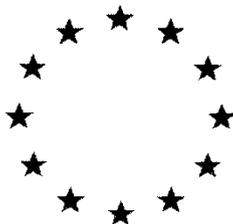


European Commission



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

Mecoprop-P

**Volume 3 – B.2 (PPP) – Mecoprop-P K 600 g/L
(CA3015)**

Rapporteur Member State : United Kingdom

Co-Rapporteur Member State : Ireland

Version History

When	What
31/03/2016	Initial Renewal Assessment Report (RAR)

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT MECOPROP-P K 600 (CA3015)

Previous evaluation:	None; All of the data studies referenced in the following table were submitted for the purpose of renewal under Regulation 844/2012. These replace the original Annex I data.
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Mecoprop-P K 600 is a soluble concentrate (SL) formulation and was not the representative product supported by Nufarm UK in Annex I (this was Combitox Plus containing 600 g/L mecoprop-P as dimethylamine salt). Nufarm have since acquired AHMarks and thus have access to the AHMarks data, the representative product was Optica containing 600 g/L mecoprop-P. The primary representative product for the BAS workforce was Duplosan KV containing 600 g/L. Note that studies conducted on Optica and Duplosan KV are applicable to the product Mecoprop-P K 600.

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	US EPA guidelines OPPTS 830	Mecoprop-P K 600, sample purity 601.4 g/l	Liquid 10YR 5/8 Yellowish brown Phenolic odour	Acceptable.	Y	Mahmood, T (2012) 12/0697
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	Case	Duplosan KV, (Mecoprop-P K 600), sample purity 602 g/l	Formulation is not explosive. From an examination of the chemical structure of the active substance and the co-formulants it was observed that non of the components contain functional groups which are characteristic of explosive properties.	Acceptable. The criteria of Appendix 6 of the UN recommendations on the transport of dangerous goods have been addressed.	Y	Turner, B (2006) NUF/133/053902
Oxidizing properties B.2.2/02	Case	Duplosan KV, (Mecoprop-P K 600),	Formulation is not oxidising. From an examination of the chemical structure of the active substance and the co-formulants it was observed that non of the components contain functional groups which are	Acceptable.	Y	Turner, B (2006) NUF/133/053902

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		sample purity 602 g/l	characteristic of oxidising properties.			
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	EEC A9	Duplosan KV, (Mecoprop-P K 600), sample purity 602 g/l	Test substance boiled at 106°C. No flash point determined.	Acceptable.	Y	Turner, B (2006) NUF/133/053902
Flammability of solid formulations B.2.3/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable.	-	-
Self-heating of formulation / auto-flammability B.2.3/03	EEC A15	Duplosan KV, (Mecoprop-P K 600), sample purity 602 g/l	> 400°C	Acceptable.	Y	Turner, B (2006) NUF/133/053902
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01	CIPAC MT 75	Mecoprop-P K 600, sample purity 601.4 g/l	pH = 9.2	Acceptable.	Y	Mahmood, T (2012) 12/0697
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3	Mecoprop-P K 600, sample purity 601.4 g/l	pH = 6.7	Acceptable.	Y	Mahmood, T (2012) 12/0697
Acidity / Alkalinity B.2.4/03	-	-	Not applicable.	Acceptable. Acidity/alkalinity not required as 4 < pH > 10	Y	Mahmood, T (2012) 12/0697

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01	OECD 114	Mecoprop-P K 600 g/L	35.1 mPa s at 20°C 15.4 mPa s at 40°C Shear rates tested = 20 – 500 s ⁻¹ . Newtonian behaviour was exhibited (viscosity independent of shear rate).	Acceptable	Y	Wilson, I. 2015 15/0968
Surface tension of the formulation B.2.5/02	OECD 115	Mecoprop-P K 600 g/L	1.0 % v/v at 20°C = 53.4 mNm ⁻¹	Acceptable. The concentration tested accommodates the highest in-use concentration specified on the product label (0.6%)	Y	L. Da Conceicao, 2015 Study 02107
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation B.2.6/01	EEC A3	Mecoprop-P K 600, sample purity 601.4 g/l	1.252 at 20°C	Acceptable.	Y	Mahmood, T (2012) 12/0697
Bulk density (pour and tap) of powder or granules B.2.6/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable. See B.2.6/01	-	-
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) B.2.7/01	CIPAC MT 46.3	Mecoprop-P K 600, sample purity 601.4 g/l	<u>Appearance</u> Initial: Brown (10YR 5/8 Munsell colour) liquid with phenolic odour. 2 wks, 54°C: Brown (10YR 6/8 Munsell colour) liquid with phenolic odour.	Acceptable. The physical and chemistry properties of the formulation	Y	Mahmood, T (2012) 12/0697

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																								
	Chiral HPLC		<u>Active content</u> Initial: 601.4 g/L 2 wks, 54°C: 601.3 g/L	are stable following accelerated storage. There is no significant loss of active content. The free phenol content was determined by CIPAC MT69, No specificity data was supplied, but a case has been made in Volume 3, section B.5.1.1. The pH remains fairly constant and there is no evidence of precipitation or solution separation after 2 weeks at 54°C. The dilution stability was conducted over a range of concentrations that accommodates the maximum in-use rate in the GAP (0.6%) The results reported in grey were supplied, but are not strictly necessary post-storage																										
	CIPAC MT 69		<u>Free phenol content</u> Initial: 2.66 g/L 2 wks, 54°C: 2.87 g/L																											
	CIPAC MT 75		<u>pH</u> Initial: 9.2 (undiluted); 6.7 (1% soln.) 2 wks, 54°C: 8.8 (undiluted); 6.4 (1% soln.)																											
	EEC A3		<u>Relative density (at 20°C)</u> Initial: 1.252 2 wks, 54°C: 1.252																											
	CIPAC MT 47.2		<u>Persistence foam</u> in CIPAC hard water D																											
			<table border="1"> <thead> <tr> <th>Conc.</th> <th>Initial (mL)</th> <th>2 wks, 54°C (mL)</th> </tr> </thead> <tbody> <tr> <td>0.5%, 10s</td> <td>10</td> <td>8</td> </tr> <tr> <td>1 min</td> <td>6</td> <td>6</td> </tr> <tr> <td>3 min</td> <td>2</td> <td>0</td> </tr> <tr> <td>12 min</td> <td>0</td> <td>0</td> </tr> <tr> <td>2%, 10s</td> <td>10</td> <td>6</td> </tr> <tr> <td>1 min</td> <td>4</td> <td>0</td> </tr> <tr> <td>3 min</td> <td>0</td> <td>0</td> </tr> </tbody> </table>				Conc.	Initial (mL)	2 wks, 54°C (mL)	0.5%, 10s	10	8	1 min	6	6	3 min	2	0	12 min	0	0	2%, 10s	10	6	1 min	4	0	3 min	0	0
	Conc.	Initial (mL)	2 wks, 54°C (mL)																											
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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference											
	CIPAC MT 41.1		12 min	0	0	properties for authorisation of the plant protection product. They have been reported for completeness.													
		5%, 10s	6	4															
		1 min	0	0															
		3 min	0	0															
		12 min	0	0															
			<u>Dilution stability</u> At 20°C <table border="1"> <thead> <tr> <th>Conc.</th> <th>Initial</th> <th>2 wks, 54°C</th> </tr> </thead> <tbody> <tr> <td>0.5%</td> <td>Clear solution, no precipitation after 24 hr.</td> <td>Clear solution, no precipitation after 24 hr.</td> </tr> <tr> <td>2%</td> <td>Clear solution, no precipitation after 24 hr.</td> <td>Clear solution, no precipitation after 24 hr.</td> </tr> <tr> <td>5%</td> <td>Clear solution, no precipitation, slightly opaque after 24 hr.</td> <td>Clear solution, no precipitation, slightly opaque after 24 hr.</td> </tr> </tbody> </table>			Conc.	Initial	2 wks, 54°C	0.5%	Clear solution, no precipitation after 24 hr.	Clear solution, no precipitation after 24 hr.	2%	Clear solution, no precipitation after 24 hr.	Clear solution, no precipitation after 24 hr.	5%	Clear solution, no precipitation, slightly opaque after 24 hr.	Clear solution, no precipitation, slightly opaque after 24 hr.		
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5%	Clear solution, no precipitation, slightly opaque after 24 hr.	Clear solution, no precipitation, slightly opaque after 24 hr.																	
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	Mecoprop-P K 600, sample purity 611 g/l	After storage at 0°C ± 2°C for 7 days the test material was found to be free from separated material. The formulation is stable under low temperature storage conditions.			Acceptable. Additionally, 'Store away from frost' is stated on the draft product label.	Y	Wilson, I (2009) 09/0453											
Shelf life following storage at ambient temperature Conducted in 100 mL HDPE bottles apart from dilution stability and packaging	visual	Mecoprop-P K 600, sample purity 597.5	<u>Appearance</u> Initial: Brownish yellow (10YR 6/8 Munsell colour) liquid with phenolic odour. 24 months: Brownish yellow (10YR 6/8 Munsell colour) liquid with phenolic odour.			Acceptable. The physical and chemistry properties of the formulation are stable following ambient	Y	Mahmood, T (2014) 12/0717											

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																											
integrity which was conducted in 1 L HDPE bottles. B.2.7/03	Validated methods (see Volume 3, section B.5.1 of the product RAR) CIPAC MT 75.3 EEC A3 CIPAC MT 47.2		<p><u>Active content</u> Initial: 597.5 g/L 24 months: 604.3 g/L</p> <p><u>Free phenol content</u> Initial: 2.70 g/L 24 months: 2.68 g/L</p> <p><u>pH</u> Initial: 9.0 (undiluted); 6.8 (1% soln.) 24 months: 9.1 (undiluted); 6.9 (1% soln.)</p> <p><u>Relative density</u> (at 20°C) Initial: 1.254 24 months: 1.253</p> <p><u>Persistence foam</u> in CIPAC Hard water D</p> <table border="1" data-bbox="701 1023 1270 1374"> <thead> <tr> <th>Conc.</th> <th>Initial (mL)</th> <th>24 months (mL)</th> </tr> </thead> <tbody> <tr> <td>0.5%, 10s</td> <td>8</td> <td>20</td> </tr> <tr> <td>1 min</td> <td>4</td> <td>10</td> </tr> <tr> <td>3 min</td> <td>0</td> <td>6</td> </tr> <tr> <td>12 min</td> <td>0</td> <td>0</td> </tr> <tr> <td>2%, 10s</td> <td>10</td> <td>28</td> </tr> <tr> <td>1 min</td> <td>4</td> <td>12</td> </tr> <tr> <td>3 min</td> <td>0</td> <td>6</td> </tr> <tr> <td>12 min</td> <td>0</td> <td>0</td> </tr> </tbody> </table>	Conc.	Initial (mL)	24 months (mL)	0.5%, 10s	8	20	1 min	4	10	3 min	0	6	12 min	0	0	2%, 10s	10	28	1 min	4	12	3 min	0	6	12 min	0	0	temperature storage. There is no significant loss of active content or change in PCOC content. There is no significant change to pH or dilution stability. The dilution stability and persistent foam were conducted over a range of concentrations that accommodates the maximum in-use rate in the GAP (0.6%) The results reported in grey were supplied, but are not strictly necessary post-storage properties for authorisation of the plant protection product. They have been reported for completeness.		
Conc.	Initial (mL)	24 months (mL)																															
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3 min	0	6																															
12 min	0	0																															

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference												
	CIPAC MT 41		5%, 10s	6	28															
			1 min	0	8															
			3 min	0	2															
			12 min	0	0															
			<p><u>Dilution stability</u> At 20°C in CIPAC water D</p> <table border="1"> <thead> <tr> <th>Conc.</th> <th>Initial</th> <th>24 months</th> </tr> </thead> <tbody> <tr> <td>0.5%</td> <td>Clear and free from precipitate. Slightly opaque after 24 hr.</td> <td>Clear solution, no precipitation after 24 hr.</td> </tr> <tr> <td>2%</td> <td>Clear and free from precipitate. Slightly opaque after 24 hr.</td> <td>Clear solution, no precipitation after 24 hr.</td> </tr> <tr> <td>5%</td> <td>Clear solution, no precipitation, slightly opaque after 24 hr.</td> <td>Clear solution, no precipitation after 24 hr.</td> </tr> </tbody> </table> <p><u>Packaging stability</u> Initial: 100 mL and 1 L HDPE containers. No signs of degradation. 24 months: No difference. No deterioration of the packaging and no significant weight change. No crystallisation, sedimentation or stratification observed in the test material samples stored in either 100 mL or 1 L HDPE containers.</p>			Conc.	Initial	24 months	0.5%	Clear and free from precipitate. Slightly opaque after 24 hr.	Clear solution, no precipitation after 24 hr.	2%	Clear and free from precipitate. Slightly opaque after 24 hr.	Clear solution, no precipitation after 24 hr.	5%	Clear solution, no precipitation, slightly opaque after 24 hr.	Clear solution, no precipitation after 24 hr.			
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B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT																				
B.2.8.1. Wettability																				
Wettability of solid formulation	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.			Acceptable.	-	-												

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference		
B.2.8.1/01								
B.2.8.2. Persistence foaming								
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	Mecoprop-P K 600, sample purity 601.4 g/l	CIPAC Hard Water ‘D’				Y	Mahmood, T (2012) 12/0697
			Time	0.5% v/v	2% v/v	5% v/v		
			10 s	10 mL	10 mL	6 mL		
			1 mi	6 mL	4 mL	0 mL		
			3 min	2 mL	0 mL	0 mL		
			12 min	0 mL	0 mL	0 mL		
B.2.8.3. Suspensibility								
Suspensibility of water dispersible formulation B.2.8.3/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-		
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-		
Dispersion stability of SE, OD or EG formulation B.2.8.3/03	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-		
B.2.8.4. Degree of dissolution and dilution stability								
Degree of dissolution of water soluble formulation	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results					Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.4/01										
Dilution stability of water soluble formulation B.2.8.4/02	CIPAC MT 41	Mecoprop-P K 600, sample purity 601.4 g/l	CIPAC Hard Water D					Acceptable. Product remains in solution. No precipitation occurs after 24 h. The test was conducted at rates accommodating the maximum in-use rate as specified on the product label (0.6 %).	Y	Mahmood, T (2012) 12/0697
			Time point	Concentration (% v/v)	Time	Clarity	Precipitation			
			Initial	0.5	Initial	Clear	None			
					After 30 mins	Clear	None			
					After 24 hours	Clear	None			
			Initial	2	Initial	Clear	None			
					After 30 mins	Clear	None			
					After 24 hours	Clear	None			
			Initial	5	Initial	Clear	None			
					After 30 mins	Clear	None			
					After 24 hours	Slightly opaque	None			
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 applicable, Mecoprop-P K 600 is a soluble concentrate.					Acceptable	-	-
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.					Acceptable	-	-
Nominal size range of granule	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.					Acceptable	-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.5.1/03						
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
Integrity of tablets B.2.8.5.4/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
Pourability of suspensions B.2.8.7/02	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Dustability of dustable powders after accelerated storage B.2.8.7/03	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
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	-	-	Tank mixes are well known (see Pesticide Manual).	Acceptable. No claims of compatibility are made on the product label.	-	Pesticides Manual, British Crop Protection Council
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.10/01	-	-	Not applicable, Mecoprop-P K 600 is a soluble concentrate.	Acceptable	-	-
B.2.11. OTHER STUDIES						
	-	-	No further studies required.	Acceptable	-	-

B.2.12. REFERENCES RELIED ON

Regarding the literature search undertaken by the applicant (report dated 15/07/2015). It is considered that the search is acceptable in terms of databases searched and the search criteria applied. The search did not reveal any references of relevance to this section.

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justificatio n if data protection is claimed	Owner	Previous evaluation
CP 2.1/01, 2.4/01, 2.6/02, 2.7.1- 3/01, 2.8.2, 2.8.4,	Mahmood, T.	2012	Mecoprop-P K 600 Accelerated Storage Stability 12/0697 Nufarm UK Limited GLP Not published	N	Y	New data to new guidelines.	Nufarm	Submitted for the purpose of renewal
CP 2.1, 2.7/03 & 5.1.2	Mahmood, T	2014	Mecoprop-p K 600 g/l - Two Year Storage Stability 12/0717 Nufarm UK Limited GLP Not published	N	Y	New data to new guidelines.	Nufarm	Submitted for the purpose of renewal
CP2.2.1, 2.2.2, 2.3.1/01, 2.3.3/01	Turner, B.	2006	Duplosan KV Physico- Chemical Properties NUF133/05390 2 Huntingdon Life Sciences Ltd, UK GLP Not published	N	N	-	Nufarm	Submitted for the purpose of renewal
CP 2.7.4/01	Wilson, I.	2009	MCP-P K 600 g/l - Certificate of Analysis and Low Temperature Stability 09/0453 Nufarm UK	N	Y	New data to new guidelines.	Nufarm	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			Limited GLP Not published					
2.5/01	Wilson, I.	2015	MCPP-P K 600 g/l Determination of dynamic viscosity 15/0968 Nufarm UK Limited GLP Not published	N	Y	New data to new guidelines	Nufarm	Submitted for the purpose of renewal
2.5/02	L. Da Conceicao	2015	CA3015 determination of surface tension 02107 Nufarm UK Limited GLP Not published	N	Y	New data to new guidelines	Nufarm	Submitted for the purpose of renewal