European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Fenoxaprop-P-ethyl

Volume 3 – B.2 (AS)

Rapporteur Member State: Austria
Co-Rapporteur Member State: Finland

Version History

When	What
2005/April	Initial DAR
2006/August	Addendum (Revision 1)
2007/August	Addendum (Revision 2)
2018/March	DRAR

Table of contents

B.2. Physical and chemical properties of the active substance 4
B.2.1. Melting point and boiling point 4
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 7
B.2.7. Partition coefficient n-octanol/water 8
B.2.8. Dissociation in water 8
B.2.9. Flamability and shelf-heating 8
B.2.10. Flash point 9
B.2.11. Explosive properties 9
B.2.12. Surface tension 9
B.2.13. Oxidising properties 9
B.2.14. Other studies 10
B.2.15. References relied on 13

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

Additional studies were performed, which were not submitted during the Annex I inclusion process. These studies will be summarized below. For all studies submitted during the frame of the first Annex I inclusion please refer to the corresponding section in the Monograph and in the baseline dossier (D-012009) provided by the Task Force Fenoxaprop-P-ethyl (grey tables).

Throughout this document the original DAR, is referred to as the DAR 2005 and this evaluation, is referred to as the RAR (Renewal assessment report). Studies that were evaluated in the DAR 2005 have not been re-evaluated and the results are presented in this report in **grey typeface**. New information (e.g. historical control data, additional experimental details) or new interpretation of the data has been taken into account or changes compared to the original DAR 2003 are written in **black typeface**.

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 (DSC)	FPP pure 99.5% AE F046360001B990003	mp = 86.5 °C (pure substance)	EU agreed endpoint DAR 2005	Y	Smeykal, H.; 1999 M-187345-01-1
	EC A.1 OECD 102 (DSC)	FPP pure 98.4% AE F046360-PU-01	mp = 89 – 111 °C (onset temp. = 90 °C; apex temp. = 94.5 °C)	**Acceptable**	Y	Cowlyn, N; 2016 M-549131-01-1
Boiling point **B.2.1/02**			Not required. The active substance is a solid.	EU agreed endpoint DAR 2005	N	Heinrich; Rexer, K.; 1988 M-120377-01-1
	EC A.2 OECD 103 (DSC)	FPP pure 98.4% AE F046360-PU-01	The substance decomposes before boiling.	**Acceptable**	Y	Cowlyn, N; 2016 M-549131-01-1
Decomposition / Sublimation temperature **B.2.1/03**	No guideline mentioned (DSC)	FPP technical grade Hoe 046360 0H ZD93 0001	No decomposition up to 260 °C	EU agreed endpoint DAR 2005	N	Heinrich; Rexer, K.; 1987 M-117569-01-1
	EC A.1, A.2 OECD 102, 103 (DSC)	FPP pure 98.4% AE F046360-PU-01	Evidence of decomposition above 330 °C	**Acceptable**	Y	Cowlyn, N; 2016 M-549131-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2. VAPOUR PRESSURE, VOLATILITY						
Vapour pressure **B.2.2/01**	OECD 104 (vapour pressure balance)	FPP pure 98.7% (purity for batch Hoe 046360 OH ZB99 0001 is reported in water solubility study Goerlitz, G.; Eyrich, U.; 1987)	5.3×10^{-7} Pa (20 °C) 1.4×10^{-6} Pa (25 °C) 1.1×10^{-4} Pa (50 °C)	EU agreed endpoint DAR 2005	N	Roechling, A.; Rexer, K.; 1987 M-125880-01-1
	EEC A.4 OECD 104 (vapour pressure balance)	FPP pure 98.4% Batch code AE F046360-PU-01	6.5×10^{-6} Pa (20 °C) 1.2×10^{-5} Pa (25 °C) 2.3×10^{-4} Pa (50 °C)	**Acceptable**	Y	Dreisch, S.; 2016 M-546227-02-1
Volatility (Henry's Law constant) **B.2.2/02**	Calculation	FPP pure 98.7% (purity for batch Hoe 046360 OH ZB99 0001 is reported in water solubility study Goerlitz, G.; Eyrich, U.; 1987)	2.739×10^{-4} Pa m^3 / mol (20 °C) Parameter for calculation: Water solubility: 0.7 mg/L (at 20 °C) Vapour pressure: 5.3×10^{-7} Pa (20 °C) 7.236×10^{-4} Pa m^3 / mol (25 °C) Parameter for calculation: Water solubility: 0.7 mg/L (at 20 °C) Vapour pressure: 1.4×10^{-6} Pa (25 °C)	EU agreed endpoint DAR 2005	N	Schollmeier, M.; 1992 M-137125-01-1
	Calculation	not applicable	Henry's law constant at 20 °C Unbuffered water [Pa m^3 / mol] 5.5×10^{-3} Parameter for calculation all at 20 °C Vapour pressure: 6.5×10^{-6} Pa Water solubility in unbuffered water: 0.43 mg /L	**Acceptable**	N	Ziemer, F; 2016 M-549129-01-1
B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)						
Physical state and colour **B.2.3/01**	Visual observation	FPP pure	Colour: white (pure substance)	EU agreed endpoint DAR 2005	N	Heinrich; Rexer, K.; 1988 M-120374-01-1
	Visual observation	FPP pure	Appearance: solid (pure substance)	EU agreed endpoint DAR 2005	N	Heinrich; Rexer, K.; 1988 M-120379-01-1
	Visual observation	FPP technical 96.3%	Appearance: flakes (technical substance) The sales product also appears to be a coarse powder or solidified melt.	EU agreed endpoint DAR 2005	N	Haase, D.; Rexer, K.; 2000 M-197170-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	Visual observation	FPP technical 96.3%	Colour: yellowish	EU agreed endpoint DAR 2005	N	Haase, D.; Rexer, K.; 2000 M-197172-01-1
	Visual observation	FPP technical 94.1% Batch code AE F046360-01-24	White powder (23 °C)	**Acceptable**	Y	Wiche, A.; Ziemer, F.; 2016 M-545655-01-1
	Visual observation	FPP technical 99.9% Batch code AE F046360-01-15	White powder (23 °C)	**Acceptable**	Y	Wiche, A.; Ziemer, F.; 2016 M-545592-01-1
	Visual observation	FPP purified 98.4% Batch code AE F046360-PU-01	White powder (23 °C)	**Acceptable**	Y	Wiche, A.; Ziemer, F.; 2016 M-545567-01-1
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	FPP pure 99.5%	In neutral acetonitrile: nm / Absorbance / Molar ext. L/mol * cm 239 / 0.6183 / 2.29×10^4 (22862) 278 / 0.2158 / 0.80×10^4 (7980) 291 / 0.0402 / 0.15×10^4 (1487) No absorbance at wavelengths above 300 nm. The spectrum is in full agreement with the structure. No UV/Vis spectra measured in acidic or in alkaline media since the active substance is unstable under these conditions.	EU agreed endpoint DAR 2005 The value for ε at 291 nm is correct 0.15×10^4 and wrong in the study (0.15×10^2).	Y	Kloeckner, C.; Weller, O.; 2000 M-197490-01-1
Infrared (IR) **B.2.4/02**	direct application onto the diamond probe and measured in the range from 600 to 4000 cm^{-1}	FPP pure 99.5%	The spectrum is in full agreement with the structure.	EU agreed endpoint DAR 2005	Y	Kloeckner, C.; Weller, O.; 2000 M-197490-01-1
Nuclear magnetic resonance (NMR) **B.2.4/03**	According to equipment	FPP pure 99.5%	^{1}H-NMR- and ^{13}C-NMR- spectra are in full agreement with the structure.	EU agreed endpoint DAR 2005	Y	Kloeckner, C.; Weller, O.; 2000 M-197490-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Mass spectra (MS) **B.2.4/04**	According to equipment MS-EI$^+$:	FPP pure 99.5%	The spectrum is in full agreement with the structure.	EU agreed endpoint DAR 2005	Y	Kloeckner, C.; Weller, O.; 2000 M-197490-01-1
Spectra for impurities **B.2.4/05**			There are no relevant impurities.			
Optical purity **B.2.4/06**		FPP pure 99.5%	$[\alpha]_D^{20}$ = + 37.7 ° (at 20 °C, acetonitrile)	**Acceptable**	N	Bogdoll, B; 2003 M-228380-01-1
B.2.5. SOLUBILITY IN WATER						
Solubility in water **B.2.5/01**	OECD 105 (column elution method)	FPP pure 98.7%	0.7 mg/L (at 20 °C, bidistilled water, pH 5.8)	EU agreed endpoint DAR 2005	N Y	Goerlitz, G.; Eyrich, U.; 1987 M-117981-01-1 Weller, O.; 1990 M-126592-01-1
	EC A.6 OECD 105 (column elution method)	FPP pure 99.3% Batch code 703-HF-24	Solubility at 20 °C pH / Solubility (mg/L) water unbuffered / 0.43 pH 4 buffer / 0.43 pH 7 buffer / 0.42 pH 10 buffer / 0.34	**Acceptable**	Y	Comb, A.L.; 2005 M-548748-01-1
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS						
Solubility in organic solvents **B.2.6/01**	OECD 105 (flask method)	FPP (D+L) 98.7% FPP (pure D) 89.8%	Solubility values at 20 °C Solvent / S (g/L) D+L / S (g/L) D / ee dissolved n-hexane / 7.5 / 7.0 / 0.857 acetone / >400 / >400 / - toluene / >500 / >500 / - dichloro-methane / >400 / >400 / - methanol / 46.3 / 43.1 / 0.862 isopropanol / 15.4 / 14.2 / 0.847	EU agreed endpoint DAR 2005	Y	Goerlitz, G.; Rutz, U.; 1989 M-123920-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			ethyl acetate: >400; >380; -			
	Based on EEC A.6 (flask method)	FPP TGAS 95.6% Batch code 660-PSH-45	Solubility values at 20 °C Solvent: Solubility (g/L) n-heptane: 7.70 acetone: >250 xylene: >250 1,2-dichloroethane: >250 methanol: 38.6 n-octanol: 19.4 ethyl acetate: >250	**Acceptable**	Y	Comb, A.L.; 2005 M-548076-01-1
B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER						
Partition coefficient n-octanol/water **B.2.7/01**	OECD 117 (HPLC method)	FPP pure 98.9%	In methanol/water (70/30) K_{ow} = 38000 log K_{ow} = 4.58	EU agreed endpoint DAR 2005	Y	Schollmeier, M.; Eyrich, U.; Uhl, A.; 1992 M-138162-01-1
Effect of pH (4 to 10) on the n-octanol/ water partition coefficient			The active substance does not dissociate at environmentally relevant pH and thus the effect of pH on the Pow is not relevant.			
B.2.8. DISSOCIATION IN WATER						
Dissociation constant **B.2.8/01**	Calculation	not relevant	pKa = -0.18 The active substance does not dissociate under environmental conditions.	EU agreed endpoint DAR 2005	N	Le Gren, I.; 2003 M-217712-01-1
B.2.9. FLAMABILITY AND SHELF-HEATING						
Flammability **B.2.9/01**	EC A.10	FPP technical 96.3%	Not readily combustible solid.	EU agreed endpoint DAR 2005	Y	Hoffmann, H.; 2000 M-198637-01-1
	EEC A.10	FPP TGAS 95.6% Batch code 660-PSH-45	Not flammable	**Acceptable**	Y	Comb, A.L.; 2005 M-548076-01-1
Self heating	EC A.16	FPP technical	No self-ignition observed up to 401 °C.	EU agreed endpoint	Y	Hoffmann, H.;

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.9/02		96.3%		DAR 2005		2000 M-198637-01-1
	EEC A.15	FPP TGAS 95.6% Batch code 660-PSH-45	No auto-ignition temperature below 400 °C	**Acceptable** EEC A.15 (for liquids) was used with the argument that the melting temperature of the test substance is below 100°C.	Y	Comb, A.L.; 2005 M-548076-01-1
B.2.10. FLASH POINT						
Flash point **B.2.10/01**			Not relevant. The active substance is a solid.			
B.2.11. EXPLOSIVE PROPERTIES						
Explosive properties **B.2.11/01**	EC A.14	FPP technical 96.3%	Not explosive	EU agreed endpoint DAR 2005	Y	Hoffmann, H.; 2000 M-198639-01-1
B.2.12. SURFACE TENSION						
Surface tension **B.2.12/01**	EC A.5	n.a.	Not relevant. The active substance solubility is less than 1 mg/L and thus the surface tension need not to be tested.	EU agreed endpoint DAR 2005	Y	Rexer, K.; 2001 M-200186-01-1
	EEC A.5 (ring method)	FPP TGAS 95.6% Batch code 660-PSH-45	70.5 mN/m (20 °C, 90% of saturated solution) The active substance is not considered surface active.	The study is not required as the solubility is less than 1 mg/L and therefore the value is not reliable.	Y	Comb, A.L.; 2005 M-548076-01-1
B.2.13. OXIDISING PROPERTIES						
Oxidizing properties **B.2.13/01**	EC A.17	FPP technical 96.3%	No oxidizing properties	EU agreed endpoint DAR 2005	Y	Hoffmann, H.; 2000 M-198642-01-1
	EEC A.17	FPP technical 94.5% Batch code: AE F046360-01-18	No oxidizing properties	**Acceptable**	Y	Cowlyn, N.; 2015 M-526732-01-1

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.14. OTHER STUDIES						
Relative density of purified active substance	OECD 109 (pyknometer)	FPP pure 98.2%	D^{20}_{4} = 1.32	EU agreed endpoint DAR 2005 No longer required and therefore not considered to be relied on	Y	Bittner, P.; Rexer, K.; 1999 M-188792-01-1*
Water solubility of metabolites	OECD 105 EC A.6 (flask method)	Metabolite AE F087795 (BCS-CA37046) 98.2 % Batch: AE F087795-PU-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (4.9) / 7.3 pH 7 (7.1) / 6.3 pH 9 (9.0) / 4.5	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Sonnenschein, L.; 2015 M-527714-01-1*
	OECD 105 EC A.6 (flask method)	Metabolite AE F054014 (BCS-AC79872) 98.5 % Batch: AE F054014-PU-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.0) / 0.242 pH 7 (7.0) / 0.248 pH 9 (9.0) / 1.27	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Sonnenschein, L.; 2015 M-527828-01-1*
	OECD 105 EC A.6 (flask method)	Metabolite AE F096918 (BSolubility-CA37065) 99.8 % Batch: BHBM3M02	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.0) / >175 pH 7 (7.0) / >135 pH 9 (9.0) / >125	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Sonnenschein, L.; 2015 M-527831-01-1*
	OECD 105 EC A.6 (column elution method)	Metabolite AE F040356 (BSolubility-AB16188) 97.0 % Batch: AE F040356-PU-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.0) / 0.002 pH 7 (7.0) / 0.002 pH 9 (9.0) / 0.003	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Fischer, A.; 2016 M-547447-01-1*
	OECD 105 EC A.6 (flask method)	Metabolite AE F088406 (BSolubility-BQ23896) 98.3 % Batch: AE F088406-PU-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.01) / 0.171 pH 7 (7.04) / 55.4 pH 9 (9.04) / >101	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Fischer, A; 2016 M-547402-01-1*
	OECD 105 EC A.6 (flask method)	Metabolite BSolubility-CY11271 94.8 % Batch: BSolubility-CY11271-01-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.0) / 0.0116 pH 7 (7.0) / 0.0140	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Fischer, A; 2016 M-547452-01-1*

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			pH 9 (9.0) 0.0214			
	OECD 105 EC A.6 (flask method)	Metabolite AE 0316854 (BSolubility-AW69425) 99.4 % Batch: AE0316854-PU-01	Solubility at 20 °C pH (final pH) / Solubility (g/L) pH 5 (5.0) 0.144 pH 7 (7.0) 0.150 pH 9 (9.0) 0.313	**Acceptable** The water solubility of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1	Y	Fischer, A; 2016 M-547425-01-1*
n-Octanol/water partition coefficient of metabolites	OECD 117 EC A.8 (HPLC method)	Metabolite AE F040356 (BCS-AB16188) 97.0 % Batch: AE F040356-PU-01	Values at 20 °C: log P_{ow} / P_{ow} pH 5: 3.1 / 1.3×10^{3} pH 7: 3.1 / 1.3×10^{3} pH 9: 2.4 / 2.5×10^{2}	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Sonnenschein, L.; 2015 M-526725-01-1*
	OECD 117 HPLC method	Metabolite AE F054014 (BCS-AC79872) 99.8% Batch: RSS 1170 Kl	Value at 20 °C (w/w)] log K_{OW} = 1.9	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Tognucci A., 1999 M-186476-01-1 *
	OECD 107 and 117 EC A.8 (HPLC [pH 5,7] and shake flask method [pH 9])	Metabolite AE F054014 (BCS-AC79872) 98.5 % Batch: AE F054014-PU-01	Values at 20 °C (HPLC method) and at 22 °C (shake flask method): log P_{ow} / P_{ow} pH 5: 1.7 / 50 pH 7: 1.5 / 32 pH 9: 1.4 / 24 At pH 9 the HPLC method was not applicable, due to the fact that the measured retention time of the test item was lower than the dead time t_0.	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Fischer, A.; 2015 M-538121-01-1
	OECD 107 EC A.8 (shake flask method)	Metabolite AE F096918 (BCS-CA37065) 99.8 % Batch: BHBM3M02	Values at 22 °C: log P_{ow} / P_{ow} pH 5: -1.6 / 2.46×10^{-2} pH 7: -2.6 / 2.35×10^{-3} pH 9: -3.1 / 8.36×10^{-4}	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Fischer, A.; 2016 M-547403-01-1*
	OECD 107 (shake flask method)	AE F053022 (fenoxaprop free acid) 98.1% Batch: Hoe 053022 0Q ZB98 0001	Values at 22 °C: log Pow / Pow pH 5: 1.81 / 68.3 pH 7: 0.46 / 2.87 pH 9: 0.24 / 1.73	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Goerlitz G., Eyrich U. 1985 M-109062-01-1 * Schollmeier, 1992 M-138350-01-1*
	OECD 107	Metabolite AE F088406 (BCS-	Values at 22 °C:	**Acceptable**	Y	Fischer, A.; 2016

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 (shake flask method)	BQ23896) 98.3 % Batch: AE F088406-PU-01	<table><tr><td></td><td>log P_{ow}</td><td>P_{ow}</td></tr><tr><td>pH 5</td><td>1.9</td><td>85.6</td></tr><tr><td>pH 7</td><td>0.3</td><td>2.07</td></tr><tr><td>pH 9</td><td>0.0</td><td>1.06</td></tr></table>	The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.		M-547422-01-1*
	OECD 107 EC A.8 (shake flask method)	Metabolite AE 0316854 (BCS-AW69425) 99.4 % Batch: AE0316854-PU-01	Values at 23 °C: <table><tr><td></td><td>log P_{ow}</td><td>P_{ow}</td></tr><tr><td>pH 5</td><td>1.0</td><td>11.0</td></tr><tr><td>pH 7</td><td>1.0</td><td>10.4</td></tr><tr><td>pH 9</td><td>0.8</td><td>6.93</td></tr></table>	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Fischer, A.; 2016 M-547427-01-1*
	OECD 117 EC A.8 (HPLC method)	Metabolite AE F087795 (BCS-CA37046) 98.2 % Batch: AE F087795-PU-01	Values at 20 °C: <table><tr><td></td><td>log P_{ow}</td><td>P_{ow}</td></tr><tr><td>pH 5</td><td>1.7</td><td>50</td></tr><tr><td>pH 7</td><td>1.7</td><td>50</td></tr><tr><td>pH 9</td><td>1.6</td><td>40</td></tr></table>	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Sonnenschein, L.; 2015 M-526723-01-1*
	OECD 117 EC A.8 (HPLC method)	Metabolite BCS-CY11271 94.8 % Batch: BCS-CY11271-01-01	Values at 20 °C: <table><tr><td></td><td>log P_{ow}</td><td>P_{ow}</td></tr><tr><td>pH 5</td><td>2.6</td><td>4.0×10^2</td></tr><tr><td>pH 7</td><td>2.6</td><td>4.0×10^2</td></tr><tr><td>pH 9</td><td>2.0</td><td>1.0×10^2</td></tr></table>	**Acceptable** The log P_{ow} of the metabolite is supporting studies of other sections and therefore the study is not listed as relied on for section 1.	Y	Sonnenschein, L.; 2015 M-526729-01-1*

* Studies concerning metabolites are supporting other sections and therefore not considered to be relied on for section 1.

B.2.15. REFERENCES RELIED ON

- References written in grey typeface have been provided for Annex I inclusion (Baseline Dossier).
- References written in black typeface are submitted for the renewal of approval (Supplementary Dossier)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.1 /01	Smeykal, H.	1999	Melting point / melting range Fenoxaprop-P-ethyl substance, pure Code: AE F046360 00 1B99 0003 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Bayer CropScience, Report No.: C004110, Edition Number: M-187345-01-1 Date: 1999-05-11 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.1 /02	Heinrich; Rexer, K.	1988	Boiling point of Hoe 046360 substance, pure Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A38754, Edition Number: M-120377-01-1 Date: 1988-07-26 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.1 /03	Heinrich; Rexer, K.	1987	Decomposition point of Hoe 046360 substance, technical Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A35719, Edition Number: M-117569-01-1 Date: 1987-06-12 GLP/GEP: no, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.1 /04	Cowlyn, N.	2016	Fenoxaprop-P-ethyl: Melting / boiling point determination using differential scanning calorimetry Envigo CRS Limited, Suffolk, United Kingdom TF- BCS-CHA, Report No.: YY29CT, Edition Number: M-549131-01-1 Date: 2016-02-29 GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA
KCA 2.2 /01	Roechling, A.; Rexer, K.	1987	Vapour pressure of Hoe 046360 substance, pure Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A42898, Edition Number: M-125880-01-1 EPA MRID No.: 43990202 Date: 1987-06-02 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.2 /02	Schollmeier, M.	1992	Calculation of the Henry's constant Fenoxaprop-P-ethyl Code: Hoe 046360 Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A48206, Edition Number: M-137125-01-1 Date: 1992-06-26 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.2 /03	Dreisch, S.	2016	Amendment no. 1 to - Fenoxaprop-P-ethyl (AE F046360), pure substance: Vapour pressure consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt am Main, Germany TF- BCS-CHA, Report No.: CSL-16-0016.01, Edition Number: M-546227-02-1 Date: 2016-02-01 **...Amended: 2016-05-31** GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.2 /04	Ziemer, F.	2016	Fenoxaprop-P-ethyl (AE F046360): Calculation of the Henry's law constants TF- BCS-CHA, Report No.: AF15/007, Edition Number: M-549129-01-1 Date: 2016-03-02 GLP/GEP: no, unpublished	N	N		TF- BCS-CHA
KCA 2.3 /01	Heinrich; Rexer, K.	1988	Physical form of Hoe 046360 substance, pure Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A38756, Edition Number: M-120379-01-1 Date: 1988-07-26 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.3 /02	Heinrich; Rexer, K.	1988	Colour of Hoe 046360 substance, pure Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A38751, Edition Number: M-120374-01-1 Date: 1988-07-26 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.3 /03	Haase, D.; Rexer, K.	2000	Determination of the physical form Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008077, Edition Number: M-197170-01-1 Date: 2000-03-21 GLP/GEP: no, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.3 /04	Haase, D.; Rexer, K.	2000	Determination of the colour Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008079, Edition Number: M-197172-01-1 Date: 2000-03-21 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.3 /05	Heinrich; Rexer, K.	1988	Odour of Hoe 046360 substance, pure Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A38752, Edition Number: M-120375-01-1 Date: 1988-07-26 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.3 /06	Haase, D.; Rexer, K.	2000	Determination of the odour Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008078, Edition Number: M-197171-01-1 Date: 2000-03-21 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.3 /07	Wiche, A.; Ziemer, F.	2016	Fenoxaprop-P-ethyl (AE F046360), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA15/143, Edition Number: M-545655-01-1 Date: 2016-01-26 GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.3 /08	Wiche, A.; Ziemer, F.	2016	Fenoxaprop-P-ethyl (AE F046360), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA15/142, Edition Number: M-545592-01-1 Date: 2016-01-26 GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	Bayer CropScience
KCA 2.3 /09	Wiche, A.; Ziemer, F.	2016	Fenoxaprop-P-ethyl (AE F046360), pure substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA15/141, Edition Number: M-545567-01-1 Date: 2016-01-26 GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	Bayer CropScience
KCA 2.4 /01	Kloeckner, C.; Weller, O.	2000	Spectral data (UV/VIS, IR, 1H-NMR, 13C-NMR, MS) and molar extinction coefficient Fenoxaprop-P-ethyl Code: AE F046360 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008445, Edition Number: M-197490-01-1 Date: 2000-05-17 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.4 /02	Wolf, R.; Le Gren, I.	2004	Fenoxaprop-P-ethyl (AE F046369) Additional information and clarification to section 1 (Annex II and III), physical / chemical properties Statement Bayer CropScience, Report No.: C044472, Edition Number: M-236174-01-1 Date: 2004-10-14 GLP/GEP: n.a., unpublished **...also filed: KCA 2.12 /02** **...also filed: KCA 2.13 /02** **...also filed: KCA 2.7 /05**	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.4 /03	Bogdoll, B.	2003	Determination of the specific optical rotation of optically pure fenoxaprop-P-ethyl Code: AE F046360 00 1B99 0003 (pure active substance) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C030734, Edition Number: M-228380-01-1 Date: 2003-03-07 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.5 /01	Goerlitz, G.; Eyrich, U.	1987	Solubility in water Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A36178, Edition Number: M-117981-01-1 Date: 1987-07-16 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.5 /02	Weller, O.	1990	Solubility in water (addendum to report CP 050/87) Code: Hoe 046360 Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A43650, Edition Number: M-126592-01-1 Date: 1990-07-20 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.5 /04	Comb, A. L.	2005	Fenoxaprop-p-ethyl (pure grade): Melting termperature and water solubility Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom TF- BCS-CHA, Report No.: CHV0129/053825, Edition Number: M-548748-01-1 Date: 2005-12-01 GLP/GEP: yes, unpublished	N	Y	New data generated to comply with to Regulation (EC) No 1107/2009	TF- BCS-CHA

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.6 /01	Goerlitz, G.; Rutz, U.	1989	Solubility in organic solvents Code: Hoe 046360 Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A40979, Edition Number: M-123920-01-1 Date: 1989-05-19 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.6 /03	Comb, A. L.	2005	Fenoxaprop-p-ethyl technical: Surface tension, flammability, auto-ignition temperature and organic solvent solubility Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom TF- BCS-CHA, Report No.: 135 FPE, Edition Number: M-548076-01-1 Date: 2005-12-01 GLP/GEP: yes, unpublished **...also filed: KCA 2.12 /03** **...also filed: KCA 2.9 /04**	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA
KCA 2.7 /01	Schollmeier, M.; Eyrich, U.; Uhl, A.	1992	Determination of the partition coefficient n-octanol/water by HPLC (according to OECD Guideline #117) Hoe 046360 Code: Hoe 046360 00 ZB98 0001 Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A49082, Edition Number: M-138162-01-1 EPA MRID No.: 44659601 Date: 1992-11-11 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.7 /05	Wolf, R.; Le Gren, I.	2004	Fenoxaprop-P-ethyl (AE F046369) Additional information and clarification to section 1 (Annex II and III), physical / chemical properties Statement Bayer CropScience, Report No.: C044472, Edition Number: M-236174-01-1 Date: 2004-10-14 GLP/GEP: n.a., unpublished **...also filed: KCA 2.12 /02** **...also filed: KCA 2.13 /02** **...also filed: KCA 2.4 /02**	N	N		Bayer CropScience
KCA 2.8 /01	Le Gren, I.	2003	pKa calculation using a modelling software Fenoxaprop-P-ethyl Code: AE C046360 Bayer CropScience S.A., Lyon, France Bayer CropScience, Report No.: C029715, Edition Number: M-217712-01-1 Date: 2003-02-12 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.9 /01	Hoffmann, H.	2000	Flammability (solids) Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Bayer CropScience, Report No.: C009471, Edition Number: M-198637-01-1 Date: 2000-08-22 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.9 /02	Hoffmann, H.	2000	Auto-flammability (solids - determination of relative self-ignition temperature) Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Bayer CropScience, Report No.: C009473, Edition Number: M-198641-01-1 Date: 2000-08-22 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.9 /04	Comb, A. L.	2005	Fenoxaprop-p-ethyl technical: Surface tension, flammability, auto-ignition temperature and organic solvent solubility Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom TF- BCS-CHA, Report No.: 135 FPE, Edition Number: M-548076-01-1 Date: 2005-12-01 GLP/GEP: yes, unpublished **...also filed: KCA 2.12 /03** **...also filed: KCA 2.6 /03**	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA
KCA 2.11 /01	Hoffmann, H.	2000	Explosive properties Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Bayer CropScience, Report No.: C009472, Edition Number: M-198639-01-1 Date: 2000-08-22 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.12 /01	Rexer, K.	2001	Determination of the surface tension Fenoxaprop-P-ethyl substance technical Code: AE F046360 00 1D96 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C011094, Edition Number: M-200186-01-1 Date: 2001-01-18 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.12 /02	Wolf, R.; Le Gren, I.	2004	Fenoxaprop-P-ethyl (AE F046369) Additional information and clarification to section 1 (Annex II and III), physical / chemical properties Statement Bayer CropScience, Report No.: C044472, Edition Number: M-236174-01-1 Date: 2004-10-14 GLP/GEP: n.a., unpublished **...also filed: KCA 2.13 /02** **...also filed: KCA 2.4 /02** **...also filed: KCA 2.7 /05**	N	N		Bayer CropScience
KCA 2.12 /03	Comb, A. L.	2005	Fenoxaprop-p-ethyl technical: Surface tension, flammability, auto-ignition temperature and organic solvent solubility Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom TF- BCS-CHA, Report No.: 135 FPE, Edition Number: M-548076-01-1 Date: 2005-12-01 GLP/GEP: yes, unpublished **...also filed: KCA 2.6 /03** **...also filed: KCA 2.9 /04**	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.13 /01	Hoffmann, H.	2000	Oxidizing properties Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1D96 0002 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Bayer CropScience, Report No.: C009474, Edition Number: M-198642-01-1 Date: 2000-08-22 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 2.13 /02	Wolf, R.; Le Gren, I.	2004	Fenoxaprop-P-ethyl (AE F046369) Additional information and clarification to section 1 (Annex II and III), physical / chemical properties Statement Bayer CropScience, Report No.: C044472, Edition Number: M-236174-01-1 Date: 2004-10-14 GLP/GEP: n.a., unpublished **...also filed: KCA 2.12 /02** **...also filed: KCA 2.4 /02** **...also filed: KCA 2.7 /05**	N	N		Bayer CropScience
KCA 2.13 /03	Cowlyn, N.	2015	Fenoxaprop-P-ethyl TGAI: Oxidising properties Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom TF- BCS-CHA, Report No.: DGV0231, Edition Number: M-526732-01-1 Date: 2015-04-23 GLP/GEP: yes, unpublished	N	Y	Study included to cover newest guidelines and data requirements under EC 283/2013	TF- BCS-CHA