency	High	1	1	1	
	8. System Type and Design	N/A	N/A	N/A	N/A	
Test Organisms	9. Test Organism - Degradation	High	1	2	2	
	10. Test Organism - Partitioning	N/A	N/A	N/A	N/A	
Outcome Assessment	11. Outcome Assessment Methodology	High	1	1	1	
	12. Sampling Methods	High	1	1	1	
Confounding/ Variable Control	13. Confounding Variables	Medium	2	1	2	
	14. Outcomes Unrelated to Exposure	Medium	2	1	2	
Data Presentation and Analysis	15. Data Reporting	High	1	2	2	
	16. Statistical Methods & Kinetic Calculations	Medium	2	1	2	
Other	17. Verification or Plausibility of Results	High	1	1	1	
	18. Other	High	1	1	1	
	18. QSAR Models	N/A	N/A	N/A	N/A	
Sum of scores:			19	21	24	
<div><div>High</div><div>Medium</div><div>Low</div></div> <div><div>≥1 and &lt;1.7</div><div>≥1.7 and &lt;2.3</div><div>≥2.3 and ≤3</div></div>			Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.143	Overall Score: (Rounded)	1.1
			Overall Quality Level:		HIGH	

<b>Study Reference:</b>	BASF. 1999. 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. Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (Study Completion Date: March, 1999).				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score (Metric Score x Metric Wt. Factor)<sup>1</sup></b>
<b>Test Substance</b>	1. Test Substance Identity	High	1	2	2
	2. Test Substance Purity	High	1	1	1
<b>Test Design</b>	3. Study Controls	High	1	2	2
	4. Test Substance Stability	High	1	1	1
<b>Test Conditions</b>	5. Test Method Suitability	High	1	1	1
	6. Testing Conditions	High	1	2	2
	7. Testing Consistency	High	1	1	1
	8. System Type and Design	N/A	N/A	N/A	N/A
<b>Test Organisms</b>	9. Test Organism - Degradation	High	1	2	2
	10. Test Organism - Partitioning	N/A	N/A	N/A	N/A
<b>Outcome Assessment</b>	11. Outcome Assessment Methodology	High	1	1	1
	12. Sampling Methods	Medium	2	1	2
<b>Confounding/ Variable Control</b>	13. Confounding Variables	High	1	1	1
	14. Outcomes Unrelated to Exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	15. Data Reporting	High	1	2	2
	16. Statistical Methods & Kinetic Calculations	N/A	N/A	N/A	N/A
<b>Other</b>	17. Verification or Plausibility of Results	High	3	1	3
	18. QSAR Models	N/A	N/A	N/A	N/A
<b>Sum of scores:</b>			17	19	22
<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>			1.158	<b>Overall Score: (Rounded)</b>	1.2
			<b>Overall Quality Level:</b>		<b>High</b>

  

High	Medium	Low
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3

<b>Study Reference:</b>	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.				
Domain	Metric	Score	Metric Score	Metric Weighting Factor	Weighted Score (Metric Score x Metric Wt. Factor)
Test substance	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	Medium	2	1	2
Test setup	4. Negative controls	High	1	2	2
	5. Negative control response	High	1	1	1
	6. Randomized allocation	High	1	1	1
Exposure characterization	7. Experimental System/Test Media Preparation	High	1	2	2
	8. Consistency of exposure administration	High	1	1	1
	9. Exposure Duration and Frequency	High	1	2	2
	10. Measurement of Test Substance Concentration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Testing at or Below Solubility Limit	High	1	1	1
Test organisms	13. Test organism characteristics	High	1	2	2
	14. Acclimatization and Pretreatment Conditions	N/A	N/A	N/A	N/A
	15. Number of Organisms and Replicates per group	High	1	1	1
	16. Adequacy of Housing Conditions	High	1	1	1
Outcome assessment	17. Outcome assessment methodology	High	1	2	2
	18. Consistency of outcome assessment	High	1	1	1
Confounding/variable control	19. Confounding variables in test setup and procedures	High	1	2	2
	20. Outcomes unrelated to exposure	N/A	N/A	N/A	N/A
Data presentation and analysis	21. Statistical methods	High	1	1	1
	22. Reporting of data	High	1	2	2
	23. Explanation of Unexpected Outcomes	N/A	N/A	N/A	N/A
Sum of scores:			21	28	29
Overall Score = Sum of Weighted Scores/Sum of Metric			1.036	Overall Score: (Rounded)	1.0
Overall Quality Level:				HIGH	

High	Medium	Low
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3

Study Reference:	BASF (2012). H-28548: Paliogen Violet 5011, <i>Daphnia magna</i> , Acute immobilization test. Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May, 2012), Pszczyna, Poland.											
Domain	Metric	Score	Metric Score	Metric Weighting Factor	Weighted Score (Metric Score x Metric Wt. Factor)							
Test substance	1. Test substance identity	High	1	2	2							
	2. Test substance source	High	1	1	1							
	3. Test substance purity	Medium	2	1	2							
Test setup	4. Negative controls	High	1	2	2							
	5. Negative control response	High	1	1	1							
	6. Randomized allocation	Low	3	1	3							
Exposure characterization	7. Experimental System/Test Media Preparation	High	1	2	2							
	8. Consistency of exposure administration	High	1	1	1							
	9. Exposure Duration and Frequency	High	1	2	2							
	10. Measurement of Test Substance Concentration	High	1	1	1							
	11. Number of exposure groups and dose spacing	High	1	1	1							
	12. Testing at or Below Solubility Limit	High	1	1	1							
Test organisms	13. Test organism characteristics	High	1	2	2							
	14. Acclimatization and Pretreatment Conditions	High	1	1	1							
	15. Number of Organisms and Replicates per group	High	1	1	1							
	16. Adequacy of Housing Conditions	High	1	1	1							
Outcome assessment	17. Outcome assessment methodology	High	1	2	2							
	18. Consistency of outcome assessment	High	1	1	1							
Confounding/variable control	19. Confounding variables in test setup and procedures	High	1	2	2							
	20. Health outcomes unrelated to exposure	High	1	1	1							
Data presentation and analysis	21. Statistical methods	N/A	N/A	N/A	N/A							
	22. Reporting of data	High	1	2	2							
	23. Explanation of Unexpected Outcomes	N/A	N/A	N/A	N/A							
<table><tr><td>High</td><td>Medium</td><td>Low</td></tr><tr><td>≥1 and &lt;1.7</td><td>≥1.7 and &lt;2.3</td><td>≥2.3 and ≤3</td></tr></table>			High	Medium	Low	≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3	Sum of scores:	24	29	32
			High	Medium	Low							
			≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3							
			Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.103	Overall Score: (Rounded)	1.1						
Overall Quality Level:		HIGH										

<b>Study Reference:</b>	BASF. 1988. Testing the acute toxicity in the fish model Zebra danio ( <i>brachydanio rerio</i> ) over the course of 96 hours. Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany.				
Domain	Metric	Score	Metric Score	Metric Weighting Factor	Weighted Score (Metric Score x Metric Wt. Factor)
<b>Test substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Medium	2	1	2
	3. Test substance purity	Low	3	1	3
<b>Test setup</b>	4. Negative controls	High	1	2	2
	5. Negative control response	High	1	1	1
	6. Randomized allocation	High	1	1	1
<b>Exposure characterization</b>	7. Experimental System/ Test Media Preparation	High	1	2	2
	8. Consistency of exposure administration	High	1	1	1
	9. Exposure Duration and Frequency	High	1	2	2
	10. Measurement of Test Substance Concentration	Medium	2	1	2
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Testing at or Below Solubility Limit	Medium	2	1	2
<b>Test organisms</b>	13. Test organism characteristics	High	1	2	2
	14. Acclimatization and Pretreatment Conditions	High	1	1	1
	15. Number of Organisms and Replicates per group	High	1	1	1
	16. Adequacy of Housing Conditions	High	1	1	1
<b>Outcome assessment</b>	17. Outcome assessment methodology	Medium	2	2	4
	18. Consistency of outcome assessment	High	1	1	1
<b>Confounding/ variable control</b>	19. Confounding variables in test setup and procedures	High	1	2	2
	20. Outcomes unrelated to exposure	High	1	1	1
<b>Data presentation and analysis</b>	21. Statistical methods	N/A	N/A	N/A	N/A
	22. Reporting of data	Medium	2	2	4
	23. Explanation of Unexpected Outcomes	N/A	N/A	N/A	N/A
<b>Sum of scores:</b>			28	29	38
<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>			1.310	<b>Overall Score: (Rounded)</b>	1.3
			<b>Overall Quality Level:</b>		<b>HIGH</b>

<b>High</b>	<b>Medium</b>	<b>Low</b>
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3



<b>Study Reference:</b>	BASF. 1975. Acute oral toxicity with rats. BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland. Report Date: January 31, 2018. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Low	3	1	3
	3. Test substance purity	Low	3	1	3
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
	13. Test animal characteristics	High	1	2	2

Test Organisms	14. Adequacy and onsistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1
Outcome Assessment	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	Medium	2	1	2
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Medium	2	1	2
	20. Negative Control Response	N/A	N/A	N/A	N/A
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	Medium	2	2	4
		Sum of scores:		27	44
<div><div>High</div><div>Medium</div><div>Low</div></div> <div><div>≥1 and &lt;1.7</div><div>≥1.7 and &lt;2.3</div><div>≥2.3 and ≤3</div></div>		Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.630	Overall Score: (Rounded)	1.6
			Overall Quality Level:		High

<b>Study Reference:</b>	BASF. 1978. Study report for CAS 81-33-4, Acute oral toxicity with rats. BASF Report 77/360. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Low	3	2	6
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	Medium	2	1	2
	18. Sampling adequacy	High	1	1	1

	19. Blinding of assessors	Medium	2	1	2
	20. Negative Control Response	N/A	N/A	N/A	N/A
<b>Confounding/ Variable Control</b>	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	23. Statistical methods	High	1	1	1
	24. Reporting of data	Medium	2	2	4
			<b>Sum of scores:</b>	<b>27</b>	<b>44</b>
			<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>	1.630	<b>Overall Score: (Rounded)</b>
					<b>1.6</b>
			<b>Overall Quality Level:</b>		<b>High</b>

<b>Study Reference:</b>	Rupprich, N, Weigand, W. 1984. Testing the acute oral toxicity in the male and female Wistar rat. Hoechst, Pharma Research Toxicology. Report No. 84.0225. Report date: May 2, 1984.				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	Low	3	1	3
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Medium	2	1	2
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Medium	2	2	4
	14. Adequacy and consistency of animal husbandry conditions	High	1	1	1
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1

Assessment	18. Sampling adequacy	High	1	1	1						
	19. Blinding of assessors	Medium	2	1	2						
	20. Negative Control Response	N/A	N/A	N/A	N/A						
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4						
	22. Health outcomes unrelated to exposure	High	1	1	1						
Data Presentation and Analysis	23. Statistical methods	High	1	1	1						
	24. Reporting of data	High	1	2	2						
		Sum of scores:		27	39						
<table><tr><td>High</td><td>Medium</td><td>Low</td></tr><tr><td>≥1 and &lt;1.7</td><td>≥1.7 and &lt;2.3</td><td>≥2.3 and ≤3</td></tr></table>		High	Medium	Low	≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3	Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.444	Overall Score: (Rounded)	1.4
		High	Medium	Low							
		≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3							
	Overall Quality Level:		HIGH								

<b>Study Reference:</b>	BASF. 1975. Acute inhalation toxicity with rats. BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland. Report Date: January 31, 2018. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Low	3	1	3
	3. Test substance purity	Low	3	1	3
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	Low	3	2	6
	10. Exposure frequency and duration	Medium	2	1	2
	11. Number of exposure groups and dose spacing	Medium	2	1	2
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Low	3	2	6
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1
	16. Outcome assessment methodology	High	1	2	2

Outcome Assessment	17. Consistency of outcome assessment	High	1	1	1						
	18. Sampling adequacy	High	1	1	1						
	19. Blinding of assessors	Medium	2	1	2						
	20. Negative Control Response	N/A	N/A	N/A	N/A						
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4						
	22. Health outcomes unrelated to exposure	High	1	1	1						
Data Presentation and Analysis	23. Statistical methods	High	1	1	1						
	24. Reporting of data	Medium	2	2	4						
		Sum of scores:		27	53						
<table><tr><td>High</td><td>Medium</td><td>Low</td></tr><tr><td>≥1 and &lt;1.7</td><td>≥1.7 and &lt;2.3</td><td>≥2.3 and ≤3</td></tr></table>		High	Medium	Low	≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3	Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.963	Overall Score: (Rounded)	2.0
High	Medium	Low									
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3									
			Overall Quality Level:		Medium						



<b>Study Reference:</b>	BASF. 1978. Study report for CAS 81-33-4, Acute inhalation toxicity with rats. BASF Report 77/360. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Note:</b>	Study report indicated that this study was not conducted according to a test guideline				
Domain	Metric	Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]	Metric Score	Metric Weighting Factor	Weighted Score
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	Low	3	2	6
	10. Exposure frequency and duration	Medium	2	1	2
	11. Number of exposure groups and dose spacing	Low	3	1	3
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Low	3	2	6
	14. Adequacy and consistency of animal husbandry conditions	Low	2	1	2
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Medium	2	1	2
	20. Negative Control Response	N/A	N/A	N/A	N/A

<b>Confounding/ Variable Control</b>	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2
<b>Sum of scores:</b>				<b>27</b>	<b>48</b>
<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>			1.778	<b>Overall Score: (Rounded)</b>	<b>1.8</b>
			<b>Overall Quality Level:</b>		<b>Medium</b>

<b>Study Reference:</b>	BASF. 1975. Summary of toxicological investigations with CAS 81-33-4, Acute intraperitoneal toxicity with mice. BASF Report XXV/454. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Low	3	1	3
	3. Test substance purity	Low	3	1	3
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	High	1	2	2
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1

Outcome Assessment	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	Medium	2	1	2
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Medium	2	1	2
	20. Negative Control Response	N/A	N/A	N/A	N/A
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	Medium	2	2	4
		Sum of scores:		27	44
<div><div>High</div><div>Medium</div><div>Low</div></div> <div><div>≥1 and &lt;1.7</div><div>≥1.7 and &lt;2.3</div><div>≥2.3 and ≤3</div></div>		Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.630	Overall Score: (Rounded)	1.6
			Overall Quality Level:		High

<b>Study Reference:</b>	BASF. 1978. Study report for CAS 81-33-4, Acute intraperitoneal toxicity with mice. BASF Report 77/360. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	High	1	2	2
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1
	16. Outcome assessment methodology	High	1	2	2

Outcome Assessment	17. Consistency of outcome assessment	Medium	2	1	2
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Medium	2	1	2
	20. Negative Control Response	N/A	N/A	N/A	N/A
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	Medium	2	2	4
		Sum of scores:		27	40
<div><div>High</div><div>Medium</div><div>Low</div></div> <div><div>≥1 and &lt;1.7</div><div>≥1.7 and &lt;2.3</div><div>≥2.3 and ≤3</div></div>		Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.481	Overall Score: (Rounded)	1.5
			Overall Quality Level:		HIGH

<b>Study Reference:</b>	Stark, D., Treumann, S., van Ravenzwaay, B. 2013. Reproduction/developmental Toxicity Screening Test in Wistar Rats Oral Administration (Gavage). BASF SE, Germany. Project No. 80R0223/11C162. For BASF SE, Germany.				
<b>Note:</b>	Study report indicates the study was conducted according to OECD TG 421 and OPPTS				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	High	1	2	2
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Medium	2	1	2
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	High	1	1	1
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	High	1	2	2
	14. Adequacy and consistency of animal husbandry conditions	High	1	1	1
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	N/A	N/A	N/A	N/A

	20. Negative Control Response	High	1	1	1
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2

			Sum of scores:		29	30
			Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.034	Overall Score: (Rounded):	1
			Overall Quality Level:		HIGH	

High	Medium	Low
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3



<b>Study Reference:</b>	BASF. 1975. Skin irritation study. BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland. Report Date: January 31, 2018. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
Domain	Metric	Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]	Metric Score	Metric Weighting Factor	Weighted Score
Test Substance	1. Test substance identity	High	1	2	2
	2. Test substance source	Low	3	1	3
	3. Test substance purity	Low	3	1	3
Test Setup	4. Negative and Vehicle controls	Medium	2	2	4
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
Exposure Characterization	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	Low	3	2	6
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
Test Organisms	13. Test animal characteristics	Medium	2	2	4
	14. Adequacy and consistency of animal husbandry conditions	Low	2	1	2
	15. Number per group	Low	3	1	3
Outcome Assessment	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Low	3	1	3

	20. Negative Control Response	Medium	2	1	2
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	Low	3	2	6
		Sum of scores:		30	60
		Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	2.000	Overall Score: (Rounded)	2.0
			Overall Quality Level:		Medium

High	Medium	Low
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3

<b>Study Reference:</b>	BASF. 1978. Study report for CAS 81-33-4, Skin irritation study. BASF Report 77/360. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	Medium	2	2	4
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Low	3	1	3
	8. Consistency of exposure administration	Low	3	1	3
	9. Reporting of doses / concentrations	Low	3	2	6
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	High	1	2	2
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	Low	3	1	3
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	Low	3	1	3

	20. Negative Control Response	Medium	2	1	2
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	Medium	2	2	4
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	Low	3	2	6
			Sum of scores:	30	54
<div> <div>High</div> <div>Medium</div> <div>Low</div> </div> <div> <div>≥1 and &lt;1.7</div> <div>≥1.7 and &lt;2.3</div> <div>≥2.3 and ≤3</div> </div>			Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.800	Overall Score: (Rounded) 1.8
			Overall Quality Level:		Medium

<b>Study Reference:</b>	BASF. 1975. Eye Irritation Study. BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland. Report Date: January 31, 2018. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Low	3	1	3
	3. Test substance purity	Low	3	1	3
<b>Test Setup</b>	4. Negative and Vehicle controls	High	1	2	2
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	N/A	N/A	N/A	N/A
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Medium	2	1	2
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	Medium	2	1	2
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Low	3	2	6
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	Low	3	1	3
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	NA	NA	N/A	NA
	20. Negative Control Response	High	1	1	1
<b>Confounding/ Variable Control</b>	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2

			Sum of scores:		28	41
High	Medium	Low	Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.464	Overall Score: (Rounded)	1.5
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3				
Overall Quality Level:					HIGH	

<b>Study Reference:</b>	Rupprich, N., Weigand, W. 1984. Perylimid Testing the acute dermal irritant effects/caustic effects on the rabbit eye. Hoechst Pharma Research Toxicology, Germany. Report No. 84.0228. For Farben Nord, Werk Höchst.				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Medium	2	1	2
	3. Test substance purity	Medium	2	1	2
<b>Test Setup</b>	4. Negative and Vehicle controls	N/A	N/A	N/A	N/A
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	N/A	N/A	N/A	N/A
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	High	1	1	1
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Medium	2	2	4
	14. Adequacy and consistency of animal husbandry conditions	High	1	1	1
	15. Number per group	High	1	1	1
	16. Outcome assessment methodology	High	1	2	2

Outcome Assessment	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	N/A	N/A	N/A	N/A
	20. Negative Control Response	N/A	N/A	N/A	N/A
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2
			Sum of scores:	25	29
<div><div>High</div><div>Medium</div><div>Low</div><div>≥1 and &lt;1.7</div><div>≥1.7 and &lt;2.3</div><div>≥2.3 and ≤3</div></div>			Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.160	Overall Score: (Rounded)  1.2
			Overall Quality Level:		HIGH



<b>Study Reference:</b>	BASF. 1978. Eye Irritation Study. BASF Report 77/360. Product Safety Basel, BASF Schweiz AG, Switzerland. Report Date: January 31, 2018. [as reported in Translated PV29 Tox Summaries, Product Safety Basel, BASF Schweiz AG, Switzerland, January 31, 2018]				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	High	1	2	2
	5. Positive controls	N/A	N/A	N/A	N/A
	6. Randomized allocation	N/A	N/A	N/A	N/A
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Medium	2	1	2
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Low	3	2	6
	14. Adequacy and consistency of animal husbandry conditions	Medium	2	1	2
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1

	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	N/A	N/A	N/A	N/A
	20. Negative Control Response	High	1	1	1
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2
		Sum of scores:		28	34
<div><div>High</div><div>Medium</div><div>Low</div></div>		Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:	1.214	Overall Score: (Rounded)	1.2
≥1 and <1.7	≥1.7 and <2.3				
			Overall Quality Level:		HIGH

<b>Study Reference:</b>	Rupprich, N, Weigand, W. 1984. Perylimid Testing the acute irritant effects/caustic effects on the rabbit eye. Hoechst Pharma Research Toxicology, Germany. Report No. 84.0229. For Farben Nord, Werk Höchst.				
Domain	Metric	Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]	Metric Score	Metric Weighting Factor	Weighted Score
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Medium	2	1	2
	3. Test substance purity	Medium	2	1	2
<b>Test Setup</b>	4. Negative and Vehicle controls	High	1	2	2
	5. Positive controls	N/A	N/A	1	N/A
	6. Randomized allocation	N/A	N/A	1	N/A
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Medium	2	1	2
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Medium	2	2	4
	14. Adequacy and consistency of animal husbandry conditions	High	1	1	1
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	N/A	N/A	N/A	N/A

	20. Negative Control Response	High	1	1	1
Confounding/ Variable Control	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
Data Presentation and Analysis	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2
Sum of scores:				30	33
Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:			1.100	Overall Score: (Rounded)	1.1
			Overall Quality Level:		HIGH

High	Medium	Low
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3

<b>Study Reference:</b>	Johnson, I.R. 1999. Perylimid F: Local Lymph Node Assay. Central Toxicology Laboratory, UK. Project No. CTL/P/6194. For BASF Aktiengesellschaft, Germany.				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative and Vehicle controls	High	1	2	2
	5. Positive controls	High	1	1	1
	6. Randomized allocation	Low	3	1	3
<b>Exposure Characterization</b>	7. Preparation and storage of test substance	Medium	2	1	2
	8. Consistency of exposure administration	High	1	1	1
	9. Reporting of doses / concentrations	High	1	2	2
	10. Exposure frequency and duration	High	1	1	1
	11. Number of exposure groups and dose spacing	High	1	1	1
	12. Exposure route and method	High	1	1	1
<b>Test Organisms</b>	13. Test animal characteristics	Medium	2	2	4
	14. Adequacy and consistency of animal husbandry conditions	High	1	1	1
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	1	1
	19. Blinding of assessors	N/A	N/A	N/A	N/A
	20. Negative Control Response	High	1	1	1

<b>Confounding/ Variable Control</b>	21. Confounding variables in test setup and procedures	High	1	2	2
	22. Health outcomes unrelated to exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	23. Statistical methods	High	1	1	1
	24. Reporting of data	High	1	2	2
			<b>Sum of scores:</b>	<b>30</b>	<b>35</b>
<b>High</b>	<b>Medium</b>	<b>Low</b>	<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>	<b>Overall Score: (Rounded)</b>	
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3	1.167		1.2
			<b>Overall Quality Level:</b>	<b>HIGH</b>	

<b>Study Reference:</b>	Jung, R., Weigand, W. 1983. Perylimid Study of the Mutagenic Potential in Strains of Salmonella Typhimurium (Ames Test) and Escherichia coli. Hoechst Aktiengesellschaft, Germany. Report No. 83.0695. For Hoechst, Farbenforschung, Germany.				
Domain	Metric	Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]	Metric Score	Metric Weighting Factor	Weighted Score
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	Medium	2	1	2
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative controls	High	1	2	2
	5. Positive controls	High	1	2	2
	6. Assay procedures	High	1	1	1
	7. Standards for test	N/A	N/A	N/A	N/A
<b>Exposure Characterization</b>	8. Preparation and storage of test substance	High	1	1	1
	9. Consistency of exposure administration	High	1	1	1
	10. Reporting of concentrations	High	1	2	2
	11. Exposure duration	High	1	2	2
	12. Number of exposure groups and dose spacing	High	1	1	1
	13. Metabolic activation	High	1	1	1
<b>Test Model</b>	14. Test model	High	1	2	2
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	2	2
	19. Blinding of assessors	N/A	N/A	N/A	N/A

<b>Confounding/ Variable Control</b>	20. Confounding variables in test setup and procedures	High	1	2	2
	21. Confounding variables in Outcomes unrelated to exposure	High	1	1	1
<b>Data Presentation and Analysis</b>	22. Data analysis	High	1	1	1
	23. Data interpretation	High	1	2	2
	24. Cytotoxicity data	N/A	N/A	N/A	N/A
	25. Reporting of data	High	1	2	2
<b>Sum of scores:</b>				<b>33</b>	<b>34</b>
<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>			1.030	<b>Overall Score: (Rounded)</b>	<b>1.0</b>
			<b>Overall Quality Level:</b>		<b>HIGH</b>

<b>High</b>	<b>Medium</b>	<b>Low</b>
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3



<b>Study Reference:</b>	Wollny, H. 2012. Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT) With Paliogen Violet 5011. Harlan Cytotest Cell Research GmbH, Germany. Report No. 1443105. For BASF SE, Germany.				
<b>Domain</b>	<b>Metric</b>	<b>Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated]</b>	<b>Metric Score</b>	<b>Metric Weighting Factor</b>	<b>Weighted Score</b>
<b>Test Substance</b>	1. Test substance identity	High	1	2	2
	2. Test substance source	High	1	1	1
	3. Test substance purity	High	1	1	1
<b>Test Setup</b>	4. Negative controls	High	1	2	2
	5. Positive controls	High	1	2	2
	6. Assay procedures	High	1	1	1
	7. Standards for test	High	1	1	1
<b>Exposure Characterization</b>	8. Preparation and storage of test substance	High	1	1	1
	9. Consistency of exposure administration	High	1	1	1
	10. Reporting of concentrations	High	1	2	2
	11. Exposure duration	High	1	2	2
	12. Number of exposure groups and dose spacing	High	1	1	1
	13. Metabolic activation	High	1	1	1
<b>Test Model</b>	14. Test model	High	1	2	2
	15. Number per group	High	1	1	1
<b>Outcome Assessment</b>	16. Outcome assessment methodology	High	1	2	2
	17. Consistency of outcome assessment	High	1	1	1
	18. Sampling adequacy	High	1	2	2
	19. Blinding of assessors	N/A	N/A	N/A	N/A
<b>Confounding/ Variable Control</b>	20. Confounding variables in test setup and procedures	High	1	2	2
	21. Confounding variables in Outcomes unrelated to exposure	High	1	1	1
	22. Data analysis	High	1	1	1

<b>Data Presentation and Analysis</b>	23. Data interpretation	High	1	2	2
	24. Cytotoxicity data	High	1	1	1
	25. Reporting of data	High	1	2	2
<b>Sum of scores:</b>				<b>35</b>	<b>35</b>
<b>Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:</b>			<b>1.000</b>	<b>Overall Score: (Rounded)</b>	<b>1.0</b>
			<b>Overall Quality Level:</b>		<b>HIGH</b>

<b>High</b>	<b>Medium</b>	<b>Low</b>
≥1 and <1.7	≥1.7 and <2.3	≥2.3 and ≤3