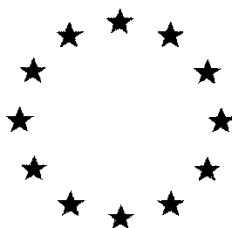


European Commission



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

ETHOFUMESATE

Volume 3 – B.2 (PPP) – Ethofol 500 SC

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Version History

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT **ETHOFOL 500 SC**

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, organoleptic	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	Creamy, off-white, flowable, homogeneous liquid, with a characteristic odour	Acceptable	Y	White, G.A., 2006
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	Statement	-	None of the components of the product is considered explosive. Therefore it can be concluded that the product is not explosive. Based on the structure of Ethofumesate, exothermic reactions are not probable. Formulation is an aqueous suspension.	Acceptable	Y	White, G.A., 2003a (submitted in Volume 4, because the report contains confidential information)
Oxidizing properties B.2.2/02	Statement	-	None of the components of the product is considered oxidising. Therefore it can be concluded that the product is not oxidising. Based on the structure of Ethofumesate, exothermic reactions are not probable. Formulation is an aqueous suspension. Formulants and a.i. are not oxidizing.	Acceptable	Y	White, G.A., 2003a (submitted in Volume 4, because the report contains confidential information)
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	EEC A.9	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate:	Flash point: No flash, sample boiled and extinguished flame. In the temperature range 25°C – 100°C no flash point was detected. Above 100°C the sample started to boil and testing was discontinued.	Acceptable However, no study necessary because it is applicable to liquids	Y	White, G.A., 2006

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		506 g/L		whose vapors can be ignited by ignition sources. The Formulation is an aqueous suspension.		
Flammability of solid formulations B.2.3/02			Not relevant the formulation is an aqueous suspension.			
Self-heating of formulation B.2.3/03	EEC A.15	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	Flammability: 384°C The flammability (Auto ignition): The specimen is water based. A flame at the end point was not detected. However a distinctive red glow, similar to the tip of a lit cigarette, was noted and taken to be the end point of the experiment. The minimum temperature of ignition is 384°C.	Acceptable	Y	White, G.A., 2006
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01	CIPAC MT 75	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	Undiluted: 6.94	Acceptable	Y	White, G.A., 2006
		Ethofol 500 SC Formulation Ref. Name: Ethofol 500g/l SC	Undiluted: 6.63	Acceptable	Y	White, G.A., 2003b
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	1% dilution: 7.49	Acceptable	Y	White, G.A., 2006
		Ethofol 500 SC Formulation Ref. Name: Ethofol	1% dilution: 6.50	Acceptable	Y	White, G.A., 2003b

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		500g/l SC				
Acidity / Alkalinity B.2.4/03			Not relevant as the pH value > 4 and < 10			
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01	OECD 114	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	295 mPa × s (20 °C ± 1)	Acceptable	Y	White, G.A., 2006
Surface tension of the formulation B.2.5/02	EEC A.5 ring tensiometer	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	34.5 mN/m (20 °C ± 1)	Acceptable	Y	White, G.A., 2006
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation B.2.6/01	CIPAC MT 3.3.2	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	Density: 1.143 g/mL Rel. density: 1.143	Acceptable CIPAC MT 3.3.2 is comparable to A.3 pyknometer method	Y	White, G.A., 2006
Bulk density (pour and tap) of powder or granules B.2.6/02			Not relevant the formulation is an aqueous suspension.			
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	HPLC method, CIPAC MT 75 CIPAC MT 148 CIPAC MT 160 CIPAC MT 47.2	Ethofol 500 SC Formulation Ref. no. C498/03/283 Ethofumesate: 516.1 g/L	Immediately and after storage for 12 weeks at 35 ± 2°C the test item was tested for: Appearance, content of active ingredient, pH, persistent foam, spontaneity of dispersion, suspensibility, wet sieve test, pourability and packaging stability.	Acceptable	Y	White, G.A., 2003a (submitted in Volume 4, report contains confidential

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	CIPAC MT 161 CIPAC MT 59.3		<u>Packaging:</u> After storage for 12 weeks at 35°C the packaging showed no sign of degradation following storage. The containers were fully intact. No leaks or evidence of distortion was noted. <u>Weight:</u> Before storage: 1291.66 g, after storage: 1286.85 g; loss of weight: 4.81 g = 0.37% <u>Appearance:</u> (no changes in appearance): Creamy white, flowable, apparently homogenous liquid with a vinyl like odour; <u>Content of Ethofumesate:</u> Before storage: 46.8%, after storage 45.9% <u>pH:</u> 1% aqueous solution (no significant changes in the pH): before storage 7.04, after storage 6.68; <u>Pourability:</u> (no significant changes in pourability): before storage: residue 1.69%, rinsed residue 0.163%, after storage: residue 1.53%, rinsed residue 0.159% <u>Suspensibility:</u> (no significant changes in suspensibility): Max. conc. before storage: 100.3%, after storage: 98.7%; Min. conc.: before storage: 99.5%, after storage: 98.6%; <u>Spontaneity of dispersion</u> (no significant changes in spontaneity of dispersion): before storage: 97.9%, after storage: 98.5%; <u>Wet sieve test</u> (no changes in wet sieve test): before storage: < 0.001%, after storage: 0.002% <u>Persistent foam:</u> <u>Before storage:</u> <u>After 12 weeks:</u> Time → Foam Time → Foam 1 min → 14 mL 1 min → 16 mL <u>Storage at 0°C over a period of 7 days after storage for 12 weeks at 35°C:</u> Before and after storage no oil or separated solids present.			information)
	CIPAC MT 75	Ethofol 500 SC Formulation Ref. Name: Ethofol 500g/l SC	<u>pH:</u> Before storage Undiluted: 6.63 1% dilution: 6.50 After storage at 35 ± 2°C for 12 weeks Undiluted: 6.60	Acceptable	Y	White, G.A., 2003b

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			1% dilution: 6.68			
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.1		<u>Stability at < 0°C over a period of 7 days:</u> Visual examination of container and content: Container: 1 Litre, white plastic container. Screw top seal unbroken. No signs of leakage, distortion or degradation were observed. Contents: No obvious sign of any solid matter. The liquid was apparently homogeneous. No oil or separated solids present. No change from initial sample. Suspensibility at highest and lowest rate: Before storage: Max. conc. 0.63 g in 250 mL water: 98.0% Min. conc. 0.23 g in 250 mL water: 97.6% After 7 days at 0°C: Max. conc. 0.63 g in 250 mL water: 98.5% Min. conc. 0.23 g in 250 mL water: 97.6% Wet sieve test: [% retained on a 75 µm mesh sieve]: Before storage: 0.001% After 7 days at < 0°C: 0.001%	Acceptable	Y	White, G.A., 2006
Shelf life following storage at ambient temperature B.2.7/03	HPLC method, CIPAC MT 75 CIPAC MT 47.2 CIPAC MT 160 CIPAC MT 161 CIPAC MT 59.3 CIPAC MT 148		Immediately and after storage for 2 years at ambient temperature the test item was tested for: Appearance, content of active ingredient, pH, persistent foam, spontaneity of dispersion, suspensibility, wet sieve test, pourability and packaging stability. <u>Results:</u> <u>Packaging:</u> After storage for 2 years at ambient temperature the packaging showed no sign of degradation following storage. The containers were fully intact. No leaks or evidence of distortion was noted. <u>Appearance before and after storage:</u> Container: 1 Litre, white bottle. Screw top seal unbroken. No signs of leakage or damage Contents: Creamy, off-white, flowable, apparently homogeneous	Acceptable	Y	White, G.A., 2006

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			<p>liquid, with a characteristic onion like odour</p> <p><u>Content of Ethofumesate:</u> Before storage: 44.3% (w/w) = 506 g/L After storage: 45.5% (w/w) = 520 g/L</p> <p><u>The following weight changes were noted.</u> Mean weight loss: 0.11%</p> <p><u>pH</u> Before storage: Undiluted: 6.94; 1% dilution: 7.49 After 2 years: Undiluted: 6.95; 1% dilution: 7.34</p> <p><u>Persistent foaming: Standard water D:</u> <u>Before storage:</u> <u>After 2 years at ambient temperature:</u> Time → Foam Time → Foam 1 min → 18 mL 1 min → 20 mL</p> <p><u>Spontaneity of dispersion:</u> CIPAC water D: (30°C ± 1) Before storage: 98.2% After 2 years at ambient temperature: 94.2%</p> <p><u>Suspensibility at highest and lowest rate:</u> Before storage: Max. conc. 0.63 g in 250 mL water: 98.0% Min. conc. 0.23 g in 250 mL water: 97.6% After 2 years at ambient temperature: Max. conc. 0.63 g in 250 mL water: 96.4% Min. conc. 0.23 g in 250 mL water: 96.8%</p> <p><u>Pourability:</u> Before storage: % residue: 3.11 % rinsed residue: 0.225 After 2 years at ambient temperature:</p>			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			% residue: 2.63 % rinsed residue: 0.196 <u>Wet sieve test: [% retained on a 75 µm mesh sieve]:</u> Before storage: 0.001% After 2 years at ambient temperature: < 0.001%			
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 applicable			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	Standard water D (30°C ± 1): Time → Foam 10 sec → 18 mL 1 min → 18 mL 3 min → 14 mL 12 min → 8 mL	Acceptable	Y	White, G.A., 2006
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	CIPAC MT 161	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	<u>Suspensibility at highest and lowest rate:</u> (30°C ± 1) Max. conc. 0.63 g in 250 mL water: 98.0% Min. conc. 0.23 g in 250 mL water: 97.6%	Acceptable	Y	White, G.A., 2006
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	CIPAC MT 160	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	CIPAC water D: (30°C ± 1) Spontaneity: 98.2%	Acceptable	Y	White, G.A., 2006
Dispersion stability of SE, OD or EG formulation			Not applicable (SC formulation)			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.3/03						
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01			Not applicable (SC formulation)			
Dilution stability of water soluble formulation B.2.8.4/02			Not applicable (SC formulation)			
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	CIPAC MT 59.3	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	0.001% retained on a 75 µm mesh sieve	Acceptable	Y	White, G.A., 2006
Size distribution of particles of powder or granules B.2.8.5.1/02			Not applicable (SC formulation)			
Nominal size range of granule B.2.8.5.1/03			Not applicable (SC formulation)			
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01			Not applicable (SC formulation)			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01			Not applicable (SC formulation)			
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01			Not applicable (SC formulation)			

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 applicable (SC formulation)			
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			Not applicable (SC formulation)			
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01			Not applicable (SC formulation)			
Pourability of suspensions B.2.8.7/02	CIPAC MT 148	Ethofol 500 SC Formulation Ref. no. C498/04/328 Ethofumesate: 506 g/L	residue: 3.11 % rinsed residue: 0.225%	Acceptable	Y	White, G.A., 2006
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not applicable (SC formulation)			
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	ASTM method E1518-99	Ethofol 500 SC	Physical compatibility of tank mixes: No physical problems were observed with different herbicide mixtures that would cause problems in the field. Ethofol 500 SC mixed with Betasana 160 SC, Goltix SC, Pyramin Turbo, Caribou 50 WG, Lontrel 300, Super Oil	Acceptable	N	Gejl, M., 2004
	Not stated	Ethofol 500 SC Batch-no: F8129	Physical compatibility of tank mixes: No physical problems with different herbicide mixtures were observed.	Acceptable	N	Sorensen, T., 1999

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Ethofol 500 SC mixed with Metafol SC, Goltix SC and WG, DLG Ethuron Flow, Nortron, DLG Super oil			
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01			Not used for seed treatment			
B.2.11. OTHER STUDIES						
			None			

Ethofol 500 SC is a creamy, off-white, flowable, homogeneous liquid, with a characteristic odour. The experiments revealed that it has no flash point between 25 and 100°C, however it developed a distinctive red glow at 384°C, the temperature regarded as self-ignition. The product is not explosive and oxidising, and has a neutral pH. The storage stability at ambient temperature over a period of 2 years and after 12 weeks at 35°C showed good stability in terms of active substance content and product characteristics. Moreover, no issues have been detected while storing it at a temperature of 0°C for 7 days.

Results of the technical tests (spontaneity of dispersion, suspensibility, wet sieve test, pourability and persistent foaming) showed that Ethofol 500 SC is a preparation of a high technical quality which is compatible with several other products commonly used in plant protection.

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny 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
KCP 2.1/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.3/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.4/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.4/02	White, G.A.	2003b	Ethofol 500g/l SC formulation: Accelerated storage stability trial ph Determinations United Phosphorus Ltd., J14765 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.5/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.6/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.7/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.7/03	White, G.A.	2003b	Ethofol 500g/l SC formulation: Accelerated storage stability trial ph Determinations United Phosphorus Ltd., J14765 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.8.2/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK	no	yes	New data for existing formulation, not previously submitted nor	UPL	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Compagny 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
			GLP: yes Published: no			evaluated		(2014)
KCP 2.8.3/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.8.5.1/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.8.7/01	White, G.A.	2006	Ethofol 500g/l SC formulation: storage stability trial United Phosphorus Ltd., J14876 G.C. Laboratories Ltd, Analytical Chemistry Centre, Stotfold, UK GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	UPL	Submitted for the purpose of renewal (2014)
KCP 2.9/01	Gejl, M.	2004	To test the tank mix compatibility of different mixtures of herbicides United Phosphorus Ltd., N°. 51 04 01 Agrolab A/S, Middelfart, Denmark GLP/GEP: no Published: no	no	no	not protected	UPL	Submitted for the purpose of renewal (2014)
KCP 2.9/02	Sorensen, T.	1999	Test of tank mixtures with SweDane Betasana 2000, 160 g/l phenmedipham. United Phosphorus Ltd., N°. 990803 Agrolab A/S, Middelfart, Denmark GLP/GEP: no Published: no	no	no	not protected	UPL	Submitted for the purpose of renewal (2014)