

# *European Commission*



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

## **MECOPROP - P**

**Volume 3 – B.6 (PPP) – Mecoprop-P K 600 g/L**

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

**Version History**

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

---

## Table of contents

<b>B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS.....</b>	<b>4</b>
<b>B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT .....</b>	<b>4</b>
B.6.1.1. Oral.....	6
B.6.1.2. Dermal.....	12
B.6.1.3. Inhalation.....	15
B.6.1.4. Skin irritation.....	16
B.6.1.5. Eye irritation.....	18
B.6.1.6. Skin sensitization.....	20
B.6.1.7. Supplementary studies on the plant protection product.....	22
B.6.1.8. Supplementary studies for combinations of plant protection products .....	22
<b>B.6.2. DERMAL ABSORPTION .....</b>	<b>22</b>
<b>B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS.....</b>	<b>27</b>
<b>B.6.4. EXPOSURE DATA .....</b>	<b>28</b>
B.6.4.1. Operator exposure .....	28
B.6.4.2. Bystander and resident exposure .....	30
B.6.4.3. Worker exposure .....	33
<b>B.6.5. EXPOSURE AND RISK ASSESSMENT .....</b>	<b>34</b>
<b>B.6.6. REFERENCES RELIED ON.....</b>	<b>35</b>

## **B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS**

### **Consideration of the tested formulations compared to the representative product formulation**

The representative product for the current renewal is Mecoprop-P 600g/L (CA3015).

In the 1998 DAR three formulations were tested:

Duplosan KV (BAS 037 29 H)

BAS 037 32 H by BASF

Compitox plus by Nufarm

Further details on these formulations are provided in Volume 4 Confidential information.

It is considered that Duplosan KV (BAS 037 29 H) is equivalent to is Mecoprop-P 600g/L (CA3015) for the purposes of acute toxicity.

No information on the other formulations tested has been provided by the applicant so equivalence of the tested formulations to Mecoprop-P 600g/L (CA3015) cannot be concluded upon.

This is potentially a data gap.

Several studies on Duplosan KV (BAS 037 29 H) were submitted in the 1998 DAR. With the exception of an acute dermal toxicity study they were not resubmitted for renewal, however the current RMS has included them in the summary table below as the formulation is considered equivalent to the formulation of the representative product for this renewal. The findings show that the acute toxicity is similar for all the formulations tested therefore it is concluded that the findings on the tested formulations submitted can be read-across to Mecoprop-P 600g/L (CA3015). There was no skin sensitisation study conducted on Duplosan KV (BAS 037 29 H) however the formulation does not contain any ingredients that are known skin sensitisers and therefore it is considered that the findings on the tested formulations may also be applied to Mecoprop-P 600g/L (CA3015).

### **B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT**

#### **Summary of acute toxicity**

Table B.6. 1 provides a summary of the studies previously submitted and their endpoints. The table also contains new studies, conducted since the previous application, which are summarised in this dossier.

**Table B.6. 1 Summary of acute toxicity studies on the preparation Mecoprop-P K 600 g/L**

New studies not submitted in the previous 1998 DAR are highlighted in **bold**.

Studies submitted in the 1998 DAR conducted on Duplosan KV (BAS 037 29 H) but **not** resubmitted in this current renewal are shaded grey.

Test or study & Annex point	Test material and purity	Formulation tested	Species	Findings	GLP	Reference	Equivalence of formulation tested to Mecoprop-P 600g/L (CA3015)
Acute oral toxicity (CP 7.1.1)	Mecoprop-P K 600, purity 599 g/L	BAS 037 32 H	Rat	500-2000 mg/kg bw	Y	██████ (1994a) █	Not confirmed
<b>Acute oral toxicity (dietary) (CP 7.1.1)</b>	<b>Mecoprop-P K 600, purity 595.6 g/L</b>	<b>Mecoprop-P K 600 g/L batch HXP/1233</b>	<b>Mice</b>	<b>&gt;3393 mg/kg/day</b>	<b>Y</b>	<b>██████ (2009) █</b>	<b>Not confirmed</b>

Test or study & Annex point	Test material and purity	Formulation tested	Species	Findings	GLP	Reference	Equivalence of formulation tested to Mecoprop-P 600g/L (CA3015)
Acute oral toxicity	Mecoprop-P K 600, purity 599 g/L	Duplosan KV/ BAS 037 29 H	Rat	LD50: 903 (both m and f)	N	██████████ (1985a)	Yes
Acute percutaneous toxicity (CP 7.1.2)	Mecoprop-P K 600, purity 599 g/L	Duplosan KV/ BAS 037 29 H	Rat	>4000 mg/kg bw	Y	██████████ (1994b)	Yes
Acute percutaneous toxicity (CP 7.1.2)	Mecoprop-P K 600, purity not stated	Mecoprop-p K 600 (Optica), Batch KBM/874	Rat	>2000 mg/kg bw	Y	██████████ (2006) 1156/0063	Not confirmed
Acute inhalation (CP 7.1.3)	Mecoprop-P K 600, purity 599 g/L	BAS 037 32 H	Rat	>5.4 mg/L	Y	██████████ (1994)	Not confirmed
Acute inhalation	Mecoprop-P K 600, purity 599 g/L	Duplosan KV/ BAS 037 29 H	Rat	LC50: 4.7 mg/L (m/f: 3.6/ appr. 5.2 mg/L)	N	██████████ al. 1985	Yes
Skin irritation (CP 7.1.4)	Mecoprop-P K 600, purity 599 g/L	BAS 037 32 H	Rabbit	Cat. 2 Irritant	Y	██████████ (1994a) 14H0034/94 2018	Not confirmed
Skin irritation (the reliability of this study was questioned due to using a non-porous dressing)	Mecoprop-P K 600, purity 599 g/L	Duplosan KV/ BAS 037 29 H	Rabbit	Non-irritant	Y	██████████ (1984a)	Yes
Eye irritation (CP 7.1.5)	Mecoprop-P K 600, purity 599 g/L	BAS 037 32 H	Rabbit	Cat 1. Severe irritant	Y	██████████ (1994b) 13H0034/94 2019	Not confirmed
Eye irritation (CP 7.1.5)	Mecoprop-P K 600, purity not stated	Unknown study not submitted with this application but considered equivalent to Optica	Rabbit	Cat 1. Severe irritant	Y	██████████ (1990)	Not confirmed
Eye irritation (CP 7.1.5)	Mecoprop-P K 600, purity not stated	Unknown study not submitted with this application	Rabbit	Not irritant	Y	██████████ (1986)	Not confirmed
Eye irritation	Mecoprop-P K 600, purity 599 g/L	Duplosan KV/ BAS 037 29 H	Rabbit	Cat 2. Severe irritant	Y	██████████ (1984b)	Yes

Test or study & Annex point	Test material and purity	Formulation tested	Species	Findings	GLP	Reference	Equivalence of formulation tested to Mecoprop-P 600g/L (CA3015)
Skin sensitisation (CP 7.1.6)	Mecoprop-P K 600, purity 599 g/L	In 98 DAR for product	Guinea pig Buehler	Not sensitising	Y	██████████ (1995)	Not confirmed
Skin sensitisation (CP 7.1.6)	Mecoprop-P K 600, purity 605 g/L	Unknown study not submitted with this application but considered equivalent to Optica	Guinea pig M & K	Not sensitising	Y	██████████ (1998)	Not confirmed

The new acute oral toxicity study in mice by dietary exposure (██████████ 2009) displays evidence for no oral classification of the formulation Mecoprop-P K 600. This is more representative of the actual exposure an animal would receive as the formulation is provided in the diet, *ad libitum*. The study is not relevant for classification purposes. In the previously evaluated study (██████████ 1994a) with a gavage administration, the LD<sub>50</sub> was 500-2000 mg/kg bw, therefore the product tested is classified for acute oral toxicity as Category 4, H302, Harmful if swallowed.

The new acute percutaneous toxicity study (██████████ 2006) shows a similar result to that of the earlier study by Kirsch 1994b, with the highest dose tested displaying less than 50% mortality. This therefore infers the same classification conclusion (not classified) with respect to acute dermal toxicity.

The tested formulations were skin irritants and severe eye irritants, but not skin sensitisers.

Under CLP classification (EC 1272/2008) the following classification applies: **Acute oral toxicity Category 4, H302 Harmful if swallowed; Skin irritation Category 2, H315 Causes skin irritation; Eye irritation/corrosion Category 1, H318 Causes serious eye damage.**

### B.6.1.1. Oral

#### B.6.1.1/01

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.

Previous evaluation:	In DAR for first review (1998)
----------------------	--------------------------------

Study	Study on the acute oral toxicity of BAS 037 32 H in rats
Reference	██████████ (1994a)
Date performed	3 to 22 March 1994
Test facility	██████████ ██████████ ██████████ ██████████ ██████████
Report reference	Report no. ██████████ (BASF doc. 94/10602)
Guideline(s)	OECD 401
Deviations from the guideline	No
GLP	Yes
Test material	BAS 037 32 H, batch 92-1, 599g/L Mecoprop-P
Study acceptable	Yes

#### Study report:

██████████ (1994a): Study on the acute oral toxicity of BAS 03732H in rats ██████████

Report no. 10A0034/941017 (BASF doc. 94/10602), 2 August 1994. Unpublished report. (Dossier ref. III 7.2)

Study design and quality:

Three groups of five male and five female Wistar rats were given single oral doses (gavage) of 200, 500, and 2000 mg/kg bw mecoprop-P formulation. The formulation (BAS 03732H, not further specified concerning the mecoprop-P content) was dosed in water at a volume of 10 ml/kg. The animals were fasted 16 h before dosing. The study was stated to comply with GLP and was conducted according to OECD 401 and the EU test method B1.

Results:

No animals died at 200 and 500 mg/kg bw during the observation period, whereas all animals at 2000 mg/kg bw died within 1 day after dosing.

At 500 and 2000 mg/kg bw the following symptoms were noted: impaired or poor general state, dyspnoea, apathy, abnormal position, staggering, atonia, paresis, exsiccosis, absence of pain reflex, absence of corneal reflex, narcotic like state, and twitching. At necropsy of dead animals agonal congestion was recorded. No findings were noted in sacrificed animals.

The LD<sub>50</sub> was concluded to be above 500 mg/kg bw and less than 2000 mg/kg bw.

Discussion and conclusion:

LD<sub>50</sub> was found to be in the 500-2000 mg/kg bw interval. A specific LD<sub>50</sub> value was not found because of too big differences between the dose levels.

The test material BAS 03732H requires classification for acute oral toxicity according to Regulation (EC) 1272/2008 Acute Toxicity Category 4, H302: Harmful if swallowed.

### B.6.1.1/02

The applicant has provided a statement confirming that the tested formulation is equivalent to the formulation code Q121 which is also known as Optica, and was a representative product formulation in the 1998 DAR submitted by AH Marks. However details for the formulation composition have not been provided.

Previous evaluation:	None; Submitted for the purpose of renewal under Regulation 844/2012 Not needed for product assessment
----------------------	---

Study	Acute Dietary Toxicity of MCPP-P in Mice
Reference	██████████ (2009)
Date performed	17 June to 3 July 2008
Test facility	██
Report reference	██████████
Guideline(s)	OECD 425 (2006)
Deviations from the guideline	Used dietary administration over 24 hours rather than gavage dose, and animals were not dosed sequentially
GLP	Yes
Test material	Formulation of MCPP-P K 600g/L (MCCPP-p potassium salt), equivalent to formulation code Q121, batch HXP/1233, containing 595.6g/L MCPP-p
Study acceptable	Can be used as evidence for ecotoxicity assessment in mammals, but is not suitable for the purposes of classification of the product for acute oral toxicity.

### Executive Summary

An acute dietary toxicity test was conducted to assess the potential acute health hazards of Mecoprop-P K 600 g/l to mammalian species. The test substance was administered as a formulation of mecoprop-P potassium salt,

containing the equivalent of 600 g/l mecoprop-P expressed as acid equivalent. The mouse was selected for this study because it represents small animals that could be found in the field. Only female mice were used as it has been previously observed that females are generally more sensitive than males to effects of mecoprop-P.

Five healthy mice were acclimatised to experimental conditions in individual housing for 7 days prior to the study. Two days before administration of the test substance, background food intake was established.

The mice were presented powdered rodent meal (Purina Certified Rodent Meal #5002) dosed with 20,000 ppm mecoprop-P acid equivalent, based on knowledge of the compound and previous studies. Prior to the offering of the test material mice were starved for 4 hours. On day 0 the test diet was offered for 24 hours and the mice were observed for 14 days after this.

No mortalities, signs of toxicity or behavioural changes were observed throughout the duration of the study. Additionally no abnormalities were found when the animals were necropsied. There were however some differences noted in the weight and food consumption, to the extent that animals showed some avoidance of the treated diet.

From the results of this study it can be determined that the oral LD<sub>50</sub> of the test material (Mecoprop-P K 600 g/l) is greater than the 3393 mg/kg/day supplied to the mice, under the experimental conditions stated and according to the OECD 425 and OPPTS 870.1100 Guidelines. This infers that no classification is required for oral toxicity. From the mortality rate observed the following acute oral LD<sub>50</sub> value was determined:

The oral LD <sub>50</sub>	for females was	> 3393 mg/kg/day
---------------------------	-----------------	------------------

## MATERIALS AND METHODS

	<b>MATERIALS</b>
Test materials:	Mecoprop-P K 600 g/l
Description:	Clear brown liquid
Lot/Batch:	HXP/1233
Purity:	Sample purity 595.6 g/l mecoprop-P
Vehicle and/or positive control:	Vehicle: Purina Certified Rodent Meal #5002
Test animals	
Species:	Mouse, albino
Strain:	CD-1
Age:	9 Weeks (young adult)
Weight at dosing:	22 – 25 g
Source:	
Acclimatisation period:	7 days
Diet:	Purina Certified Rodent Meal #5002, <i>ad libitum</i> , during acclimatisation. Test diets prepared with the same feed. In the 2 days after test diet presentation and for 14 days after the 24 hour exposure period Purina Certified Rodent Meal #5002 was available, <i>ad libitum</i> .
Water:	Filtered potable tap water supplied <i>ad libitum</i> via an automatic water dispensing system.
Housing:	Singly housed in suspended stainless steel caging with mesh floors. Litter paper beneath cage.
Environmental conditions	
Temperature:	19 – 23 °C
Humidity:	59 – 71 % RH
Air changes:	Not specified
Photoperiod:	12 hour light/dark cycle

## STUDY DESIGN AND METHODS

In life dates:	17/06/2008 – 03/07/2008
Animal assignment and treatment	<p>A group of five female, non-pregnant mice were selected two days prior to the start of the study to establish a baseline dietary assessment. Female mice were selected for the test because they have been previously shown to be more sensitive to the effects of mecoprop-P than males. Each mouse was fasted for 4 hours prior to basal diet presentation. After fasting the animals were weighed and examined. Food consumption was monitored once the mice had been presented with the food.</p> <p>The dose level to be administered via diet was selected based on knowledge of the metabolism and toxicity of the compound and previous test results on similar compounds. The dose was therefore set at 20,000 ppm of test substance.</p> <p>The test diet was prepared by adding 42.07g of test substance to 957.9g of Purina Certified Rodent Meal #5002.</p> <p>On day 0 mice were fasted for 4 hours again before being offered the test diets at the beginning of the dark cycle on day 1. The treated diet was then available for 24 hours.</p> <p>Mice were observed for signs of toxicity up to 14 days after being offered the test diet. Body weights and food consumption were also measured throughout the study.</p> <p>At the end of the 14 days mice were euthanized using CO<sub>2</sub> inhalation and necropsies were performed on all animals. Tissues and organs of the thoracic and abdominal cavities were examined.</p>
Statistics	No statistical analyses were performed.

## RESULTS AND DISCUSSIONS

**Mortality** All animals survived the duration of the study.

**Clinical observations** No signs of toxicity or behavioural changes were observed throughout the duration of the study.

**Body weight** All animals exhibited a slight reduction in body weight from day 0 to day 1, although this is possibly due to decreased food consumption when presented with the treated diet on day 0. Over the 14 day duration of the study all animals but one gained weight. The one animal that lost weight lost 1.0g in total from day 0-14. This weight was however lost between days 7 and 14.

For further information on body weight please refer to Table B.6. 2

**Table B.6. 2 Individual bodyweights of mice following dietary administration of 20,000 ppm Mecoprop-P K 600 g/L for 24 hours**

Animal No.	Bodyweight (g)									
	Day -2	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 14
1001	22.0	22.6	22.0	24.7	24.7	25.0	25.3	24.6	24.7	25.5
1002	22.5	21.7	20.8	23.1	24.4	24.3	24.0	23.2	23.5	25.8
1003	22.9	24.4	24.0	24.9	25.4	25.8	26.1	26.1	25.7	27.3
1004	25.2	26.0	26.1	27.8	28.0	28.6	29.5	29.2	30.2	25.0
1005	22.0	22.6	22.2	24.4	25.8	25.2	25.7	25.5	25.4	26.3
<b>Mean</b>	<b>22.9</b>	<b>23.5</b>	<b>23.0</b>	<b>25.0</b>	<b>25.7</b>	<b>25.8</b>	<b>26.1</b>	<b>25.7</b>	<b>25.9</b>	<b>26.0</b>

**Food consumption** The overall daily food consumption of the test diet was approximately 50% less than that of the control. Average day 0 (treated diet) food consumption was 4.0g, day 1 was 9.0g and day 2 was 7.7g. Averages of day 1-6 and 7-14 were 6.2g and 5.5g respectively. The reduction in day 0 consumption indicates a level of avoidance of the treated diet.

For more detailed information on food consumption please refer to Table B.6. 3, Table B.6. 4 and Table B.6. 5.

**Table B.6. 3 Individual food consumption on Day –2 (basal diet) of mice prior to dietary administration of Mecoprop-P K 600g/L**

Time (hours)	Measurement	Animal No.					Total Consumed
		1001	1002	1003	1004	1005	
2	Spillage	7.1	2.3	0.4	2.5	0.0	6.2
	Consumed	1.6	1.0	1.0	1.8	0.8	
4	Spillage	10.1	0.4	0.1	0.2	1.0	8.4
	Consumed	2.9	0.5	1.0	3.0	1.0	
6	Spillage	0.7	0.4	0.2	0.9	1.2	3.0
	Consumed	0.1	0.7	0.5	0.9	0.8	
8	Spillage	0.6	0.1	0.3	0.8	1.2	1.9
	Consumed	0.3	0.1	0.5	0.5	0.5	
24	Spillage	4.8	1.0	4.5	5.3	2.1	18.9
	Consumed	3.7	2.8	4.6	4.7	3.1	
2-24	Spillage	23.3	4.2	5.5	9.7	6.2	38.4
	Consumed	8.6	5.1	7.6	10.9	6.2	
Mean consumption:							7.7

**Table B.6. 4 Individual food consumption on Day 0 (test diet) of mice administered 20,000 ppm Mecoprop-P K 600 g/L in the diet for 24 hours**

Time (hours)	Measurement	Animal No.					Total Consumed
		1001	1002	1003	1004	1005	
2	Spillage	18.8	1.9	2.9	22.4	0.0	3.5
	Consumed	1.3	0.3	0.4	1.2	0.3	
4	Spillage	5.5	7.2	11.9	10.5	3.9	4.7
	Consumed	0.6	0.8	1.0	1.4	0.9	
6	Spillage	0.0	0.0	0.0	0.4	0.5	0.6
	Consumed	0.0	0.1	0.0	0.4	0.1	
8	Spillage	0.0	0.0	0.0	0.0	0.0	0.0
	Consumed	0.0	0.0	0.0	0.0	0.0	
24	Spillage	3.4	3.6	17.2	2.0	5.1	11.1
	Consumed	1.7	1.0	1.5	2.2	4.7	
2-24	Spillage	27.7	12.7	32.0	35.3	9.5	19.9
	Consumed	3.6	2.2	2.9	5.2	6.0	

Mean consumption:	4.0
-------------------	-----

**Table B.6. 5 Individual food consumption on Day 1-14 (basal diet) of mice following dietary administration of 20,000 ppm Mecoprop-P K 600 g/L for 24 hours**

Time (Day)	Measurement	Animal No.					Total Consumed
		1001	1002	1003	1004	1005	
1	Spillage	22.2	12.2	12.3	14.2	8.3	9.0
	Consumed	9.7	8.3	9.6	9.1	8.3	
2	Spillage	11.0	2.1	4.8	12.7	4.3	7.2
	Consumed	11.8	6.1	6.0	5.9	6.2	
3	Spillage	2.0	0.6	4.3	2.5	1.4	5.3
	Consumed	5.4	4.5	5.7	5.6	5.4	
4	Spillage	0.4	1.8	2.0	0.1	3.4	5.1
	Consumed	5.3	4.2	5.8	5.6	5.1	
5	Spillage	1.3	0.2	0.2	0.0	0.6	5.5
	Consumed	5.4	4.6	5.1	6.0	5.7	
6	Spillage	0.3	0.0	0.1	0.0	0.1	5.1
	Consumed	5.4	5.0	4.9	6.1	4.6	
7-14	Spillage	46.4	4.2	23.1	9.2	14.3	4.7
	Consumed	5.2	5.5	4.2	4.3	4.5	
Mean consumption:							5.5

Necropsy No macroscopic abnormalities were observed when animals were necropsied.

Deviations from protocol The protocol indicates that 50g of the test diet should be frozen until analysed/discarded. In this study only 40g were frozen. This deviation had no impact on the study, as the sample taken was discarded anyway, but would have been large enough for analysis if it were needed.

## CONCLUSIONS

No mortalities, signs of toxicity or behavioural changes were observed during the study. Additionally no abnormalities were found when the animals were necropsied. From this result it can be determined that the oral LD<sub>50</sub> of the test material (Mecoprop-P K 600g/L) following dietary administration for 24h is greater than the highest dose received by the mice of 3393 mg/kg/day, under the experimental conditions stated and according to the OECD 425 and OPPTS 870.1100 guidelines. This infers that no classification is required for oral toxicity.

From the mortality rate observed the following acute oral LD<sub>50</sub> value was determined:

The oral LD <sub>50</sub>	for females was	> 3393 mg/kg bw
---------------------------	-----------------	-----------------

**B.6.1.2. Dermal****B.6.1.2/01**

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.

Previous evaluation:	In DAR for first review (1998)
----------------------	--------------------------------

Study	Study on the acute dermal toxicity of BAS 03732H in rats
Reference	██████████ (1994b)
Date performed	10 March to 28 April 1994
Test facility	██████████ ██████████ ██████████ ██████████ ██████████
Report reference	Report no. ██████████ BASF doc. 94/10600)
Guideline(s)	OECD 402 (1987)
Deviations from the guideline	No
GLP	Yes
Test material	BAS 037 32 H, batch 92-1, 599g/L mecoprop-P
Study acceptable	Yes

Study report:

██████████ (1994b): Study on the acute dermal toxicity of BAS 03732H in rats ██████████  
 ██████████ Report no ██████████ (BASF doc. 94/10600), 2 August 1994. Unpublished report. (Dossier ref. III 7.4).

Study design, reporting and quality:

Three groups of five male and five female Wistar rats were exposed by dermal application to doses of 2000, 3000, and 4000 mg/kg bw mecoprop-P formulation. The formulation (BAS 03732H, not further specified concerning the mecoprop-P content) was applied undiluted and covered with semi-occlusive dressing for 24 h.

The study was stated to comply with GLP and was conducted according to OECD 402 and EU test method B3.

Results:

Three animals (2m and 1f) died on day one after application at 4000 mg/kg bw. At 3000 and 4000 mg/kg bw toxic signs such as impaired or poor general state, dyspnoea, apathy, abnormal position, staggering, paresis, tremor, and twitching were noted up to day four of observation. No toxic symptoms were noted at 2000 mg/kg bw. Signs of irritation occurred in all dose groups comprising of very slight to slight edema, very slight to well-defined erythema, scaling and severe scaling, and encrustation. At necropsy of dead animals agonal congestion was recorded. No findings were noted in sacrificed animals.

The LD<sub>50</sub> was concluded to be about 4000 mg/kg bw for males and above this level for females.

Discussion and conclusion:

The LD<sub>50</sub> value for dermal exposure to mecoprop-P formulation BAS 03732H is above 4000 mg/kg bw and thus, does not meet the criteria for classification for acute dermal toxicity according to Regulation (EC) 1272/2008.

**B.6.1.2/02**

The applicant has provided a statement confirming that the tested formulation is equivalent to the formulation code Q121 which is also known as Optica, and was a representative product formulation in the 1998 DAR submitted by AH Marks. However details for the formulation composition have not been provided.

Previous evaluation:	None; Submitted for the purpose of renewal under Regulation 844/2012
----------------------	--

Study	Mecoprop-P K 600 (Optica) Acute Dermal Toxicity (Limit Test) in the Rat
Reference	██████████ (2006)
Date performed	8 to 22 June 2006
Test facility	██
Report reference	██████████
Guideline(s)	OECD 402 (1987)
Deviations from the guideline	None
GLP	Yes
Test material	Mecoprop-p K 600 (Optica), Batch KMB/874 (content of mecoprop-P and the formulation tested needs to be specified as there was no certificate of analysis)
Study acceptable	Yes

### Executive Summary

An acute dermal toxicity study (limit test) was conducted on rats according to the guidelines EEC B3 and OECD 402 to establish the potential hazardous effects of Mecoprop-P K 600 to mammalian species.

The test material (Mecoprop-P K 600 g/l) was applied to the clipped backs and flanks of five male and five female Sprague-Dawley rats at a dose level of 2000 mg/kg. The test site was protected with a semi-occlusive bandage for 24 hours. After 24 hours the bandage was removed and the test site decontaminated to remove residual test material. Animals were examined for deaths and overt signs of toxicity, several times on the day of dosing and then once daily for 14 days. Individual bodyweights were recorded prior to the application of the test material and on days 0, 7 and 14.

After the removal of the dressing and subsequently once daily for 14 days, the test sites were examined for evidence of primary irritation according to the Draize scale.

After 14 days the animals were killed and subjected to gross necropsy.

No deaths and no signs of irritation were recorded at any point during the study. The LD<sub>50</sub> is therefore greater than the maximum dose applied in this study.

From the mortality rate observed the following acute dermal LD<sub>50</sub> values were determined:

The dermal LD <sub>50</sub>	for females was	> 2000 mg/kg bw
	for males was	> 2000 mg/kg bw
	for combined sexes was	> 2000 mg/kg bw

### MATERIALS AND METHODS

<b>A</b>	<b>MATERIALS</b>
<b>Test materials:</b>	Mecoprop-P K 600 (Optica)
<b>Description:</b>	Brown liquid
<b>Lot/Batch:</b>	KMB/874
<b>Purity:</b>	Not stated
<b>Vehicle and/or positive control:</b>	Material was used as supplied.
<b>Test animals</b>	
<b>Species:</b>	Rat
<b>Strain:</b>	Sprague-Dawley CD (CrI:CD (SD) IGS BR)
<b>Age:</b>	8-12 weeks
<b>Weight at dosing:</b>	Males 239-259 g; Females 212-230 g
<b>Source:</b>	██
<b>Acclimatisation period:</b>	At least 5 days
<b>Diet:</b>	BCM IPS Ltd, Certified Rat and Mouse Diet (5LF2), supplied by BCM IPS

	Limited, London, UK.
<b>Water:</b>	Tap water <i>ad libitum</i> .
<b>Housing:</b>	Single housed during exposure, groups of 5 post-exposure in solid-floor polypropylene cages furnished with woodflakes.
<b>Environmental conditions</b>	
<b>Temperature:</b>	19 – 25 °C
<b>Humidity:</b>	30 – 70 % RH
<b>Air changes:</b>	At least 15/hour
<b>Photoperiod:</b>	12 hour light/dark cycle (06:00 – 18:00 light)

<b>B</b>	<b>STUDY DESIGN AND METHODS</b>
<b>In life dates:</b>	08 June 2006 to 28 June 2006
<b>Animal assignment and treatment</b>	<p>Five male and five female rats were randomly allocated to cages upon receipt. After an acclimatisation period the animals were selected at random and given a unique number. One day before treatment the back and flanks of each rat were clipped free of hair.</p> <p>The test material was applied to the clipped backs and flanks at a dose level of 2000 mg/kg using a graduated syringe. The test site was protected with a semi-occlusive bandage for 24 hours. After 24 hours the bandage and residual test material was removed. Death and overt signs of toxicity were recorded at ½, 1, 2 and 4 hours on the day of dosing and then once daily for 14 days. Individual bodyweights were recorded prior to the application of the test material and on day 0, 7 and 14.</p> <p>After the removal of the dressing and subsequently once daily for 14 days, the test sites were examined for evidence of primary irritation according to the Draize scale.</p> <p>Individual bodyweights were recorded on days 0, 7 and 14.</p> <p>After 14 days the animals were killed by cervical dislocation and subjected to gross necropsy.</p>
<b>Statistics</b>	None.

## RESULTS AND DISCUSSION

Mortality Details are provided in Table B.6. 6. No mortalities occurred during the study.

**Table B.6. 6 Mortality of rats following dermal administration of Mecoprop-P K 600 (Optica)**

Dose (mg/kg bw)	Males	Females	Combined
2000	0/5	0/5	0/10

Clinical observations No signs of dermal irritation or systemic toxicity were observed at any point during the study.

Body weight All animals showed expected bodyweight gains over the study period. For further details of the body weights over the study period, please refer to Table B.6. 7.

**Table B.6. 7 Individual bodyweights**

Animal no. & sex	Bodyweight (g) at day			Bodyweight change (g) during week	
	0	7	14	1	2
1-0 male	254	312	363	58	51

1-1 male	259	316	370	57	54
1-2 male	239	287	347	48	60
1-3 male	241	292	338	51	46
1-4 male	249	318	380	69	62
2-0 female	230	244	254	14	10
2-1 female	212	223	233	11	10
2-2 female	229	236	251	7	15
2-3 female	229	246	266	17	20
2-4 female	221	236	247	15	11

Necropsy No abnormalities were noted at necropsy.

Deviations from protocol None.

## CONCLUSIONS

As there were no signs of toxicity observed in any of the rats in this study the LD<sub>50</sub> of the test material (Mecoprop-P K 600 g/l) was found to be greater than the highest dose applied of 2000 mg/kg bw, under the experimental conditions stated and according to the guidelines EEC B3 and OECD 402. This infers that no classification is required for acute dermal toxicity according to Regulation (EC) 1272/2008.

From the mortality rate observed the following acute dermal LD<sub>50</sub> values were determined:

The dermal LD <sub>50</sub>	for females was	> 2000 mg/kg bw
	for males was	> 2000 mg/kg bw
	for combined sexes was	> 2000 mg/kg bw

### B.6.1.3. Inhalation

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.

Previous evaluation:	In DAR for first review (1998)
----------------------	--------------------------------

Study	Study on the acute inhalation toxicity LC <sub>50</sub> of BAS 037 32 H as a liquid aerosol in rats 4-hour exposure
Reference	██████████ (1994)
Date performed	7 to 21 March 1994
Test facility	██████████ ██████████ ██████████ ██████████ ██████████
Report reference	Report no. ██████████ (BASF doc. 94/10590)
Guideline(s)	OECD 403 (1981)
Deviations from the guideline	None
GLP	Yes
Test material	BAS03732H, Lot 92-1, 599g/L mecoprop-P
Study acceptable	Yes

#### Study report:

██████████ (1994): Study on the acute inhalation toxicity LC<sub>50</sub> of BAS03732H as a liquid aerosol in rats 4-hour exposure. ██████████. Report no. ██████████ BASF doc. 94/10590), 26 July 1994. Unpublished report. (Dossier ref. III 7.6).

Study design and quality:

Five male and five female Wistar rats were by inhalation (nose-head exposure) exposed to aerosols of a mecoprop-P formulation (BAS 03732H, the content not further specified) at a dose level of 5.4 mg/l for 4 hours. The aerosol was generated by a two-compartment atomizer. The mass median aerodynamic diameter (MMAD) of the aerosol was determined to 0.57 mm and the respirable aerosol fraction was by particle size analysis determined to 86.4%.

The study was stated to follow GLP and comply to OECD 403 and with EU test method B2.

Results:

No mortality occurred in the test group. Clinical examination showed accelerated and irregular respiration during exposure. After exposure no abnormalities were observed. The exposure did not affect body weight and no pathologic findings were noted at necropsy. LC<sub>50</sub> was concluded to be above 5.4 mg/l.

Discussion and conclusion:

The mecoprop-P formulation BAS 03732H showed only marginal toxicity (accelerated and irregular respiration) at acute inhalation exposure.

The test was conducted to OECD 403 (1981) and meets the requirements of this guideline. OECD 404 was revised in 2009 and included criteria for droplet size of aerosols to ensure that they were within the respirable range. According to OECD 404 the MMAD should be between 1 and 4 µm and the geometric standard deviation should be between 1.5 to 3.0. In this study the MMAD was 0.577 mm and the geometric standard deviation was 4.5 so these are not within the recommended range of the new guidance document. These results indicate that most of the droplets were very small and possibly too small to be readily respirable but overall there was a very high degree of variability on the droplet size. Overall it is considered that these deviations are unlikely to affect the overall result of the test.

LC<sub>50</sub> was concluded to be greater than 5.4 mg/L. The test material BAS03732H does not require classification with respect to acute inhalation toxicity according to Regulation (EC) 1272/2008.

**B.6.1.4. Skin irritation**

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.

Previous evaluation:	In DAR for first review (1998)
----------------------	--------------------------------

Study	Study on the acute dermal irritation/ corrosion of BAS 037 32 H in the rabbit
Reference	██████████ (1994)
Date performed	28 Feb 1994
Test facility	██████████ ██████████ ██████████ ██████████ ██████████
Report reference	Report no. ██████████
Guideline(s)	OECD 404 (1992)
Deviations from the guideline	None
GLP	Yes
Test material	BAS 03732H, Batch 92-1, 599g/L mecoprop-P
Study acceptable	Yes

Study report:

██████████ (1994): Study on the acute dermal irritation/ corrosion of BAS 03732H in the rabbit. ██████████ ██████████ Report no. ██████████, 26 July 1994. Unpublished report. (Dossier ref. III 7.8).

Study design and quality:

Six White Vienna rabbits were on the shaven intact skin for 4 hours exposed to 0.5 ml of the mecoprop-P formulation BAS 03732H (not further specified). The test patch containing the liquid test substance was covered with a semi-occlusive dressing. The study was stated to comply to GLP and with OECD 404 and EU test method B4.

**Results:**

The following results according to the scoring system in OECD guideline 404 were obtained at the 24h, 48h and 78h readings:

**Table B.6. 8 Skin irritation of mecoprop-P formulation BAS 03732H**

Time of examination	Animal	Erythema score	Oedema score	Additional findings
1hr	1	2	0	
	2	2	0	
	3	2	0	
	4	2	1	
	5	2	1	
	6	1	0	
24hr	1	2	0	
	2	3	0	
	3	3	0	
	4	3	1	
	5	3	1	E
	6	3	0	E
48hr	1	2	0	
	2	2	0	
	3	3	0	
	4	3	0	
	5	3	0	E
	6	3	0	
72hr	1	2	0	
	2	2	0	
	3	3	0	
	4	3	0	
	5	3	0	E, N
	6	2	0	
8 Days	1	2	0	S
	2	1	0	
	3	2	0	S
	4	1	0	
	5	2	0	S, N
	6	1	0	S
15 days	1	1	0	
	2	0	0	
	3	2	0	
	4	1	0	
	5	2	0	I
	6	1	0	
Mean of 24-72hr		2.0	0.0	
		2.3	0.0	
		3.0	0.0	

		3.0	0.3	
		3.0	0.3	
		2.7	0.0	
Overall mean		2.7	0.1	

E = erythema extending beyond the area of exposure

S = scaling

N = superficial necrosis

I = incrustation

On day 15 three animals scored 1 and two animals scored 2 for erythema and in one of them encrustation was noted. Scaling was observed in three animals day 8. In one animal superficial necrosis was observed. The formulation was concluded to possess irritant property.

#### Discussion and conclusion:

The findings for irritative response of the mecoprop-P formulation BAS 03732H meet the EU criteria in directive 67/548/EEC for classification as Xi; R38 (irritating to skin).

The test material BAS 03732H should be classified according to Regulation (EC) 1272/2008 Skin Irritation Category 2 H315 Causes skin irritation.

### **B.6.1.5. Eye irritation**

#### **B.6.1.5/01**

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.

Previous evaluation:	In DAR for first review (1998)
----------------------	--------------------------------

Study	Study of the acute eye irritation of BAS 03732H in the rabbit
Reference	██████████ (1994b)
Date performed	28 February 1994
Test facility	██████████ ██████████ ██████████ ██████████ ██████████
Report reference	██████████
Guideline(s)	OECD 405 (1987)
Deviations from the guideline	None
GLP	Yes
Test material	BAS 037 32 H, Batch 92-1, 599g/L mecoprop-P
Study acceptable	Yes

#### Study report:

██████████ (1994b): Study of the acute eye irritation of BAS 03732H in the rabbit. ██████████  
██████████. Report no. ██████████ 26 July  
1994. Unpublished report. (Dossier ref. III 7.10).

#### Study design and quality:

One White Vienna rabbit was by application in the conjunctival sac exposed to 0.1 ml of the mecoprop-P formulation BAS 03732H (content not further specified). Signs of irritation were evaluated 1h, 24 h, 48 h, 8 days and 15 days after the application. The study was stated to comply to GLP and with OECD 405 and EU test method B5.

#### Results:

**Table B.6. 9 Scores for Eye Irritation in the Rabbit following administration of BAS 03732H**

Time	Corneal opacity	Iris lesion	Conjunctiva - redness	Conjunctiva – chemosis	Other symptoms*
after 1 hour	1	0	2	2	SR PC LC
after 24 hours	1	1	2	2	SR PC
after 48 hours	1	1	3	3	SR PC S DB
after 72 hours	2	1	3	3	SR PC S DB LC 20
after 8 days	3	1	3	3	SR PC S DB LC LH MV
After 15 days	4	1	3	2	SR S LC LH MV PA SI
<b>mean scores 24-72h</b>	1.3	1.0	2.3	2.7	

## \* Key

SR = small retractions in the eyelids

PC = pupil contracted

LC = loss of corneal tissue

S = suppuration

DB = discharge of blood

20 = Index for area that could not be read because of severe oedema

LH = loss of hair at margins of eyelids

MV = marginal vascularization of cornea

PA = pannus

SI = study discontinued because of sever irritation

Corneal opacity: the signs progressed from score "1" (scattered or diffuse opacity) from the 1 h reading to score "4" (opaque cornea, iris not discernable) at day 15.

Iris: a score of "1" (markedly deepened rugae/ congestion/ swelling/ moderate circumcorneal hyperaemia or injection, iris still reacting to light) was obtained at the 24 h reading and throughout the 15 days observation period. Conjunctival redness: A score "2" (diffuse crimson colour, individual vessels not easily discernible) was obtained throughout the study period. However a score of "3" was reached at the 72 h reading (diffuse beefy red).

Conjunctival swelling: Score "2" (obvious swelling with partial eversion of lids) was recorded at the 1 h, 24 h, and 15 day readings. Score "3" (swelling with lids about half closed) was recorded at the 48 h, 72 h, and 8 day readings.

The study was discontinued because of signs of severe irritation.

The test formulation was concluded to be a severe eye irritant.

Discussion and conclusion:

According to the EU criteria the mecoprop-P formulation BAS 03732H should be classified Xi; R41 (risk of serious damage to eyes) because of the observation of the irreversible nature of the eye damage.

The test material BAS 03732H should be classified according to Regulation (EC) 1272/2008 Eye Irritation Category 1 H318 Causes serious eye damage.

**B.6.1.5/02**

The applicant has not provided details of the exact composition of coformulants in this tested formulation.

Previous evaluation:	Not in the DAR for the first review. This study was previously evaluated by the UK for the product Optica (HSE ref M09963 COP 2006/01151). RMS has not re-evaluated this study as the study was not submitted by the applicant. It was concluded to be a severe eye irritant when it was previously evaluated.
----------------------	--

Study	Irritant effects on the rabbit eye of mecoprop-P K salt 600 g/L
Reference	██████████ (1990)
Date performed	25 to 26 September 1989
Test facility	██
Report reference	████████████████
Guideline(s)	OECD 405 (1987)
Deviations from the guideline	Not evaluated
GLP	Yes
Test material	Mecoprop-P K salt 600g/L, batch 4118
Study acceptable	Study is superfluous

### B.6.1.5/03

The applicant has provided a statement confirming that the tested formulation is equivalent to the formulation code Q121 which is also known as Optica, and was a representative product formulation in the 1998 DAR submitted by AH Marks. However details for the formulation composition have not been provided.

Previous evaluation:	Not in the DAR for the first review. This study was previously submitted to the UK for the product Optica (HSE ref M09963 COP 2006/01151) but it does not appear to have been evaluated by the UK, instead the study by Liggett (1990) was used to support the product Optica. RMS has not evaluated this study as the study was not submitted by the applicant. The applicant claims that in this study the test substance was not an eye irritant.
----------------------	--

Study	R(+) CMPP/K 600g/L Acute eye irritation/corrosion test in the rabbit
Reference	██████████ (1986)
Date performed	4 to 8 November 1986
Test facility	██
Report reference	86/AMS004/663
Guideline(s)	OECD 405 (1981)
Deviations from the guideline	Not evaluated
GLP	No
Test material	R(+) CMPP/K 600g/L, applicant states that product code is Q121 (Optica)
Study acceptable	Study is superfluous

### B.6.1.6. Skin sensitization

#### B.6.1.6/01

The applicant has stated that this formulation contains mecoprop-P as a DMA salt (726 g/L mecoprop-P DMA) although the exact composition of coformulants has not been provided.



The skin of the positively reacting animals was subjected to microscopic examination. No distinction could be made with regard to intensity and morphological characteristics between the control animals and the animals from the test group. Based on this, it was concluded that the reactions were not due to sensitizing effects but rather due to slight irritant action of the test formulation.

Discussion and conclusion:

The positive results after the second challenge is explained by primary irritation of the 50% aqueous solution of the formulation. Nevertheless, irritation did not occur after the first challenge, where a 75% aqueous solution was used. Furthermore, a response of 8/19 animals in the test group compared to 2/10 in the control group indicate increased sensitivity in these animals. It is considered questionable whether it is possible by microscopic examination to differentiate between an irritative and an allergic response. Due to these uncertainties no firm conclusion can be drawn from this study.

For mecoprop-P, active substance (see section B.5.2.7) retesting in the guinea pig maximization test (using a vehicle able to dissolve mecoprop-P) is proposed. The result from this test should also form the basis for the evaluation of the sensitizing potential of mecoprop-P preparations.

### B.6.1.6/01

The applicant has provided a statement confirming that the tested formulation is equivalent to the formulation code Q121 which is also known as Optica, and was a representative product formulation in the 1998 DAR submitted by AH Marks. However details for the formulation composition have not been provided.

Previous evaluation:	Not in the DAR for the first review. This study was previously submitted and evaluated by the UK for the product Optica (HSE ref M09963 COP 2006/01151). RMS has not re-evaluated this study as the study was not submitted by the applicant. It was concluded to be negative for skin sensitisation when it was previously evaluated.
----------------------	--

Study	Optica: skin sensitisation study in the guinea pig (after Magnusson and Kligman)
Reference	██████████ 1998)
Date performed	16 June to 17 July 1998
Test facility	████████████████████
Report reference	785/30 – D6144
Guideline(s)	OECD 406
Deviations from the guideline	No
GLP	Yes
Test material	Optica, CMPP p K 605g/L, batch KMW/98/15
Study acceptable	Study is superfluous

### B.6.1.7. Supplementary studies on the plant protection product

No information available.

### B.6.1.8. Supplementary studies for combinations of plant protection products

No information available.

## B.6.2. DERMAL ABSORPTION

### Introduction

No dermal absorption studies were submitted in the 1998 DAR. In the 2002 DAR addendum an *in vivo* rat study (by ██████████ 1997) was submitted and it was concluded that the dermal absorption was 20% for both the

concentrate and the spray dilution. In the Review Report for mecoprop-P (14 April 2003) the dermal absorption was 20%. The Lappin study is not included in this renewal submission. Instead a new dermal *in vitro* dermal absorption study conducted on human skin is submitted.

#### Conclusion on dermal absorption values to be applied to Mecoprop-P K 600 g/L (CA3015)

The dermal absorption values from the study by Davies (2006) are:

1% for the 600g/L concentrate

5% for the 1/80 dilution (7.5g/L mecoprop-p).

According to the product label the in-use dilutions of Mecoprop-P K 600 g/L (CA3015) will be as follows:

2L product/ha (containing 1200 g a.s.) in 200-400 L water/ha equating to an in-use dilution of 3 to 6 g a.s./litre of spray solution.

As the applied use is more dilute (1:100 to 1:200 dilution) compared to the tested dilution (1:80) a pro-rata correction should be applied.

The concentrate at 600g/Litre is 1%

At 7.5g/L it is 4%

The pro-rata calculations according to the dermal absorption guidance document is:

$4\% \times 200/80 = 10\%$  dermal absorption for the 1:200 dilution (3g/L)

$4\% \times 100/80 = 5\%$  dermal absorption for the 1:100 dilution (6g/L)

**The dermal absorption of the 600g/L concentrate is 1%**

*Applicant conclusion: For risk assessment purposes the dermal absorption values of 0.59% for the concentrate and 2.86% for the spray strength material were proposed during the previous evaluation of mecoprop-P in Europe.*

*Based on the dermal absorption report by [REDACTED] (2006), these values should be amended to 0.82% for the concentrate and 3.46% for the spray strength material, rounded to 0.8% and 3% respectively, according to the current guidance document.*

*These values (0.7% and 3% for the concentrate and spray strength solution respectively) can then be used in the calculations for operator, worker and bystander exposure.*

#### B.6.2.1 *In vitro* dermal absorption

The tested formulation in this study [REDACTED] (2006) is slightly different to the representative product Mecoprop-P K 600 g/L (CA3015). A formulation comparison has been provided in Volume 4, Section C.1.4 d. In conclusion though the tested formulation is different from the formulation of the representative product, it is considered to be sufficiently similar to allow a read-across to be made.

Previous evaluation:	None; Submitted for the purpose of renewal under Regulation 844/2012. For this renewal a new <i>in vitro</i> dermal absorption study by Davies (2006) has been submitted.
----------------------	--

Study	Mecoprop-P: <i>In vitro</i> absorption from a formulation through human epidermis
Reference	[REDACTED] (2006)
Date performed	20 February to 3 March 2006
Test facility	[REDACTED]

Report reference	Report no. JV1911-REG
Guideline(s)	OECD 428 (2004)
Deviations from the guideline	No significant deviations
GLP	Yes
Test material	M CPP-p 600g/L (product code G750A(10)) concentrate and 1/80 v/v aqueous dilution (7.5g/L M CPP-p), with radiolabelled [ <sup>14</sup> C]M CPP-p 892 MBq/mg.
Study acceptable	Yes

### Executive Summary

The absorption and distribution of mecoprop-P (M CPP-p) was measured *in vitro* through human epidermis. The doses were applied as the concentrate formulation, nominally 600 g Mecoprop-P/L and as a 1/80 v/v aqueous spray strength dilution containing a nominal 7.5 g Mecoprop-P/L of the formulation in water. The doses were applied to the epidermal membranes at a rate of 10 µl/cm<sup>2</sup> and left unoccluded for an exposure period of 24 hours.

The spray strength dilution used represented a typical field application rate equivalent to 2.5 litre 600 g/L concentrate in 200 litres of water. These doses were designed to simulate potential human dermal exposure to the formulation during normal use. The absorption process was followed using [<sup>14</sup>C]-labelled mecoprop-P, which was incorporated into the formulation. The receptor fluid was sampled at frequent time intervals throughout the 24 hour exposure. Test material remaining on the skin at 24 hours was removed by gentle washing and quantified. Test material in the upper layers of the skin was quantified by a tape stripping technique. Material remaining in the membrane was also determined.

The distribution of mecoprop-P within the test system, a 24 hour absorption profile and absorption rate (µg/cm<sup>2</sup>/h) were determined. The samples were analysed by liquid scintillation counting (LSC). For both the concentrate and spray dilution, absorption was essentially linear over the entire 24 hour exposure period. Between 0-24 hours, the rate of mecoprop-P absorption was 1.64 and 0.16 µg/cm<sup>2</sup>/h for the concentrate and spray dilution, respectively.

The mean recovery of radio-labelled test material in these experiments was 119% and 97.5% of the applied dose for the concentrate and spray dilution, respectively. For both the concentrate and spray dilution, the majority of the applied dose (116% and 89.4%) was removed by gentle skin washing 24 hours after application. The proportion of the applied dose present in receptor fluid following a 24 hour exposure was 0.70% for the concentrate and 4.91% spray dilution. A total of 0.73% (concentrate) and 1.94% (spray strength dilution) of applied radioactivity remained in the membrane at termination. Of this total 0.11% (concentrate) and 0.29% (spray strength dilution) was found in the outer layers of the *stratum corneum* (first 2 tape strips).

The results obtained in the study indicate that the majority of the applied dose was removed by gentle skin washing at 24 hours. These data predict that the human dermal absorption of mecoprop-P from potential exposure to this SL formulation containing a nominal 600 g Mecoprop-P /L, either as the concentrate formulation or as a spray strength dilution, would be 1.64 or 0.16 µg/cm<sup>2</sup>/h respectively.

### MATERIALS AND METHODS

A	MATERIALS
Test materials:	Unlabelled mecoprop-P, 93.9% purity [ <sup>14</sup> C]-radiolabelled mecoprop-P, 99.7% purity
Description:	Beige solid
Lot/Batch:	Unlabelled: MH/06/03 Radiolabelled: SEL/1894
Vehicle and/or positive control:	Vehicle: Water, CTL ref no: Y04517/015
Test object:	Human skin from 2 donors
Source:	Obtained at surgery or <i>post mortem</i>

Storage:	Stored frozen at approximately -20°C on aluminium foil until required for use.
----------	--

B	STUDY DESIGN AND METHODS
Dose preparation:	<p>The doses were prepared to mimic the commercial 600 g/L Mecoprop-P formulation and its 1/80 v/v aqueous spray dilution.</p> <p>Concentrate formulation:</p> <p>The ethanol was removed from a volume of [<sup>14</sup>C]-radiolabelled mecoprop-P and mixed with 1120 mg unlabelled mecoprop-P and 32.7 mg chelating agent. Aqueous dimethylamine (DMA) was prepared by combining 383 mg water and 465 mg 60% DMA then added to the other ingredients and sonicated. Further aqueous DMA was added until it reached pH 9.0. 1.17 mg antifoam was added in accordance with the formulation specification.</p> <p>Spray strength dilution:</p> <p>The ethanol was removed from a volume of [<sup>14</sup>C]-radiolabelled mecoprop-P and mixed with 13.7 mg water and 16.6 mg 60% DMA, followed by 36.7 mg unlabelled mecoprop-P and 1.32 mg chelating agent. The preparation was then mixed thoroughly until homogeneous. Further 60% DMA was added until it reached pH 9.0, followed by 0.01 mg antifoam.</p>
Preparation of skin:	<p>Epidermal membranes were prepared by immersing skin samples in water at 60°C for 40-45 seconds; the epidermis was teased away from the dermis. Each epidermal membrane was stored at -20°C until use.</p> <p>Discs of prepared skin were mounted in diffusion cells and placed in a water bath at 32 ± 1°C.</p> <p>Membrane integrity was determined by measuring electrical resistance. Membranes measuring &lt;10 kΩ were regarded as having low integrity and were not used. This left six replicates from at least two different donors for each concentration tested.</p>
Application to the skin:	<p>Receptor chambers of the cells were filled with a recorded volume of receptor fluid (water) and placed in a water bath at 32 ± 1°C. A pre-treatment sample was taken from each receptor chamber for analysis by liquid scintillation counting (LSC). This volume was replaced prior to the start of the test.</p> <p>The formulations were then applied to the skin as the concentrate and as a 1/80 v/v aqueous dilution and left unoccluded for the duration of the 24 hour exposure period.</p>
Sampling:	<p>Samples of receptor fluid were taken at 1, 2, 3, 4, 6, 8, 10, 12, 16, 20 and 24 hours after application and were analysed by LSC. Upon removal of fluid the volume was maintained by replacing with an equal volume of receptor fluid.</p> <p>After the 24 hour exposure period the donor chamber was removed, washed with water and the sample analysed for mecoprop-P by LSC.</p> <p>After 24 hours the epidermal skin was swabbed with sponges then allowed to dry naturally and up to 5 strips of adhesive tape were pressed onto the skin surface and peeled off to remove the <i>stratum corneum</i>. The extracts were then soaked in Soluene 350® and analysed by LSC. The remaining epidermis was removed from the receptor chamber, digested in Soluene 350® and analysed.</p> <p>The receptors and grids were soaked in water and the washings retained in the event of poor recoveries being achieved.</p>

## RESULTS AND DISCUSSION

Solubility:	Mecoprop-P solubility in the receptor fluid (water) was acceptable up to a concentration of 1 mg/ml, which provided adequate solubility.
Membrane integrity and outliers:	Membranes with absorption profiles indicating that membrane integrity had become compromised during the experiment were excluded from the mean calculations. This led to the exclusion of one well for the concentrate giving a total of 5 replicates for the concentrate and 6 replicates for the spray dilution. The RMS has seen the original data and agrees that this was an outlier due to the fact that the first receptor fluid sample taken one hour after dosing showed that 65% of the total absorption in 24 hours had already occurred – this very rapid absorption with no lag time suggests damage to the membrane. It should be noted that this study used epidermal membranes although the EFSA guidance recommends using split thickness skin as epidermal membranes can overestimate dermal absorption.
Relevant exposure time:	This study used a 24 hour exposure period. This is longer than the EFSA guidance which recommends 6 to 10 hour exposure representative of a typical working day. Therefore for the calculation of dermal absorption the amount of test substance in the receptor fluid after 8 hours has been used as the more relevant time point. The measurements of test substance in the skin were only measured at 24 hours so may slightly over-estimate absorption after 8 hours exposure.
Absorption:	For both the concentrate and the 1/80 v/v aqueous spray dilution, absorption was essentially linear. Between 0 and 24 hours the rate of mecoprop-P absorption was 1.64 and 0.16 µg/cm <sup>2</sup> /h for the concentrate and spray dilution, respectively.
Distribution:	<p>Recovery of the radiolabelled test material was 119 and 97.7% of the applied dose for the concentrate and the spray strength dilution, respectively. The recovery of the concentrate is higher than acceptable but most of this appears to be in the skin wash so is not thought to underestimate dermal absorption. The recovery of the dilution is acceptable.</p> <p>There was considerable variability between replicates as shown by the large standard deviations. Therefore for the final dermal absorption values the standard deviation has been added to the final mean value to take account of this variability.</p> <p>For both the concentrate and the spray strength dilution most of the mecoprop-P was removed by the gentle skin wash (116 and 89.4%, respectively). The remaining proportion recovered from the <i>stratum corneum</i> in the tape strips 1-5 was 0.23% and 0.6% for the concentrate and spray strength dilution, respectively. Thus leaving means of 0.50 and 1.34% remaining in the epidermal tissue.</p> <p>A total of 0.73% (concentrate) and 1.94% (spray strength dilution) of the applied dose remained in the epidermal membrane after the 24 hour exposure. Of this total 0.11% (concentrate) and 0.29% (spray strength dilution) was present in the first two tape strips of the <i>stratum corneum</i> and can be excluded from the absorbed dose.</p> <p>The proportion of the applied dose present in the receptor fluid after 24 hour exposure was 0.70% and 5.09% for the concentrate and spray strength dilution, respectively.</p> <p>The proportion of the applied dose present in the receptor fluid after 8 hours exposure was 0.09% and 1.52% for the concentrate and spray dilution respectively and is more representative of the exposure period of a typical working day for operators and workers.</p> <p>Dermal absorption after 8 hours exposure = radioactivity in receptor fluid content at 8 hours, plus tape strips 3-5 and remaining epidermis measured at 24 hours. The standard deviation is added to the mean and the final values rounded.</p>

Table B.6. 10 Summary of dermal absorption of the formulation Mecoprop 600g/L applied to human epidermal membranes in vitro

Tested concentration	Concentrate 600g/L mecoprop-p				Dilution 1/80 v/v containing 7.5g/L mecoprop-P			
	ug/cm2 5996		%		ug/cm2 75.5		%	
total applied dose	mean	sd	mean	sd	mean	sd	mean	sd
donor chamber	65.91	106.66	1.10	1.78	0.94	1.00	1.24	1.32
skin wash	6982.60	347.66	116.45	5.80	67.52	2.00	89.19	2.64
tape strips 1-2	6.88	3.67	0.11	0.06	0.22	0.13	0.29	0.18
tape strips 3-5	7.11	3.15	0.12	0.05	0.23	0.11	0.31	0.15
remaining epidermis	29.7	21.3	0.50	0.36	1.01	0.33	1.33	0.44
receptor fluid (at 8 hours)*	5.36	6.35	0.09	0.11	1.15	0.45	1.52	0.60
total recovery	7134.23	235.32	118.98	3.92	73.73	1.38	97.66	1.82
total absorbed dose	42.18	30.85	0.70	0.51	2.39	0.90	3.16	1.19
Adjusted dermal absorption value where sd >25% of man (= mean + sd)	1.22% rounded to 1%				4.35% rounded to 4%			

sd = standard deviation

\* 8 hours is most representative of exposure of workers and operators, all other measurements were taken at 24 hours

### CONCLUSIONS

The dermal absorption of the formulation Mecoprop-P 600g/L was 1% for the 600g/L concentrate and 5% for the 1/80 dilution (7.5g/L mecoprop-P).

*Applicant: Proposed dermal absorption of 0.71% for concentrate and 3.17% for dilution as they did not add on the standard deviation to account for variability.*

### B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS

Refer to RAR Volume 4 Confidential information.

## B.6.4. EXPOSURE DATA

### B.6.4.1. Operator Exposure

A summary of the application parameters pertinent to the operator, bystander, resident and worker exposure assessment for ‘Mecoprop-P K 600’ are presented below.

**Table B.6. 11 Summary of ‘Mecoprop-P K 600’ application parameters pertinent to the operator, bystander, resident and worker exposure assessment**

<b>‘Mecoprop-P K 600’</b>	
<b>Formulation type</b>	Soluble concentrate (SL), containing 600 g/L Mecoprop-P
<b>Use</b>	Cereal
<b>Application method</b>	Tractor-mounted/trailed field crop sprayer
<b>Max individual dose</b>	2 L product/ha (1.2 kg a.s./ha)
<b>Max total dose</b>	2 L product/ha/crop (1.2 kg a.s./ha)
<b>Application volume</b>	200 to 400 L/ha
<b>Number of applications</b>	1 per year
<b>Latest time of application</b>	BBCH 32
<b>Packaging</b>	1-20 L containers
<b>Classification in respect to human health</b>	H302- Harmful if swallowed H315- Causes skin irritation H318- Causes serious eye damage
<b>Systemic AOEL</b>	0.04 mg/kg bw/day
<b>Dermal absorption</b>	1% for the concentrate, 5% for the highest spray concentration (6 g a.s./litre of spray solution) and 10% for the lowest spray concentration (3 g a.s./litre of spray solution); please refer to section B.6.2 for further information on dermal absorption.

In respect to human health, the plant protection product ‘Mecoprop-P K 600’ is classified as H302 (harmful if swallowed), H315 (causes skin irritation) and H318 (causes serious eye damage). On the basis of the classification alone, the following personal protective equipment (PPE) is recommended

- Wear suitable protective clothing (coveralls), suitable protective gloves and face protection (faceshield) when handling the concentrate

Estimates of operator exposure have been conducted using the following models:

- UK POEM<sup>1</sup>
- German Model<sup>2</sup>

Operator exposure estimates for ‘Mecoprop-P K 600’ are summarised below and presented in full at the end of this section in Appendix 1.

#### B.6.4.1.1 Operator exposure estimates using UK POEM

As a realistic worst case, the use of a 10 litre container has been assumed.

Model: UK POEM

Scenario: Outdoor application to cereal

<sup>1</sup> Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992, 2007 version. (“UK POEM”).

<sup>2</sup> Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992. (“German Model”).

Application method: Field crop boom sprayer

Formulation type: Water based

Dose: 2 L product/ha

Work rate: 50 ha/day

Operator body weight: 60kg

Container: 10 L

Water volume: 200 L/ha

Duration of spraying: 6 hours

For the purpose of the operator risk assessment using UK POEM, the realistic worst case is to consider 2 L of product in 200 L of water with the corresponding dermal absorption value for the spray solution of 5% (i.e. the dermal absorption value corresponding to the 1 in 100 dilution).

**Table B.6. 12 Operator exposure to Mecoprop-P resulting from the use of ‘Mecoprop-P K 600’ on cereals (UK POEM for field crop boom sprayers)**

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure*	
Mix/loading	Application	Mix/loading	Application	mg/kg bw/day**	% of AOEL
<b>No PPE</b>					
300	249.3	Negligible	0.36	0.26375	659%
<b>Gloves during mixing/loading</b>					
15	249.3	Negligible	0.36	0.21625	541%
<b>Gloves during mixing/loading and application</b>					
15	38.7	Negligible	0.36	0.04075	102%
* Assuming a dermal absorption of 1% for the concentrate and 5% for the spray solution					
** Assuming a body weight of 60 kg					
AOEL Systemic AOEL of 0.04 mg/kg bw/day					

Based on UK POEM, the predicted level of operator exposure to mecoprop-P is calculated to be in excess of acceptable limits at 102% of the AOEL for an operator wearing gloves during mixing/loading and application.

#### B.6.4.1.2 Operator Exposure Estimates using the German Model

Model: German model

Scenario: Outdoor application to cereal

Application method: Field crop boom sprayer

Formulation type: Liquid

Dose: 2 L product/ha

Work rate: 20 ha/day

Operator body weight: 70kg

For the purpose of the operator risk assessment using the German model, a precautionary approach has been taken using the highest dermal absorption value for the spray solution of 10%. This approach was taken as the German model does not consider the spray concentration when calculating operator exposure.

**Table B.6. 13 Operator exposure to mecoprop-P resulting from the use of ‘Mecoprop-P K 600’ on cereals (German model for field crop boom sprayers)**

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure*	
Mix/loading	Application	Mix/loading	Application	mg/kg bw/day**	% of AOEL

No PPE					
57.6	48.96	0.0144	0.024	0.07872	197%
Gloves during mixing/loading					
0.576	48.96	0.0144	0.024	0.07057	176%
Gloves during mixing/loading and application					
0.576	39.93	0.0144	0.024	0.05768	144%
Gloves during mixing/loading, and gloves, coveralls and sturdy footwear during application					
0.576	3.45	0.0144	0.024	0.00556	14%
*	Assuming a dermal absorption of 1% for the concentrate and 10% for the spray solution				
**	Assuming a body weight of 70 kg				
AOEL	Systemic AOEL of 0.04 mg/kg bw/day				

Based on the German model, the predicted level of operator exposure to mecoprop-P is calculated to be within acceptable limits at 14% of the AOEL for an operator wearing gloves during mixing/loading, and gloves, coveralls and sturdy footwear during application.

#### B.6.4.2. Bystander and resident exposure

In the absence of a harmonised approach to bystander and resident exposure assessment throughout the EU, this evaluation presents calculations using the UK (CRD) approach.

##### B.6.4.2.1 Bystander and Resident Exposure to Vapour (UK approach)

Bystander and resident exposure to mecoprop-P resulting from the proposed use of ‘Mecoprop-P K 600’ is likely to result primarily from spray drift. However, as a worst case the level of bystander and resident exposure to mecoprop-P vapour following the application of ‘Mecoprop-P K 600’ can be estimated using a surrogate value for residues in air adjacent to treated crops, derived from Californian Environmental Protection Agency studies<sup>3</sup>. In these studies, a 24 ha orange orchard was treated with chlorpyrifos using broadcast air-assisted sprayers. During application, wind speeds ranged from 2 to 20 km/h and the maximum temperature was 42 °C. Chlorpyrifos residues in air adjacent to the orchard were monitored over 72 hours. The highest 24 hour time-weighted average residue in air was 15 µg/m<sup>3</sup>. For comparison, the vapour pressure of chlorpyrifos is 3.35 x 10<sup>-3</sup> Pa at 25°C and that of mecoprop-P is 1.4 x 10<sup>-3</sup> Pa at 25°C.

Bystander and resident exposure to vapour can be based on these measurements and assuming:

- a body weight of 60 kg for an adult (based on the 50th percentile value for females aged 16 to 24 years in 1995-7 Health Surveys for England);
- a body weight of 15 kg for a small child (based on the average value for male and female children aged 2 and 3 years in 1995-7 Health Surveys for England);
- a respired volume of 15.2 m<sup>3</sup>/day (based on mean values for the long term inhalation rate for adult males aged 19 to >65 years published in the United States Environmental Protection Agency (US EPA) Exposure Factors Handbook); and
- a respired volume of 8.3 m<sup>3</sup>/day (based on mean values for the long term inhalation rate for children aged 3 to 5 years published in the US EPA Exposure Factors Handbook);

On this basis, potential exposure to vapour is estimated to be 0.0038 mg/kg bw/day for an adult and 0.0083 mg/kg bw/day for a child.

<sup>3</sup> California Environmental Protection Agency, Air Resources Board (1998). Report for the application and ambient air monitoring for chlorpyrifos (and the oxon analogue) in Tulare County during spring/summer 1996

**Table B.6. 14 Bystander and resident exposure to mecoprop-P vapour resultant from the use of ‘Mecoprop-P K 600’ on cereals.**

Parameter	Systemic exposure to mecoprop-P	
	mg/kg bw/day	% of AOEL
Adult exposure	0.0038	10%
Child exposure	0.0083	21%

The predicted bystander and resident exposure to vapour is calculated to be 10% of the AOEL for an adult and 21% of the AOEL for a child for mecoprop-P. The calculated bystander and resident exposure to vapour values are within acceptable limits and no further assessment is required.

#### B.4.6.2.2 Bystander and Resident Exposure to Spray Drift

Bystander and resident exposure through dermal and inhalation exposure to spray drift can be estimated on the basis of direct measurements of simulated bystander and resident exposure for field crop sprayers in a UK study<sup>4</sup>.

In this study, a single pass of the sprayer resulted in a mean potential dermal exposure (PDE) of 0.1 ml of spray solution on a bystander positioned 8 m downwind from the edge of the treatment area. Mean potential inhalation exposure (PIE) was 0.006 ml of spray solution.

For the purpose of the bystander and resident exposure to drift assessment, the realistic worst case is to consider 2 L of product in 200 L of water with the corresponding dermal absorption value for the spray solution of 5% (i.e. the dermal absorption value corresponding to the 1 in 100 dilution).

Bystander and resident exposure to spray drift can be calculated using these values and assuming:

- The proposed use of ‘Mecoprop-P K 600’ involves a maximum concentration of 6 mg mecoprop-P per ml of spray solution;
- there is no exposure reduction from clothing;
- there is 5% dermal absorption of mecoprop-P from the spray solution and 100% absorption and retention of potential inhalation exposure; and
- the bystander has a body weight of 60 kg,

On this basis, total systemic bystander and resident exposure is calculated to be as follows.

$$\frac{(0.1 \text{ ml PDE} \times 6 \text{ mg/ml conc.} \times 5\% \text{ dermal abs.}) + (0.006 \text{ ml PIE} \times 6 \text{ mg/ml conc.})}{60 \text{ kg}}$$

= 0.0011 mg/kg bw (equivalent to 3% of the systemic AOEL of 0.04 mg/kg bw/day).

The predicted bystander and resident exposure to spray drift is calculated to be equivalent to 3% of the AOEL for mecoprop-P. The calculated bystander and resident exposure to spray drift value is within acceptable limits and no further assessment is required.

Although these estimates are based on a situation in which acute exposure to the spray solution occurs, as the levels of systemic exposure are compared with AOELs considered appropriate for assessing the risks associated with repeated exposures for operators, this exposure assessment is also relevant to situations of repeated bystander exposure to spray drift (for example, the exposure of residents in property adjoining sprayed crops).

#### B.4.6.2.3 Bystander and Resident Exposure to Drift Fallout (UK approach)

It is also possible that spray drift fallout may be deposited in gardens adjacent to the treated area and that users of these gardens may become exposed through contact with deposits.

<sup>4</sup> Lloyd G.A. and Bell G.J. (1983). Hydraulic nozzles: comparative spray drift study (MAFF/ADAS).

The following calculations predict the amount of mecoprop-P likely to be deposited in gardens next to the treated crop (due to fallout from spray drift) and the level of exposure likely to result when children playing in the garden are exposed through dermal, hand-to-mouth and object-to-mouth routes. Using a precautionary approach, the highest dermal absorption value for the spray solution of 10% has been used to calculate bystander and resident exposure to drift fallout. This approach was taken as this calculation does not consider the spray concentration.

Estimates of fallout from spray drift are based on the following published data.

- Rautmann, D., Strelke, M. and Winkler, R. (2001). New basic drift values in the authorisation procedure for plant protection Products. In Forster, R. and Strelke, M. Workshop on risk assessment and risk mitigation measures in the context of the authorisation of plant protection Products (WORMM). Mitt. Biol. Bundesanst. Land-Forstwirtschaft. Berlin-Dahlem, Heft 381.

Exposure estimates for children playing on contaminated turf are based on the following published data.

- USA EPA (1998). Occupational and residential exposure test guidelines: Group B, Post-application exposure monitoring test guidelines. Series 875 v 5.4.
- USA EPA (2001). Recommended revisions to the standard operating procedures (SOPs) for residential exposure assessment. Science Advisory Council for Exposure Policy, 12.
- USA EPA (1999). Overview of issues related to the standard operating procedures for residential exposure assessment. Presentation to the FIFRA Scientific Appraisal Panel.

#### Spray drift fallout for field crop sprayers

Allowing for an untreated headland of 1 m, the level of fallout from spray drift at the boundary with a neighbouring area is predicted to be equivalent to 2.77% of the applied dose. This level of fallout is predicted to decline to 0.57% at a distance of 5 m from the boundary. By integration, the average level of fallout over the whole area from the boundary to a point 3 m outside is estimated to be about 1%.

#### Children's dermal exposure

A child's systemic exposure resulting from dermal contact with a lawn contaminated by spray drift during the application of 'Mecoprop-P K 600' is calculated as follows.

$$SE(d) = (AR \times DF \times TTR \times TC \times H \times DA) / BW$$

Where:

- SE(d) = Systemic exposure via the dermal route  
 AR = total application rate of a.s. in  $\mu\text{g}/\text{cm}^2$  (= 10x rate in kg a.s./ha)  
 DF = drift fallout value of 1% of the applied dose for boom sprayers  
 TTR = turf transferable residue value of 5% (EPA default value)  
 TC = transfer coefficient of 5200  $\text{cm}^2/\text{h}$  (standard EPA value for this situation)  
 H = duration of exposure of 2 hours per day (standard EPA 75th percentile value)  
 DA = dermal absorption of the a.s. in the spray solution  
 BW = body weight of 15 kg

For mecoprop-P:

$$SE(d) = (12 \mu\text{g a.s.}/\text{cm}^2 \times 1\% \times 5\% \times 5200 \text{ cm}^2/\text{h} \times 2\text{h}/\text{d} \times 10\%) / 15 \text{ kg bw}$$

$$= 0.416 \mu\text{g}/\text{kg bw}/\text{d}$$

#### Children's hand-to-mouth exposure

Additional systemic exposure to mecoprop-P resulting from ingestion of turf residues transferred from contaminated hands to the mouth is calculated as follows.

$$SE(h) = (AR \times DF \times TTR \times (SE/100) \times SA \times \text{Freq} \times H) / BW$$

Where:

- SE(h) = Systemic exposure via the hand-to-mouth route

AR = total application rate of a.s. in  $\mu\text{g}/\text{cm}^2$  (= 10x rate in kg a.s./ha)  
 DF = drift fallout value of 1% of the applied dose for boom sprayers  
 TTR = turf transferable residue value of 5% (EPA default value for wet hands)  
 SE = saliva extraction factor of 50% (EPA default value)  
 SA = surface area of the hands in contact with the mouth (the value of 20  $\text{cm}^2$ /event represents the palmar surface of three fingers)  
 Freq = frequency of hand to mouth events/hour (the value of 20 events/hour is the 90th percentile of observations ranging from 0 to 70 events/hour)  
 H = duration of exposure of 2 hours per day (standard EPA 75th percentile value)  
 BW = body weight of 15 kg

For mecoprop-P :

$$\text{SE(h)} = (12 \mu\text{g a.s./cm}^2 \times 1\% \times 5\% \times 50\% \times 20 \text{ cm}^2 \times 20/\text{h} \times 2\text{h/d}) / 15 \text{ kg bw}$$

$$= 0.160 \mu\text{g/kg bw/d}$$

#### Children's object-to-mouth exposure

Additional systemic exposure to mecoprop-P resulting from direct ingestion of turf residues is calculated as follows.

$$\text{SE(o)} = (\text{AR} \times \text{DF} \times \text{TTR} \times \text{IgR})/\text{BW}$$

Where:

SE(o) = Systemic exposure via mouthing activity  
 AR = total application rate of a.s. in  $\mu\text{g}/\text{cm}^2$  (= 10x rate in kg a.s./ha)  
 DF = drift fallout value of 1% of the applied dose for boom sprayers  
 TTR = turf transferable residue value of 20% (EPA default value for object-to-mouth assessments)  
 IgR = ingestion rate for mouthing of 25  $\text{cm}^2$  grass/day (EPA default value)  
 BW = body weight of 15 kg

For mecoprop-P:

$$\text{SE(o)} = (12 \mu\text{g a.s./cm}^2 \times 1\% \times 20\% \times 25 \text{ cm}^2) / 15 \text{ kg bw}$$

$$= 0.040 \mu\text{g/kg bw/d}$$

#### Children's total exposure

On the basis of the above estimates, the total systemic exposure for a child playing on a lawn contaminated by spray drift during the application of 'Mecoprop-P K 600' is calculated to be as follows.

Systemic exposure to mecoprop-P = 0.000616 mg/kg bw/day. This is equivalent to 2% of the AOEL of 0.04 mg/kg bw/day. This value is within acceptable limits and as such no further assessment is required for this route of exposure.

#### **B.6.4.3. Worker Exposure**

Estimates of worker exposure during crop inspection activities using the EUROPOEM II worker re-entry model<sup>5</sup> are presented below.

These estimates are based on the following assumptions.

Active substance	Maximum total dose (kg a.s./ha)	Latest time of application	Re-entry task	Transfer coefficient ( $\text{cm}^2/\text{h}$ )
Mecoprop-P	1.2	BBCH 32	Inspection	2500*

<sup>5</sup> van Hemmen et al (2002). Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group, EUROPOEM II project: FAIR3-CT96-1406US EPA (2000). Policy paper on agricultural transfer coefficients.

\* A transfer coefficient (TC) value of 2500 cm<sup>2</sup> is considered appropriate for crop inspection activities for cereals at a growth stage of ≤ BBCH 32 where it is assumed that individuals are wearing long sleeved shirt and trousers but the hands are bare.

In accordance with the EUROPOEM II worker re-entry model, the following worst-case assumptions have been used:

Maximum total dose for ‘Mecoprop-P K 600’(R):	As above
Initial dislodgeable foliar residue (DFR):	3 µg/cm <sup>2</sup> x R
Task-related transfer coefficient (TC):	As above
Duration of task (A):	
Crop inspection	2 h/day

On this basis, the potential dermal exposure ( $D = DFR \times TC \times A$ ) and systemic exposure (assuming a precautionary dermal absorption value for dry transferred foliar residues of 10% for mecoprop-P and a worker body weight of 60 kg) are estimated to be as follows for an unprotected worker.

Active substance	Dermal exposure (µg/person)	Systemic exposure (mg/kg bw/day)	% of AOEL *
Mecoprop-P	18000	0.03	75%
* 0.04 mg/kg bw/day			

This estimate predicts that the proposed use of ‘Mecoprop-P K 600’ will result in an acceptable level of systemic exposure to mecoprop-P (75% of the AOEL) for a worker inspecting treated crops wearing no PPE.

### B.6.5. EXPOSURE AND RISK ASSESSMENT

Operator exposure estimates based on the German Model predict that the proposed use of ‘Mecoprop-P K 600’ through field crop sprayers will result in a level of systemic exposure to mecoprop-P equivalent to 14% of the AOEL for an operator wearing gloves during mixing/loading, and gloves, coveralls and sturdy footwear during application. According to UK POEM operator exposure to mecoprop-P is predicted to be in excess of acceptable limits at 102% of the AOEL for an operator wearing gloves during mixing/loading and application.

On the basis of the German model estimates and considering the classification of the formulation with respect to human health, the risk to operators resulting from the proposed use of ‘Mecoprop-P K 600’ is considered to be acceptable for an operator wearing coveralls, gloves and face protection when mixing/loading, and gloves, coveralls and sturdy footwear during application. An acceptable level of risk to operators from the proposed use of ‘Mecoprop-P K 600’ cannot be demonstrated using UK POEM.

The UK approach predicts that the proposed use of ‘Mecoprop-P K 600’ will result in the following levels of systemic exposure to mecoprop-P for unprotected bystanders and residents:

- Vapour exposure to an adult = 10% of the AOEL
- Vapour exposure to a child = 21% of the AOEL
- Drift exposure = 3% of the AOEL
- Children’s exposure to fallout = 2% of the AOEL

On the basis of these estimates, the level of exposure for unprotected bystanders and residents resulting from the proposed use of ‘Mecoprop-P K 600’ is considered to be acceptable.

Worker exposure estimates using the EUROPOEM II worker re-entry model predict that the proposed use of 'Mecoprop-P K 600' will result in a level of systemic exposure to mecoprop-P equivalent to 75% of the AOEL for a worker entering treated areas to carry out crop inspection activities wearing no PPE.

On the basis of these estimates, the level of exposure for unprotected workers entering and handling crops treated with 'Mecoprop-P K 600' is considered to be within acceptable limits.

### B.6.6. REFERENCES RELIED ON

See Volume 3 CA Section B.6.10 for details of the literature search.

The references relied on list has been updated to include the newly submitted data relied on as well as those original submitted tests and studies (in *italics*) that are still considered relevant to support the application for 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
CP 7.1.1/01	██████ ██████	1994a	<i>Study on the acute oral toxicity of BAS 037 32 H in Rats</i> ██████ ██████ ██████ ██████ GLP Not published	Y	N	N/A	Nufarm	In 1998 DAR
CP 7.1.2/01	██████ ██████	1994b	<i>Study on the acute dermal toxicity of BAS 037 32 H in Rats</i> ██████ ██████ ██████ ██████ GLP Not published	Y	N	N/A	Nufarm	In 1998 DAR
CP 7.1.3/01	██████ ██████ ██████	1994	<i>Study on the acute inhalation toxicity LC<sub>50</sub> of BAS 037 32 H as a liquid aerosol in rats 4 hour exposure</i>	Y	N	(However used in UK national assessment – data protection)	Nufarm	In 1998 DAR

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
			██████████ ██████████ ██████████ ██████████ GLP Not published		expires 27/01/19)			
CP 7.1.4/01	██████████ ██████████ ██████████	1994a	Study on the acute dermal irritation/corro sion of BAS 037 32 H in the Rabbit ██████████ ██████████ ██████████ ██████████ GLP Not published	Y	N	N/A	Nufarm	In 1998 DAR
CP 7.1.5/01	██████████ ██████████ ██████████	1994b	Study on the acute eye irritation of BAS 037 32 H in the Rabbit ██████████ ██████████ ██████████ ██████████ GLP Not published	Y	N	N/A	Nufarm	In 1998 DAR
CP 7.1.6/01	██████████ ██████████	1995	Skin Sensitisation Test in Guinea- Pigs Modified Buehler Test: 9 applications ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ Report No. ██████████ ██████████ GLP	Y	N	(However used in UK national assessment – data protection expires 27/01/19)	Nufarm	In 1998 DAR

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
			<i>Not published</i>					
CP 7.1.6/02	██████████ ██████████	1998	Optica: Skin Sensitisation Study after Magnusson and Kligman and amendment ██████████ ██████████ GLP Not published	Y	N  <i>(However used in UK national assessment – data protection expires 27/01/19)</i>	N/A	Nufarm	Previously evaluated by the UK for the product Optica (HSE ref M09963 COP 2006/01151.
CP 7.3/01	██████████	2006	Mecoprop-p: In vitro Absorption from a Formulation through Human Epidermis ██████████ ██████████ GLP Not published	Y	Y  <i>(However used in UK national assessment – data protection expires 27/01/19)</i>	Newly submitted data	Nufarm	Submitted for the purposes of renewal

**APPENDIX 1: OPERATOR EXPOSURE CALCULATIONS****Estimate 1: UK POEM estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing no PPE****THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)**

Application method			
Product	<b>Mecoprop-P K 600</b>	Active substance	<b>mecoprop-P</b>
Formulation type		a.s. concentration	<b>600 mg/ml</b>
Dermal absorption from product	<b>1 %</b>	Dermal absorption from spray	<b>5 %</b>
Container			
PPE during mix/loading		PPE during application	
Dose	<b>2 l/ha</b>	Work rate/day	<b>50 ha</b>
Application volume	<b>200 l/ha</b>	Duration of spraying	<b>6 h</b>

**EXPOSURE DURING MIXING AND LOADING**

Container size	10 litres
Hand contamination/operation	0.05 ml
Application dose	2 litres product/ha
Work rate	50 ha/day
Number of operations	10 /day
Hand contamination	0.5 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.5 ml/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Application volume	200	spray/ha	
Volume of surface contamination	10	ml/h	
Distribution	Hands	Trunk	Legs
	65%	10%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	5%	15%
Dermal exposure	6.5	0.05	0.375 ml/h
Duration of exposure	6	h	
Total dermal exposure to spray	41.55	ml/day	

**ABSORBED DERMAL DOSE**

	Mix/load	Application	
Dermal exposure	0.5 ml/day		41.55 ml/day
Concen. of a.s. product or spray	600 mg/ml		6 mg/ml
Dermal exposure to a.s.	300 mg/day		249.3 mg/day
Percent absorbed	1 %		5 %
Absorbed dose	3 mg/day		12.465 mg/day

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure	0.01 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	6 mg/ml
Inhalation exposure to a.s.	0.36 mg/day
Percent absorbed	100 %
Absorbed dose	0.36 mg/day

**PREDICTED EXPOSURE**

Total absorbed dose	15.825 mg/day
Operator body weight	60 kg
Operator exposure	0.26375 mg/kg bw/day

AOEL	0.04 mg/kg bw/day
% AOEL	659.375

Estimate 2: UK POEM estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing gloves when handling the concentrate

**THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)**

Application method			
Product	Mecoprop-P K 600	Active substance	mecoprop-P
Formulation type		a.s. concentration	600 mg/ml
Dermal absorption from product	1 %	Dermal absorption from spray	5 %
Container			
PPE during mix/loading		PPE during application	
Dose	2 l/ha	Work rate/day	50 ha
Application volume	200 l/ha	Duration of spraying	6 h

**EXPOSURE DURING MIXING AND LOADING**

Container size	10 litres
Hand contamination/operation	0.05 ml
Application dose	2 litres product/ha
Work rate	50 ha/day
Number of operations	10 /day
Hand contamination	0.5 ml/day
Protective clothing	Gloves
Transmission to skin	5 %
Dermal exposure to formulation	0.025 ml/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Application volume	200	spray/ha	
Volume of surface contamination	10	ml/h	
Distribution	Hands	Trunk	Legs
	65%	10%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	5%	15%
Dermal exposure	6.5	0.05	0.375 ml/h
Duration of exposure	6	h	
Total dermal exposure to spray	41.55	ml/day	

**ABSORBED DERMAL DOSE**

	Mix/load	Application	
Dermal exposure	0.025 ml/day	41.55 ml/day	
Concen. of a.s. product or spray	600 mg/ml	6 mg/ml	
Dermal exposure to a.s.	15 mg/day	249.3 mg/day	
Percent absorbed	1 %	5 %	
Absorbed dose	0.15 mg/day	12.465 mg/day	

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure	0.01 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	6 mg/ml
Inhalation exposure to a.s.	0.36 mg/day
Percent absorbed	100 %
Absorbed dose	0.36 mg/day

**PREDICTED EXPOSURE**

Total absorbed dose	12.975 mg/day
Operator body weight	60 kg
Operator exposure	0.21625 mg/kg bw/day
AOEL	0.04 mg/kg bw/day
% AOEL	540.625

Estimate 3: UK POEM estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing gloves when handling the concentrate and contaminated surfaces

**THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)**

Application method			
Product	<b>Mecoprop-P K 600</b>	Active substance	<b>mecoprop-P</b>
Formulation type		a.s. concentration	<b>600 mg/ml</b>
Dermal absorption from product	<b>1 %</b>	Dermal absorption from spray	<b>5 %</b>
Container			
PPE during mix/loading		PPE during application	
Dose	<b>2 l/ha</b>	Work rate/day	<b>50 ha</b>
Application volume	<b>200 l/ha</b>	Duration of spraying	<b>6 h</b>

**EXPOSURE DURING MIXING AND LOADING**

Container size	10 litres
Hand contamination/operation	0.05 ml
Application dose	2 litres product/ha
Work rate	50 ha/day
Number of operations	10 /day
Hand contamination	0.5 ml/day
Protective clothing	Gloves
Transmission to skin	5 %
Dermal exposure to formulation	0.025 ml/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Application volume	200 spray/ha		
Volume of surface contamination	10 ml/h		
Distribution	Hands	Trunk	Legs
	65%	10%	25%
Clothing	Gloves	Permeable	Permeable
Penetration	10%	5%	15%
Dermal exposure	0.65	0.05	0.375 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	6.45 ml/day		

**ABSORBED DERMAL DOSE**

	Mix/load	Application
Dermal exposure	0.025 ml/day	6.45 ml/day
Concen. of a.s. product or spray	600 mg/ml	6 mg/ml
Dermal exposure to a.s.	<b>15 mg/day</b>	<b>38.7 mg/day</b>
Percent absorbed	1 %	5 %
Absorbed dose	0.15 mg/day	1.935 mg/day

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure	0.01 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	6 mg/ml
Inhalation exposure to a.s.	<b>0.36 mg/day</b>
Percent absorbed	100 %
Absorbed dose	0.36 mg/day

**PREDICTED EXPOSURE**

Total absorbed dose	2.445 mg/day
Operator body weight	60 kg
Operator exposure	<b>0.04075 mg/kg bw/day</b>
AOEL	0.04 mg/kg bw/day
% AOEL	<b>101.875</b>

Estimate 4: German model estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing no PPE

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method				
Product	Mecoprop-P K 600		Active substance	mecoprop-P
Formulation type			a.s. concentration	600 g/l
Dermal absorption from product	1 %		Dermal absorption from spray	10 %
RPE during mix/loading			RPE during application	
PPE during mix/loading				
PPE during application:	Head		Hands	Body
Dose	2 l product/ha		Work rate/day	20 ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4 mg/kg a.s.
Hand contamination/day	57.6 mg/day
Protective clothing	none
Transmission to skin	100 %
Dermal exposure to a.s.	57.6 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006 mg/kg a.s.
Inhalation exposure/day	0.0144 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.0144 mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
	Head	Hands	Rest of body
Dermal contamination/kg a.s.	0.06	0.38	1.6
Dermal contamination/day	1.44	9.12	38.4
Protective clothing	none	none	none
Transmission to skin	100	100	100 %
Total dermal exposure to a.s.	48.96 mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001 mg/kg a.s.
Inhalation exposure/day	0.024 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.024 mg/day

ABSORBED DOSE

	Mix/load	Application
Dermal exposure to a.s.	57.6 mg/day	48.96 mg/day
Percent absorbed	1 %	10 %
Absorbed dose (dermal route)	0.576 mg/day	4.896 mg/day
Inhalation exposure to a.s.	0.0144 mg/day	0.024 mg/day
Total systemic exposure	0.5904 mg/day	4.92 mg/day

PREDICTED EXPOSURE

Total systemic exposure	5.5104 mg/day
Operator body weight	70 kg
Operator exposure	0.07872 mg/kg bw/day
AOEL	0.04 mg/kg bw/day
% AOEL	196.8

Estimate 5: German model estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing gloves when handling the concentrate

**THE GERMAN MODEL (GEOMETRIC MEAN VALUES)**

Application method				
Product	<b>Mecoprop-P K 600</b>		Active substance	<b>mecoprop-P</b>
Formulation type			a.s. concentration	<b>600 g/l</b>
Dermal absorption from product	<b>1 %</b>		Dermal absorption from spray	<b>10 %</b>
RPE during mix/loading			RPE during application	
PPE during mix/loading				
PPE during application: Head		Hands		Body
Dose	<b>2 l product/ha</b>	Work rate/day		<b>20 ha</b>

**DERMAL EXPOSURE DURING MIXING AND LOADING**

Hand contamination/kg a.s.	2.4 mg/kg a.s.
Hand contamination/day	57.6 mg/day
Protective clothing	gloves
Transmission to skin	1 %
Dermal exposure to a.s.	0.576 mg/day

**INHALATION EXPOSURE DURING MIXING AND LOADING**

Inhalation exposure/kg a.s.	0.0006 mg/kg a.s.
Inhalation exposure/day	0.0144 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.0144 mg/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
	Head	Hands	Rest of body
Dermal contamination/kg a.s.	0.06	0.38	1.6
Dermal contamination/day	1.44	9.12	38.4
Protective clothing	none	none	none
Transmission to skin	100	100	100 %
Total dermal exposure to a.s.	48.96 mg/day		

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure/kg a.s.	0.001 mg/kg a.s.
Inhalation exposure/day	0.024 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.024 mg/day

**ABSORBED DOSE**

	Mix/load	Application
Dermal exposure to a.s.	0.576 mg/day	48.96 mg/day
Percent absorbed	1 %	10 %
Absorbed dose (dermal route)	0.00576 mg/day	4.896 mg/day
Inhalation exposure to a.s.	0.0144 mg/day	0.024 mg/day
Total systemic exposure	0.02016 mg/day	4.92 mg/day

**PREDICTED EXPOSURE**

Total systemic exposure	4.94016 mg/day
Operator body weight	70 kg
Operator exposure	0.070573714 mg/kg bw/day
AOEL	0.04 mg/kg bw/day
% AOEL	176.4342857

Estimate 6: German model estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing gloves when handling the concentrate and during application

**THE GERMAN MODEL (GEOMETRIC MEAN VALUES)**

Application method				
Product	<b>Mecoprop-P K 600</b>		Active substance	<b>mecoprop-P</b>
Formulation type			a.s. concentration	<b>600 g/l</b>
Dermal absorption from product	<b>1 %</b>		Dermal absorption from spray	<b>10 %</b>
RPE during mix/loading			RPE during application	
PPE during mix/loading				
PPE during application:	Head		Hands	Body
Dose	<b>2 l product/ha</b>		Work rate/day	<b>20 ha</b>

**DERMAL EXPOSURE DURING MIXING AND LOADING**

Hand contamination/kg a.s.	2.4 mg/kg a.s.
Hand contamination/day	57.6 mg/day
Protective clothing	gloves
Transmission to skin	1 %
Dermal exposure to a.s.	0.576 mg/day

**INHALATION EXPOSURE DURING MIXING AND LOADING**

Inhalation exposure/kg a.s.	0.0006 mg/kg a.s.
Inhalation exposure/day	0.0144 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.0144 mg/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
	Head	Hands	Rest of body
Dermal contamination/kg a.s.	0.06	0.38	1.6
Dermal contamination/day	1.44	9.12	38.4
Protective clothing	none	gloves	none
Transmission to skin	100	1	100 %
Total dermal exposure to a.s.	39.9312 mg/day		

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure/kg a.s.	0.001 mg/kg a.s.
Inhalation exposure/day	0.024 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.024 mg/day

**ABSORBED DOSE**

	Mix/load	Application
Dermal exposure to a.s.	0.576 mg/day	39 9312 mg/day
Percent absorbed	1 %	10 %
Absorbed dose (dermal route)	0.00576 mg/day	3.99312 mg/day
Inhalation exposure to a.s.	0.0144 mg/day	0.024 mg/day
Total systemic exposure	0.02016 mg/day	4.01712 mg/day

**PREDICTED EXPOSURE**

Total systemic exposure	4.03728 mg/day
Operator body weight	70 kg
Operator exposure	0.057675429 mg/kg bw/day
AOEL	0.04 mg/kg bw/day
% AOEL	144.1885714

Estimate 7: German model estimate for an operator applying ‘Mecoprop-P K 600’ through a field crop boom sprayer wearing gloves when handling the concentrate, and gloves, coveralls and sturdy footwear during application

**THE GERMAN MODEL (GEOMETRIC MEAN VALUES)**

Application method			
Product	Mecoprop-P K 600	Active substance	mecoprop-P
Formulation type		a.s. concentration	600 g/l
Dermal absorption from product	1 %	Dermal absorption from spray	10 %
RPE during mix/loading		RPE during application	
PPE during mix/loading			
PPE during application:	Head	Hands	Body
Dose	2 l product/ha	Work rate/day	20 ha

**DERMAL EXPOSURE DURING MIXING AND LOADING**

Hand contamination/kg a.s.	2.4 mg/kg a.s.
Hand contamination/day	57.6 mg/day
Protective clothing	gloves
Transmission to skin	1 %
Dermal exposure to a.s.	0.576 mg/day

**INHALATION EXPOSURE DURING MIXING AND LOADING**

Inhalation exposure/kg a.s.	0.0006 mg/kg a.s.
Inhalation exposure/day	0.0144 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.0144 mg/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
	Head	Hands	Rest of body
Dermal contamination/kg a.s.	0.06	0.38	1.6
Dermal contamination/day	1.44	9.12	38.4
Protective clothing	none	gloves	coverall and sturdy footwear
Transmission to skin	100	1	5 %
Total dermal exposure to a.s.	3.4512	mg/day	

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure/kg a.s.	0.001 mg/kg a.s.
Inhalation exposure/day	0.024 mg/day
RPE	none
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.024 mg/day

**ABSORBED DOSE**

	Mix/load	Application
Dermal exposure to a.s.	0.576 mg/day	3.4512 mg/day
Percent absorbed	1 %	10 %
Absorbed dose (dermal route)	0.00576 mg/day	0.34512 mg/day
Inhalation exposure to a.s.	0.0144 mg/day	0.024 mg/day
Total systemic exposure	0.02016 mg/day	0.36912 mg/day

**PREDICTED EXPOSURE**

Total systemic exposure	0.38928 mg/day
Operator body weight	70 kg
Operator exposure	0.005561143 mg/kg bw/day
AOEL	0.04 mg/kg bw/day
% AOEL	13.90285714