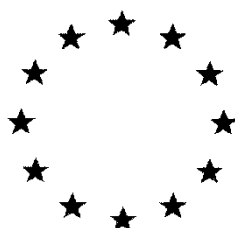


European Commission



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

MECOPROP-P

Volume 3 – B.4 (PPP) – Mecoprop-P K 600 g/L

**Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : Ireland**

Version History

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

Table of contents

B.4. FURTHER INFORMATION	4
B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT	4
B.4.2. RECOMMENDED METHODS AND PRECAUTIONS	5
B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT	9
B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS.....	10
B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING	11
B.4.5.1. Neutralisation procedure.....	11
B.4.5.2. Controlled incineration	11
B.4.6. REFERENCES RELIED ON.....	11

B.4. FURTHER INFORMATION

The Applicant has provided the following information in their renewal dossier:

B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

B.4.1.1 PRE-HARVEST INTERVAL (IN DAYS) FOR EACH RELEVANT CROP:

Cereals:

A pre-harvest interval is not relevant as the latest application time for cereals is before the second node detectable stage (BBCH GS 32), which is at least 60 days before harvest and would therefore represent a PHI of >60 days.

B.4.1.2 RE-ENTRY PERIOD (IN DAYS) FOR LIVESTOCK, TO AREAS TO BE GRAZED:

Not applicable to the submission. Cereal crops are not grazed.

B.4.1.3 RE-ENTRY PERIOD (IN HOURS OR DAYS) FOR MAN TO CROPS, BUILDINGS OR SPACES TREATED:

Re-entry in to cropped areas is usually not necessary.

Under practical conditions of use there is no reason for workers to re-enter shortly after treatment, thus a specific re-entry period is not required.

It is good husbandry practice not to enter treated fields until the plants are dry (24 hours is recommended), without wearing protective clothing, similar to that used in application of the product and stout footwear.

B.4.1.4 WITHHOLDING PERIOD (IN DAYS) FOR ANIMAL FEEDING STUFFS:

No withholding period for animal feedstuffs is required because the last recommended application to cereals is growth stage BBCH 32, which is at least 60 days before harvest. Considering the interval between the last application and harvest, it is expected that no significant residues will occur in either straw or grain (see residue trials in Data Point CA 6.3).

B.4.1.5 WAITING PERIOD (IN DAYS) BETWEEN APPLICATION AND HANDLING OF TREATED PRODUCTS:

Not applicable. Crop is not handled before harvest.

B.4.1.6 WAITING PERIOD (IN DAYS) BETWEEN LAST APPLICATION AND SOWING OR PLANTING SUCCEEDING CROPS:

No waiting period is required for cereals as the last recommended application to cereals is growth stage BBCH 32, which is at least 60 days before harvest. After application according to the critical GAP no soil residues should be present and therefore any crop can be drilled.

Where rotations with alternative crops are possible, mecoprop-P will be applied post emergence, in spring, on plants that are well established and no longer susceptible to crop failure. Consequently, succeeding crops will only be drilled post- harvest. However, should crop failure occur and re-drilling

be required, mecoprop-P, is rapidly degraded in aerobic soils, with a geometric mean DT₅₀ of 6.0 days. It should therefore be possible to safely re-drill four weeks after treatment.

B.4.1.7 INFORMATION ON SPECIFIC CONDITIONS UNDER WHICH THE PREPARATION MAY OR MAY NOT BE USED:

None if used in accordance with the label.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Handle in well ventilated areas. Do not eat, drink or smoke in application area. Safety advice is to wear impermeable gloves, goggles or face shield and suitable protective clothing.

B.4.2.1 CLEANING PROCEDURES

The applicant has provided the following information:

A previously submitted study (Stadler, R¹) showed that rinsing twice with water gave adequate results with 2.6% mecoprop-P residue after the first wash and 0.03% mecoprop-P residue in the following application. Triple rinsing with water will reduce this residue further.

Further to this a new study (Wilson, 2012) has been performed to investigate the effectiveness of a triple rinse procedure for cleaning equipment used during the application of Mecoprop-P K 600 g/l. A summary of this study can be found below (CP 4.2.1/01). This provides evidence that a triple rinse procedure using water is more than adequate as a method for cleaning equipment.

Report:	CP 4.2.1/01 Wilson I (2012) Mecoprop-p K 600 g/l – Small Scale Jar Test Report No: 12/0710 Generated by: Nufarm UK Ltd. Unpublished
Method:	CRD Efficacy Guideline 305
GLP:	Yes

Executive Summary

A study was conducted to investigate the efficiency of a triple rinse with water cleaning procedure, according to CRD Efficacy Guideline 305² for the formulated product Mecoprop-P K 600 g/l.

A tank-mix solution was prepared according to the CRD Efficacy Guideline 305, which was then poured into three 100 ml bottles and left to stand overnight.

The tank-mix solution was analysed for active substance (mecoprop-P) content by HPLC. The analytical method used to determine the mecoprop-P content was fully validated within the study. Results of the amount of active ingredient present in the tank-mix can be found in Table CP 4.2.1/03.

¹ Stadler R (2002) BAS 037 32 H - Duplosan. Effectiveness of procedures for cleaning application equipment and protective clothing; BASF Aktiengesellschaft; Unpublished; Report Number: 2002/1005097.

²Efficacy guidelines: Cleaning Application Equipment Small Scale Jar Test Protocol.
<http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/G/g305.pdf>

After the three 100 ml bottles had been left overnight the bottles were shaken to re-suspend any settled matter and the solutions were discarded. 10ml of tap water was added to each bottle, the bottles were inverted twice and the rinsate discarded. This process was carried out three times (triple rinse). After the third rinse, 10 ml of acetonitrile was added to each bottle, the bottles were shaken and the acetonitrile analysed for active substance content.

The mean percentage of mecoprop-P removed following the triple rinse procedure with water was 99.9997%. In conclusion, the triple rinse procedure using water is more than sufficient as a method for cleaning equipment used during the application of Mecoprop-P K 600 g/l.

1. MATERIALS AND METHODS

A	MATERIALS
Test materials:	MCPP-p K 600 g/l, sample purity 601.4 g/l
Description:	10YR 5/8 yellowish brown liquid with a phenolic odour
Lot/Batch:	33-01-119

B	STUDY DESIGN AND METHODS													
Study dates:	06/08/2012 – 09/08/2012													
Tank-mix preparation (5% v/v solution)	20 ml of the test substance (Mecoprop-P K 600 g/l) was added to 380 ml of CIPAC Standard Hard Water ‘D’ in a 600 ml beaker. The contents were stirred for 4 minutes using a magnetic stirrer. From this 100 ml aliquots were poured into 3 x 100 ml High Density Polyethylene (HDPE) bottles and allowed to stand overnight (approx. 28 hours). The remainder of the tank-mix was retained for active substance content analysis.													
Analysis of tank-mix:	<p>Duplicate solutions were prepared for analysis by taking 1ml of the tank-mix and diluting it using acetonitrile to a volume of 100 ml in volumetric flasks. The results of this can be seen below in Table CP 4.2.1/01.</p> <p>Table CP 4.2.1/01 Active ingredient content of duplicate 100 ml tank-mix samples</p> <table><tr><th>Component</th><th>Sample ref.</th><th>mg ml⁻¹</th><th>Total (mg)</th><th>Mean amount of AI charged (mg)</th></tr><tr><td rowspan="2">Mecoprop-P</td><td>710/W/6A</td><td>25.886</td><td>2588.6</td><td rowspan="2">2540.5</td></tr><tr><td>710/W/6B</td><td>24.924</td><td>2492.4</td></tr></table>	Component	Sample ref.	mg ml ⁻¹	Total (mg)	Mean amount of AI charged (mg)	Mecoprop-P	710/W/6A	25.886	2588.6	2540.5	710/W/6B	24.924	2492.4
Component	Sample ref.	mg ml ⁻¹	Total (mg)	Mean amount of AI charged (mg)										
Mecoprop-P	710/W/6A	25.886	2588.6	2540.5										
	710/W/6B	24.924	2492.4											
Clean-out procedure:	<p>After leaving the tank-mix samples to stand overnight they were shaken to re-suspend any settled matter. The solutions were discarded.</p> <p>10ml of tap water was added to each of the three bottles and the bottles were inverted twice. The rinsate was discarded. This process was carried out three times (triple rinse).</p>													

	After the third rinse 10 ml of acetonitrile was added to each bottle and the bottles were shaken. The acetonitrile was analysed for active substance content. From this the percentage of mecoprop-P removed was calculated.								
Statistics	None.								
Method validation:	<p>The analytical method for the determination of mecoprop-P in the rinsate was validated for linearity, precision, accuracy and selectivity. The results of this method validation are summarised in Table CP 4.2.1/02.</p> <p>Table CP 4.2.1/02 Results of the method validation for determination of Mecoprop-P content.</p> <table><tr><th>Linearity Correlation coefficient Concentration range (mg ml⁻¹)</th><th>Precision (% RSD at concentration) n=5</th><th>Accuracy (mean recovery % at concentration) n=5</th><th>Specificity /Selectivity</th></tr><tr><td>n=5 r = 0.9975 0.0004-0.5 mg ml⁻¹</td><td>15.33% at 0.0005 mg ml⁻¹ (LOQ) 0.14% at ca. 0.4 mg ml⁻¹</td><td>78.9% at 0.0005 mg ml⁻¹ (LOQ) 102.4% at ca. 0.4 mg ml⁻¹</td><td>No interferences observed. Separation of optical isomers confirmed.</td></tr></table> <p>The method meets the validation criteria and is deemed acceptable for use.</p>	Linearity Correlation coefficient Concentration range (mg ml ⁻¹)	Precision (% RSD at concentration) n=5	Accuracy (mean recovery % at concentration) n=5	Specificity /Selectivity	n=5 r = 0.9975 0.0004-0.5 mg ml ⁻¹	15.33% at 0.0005 mg ml ⁻¹ (LOQ) 0.14% at ca. 0.4 mg ml ⁻¹	78.9% at 0.0005 mg ml ⁻¹ (LOQ) 102.4% at ca. 0.4 mg ml ⁻¹	No interferences observed. Separation of optical isomers confirmed.
Linearity Correlation coefficient Concentration range (mg ml ⁻¹)	Precision (% RSD at concentration) n=5	Accuracy (mean recovery % at concentration) n=5	Specificity /Selectivity						
n=5 r = 0.9975 0.0004-0.5 mg ml ⁻¹	15.33% at 0.0005 mg ml ⁻¹ (LOQ) 0.14% at ca. 0.4 mg ml ⁻¹	78.9% at 0.0005 mg ml ⁻¹ (LOQ) 102.4% at ca. 0.4 mg ml ⁻¹	No interferences observed. Separation of optical isomers confirmed.						

II. RESULTS AND DISCUSSION

The results of the triple-rinse cleaning procedure can be found in Table CP 4.2.1/03. This table displays the % of mecoprop-P removed by rinsing three times.

Table CP 4.2.1/03 Percentage Mecoprop-P removed during a triple rinse procedure

Sample ref.	Total Mecoprop-P recovered (mg)	% removed	Mean recovered %
710/W/5A	0.00800	99.9997	99.9997
710/W/5Ar	0.00682	99.9997	
710/W/5B	0.00733	99.9997	
710/W/5Br	0.00668	99.9997	
710/W/5C	0.00782	99.9997	
710/W/5Cr	0.00777	99.9997	

III. CONCLUSIONS

The mean percentage of mecoprop-P removed following the triple rinse procedure with water, according to CRD Efficacy Guideline 305, was 99.9997%. This demonstrates that the triple rinse

procedure as described is more than sufficient as a method for cleaning equipment used during the application of Mecoprop-P K 600 g/l.

RMS conclusion:

The applicant has submitted two studies relating to equipment cleaning. Neither can be relied upon.

1. **CP 5.1.2/07, Wilson, I. (2012)** Mecoprop-P K 600 g/l – Small Scale Jar Test, Report No. 12/0710.

The method of analysis is not strictly validated in accordance with the EU guidance document SANCO/3030/99/rev. 4, due to the mean recovery and precision at the lower fortification level being outside the acceptable SANCO range, 80 – 120 %. Additionally, the individual recoveries at the lower fortification level fall well below this range. The method is however, likely to be fit for purpose at the higher fortification level (0.04 % w/w). The supported LOQ would be 0.04% w/w, rather than the 0.00005% the applicant claims. This is not low enough for the levels claimed.

2. **CP 4.1.2/07, Stadler, R. (2002)** BAS 037 32H – Duplosan Effectiveness of procedures for cleaning application equipment and protective clothing. Report No. 2002/1005097

The method of analysis is not validated in accordance with the EU guidance document SANCO/3030/99/rev. 4. No method validation data was provided.

However mecoprop-P is very soluble in water (List of end points)

pH 7: >250g/L, distilled, 20°C (99.8%)) and a standard rinsing procedure would be expected to provide adequate cleansing of spray equipment following use of a salt in water formulation.

B.4.2.2 Warehouse storage

Keep container tightly closed. Store in a cool, dry, well ventilated place, separated from food.

B.4.2.3 User level storage

Keep out of reach of children. Keep away from food, drink and animal feeding stuffs. Keep only in original container. Minimum shelf life is two years.

B.4.2.4 Transport

This product is not classified as hazardous for transport (see Section 14 of the product safety data sheet).

B.4.2.5 Fire

Mecoprop-P K 600 g/l is not classified as flammable. However if involved in a fire it may give off toxic fumes and foam of carbon monoxide, carbon dioxide and hydrogen chloride gas. Use water-spray, CO₂ or dry chemical extinguishing media in case of fire. Fire-fighters should be equipped with self-contained breathing apparatus.

B.4.2.6 Nature of protective clothing proposed

Avoid contact with skin, eyes, clothing and inhalation of vapours. Wear suitable protective clothing, boots, PVC gloves, eye and face protection.

B.4.2.7 Characteristics of protective clothing proposed

Eye protection used should conform to EN166 and be suitable for liquid chemicals.

PVC gloves used should conform to EN374 - protection against chemical hazards.

B.4.2.8 Suitability and effectiveness of protective clothing and equipment

Equipment conforming to European standards EN166 and EN374 give effective protection against chemical hazards.

B.4.2.9 Procedures to minimise the generation of waste

Mecoprop-P K 600 g/l is packaged in containers of suitable size commensurate to its use. This ensures that the minimum number of containers is required to treat any given area.

B.4.2.10 Combustion products likely to be generated in the event of fire

If involved in a fire Mecoprop-P K 600 g/l may give off toxic fumes of carbon monoxide, carbon dioxide and hydrogen chloride gas.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

In case the material is released or spilled, the product should be absorbed onto an inert absorbent material (sand, earth, sawdust). Do not allow to enter drains or water courses.

In case of contamination of water, telephone the relevant Water Management Company or Government Bureau, Police and Emergency Services, The Pollution Inspectorate or Environmental Protection Agency.

B.4.3.1 Decontamination of areas, vehicles and buildings

There are no specific instructions for decontamination. Follow advice on the safety data sheet (please see Document H) and follow the Local Authority instructions.

B.4.3.2 Disposal of damaged packaging, adsorbents and other materials

Transfer to a suitable container and arrange for collection by specialised disposal company in accordance with national legislation or local authority instructions.

Disposal by incineration should be in accordance with the criteria set out in Council Directive 94/67/EC.

B.4.3.3 Protection of emergency workers and bystanders

Use Personal Protective Equipment as detailed under data point B.4.2.6 and B.4.2.7.

Personal precautions:

Engineering measures: Ensure there is sufficient ventilation of the area.

The floor of the storage room must be impermeable to prevent the escape of liquids.

Respiratory protection: Self-contained breathing apparatus must be available in case of emergency e.g. respiratory protective device with particle filter.

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing. Ensure safety shower is to hand.

If outside do not approach from downwind.

If outside keep bystanders upwind and away from danger point.

Mark out the contaminated area with signs and prevent access to unauthorised personnel.

Clean-up procedures:

Transfer to a closable, labelled salvage container for disposal by an appropriate method and according to national legislation or local authority instructions.

In case of contamination in water, telephone the relevant water management company or government bureau, police and emergency services or Environmental Protection Agency.

If contamination occurs during transportation refer to the drivers TREM card.

B.4.3.4 First aid measures

Inhalation: Remove patient from exposure, whilst ensuring one's own safety. Consult a doctor.

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Consult a doctor.

Eye contact: Irrigate eye with fresh water for at least 15 minutes. Seek medical attention.

Ingestion: Wash out mouth with water. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Consult a doctor.

Please refer to the safety data sheet in Document H.

B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

B.4.4.1 Description and specification of the packaging

Mecoprop-P K 600 can be provided in containers of sizes 1-20 litres, depending upon requirements. Below is the specification for the containers used, including an example packaging description of a 10 L container.

Pack Size:	<i>1 – 20 L</i>
Material:	High density polyethylene (HDPE)
Type:	Bottle
Example specification of a 10L pack	
Capacity:	Nominal volume 10,000 ml

Size:	375 mm x 240 mm x 179 mm (H – L – B)
Neck diameter:	63 mm
Type of closure and seals:	Tamper evident cap with compression or heat seal

B.4.4.2 Suitability of the packaging and closures

The product will be supplied in UN approved packaging, which has been tested for suitability in terms of strength, leakproofness and resistance. Individual packaging displays a UN certification number with guidelines on its suitability.

B.4.4.3 Resistance of the packaging material to its contents

The containers are checked for corrosion and weight loss during storage stability testing. The contents have no negative effect on the integrity of the packaging.

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

B.4.5.1. Neutralisation procedure

Not applicable Mecoprop-P K 600 is already present as the potassium salt form.

B.4.5.2. Controlled incineration

No study is available. However, the halogen content of mecoprop-P is less than 60 % therefore dioxin production is not expected. Complete degradation is possible at temperatures in excess of 900°C. A temperature of approximately 1100°C is advised for incineration. The formation of hydrogen chloride gas (HCl) and chlorine gas (Cl₂) should be noted. Incineration will also produce carbon dioxide (CO₂), carbon monoxide (CO) and water (H₂O).

Disposal by incineration should be by specialist operators in accordance with the criteria set out in Council Directive 94/67/EC.

B.4.6. REFERENCES RELIED ON

None.