European Commission

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

Fenoxaprop-P-ethyl

Volume 3 – B.2 (PPP) – CHA 4960

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

Version History

When	What
2005/April	Initial DAR of the active substance. CHA 4960 was not the representative formulation
2018/March	DRAR

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT CHA 4960

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of an opaque white liquid, with a weak aromatic odour. It is not explosive, has no oxidising properties. It has no auto-ignition temperature below 400°C. In aqueous solution, it has a pH value around 6.5 – 7.3. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored as recommended. Its technical characteristics are acceptable for an oil emulsion in water (EW) formulation.
The label should contain the recommendation "Shake well before use"

The formulation was not the representative formulation for the Annex I inclusion of fenoxaprop-P-ethyl. The specification and purity are given in Part C.

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

1. batch 660-PSH-76; 69 g/L (6.97 % w/w) fenoxaprop-P-ethyl
2. batch 660-PSH-49; 69 g/L (7.11 % w/w) fenoxaprop-P-ethyl
3. batch 0001002083, 69 g/L (7.08% w/w) fenoxaprop-P-ethyl

Tests performed at 0.024% a.s, 0.046% a.s, and 0.074% a.s.
Application rate according to the GAP is 1.0 to 1.2% of CHA4960 (≙ 0.069% a.s. to 0.083% a.s.)

Table B.2-1 Physical and chemical properties

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour **B.2.1/01**	Visual and olfactory assessment	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Before homogenization: Opaque white liquid with a small oil like layer on the top. Weak aromatic odour After homogenization: Opaque white homogeneous liquid with a weak aromatic odour	**Acceptable** Due to this information the label/instruction of use should contain: **Shake well before use**	Y	Hinz B. (2008) Report No.: PYC 181 (238 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties **B.2.2/01**	Statement according to EEC A14	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	Not explosive	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0135/053400 (92 FPE)
Oxidizing properties **B.2.2/02**	Statement according to EEC A21	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	No oxidizing properties	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0136/053403 (93 FPE)
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations **B.2.3/01**	EEC A9 Pensky-Martens closed apperatus	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	No flash observable up to 100 °C. At approximately 100 °C the test substance was observed to boil and the flash point could not be determined.	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0126/053431 (91 FPE)
Flammability of solid formulations **B.2.3/02**			Not applicable as formulation is a liquid			
Self-heating of formulation **B.2.3/03**	EEC A15	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	No auto-ignition temperature below 400 °C	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0126/053431 (91 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation **B.2.4/01**	CIPAC MT 75.3	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	Undiluted pH = 7.3 (25 ± 0.5 °C)	**Acceptable**	Y	Hinz B. (2005) Report No.: PYC 144 (100 FPE
pH of a 1 % dilution of the solid or non aqueous formulation **B.2.4/02**	CIPAC MT 75.3	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	1% solution in water = 6.53 (25 ± 0.5 °C)	**Acceptable**	Y	Hinz B. (2005) Report No.: PYC 144 (100 FPE)
Acidity / Alkalinity **B.2.4/03**			Not relevant as pH of the formulation is > 4 and < 10			
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation **B.2.5/01**	OECD 114 (by rotational viscosimeter)	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	Dynamic Viscosity: lowest dynamic viscosity at 20 °C = 140 mPa × s (140 - 2200 mPa × s at 20.0 °C) lowest dynamic viscosity at 40 °C =70 mPa × s (70 - 1700 mPa × s at 40 °C) CHA 4960 was found to be pseudo-plastic in its flow behaviour (decreasing viscosity with increasing shear rate)	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0126/053431 (91 FPE)
	OECD 114 and CIPAC MT 192	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	763 cP = 763 mPa*s at 20.0 °C (spindle LV2 and 12 rpm) 487 cP = 487 mPa*s at 40 °C(spindle LV2 and 12 rpm) CHA 4960 is characterised as a non-Newtonian, time independent, pseudoplastic and shear thinning liquid at 20 °C and 40 °C.	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 182 (184 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Surface tension of the formulation **B.2.5/02**	EEC A.5 OECD 115	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.11% w/w Batch No.: 660-PSH-49	1 g/L dilution: 40.0 mN/m (at 20 °C); Undiluted: 31.0 mN/m (at 25 °C)	**Acceptable**	Y	Comb, A. L. (2005) Report No.: CHV0126/053431 (91 FPE)
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation **B.2.6/01**		Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	D^{20}_{4}: 1.03 (Density: 1.03 g/mL)	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 177 (158 FPE)
Bulk density (pour and tap) of powder or granules **B.2.6/02**			Not required for EW formulations			
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) **B.2.7/01**	CIPAC MT 46.3 In-house method VAM 074-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Stable throughout the test period of 2 weeks at 54 °C with respect to active content, appearance, pH, persistence of foam, emulsifiability, and pourability; tested at two concentration levels 0.024 and 0.046% a.s. Packaging material: HDPE For detailed results see table B.2-2.	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 179 (177 FPE)
Effect of low temperature on stability of liquid formulation **B.2.7/02**	CIPAC MT 39.3	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.08% w/w Batch No.: 0001002083	All tested concentrations (0.024 and 0.046 % a.s.) in CIPAC standard water D show very good results for cold stability. Detailed information is given in. For detailed results see table B.2-3.	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 178 (176 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Shelf life following storage at ambient temperature **B.2.7/03**	OPPTS 830.6317 GIFAP 17 In-house methods VAM 148-01 (24 month samples only) and VAM 074-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Stable throughout the test period of 2 years at ambient temperature with respect to active content, appearance, pH, persistence of foam, emulsifiability, pourability; tested at two concentration levels 0.024 and 0.046% a.s. Packaging material: HDPE For detailed results see table B.2-4.	**Acceptable**	Y	Hinz B. (2008) Report No.: PYC 181 (238 FPE)
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**			Not required for EW formulations			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.2 In-house method PCM 014-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Mean persistent foam in CIPAC water D concentration = 0.46 g a.s./L After 1 min.: 21.0 mL concentration = 0.74 g a.s./L After 1 min.: 29.9 mL	**Acceptable**	Y	Hinz B. (2011) Report No.: PYC 525 (444 FPE)
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**			Not required for EW formulations			
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**			Not required for EW formulations			
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**			Not required for EW formulations			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation **B.2.8.4/01**			Not required for EW formulations			
Dilution stability of water soluble formulation **B.2.8.4/02**			Not required for EW formulations			
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**			Not required for EW formulations			
Size distribution of particles of powder or suspension concentrate formulation **B.2.8.5.1/02**			Not required for EW formulations			
Nominal size range of granule **B.2.8.5.1/03**			Not required for EW formulations			
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**			Not required for EW formulations			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**			Not required for EW formulations			
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**			Not required for EW formulations			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Integrity of tablets **B.2.8.5.4/02**			Not required for EW formulations			
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Initial emulsification: CIPAC Water A c = 0.24 g a.s./L: complete c = 0.46 g a.s./L: complete CIPAC Water D c = 0.24 g a.s./L: complete c = 0.46 g a.s./L: complete (≤ 0.25 mL foam)	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 179 (177 FPE)
	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.08% w/w Batch No.: 0001002083	Initial emulsification: CIPAC Water A c = 0.74 g a.s./L: complete CIPAC Water D c = 0.74 g a.s./L: complete	**Acceptable**	Y	Hinz B. (2011) Report No.: PYC 525 (444 FPE)
	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Re-emulsification after 24 h: CIPAC Water A c = 0.24 g a.s./L: complete, 4 mL foam c = 0.46 g a.s./L: complete, 7 mL foam CIPAC Water D c = 0.24 g a.s./L: complete, 4.5 mL foam c = 0.46 g a.s./L: complete, 7 mL foam	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 179 (177 FPE)
	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.08% w/w Batch No.: 0001002083	Re-emulsification after 24 h: CIPAC Water A c = 0.74 g a.s./L: complete CIPAC Water D c = 0.74 g a.s./L: complete	**Acceptable**	Y	Hinz B. (2011) Report No.: PYC 525 (444 FPE)
	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w	Emulsion stability: CIPAC Water A c = 0.24 g a.s./L 0.5 h: 2 mL foam, no oil or cream	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 179 (177 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		Batch No.: 660-PSH-76	2 h: ≤ 0.25 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: 2 mL foam, no oil, cream or solid matter <u>c = 0.46 g a.s./L</u> 0.5 h: 4 mL foam, no oil or cream 2 h: 1.5 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: 4 mL foam, no oil, cream or solid matter CIPAC Water D <u>c = 0.24 g a.s./L</u> 0.5 h: 2 mL foam, no oil or cream 2 h: ≤ 0.25 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: 3.5 mL foam, no oil, cream or solid matter <u>c = 0.46 g a.s./L</u> 0.5 h: 4 mL foam, no oil or cream 2 h: 1.5 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: 3.5 mL foam, no oil, cream or solid matter			
	CIPAC MT 36.3 In-house method PCM 009-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 7.08% w/w Batch No.: 0001002083	Emulsion stability: CIPAC Water A <u>c = 0.74 g a.s./L</u> 0.5 h: 4 mL foam, no oil or cream 2 h: 1.5 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: complete, no oil, cream or solid matter CIPAC Water D <u>c = 0.74 g a.s./L</u> 0.5 h: 4 mL foam, no oil or cream 2 h: 1.5 mL foam, no oil or cream 24 h: No foam, oil or cream, ≤ 0.25 mL solid matter 24.5 h: complete, no oil, cream or solid matter	**Acceptable**	Y	Hinz B. (2011) Report No.: PYC 525 (444 FPE)

B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**			Not required for EW formulations			
Pourability of suspensions **B.2.8.7/02**	CIPAC MT 148 In-house method PCM 010-01	Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960) purity: 6.97% w/w Batch No.: 660-PSH-76	Residue 2.45% Rinsed residue 0.14% Study temperature: 20 ± 2 °C	**Acceptable**	Y	Hinz B. (2006) Report No.: PYC 179 (177 FPE)
Dustability of dustable powders after accelerated storage **B.2.8.7/03**			Not required for EW formulations			
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures **B.2.9/01**		Foxtrot Fenoxaprop-P-ethyl 69g/L EW (CHA 4960)	Mixtures of the test material with a wide range of other plant protection and micro-nutrient products were tested – see below. All mixtures were determined to be physically compatible and can be used in spray applications, except for the product "Bushel" Fenoxaprop-P-ethyl, the active substance in the formulation, is stable under diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. In the physical compatibility test no indication of any chemical reaction between the mixed products was observed. Therefore CHA 4960 is chemically compatible with the tested products	**Acceptable**	N	Gamblin A. 2005 Study No.: ACE-05-001 (111 FPE)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Flexity: Compatible Opus: Compatible Tracker: Compatible Instinct: Compatible Hussar: Compatible Chekker: Compatible Jau + Hec: Compatible Jau + spiroxamine: Compatible Jau + tebuconazole: Compatible Jau: Compatible Atlantis: Compatible Blazer: Compatible Strane XL: Compatible Ally: Compatible Eagle: Compatible Harmony M: Compatible Oxytril CM: Compatible Quantum: Compatible Strane XL: Compatible Boxer: Compatible Tolkan liquid: Compatible Amistar: Compatible Ensign: Compatible Landmark: Compatible Mantra: Compatible Twist: Compatible Eclipse: Compatible Foil: Compatible Folicur: Compatible Flamenco: Compatible Pointer: Compatible Sanction: Compatible Tilt: Compatible			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Bravo: Compatible Corbel: Compatible Fortress: Compatible Tern: Compatible Unix: Compatible Cerone: Compatible Chlormequat: Compatible Moddus: Compatible Meteor: Compatible Terpal: Compatible Upgrade: Compatible Impact Excel: Sedimentation but goes on agitation - compatible Tebuconazole: Sedimentation but goes on agitation - compatible DFF+IPU products: Sedimentation but it goes on agitation - compatabile Jett: Compatible Respond: Compatible Stag: Compatible Spirit: Compatible Root 66: Compatible Copper: Compatible Manganese sulphate: Compatible Bushel: Homogenous but blocks the seive on seiving - not considered compatible Brock: Sediimentation but goes on agitation - compatible Headland classic: Sedimentation but goes on agitation - compatible Trice: Sedimentation but goes on agitation - compatible			
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds **B.2.9.10/01**			Not relevant as the formulation is not used as a seed treatment			
B.2.11. OTHER STUDIES						
			Not relevant			

Table B.2.2-2: Detailed results: Accelerated storage stability study (Hinz B. (2006), PYC 179 (177 FPE))

Test	Initial	14 Days at 54°C
Content of active method VAM 074-01	7.17%	7.17%
Content of safener method VAM 074-01	3.37%	3.37%
Weigh of container	Product and packaging	
	1136.1 g	1131.7 g
	Empty packaging	
	122.4 g	122.2 g
	Glass container	
	159.3 g	159.2 g
Appearance visual estimation at room temperature	Before homogenization	
	-	Opaque white homogeneous liquid
	After homogenization	
	Opaque white liquid with 3 to 4 small oil like layers of approximately 0.5 cm × 0.5 cm on the top	Opaque white homogeneous liquid
pH-Value CIPAC Handbook MT 75.3, method PCM 001-01	Undiluted	
	6.3	5.6
	1% w/v solution	
	6.0	5.6
Persistence of foam CIPAC Handbook MT 47.2, method PCM 014-01	CIPAC water D (0.46 g a.s./L)	
	10 sec	
	21.0 mL	24.4 mL
	1 min	
	21.0 mL	24.0 mL
	3 min	
	19.5 mL	23.2 mL
	12 min	
	18.3 mL	20.5 mL

Test	Initial	14 Days at 54°C
Persistence of foam CIPAC Handbook MT 47.2, method PCM 014-01	CIPAC water D (0.74 g a.s./L)	
	10 sec	
	32.6 mL	36.1 mL
	1 min	
	29.9 mL	34.2 mL
	3 min	
	25.7 mL	33.0 mL
	12 min	
	19.4 mL	27.2 mL
Emulsion stability CIPAC Handbook MT 36.3, method PCM 009-01	CIPAC water A (0.24 g a.s./L)	
Initial emulsification	Complete	Complete
Emulsion stability after 0.5 h	4 mL foam. No oil, no cream	0.5 mL foam. No oil, no cream
Emulsion stability after 2 h	1.5 mL foam. No oil, no cream	0 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream
Re-emulsification after 24 h	Complete (4 mL foam). No oil, no cream, no solid matter	Complete (5 mL foam). No oil, no cream, no solid matter
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	4 mL foam. No oil, no cream, no solid matter
	CIPAC water A (0.46 g a.s./L)	
Initial emulsification	Complete	Complete (≤ 0.25 mL foam)
Emulsion stability after 0.5 h	5 mL foam. No oil, no cream	6 mL foam. No oil, no cream
Emulsion stability after 2 h	2.5 mL foam. No oil, no cream	2.5 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream
Re-emulsification after 24 h	Complete (7 mL foam). No oil, no cream, no solid matter	Complete (7 mL foam). No oil, no cream, no solid matter
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	4.5 mL foam. No oil, no cream, no solid matter
	CIPAC water D (0.24 g a.s./L)	
Initial emulsification	Complete	Complete
Emulsion stability after 0.5 h	2 mL foam. No oil, no cream	0.5 mL foam. No oil, no cream
Emulsion stability after 2 h	≤ 0.25 mL foam. No oil, no cream	0 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream
Re-emulsification after 24 h	Complete (4.5 mL foam). No oil, no cream, no solid matter	Complete (5 mL foam). No oil, no cream, no solid matter
Final emulsion stability 24.5 h	3.5 mL foam. No oil, no cream, no solid matter	0.5 mL foam. No oil, no cream, no solid matter

Test	Initial	14 Days at 54°C
	CIPAC water D (0.46 g a.s./L)	
Initial emulsification	Complete (≤ 0.25 mL foam)	Complete
Emulsion stability after 0.5 h	4 mL foam. No oil, no cream	5 mL foam. No oil, no cream
Emulsion stability after 2 h	1.5 mL foam. No oil, no cream	1 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream	0 mL foam, ≤ 0.25 mL solid matter, no oil, no cream
Re-emulsification after 24 h	Complete (7 mL foam). No oil, no cream, no solid matter	Complete (7 mL foam). No oil, no cream, no solid matter
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	2.5 mL foam. No oil, no cream, no solid matter
	CIPAC water A (0.74 g a.s./L)	
Initial emulsification	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 0.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 2 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 24 h	< 0.25 mL cream at the bottom, no oil and no solid matter	< 0.25 mL cream at the bottom, no oil and no solid matter
Re-emulsification after 24 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Final emulsion stability 24.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
	CIPAC water D (0.74 g a.s./L)	
Initial emulsification	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 0.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 2 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 24 h	< 0.25 mL cream at the bottom, no oil and no solid matter	< 0.25 mL cream at the bottom, no oil and no solid matter
Re-emulsification after 24 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Final emulsion stability 24.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Pourability CIPAC Handbook MT 148, method PCM 010-01	Residue	
	2.45%	2.80%
	Rinsed residue	
	0.14%	0.14%

Table B.2.2-3: Detailed results: Cold stability study (Hinz B. (2006), PYC 178 (176 FPE))

Test	Initial	After 7 Days at 0 °C
Appearance	Before homogenization	
	-	Opaque white homogeneous liquid
	After homogenization	
	Opaque white liquid with an ice layer of approximately 3 cm on the top	Opaque white homogeneous liquid
Content of active method VAM 074-01	7.17% w/v	7.16% w/v
Content of safener method VAM 074-01	3.37% w/v	3.37% w/v
pH-value CIPAC Handbook MT 75.3, method PCM 001-01	Undiluted	
	6.3	6.3
	1% w/v solution	
	6.0	5.9
Emulsion stability CIPAC Handbook MT 36.3, method PCM 009-01	CIPAC water A (0.24 g a.s./L)	
Initial emulsification	Complete	Complete
Emulsion stability after 0.5 h	4 mL foam. No oil, no cream	2 mL foam. No oil, no cream
Emulsion stability after 2 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 24 h	No foam, ≤ 0.25 mL solid matter. No oil, no cream	No foam, ≤ 0.25 mL solid matter. No oil, no cream
Re-emulsification after 24 h	Complete	Complete
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	1 mL foam. No oil, no cream, no solid matter
	CIPAC water A (0.46 g a.s./L)	
Initial emulsification	Complete	Complete (≤ 0.25 mL foam)
Emulsion stability after 0.5 h	5 mL foam. No oil, no cream	4.5 mL foam. No oil, no cream
Emulsion stability after 2 h	2.5 mL foam. No oil, no cream	2.0 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter. No oil, no cream	No foam, ≤ 0.25 mL solid matter. No oil, no cream
Re-emulsification after 24 h	Complete (4 mL foam). No oil, no cream, no solid matter)	Complete (6 mL foam). No oil, no cream, no solid matter)
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	4 mL foam. No oil, no cream, no solid matter

Test	Initial	After 7 Days at 0 °C
	CIPAC water D (0.24 g a.s./L)	
Initial emulsification	Complete	Complete
Emulsion stability after 0.5 h	2 mL foam. No oil, no cream	2 mL foam. No oil, no cream
Emulsion stability after 2 h	≤ 0.25 mL foam. No oil, no cream	≤ 0.25 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter. No oil, no cream	0 mL foam, ≤ 0.25 mL solid matter. No oil, no cream
Re-emulsification after 24 h	Complete (4.5 mL foam). No oil, no cream, no solid matter)	Complete (5 mL foam). No oil, no cream, no solid matter)
Final emulsion stability 24.5 h	3.5 mL foam. No oil, no cream, no solid matter	2 mL foam. No oil, no cream, no solid matter
	CIPAC water D (0.46 g a.s./L)	
Initial emulsification	Complete (≤ 0.25 mL foam)	Complete (≤ 0.25 mL foam)
Emulsion stability after 0.5 h	4 mL foam. No oil, no cream	6 mL foam. No oil, no cream
Emulsion stability after 2 h	1.5 mL foam. No oil, no cream	3 mL foam. No oil, no cream
Emulsion stability after 24 h	0 mL foam, ≤ 0.25 mL solid matter. No oil, no cream	0 mL foam, ≤ 0.25 mL solid matter. No oil, no cream
Re-emulsification after 24 h	Complete (7 mL foam). No oil, no cream, no solid matter)	Complete (9 mL foam). No oil, no cream, no solid matter)
Final emulsion stability 24.5 h	4 mL foam. No oil, no cream, no solid matter	7 mL foam. No oil, no cream, no solid matter
	CIPAC water A (0.74 g a.s./L)	
Initial emulsification	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 0.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 2 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 24 h	< 0.25 mL cream at the bottom, no oil and no solid matter	< 0.25 mL cream at the bottom, no oil and no solid matter
Re-emulsification after 24 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Final emulsion stability 24.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter

Test	Initial	After 7 Days at 0 °C
	CIPAC water D (0.74 g a.s./L)	
Initial emulsification	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 0.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 2 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Emulsion stability after 24 h	< 0.25 mL cream at the bottom, no oil and no solid matter	< 0.25 mL cream at the bottom, no oil and no solid matter
Re-emulsification after 24 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter
Final emulsion stability 24.5 h	No cream, no oil and no solid matter	No cream, no oil and no solid matter

Table B.2.2-4: Detailed results: Ambient storage stability study (Hinz B. (2008), PYC 181 (238 FPE))

Test	Initial	One year at RT	Two years at RT
Content of active method VAM 074-01	7.17% w/w	7.14% w/w	7.13% w/w
Content of safener method VAM 074-01	3.37% w/w	3.39% w/w	3.39% w/w
Weigh of container	Product and packaging		
	1143.8 g	1136.8 g	1129.5 g
	Empty packaging		
	122.8 g	122.9 g	122.8 g
Appearance visual estimation at room temperature	Before homogenization		
	Opaque white liquid with a small oil like layer on the top	Opaque white liquid with a small oil like layer on the top	Opaque white liquid with approximately 1 cm of a clear liquid on the bottom
	After homogenization		
	Opaque white homogeneous liquid	Opaque white homogeneous liquid	Opaque white homogeneous liquid
pH-value CIPAC Handbook MT 75.3, method PCM 001-01 at 25 °C	Undiluted		
	6.3	5.5	5.1
	1% w/v solution		
	6.0	5.7	5.3
Persistence of foam CIPAC Handbook MT 47.2, method PCM 014-01	CIPAC water D (0.46 g a.s./L)		
	10 sec		
	21.0 mL	29.9 mL	32.3 mL
	1 min		
	21.0 mL	28.7 mL	31.9 mL
	3 min		
	19.5 mL	28.4 mL	30.3 mL
	12 min		
	18.3 mL	26.0 mL	28.4 mL

Test	Initial	One year at RT	Two years at RT
Emulsion stability CIPAC Handbook MT 36.3, method PCM 009-01	CIPAC water A (0.24 g a.s./L)		
Initial emulsification	Complete	Complete	Complete
Emulsion stability after 0.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 2 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 24 h	No oil, no cream and ≤ 0.25 mL solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Re-emulsification after 24 h	Complete	Complete	Complete
Final emulsion stability 24.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
	CIPAC water A (0.46 g a.s./L)		
Initial emulsification	Complete	Complete	Complete
Emulsion stability after 0.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 2 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 24 h	No oil, no cream and ≤ 0.25 mL solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Re-emulsification after 24 h	Complete	Complete	Complete
Final emulsion stability 24.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
	CIPAC water D (0.24 g a.s./L)		
Initial emulsification	Complete	Complete	Complete
Emulsion stability after 0.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 2 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 24 h	No oil, no cream and ≤ 0.25 mL solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Re-emulsification after 24 h	Complete	Complete	Complete
Final emulsion stability 24.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter

Test	Initial	One year at RT	Two years at RT
	CIPAC water D (0.46 g a.s./L)		
Initial emulsification	Complete	Complete	Complete
Emulsion stability after 0.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 2 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Emulsion stability after 24 h	No oil, no cream and ≤ 0.25 mL solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Re-emulsification after 24 h	Complete	Complete	Complete
Final emulsion stability 24.5 h	No oil, no cream and no solid matter	No oil, no cream and no solid matter	No oil, no cream and no solid matter
Pourability CIPAC Handbook MT 148, method PCM 010-01	Residue		
	2.45%	2.21%	2.37%
	Rinsed residue		
	0.14%	0.097%	0.14%

B.2.12. REFERENCES RELIED ON

Annex point / reference number	Author(s)	Year	Title Source Company name, Report No., Date, GLP status, published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01 / 2.7/05	Hinz B.	2008	Determination of long term storage stability (2 years) of Fenoxaprop-P-ethyl 69 g/L EW formulation, in commercial packaging Cheminova A/S, Study No. PYC 181 Cheminova A/S, Report No. 238 FPE GLP, Unpublished	N	Y	New representative formulation	CHE
KCP 2.2/01	Comb A.	2005	Fenoxaprop-P-ethyl 69 g/L EW Explosive Properties Huntington Life Sciences Ltd., Study No. CHV0135/053400 Cheminova A/S Report No. 92 FPE GLP, Unpublished	N	N		CHE
KCP 2.2/02	Comb A.	2005	Fenoxaprop-P-ethyl 69 g/L EW Oxidising Properties Huntington Life Sciences Ltd., Study No. CHV0136/053403 Cheminova A/S Report No. 93 FPE GLP, Unpublished	N	N		CHE
KCP 2.3/01 / 2.5/01 / 2.5/03	Comb A.	2005	Fenoxaprop-P-ethyl 69 g/L EW Surface Tension, Flash Point, Auto-Ignition Temperature and Viscosity Huntington Life Sciences Ltd., Study No. CHV0126/053431 Cheminova A/S Report No. 91 FPE GLP, Unpublished	N	N		CHE
KCP 2.4/01	Hinz B.	2005	Determination of the pH (undiluted and 1% diluted sample) of Fenoxaprop-P-ethyl 69 g/L EW formulation (CHA 4960) Cheminova A/S, Study No. PYC 144 Cheminova A/S, Report No. 100 FPE GLP, Unpublished	N	N		CHE
KCP 2.5/02	Hinz B.	2006	Determination of the viscosity of Fenoxaprop-P-ethyl 69 g/L EW, batch No. 660-PSH-76 Cheminova A/S, Study No. PYC 182 Cheminova A/S, Report No. 184 FPE GLP, Unpublished	N	Y	New representative formulation	CHE

Annex point / reference number	Author(s)	Year	Title Source Company name, Report No., Date, GLP status, published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.6/01	Hinz B.	2006	Determination of the relative density at 20 °C of Fenoxaprop-P-ethyl 69 g/L EW formulation (CHA 4960) Cheminova A/S, Study No. PYC 177 Cheminova A/S, Report No. 158 FPE GLP, Unpublished	N	N		CHE
KCP 2.7/01 / 2.8.2/01 / 2.8.6/01 / 2.8.7/01	Hinz B.	2006	Determination of storage stability for 14 days at 54 °C of Fenoxaprop-P-ethyl 69 g/L EW formulation, in commercial packaging Cheminova A/S, Study No. PYC 179 Cheminova A/S, Report No. 177 FPE GLP, Unpublished	N	N		CHE
KCP 2.7/02 / 2.8.2/02 / 2.8.6/02	Hinz B.	2011	Determination of emulsion stability and the persistent foam of Fenoxaprop-P-ethyl 69 g/L EW formulation before and after storage for 14 days at 54 °C in commercial packaging Cheminova A/S, Study No. PYC 525 Cheminova A/S, Report No. 444 FPE GLP, Unpublished	N	Y	New representative formulation	CHE
KCP 2.7/03	Hinz B.	2006	Determination of cold stability (7 days at 0 °C) of Fenoxaprop-P-ethyl 69 g/L EW formulation Cheminova A/S, Study No. PYC 178 Cheminova A/S, Report No. 176 FPE GLP, Unpublished	N	N		CHE
KCP 2.7/04	Hinz B.	2011	Determination of the emulsion stability of Fenoxaprop-P-ethyl 69 g/L EW formulation before and after cold stability test (7 days at 0 °C) Cheminova A/S, Study No. PYC 524 Cheminova A/S, Report No. 443 FPE GLP, Unpublished	N	Y	New representative formulation	CHE
KCP 2.7/05	Hinz B.	2008	Determination of long term storage stability (2 years) of Fenoxaprop-P-ethyl 69 g/l EW formulation, in commercial packaging Cheminova A/S, Study No. PYC 181 Cheminova A/S, Report No. FPE 238 GLP, Unpublished	N	Y	New representative formulation	CHE

Annex point / reference number	Author(s)	Year	Title Source Company name, Report No., Date, GLP status, published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.9/01	Gamblin A.	2005	Physical Compatibility of CH4960 - Fenoxaprop-P-ethyl + Cloquintocet-mexyl AgroChemex Ltd., Study No. ACE-05-001 Cheminova A/S, Report No. 111 FPE GLP, Unpublished	N	N		CHE