Asulam-sodium

Annex B (Volume 3)

B.2 Physical and chemical properties

Version history

When	What
2016-04-18	Initial DAR

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance asulam sodium

These studies have been evaluated at EU level and the conclusions presented are consistent with those in the EFSA report, with the exception of the Mills 2007study

Table B.2.1 Summary of the physical and chemical properties of the active substance (studies were completed to an acceptable standard and results were considered to be valid unless specified otherwise) [studies were conducted using purified and technical asulam sodium]

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.1 (IIA 2.1)	Melting point	Pure 99.1% Techn. 89.6%	EPA/OPPTS series 830	230°C 223°C		Francon, 1999a
B.2.1.2 (IIA 2.1)	Boiling point			Not measureable, pure active decomposes at 230°C and technical at 223°C		Francon, 1999a
B.2.1.3 (IIA 2.1)	Temperature of decomposition or sublimation			Decomposition occurs at - pure = 230°C technical = 223°C		Francon, 1999a
B.2.1.4 (IIA 2.2)	Relative density	Pure 99.1%	EPA/OPPTS series 830	1.525 kg/m^3 at 20°C	Pycnometer	Francon, 1999a
B.2.1.5 (IIA 2.3)	Vapour pressure	Pure 99.1%	EEC method A 4	5 x 10^{-7} Pa at 45°C	Very slightly volatile Test was conducted at 45°C instead of 20°C due to the low result	Francon, 2000

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.6 (IIA 2.3)	Volatility, Henry's law constant		Calculated	<1.31 x 10^{-10} Pa m^3 mol^{-1}	Very slightly volatile	Brachet, 2008a
B.2.1.7 (IIA 2.4)	Appearance: physical state	Pure 99.1% Techn. 89.6%	EPA/OPPTS series 830	Solid Solid		Francon, 1999a
B.2.1.8 (IIA 2.4)	Appearance: colour	Pure 99.1% Techn. 89.6%	EPA/OPPTS series 830	White White		Francon, 1999a
B.2.1.9 (IIA 2.4)	Appearance: odour	Pure 99.1% Techn. 89.6%	EPA/OPPTS series 830	Unidentified chemical odour Odourless		Francon, 1999a
B.2.1.10 (IIA 2.5)	Spectra	Pure 99.1%	UV/VIS, IR, ^{1}H-NMR and MS	UV/VIS, IR, ^{1}H-NMR and MS spectra were submitted on asulam sodium and were consistent with the structure of the molecule. <u>UV/VIS</u> UV absorb 203 nm (ε = 22177 l mol^{-1} cm^{-1}) UV absorb 293 nm (ε = 2750 l mol^{-1} cm^{-1}) <u>IR</u> 3377 cm^{-1} N-H stretch 2956 cm^{-1} C-H stretch		Guesnet, 1999

section (Annex point)	study	purity	method	results	comment	reference
				1622 cm^{-1} C=O stretch 1598 cm^{-1} C=C stretch 1300 cm^{-1} SO_2 strech 1074 cm^{-1} C-O strech H^1-NMR 7.4 CH-C(NH_2)-CH (aromatic) 6.5 CH-C-(SO_2)-CH (aromatic) 5.4 NH_2 3.3 O-CH_3 C^{13}-NMR 159 N-C(O)-CH_3 150 CH-C(NH_2)-CH (aromatic) 133 CH-C-(SO_2)-CH (aromatic) 128 C(SO_2)-CH-CH (aromatic) 112 C(NH_2)-CH-CH (aromatic) 51 CH_3-O Mass Spec m/z 779 $[3M+Na]^+$ m/z 527 $[2M+Na]^+$ m/z 275 $[M+Na]^+$ m/z 253 $[MH]^+$ UV/VIS, IR, ^{1}H-NMR, ^{13}C-NMR and MS spectra submitted on [redacted]		Diepenhorst, 2008a

section (Annex point)	study	purity	method	results	comment	reference
				were consistent with the structure of the molecule. UV/VIS [redacted] IR [redacted] H^1-NMR [redacted] C^{13}-NMR [redacted]		Marshall, 2008

section (Annex point)	study	purity	method	results	comment	reference
				[redacted] Mass Spec [redacted] UV/VIS, IR, ^{1}H-NMR, ^{13}C-NMR and MS spectra submitted on methanol were consistent with the structure of the molecule. UV/VIS UV absorb 210 nm IR 3350 cm^{-1} O-H stretch 2950 cm^{-1} C-H stretch 2850 cm^{-1} C-H stretch 1450 cm^{-1} C-H bend 1050 cm^{-1} C-O stretch 680 cm^{-1} C-H bend H^{1}-NMR 3.6 OH 3.4 CH_4		Anon and Anon, 2008

section (Annex point)	study	purity	method	results	comment	reference
				C^{13}-NMR 50 CH_3-OH Mass Spec m/z 32 Molecular ion m/z 31 M - H m/z 29 M - 2H m/z 15 CH_3		
B.2.1.11 (IIA 2.6)	Solubility in water	Pure 99.1%	EEC method A 6	5.5 g/l at pH 4 (biphtalate buffer) and 20°C 962 g/l at pH 8 (double distilled water) and 20°C 1048 g/l at pH 9 (borate buffer) and 20°C	Really soluble in distilled water	Francon, 1999b
B.2.1.12 (IIA 2.7)	Solubility in organic solvents (technical active substance)	Pure 99.1%	Similar method to EEC method A6	n-heptane 0.00007 g/L at 25°C xylene 0.098 g/L at 25°C dichloromethane 0.033 g/L at 25°C methanol 117 g/L at 25°C n-octanol 0.03 g/L at 25°C acetone 1.1 g/L at 25°C ethyl acetate 0.5 g/L at 25°C acetonitrile 2.3 g/L at 25°C		Francon, 1999b
B.2.1.13 (IIA 2.8)	Partition co-efficient	Pure 99.1%	EEC method A 8	Log P_{ow} = 0.11 at pH 4 and 25°C Log P_{ow} = 0.15 at pH 7 and 25°C Log P_{ow} = 0.77 at pH 9 and 25°C		Francon, 1999c
B.2.1.14 (IIA 2.9)	Stability in water			See section 2.1.15		

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.15 (IIA 2.9)	Hydrolysis rate	[^{14}C] phenyl label >94%	EPA guideline 161-1	Stable to hydrolysis at pH 5-9 at 25°C for at least 30 days (less than 5% of asulam had degraded to its metabolites)	See section B.8.4.1	Gohdes, 1989
B.2.1.16 (IIA 2.9)	Photochemical degradation	[^{14}C] phenyl label >98%	EPA guideline 161-2	Photolytic half life = 0.44 days (DT90 = 1.5 days) at pH 4 in sterile aqueous buffered solution, continuously irradiated with a Xenon lamp for a test period of 26 hours [major degradation product was sulphanilic acid representing 56% of the total radioactivity]. Photolytic half life = 0.87 days (DT90 = 2.9 days) at pH 9 in sterile aqueous buffered solution, continuously irradiated with a Xenon lamp for a test period of 52 hours [major degradation product was N-(4-aminophenyl) formamide representing 24% of the total radioactivity]. Photolytic half life = 0.28 days (DT90 = 0.94 days) at pH 4 in sterile aqueous buffered solution, continuously irradiated with a Xenon lamp for a test period of 25 hours [major degradation product was sulphanilic acid representing 64% of the total radioactivity].	See section B.8.4.2	Mills, 2003 Mills, 2007

section (Annex point)	study	purity	method	results	comment	reference
				Photolytic half life = 0.86 days (DT90 = 2.9 days) at pH 9 in sterile aqueous buffered solution, continuously irradiated with a Xenon lamp for a test period of 47 hours [major degradation products were sulphanilic acid representing 15% of the total radioactivity and N-(4-aminophenyl) formamide representing 19% of the total radioactivity].		
B.2.1.17 (IIA 2.9)	Quantum yield		calculated	0.114 at pH4 0.157 at pH9 0.168 at pH4 0.0612 at pH9	See section B.8.4.2	Mills, 2003 Mills, 2007
B.2.1.18 (IIA 2.9)	Dissociation constant (pKa)	Pure 99.1%	OECD Test Guideline 112	pKa1 = 1.29 at 20°C pKa2 = 4.68 at 20°C	Asulam sodium behaves as an alkaline molecule with 2 dissociation centres	Francon, 1999d
B.2.1.19 (IIA 2.10)	Stability in air, photochemical oxidative degradation		Calculated (Atkinson)	Atmospheric $t_{½}$ = 0.4 days		van der Gaauw, 2001

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.20 (IIA 2.11)	Flammability and auto-flammability (technical active substance)	81.2%	Flammability: EEC method A 10	Flammability: Not considered highly flammable	Soluble granule formulation was tested containing 81.2% asulam – data accepted as the majority of the formulation is asulam	van Helvoirt, 1993b
			UN-Bowes-Cameron-Cage-Test	Auto flammability: No self ignition up to a temperature of 140°C		van Helvoirt, 1993a
		82.3%	EEC method A 16	Auto flammability: No self ignition up to a temperature of 400°C	Soluble granule formulation was tested containing ≈74%asulam	Maarsingh, 2008
B.2.1.21 (IIA 2.12)	Flash point (technical active substance)			Melting point > 40°C, therefore flash point not required		
B.2.1.22 (IIA 2.13)	Explosive properties (technical active substance)	82.2%	EEC method A 14	Non-explosive	Soluble granule formulation was tested containing 82.2% asulam - data accepted as the majority of the formulation is asulam	Smeykal, 2001
B.2.1.23 (IIA 2.15)	Oxidising properties (technical active substance)	Techn. 89.6%	EEC method A 17	Non-oxidising		Tran Thanh Phong, 1999
B.2.1.24 (IIA 2.14)	Surface tension	Techn. 89.6%	EPA/OPPTS series 830	71.5 mN/m at 20°C (90% saturated solution – 1 g/l)		Francon, 1999a

B.2.2 Physical, chemical and technical properties of the plant protection product

These studies have been evaluated at EU level and the conclusions presented are consistent with those in the EFSA report, with the exception of the Bos 2010 study

Product name: 'Asulox' (Soluble concentrate containing 438 g/l asulam sodium)

Table B.2.2 Summary of the physical and chemical properties of the plant protection product

section (Annex point)	study	method	results	comment	reference
B.2.2.1 (IIIA 2.1)	Appearance: physical state	Visual	Liquid		Uceda, 1997
B.2.2.2 (IIIA 2.1)	Appearance: colour	Visual	Bright ivory		Uceda, 1997
B.2.2.3 (IIIA 2.1)	Appearance: odour	Smell	None detected		Uceda, 1997
B.2.2.4 (IIIA 2.2)	Explosive properties	EEC method A 14	Non-explosive		Fillion, 1997
B.2.2.5 (IIIA 2.2)	Oxidising properties	EEC method A 21	Non-oxidising		Le Gren, 2004
B.2.2.6 (IIIA 2.3)	Flammability			Not required for liquid preparations	

section (Annex point)	study	method	results	comment	reference
B.2.2.7 (IIIA 2.3)	Auto-flammability	EEC method A 15	No self ignition at a temperature of 600°C		Fillion, 1997
B.2.2.8 (IIIA 2.3)	Flash point			Not required as the formulation is a water based soluble concentrate	
B.2.2.9 (IIIA 2.4)	Acidity/alkalinity			Not required as pH is>4 and <10	
B.2.2.10 (IIIA 2.4)	pH	CIPAC MT 75	pH = 6.8 (1% dilution)		Uceda, 1997
B.2.2.11 (IIIA 2.5)	Surface tension	EEC method A 5	72 mN/m at 20°C		Uceda, 1997
B.2.2.12 (IIIA 2.5)	Viscosity	CIPAC MT22	2.36 $mm^2.s^{-1}$ at 40°C (Kinematic)		Uceda, 2001
B.2.2.13 (IIIA 2.6)	Relative density	EEC Method A 3	1.202 g/ml at 20°C		Uceda, 1997
B.2.2.14 (IIIA 2.6)	Bulk (tap) density			Not required for liquid preparations	
B.2.2.14 (IIIA 2.7)	Storage stability	CIPAC Method MT 46	Chemically and physically stable for two weeks at 54°C. Formulation tested for shelf life was packaged into a 1 L PE-HD (high density		Uceda, 1997

section (Annex point)	study	method	results	comment	reference
			polyethyene) grey opaque can. Physical properties tested before and after storage – appearance (before storage only), pH, dilution stability and persistent foam. Chemically and physically stable for two weeks at 54°C in the formulated product Asulox 400 SL - glass bottle. Asulam content decreased slightly from 407.3 to 399.8 g/L. **Storage stability (Accelerated) - impurities in the formulated product: sulphanilimide and methanol** Sulphanilamide content increased slightly from 9.0 to 9.3 g/l. Methanol content increased slightly from 8.0 to 8.4 g/l. Expected nominal sulphanilamide content in the product is 11 g/l. Expected nominal methanol content in the product is 4 g/l (max content 11 g/l).		Bos, 2008a Bos, 2008a
		CIPAC Methods MT 39	Less than 0.05 ml of sedimentation after 7 days at 0°C.		Uceda, 1997

section (Annex point)	study	method	results	comment	reference
B.2.2.15 (IIIA 2.7)	Shelf life		Chemically and physically stable for two years at ambient temperatures in a 1 L PE-HD (high density polyethylene) grey opaque can. Physical properties tested before and after storage – appearance, pH, dilution stability and persistent foam.		Uceda, 1999
			Stability at ambient temperatures in 1 L PET (polyethylene) – : asulam content decreased slightly from 407.3 to 405.5 g/L (after storage for 2 year).		Bos, 2010
			Shelf life - impurities in the formulated product: sulphanilimide and methanol Sulphanilamide content decreased slightly from 9.0 to 8.9 g/l (after storage for 2 year). Methanol content decreased slightly from 8.0 to 7.0 g/l (after storage for 2 year). Expect nominal Sulphanilamide content in the product is 11 g/l. Expected nominal methanol content in the product is 4 g/l (max content 11 g/l).		Bos, 2010

section (Annex point)	study	method	results	comment	reference
B.2.2.16 (IIIA 2.8)	Wettability			Not required for soluble concentrates	
B.2.2.17 (IIIA 2.8)	Persistent foaming	CIPAC Method MT 47.2	<1 ml of foam after 1 minute		Uceda, 1997
B.2.2.18 (IIIA 2.8)	Suspensibility			Not required for soluble concentrates	
B.2.2.19 (IIIA 2.8)	Suspension stability			Not required for soluble concentrates	
B.2.2.20 (IIIA 2.8)	Dilution stability	CIPAC Method MT 41	Less than 0.1%w/w of sedimentation		Uceda, 1997
B.2.2.21 (IIIA 2.8)	Dry sieve test			Not required for soluble concentrates	
B.2.2.22 (IIIA 2.8)	Wet sieve test			Not required for soluble concentrates	
B.2.2.23 (IIIA 2.8)	Particle size distribution			Not required for soluble concentrates	
B.2.2.24 (IIIA 2.8)	Content of dust/fines			Not required for soluble concentrates	

section (Annex point)	study	method	results	comment	reference
B.2.2.25 (IIIA 2.8)	Attrition and friability			Not required for soluble concentrates	
B.2.2.26 (IIIA 2.8)	Emulsifiabilty, re-emulsifiabilty and emulsion stability			Not required for soluble concentrates	
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion			Not required for soluble concentrates	
B.2.2.28 (IIIA 2.8)	Flowability			Not required for soluble concentrates	
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)			Not required for soluble concentrates	
B.2.2.30 (IIIA 2.8)	Dustability			Not required for soluble concentrates	
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds			Not required for soluble concentrates	

section (Annex point)	study	method	results	comment	reference
	Effectiveness of cleaning	In house method	Residue in tank after 2 water washes cleaning =0.68% Residue in fifth tank wash after 4 water washes 2 of which with 'All Clear Extra' = 5.3 mg/l (0.02%)	Applicant stated at these levels asulam would not be phytotoxic	Friessleben 2002 Richards, 2009

B.2.2.1 Summary of physical and chemical compatibility with other products (IIIA 2.9)

There are no recommendations for tank mixes with other products.

B.2.3 Summary of physical and chemical properties

B.2.3.1 Active substance

Asulam sodium is a white solid with a moderately high melting point (228-232°C) and a very low volatility (5 x 10^{-7} Pa at 45°C). It is readily soluble in water (962 g/L at 20°C) and is soluble (117 g/L at 25°C) in methanol. The octanol/water partition coefficient (Log P_{OW} = 0.15 at 25°C) does not indicate the potential to bio-accumulate or to be fat soluble. The pure active substance is hydrolytically stable at pH 5, 7 and 9 after 30 days at 25°C, has a photolytic half life of less than 1 day at pH 7 in sterile aqueous buffered solution and does not require classification with regards to flammability, explosive and oxidising properties.

B.2.3.2 Plant protection product

Asulam sodium is formulated as a soluble concentrate 'Asulox', containing 438 g/L asulam sodium. Data submitted indicated that the formulation was chemically and physically stable for 2 years at ambient temperatures and does not require classification with regards to flammability, explosive and oxidising properties. With regards to relevant impurities, none of them had altered significantly.

B.2.4 Literature search

It is considered that the literature searches are acceptable in terms of databases searched and the search criteria applied. On checking the references list, agree with the applicant assessment that the search did not reveal any references of relevance to this section. In addition, the applicant submitted new studies to cover the areas of concern raised in the EFSA conclusion.

B.2.5 References relied on

In every chapter (B.1, B.2, etc.) in Volume 3 (AS) the reference relied on heading should start with a paragraph indicating how the literature search was carried out and if this is considered acceptable. It should also be indicated if the RMS can agree with the justifications given by the notifier (especially for non-relevant literature).This is not expected to be a detailed study-by-study consideration. Relevant literature would be evaluated and assessed in the normal way within each section.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study:
Previous evaluation: responded “N.A”. for NAS, “Submitted for the purpose of renewal”, or “In DAR (year)”, “In addendum to DAR (year)” or any other appropriate.

Active substance

*details to be added during Peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.1.1/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.1.2/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.1.3/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.2/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.3.1/01	Françon, B.	2000	Asulam sodium - vapour pressure United Phosphorus Limited Report No.: R006757 Battelle Europe, Battelle-Institut e.V.; GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.3.2/01	Brachet, A.	2008a	Calculation of Henry's law constant of Asulam sodium United Phosphorus Limited Report No.: P-72-08-01 Battelle Switzerland GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.4.1/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.4.1/02	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.4.2/01	Françon B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.4.2/02	Françon B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.5.1/01	Zinini, N.; Guesnet J.-L.	1999	Asulam Na+ salt - NMR, IR, MS and UV-visible spectra United Phosphorus Limited Report No.: R006753 Rhone Poulenc Agro, France GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.5.1/02	Zinini, N.; Guesnet J.-L.	1999	Asulam Na+ salt - NMR, IR, MS and UV-visible spectra United Phosphorus Limited Report No.: R006753 Rhone Poulenc Agro, France GLP, Unpublished ⇒ CA 2.5.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.5.1/03	Zinini, N.; Guesnet J.-L.	1999	Asulam Na+ salt - NMR, IR, MS and UV-visible spectra United Phosphorus Limited Report No.: R006753 Rhone Poulenc Agro, France GLP, Unpublished ⇒ CA 2.5.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.5.1/04	Zinini, N.; Guesnet J.-L.	1999	Asulam Na+ salt - NMR, IR, MS and UV-visible spectra United Phosphorus Limited Report No.: R006753 Rhone Poulenc Agro, France GLP, Unpublished ⇒ CA 2.5.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.5.2/01	Anon.	2008	IMPCA Methanol Reference Specifications International Methanol Producers & Consumers Association Not GLP, Published	N	N	-	Published	
CA 2.5.2/04 - CA 2.5.2/07	Anon.	-	Spectral Database for Organic Compounds, SDBS, Web site: http://sdbs.riodb.aist.go.jp (National Institute of Advanced Industrial Science and Technology, October 2013) Not GLP, Published	N	N	-	Published	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.5.2/08	Diepenhorst, P.C.	2008a	UV/Visible and IR-spectra of [redacted] United Phosphorus Limited Report No.: DL 08-024 Cerexagri B.V., The Netherlands GLP, Unpublished Confidential information	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.5.2/09	Marshall, I.	2008	Evaluation of Spectroscopic Properties of [redacted] United Phosphorus Limited Report No.: SEL/2983/1 Selcia Ltd., UK GLP, Unpublished Confidential information	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.6/01	Françon, B.	1999b	Asulam sodium water and solvent solubility United Phosphorus Limited Report No: R006749 Battelle Europe, Battelle-Institut e.V.; GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.7/01	Françon, B.	1999b	Asulam sodium water and solvent solubility United Phosphorus Limited Report No: R006749 Battelle Europe, Battelle-Institut e.V.; GLP, Unpublished ⇒ CA 2.6/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.8/01	Françon B.	1999c	Asulam sodium n-octanol/water partition coefficient United Phosphorus Limited Report No.: R006755 Battelle Europe, Battelle-Institut e.V.; GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.9.1/01	Gohdes, M.	1989	Hydrolysis of ^{14}C-asulam in buffered aqueous solutions United Phosphorus Limited Report No.: R000015 Hazleton Laboratories America Inc. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.9.2/01	Mills, E.A, Simmonds, M.B..	2003	[^{14}C]-asulam: aqueous photolysis and quantum yield at pH9 and pH4 United Phosphorus Limited Report No.: C031419 Battelle AgriFood Ltd. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.9.2/02	Mills, E.A.	2007	Asulam: [^{14}C]-Aqueous Photolysis and Quantum Yield in Buffers at pH 4 and 9. United Phosphorus Limited Report No.: OU/07/008 Battelle UK Ltd. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.9.3/01	Mills, E.A, Simmonds, M.B..	2003	[^{14}C]-asulam: aqueous photolysis and quantum yield at pH9 and pH4 United Phosphorus Limited Report No.: C031419 Battelle AgriFood Ltd. GLP, Unpublished ⇒ CA 2.9.2/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.9.3/02	Mills, E.A.	2007	Asulam: [^{14}C]-Aqueous Photolysis and Quantum Yield in Buffers at pH 4 and 9. United Phosphorus Limited Report No.: OU/07/008 Battelle UK Ltd. GLP, Unpublished ⇒ CA 2.9.2/02	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.9.4/01	Françon, B.	1999d	Asulam sodium - pH and dissociation constant United Phosphorus Limited Report No.: R006747 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.10/01	Van der Gaauw, A.	2001	Estimation of the degradation of asulam by photo-oxidation in air United Phosphorus Limited Report No.: C011468 RCC Ltd. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.11.1/01	van Helvoirt, J.A.M.W.	1993a	Determination of the flammability of Asulox 80 SG (EXP04507) United Phosphorus Limited Report No.: R002281 NOTOX B.V. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.11.2/01	van Helvoirt, J.A.M.W.	1993b	Determination of the ability for self-heating of Asulox 80 SG (EXP04507) (modified Bowes-Cameron cage test) Report No.: R002282 NOTOX B.V. Study No.: 107639 NOTOX B.V. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.11.2/02	Maarsingh, P.	2008	Autoflammability of asulam SG according to EC method A.16 United Phosphorus Limited Report No.: DL 08-023 Cerexagri B.V., Development Laboratory, The Netherlands GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 2.13/01	Smeykal, H.	2001	Explosive properties asulam (EXP04507A) United Phosphorus Limited Report No.: C013870 Siemens Axiva GmbH & Co. GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.14/01	Françon, B.	1999a	Asulam sodium - physical properties United Phosphorus Limited Report No.: R006751 Battelle Europe, Battelle-Institut e.V. GLP, Unpublished ⇒ CA 2.1.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 2.15/01	Tran Thanh Phong, J.	1999	Asulam Sodium - oxidizing properties United Phosphorus Limited Report No.: R006745 Safety Process Laboratory GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

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*details to be added during Peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CP 2.1/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.1/02	Uceda, L., Le Gren, I.	1999	EXP04668A - Stability after 2 years storage at ambient temperature United Phosphorus Limited Report No.: R004779 Rhone-Poulenc Agro, France GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.2.1/01	Fillion, J.	1997	Determination of the flash point, the auto-flammability and the explosion properties of EXP04668A United Phosphorus Limited Report No.: C031112 Rhone Poulenc Industrialisation, France GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.2.2/01	Le Gren, I.	2004	Assessment of the	N	Y	Data protection	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			oxidising properties Asulox(R) Code: AE F074383 00 SL33 A1 or EXP04668A United Phosphorus Limited Report No.: C041640 Bayer CropScience, France Not GLP, Unpublished			is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009		
CP 2.3.1/01	Fillion, J.	1997	Determination of the flash point, the auto-flammability and the explosion properties of EXP04668A United Phosphorus Limited Report No.: C031112 Rhone Poulenc Industrialisation, France GLP, Unpublished ⇒ CP 2.2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.3.3/01	Fillion, J.	1997	Determination of the flash point, the auto-flammability and the explosion properties of EXP04668A United Phosphorus Limited Report No.: C031112 Rhone Poulenc	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			Industrialisation, France GLP, Unpublished ⇒ CP 2.2.1/01					
CP 2.4.2/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.4.2/02	Uceda, L., Le Gren, I.	1999	EXP04668A - Stability after 2 years storage at ambient temperature United Phosphorus Limited Report No.: R004779 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/02	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.5.1/01	Uceda, L., Le Gren, I.	2001	EXP04668A Determination of kinematic viscosity at 40 deg C United Phosphorus Limited Report No.:	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC)	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			C014413 Aventis CropScience, France GLP, Unpublished			No 1107/2009		
CP 2.5.3/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.6.1/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.6.1/02	Bos, M.W.S.	2010	Asulox 400 SL (asulam 400 g/l) asulam and impurity content in 2 years shelf-life and accelerated	N	Y	Data protection is claimed in accordance with Article 59 of	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			storage stability test United Phosphorus Limited Report No.: DL 08-021 –Final report Cerexagri B.V., The Netherlands GLP, Unpublished ⇒ Document J, CP 2.7.1/01			Regulation (EC) No 1107/2009		
CP 2.7.1/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.7.1/02	Bos, M.W.S.	2010	Asulox 400 SL (asulam 400 g/l) asulam and impurity content in 2 years shelf-life and accelerated storage stability test United Phosphorus Limited Report No.: DL 08-021 –Final report Cerexagri B.V., The Netherlands	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			GLP, Unpublished ⇒ CP 2.6.1/02					
CP 2.7.1/03	Bos, M.W.S.	2008	Asulox 400 SL (asulam 400 g/l) asulam and impurity content in 2 years shelf-life and accelerated storage stability test United Phosphorus Limited Report No.: DL 08-021 Cerexagri B.V., The Netherlands GLP, Unpublished Confidential information	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.7.4/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.7.5/01	Uceda, L., Le Gren, I.	1999	EXP04668A - Stability after 2 years storage at ambient temperature United Phosphorus Limited Report No.: R004779	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/02					
CP 2.7.5/02	Bos, M.W.S.	2010	Asulox 400 SL (asulam 400 g/l) asulam and impurity content in 2 years shelf-life and accelerated storage stability test United Phosphorus Limited Report No.: DL 08-021 –Final report Cerexagri B.V., The Netherlands GLP, Unpublished ⇒ CP 2.6.1/02	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.7.5/03	Bos, M.W.S.	2008a	Asulox 400 SL (asulam 400 g/l) asulam and impurity content in 2 years shelf-life and accelerated storage stability test United Phosphorus Limited Report No.: DL 08-021 Cerexagri B.V., The Netherlands GLP, Unpublished Confidential information ⇒ CP 2.7.1/03	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.8.2/01	Uceda, L., Le	1997	Determination of physico-	N	Y	Data protection	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
	Gren, I.		chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/01			is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009		
CP 2.8.2/02	Uceda, L., Le Gren, I.	1999	EXP04668A - Stability after 2 years storage at ambient temperature United Phosphorus Limited Report No.: R004779 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/02	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 2.8.4/01	Uceda, L., Le Gren, I.	1997	Determination of physico-chemical characteristics and storage stability EXP04668A United Phosphorus Limited Report No.: C031109 Rhone-Poulenc Agro, France GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			⇒ CP 2.1/01					
CP 2.8.4/02	Uceda, L., Le Gren, I.	1999	EXP04668A - Stability after 2 years storage at ambient temperature United Phosphorus Limited Report No.: R004779 Rhone-Poulenc Agro, France GLP, Unpublished ⇒ CP 2.1/02	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 4.2/01	Richards, K.	2008	Asulox Tank Cleaning Study Agro Chemex Ltd Document No: ACE-08-226 GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP 4.2.2/01	Friessleben, R.	2002	Instructions/ recommendations for tank cleaning after application of Asulox Code: EXP04668A United Phosphorus Limited Report No.: C019817 Aventis CropScience GmbH Non GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	