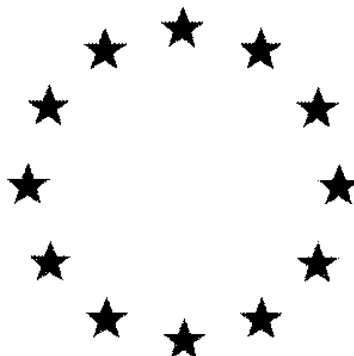


European Commission



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

Daminozide

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

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	Notifier's and co-RMS comments
June, 2019	Version 3	Update following the ECHA accordance check

TABLE OF CONTENTS

B.2 Physical and chemical properties	4
B.2.1 Appearance	4
B.2.2 Explosive and oxidizing properties	5
B.2.3 Flammability and auto-flammability of the preparation	5
B.2.4 Acidity/alkalinity and pH value	6
B.2.5 Viscosity and surface tension	6
B.2.6 Relative Density and Bulk Density	6
B.2.7 Storage Stability and Shelf Life: effects of temperature on technical characteristics of the plant protection product	7
B.2.8 Technical characteristics of the plant protection product	8
B.2.9 Physical compatibility with other products including plant protection products with which its use is to be authorised	10
B.2.10 Adherence and distribution to seeds	10
B.2.11 Other studies	10
B.2.12 References Relied On	15

B.2 PHYSICAL AND CHEMICAL PROPERTIES

Details of the literature search undertaken are available. No relevant scientifically peer-reviewed open literature reference has been identified for plant protection product Alar. ALAR (UBI 6899-00, also known as Alar 85 SG, Daminozide SG) was not the formulation supported for the original Annex I inclusion of Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid ('hereafter referred to as 'daminozide'), therefore, the following studies have not previously been reviewed. The flammability and auto-flammability, explosive and oxidising properties, bulk density and flowability of the product have been carried out with the similar formulation UBI 2231-05. The formulation statement for UBI 2231-05 and a comparison to UBI 6899-00 is in the Volume 4 CA-CP Alar_C (confidential information). Data can be extrapolated from UBI 2231-05 to UBI 6899-00. All studies are submitted for the purpose of renewal.

The SP formulation (ALAR 85) was the representative formulation for the Annex I inclusion of Daminozide. Composition is given in Volume 4 CA-CP Alar_C (confidential information).

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a white opaque, hard, granular odourless solid. It is not explosive, not flammable and has no oxidising properties. It does not have a relative self-ignition temperature below its melting point. In aqueous solution, it has a pH value around 4. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored as recommended. HDPE packaging material was used in shelf-life study. Its technical characteristics are acceptable for a water soluble granules (SG) formulation.

Tested concentrations of PPP in the respective studies (min 0.094 g/L and max 18.35 g/L) cover use concentrations of PPP as stated in the proposed GAP (min 3.33 g/L and max 18 g/L).

The following batches have been used in the physico-chemical studies:

1. Alar (UBI 6899-00) - batch EF 6804 (82.9 % Daminozide), batch B06B20P009 (85.5 %) and batch B09A14P007 (85.7 %)
2. Daminozide SG (UBI 2331-05) - batch B02B09P013 (86.3 %)

Table B.2 Physical and chemical properties of the plant protection product Alar

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
B.2.1 Appearance						
Physical state, colour and odour of the preparation	Visual Olfactory	Daminozide SG UBI 6899-00	<u>Physical state</u> : hard granular solid <u>Colour</u> : white opaque <u>Odour</u> : odourless	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
		Batch: EF 6804 82.9%				
B.2.2 Explosive and oxidizing properties						
Explosive properties of the preparation	EC A.14	Daminozide SG UBI 2331-05 Batch: B02B09P013 86.3%	<u>Mechanical sensitivity:</u> BAM fall hammer shock test: 6 negative tests (no signs of ignition, explosion or decomposition) BAM friction test: 6 negative tests (no signs of ignition, or explosion, a mark on the porcelain plate and peg indicated decomposition) The test item has not mechanical sensitivity to explosion. <u>Thermal sensitivity:</u> Koenen steel tube test: 2x 3 negative tests with 6 mm and 2 mm orifice plate The test item has not thermal sensitivity to explosion. The test material does not possess explosive properties.	Acceptable (not explosive)	Y	Tremain, S.P. (2003), 666/074
Oxidizing properties of the preparation	EC A.17	Daminozide SG UBI 2331-05 Batch: B02B09P013 86.3%	The three fastest test items / cellulose burning rate mixtures were tested a further six times (max burning rate 0.784 mm/s). The test item / cellulose mixtures failed to propagate combustion at a rate greater than the reference mixtures of barium nitrate / cellulose (max burning rate 1.639 mm/s). The test material does not possess oxidising properties.	Acceptable (not oxidising)	Y	Tremain, S.P. (2003), 666/074
B.2.3 Flammability and auto-flammability of the preparation						
Flash point of the preparation			Not applicable to SG formulations.			
Flammability of the preparation, evolution on	EC A.10	Daminozide SG UBI 2331-05	The test material has been determined to be not highly flammable as it did not propagate combustion over the 200 mm of the preliminary screening test in under 4 minutes.	Acceptable (not flammable)	Y	Tremain, S.P. (2003), 666/074

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
contact with water		Batch: B02B09P013 86.3%				
Auto-flammability of the preparation	EC A.16	Daminozide SG UBI 2331-05 Batch: B02B09P013 86.3%	The test material does not have a relative self-ignition temperature below its melting point (oven temperature was programmed from ambient to 160°C).	Acceptable (not auto-flammable)	Y	Tremain, S.P. (2003), 666/074
B.2.4 Acidity/alkalinity and pH value						
Acidity / alkalinity and pH of the preparation			Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).			
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	The method was carried out using an electrometric determination (pH-meter). 1 % dilution in distilled water at 25°C pH = 4.04	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090
B.2.5 Viscosity and surface tension						
Kinematic viscosity of the preparation			Not applicable to SG formulations.			
Dynamic viscosity of the preparation and details of the test conditions			Not applicable to SG formulations.			
Surface tension of the preparation			Not applicable to SG formulations.			
B.2.6 Relative Density and Bulk Density						
Relative density of the preparation			Not applicable to SG formulations.			
Bulk (tap) density	CIPAC MT 159	Daminozide SG UBI 2331-05	Pour density: 0.488 g/ml Tap density: 0.532 g/ml	Acceptable	Y	Evans, A.J.; Mullee, D.M. (2003a), 666/071

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
		Batch: B02B09P013 86.3%				
	CIPAC MT 58.3	Alar 85 SG UBI 6899.00 Batch: B06B20P009 85.5%	Apparent density: 0.52 g/ml	Acceptable	Y	Dunn, N. L. (2009), GRL-12410
B.2.7 Storage Stability and Shelf Life: effects of temperature on technical characteristics of the plant protection product						
Stability at elevated temperature 14 days at 54°C	CIPAC MT 46.3	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	No significant decrease in active substance content was observed following the 14 day storage period. No significant variation in the technical characteristics of the product was observed following the 14-day storage period. Results for individual parameters are presented in Table B.2.7.1 below.	Acceptable (the product is stable)	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090
Stability at 0°C for 7 days			Not applicable to SG formulations.			
Shelf life following storage at ambient temperature	GIFAP Monograph No. 17	Alar 85 SG UBI 6899-00 Batch: B06B20P009 85.5%	No significant decrease in active substance content was observed following the 24 month storage period. No significant variation in the technical characteristics of the product was observed following the 24-month storage period. Results for individual parameters are presented in Table B.2.7.2 below.	Acceptable (the product is stable) pH of 1 % aqueous solution was 3.85 before shelf life test (pH < 4)	Y	Dunn, N. L. (2009), GRL-12410
	GIFAP Monograph No. 17	Alar 85 SG UBI 6899-00 Batch: B09A14P007 85.7%	No significant decrease in active substance content and no significant increase in the content of relevant impurities UDMH and NDMA were observed following the 24 month storage period. Results for individual parameters are presented in Table B.2.7.3 below.	Acceptable (the product is stable)	Y	Hart, C.J. (2012), GRL-12901

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference										
B.2.8 Technical characteristics of the plant protection product																
Wettability	CIPAC MT 53.3.1	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	< 1 second	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090										
Persistent foaming	CIPAC MT 47.2	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	Maximum Concentration Rate 1.835g Test Item in 100 ml CIPAC Water D	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090										
			<table><tr><td>Initial</td><td>92 ml</td></tr><tr><td>10 sec</td><td>80 ml</td></tr><tr><td>1 min</td><td>37 ml</td></tr><tr><td>3 min</td><td>20 ml</td></tr><tr><td>12 min</td><td>14 ml</td></tr></table>				Initial	92 ml	10 sec	80 ml	1 min	37 ml	3 min	20 ml	12 min	14 ml
			Initial				92 ml									
			10 sec				80 ml									
			1 min				37 ml									
			3 min				20 ml									
			12 min				14 ml									
			Minimum Concentration Rate 0.0094g Test Item in 100 ml CIPAC Water D													
			<table><tr><td>Initial</td><td>28 ml</td></tr><tr><td>10 sec</td><td>21 ml</td></tr><tr><td>1 min</td><td>19 ml</td></tr><tr><td>3 min</td><td>18 ml</td></tr><tr><td>12 min</td><td>13 ml</td></tr></table>				Initial	28 ml	10 sec	21 ml	1 min	19 ml	3 min	18 ml	12 min	13 ml
			Initial				28 ml									
			10 sec				21 ml									
			1 min				19 ml									
3 min	18 ml															
12 min	13 ml															
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Not applicable to SG formulations.																
Degree of dissolution and dilution stability	CIPAC MT 179	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	< 0.1% residue observed after 5 minutes. No insoluble residue observed after 18 hours. Stable dilution.	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090										
Particle size distribution, dust content, attrition and mechanical stability	Dry sieve CIPAC MT 58.3	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	Determinations performed in duplicate: <table><tr><td>Sieve (µm)</td><td>Residue (%)</td></tr><tr><td>2000</td><td>0.0067, 0.0067</td></tr><tr><td>1400</td><td>3.39, 2.64</td></tr><tr><td>1180</td><td>25.6, 25.6</td></tr></table>	Sieve (µm)	Residue (%)	2000	0.0067, 0.0067	1400	3.39, 2.64	1180	25.6, 25.6	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090		
Sieve (µm)	Residue (%)															
2000	0.0067, 0.0067															
1400	3.39, 2.64															
1180	25.6, 25.6															

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
			850 68.0, 67.1 710 1.66, 2.61 500 0.918, 1.60 425 0.04, 0.073 355 0.0067, 0.02 250 0.013, 0.013 150 0.013, 0.013 Pan 0.506, 0.405 Mean percentage less than 150 µm: 0.456% Mean percentage less than 250 µm: 0.469%			
	Wet sieve CIPAC MT 59.3	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	No residue remained on a 75 µm sieve	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090
	Dust content CIPAC MT 171	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	0.4 mg of dust collected (mean of 2 determinations)	Acceptable (nearly dust free)	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090
	Attrition CIPAC MT 178	Daminozide SG UBI 6899-00 Batch: EF 6804 82.9%	Attrition resistance: 100% (mean of 2 determinations)	Acceptable	Y	Woolley, A.J.; Mullee, D.M. (2005), 666/090
	Hardness and Integrity		Not applicable to SG formulations.			
Emulsifiability/ Re-emulsifiability/ Emulsion stability			Not applicable to SG formulations.			
Flowability, pourability and dustability	Flowability CIPAC MT 172	Daminozide SG UBI 2331-05 Batch: B02B09P013 86.3%	The test item passed spontaneously through a 4.75 mm aperture sieve.	Acceptable	Y	Evans, A.J.; Mullee, D.M. (2003b), 666/073

Test or Study & Annex Point	Guideline & method(s)	Test material purity and specification	Results	RMS comments	GLP	Reference
	Pourability		Not applicable to SG formulations.			
	Dustability		Not applicable to SG formulations. (for further information please refer to dust content)			
B.2.9 Physical compatibility with other products including plant protection products with which its use is to be authorised						
Physical compatibility of tank mixes			The preparation is not recommended to be used in tank mixes.			
Chemical compatibility of tank mixes			The preparation is not recommended to be used in tank mixes.			
B.2.10 Adherence and distribution to seeds						
Distribution (seed treatment)			Not required as the preparation is not recommended for seed treatment.			
Adhesion (seed treatment)			Not required as the preparation is not recommended for seed treatment.			
B.2.11 Other studies						
Other studies			None			

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

ALAR is a water soluble granule (SG) formulation containing 85% w/w daminozide as active substance. It is a white, granular solid and the pH of a 1% dilution is 4.04. The product is neither flammable nor auto-flammable and does not possess oxidizing or explosive properties. ALAR has good dilution, wettability, flowability and attrition characteristics, is 'nearly dust free' and does not produce excessive amounts of foam. The product has been demonstrated to be stable in studies at 54°C for 14 days and room temperature for 2 years, with no significant loss of active substance content. The packaging of the product remained free from any corrosion or degradation for the duration of the stability studies and the shelf life of the product is 24 months. The technical properties of ALAR indicate that no particular problems are expected when it is used as recommended and there are no implications for classification.

Table B.2.7.1 Accelerated Storage Stability Data (Woolley & Mullee, 2005)

Parameter	Method	Initial	2 Weeks at 54°C Sample A	2 Weeks at 54°C Sample B
Daminozide Content	HPLC Method M191/F (J14313)	83.7% w/w	83.8% w/w	84.1% w/w
Physical state	Visual	Opaque, hard granular solid	Opaque, hard granular solid	Opaque, hard granular solid
Colour	Visual	White	White	White
Odour	Olfactory	Odourless	Odourless	Odourless
Packaging description	Visual	2500 mL white, opaque, HDPE tamper evident snap cap jar.	2500 mL white, opaque, HDPE tamper evident snap cap jar.	2500 mL white, opaque, HDPE tamper evident snap cap jar.
Pack / product interactions	Visual	No signs of corrosion or degradation inside or outside of the jar.	No signs of corrosion or degradation inside or outside of the jar	No signs of corrosion or degradation inside or outside of the jar
Weight change	Gravimetric	-	4.42 x 10 ⁻² % (loss)	5.31 x 10 ⁻² % (loss)
pH of a 1% dilution	CIPAC 75.3	4.04	4.01	4.00
Particle size distribution	CIPAC MT 58.3	Determinations performed in duplicate: Sieve (µm) Residue (%) 2000 0.0067, 0.0067 1400 3.39, 2.64 1180 25.6, 25.6 850 68, 67.1 710 1.66, 2.61 500 0.918, 1.60 425 0.04, 0.073 355 0.0067, 0.02 250 0.013, 0.013 150 0.013, 0.013 Pan 0.506, 0.405 Mean % less than 150 µm: 0.456 Mean % less than 250 µm: 0.469	Determinations performed in duplicate: Sieve (µm) Residue (%) 2000 0.013, 0 1400 3.31, 3.66 1180 27.0, 30.7 850 64.8, 64.1 710 2.47, 0.93 500 1.83, 0.27 425 0.12, 0.02 355 0.0067, 0.013 250 0, 0.0067 150 0.02, 0.013 Pan 0.473, 0.340 Mean % less than 150 µm: 0.407 Mean % less than 250 µm: 0.423	Determinations performed in duplicate: Sieve (µm) Residue (%) 2000 0.02, 0 1400 3.64, 3.03 1180 29.8, 26.5 850 64.4, 67.0 710 1.31, 1.92 500 0.612, 1.12 425 0.047, 0.067 355 0.027, 0.02 250 0.013, 0.0067 150 0.02, 0.02 Pan 0.386, 0.346 Mean % less than 150 µm: 0.366 Mean % less than 250 µm: 0.386
Wettability	CIPAC MT 53.3.1	< 1 second	< 1 second	< 1 second
Wet sieving	CIPAC MT 59.3	No residue remained on a 75 µm sieve	No residue remained on a 75 µm sieve	No residue remained on a 75 µm sieve

Parameter	Method	Initial	2 Weeks at 54°C Sample A	2 Weeks at 54°C Sample B
Dilution stability	CIPAC MT 179	Stable dilution	Stable dilution	Stable dilution
Dustiness	CIPAC MT 171	Nearly dust-free	Nearly dust-free	Nearly dust-free
Friability/attrition resistance	CIPAC MT 178	Attrition resistance: 100%	Attrition resistance: 100%	Attrition resistance: 100%
Persistent foaming	CIPAC MT 47.2	1.835% w/v, CIPAC D Initial: 92 mL Foam 10 seconds: 80 mL Foam 1 minute: 37 mL Foam 3 minutes: 20 mL Foam 12 minutes: 14 mL Foam 0.0094% w/v, CIPAC D Initial: 28 mL Foam 10 seconds: 21 mL Foam 1 minute: 19 mL Foam 3 minutes: 18 mL Foam 12 minutes: 13 mL Foam	1.835% w/v, CIPAC D Initial: 92 mL Foam 10 seconds: 75 mL Foam 1 minute: 29 mL Foam 3 minutes: 19 mL Foam 12 minutes: 14 mL Foam 0.0094% w/v, CIPAC D Initial: 29 mL Foam 10 seconds: 23 mL Foam 1 minute: 20 mL Foam 3 minutes: 19 mL Foam 12 minutes: 13 mL Foam	1.835% w/v, CIPAC D Initial: 96 mL Foam 10 seconds: 85 mL Foam 1 minute: 33 mL Foam 3 minutes: 19 mL Foam 12 minutes: 15 mL Foam 0.0094% w/v, CIPAC D Initial: 31 mL Foam 10 seconds: 22 mL Foam 1 minute: 21 mL Foam 3 minutes: 20 mL Foam 12 minutes: 15 mL Foam

Table B.2.7.2 2-Year Room Temperature Storage Stability Data (Dunn, 2009)

Parameter	Method	Initial	24 Months at 25°C Sample A
Active Substance Content	HPLC Method GRL-GM-1139 (GRL-12410)	84.9% w/w	84.5% w/w
Physical state	Visual	Solid granular (elongated, extruded)	Solid granular (elongated, extruded)
Colour	Visual	White	White
Odour	Olfactory	Slight	Slight
Packaging description	Visual	2500 mL white, HDPE jars	2500 mL white, HDPE jars
Pack / product interactions	Visual	No signs of corrosion, leakage or panelling/bulging observed	No signs of corrosion, leakage or panelling/bulging observed

Parameter	Method	Initial	24 Months at 25°C Sample A
Weight change	Gravimetric	-	0.04% (Gain)
pH of a 1% dilution	CIPAC 75.3	3.85	4.03
Wettability	CIPAC MT 53.3.1	1 second	1 second
Persistent foaming	CIPAC MT 47.2	0.6% w/v, CIPAC C 10 seconds: 47 mL Foam 1 minute: 29 mL Foam 3 minutes: 16 mL Foam 12 minutes: 11 mL Foam	0.6% w/v, CIPAC C 10 seconds: 48 mL Foam 1 minute: 30 mL Foam 3 minutes: 17 mL Foam 12 minutes: 10 mL Foam
Apparent Density	CIPAC MT 58.3	0.52 g/mL	0.54 g/mL
Wet sieving	CIPAC MT 59.3	0.06% residue remained on a 75 µm sieve	0.07% residue remained on a 75 µm sieve
Dustiness	CIPAC MT 171	nearly dust free	nearly dust free
Dilution Stability	CIPAC MT 179	5 min test (% residue): 0.05 18 hour test (% residue): none, filtrate clear	5 min test (% residue): 0.07 18 hour test (% residue): none, filtrate clear
Attrition resistance	CIPAC MT 178	100%	100%

Table B.2.7.3 2-Year Room Temperature Storage Stability Data (Hart, 2012)

Parameter	Method	Initial	24 Months at Room Temperature
Daminozide content	HPLC Method GRL-GM-1139 (GRL-12901)	85.7% w/w	86.6% w/w
UDMH content	HPLC Method GRL-GM-1062 (GRL-12901)	< 5.3 ppm	< 5.1 ppm
NDMA content	HPLC Method GRL-GM-1268 (GRL-12901)	0.131 ppm	0.123 ppm
Physical state	Visual	Solid granules	Solid granules
Colour	Visual	White	White
Packaging description	Visual	5 L, white rectangular HDPE pails with caps.	5 L, white rectangular HDPE pails with caps; no signs of cracking or imperfections. Inner reflectivity is slightly duller than control.

Parameter	Method	Initial	24 Months at Room Temperature
Pack / product interactions	Visual	No signs of corrosion or degradation inside or outside of the jar.	Excellent pack stability. No signs of corrosion or degradation.
Weight change	Gravimetric	-	0.04% (Gain)

B.2.12 References Relied On

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.2.1 B.2.4 B.2.7/01 B.2.8/01	Woolley, A.J. Mullee, D.M.	2005	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
B.2.2 B.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
B.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
B.2.6/02 B.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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.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
B.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