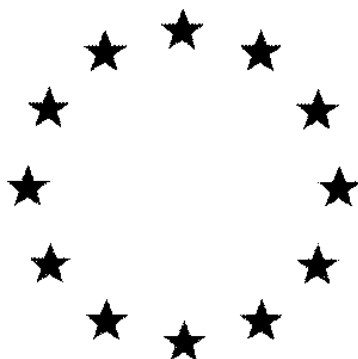


European Commission



**Draft (Renewal) Assessment Report prepared
according to the Commission Regulation (EC) No
1107/2009**

**Daminozide (ISO); 4-(2,2-
dimethylhydrazino)-4-oxobutanoic
acid; *N*-dimethylaminosuccinamic
acid**

Volume 3 - B.2 (AS)

Rapporteur Member State: Czech Republic
Co-Rapporteur Member State: Hungary

Version history page

Date	Version	Reason for revision
April, 2018	Version 1	First draft
October, 2018	Version 2	Co-RMS, notifier comments
June, 2019	Version 3	Update following the ECHA accordance check

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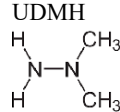
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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Details of the literature search undertaken are available. No relevant scientifically peer-reviewed open literature reference has been identified for active substance Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid ('hereafter referred to as 'daminozide'). The table below contains old study reports (grey colour), already submitted for the first Annex I inclusion of Daminozide, as well as new data (black colour) that have not been evaluated at EU level and submitted for the purpose of renewal. Batches used and purity are described in the table.

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
B.2.1. Melting and boiling point						
Melting point	OECD 102	2842-65-RRG 999 g/kg	Melting point: 153 - 154.5°C	The previous study was not performed to GLP. Acceptable.	Y	Riggs, A.S. (2010) GRL-12838
Boiling point	OECD 103	GE3C27H 994 g/kg	The boiling point could not be determined as the test material decomposed in the range of 142 - 145°C.	The previous study was not performed using purified material. Acceptable.	Y	Riggs, A.S. (2003) GRL-12029
Temperature of decomposition or sublimation	OECD 103	GE3C27H 994 g/kg	Decomposition of Daminozide was observed in the boiling point study. Decomposition occurred at about 142 - 145°C. (Daminozide, melted and decomposed material were identified by NMR)	Acceptable.	Y	Riggs, A.S. (2003) GRL-12029
B.2.2. Vapour pressure (in Pa), Volatility (e.g. Henry's Law Constant)						
Vapour pressure	EC A.4	AC-1483-3 997 g/kg	1.5 x 10 ⁻⁶ Pa at 25°C (very slightly volatile)	The previous study was not performed using purified material. The results are still acceptable.	Y	Tremain, S.P. (2001) 666-059 (DAR addendum Volume 3, Annex B, June 2002)
Volatility (Henry's Law Constant)	Calculation		1.0 x 10 ⁻⁹ Pa x m ³ x mol ⁻¹ at 25°C (very slightly volatile) water solubility: 128000 mg/L (799 mol/m ³) at 20°C vapour pressure: 1.5 x 10 ⁻⁶ Pa at 25°C	Calculated using new water solubility and vapour pressure results. Acceptable.	N	Liney, P.; Miles, D. (2014) 1007582.UK0

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference												
B.2.3. Appearance (physical state, colour and odour)																		
Physical state, colour and odour of the pure active substance.	Visual assessment	AC-1483-3-A 998 g/kg	Solid at 20.5°C with the sub-classification crystalline consisting of small fine approximately cubic shaped crystals. Slightly off-white with Munsell Notation N 9.5/. No detectable odour.	No data previously presented on purified material.	Y	Riggs, A.S. (2008) GRL-12662												
		Technical GE7D09H101 999 g/kg	Solid at 20.5°C with the sub-classification crystalline consisting of small fine approximately cubic shaped crystals. Slightly off-white with Munsell Notation N 9.5/. No detectable odour.	Acceptable.														
B.2.4. Spectra (UV/VIS, IR, NMR, MS)																		
UV, IR, NMR and Mass spectrum of active substance	UV-Vis OPPTS 830.7050	2007-11-05 994 g/kg	<table><thead><tr><th>pH</th><th>Maxima (nm)</th><th>Molar Absorption Coefficient</th></tr></thead><tbody><tr><td>1.95</td><td>198</td><td>951 L mol⁻¹ cm⁻¹</td></tr><tr><td>6.99</td><td>191</td><td>6520 L mol⁻¹ cm⁻¹</td></tr><tr><td>10.10</td><td>192</td><td>6966 L mol⁻¹ cm⁻¹</td></tr></tbody></table> No absorption at wavelengths above 290 nm.	pH	Maxima (nm)	Molar Absorption Coefficient	1.95	198	951 L mol ⁻¹ cm ⁻¹	6.99	191	6520 L mol ⁻¹ cm ⁻¹	10.10	192	6966 L mol ⁻¹ cm ⁻¹	No extinction coefficients presented in the DAR. Acceptable.	Y	Kelly, K. (2011) J18897
	pH	Maxima (nm)	Molar Absorption Coefficient															
	1.95	198	951 L mol ⁻¹ cm ⁻¹															
6.99	191	6520 L mol ⁻¹ cm ⁻¹																
10.10	192	6966 L mol ⁻¹ cm ⁻¹																
IR	S-3410 995 g/kg	The spectrum was consistent with the structure of daminozide and contained the following signals: OH & NH stretch, C=O stretch, N-H bend, CH bend, OH bend, C-O stretch, C-N stretch, C-C stretch, CH rock, NH rock, alcohol O-H, amine N-H, alkane C-H, aldehyde C-H, aldehyde C=O, ketone C=O, ester C-O, ester C=O, amide C=O, amide C-O	No peak wave numbers or assignments presented in the DAR. Acceptable.	Y	Knowles, R.J. (2006) J15709													
NMR	081028092 > 990 g/kg	The ¹ H and ¹³ C NMR spectra for the test substance were consistent with the structure of daminozide and practically identical to the spectra obtained for a daminozide reference standard. The chemical shift values are presented below and detailed structural assignments are presented in the study report. ¹ H NMR Signal <u>NMR Shift (ppm)</u>	The previous study was not performed to GLP. Acceptable.	Y	Riggs, A.S. (2010b) GRL-12900													

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference																			
			2.50 > 2.57 2.15 > 2.41 2.43 > 2.44 8.26 ¹³ C NMR Signal <u>NMR Shift (ppm)</u> 39.523 > 41.193 27.415 > 29.855 47.218 > 48.432 169.192 > 174.892																						
	MS	Daminozide	The following fragmentation pathway has been assigned for the mass spectrum of daminozide. <table><thead><tr><th><u>Fragment (m/z)</u></th><th><u>Data</u></th></tr></thead><tbody><tr><td>160</td><td>Molecular ion</td></tr><tr><td>143</td><td>Loss of -OH group</td></tr><tr><td>118</td><td>Loss of N (CH₂)₂ group</td></tr><tr><td>101</td><td>Loss of OH-C=O plus CH₃</td></tr><tr><td>100</td><td>Loss of NH-C-(CH₃)₂</td></tr><tr><td>73</td><td>Cleavage of O=C(OH)-CH₂-CH₂</td></tr><tr><td>59</td><td>Base peak from NH-N-(CH₃)₂</td></tr><tr><td>45</td><td>O=C-OH</td></tr><tr><td>44</td><td>N-(CH₃)₂</td></tr></tbody></table>	<u>Fragment (m/z)</u>	<u>Data</u>	160	Molecular ion	143	Loss of -OH group	118	Loss of N (CH ₂) ₂ group	101	Loss of OH-C=O plus CH ₃	100	Loss of NH-C-(CH ₃) ₂	73	Cleavage of O=C(OH)-CH ₂ -CH ₂	59	Base peak from NH-N-(CH ₃) ₂	45	O=C-OH	44	N-(CH ₃) ₂	No fragmentation data were presented in the previous study. GLP status, batch, purity and date of study are unknown. However, identification of daminozide by MS seems to be acceptable.	N
<u>Fragment (m/z)</u>	<u>Data</u>																								
160	Molecular ion																								
143	Loss of -OH group																								
118	Loss of N (CH ₂) ₂ group																								
101	Loss of OH-C=O plus CH ₃																								
100	Loss of NH-C-(CH ₃) ₂																								
73	Cleavage of O=C(OH)-CH ₂ -CH ₂																								
59	Base peak from NH-N-(CH ₃) ₂																								
45	O=C-OH																								
44	N-(CH ₃) ₂																								
Spectra of relevant impurities 	UV-Vis OECD 101	UDMH BCBJ7409V 998 g/kg	The UV/Vis spectra only show minor absorbance at low wavelengths for the neutral and basic solutions; however the spectra obtained were consistent with the assigned structure of UDMH.	No spectral data for UDMH previously presented. Acceptable.	Y	Cowlyn, N. (2014a) FDD0119																			
	IR	UDMH BCBJ7409V 998 g/kg	<table><thead><tr><th><u>Frequency (cm⁻¹)</u></th><th><u>Assignment</u></th></tr></thead><tbody><tr><td>3100 - 3300</td><td>N-H stretches</td></tr><tr><td>2700 - 3000</td><td>C-H (alkyl) stretches</td></tr><tr><td>1601</td><td>NH₂ deformation</td></tr><tr><td>1400 - 1500</td><td>CH₃ deformation</td></tr><tr><td>1319</td><td>C-N stretch</td></tr><tr><td>< 1250</td><td>NH₂ deformation, CH₃ vibrations</td></tr></tbody></table>	<u>Frequency (cm⁻¹)</u>	<u>Assignment</u>	3100 - 3300	N-H stretches	2700 - 3000	C-H (alkyl) stretches	1601	NH ₂ deformation	1400 - 1500	CH ₃ deformation	1319	C-N stretch	< 1250	NH ₂ deformation, CH ₃ vibrations	No spectral data for UDMH previously presented. Acceptable.	Y	Cowlyn, N. (2014a) FDD0119					
<u>Frequency (cm⁻¹)</u>	<u>Assignment</u>																								
3100 - 3300	N-H stretches																								
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1319	C-N stretch																								
< 1250	NH ₂ deformation, CH ₃ vibrations																								

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
NDMA $\begin{array}{c} \text{CH}_3 \\ \\ \text{H}_3\text{C}-\text{N}-\text{NO} \end{array}$			The IR spectrum was consistent with the assigned structure of UDMH.			
	NMR	UDMH BCBJ7409V 998 g/kg	<u>Chemical Shift</u> <u>Number of protons</u> <u>Assignment (ppm)</u> 2.4 6 CH ₃ group 3.0 2 NH ₂ group 7.3 - Solvent The proton NMR spectrum was consistent with the assigned structure of UDMH.	No spectral data for UDMH previously presented. Acceptable.	Y	Cowlyn, N. (2014a) FDD0119
	MS	UDMH BCBJ7409V 998 g/kg	Molecular Ion - m/z 61. No assignable fragments or adducts were observed. The mass spectrum was consistent with the assigned structure of UDMH.	No spectral data for UDMH previously presented. Acceptable.	Y	Cowlyn, N. (2014a) FDD0119
	UV-Vis OECD 101	NDMA 30924 972 g/kg	<u>pH</u> <u>λ_{max} (nm)</u> <u>(ϵ)</u> 7.2 227 7600 333 92.7 1.3 227 7630 332 117 12.8 228 7570 332 99.8 The UV/Vis spectra were consistent with the assigned structure of NDMA.	No spectral data for NDMA previously presented. Acceptable.	Y	Cowlyn, N. (2014b) FDD0118
	IR	NDMA 30924 972 g/kg	<u>Frequency (cm⁻¹)</u> <u>Assignment</u> 2840 - 3000 C-H (alkyl stretches) 1000 - 1400 CH ₃ deformation C-N stretch N=O stretch < 1000 Skeletal vibrations The IR spectrum was consistent with the assigned structure of NDMA.	No spectral data for NDMA previously presented. Acceptable.	Y	Cowlyn, N. (2014b) FDD0118
	NMR	NDMA 30924 972 g/kg	<u>Chemical Shift</u> <u>Assignment (ppm)</u> 3.06 CH ₃ group 3.78 NH ₂ group 7.27 Solvent	No spectral data for NDMA previously presented. Acceptable.	Y	Cowlyn, N. (2014b) FDD0118

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
			The proton NMR spectrum was consistent with the assigned structure of NDMA.			
	MS	NDMA 30924 972 g/kg	Molecular Ion - m/z 75. No assignable fragments or adducts were observed. The mass spectrum was consistent with the assigned structure of NDMA.	No spectral data for NDMA previously presented. Acceptable.	Y	Cowlyn, N. (2014b) FDD0118
B.2.5. Solubility in water						
Solubility in water	OECD 105 (Shake-flask) HPLC/UV (GRL-GM-1139)	101218026 1000 g/kg	128 g/L at 20°C and pH 4 (readily soluble)	The previous studies were not performed to GLP or not performed using purified material. Acceptable.	Y	Friedlander, B.T. (2011a) GRL-12954
B.2.6. Solubility in organic solvents						
Solubility in organic solvents/vehicles	OECD 105 (Shake-flask) HPLC/UV (GRL-GM-1139)	101219027 1000 g/kg	Solubility at 20°C (readily soluble in acetone and methanol) Acetone 1.61 g/L Methanol 48.0 g/L	An insufficient range of organic solvents was used in the previous study. Acceptable.	Y	Friedlander, B.T. (2011b) GRL-12955
	OECD 105 (Shake-flask)	6B17-21DA 1001 g/kg	Solubility at 25°C (slightly soluble in toluene and moderately soluble in dichloromethane) Toluene < 0.01 g/L Dichloromethane 0.157 g/L	An insufficient range of organic solvents was used in the previous study. Acceptable.	Y	Parsons, A.H. (2006) J16017
	OECD 105 OECD 116 CIPAC MT 157	SW991 999 g/kg	Solubility at 20°C (readily soluble in acetone and methanol, moderately soluble in ethyl acetate) Acetone 1.47 g/L Methanol 50.0 g/L Ethyl acetate 0.27 g/L	The results are still acceptable.	Y	Thompson, A.K. (1999a) 17587 (DAR addendum Volume 3, Annex B, June 2002)

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
B.2.7. Partition coefficient n-octanol/water						
Partition coefficient n-octanol/water	OECD 107 HPLC/UV (GRL-GM-1275)	101218026 1000 g/kg	Log P _{ow} (20°C): -1.53 (pH 3) (no possibility for bioaccumulation)	The previous study was not performed to GLP. Acceptable.	Y	Riggs, A.S. (2011) GRL-12953
	Prediction (EPIWIN v.1.68)	Methanol	The Log P _{ow} for methanol was estimated to be -0.63	New data requirement. Acceptable.	N	Miles, D. (2015) 1007582.UK0 - 7880
B.2.8. Dissociation in water						
Dissociation constant	OECD 112	AC-941-143 993 g/kg	pKa = 4.68 at 20°C	The results are still acceptable.	Y	Tang, C.L.; Rose, K.G. (1988) 1961-88-0195-AS-001 (DAR Volume 3, Annex B, June 1999)
B.2.9. Flammability and self-heating						
Flammability and Auto-flammability	EC A.10	- 999 g/kg	not highly flammable in the sense of EC A.10	GLP status and batch are unknown; new study is available.	N	Jackson, W.A. (1999b) HT99/196 (197) (DAR addendum Volume 3, Annex B, June 2002)
	EC A.10	Technical 903M014 SI 6956	not highly flammable in the sense of EC A.10 (not flammable)	Purity is unknown. Acceptable.	Y	Tremain, S.P. (1999) 666/022
	EC A.16	- 999 g/kg	no self-ignition below melting point (about 154°C) (not auto-flammable)	GLP status and batch are unknown; new study is not available. The results are still acceptable.	N	Jackson, W.A. (1999b) HT99/196 (197) (DAR addendum Volume 3, Annex B, June 2002)

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
B.2.10. Flash Point						
Flash point			Not relevant, as test substance is a solid with a melting point > 40°C.			
B.2.11. Explosive properties						
Explosive properties	EC A.14	- 999 g/kg	no explosive properties	GLP status and batch are unknown; new study is available.	N	Jackson, W.A. (1999b) HT99/196 (197) (DAR addendum Volume 3, Annex B, June 2002)
	EC A.14	Technical 903M014 SI 6956	Mechanical sensitivity (friction): Negative Mechanical sensitivity (shock): Negative Thermal sensitivity: Negative The test material does not possess explosive properties. (not explosive)	Purity is unknown. Acceptable.	Y	Tremain, S.P. (1999) 666/022
B.2.12. Surface tension						
Surface tension	OECD 115	SW991 999 g/kg	69.8 mN/m at 25°C (0.1% solution of Daminozide in Milli-RO water)	The results are still acceptable.	Y	Thompson, A.K. (1999a) 17587 (DAR addendum Volume 3, Annex B, June 2002)
B.2.13. Oxidising properties						
Oxidising properties	EC A.17	Technical 903M014 SI 6956	None of the test substance/cellulose mixtures burned to completion. The test material does not possess oxidising properties. (not oxidising)	Purity is unknown. Acceptable.	Y	Tremain, S.P. (1999) 666/022
	EC A.17	Technical ZJ 00-05-14 999 g/kg (Technical	no oxidising properties	The results are still acceptable.	Y	Comb, A.L. (2001a) FNA102/014401 (Flack, I. (2001a) URO 016/012463)

Test or Study & Annex Point	Guideline and method	Test material purity and specification	Findings	RMS Comments	GLP	Reference
		009M009 997 g/kg)				(DAR addendum Volume 3, Annex B, June 2002)
	EC A.17	Technical 4A27-21DA 997 g/kg	None of the test substance/cellulose mixtures burned to completion. The test material does not possess oxidising properties. (not oxidising)	Acceptable.	Y	Cowlyn, N. (2014c) FDD0116
B.2.14. Other studies						
			None.			

Summary and Assessment of Physical, Chemical and Technical Properties for Daminozide

Daminozide is a white crystalline solid with a melting point of 153-154.5°C. It has a very low vapour pressure and is only very slightly volatile. It is readily soluble in water and solubility in organic solvents ranges from <0.01 g/L to 50 g/L. It has a dissociation constant of 4.68 and a log P_{ow} (n-octanol/water partition co-efficient) of -1.53, indicating that it does not bioaccumulate. Daminozide is neither flammable nor self-heating and does not possess explosive or oxidising properties, indicating that it does not create problems during transport and storage. There are no implications for classification.

B.2.15. References Relied On

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.2.1/01	Riggs, A.S.	2010a	The melting point of daminozide Chemtura Canada Co./Cie. Report no. GRL-12838 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.1/02	Riggs, A.S.	2003	The boiling point of daminozide Crompton Corporation. Report no. GRL-12029 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.2/01	Tremain, S.P.	2001	Daminozide Pure SI 7985: Determination of vapour pressure Crompton Europe Ltd. Report No. 666/059 GLP Unpublished	N	N (DAR addendum Volume 3, Annex B, June 2002)	N/A	Arysta LifeScience Great Britain Limited
B.2.2/02	Liney, P. Miles, D.	2014	Daminozide - Henry's Law Constant Exponent International Ltd, United Kingdom Project no.: 1007582.UK0 Non-GLP Unpublished	N	Y	New study for AIR 3 dossier	EU Daminozide Task Force
B.2.3	Riggs, S.A.	2008	The colour, physical state and odour of technical and purified daminozide Chemtura Canada Co./Cie. Report No. GRL-12662 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.4/01	Kelly, K.	2011	Determination of the UV/Visible Absorption Characteristics of Daminozide in Accordance with OPPTS 830.7050 GC Laboratories Ltd. Report No. J18897 GLP Unpublished	N	Y	New study for AIR 3 dossier	Fine Agrochemicals Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.2.4/02	Knowles, R.J.	2006	Preparation of IR Spectrum of Daminozide G.C. Laboratories Ltd. Report No. J15709 GLP Unpublished	N	Y	New study for AIR 3 dossier	Fine Agrochemicals Limited
B.2.4/03	Riggs, A.S.	2010b	The NMR spectra of technical daminozide Chemtura Canada Co./Cie. Report No. GRL-12900 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.4/04	Parson, A.H White, G.A.	Unknown	Assignment of Fragments of Mass Spectrum of Daminozide G.C. Laboratories Ltd. VAT REG No. 196715425 GLP status unknown Unpublished	N	Y	New study for AIR 3 dossier	Fine Agrochemicals Limited
B.2.4/05	Cowlyn, N.	2014a	UDMH Spectra Huntingdon Life Sciences. Report No. FDD0119 GLP Unpublished	N	Y	New study for AIR 3 dossier	EU Daminozide Task Force
B.2.4/06	Cowlyn, N.	2014b	NDMA Spectra Huntingdon Life Sciences. Report No. FDD0118 GLP Unpublished	N	Y	New study for AIR 3 dossier	EU Daminozide Task Force
B.2.5	Friedlander, B.T.	2011a	The solubility of technical daminozide in water Chemtura Canada Co./Cie. Report No. GRL-12954 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.6/01	Friedlander, B.T.	2011b	The solubility of technical daminozide in acetone and methanol Chemtura Canada Co./Cie. Report No. GRL-12955 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.6/02	Parsons, A.H.	2006	Determination of the solubility of daminozide in solvents G.C. Laboratories Ltd. Report No. J16017 GLP Unpublished	N	Y	New study for AIR 3 dossier	Fine Agrochemicals Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.2.6/03 B.2.12	Thompson, A.K.	1999a	Physico-chemical testing with daminozide, Inveresk report: 17587 GLP Unpublished	N	N (DAR addendum Volume 3, Annex B, June 2002)	N/A	Fine Agrochemicals Limited
B.2.7/01	Riggs, A.S.	2011	The partition coefficient (n-octanol/water) of technical daminozide Chemtura Canada Co./Cie. Report No. GRL-12953 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.7/02	Miles, D.	2015	Methanol Partition Coefficient Exponent International Ltd, United Kingdom Project no.: 1007582.UK0 - 7880 Non-GLP Unpublished	N	Y	New study for AIR 3 dossier	EU Daminozide Task Force
B.2.8	Tang, C.L. Rose K.G.	1988	Alar - determination of dissociation constant Ricerca, Inc., Document no.: 1961-88-0195-AS-001 Project no.: 88127 GLP Unpublished	N	N (DAR Volume 3, Annex B, June 1999)	N/A	Arysta LifeScience Great Britain Limited
B.2.9/01 B.2.9/03 B.2.11/01	Jackson, W.A.	1999b	Determination of flammability and auto-flammability characteristics of 333199 (some phys-chem properties) Zeneca Process Technology, Report no. HT99/196 (197) GLP status unknown Unpublished	N	N (DAR addendum Volume 3, Annex B, June 2002)	N/A	Fine Agrochemicals Limited
B.2.9/02 B.2.11/02	Tremain, S.P.	1999	Daminozide technical (Lot number: 903M014 SI 6956): Determination of flammability (solids), explosive properties and oxidising properties Safepharm Laboratories Limited. Report no. 666/022 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.2.13/01	Tremain, S.P.	1999	Daminozide technical (Lot number: 903M014 SI 6956): Determination of flammability (solids), explosive properties and oxidising properties Safepharm Laboratories Limited. Report no. 666/022 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
B.2.13/02	Comb, A.L. (Flack, I.)	2001a	Daminozide (technical) oxidizing properties, Report no.: FNA102/014401 (URO 016/012463) GLP Unpublished	N	N (DAR addendum Volume 3, Annex B, June 2002)	N/A	EU Daminozide Task Force
B.2.13/03	Cowlyn, N.	2014c	Daminozide Technical Oxidising Properties Huntingdon Life Sciences. Report No. FDD0116 GLP Unpublished	N	Y	New study for AIR 3 dossier	EU Daminozide Task Force