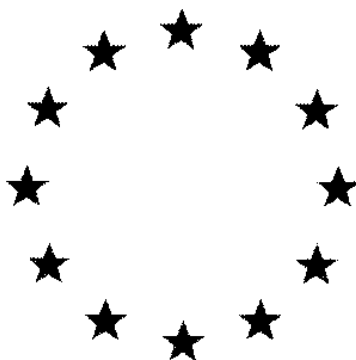


European Commission



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

Volume 2

Rapporteur Member State: Czech Republic

Co-Rapporteur Member State: Hungary

Version history page:

Date	Version	Reason for revision
May 2018	Version 1	First draft
October 2018	Version 2	Co-RMS + Notifier's comments
June 2019	Version 3	Update following the ECHA accordance check

TABLE OF CONTENTS

1	LIST OF THE TESTS AND STUDIES SUBMITTED AND OF INFORMATION AVAILABLE	2
1.1	<i>Identity</i>	2
1.2	<i>Physical and Chemical Properties</i>	2
1.3	<i>Data on Application and Efficacy</i>	11
1.4	<i>Further Information</i>	11
1.5	<i>Methods of Analysis</i>	12
1.6	<i>Toxicology and Metabolism Data</i>	21
1.7	<i>Residue Data</i>	34
1.8	<i>Environmental Fate and Behaviour</i>	34
1.9	<i>Ecotoxicology Data</i>	42

1 LIST OF THE TESTS AND STUDIES SUBMITTED AND OF INFORMATION AVAILABLE

1.1 Identity

Active substance

New studies

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 1.11/01	Barker, C.H.	2015	Preliminary analysis of technical daminozide MacDermid Agricultural Solutions Canada Company, Guelph, Canada Report: GRL-13301 GLP: Yes Published: No	N	Y	Confidential data	Arysta LifeScience Great Britain Limited
CA 1.11/02	Kelly, K	2015a	5 batch analysis of Daminozide G C Laboratories Ltd Report J20131 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited
CA 1.11/03	Kelly, K	2015b	5 batch analysis of Daminozide G C Laboratories Ltd Report J20130 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited

Plant protection product

-

1.2 Physical and Chemical Properties

Active substance

New Studies

Annex point / reference number	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
CA 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 GRL-12838 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CA 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
CA 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
CA 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
CA 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
CA 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
CA 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

Annex point / reference number	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
CA 2.4/04	Parson, A.H White, G.A.	Unknow n	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
CA 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
CA 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
CA 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
CA 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
CA 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
CA 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

Annex point / reference number	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
CA 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
CA 2.9/02 CA 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
CA 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
CA 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

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex point / reference number	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
CA 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
CA 2.6/03 CA 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
CA 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
CA 2.9/01 CA 2.9/03 CA 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
CA 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

Plant protection product (Alar)**New studies**

Annex point / reference number	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
CP 2.1 CP 2.4 CP 2.7/01 CP 2.8/01	Woolley, A.J. Mullee, D.M.	2005b	Daminozide SG: Determination of accelerated storage stability (2 weeks at 54°C) and physico-chemical characteristics in 2500 mL white high density polyethylene tamper evident snap cap jars including appearance, particle size distribution, wettability, wet sieve test analysis, dust content, dilution stability, pH, persistent foam, friability and attrition, assay of active ingredient and pack stability. Safepharm Laboratories Ltd., UK. Report no. 666/090 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 2.2 CP 2.3	Tremain, S.P.	2003	Daminozide SG: Study report determination of hazardous physico-chemical properties including flammability, explosive properties, relative self-ignition temperature and oxidising properties. Safepharm Laboratories Ltd., UK. Report No. 666/074 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 2.6/01	Evans, A.J. Mullee, D.M.	2003a	Daminozide SG: Study report determination of bulk density. Safepharm Laboratories Ltd., UK. Report no. 666/071 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited

Annex point / reference number	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
CP 2.6/02 CP 2.7/02	Dunn, N.L.	2009	Storage stability of ALAR 85 SG (UBI 6899.00) over two years at ambient temperatures in HDPE containers Chemtura Canada Co./Cie, Report no. GRL-12410 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 2.7/03	Hart, C.J.	2012	Determination of the shelf Life over 2 years at ambient conditions of Alar 85 SG in 5L HDPE pails with evaluation of physical state, colour and analysis of the active ingredient content and the impurities Unsymmetrical Dimethyl Hydrazine (UDMH) and N-Nitrosodimethylamine (NDMA) Chemtura Canada Co., Canada. Report No. GRL-12901 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 2.8/02	Evans, A.J. Mullee, D.M.	2003b	Daminozide SG: Study report determination of flowability. Safepharm Laboratories Ltd., UK, report no. 666/073 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited

Plant protection product (Dazide Enhance)**New studies**

Annex point / reference number	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
CP 2.1 CP 2.4 CP 2.6/02 CP 2.8.1 CP 2.8.4/02 CP 2.8.5.1	Atkins, B.K.	2011a	Physical and chemical properties for the FAL 2400 formulation G C Laboratories Ltd., Report No. J18511 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.2/01	Mak, W.A.	2003	Explosive Properties of Dazide SG. TNO. Report No. PML 2003-C54 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.2/02 CP 2.6/01	Parsons, A.H.	2007	Physico-Chemical Testing of Dazide 85 WSG (testing facility J16524) GC Laboratories Ltd. Report No. Ref. J16524 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.3 CP 2.8.7	Comb, A.L.	2002a	Dazide 85 WG Physico-chemical Properties Huntingdon Life Sciences Ltd, UK. Report No. FNA/100/014405 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.7/01	Comb, A.L.	2002b	Dazide 85 WG Accelerated storage stability Huntingdon Life Sciences Ltd, UK. Report No. FNA101/014405 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.7/02	Parsons, A.H.	2003	Determination of the Particle Size Distribution and Persistent Foaming of Dazide SG Formulation G.C. Laboratories Ltd. Report No. J14470 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

Annex point / reference number	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
CP 2.7/03	Atkins, B.K.	2011b	Accelerated storage stability study on Dazide Enhance formulation GC Laboratories Ltd. Report No. J18771 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.7/04	Bates, G.J.D.	2012a	Accelerated Storage Stability Trial for the FAL 2400 Formulation G C Laboratories Ltd., Report No. J19005 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.7/05	Comb, A.L.	2003	Dazide 85 WG Two Year Storage Stability Huntingdon Life Sciences Ltd, UK. Report No. FNA/104/033834 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.8.2/01 CP 2.8.4/01 CP 2.8.5.2 CP 2.8.5.3	White, G.A.	2011	Attrition resistance, dust content, persistent foam and dilution stability of FAL 2400 G.C. Laboratories Ltd. Report No. J18509 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 2.8.2/02	Bates, G.J.D	2012b	Determination of the Persistent Foam on the Dazide Enhance and FAL 2400 Formulations G.C. Laboratories Ltd. Report No. J19254 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

1.3 Data on Application and Efficacy

Active substance

No study included on this part of documentation.

Plant protection products:

No study included on this part of documentation.

1.4 Further Information

Active substance

New studies

Annex point / reference number	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
CA 4/01	Anon.	2014	Daminozide technical (MSDS) Report No.: - (Author: Chemtura AgroSolutions) Edition Number: 2.1 GLP/GEP: n.a. not published	N	N	N/A	Arysta LifeScience Great Britain Limited
CA 4/02	Anon.	2014	Daminozide technical (MSDS) Report No.: - (Author: Fine Agrochemicals Limited) Edition Number: 1.0 GLP/GEP: n.a. not published	N	N	N/A	Fine Agrochemicals Limited

Plant protection product (Alar)

New studies

Annex point / reference number	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
CP 4/01	Anon.	2013	ALAR® 85 SG (MSDS) Report No.: - (Author: Chemtura AgroSolutions) Edition Number: 1.5 GLP/GEP: n.a. not published	N	N	N/A	Arysta LifeScience Great Britain Limited

Plant protection product (Dazide Enhance)

New studies

Annex point / reference number	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
CP 4/01	Anon.	2014	Dazide Enhance (MSDS) Report No.: - (Author: Fine Agrochemicals Limited) Edition Number: 1.0 GLP/GEP: n.a. not published	N	N	N/A	Fine Agrochemicals Limited

1.5 Methods of Analysis

Active substance

New studies

Annex point / reference number	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
CA 5.1.1/01	Bates, G.J.D.	2012	Validation of analytical method M741 "High performance liquid chromatographic determination of daminozide in technical material and formulations" for the FAL 2400 formulation G.C. Laboratories Ltd. Report No. J19126 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.1.1/02	Kelly, K.	2015c	Partial validation of analytical method M741 "High performance liquid chromatographic determination of daminozide in technical material and formulations" for technical material G.C. Laboratories Ltd. Report No. J20158 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.1.1/03	Barker, C.H.	2015	Preliminary analysis of technical daminozide MacDermid Agricultural Solutions Canada Company, Guelph, Canada Report: GRL-13301 (only Appendix II) GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/04	Riggs, A.S.	2011	Validation of an analytical method for the determination of daminozide in daminozide technical Chemtura Canada Co. Report No. GRL-12970 GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/05	Kelly, K.	2015g	Validation of Analytical Method M851 UDMH and NDMA G.C. Laboratories Ltd. Report No. J20157 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

Annex point / reference number	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
CA 5.1.1/06	Barker, C.H.	2015	Preliminary analysis of technical daminozide MacDermid Agricultural Solutions Canada Company, Guelph, Canada Report: GRL-13301 (only Appendix V) GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/07	Yu, W.S.	2000a	Validation of an analytical method for the determination of unsymmetrical dimethyl hydrazine (UDMH) in B- Nine technical and B-Nine SP formulation. Uniroyal Chemical Co., Guelph, Canada Report: GRL-11423 GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/08	Riggs, A.S.	2009a	Validation of an analytical method for the determination of unsymmetrical dimethyl hydrazine (UDMH) in Alar 85 WG. Chemtura Canada Co./Cie, Guelph, Canada Report: GRL-12643 (GRL-12870, GRL-13222) GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/09	Barker, C.H.	2015	Preliminary analysis of technical daminozide MacDermid Agricultural Solutions Canada Company, Guelph, Canada Report: GRL-13301 (only Appendix VI) GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.1/10	Yu, W.S.	2000b	Validation of an analytical method for the determination of N-nitrodimethylamine (NDMA) in B-Nine technical Uniroyal Chemical Co., Guelph, Canada Report: GRL-11450 GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited

Annex point / reference number	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
CA 5.1.1/11	Riggs, A.S.	2009b	Validation of an analytical method for the determination of N-Nitrosodimethylamine (NDMA) in Alar 85 WG Chemtura Canada Co./Cie, Guelph, Canada Report: GRL-12644 (GRL-12844, GRL-13223) GLP: Yes Published: No	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.2/01	Hart, C.	2012b	Determination of the concentration of Unsymmetrical Dimethyl Hydrazine (UDMH) in a mixture of daminozide and water over a storage period of 24 hours Chemtura Canada Co., Canada. Report No. GRL-13025 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CA 5.1.2/02	██████████ ██████████ ██████████ ██████████	2012	Daminozide: a reproduction study with the Northern bobwhite ██████████ Report. No. 616-104 GLP Unpublished	Y	Y	New data for AIR 3 renewal	Arysta LifeScience Great Britain Limited
CA 5.1.2/03	██████████ ██████████ ██████ ██████████ ██████████ ██████	2015	Daminozide: an early life-stage toxicity test with the fathead minnow (Pimephales promelas) ██████████ Report No. 616A-123 GLP Unpublished	Y	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 5.1.2/04	Last, G.	2012	Chronic effects to Daphnia magna from exposure to daminozide and formaldehyde Covance Laboratories Ltd, UK. Report No. 8252736. GLP Unpublished	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 5.1.2/05	Manson, P.S. Scholey, A.	2006	Daminozide Technical: Inhibition of growth to the alga Pseudokirchneriella subcapitata Covance Laboratories Ltd. Report No. 2242/049-D2149 GLP Unpublished	N	Y	New data for AIR 3 renewal	Fine Agrochemicals Limited

Annex point / reference number	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
CA 5.1.2/06	Seeland- Fremer, A. Mosch, W.	2014	Toxicity of daminozide technical to Anabaena flos-aquae in an Algal Growth Inhibition Test IBACON. Report No. 87711210 GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 5.1.2/07	Friedlander, B.T.	2011	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
CA 5.1.2/08	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
CA 5.2/01	Munro, S.	2012	Validation of an analytical method for the determination of daminozide in soil Huntingdon Life Sciences, UK. Report No. FDD0080 GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.2/02	Jooß, S.	2012	Validation of an analytical method for the determination of daminozide in surface water PTRL Europe, Germany. Report No. P 2516 G GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Limited
CA 5.2/03	Austin, R.	2015	Independent laboratory validation of method validation for daminozide in drinking water Battelle UK Ltd. Study No. BH/14/023 GLP Unpublished	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 5.2/04	Miller, C.	2015	Daminozide and UDMH: Validation of methodology for the determination of residues in air Huntingdon Life Sciences. Study No. FDD0124 GLP Unpublished	N	Y	New data for AIR3 renewal	EU Daminozide Task Force

Annex point / reference number	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
CA 5.2/05	Bendig, P. Wabbel, C.	2016	Development and Validation of an Analytical Method for the Determination of Unsymmetrical Dimethylhydrazine (UDMH) in air PTRL Europe, Germany. Report No. P 3210 G GLP Unpublished	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 1.11/01	Barker, C.H.	2015	Preliminary analysis of technical daminozide MacDermid Agricultural Solutions Canada Company, Guelph, Canada Report: GRL-13301 GLP: Yes Published: No	N	Y	Confidential data	Arysta LifeScience Great Britain Limited
CA 5.1.1/12	Riggs, A.S.	1999	Validation of an analytical method for the determination of IMPURITY Uniroyal Chemical Co., Guelph, Canada Report: GRL-11612 (GRL-13034, GRL-13214) GLP: Yes Published: No	N	Y	Confidential data	Arysta LifeScience Great Britain Limited
CA 5.1.1/13	Riggs, A.S.	2000	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF IMPURITIES IN B-NINE TECHNICAL Uniroyal Chemical Co., Guelph, Canada Report: GRL-11013 (GRL-13035) GLP: Yes Published: No	N	Y	Confidential data	Arysta LifeScience Great Britain Limited
CA 5.1.1/14	Riggs, A.S.	2013	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF IMPURITIES IN DAMINOZIDE TECHNICAL Chemtura Canada Co./Cie, Guelph, Canada Report: GRL-13199 GLP: Yes Published: No	N	Y	Confidential data	Arysta LifeScience Great Britain Limited

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 1.11/02	Kelly, K	2015a	5 batch analysis of Daminozide G C Laboratories Ltd Report J20131 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited
CA 1.11/03	Kelly, K	2015b	5 batch analysis of Daminozide G C Laboratories Ltd Report J20130 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited
CA 5.1.1/15	Kelly, K	2015d	Validation of Analytical Method M856 'Impurity G C Laboratories Ltd Report J20155 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited
CA 5.1.1/16	Kelly, K	2015e	Validation of Analytical Method M847 'Impurity G C Laboratories Ltd Report J20156 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited
CA 5.1.1/17	Kelly, K	2015f	Validation of Analytical Method M848 'Impurity G C Laboratories Ltd Report J20183 GLP unpublished	N	Y	Confidential data	Fine Agrochemicals Limited

Plant protection product (Alar)**New studies**

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 5.1.1/01	White, G.A.	2002	Validation of analytical method M191/F for the HPLC determination of daminozide in technical material and formulations G.C. Laboratories Ltd., UK. Report No. J14313 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 5.1.1/02	Hart, C.	2012a	Determination of the shelf Life over 2 years at ambient conditions of Alar 85 SG in 5L HDPE pails with evaluation of physical state, colour and analysis of the active ingredient content and the impurities Unsymmetrical Dimethyl Hydrazine (UDMH) and N-Nitrosodimethylamine (NDMA) Chemtura Canada Co., Canada. Report No. GRL-12901 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 5.1.2	Dunn, N.L.	2009	Storage stability of Alar 85 SG (UBI 6899.00) over two years at ambient temperatures in HDPE containers Chemtura Canada Co./Cie. Report No. GRL-12410 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited
CP 5.2/01	Riggs, A.S.	2009a	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF UNSYMMETRICAL DIMETHYL HYDRAZINE (UDMH) IN ALAR 85 WG Chemtura Canada Co./Cie, Guelph, Canada Report: GRL-12643 (GRL-11423) GLP: Yes Published: No	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 5.2/02	Riggs, A.S.	2009b	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF N-NITROSODIMETHYLAMINE (NDMA) IN ALAR 85 WG Chemtura Canada Co./Cie, Guelph, Canada Report: GRL-12644 (GRL-11450) GLP: Yes Published: No	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Limited

Plant protection product (Dazide Enhance)**New studies**

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 5.1.1/01	Bates, G.J.D.	2012	Validation of Analytical Method M741 'High Performance Liquid Chromatographic Determination of Daminozide in Technical Material and Formulations' for the FAL 2400 Formulation Amended Final Report GC Laboratories Ltd., UK. Report No. J19126 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 5.1.1/02	Knowles, R. J.	2010	Validation of GC Laboratories Ltd Method M487 'Determination of Unsymmetrical Dimethylhydrazine (UDMH) and N-Nitrosodimethylamine (NDMA) in Daminozide by Gas Chromatography' for the Dazide Enhance Formulation GC Laboratories Ltd., UK. Report No. J17929 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CP 5.1.2/01	Knowles, R. J.	2007	Validation of Analytical Method M485 'High Performance Liquid Chromatographic Determination of	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
			Daminozide in Technical Material and Formulations' for the Daminozide WSG Formulation GC Laboratories Ltd., UK. Report No. J16147 GLP Unpublished				
CP 5.1.2/02	Comb, A.L.	2003	Dazide 85 WG Two Year Storage Stability Huntingdon Life Sciences Ltd, UK. Report No. FNA/104/033834 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

1.6 Toxicology and Metabolism Data

Active substance:

New studies

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.2.6/02	████████	2003	Daminozide Technical: Local Lymph Node Assay in the Mouse (Individual Method) ████████. Report No. 2242/012 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.3.2/01	████████	2005	Daminozide: 13 week oral (gavage) administration toxicity study in the rat ████████. Report No. 2242/040 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.3.3/01	██████	2012	28 day dermal toxicity study in rats with daminozide technical ██████ Report No. 10519 GLP Unpublished	Y	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 5.4.1/01	Williams, L.	2006	Daminozide: reverse mutation in one Tryptophan-requiring strain of Escherichia coli Covance Laboratories Ltd. Report No. 2242/50-D6171 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.6.2/03	██████ ██████	2006a	Oral Dosage-Range Developmental Toxicity Study of Daminozide Technical in Rabbits ██████. Report No. TZE00003 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.6.2/05	██████ ██████	2006b	Oral Developmental Toxicity Study of Daminozide Technical in Rabbits ██████. Report No. TZE00002 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Limited
CA 5.7.1/01	██████	2012a	Daminozide: An acute neurotoxicity study in rat ██████. Report No. 399-232 GLP Unpublished	Y	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 5.7.1/02	██████	2012b	Daminozide: A 90-day oral (gavage) neurotoxicity study in rats ██████. Report No. 399-233 GLP Unpublished	Y	Y	New data for AIR3 renewal	EU Daminozide Task Force

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.2/01	[REDACTED]	2011	Immunotoxicity evaluation of daminozide technical in CD-1 female mice: anti-sheep red blood cell (SBRC) response [REDACTED]. Report No. BRT 20110408 GLP Unpublished	Y	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 5.9.1/01	Zorzitto, A.K.	2014	Description of occupational health surveillance program and monitoring studies at Xi'am aerospace propulsion testing technique institute for production of daminozide technical MacDermid Agricultural Solutions Inc. Report No. GAI-14-07 Non-GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Ltd.

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.1.1/01	[REDACTED]	1966	Radiotracer metabolism study 14C-ALAR in rats [REDACTED]. Report No. A.8.3.2 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.1.1/02	[REDACTED]	1987	Metabolism of daminozide in miniature swine [REDACTED]. Report No. A.8.3.21 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.1.1/03	[REDACTED]	1987	Metabolism of daminozide in miniature swine. Analysis for UDMH in liver tissue Uniroyal Chemical Co., Inc. Report No. A.8.3.23 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.1.1/04	██████████ ██████████ ██████████	1993	Metabolism and excretion of daminozide in male rats at a single oral dose level ██████████. Report No. 64C-5315 GLP Unpublished	Y	N	Not applicable	Fine Agrochemicals Limited
CA 5.2.1/01	██████████	1994a	Single dose oral toxicity in rats ██████████. Report No. A.7.1.11 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.2.2/01	██████████	1994b	Acute dermal toxicity in rabbits ██████████. Report No. A.7.1.12 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.2.3/01	██████████	1994a	An acute (4 hour) inhalation toxicity study of Alar Technical in the rat via nose only exposure ██████████. Report No. A.7.1.15 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.2.4/01	██████████	1994	Primary dermal irritation in albino rabbits ██████████. Report No. A.7.1.13 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.2.5/01	██████████	1994c	Primary eye irritation and/or corrosion in rabbits ██████████. Report No. A.7.1.14 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.2.6/01	██████████	1994b	Closed patch repeated insult dermal sensitization study of Alar Technical in guinea pigs (Buehler method) ██████████. Report No. A.7.1.16 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.

26

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.5/02	[REDACTED]	1988c	Two year dietary oncogenicity study in mice [REDACTED]. Report No. A.7.3.8 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.6.1/01	[REDACTED] [REDACTED]	1987	Two-generation reproduction study with Alar in rats (one litter per generation) [REDACTED]. Report No. A.7.6.15 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.6.1/02	[REDACTED] [REDACTED]	1994	Oral (gavage) rat two-generation reproductive toxicity study [REDACTED]. Report No. FAL 0015 GLP Unpublished	Y	N	Not applicable	Fine Agrochemicals Limited
CA 5.6.2/01	Khra, K.S., Whalen, C., Trivett, G., Angers, G	1979	Teratologic assessment of maleic hydrazide and daminozide, and formulations of ethoxyquin, thiabendazole and Haled in rats J. Environ Sci Health (1979) Vol. B14(6), pp. 563-577	Y	N	Not applicable	Public domain
CA 5.6.2/02	[REDACTED]	1993	Daminozide oral (gavage) rat developmental toxicity (teratogenicity) [REDACTED]. Report No. FAL 0016 GLP Unpublished	Y	N	Not applicable	Fine Agrochemicals Limited
CA 5.6.2/04	[REDACTED] [REDACTED] [REDACTED]	1985	Alar-Teratology study in rabbits [REDACTED]. Report No. A.7.6.9 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/01	[REDACTED]	1987a	13 week toxicity study in rats [REDACTED] Report No. A.7.2.4 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/02	[REDACTED]	1987b	13 week toxicity study in mice [REDACTED] Report No. A.7.2.5 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/03	[REDACTED] [REDACTED]	1989a	Two year oncogenicity study in rats (UDMH) [REDACTED] Report No. A.7.3.18 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/04	[REDACTED] [REDACTED]	1989b	Two year oncogenicity study in mice (UDMH) – low dose [REDACTED] Report No. A.7.3.19 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/05	[REDACTED] [REDACTED]	1990	Two year oncogenicity study in mice (UDMH) – high dose [REDACTED] Report No. A.7.3.21 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/06	Stanowski, L.F.	1988	Unsymmetrical dimethylhydrazide (UDMH) CHO/HPRT mammalian cell forward gene mutation assay Pharmakon Research International, Inc. Report No. A.7.6.17 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/07	Stanowski, L.F., Tunman, W.	1987	Unsymmetrical dimethylhydrazide (UDMH) CHO/HPRT mammalian cell forward gene mutation assay Pharmakon Research International, Inc. Report No. A.7.6.17 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/08	Barknecht, T.R.	1986	UDMH – Rat hepatocyte primary culture/DNA repair test Pharmakon Research International, Inc. Report No. A.7.6.12 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/09	San Sebastian, J.R.	1986	In Vitro chromosome aberration analysis in Chinese Hamster Ovary (CHO) cells Pharmakon Research International, Inc. Report No. A.7.6.13 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 5.8.1/10	Cliet, I., Fournier, E., Melcion, C., Cordier, A.	1989	In vivo micronucleus test using mouse hepatocytes Mutation Research/Environmental Mutagenesis and Related Subjects, 216(6), 321-326 Non-GLP Unpublished	Y	N	Not applicable	Public domain
CA 5.8.1/11	Sagelsdorff, P., Lutz, W. K., Schlatter, C.	1988	DNA methylation in rat liver by daminozide, 1, 1-dimethylhydrazine, and dimethylnitrosamine Fundamental and Applied Toxicology, 11(4), 723-730 Non-GLP Unpublished	Y	N	Not applicable	Public domain

Plant protection product: Alar**New studies**

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 7.1.1/01	██████████	1997a	Acute oral toxicity study with B-Nine® WSG in rats ██████████. Report No. 96-1463 GLP Unpublished	Y	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.
CP 7.1.2/01	██████████	1997b	Acute dermal toxicity study with B-Nine® WSG in rabbits ██████████. Report No. 96-1464 GLP Unpublished	Y	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.
CP 7.1.4/01	██████████	1997c	Primary dermal irritation study with B-Nine® WSG in rabbits ██████████. Report No. 94-1465 GLP Unpublished	Y	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 7.1.5/01	████████	2005	ALAR 85 SG: acute eye irritation in the rabbit ████████████████████. Report No. 1133/029 GLP Unpublished	Y	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.
CP 7.1.6/01	████████	1997d	Closed-patch repeated dose insult dermal sensitization study with B-Nine® WSG in guinea pigs (Buehler Method) ████████████████████. Report No. 94-1466 GLP Unpublished	Y	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.
CP 7.2.3.2/01	van der Jagt, K.E., Ravensberg, J.C., de Wold, J.M., Links, I.H.M.	2002	Dislodgeable foliar residue determination of daminozide, UDMH and NDMA and air monitoring of UDMH, NDMA and formaldehyde following indoor treatment of ornamental plants with Alar® 64 SP TNO Nutrition and Research. Report No. V3876 GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Ltd.
CP 7.3/01	Meers, I.A.T.M.	2011	Determination of the dermal absorption of daminozide technical in human and rat skin NOTOX B.V. Report No. 495333 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 7.1.3/01	██████████	1997	An acute (4-hour) inhalation toxicity study of B-Nine® WSG in the rat via nose-only exposure ██████████. Report No. 96-5289 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 7.3	██████████ ██████	1991	Dermal Absorption of 14C-UDMH in B-Nine Using Male Sprague-Dawley Rats. ██ Report No. A.7.5.1.4 GLP	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd..

Plant protection product: Dazide Enhance

New studies

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 7.1.1/01	████████	2003a	Dazide 85 WG: Acute Oral Toxicity Study in the Female Rat (Acute Toxic Class) ████████████████████. Report No. 2242/004 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 7.1.2/01	████████	2003b	Dazide 85 WG: Acute Dermal Toxicity Study in the Rat ████████████████████. Report No. 2242/005 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 7.1.4/01	████████	2002a	Dazide WSG (New Formulation) Skin Irritation to the Rabbit ████████████████████. Report No. FNA 106/022932 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 7.1.5/01	████████	2002b	Dazide WSG (New Formulation) Eye Irritation to the Rabbit ████████████████████. Report No. FNA 107/023169 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 7.1.6/01	████████	2003c	Dazide 85 WSG: Local Lymph Node Assay in the Mouse (Individual Method) ████████████████████. Report No. 2242/006 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 7.2.3.2/01	van der Jagt, K.E., Ravensberg, J.C., de Wold, J.M., Links, I.H.M.	2002	Dislodgeable foliar residue determination of daminozide, UDMH and NDMA and air monitoring of UDMH, NDMA and formaldehyde following indoor treatment of ornamental plants with Alar® 64 SP TNO Nutrition and Research. Report No. V3876 GLP Unpublished	N	Y	New data for AIR3 renewal	Arysta LifeScience Great Britain Ltd.

CP 7.3/01		2012	Daminozide: The In Vitro Percutaneous Absorption of Radiolabelled Daminozide in the Water Soluble Granule (SG) Concentrate, Two In-Use Spray Dilutions and Two Test Preparations Representing Re-Entry Scenarios Through Human Skin Report No. 32807 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
-----------	--	------	---	---	---	---------------------------	-------------------------

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 7.3		1991	Dermal Absorption of 14C-UDMH in B-Nine Using Male Sprague-Dawley Rats. Report No. A.7.5.1.4 GLP	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.

1.7 Residue Data

Active substance:

No study included on this part of documentation.

Plant protection products:

No study included on this part of documentation.

1.8 Environmental Fate and Behaviour

Active substance:

New studies

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.1.1/01	Möndel, M.,	2014	Degradation of [¹⁴ C]-Daminozide in four soils incubated under aerobic conditions at 20 ± 2 °C in the dark Agroscience. Report No. AS358 GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 7.1.1.1/02	Jones, M.,	2015	Daminozide: Analysis of Unknown Metabolites in Soil Selcia. Report No. SEL/8273/1 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 7.1.1.1/03	DeMaio, W.	2015	Degradation of [¹⁴ C]-Daminozide in Four Soils Incubated Under Aerobic Conditions at 20 ± 2 °C in the Dark: Characterization of a Daminozide Degradation Product Report No. 033709-1 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	Y	New data for AIR3 renewal	EU Daminozide Task Force
CA 7.2.1.2/01	Brice, A., Scholey, A.	2006	[¹⁴ C]-Daminozide: photodegradation in sterile, aqueous solution Covance Laboratories Ltd. Report No. 2242/044 GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	Y	New data for AIR3 renewal	Fine Agrochemicals Limited

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.2.1.2/02	Hilton, M., Callow, B.	2014	Determination of rates of decline for daminozide and its metabolites in aqueous photolysis and water/ sediment studies according to FOCUS kinetics guidance document Report No. 1007582.UK0/7393 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CA 7.2.1.2/02	Hilton, M., Callow, B.	2016	Determination of rates of decline for daminozide and its metabolites in aqueous photolysis and water/ sediment studies according to FOCUS kinetics guidance document Document No. 1007582.UK0/7393 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CA 7.2.2.2/01	Button, S.	2015	Daminozide: Aerobic mineralisation in surface water (pelagic test) Huntingdon Life Sciences. Report No. FDD0108 GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	Y	Not applicable	EU Daminozide Task Force

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.1.1.1/01	Dannals, L., Puhl, R., Kucharczyk, N.	1972	Environmental Fate Studies on Alar: Second Status Report on PR 70-15 Generated by: (Not identified in report) Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.3 Date: March 27, 1972 Not GLP, Unpublished Previous evaluation: In DAR 1999	N	N		Arysta LifeScience Great Britain Ltd.
CA 7.1.1.1.1/02	Dannals, L., Puhl, R., Kucharczyk, N.	1994	Dissipation and Degradation of Alar® in Soils Under Greenhouse Conditions Generated by: Uniroyal Chemical Submitted by: Fine Agrochemicals Ltd. FAL file No. (not provided) Date: 1974 Not GLP, Published Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.1.1.1.1/03	Goodyear, A.	1995	(14C)-Daminozide Soil metabolism and Degradation Generated by: Corning Hazleton Submitted by: JSC International Ltd. for Fine Agrochemical Ltd. FAL file No. (not provided) (report #1137/2-1015) Date: August 1995 GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Fine Agrochemicals Limited
CA 7.1.1.1.1/04	Yu, W.	1993	Characterization of Volatiles from Daminozide Aerobic Soil Metabolism Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. not provided Date: November 4, 1993 GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.1.1.1/05	Yu, W., Kobryn, K.	1993	Daminozide Aerobic Soil Metabolism Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.21 Date: March 3, 1993 GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.1.1.2/01	Dzialo, D.G., Harned, W.H.	1986	Daminozide aerobic and anaerobic soil metabolism studies Uniroyal Chemical. Report No. A.8.1.5 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.1.1.1.2/01	Lengen, M. Dzialo, D.	1984	Daminozide Photolysis in Water and on Soil (Interim Report) Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.6 Date: December 1984 Not GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.1.1.1.2/02	Lengen, M.	1985	Addendum to: Hydrolysis of Daminozide (Project No. 84244) and Daminozide Photolysis in Water and on Soil (Project No. 84246) Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.9 Date: June 1985 Not GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.3.1.1/01	Beeching, A.	1987	Determination of adsorption isotherms for daminozide on two soil types Resource Consultants Cambridge Ltd. Report No. FAL 0018 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 7.1.3.1.1/02	Spare, W.	1987	Determination of the adsorption/desorption constants of ALAR Agriseach Incorporated. Report No. A.8.1.11 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.1.4.1.1/01	McManus, J., Dzialo, D., Lengen, M.	1984	Daminozide column leaching study with aged sandy loam Uniroyal Chemical. Report No. A.8.1.8 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.2.1.1/01	Lengen, M.	1982	Hydrolysis of Daminozide Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.12 Date: February 1982 Not GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.2.1.1/02	Lengen, M., Abdel-Kader, H., Peterson, G.	1984	Hydrolysis of Daminozide Generated by: Uniroyal Chemical Submitted by: Uniroyal Chemical Uniroyal file No. A.8.1.4 Date: December 1984 Not GLP, Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.2.2.1/01	Ritter, A.	1989a	Ready Biodegradability, Modified OECD Screening Test for Alar Technical RCC Umweltchemie AG. Report No. A.8.1.19 GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 7.2.2.3/01	De Vette, H.Q.M., van Es, C.	2002	A study on the degradation of [¹⁴ C] daminozide in two water/sediment systems TNO Chemistry. Report No. 01-2482/01 GLP Unpublished Previous evaluation: In Addendum II (2002)	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Plant protection product:

New studies

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CP 9.2.4.1/01	Hilton, M., Callow, B.	2015a	Predicted Environmental Concentrations of daminozide and its metabolite in groundwater using FOCUS PEARL 4.4.4 model and FOCUS groundwater scenarios Exponent International Limited. Report No. 1007582.UK0 – 5338 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CP 9.2.4.1/01	Hilton, M., Callow, B.	2016	Predicted Environmental Concentrations of daminozide and its metabolite in groundwater using FOCUS PEARL 4.4.4 model and FOCUS groundwater scenarios Exponent International Limited. Report No. 1007582.UK0 – 1916 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CP 9.2.5/01	Hilton, M., Callow, B.	2015b	Predicted Environmental Concentrations of daminozide and its metabolite in surface water in the EU using the FOCUS surface water scenarios Exponent International Limited. Report No. 1007582.UK0 – 2679 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CP 9.2.5/01	Hilton, M., Callow, B.	2016	Predicted Environmental Concentrations of daminozide and its metabolite in surface water in the EU using the FOCUS surface water scenarios Exponent International Limited. Report No. 1007582.UK0 – 1770 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex Point	Author	Year	Title Source, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.2.2.1/01	Smilo, A., Blaszczynski, E., Stanton, D.T., Harned, W.H.	1986	Daminozide field dissipation study Uniroyal Chemical. Report No. A.8.1.7 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

1.9 Ecotoxicology Data

Active substance*New submitted studies relied upon for renewal of approval under Regulation (EC) No 1107/2009*

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
CA 8.1.1.1/02	██████████ ██████████	2006	Daminozide technical: An acute oral toxicity study with the Japanese quail ██████████ Report No. 429-104 GLP Unpublished	Y	Y	New data for AIR 3 renewal	Fine Agrochemicals Ltd.
CA 8.1.1.3/01	██████████ ██████████ ██████████ ██████████	2012	Daminozide: a reproduction study with the Northern bobwhite ██████████ Report. No. 616-104 GLP Unpublished	Y	Y	New data for AIR 3 renewal	Arysta LifeScience Great Britain Ltd.

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
CA 8.2.1/04	Poirier, S.H., Knuth, M.L., Anderson-Buchou, C.D., Brooke, L.T., Lima, A.R., Shubat, P.J.	1986	Comparative toxicity of methanol and N,N-dimethylformamide to freshwater fish and invertebrates Bulletin of Environmental Contamination and Toxicology (1986) Vol. 37, pp. 615-621 Non-GLP Published	Y	N	New data for AIR 3 renewal	Public domain
CA 8.2.2.1/01	██████████ ██████████ ██████████ ██████████	2015	Daminozide: an early life-stage toxicity test with the fathead minnow (<i>Pimephales promelas</i>) ██████████. Report No. 616A-123 GLP Unpublished	Y	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 8.2.4.1/04	Dom, N., Pennick, M., Knapen, D., Blust, R.	2012	Discrepancies in the acute versus chronic toxicity of compounds with a designated narcotic mechanism Chemosphere (2012) Vol. 87, pp. 742-749 Non-GLP Published	Y	N	New data for AIR 3 renewal	Public domain
CA 8.2.5.1/01	Last, G.	2011	Chronic effects to <i>Daphnia magna</i> from exposure to daminozide and formaldehyde Covance Laboratories Ltd. Report No. 8252736 Non-GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 8.2.6.1/02	Manson, P.S., Scholey, A.	2006	Daminozide Technical: Inhibition of growth to the alga <i>Pseudokirchneriella subcapitata</i> Covance Laboratories Ltd. Report No. 2242/049-D2149 GLP Unpublished	N	Y	New data for AIR 3 renewal	Fine Agrochemicals Ltd.

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
CA 8.2.6.1/03	Cho, C-W., Heon, Y-C., Pham, T.P.T., Vijayaraghavan, K., Yun, Y-S.	2008	The ecotoxicity of ionic liquids and traditional organic solvents on microalga <i>Selenastrum capricornutum</i> Ecotoxicology and Environmental Safety (2008) Vol. 71, pp. 166-171 Non-GLP Published	Y	N	New data for AIR 3 renewal	Public domain
CA 8.2.6.2/01	Seeland-Fremer, A., Mosch, W.	2014	Toxicity of daminozide technical to <i>Anabaena flos-aquae</i> in an Algal Growth Inhibition Test IBACON. Report No. 87711210 GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 8.3.1.2/01	Haupt, S.	2014	Chronic oral toxicity of daminozide technical on the honey bee (<i>Apis mellifera</i> L.) in the laboratory IBACON. Report No. 87715136 GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 8.3.1.3/01	Odemer, R.	2015	Daminozide: toxicity to honey bee (<i>Apis mellifera</i> L.) larvae after repeated exposure under in vitro laboratory conditions IES. Report No. 20150038 GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force
CA 8.4.1/01	Pavić, B.	2014	Effects of daminozide technical on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 10% peat IBACON. Report No. 87714022 GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force

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
CA 8.4.1/02	McCormac, A.	2015	Formaldehyde – Determination of chronic toxicity to the earthworm <i>Eisenia andrei</i> in an artificial soil substrate Mambo-tox. Report No. CHEM-15-1 Non-GLP Unpublished	N	Y	New data for AIR 3 renewal	EU Daminozide Task Force

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.1.1.1/01	██████████ ██████████	1992	Alar technical: an acute oral toxicity study with the mallard ██████████ Report No. A.7.4.29 GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.1.1.2/01	██████████ ██████████	1977	Eight-day dietary LC50 – bobwhite quail: technical Alar ██████████ Report No. A.7.4.2.4 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.1.1.2/02	██████████	1974	Eight-day dietary toxicity – mallard ducks: technical Alar ██████████ . Report No. A.7.4.2.5 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.1.4/01	Helms, D.R.	1967	Use of formalin for selective control of tadpoles in the presence of fishes The Progressive Fish-Culturist, January, 43-37 Non-GLP Published	Y	N	Not applicable	Public domain

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.1/01	██████	1987	The toxicity of daminozide to rainbow trout ████████████████████. Report No. FAL 0020 Non-GLP Unpublished	Y	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.2.1/02	██████	1977	Acute toxicity of Alar technical, Lot BL 8190 to the rainbow trout (<i>Salmo gairdneri</i>) Report No. A.7.4.1.5 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.2.1/03	██████	1972	Acute toxicity of Alar to bluegill (<i>Lepomis macrochirus</i>) Report No. A.7.4.1.4 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.2.1/04	Reardon, I.S., Harrell, R.M.	1990	Acute toxicity of formalin and coppersulfate to striped bass fingerlings held in varying salinities Aquaculture 87, 255-270 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/05	Wellens, H.	1982	Vergleich der Empfindlichkeit von <i>Brachydanio rerio</i> und <i>Leuciscus idus</i> bei der Untersuchung der Fischtoxizität von chemischen Verbindungen und Abwässern Wasser-und Abwasser-Forschung, 15, 49-52 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/06	Bills, T., Marking, L.L., Chandler Jr, J.H.	1977	Formalin: its toxicity to nontarget aquatic organisms, persistence, and counteraction Investigations in Fish Control. U.S. Department of the Interior Fish and Wildlife Service. No. 73, pp. 1-7 Non-GLP Published	Y	N	Not applicable	Public domain

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.1/07	Helms, D.R.	1967	Use of formalin for selective control of tadpoles in the presence of fishes The Progressive Fish-Culturist, January, 43-37 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/08	Clemens, H.P., Sneed, K.E.	1958	The chemical control of some diseases and parasites of channel catfish The Progressive Fish-Culturist, January, 8-15 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/09	Hinton, M.J., Eversole, A.G.	1980	Toxicity and tolerance studies with yellow-phase eels: five chemicals The Progressive Fish-Culturist, 42, 201-203 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/10	Hinton, M.J., Eversole, A.G.	1979	Toxicity of ten chemicals commonly used in aquaculture to the black eel stage of the American eel Proc. World Maricul. Soc., 10, 554-560 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1/11	Jühnke, I., Lüdemann, D.	1978	Ergebnisse der Untersuchung von 200 chemischen Verbindungen auf akute Fisch toxisität mit dem Goldorfontest Wasser-und Abwasser-Forschung, 11, 161-164 Non-GLP Published	Y	N	Not applicable	Public domain
CA 8.2.1.2/12	Hinton, M.J., Eversole, A.G.	Unknown	Toxicity of ten commonly used chemicals to American eels Proc. Ann. Conf. S.E. Assoc. Fish & Wildl. Agencies, 32, 599-604 Non-GLP Published	Y	N	Not applicable	Public domain

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4.1/01	Lintott, D.	1992	Alar technical: Acute toxicity to the water flea, Daphnia magna, under flow-through test conditions Toxikon Environmental Sciences. Report No. A.7.4.1.8 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.2.4.1/02	LeBlanc, G.	1976	Acute toxicity of Alar standard to Daphnia magna E G & G Bionomics, Report No. A.7.4.1.3 Non-GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.2.4.1/03	Abram, F.	1987	The toxicity of daminozide to Daphnia magna Report No. FAL 3 Non-GLP Unpublished	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.2.4.1/04	Bringmann, G., Kühn, R.	1982	Ergebnisse der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna in einem weiterentwickelten standardisierten Testverfahren Wasser-und Abwasser-Forschung, 15, 1-6 Non-GLP Published	N	N	Not applicable	Public domain
CA 8.2.4.1/05	Prasad, D.Y.	1980	The effect of kraft pulpmill waste components on some aquatic organisms Indian J. Environ. Hlth, 23, 340-341 Non-GLP Published	N	N	Not applicable	Public domain
CA 8.2.4.1/06	Bringmann, G., Kühn, R.	1977	Befunde der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna Wasser-und Abwasser-Forschung, 10, 161-166 Non-GLP Published	N	N	Not applicable	Public domain

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4.2/01	Bills, T., Marking, L.L., Chandler Jr, J.H.	1977	Formalin: its toxicity to non-target aquatic organisms, persistence, and counteraction Investigations in Fish Control, U.S. Department of the Interior Fish and Wildlife Service Non-GLP Published	N	N	Not applicable	Public domain
CA 8.2.5.4/01	Prasad, D.Y.	1980	The effect of kraft pulpmill waste components on some aquatic organisms Indian J. Environ. Hlth, 23, 340-341 Non-GLP Published	N	N	Not applicable	Public domain
CA 8.2.6.1/01	Douglas, M., Pell, I.	1986	The algistatic activity of Alar Technical Huntingdon Research Centre, Ltd. Report No. A.7.4.1.7 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.2.6.1/02	Abram, F.	1987	The Toxicity of Daminozide to a Green Alga Report No. FAL 4 Non-GLP Unpublished	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.2.6.1/03	Bringmann, G., Kühn, R.	1980	Comparison of the toxicity threshold of water pollutants to bacteria, algae and protozoa in the cell multiplication inhibition test Water Research, 14, 231-241 Non-GLP Published	N	N	Not applicable	Public domain
CA 8.2.6.1/04	Bringmann, G., Kühn, R.	1960	Vergleichende toxikologische Befunde an Wasser-Bakterien Gesundheits-Ingenieur, 11, 337-339 Non-GLP Published	N	N	Not applicable	Public domain

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.7/01	Palmer, S.J., Kendall, T.Z., Krueger, H.O.	2001	A 7-day toxicity test with duckweed (<i>Lemna gibba</i> G3) Wildlife International Ltd. Report No. 117A-1197 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CA 8.3.1.1.1/01	Davies, L.	1987	Report on a laboratory investigation into the toxicity of daminozide to honey bees (<i>Apis mellifera</i>) Report No. FAL 5 Non-GLP Unpublished	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.3.1.1.2/01	Davies, L.	1987	Report on a laboratory investigation into the toxicity of daminozide to honey bees (<i>Apis mellifera</i>) Report No. FAL 5 Non-GLP Unpublished	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.3.2.1/01	Harwood et al.	2000	A laboratory evaluation of the side effects of daminozide on the predatory mite <i>Typhlodromus pyri</i> . Inveresk Research Scotland Inveresk Report Number 18099 GLP, Unpublished.	N	N	Not applicable	Fine Agrochemicals Ltd.
CA 8.7/01	Lengen	2001	Review of the effects of daminozide on non-target fauna and flora Uniroyal Chemical Co. Inc. Non-GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Plant protection product (Alar)

New submitted studies relied upon for renewal of approval under Regulation (EC) No 1107/2009

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
CP 10.6.2/01	Sindermann, A.B., Porch, J.R., Krueger, H.O., Martin, K.H.	2012a	Daminozide formulation: A toxicity test to determine the effects (Tier II) on seedling emergence of ten species of plants Wildlife International Ltd. Report No. 616-107 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.
CP 10.6.2/02	Sindermann, A.B., Porch, J.R., Krueger, H.O., Martin, K.H.	2012b	Daminozide formulation: A toxicity test to determine the effects (Tier II) on vegetative vigour of ten species of plants Wildlife International Ltd. Report No. 616-108 GLP Unpublished	N	Y	New study for AIR 3 dossier	Arysta LifeScience Great Britain Ltd.

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CP 10.1.1.1/01	██████████	1966a	Acute dietary toxicity: Bobwhite quail Alar-85 and D-198 ██████████. Report No. A.7.4.2.1 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.2.1.1/01	██████████	1966b	Acute toxicity in aqueous exposure to rainbow trout: Alar-85 and F461-75W ██████████. Report No. A.7.4.1.1 Non-GLP Unpublished	Y	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.2.1.1/02	██████████	1966c	Acute toxicity in aqueous exposure to bluegill sunfish ██████████. Report No. A.7.4.1.2 Non-GLP	Y	N	Not applicable	Arysta LifeScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				Great Britain Ltd.
CP 10.3.1.1.1/01	Cole, J.	1985	The acute oral and contact toxicity to honey bees of Alar 85 Huntingdon research Centre. Report No. A.7.4.2.7 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.1.1.2/01	Cole, J.	1985	The acute oral and contact toxicity to honey bees of Alar 85 Huntingdon research Centre. Report No. A.7.4.2.7 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.1/01	Baxter, I.	1999a	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water soluble powder formulation of daminozide) on the parasitic wasp <i>Aphidius rhopalosiphii</i> Mambo-Tox Ltd. Report No. UNI-99-9 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.1/02	Vinall, S.	1999	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the predatory mite, <i>Typhlodromus pyri</i> Mambo-Tox Ltd. Report No. UNI-99-8 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.1/03	Halsall, N.	2000	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the whitefly parasitoid <i>Encarsia formosa</i> Gahan (Hymenoptera, Aphelinidae) Mambo-Tox Ltd. Report No. UNI-00-2 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.2.1/04	Vinall, S.	2000	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the predatory bug Orius laevigatus Mambo-Tox Ltd. Report No. UNI-00-3 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.1/05	Baxter, I.	1999b	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the ground beetle, Poecilus cupreus Mambo-Tox Ltd. Report No. UNI-99-10 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.1/06	Barton, R.	1999	A laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the green lacewing Chrysoperla carnea Mambo-Tox Ltd. Report No. UNI-99-11 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.3.2.2/01	Tazura, S.	2001a	An extended laboratory test to determine the effect of ALAR 85 SP (an 850 g/kg water-soluble powder formulation of daminozide) on the predatory mite Typhlodromus pyri (Acari, Phytoseiidae) Mambo-Tox Ltd. Report No. UNI-01-1 GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.
CP 10.5/01	Maas, G.	1987 1989	Effects on soil non-target organisms Report No. A.8.1.18 Non-GLP Unpublished	N	N	Not applicable	Arysta LifeScience Great Britain Ltd.

Plant protection product (Dazide Enhance)

New Studies

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CP 10.2.1.1/0 1	██████████ ██████████ ██████████	2009	Acute Toxicity to Common Carp (Cyprinus carpio) ██████████, ██████████ Report No.0673/0006 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 10.2.1.1/0 2	██████████ ██████████ ██████████	2010	FAL 2400: Acute Toxicity to Common Carp (Cyprinus carpio) ██ Report No.41004365 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 10.2.1.2/0 1	Goodband, T.J. and Mullee, D.M.	2010	FAL 2400: Acute Toxicity to Daphnia magna Harlan Laboratories Ltd., Debyrshire, UK Report No.41004366 GLP Unpublished	Y	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 10.2.1.2/0 2	Hernádi, D.	2007a	Acute immobilisation test with Dazide Enhance SG (Dazide 85 WSG) on Daphnia magna LAB. Report No. 07/482-023DA GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP 10.2.1.3/0 1	Hernádi, D.	2007b	Dazide Enhance SG (Dazide 85 WSG) growth inhibition test on algae (Pseudokirchneriella subcapitata) LAB. Report No. 07/482-022AL GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.
CP/10.6.2/ 01	Brambury-Gunary, J.	2015a	FAL 2400 – Evaluation of the phytotoxicity to non target terrestrial plant – vegetative vigour test Agrochemex Ltd. Report No. ACE-14-159 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CP/10.6.2/02	Brambury-Gunary, J.	2015b	FAL 2400 – Evaluation of the phytotoxicity to non target terrestrial plant – vegetative vigour test Agrochemex Ltd. Report No. ACE-15-075 GLP Unpublished	N	Y	New data for AIR3 renewal	Fine Agrochemicals Ltd.

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.2.2/02	Harwood et al.	2000	A laboratory evaluation of the side effects of Dazide 85 on the predatory mite Typhlodromus pyri. Inveresk Research Scotland Inveresk Report Number 18133 GLP, Unpublished.	N	N	Not applicable	Fine Agrochemicals Ltd..
CP 10.3.2.2/01	Tazura, S.	2001b	An extended laboratory test to determine the effect of fresh residues of Dazide 85 on the predatory mite Typhlodromus pyri (Acari, Phytoseiidae) Mambox-Tox Ltd. Report No. RIV-02-1 GLP Unpublished	N	N	Not applicable	Fine Agrochemicals Ltd.