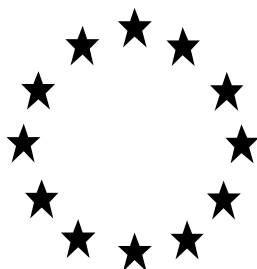


Draft Renewal Assessment Report under Regulation (EC) 1107/2009



FORAMSULFURON

Volume 3 – B.2 (AS)

Rapporteur Member State: Finland
Co-Rapporteur Member State: Slovakia

March 2015

Volume 1

Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application

Level 2: Summary of active substance hazard and of product risk assessment

Level 3: Proposed decision with respect to the application

Appendix 1: Guidance documents used in this assessment

Appendix 2: Reference list

Volume 2

Annex A: List of the tests, studies and information submitted

Volume 3

Annex B (Active Substance): Summary, evaluation and assessment of the data and information

Annex B.1 (AS): Identity

Annex B.2 (AS): Physical and chemical properties of the active substance

Annex B.3 (AS): Data on application

Annex B.4 (AS): Further information

Annex B.5 (AS): Methods of analysis

Annex B.6 (AS): Toxicology and metabolism data

Annex B.7 (AS): Residue data

Annex B.8 (AS): Environmental fate and behaviour

Annex B.9 (AS): Ecotoxicology data

Volume 3

Annex B (Plant Protection Product): Summary, evaluation and assessment of the data and information

Annex B.1 (PPP): Identity

Annex B.2 (PPP): Physical and chemical properties of the plant protection product

Annex B.3 (PPP): Data on application and efficacy

Annex B.4 (PPP): Further information

Annex B.5 (PPP): Methods of analysis

Annex B.6 (PPP): Toxicology and metabolism data and assessment of risks to humans

Annex B.7 (PPP): Residue data

Annex B.8 (PPP): Environmental fate and behaviour and environmental exposure assessment

Annex B.9 (PPP): Ecotoxicology data and assessment of risks for non-target species

Volume 4

Annex C: Confidential information and, where relevant, details of any task force formed for the purpose of generating tests and studies submitted

List of Endpoints

Version History

When	What
2015/March	First draft RAR

Table of contents

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE.....	5
B.2.1. MELTING POINT AND BOILING POINT.....	5
B.2.2. VAPOUR PRESSURE, VOLATILITY	5
B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)	5
B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY	6
B.2.5. SOLUBILITY IN WATER	7
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS	8
B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER.....	8
B.2.8. DISSOCIATION IN WATER	10
B.2.9. FLAMABILITY AND SHELF-HEATING	10
B.2.10. FLASH POINT	10
B.2.11. EXPLOSIVE PROPERTIES	10
B.2.12. SURFACE TENSION	11
B.2.13. OXIDISING PROPERTIES	11
B.2.14. OTHER STUDIES	11
B.2.15. REFERENCES RELIED ON.....	14

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

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. MELTING POINT AND BOILING POINT						
Melting, freezing or solidification point B.2.1/01	EC A.1, OECD 102	Batch no.: AE F130360 00 1B98 0001 purity 98.4 %	The melting point was found to be 194.5 °C (coupled with decomposition)	Acceptable	Y	KCA 2.1 /01; Smeykal, H.; 2000; M-194875-01-1
Boiling point B.2.1/02	EC A.2, OECD 113	Batch no.: AE F130360 00 1B98 0001 purity 98.4 %	Not measurable, decomposition above 190 °C.	Acceptable	Y	KCA 2.1 /01; Smeykal, H.; 2000; M-194875-01-1
Decomposition / Sublimation temperature B.2.1/03	EC A.2, OECD 113	Batch no.: AE F130360 00 1B98 0001 purity 98.4 %	Not measurable, decomposition above 190 °C.	Acceptable	Y	KCA 2.1 /01; Smeykal, H.; 2000; M-194875-01-1
B.2.2. VAPOR PRESSURE, VOLATILITY						
Vapour pressure B.2.2/01	EC A.4, OECD 104	Batch no.: AE F13036 0 00 1B98 0001 purity 98.4 %	4.2 x 10 ⁻¹¹ Pa for 20 °C 1.3 x 10 ⁻¹⁰ Pa for 25 °C	Acceptable	Y	KCA 2.2 /01; Stalker, A. M.; Friling, R.;1997; M-142401-01-1
Volatility (Henry's Law constant) B.2.2/02	Calculation		Henry's law constant at 20 °C 5.8 x 10 ⁻¹² Pa x m ³ x mol ⁻¹	Acceptable	N	KCA 2.2 /02; Stalker, A.M.;1997; M-142399-02-1
B.2.3. APPEARANCE (PHYSICAL STATE, COLOR)						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Physical state and color B.2.3/01	Visual and olfactory assessment					
		Batch no.: ELIR004294 purity 97.3%	Active substance as manufactured: Powder	Acceptable	Y	KCA 2.3 /07; Ziemer, F.; Strunk, B.;2013; M-469106-01-1
		Batch no.: ELIR004294 purity 97.3 %	Active substance as manufactured: White	Acceptable	Y	KCA 2.3 /07; Ziemer, F.; Strunk, B.;2013; M-469106-01-1
B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY						
Ultraviolet/visible (UV/VIS) B.2.4/01	OECD 101	Batch no.: Hoe 130360 00 ZB99 0001 purity 99.0 %	UV (methanol)	Acceptable	Y	KCA 2.4 /01; Cichy, M.; Kloeckner, C.; 1996; M-141134-01-1
		Batch no.: AE F130360 00 1B99 0001 purity 99.0 %	UV (methanol)	Acceptable	Y	KCA 2.4 /02; Cichy, M.; Poerschke, R.; 2000; M-194722-01-1
Infrared (IR) B.2.4/02	OECD 101	Batch no.: Hoe 130360 00 ZB99 0001 purity 99.0 %	IR (KBr-plate), the spectral data confirm the chemical structure.	Acceptable	Y	KCA 2.4 /01; Cichy, M.; Kloeckner, C.; 1996; M-141134-01-1
Nuclear magnetic resonance (NMR)	OECD 101	Batch no.: Hoe 130360 00	¹ H-NMR (300 MHz, CDCl ₃ /CD ₃ OD), the spectral data confirm the chemical structure	Acceptable	Y	KCA 2.4 /01; Cichy, M.;

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.4/03		ZB99 0001 purity 99.0 %				Kloeckner, C.; 1996; M-141134-01-1
Mass spectra (MS) B.2.4/04	OECD 101	Batch no.: Hoe 130360 00 ZB99 0001 purity 99.0 %	Mass spectra (Electron Impact and Chemical Ionisation), The spectral data confirm the chemical structure. the highest significant mass is m/z 453 (M+ + H) which agrees with the molar mass of foramsulfuron	Acceptable	Y	KCA 2.4 /01; Cichy, M.; Kloeckner, C.; 1996; M-141134-01-1
Spectra for purified active substance Wavelengths at which UV/VIS molecular extinction occurs, max >290 nm B.2.4/05	OECD 101	Batch no.: Hoe 130360 00 ZB99 0001 purity 99.0 %	UV (methanol, neutral) Wavelength molar extinction [nm] [L x mol ⁻¹ x cm ⁻¹] 204 30162 219 29418 252 31386 291 2713	Acceptable	Y	KCA 2.4 /01; Cichy, M.; Kloeckner, C.; 1996; M-141134-01-1
		Batch no.: AE F130360 00 1B99 0001 purity 99.0 %	UV (methanol, neutral) Wavelength molar extinction [nm] [L x mol ⁻¹ x cm ⁻¹] 202 42363 219 31939 252 33298 291 3245	Acceptable	Y	KCA 2.4 /02; Cichy, M.; Poerschke, R.; 2000; M-194722-01-1
Spectra for impurities B.2.4/06			None of the impurities present in the active substance as manufactured is of toxicological or environmental significance			
B.2.5. SOLUBILITY IN WATER						
Solubility in water B.2.5/01	EC A.6, OECD 105	Batch no.: AE F130360 00 1C98 0001 purity 98.4 %	pH 4.90 37.2 mg/L at 20°C pH 6.91 3293 mg/L at 20°C pH 8.05 94577 mg/L at 20°C	Acceptable. Water solubility is strongly influenced by pH.	Y	KCA 2.5 /01; Stalker, A. M.; 1997; M-142398-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	EC A.8, OECD 107 (shake flask method)	Batch no.: 30837-108 purity 98.5 %	AE F092944 (20 °C) Pow pH 6.3 8.36 log Pow 0.92		Y	KCA 2.7 /03; Mills, E. A. M.;2000; M-194629-01-1
		Batch no.: 23503LR purity 99.8 %	AE F09244 (23 °C) Pow pH 5 8.6 pH 7 9.2 pH 9 8.6 log Pow 0.9 1.0 0.9		Y	KCA 2.7 /04; Ziemer, F.; Kloeckner, C.; 2012; M-439569-01-1
		Batch no.: BCOO 6090-2-3 purity 99.3%	AE F099095 (23 °C) Pow pH 5 11 pH 7 11 pH 9 10 log Pow 1.0 1.0 1.0		Y	KCA 2.7 /05; Ziemer, F.; Kloeckner, C.; 2012; M-438348-01-1
		Batch no.: 30773-47 Purity 97.8 %	AE F153745 (20 °C) Pow pH 7.5 0.238 log Pow -0.62		Y	KCA 2.7 /06; Mills, E. A. M.; 2000; M-194736-01-1
		Batch no.: D IV-44 purity 90.2 %	AE 0338795 (20 °C) Pow (corrected) pH 3.5 0.186 log Pow (corrected) -0.73		Y	KCA 2.7 /07; Mills, E. A. M.; 2000; M-194739-01-1
		Batch no.: D IV-44 purity 90.2 %	AE 0338795 (23 °C) Pow pH 4 0.0062 pH 7 0.0047 pH 9 0.0033 log Pow -2.21 -2.33 -2.48		Y	KCA 2.7 /08; Muehlberger, B.; Strunk, B.; 2004; M-236158-01-1
	Calculation		4-Amino-N-methylbenz-amide log Pow 0.29		N	
	Calculation		4-Formamido-N-methyl-benzamide log Pow 0.34		N	
	Calculation		N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-sulfamic acid log Pow -3.41 (Calculated with "The estimations programs interface (EPI)Suite™ [EPI v4.10] by the US Environmental Protection Agency's Office of Pollution Prevention and Toxics")		N	

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8. DISSOCIATION IN WATER						
Dissociation constant B.2.8/01	OECD 112	Batch no.: AE F130360 00 1C98 0001 purity 98.4 %	Dissociation constant at 21.5 °C: pKa = 4.6	Acceptable	Y	KCA 2.8 /01; Stalker, A. M.; Bright, A. A. S.; 1997; M-142400-01-1
B.2.9. FLAMMABILITY AND SHELF-HEATING						
Flammability B.2.9/01	EC A.10	Batch no.: ELIR004294 purity 97.3 %	Foramsulfuron is not highly flammable in the sense of EC Guideline A.10	Acceptable	Y	KCA 2.9 /03; Krack, M.; 2013; M-471144-01-1
Auto-flammability B.2.9/02	EC A.16	Batch no.: ELIR004294 purity 97.3 %	No self-ignition temperature was observed until the maximum temperature of 400 °C	Acceptable	Y	KCA 2.9 /04; Krack, M.; 2013; M-471147-01-1
B.2.10. FLASH POINT						
Flash point B.2.10/01			Not applicable. The active substance is a solid; its melting point is > 40 °C	Acceptable		
B.2.11. EXPLOSIVE PROPERTIES						
Explosive properties B.2.11/01	EC A.14	Batch no.: ELIR004294 purity 97.3 %	Foramsulfuron is not explosive in the sense of EC guideline A.14.	Acceptable	Y	KCA 2.11 /03; Krack, M.; 2013; M-471145-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.12. SURFACE TENSION						
Surface tension B.2.12/01	EC A.5, OECD 115	Batch no.: AE F130360 00 1C98 0001 purity 96.8 %	$\sigma = 65.1$ mN/m at 20 °C (1.0 g/L in distilled water)	Acceptable	Y	KCA 2.12 /01; Smeykal, H.;2000; M-194884-01-1
B.2.13. OXIDIZING PROPERTIES						
Oxidizing properties B.2.13/01	EC A.17	Batch no.: ELIR004294 purity 97.3 %	Foramsulfuron has no oxidizing properties in the sense of EC guideline A.17	Acceptable	Y	KCA 2.13 /02; Krack, M.; 2013; M-471153-01-1
B.2.14. OTHER STUDIES						
Relative density B.2.14/01	EC A.3, OECD 109	Batch no.: AE F130360 00 1B98 0001 purity 98.4 %	D = 1.44 at 25.5 °C	Acceptable	Y	KCA 2.14 /01; Smeykal, H.; 2000; M-194877-01-1
PC data on metabolites						
AE F130619	water solubility: EC A.6, OECD 105	Batch no.: 30497-15 purity 96.7%	water solubility of AE F130619 (20 °C): in distilled water 2.2 mg/L pH 7: 35.5 mg/L pH 7.8: 233.7 mg/L pH 9: 5788.0 mg/L	Data required for the environmental risk assessment	Y	KCA 2.14 /04; Reary, J. B.; Bright, A. A. S.; 2000; M-194625-01-1
AE F092944	water solubility: EC A.6, OECD 105, (flask method)	Batch no.: 23503LR purity 99.8%	water solubility of AE F092944: pH 5: 5.4 g/L pH 7: 5.2 g/L pH 9: 5.0 g/L	Data required for the environmental risk assessment	Y	KCA 2.14 /05; Ziemer, F.; Kloeckner, C.; 2012; M-433172-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	vapour pressure: EC A.4, OECD 104	Batch no.: Op2911-3 purity 99.8 %	vapour pressure of AE F092944: 3.72 x 10 ⁻² Pa for 20 °C 8.08 x 10 ⁻² Pa for 25 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /06; Betteley, J.; Howes, D. A.; Bright, A. A. S.;1999; M-193039-02-1
		Batch no.: 23503LR purity 99.8%	vapour pressure of AE F092944: 2.6 x 10 ⁻² Pa for 20 °C 6.1 x 10 ⁻² Pa for 25 °C 2.8 Pa for 50 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /07; Smeykal, H.; 2012; M-429120-01-1
	Henrys law constant	Calculation	Henrys law constant of AE F092944: 9.01 x 10 ⁻⁴ Pa x m ³ x mol ⁻¹	Data required for the environmental risk assessment	N	KCA 2.14 /08; Fisk, P. R.; 2000; M-194707-01-1
		Calculation	Henrys law constant of AE F092944: pH 5: 7.5 x 10 ⁻⁴ Pa x m ³ x mol ⁻¹ pH 7: 7.8 x 10 ⁻⁴ Pa x m ³ x mol ⁻¹ pH 9: 8.1 x 10 ⁻⁴ Pa x m ³ x mol ⁻¹	Data required for the environmental risk assessment	N	KCA 2.14 /09; Ziemer, F.; 2012; M-433639-01-1
	dissociation constant: OECD 112		dissociation constant AE F092944: pKa = 3.6	Data required for the environmental risk assessment	Y	KCA 2.14 /10; Winkler, S.;2012; M-431676-01-1
AE F099095	water solubility: EC A.6, OECD 105	Batch no.: BCOO 6090-2-3 purity 99.3 %	water solubility of AE F099095: pH 5: 0.20 g/L pH 7: 0.19 g/L pH 9: 0.18 g/L at 20 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /11; Bogdoll, B.; Strunk, B.; 2012; M-428381-01-1
	vapour pressure: EC A.4, OECD 104	Batch no.: BCOO 6090-2-3 purity 99.3 %	vapour pressure of AE F099095: 1.9 x 10 ⁻⁵ Pa for 20 °C 3.9 x 10 ⁻⁵ Pa for 25 °C 1.1 x 10 ⁻³ Pa for 50 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /12; Smeykal, H.; 2012; M-429178-01-1
	Henrys law constant	Calculation	Henrys law constant of AE F099095: pH 5: 1.9 x 10 ⁻⁵ Pa x m ³ x mol ⁻¹ pH 7: 2.0 x 10 ⁻⁵ Pa x m ³ x mol ⁻¹ pH 9: 2.1 x 10 ⁻⁵ Pa x m ³ x mol ⁻¹	Data required for the environmental risk assessment	N	KCA 2.14 /13; Ziemer, F.; 2012; M-431263-01-1
	dissociation	Batch no.:	dissociation constant AE F099095:	Data required for	Y	KCA 2.14 /14;

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	constant: OECD 112	BCOO 6090-2-3 purity 99.3 %	pKa = 1.7	the environmental risk assessment		Wiche, A.; Ziemer, F.; 2013; M-448835-01-1
AE F153745	water solubility: EC A.6, OECD 105	Batch no.: 30773-47 purity 97.8%	water solubility of AE F153745: in distilled water:6.88g/L pH 7: 5.83 g/L pH 7.9: 5.97g/L pH8.8: 6.47g/L at 20 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /15; Bright, A. A. S.; 2000; M-194238-01-1
	vapour pressure: EC A.4, OECD 104	Batch no.: 30773-47 purity 97.8%	vapour pressure of AE F153745: 3.47 x 10-8 Pa for 20 °C 8.48 x 10-8 Pa for 25 °C	Data required for the environmental risk assessment	Y	KCA 2.14 /16; Betteley, J.; Howes, D. A.; 1999; M-193036-01-1
	Henrys law constant	Calculation	Henrys law constant of AE F153745: 1.37 x 10-9 Pa x m3 x mol-1	Data required for the environmental risk assessment	N	KCA 2.14 /17; Fisk, P. R.; 2000; M-194709-01-1
AE 0338795	water solubility: EC A.6, OECD 105	Batch no.: D IV-44 purity 90.2 %	water solubility of AE 0338795: in distilled water: 2.12 g/L pH 4: 52.4 g/L pH 5:200.0 g/L at 19°C	Data required for the environmental risk assessment	Y	KCA 2.14 /18; Reary, J. B.; Bright, A. A. S.; 2000; M-194905-01-1
	dissociation constant: OECD 112	Batch no.: D IV-44 purity 90.2 %	dissociation constant AE F099095: pKa = 2.4	Data required for the environmental risk assessment	Y	KCA 2.14 /19; Bright, A. A. S.; 2000; M-194521-01-1

B.2.15. REFERENCES RELIED ON

This dossier contains old study reports, already submitted by Bayer for the first Annex I inclusion of foramsulfuron, as well as new data that have not been evaluated yet at EU level and that are considered by BCS to be necessary for the re-approval of this active substance. Information has been given under each point. Where studies were previously submitted at EU level the endpoints and the references are provided in grey text. All new data presented is provided in standard black text.

Studies KCA 2.3/01; 2.3/02; 2.3/03; 2.3.04; KCA 2.9/01; 2.9/02; KCA 2.11/01 and KCA 2.13/01 were replaced with studies done with new purity and specification (Batch no.:ELIR004294; purity 97.3 %) all relevant information are included in the new studies. Studies and results used for re-approval are acceptable.

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	Previous evaluation
B.2.1/01 B.2.1/02 B.2.1/03 KCA 2.1/01	Smeykal, H.	2000	Melting point / melting range. Boiling point / boiling range. Thermal stability AE F130360 substance, pure Code: AE F130360 00 1B98 0001 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Report No.: C006924, Edition Number: M-194875-01-1 EPA MRID No.: 45109307 Date: 2000-02-03 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.2 /01 KCA 2.2/01	Stalker, A. M.; Friling, R.	1997	AE F130360; 98.4 % w/w; AE F130360 00 1C98 0001- Vapour pressure at 20 degrees C and 25 degrees C AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58673, Report includes Trial Nos.: 96042201D Edition Number: M-142401-01-1 Date: 1997-09-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.2 /02 KCA 2.2/02	Stalker, A. M	1997	AE F130360; 98.4 percent w/w; AE F130360 00 1C98 0001- Henry's Law constant at 20 degrees C AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58671, Report includes Trial Nos.: 96042201G Edition Number: M-142399-02-1 Date: 1997-04-22Amended: 1997-09-26 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001

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	Previous evaluation
B.2.3 /01 KCA 2.3/07	Ziemer, F.; Strunk, B.	2013	Foramsulfuron (AE F130360), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA13/143, Edition Number: M-469106-01-1 Date: 2013-11-08 GLP/GEP: yes, unpublished	N	Y	Triggered by new specification	Bayer CropScience	Submitted for the purpose of renewal.
B. 2.4 /01 B.2.4/02 B.2.4/03 B.2.4/04 B.2.4/05 KCA 2.4/01	Cichy, M.; Kloeckner, C.	1996	Hoe 130360-Spectral data (UV/VIS, IR, ¹ H -NMR, MS) and molar extinction coefficient Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: A57412, Edition Number:M-141134-01-1 EPA MRID No.: 45109319 Date: 1996-08-27 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.4/01 B.2.4/05 KCA 2.4/02	Cichy, M.; Poerschke, R.	2000	Spectral data (UV / VIS and molar extinction coefficient) Foramsulfuron (proposed ISO) technical grade active ingredient Code: AE F130360 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006840, Edition Number: M-194722-01-1 EPA MRID No.: 45109320 Date: 2000-02-07 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.5 /01 KCA 2.5/01	Stalker, A. M.	1997	AE F130360; 98.4 % w/w; AE F130360 00 1C98 0001- Solubility in water at 20 degrees C AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58670, Report includes Trial Nos.: 96042201B Edition Number:M-142398-01-1 EPA MRID No.: 45109321 Date: 1997-09-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001

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	Previous evaluation
B.2.6 /01 KCA 2.6/01	Stalker, A. M.	1997	AE F130360; 98.4 % w/w; AE F13 0360 00 1C98 0001-Solubility in organic solvents AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58675, Report includes Trial Nos.: 96042201A Edition Number:M-142403-01-1 EPA MRID No.: 45109322 Date: 1997-09-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.7 /01 B.2.7/02 KCA 2.7/01	Reary, J. B.; Stalker, A. M.	1997	AE F130360; 98.4 % w/w; AE F130360 00 1C98 0001-n- Octanol-water partition coefficient at 20 degrees C AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58669, Report includes Trial Nos.: 96042201C Edition Number: M-142397-01-1 EPA MRID No.: 45109323 Date: 1997-09-22G LP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.7/02 KCA 2.7/02	Bright, A. A. S.	2000	Partition coefficient AE F130619 96.7% w/w AE F130619 00 1C97 0001 Aventis CropScience;Chemistry Report No.: C005894, Report includes Trial Nos.: 99030514 Edition Number: M-192883-01-1 Date: 2000-02-15 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.7/02 KCA 2.7/03	Mills, E. A. M.	2000	Partition coefficient AE F092944 98.5% w/w Code: AE F092944 00 1C99 0002 Aventis UK;Chemistry, CP Report No.: C006792, Report includes Trial Nos.: 99030502 Edition Number:M-194629-01-1 Date: 2000-02-15 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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	Previous evaluation
B.2.7/02 KCA 2.7/04	Ziemer, F.; Kloeckner, C.	2012	AE F092944: Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.:PA12/011, Edition Number:M-439569-01-1 Date: 2012-10-15 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.7/02 KCA 2.7/05	Ziemer, F.; Kloeckner, C.	2012	AE F099095: Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA11/016, Edition Number:M-438348-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.7/02 KCA 2.7/06	Mills, E. A. M.	2000	Partition coefficient AE F153745 97.8% w/w Metabolite of AE F130360 AE F153745 00 1C98 0001 Aventis UK;Chemistry, CP Report No.: C006847, Report includes Trial Nos.: 99030508 Edition Number:M-194736-01-1 Date: 2000-02-17 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.7/02 KCA 2.7/07	Mills, E. A. M.	2000	Partition coefficient AE 0338795 90.2% w/w Metabolite of AE F130360 AE F0338795 00 1C90 0001 Aventis UK;Chemistry, CP Report No.: C006848, Report includes Trial Nos.: 99052602 Edition Number:M-194739-01-1 Date: 2000-02-17 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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B.2.7/03 KCA 2.7/08	Muehlberger, B.; Strunk, B.	2004	AE 0338795 Partition coefficient 1-octanol / water (Shake flask method) Code: AE 0338795 00 1C90 0001 Bayer CropScience GmbH, Frankfurt am Main, Germany Report No.: C044454, Edition Number: M-236158-01-1 Date: 2004-10-12 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B. 2.8 /01 KCA 2.8/01	Stalker, A. M.; Bright, A. A. S.	1997	AE F130360; 98.4 % w/w; AE F130360 00 1C98 0001- Dissociation constant AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Report No.: A58672, Report includes Trial Nos.: 96042201E Edition Number: M-142400-01-1 EPA MRID No.: 45109326 Date: 1997-09-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.9 /01 KCA 2.9/03	Krack, M.	2013	Foramsulfuron (AE F130360), technical substance: Flammability (solids) Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20130400.01, Edition Number: M-471144-01-1 Date: 2013-11-21 GLP/GEP: yes, unpublished	N	Y	Triggered by new specification	Bayer CropScience	Submitted for the purpose of renewal.
B.2.9/2 KCA 2.9/04	Krack, M.	2013	Foramsulfuron (AE F130360), technical substance: Auto-flammability (solids-determination of relative self-ignition temperature) Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20130400.03, Edition Number: M-471147-01-1 Date: 2013-11-21 GLP/GEP: yes, unpublished	N	Y	Triggered by new specification	Bayer CropScience	Submitted for the purpose of renewal.
B.2.11/01 KCA 2.11/03	Krack, M.	2013	Foramsulfuron (AE F130360), technical substance: Explosive properties Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20130400.02, Edition Number: M-471145-01-1 Date: 2013-11-21 GLP/GEP: yes, unpublished	N	Y	Triggered by new specification	Bayer CropScience	Submitted for the purpose of renewal

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B.2.12 /01 KCA 2.12/01	Smeykal, H.	2000	Surface tension AE F130360 substance, technical Code: AEF130360 00 1C98 0001 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Report No.: C006929, Edition Number: M-194884-01-1 EPA MRID No.: 45109332 Date: 2000-02-03 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.13/01 KCA 2.13/02	Krack, M.	2013	Foramsulfuron (AE F130360), technical substance: Oxidizing properties Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20130400.04, Edition Number: M-471153-01-1 Date: 2013-11-21 GLP/GEP: yes, unpublished	N	Y	Triggered by new specification	Bayer CropScience	Submitted for the purpose of renewal
B.2.14 /01 KCA 2.14/01	Smeykal, H.	2000	Relative density AE F130360 substance, pure Code: AEF130360 00 1B98 0001 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Report No.: C006926, Edition Number: M-194877-01-1 EPA MRID No.: 45109309 Date: 2000-02-03 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.14 KCA 2.14/04	Reary, J. B.; Bright, A. A. S.	2000	Solubility in water AE F130619 96.7% AE F130619 00 1C97 0001 Aventis CropScience UK;Chemistry Report No.: C006790, Report includes Trial Nos.: 99030513 Edition Number:M-194625-01-1 Date: 2000-02-16 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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B.2.14 KCA 2.14/05	Ziemer, F.; Kloekner, C.	2012	AE F092944: Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA11/110, Edition Number:M-433172-01-1 Date: 2012-06-21 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/06	Betteley, J.; Howes, D. A.; Bright, A. A. S.	1999	Vapour Pressure AE F 092944 99.8% w/w Code: AE F092944 00 1C99 0001 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom Report No.: C005965, Edition Number:M-193039-02-1 Date: 1999-11-05 ...Amended: 2000-02-22 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/07	Smeykal, H.	2012	AE F092944: Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110473.01, Edition Number: M-429120-01-1 Date: 2012-04-05 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/08	Fisk, P. R.	2000	Henry's law constant AE F092944 99.8% w/w (metabolite of AE F130360) AE F092944 00 1c99 0001 Aventis UK;Chemistry, CP Report No.: C006833, Report includes Trial Nos.: 99030506 Edition Number:M-194707-01-1 Date: 2000-02-01 GLP/GEP: no, unpublished	N	N	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/09	Ziemer, F.	2012	AE F092944: Calculation of the Henry's law constants Bayer CropScience, Report No.: AF12/022, Edition Number:M-433639-01-1 Date: 2012-07-02 GLP/GEP: no, unpublished	N	N	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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B.2.14 KCA 2.14/10	Winkler, S.	2012	AE F092944: Dissociation constant in water Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110473.02, Edition Number:M-431676-01-1 Date: 2012-05-22 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/11	Bogdoll, B.; Strunk, B.	2012	AE F099095: Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA11/017, Edition Number:M-428381-01-1 Date: 2012-04-03 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/12	Smeykal, H.	2012	AE F099095: Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110470.01, Edition Number:M-429178-01-1 Date: 2012-04-11 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/13	Ziemer, F.	2012	AE F099095: Calculation of the Henry's law constants Bayer CropScience, Report No.: AF12/015, Edition Number:M-431263-01-1 Date: 2012-05-15 GLP/GEP: no, unpublished	N	N	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/14	Wiche, A.; Ziemer, F.	2013	AE F099095: Dissociation constant in water Bayer CropScience, Report No.: PA12/125, Edition Number:M-448835-01-1 Date: 2013-03-06 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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B.2.14 KCA 2.14/15	Bright, A. A. S.	2000	Solubility in water AE F153745 (Metabolite of AE F130360) 97.8% w/w Code: AE F153745 00 1C98 0001 Aventis CropScience UK;Chemistry Report No.: C006588, Report includes Trial Nos.: 99030507 Edition Number:M-194238-01-1 Date: 2000-02-16 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/16	Betteley, J.; Howes, D. A.	1999	Vapour pressure AE F153745 97.8% w/w Code: AE F153745 00 1C98 0001 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom Report No.: C005964, Edition Number: M-193036-01-1 Date: 1999-11-05 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/17	Fisk, P. R.	2000	Henry's law constant AE F153745 97.8% w/w (metabolite of AE F130360) Aventis UK;Chemistry, CP Report No.: C006834, Edition Number:M-194709-01-1 Date: 2000-02-01 GLP/GEP: no, unpublished	N	N	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.
B.2.14 KCA 2.14/18	Reary, J. B.; Bright, A. A. S.	2000	Solubility in water AE 0338795 90.2% w/w (metabolite of AE F130360) AE 0338795 00 1C90 0001 Aventis UK;Chemistry Report No.: C006939, Report includes Trial Nos.: 99052601 Edition Number:M-194905-01-1 Date: 2000-02-17 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.

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B.2.14 KCA 2.14/19	Bright, A. A. S.	2000	Dissociation constant AE C0338795 90.2% w/w AE 0338795 00 1C90 0001 Aventis CropScience;Chemistry Report No.: C006731, Report includes Trial Nos.: 99052605 Edition Number: M-194521-01-1 Date: 2000-02-16 GLP/GEP: yes, unpublished	N	Y	Data required for the environmental risk assessment	Bayer CropScience	Submitted for the purpose of renewal.