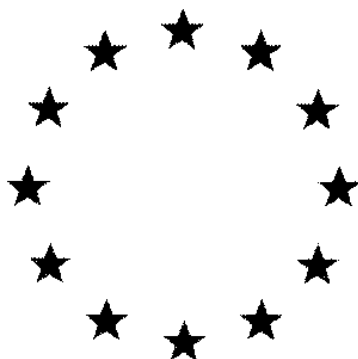


European Commission



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

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

Volume 3 - B.5 (PPP) - Alar

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
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B.5 METHODS OF ANALYSIS

Details of the literature search undertaken are available. No relevant scientifically peer-reviewed open literature reference has been identified for plant protection product Alar.

B.5.1 Methods used for generation of pre-authorisation data**B.5.1.1 Analysis of the Plant Protection Product*****(a) Methods for the determination of the active substance and/or variant in the plant protection product***

The following study was submitted by the Notifier to cover the analysis of the active substance in the plant protection product Alar.

Reference:	White, G.A. (2002): Validation of analytical method M191/F for the HPLC determination of daminozide in technical material and formulations
Report No.:	J14313
Guideline:	SANCO/3030/99 rev. 4 (11/07/00)
GLP:	Yes
Published:	No
Previous evaluation:	Submitted for the purpose of renewal

Principle of the method M191/F (Daminozide in formulation UBI 2331-05)

Samples of the formulation are transferred to volumetric flasks (25 mL) and pyridoxine hydrochloride internal standard (10 mL) is added. The samples are diluted to volume with water, sonicated for 10 minutes and filtered through GF/C filter papers into small glass vials. The samples are analysed by HPLC-UV at 240 nm, using a Phenomenex Synergy Polar-RP column and isocratic elution with a mobile phase of perchloric acid in water. Quantification is performed using daminozide reference standard solutions containing pyridoxine hydrochloride as an internal standard.

Column	Phenomenex 'Synergy' Polar-RP (250 mm x 4.6 mm, 4 µm particle size)
Column temperature	35°C
Detection	UV 240 nm
Injection volume	20 µL
Flow rate	1 ml/min
Mobile phase	98.8/0.2 water/perchloric acid (60%)

Specificity

No interferences were observed at the retention time of interest in any control samples, demonstrating specificity of the method. Analyte identity was confirmed by retention time match with an analytical standard and by comparison of UV spectra.

Linearity

The linearity of detector response was demonstrated using six standard solutions across the range of nominal daminozide concentration $\pm 50\%$ (0.04 to 0.13 g daminozide), with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 5.8467x - 0.0017$).

Precision (Repeatability)

Repeatability data was generated from six sample solutions. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (%)	RSD (%)	Acceptable RSD (%)
Daminozide	6	85.4	0.191	1.37

Accuracy (Recovery)

Recovery data was generated from six samples of blank formulation fortified with a known amount of daminozide. The mean percentage recovery obtained was within the guideline requirements and is presented in table below.

Analyte	Fortification Range (% of Nominal)	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
Daminozide	50 - 150	6	99.88	1.043	98 - 102

RMS comments and conclusion

The method was validated on linearity, precision, accuracy and specificity in accordance with SANCO/3030/99 rev. 4. Thus, the method M191/F is valid and suitable for determination of Daminozide in Alar. Representative chromatograms attached.

(b) Methods for determination of relevant impurities identified in the technical material or which may be formed during manufacture of the plant protection product or from degradation of the plant protection product during storage

The following study was submitted by the Notifier to cover the analysis of the relevant impurities Unsymmetrical Dimethylhydrazine (UDMH) and N-Nitrosodimethylamine (NDMA) in the plant protection product Alar.

Reference:	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)
Report No.:	GRL-12901
Guideline:	SANCO/3030/99 rev. 4 (11/07/00)
GLP:	Yes
Published:	No
Previous evaluation:	Submitted for the purpose of renewal

Principle of the method GRL-GM-1139 version 3.0 (Daminozide in formulation UBI 6899-00)

The method is based on method HPLC/UV (M191/E) just as M191/F above.

Samples of the formulation (117 mg) are transferred to 100 mL volumetric flasks and pyridoxine hydrochloride internal standard (20 mL) is added. The samples are made to volume with water, mixed well and analysed by HPLC-UV at 220 nm, using a Phenomenex Prodigy ODS2 column and isocratic elution with a mobile phase of 0.15% phosphoric acid in water. Quantification is performed using daminozide reference standard solutions containing pyridoxine hydrochloride as an internal standard.

Column	Phenomenex Prodigy (250 mm x 4.6 mm, 5 µm particle size)
Column temperature	40°C
Detection	UV 220 nm
Injection volume	10 µL
Flow rate	1.2 ml/min
Mobile phase	1.5 ml phosphoric acid in 1 L water

Specificity

Analyte identity was confirmed by retention time match with an analytical standard and by comparison of UV spectra. No interferences were observed at the retention time of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using five standard solutions across the concentration range of 40.21 to 160.48 mg/100ml, with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 0.012273x + 0.002674$).

Precision (Repeatability)

Repeatability data was generated from six sample solutions. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (%)	RSD (%)	Acceptable RSD (%)
Daminozide	6	85.5	0.27	1.37

Accuracy (Recovery)

Recovery data was generated from five samples of blank formulation fortified with a known amount of daminozide. The mean percentage recovery obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
Daminozide	5	100.3	0.39	98 - 102

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 2.09 mg/100ml (LOQ is not required).

RMS comments and conclusion

The method was validated on linearity, precision, accuracy and specificity in accordance with SANCO/3030/99 rev. 4. Thus, the method GRL-GM-1139 version 3.0 is valid and suitable for determination of Daminozide in Alar. Representative chromatograms attached.

Principle of the method GRL-GM-1062 version 3.1 (UDMH in formulation UBI 6899-00)

Samples of the formulation (1 g) are weighed into 250 mL bottles and dissolved in 10/90, v/v, methyl ethyl ketone/ethyl alcohol (100 mL) with stirring. An aliquot (10 mL) of the samples is removed to a round bottomed flask and distilled under vacuum at 30°C. The distillate is analysed by GC-NPD using a Supelco SPB-1 column. Quantification is performed using external standard solutions.

Column	Supelco, SPB-1 (15 m x 0.53 mm, 1.50 µm film thickness)
Detector temperature	300°C
Detection	NPD
Injection volume	1.0 µL
Carrier gas (He) flow-rate	Approx. 2.5 ml/min (constant flow mode)

Specificity

Analyte identity was confirmed by retention time match with analytical standards. No interferences were observed at the retention times of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using seven standard solutions across the nominal concentration range of 44.96 - 314.72 µg/L, with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 733.45x - 6114.17$).

Precision (Repeatability)

Repeatability data was generated from six sample determinations of formulation. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (mg/kg)	RSD (%)	Acceptable RSD (%)
UDMH	6	5.18	4.09	8.37

Accuracy (Recovery)

Recovery data was generated using the standard addition technique. Samples of formulation were fortified with known amounts of UDMH. The mean recovery obtained was within the guideline requirement and is presented in table below.

Analyte	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
UDMH	5	83.0	2.30	75 - 125

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 5.2 mg/kg.

Confirmation

Confirmation was not provided. Confirmation can only be carried out by comparison retention times from recovery samples and standards. In this case the retention time was essentially the same.

RMS comments and conclusion

The analytical procedure has been successfully validated in terms of specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANCO/3030/99 rev. 4. Confirmatory analysis was not provided. Nevertheless the method GRL-GM-1062 version 3.1 is suitable for determination of UDMH in Alar. Representative chromatograms attached.

Principle of the method GRL-GM-1268 version 1.0 (NDMA in formulation UBI 6899-00)

Samples of the formulation (5.8 g) are weighed into 250 mL bottles and dissolved in water (100 mL) and d₆-NDMA solution (4 ppm, 500 µL). An aliquot (20 mL) of the samples is removed to a separating funnel, water (80 mL) is added and the solution is extracted with dichloromethane (3 x 40 mL). The combined extracts are filtered through sodium sulphate and rotary evaporated at 35°C to a volume of 0.5 mL. The samples are analysed by GC-MSD using a HP-5MS column. Quantification is performed using NDMA reference standard solutions containing the d₆-NDMA internal standard (ion m/z 80.2 is used for quantification and the ion m/z 46.2 is used for confirmation). The NDMA ion m/z 74.2 is used for quantification and the ion m/z 42.2 is used for confirmation.

Column	HP-5MS (30 m x 0.25 mm, 0.25 µm film thickness)
Detector temperature	230°C
Injection temperature	175°C
Detection	MSD
Injection volume	1.0 µL
Carrier gas (He) flow-rate	Approx. 1.0 ml/min (constant flow mode)

Specificity

Analyte identity was confirmed by retention time match with analytical standards and by comparison of mass spectra. No interferences were observed at the retention times of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using five standard solutions across the nominal concentration range of 0.0248 - 1.34 µg/vial, with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 2.1365x - 0.0219$).

Precision (Repeatability)

Repeatability data was generated from six sample determinations of formulation. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (mg/kg)	RSD (%)	Acceptable RSD (%)
NDMA	6	0.119	1.89	14.8

Accuracy (Recovery)

Recovery data was generated using the standard addition technique. Samples of formulation were fortified with known amounts of NDMA. The mean recoveries obtained were within the guideline requirement and are presented in table below.

Analyte	Nominal Level (mg/kg)	Number of Samples (n)	Mean Recovery (%)	Acceptable Recovery (%)
NDMA	0.042	5	98.5	75 - 125
	0.18	5	102	75 - 125

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 0.042 mg/kg.

Confirmation

Confirmation is not required because of using highly specific method GC-MSD as a primary method.

RMS comments and conclusion

The analytical procedure has been successfully validated in terms of specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANCO/3030/99 rev. 4. For internal standard d₆-NDMA ion m/z 80.2 is used for quantification and the ion m/z 46.2 is used for confirmation and for NDMA ion m/z 74.2 is used for quantification and the ion m/z 42.2 is used for confirmation. Confirmatory analysis is not required. The method GRL-GM-1268 version 1.0 is suitable for determination of NDMA in Alar. Representative chromatograms attached.

(c) Methods for the determination of relevant co-formulants or components of co-formulants, where required by the national competent authorities

With respect to toxicological, eco-toxicological or environmental aspects the product Alar does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

CIPAC methods

A CIPAC method for the determination of Daminozide in SG formulations is not available.

B.5.1.2 Methods for the Determination of Residues

All methods for the determination of daminozide residues are included in Volume 3 CA_B-5.

(a) Methods In soil, water, sediment, air and any additional matrices used in support of environmental fate studies

No new environmental fate studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(b) Methods in soil, water and any additional matrices used in support of efficacy studies

No new efficacy studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(c) Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicology studies

No new toxicology studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(d) Methods in body fluids, air, and any additional matrices used in support of operator, worker, resident and bystander exposure studies

No new operator, worker, resident or bystander exposure studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(e) Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies

No new residue studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(f) Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies

No new ecotoxicology studies on Alar for which analytical methods are required are being submitted in support of the renewal of approval of daminozide.

(g) Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests

Reference:	Dunn, N.L. (2009): Storage stability of Alar 85 SG (UBI 6899.00) over two years at ambient temperatures in HDPE containers
Report No.:	GRL-12410
Guideline:	SANCO/3030/99 rev. 4 (11/07/00)
GLP:	Yes
Published:	No
Previous evaluation:	Submitted for the purpose of renewal

Principle of the method GRL-GM-1139 version 2.1 (Daminozide in formulation UBI 6899-00)

Samples of the formulation (117 mg) are transferred to 100 mL volumetric flasks and pyridoxine hydrochloride internal standard (20 mL) is added. The samples are made to volume with water, mixed well and analysed by

HPLC-UV at 220 nm, using a Phenomenex Prodigy ODS2 column and isocratic elution with a mobile phase of 0.15% phosphoric acid in water. Quantification is performed using daminozide reference standard solutions containing pyridoxine hydrochloride as an internal standard.

Column	Phenomenex Prodigy (250 mm x 4.6 mm, 5 µm particle size)
Column temperature	40°C
Detection	UV 220 nm
Injection volume	10 µL
Flow rate	1.2 ml/min
Mobile phase	1.5 ml phosphoric acid in 1 L water

Specificity

Analyte identity was confirmed by retention time match with an analytical standard and by comparison of UV spectra. No interferences were observed at the retention time of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using five standard solutions across the concentration range of 40.21 to 160.48 mg/100ml, with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 0.012273x + 0.002674$).

Precision (Repeatability)

Repeatability data was generated from six sample solutions. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (%)	RSD (%)	Acceptable RSD (%)
Daminozide	6	85.5	0.27	1.37

Accuracy (Recovery)

Recovery data was generated from five samples of blank formulation fortified with a known amount of daminozide. The mean percentage recovery obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
Daminozide	5	100.3	0.39	98 - 102

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 2.09 mg/100ml (LOQ is not required).

RMS comments and conclusion

The method was validated on linearity, precision, accuracy and specificity in accordance with SANCO/3030/99 rev. 4. Thus, the method GRL-GM-1139 version 2.1 is valid and suitable for determination of Daminozide in Alar. Representative chromatograms attached.

B.5.2 Methods for Post-Authorisation Control and Monitoring Purposes

All enforcement methods for the determination of daminozide residues are included in Volume 3 CA_B-5.

The following studies were submitted by the Notifier for post-authorisation control and monitoring purposes:

Reference:	Riggs, A.S. (2009a): VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF UNSYMMETRICAL DIMETHYL HYDRAZINE (UDMH) IN ALAR 85 WG
Report No.:	GRL-12643 (GRL-11423)
Guideline:	SANCO/3030/99 rev. 4 (11/07/00)
GLP:	Yes
Published:	No
Previous evaluation:	Submitted for the purpose of renewal

Principle of the method GRL-GM-1062 version 2.0 (UDMH in formulation UBI 6899-00)

Samples of the formulation (1 g) are weighed into 250 mL bottles and dissolved in 10/90, v/v, methyl ethyl ketone/ethyl alcohol (100 mL) with stirring. An aliquot (10 mL) of the samples is removed to a round bottomed flask and distilled under vacuum at 30°C. The distillate is analysed by GC-NPD using a Supelco SPB-1 column. Quantification is performed using external standard solutions.

Column	Supelco, SPB-1 (15 m x 0.53 mm, 1.50 µm film thickness)
Detector temperature	300°C
Detection	NPD
Injection volume	1.0 µL
Carrier gas (He) flow-rate	Approx. 2.5 ml/min (constant flow mode)

Specificity

Analyte identity was confirmed by retention time match with analytical standards. No interferences were observed at the retention times of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using seven standard solutions across the nominal concentration range of 44.96 - 314.72 µg/L, with a coefficient of determination (R^2) of 0.999 (regression line equation $y = 733.45x - 6114.17$).

Precision (Repeatability)

Repeatability data was generated from six sample determinations of formulation. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (mg/kg)	RSD (%)	Acceptable RSD (%)
UDMH	6	5.18	4.09	8.37

Accuracy (Recovery)

Recovery data was generated using the standard addition technique. Samples of formulation were fortified with known amounts of UDMH. The mean recovery obtained was within the guideline requirement and is presented in table below.

Analyte	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
UDMH	5	83.0	2.30	75 - 125

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 5.2 mg/kg.

Confirmation and non-analyte interferences

Confirmation was not provided. Confirmation can only be carried out by comparison retention times from recovery samples and standards. In this case the retention time was essentially the same.

There was no evidence of peak interference from the inert ingredients in Alar 85 WG when analysed by this method.

Stability in Solution

The UDMH concentration in 6 replicate samples of Afar 85 WG was measured in duplicate at time zero after approximately 21 hours at room temperature. A t-test analysis indicates that the assays at the two time periods were not significantly different at the 99.5 % confidence level.

RMS comments and conclusion

The analytical procedure has been successfully validated in terms of specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANCO/3030/99 rev. 4. Confirmatory analysis was not provided. Nevertheless the method GRL-GM-1062 version 2.0 is suitable for determination of UDMH in Alar. Representative chromatograms attached.

Reference:	Riggs, A.S. (2009b): VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF N-NITROSODIMETHYLAMINE (NDMA) IN ALAR 85 WG
Report No.:	GRL-12644 (GRL-11450)
Guideline:	SANCO/3030/99 rev. 4 (11/07/00)
GLP:	Yes
Published:	No
Previous evaluation:	Submitted for the purpose of renewal

Principle of the method GRL-GM-1144 version 2.0 (NDMA in formulation UBI 6899-00)

Daminozide technical and Alar 85 SG are dissolved in HPLC grade water and d_6 -NDMA is added as an internal standard. The solution is adjusted to $pH \geq 10$ with 50% sodium hydroxide to promote NDMA extraction. The solution is then extracted with dichloromethane.

The extract is dried by filtration through a bed of anhydrous sodium sulphate and concentrated for analysis using gas chromatography and a mass spectrometer for detection. For internal standard d_6 -NDMA ion m/z 80.2 is used for quantification and the ion m/z 46.2 is used for confirmation and for NDMA ion m/z 74.2 is used for quantification and the ion m/z 42.2 is used for confirmation

Column	HP-5MS (30 m x 0.25 mm, 0.25 μ m film thickness)
Detector temperature	230°C
Injection temperature	175°C
Detection	MSD
Injection volume	1.0 μ L
Carrier gas (He) flow-rate	Approx. 1.0 ml/min (constant flow mode)

Specificity

Analyte identity was confirmed by retention time match with analytical standards and by comparison of mass spectra. No interferences were observed at the retention times of interest in any control samples, demonstrating specificity of the method.

Linearity

The linearity of detector response was demonstrated using seven standard solutions across the nominal concentration range of 0.051 - 1.275 μ g/vial, with a coefficient of determination (R^2) of 0.9997 (regression line equation $y = 2.050x - 0.0236$).

Precision (Repeatability)

Repeatability data was generated from six sample determinations of formulation. The relative standard deviation (RSD) obtained was within the guideline requirements and is presented in table below.

Analyte	Number of Samples (n)	Mean Content (mg/kg)	RSD (%)	Acceptable RSD (%)
NDMA	6	0.446	9.33	12.0

Accuracy (Recovery)

Recovery data was generated using the standard addition technique. Samples of formulation were fortified with known amounts of NDMA. The mean recoveries obtained were within the guideline requirement and are presented in table below.

Analyte	Number of Samples (n)	Mean Recovery (%)	RSD (%)	Acceptable Recovery (%)
NDMA	5	100	8.92	75 - 125

Limit of quantification (LOQ)

The limit of quantification (LOQ) was determined to be 0.049 mg/kg.

Confirmation and non-analyte interferences

Confirmation is not required because of using highly specific method GC-MSD as a primary method.

No interference was observed when an extract of water analysed as per the method. No significant interference was observed when an extract of a solution of the placebo of Alar 85 WG was analysed as per the method.

Stability in Solution

Using this method, no significant change in the NDMA analytical results were observed when solutions for the analysis of Alar 85 WG were stored at ambient conditions for 6 days.

RMS comments and conclusion

The analytical procedure has been successfully validated in terms of specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANCO/3030/99 rev. 4. For internal standard d₆-NDMA ion m/z 80.2 is used for quantification and the ion m/z 46.2 is used for confirmation and for NDMA ion m/z 74.2 is used for quantification and the ion m/z 42.2 is used for confirmation. Confirmatory analysis is not required. The method GRL-GM-1144 version 2.0 is suitable for determination of NDMA in Alar. Representative chromatograms attached.

B.5.3 References relied on

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

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