

European Commission



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

Mecoprop-P

**Volume 3 – B.9 (PPP) – Mecoprop-P K 600 g/L
(CA3015)**

**Rapporteur Member State : United Kingdom
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Table of contents

B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES	4
B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES	5
B.9.1.1. Effects on birds.....	5
B.9.1.2. Effects on terrestrial vertebrates other than birds	6
B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES	13
B.9.3. EFFECTS ON AQUATIC ORGANISMS.....	23
B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes.....	23
B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms	50
B.9.3.3. Further testing on aquatic organisms.....	50
B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS.....	50
B.9.5. EFFECTS ON ARTHROPODS	63
B.9.5.1. Effects on bees.....	63
B.9.5.2. Effects on non-target arthropods other than bees	64
B.9.6. RISK ASSESSMENT FOR ARTHROPODS.....	76
B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA	81
B.9.7.1. Earthworms	81
B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms)	81
B.9.8. RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA	89
B.9.9. EFFECTS ON SOIL NITROGEN TRANSFORMATION	90
B.9.10. RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION.....	90
B.9.11. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS.....	90
B.9.11.1. Summary of screening data	90
B.9.11.2. Testing on non-target plants	91
B.9.11.3. Extended laboratory studies on non-target plants.....	95
B.9.11.4. Semi-field and field tests on non-target plants	95
B.9.12. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS.....	105
B.9.13. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA).....	109
B.9.14. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA).....	109
B.9.15. REFERENCES RELIED ON.....	110

B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

This document has been updated under the active substance renewal process under Regulation 844/2012. All new studies conducted with the representative formulation identified for renewal of the active substance; Mecoprop-P are included in summary form below. Some old studies from the original EU review of the active substance are also included in the original summary form. Any subsequent consideration of these studies by the RMS for renewal purposes is clearly noted in the supporting summary.

Guidance used in this Assessment Report to conduct the environmental risk assessments for the purpose of renewal are as follows:

- Guidance of EFSA : Risk Assessment for Birds and Mammals: EFSA Journal 2009; 7(12):1438
- Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC: Sanco/3268/2001
- Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters: EFSA Journal 2013;11(7):3290
- Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods ESCORT II (2000)
- Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC: SANCO/10329/2002

Background information

The representative product, 'Mecoprop-p K 600 g/L' (CA3015) is a soluble concentrate (SL) formulation and was not the representative product supported by Nufarm UK in Annex I. Nufarm have since acquired AH Marks and thus have access to the AH Marks data, the representative product was Optica containing 600 g/L mecoprop-P. The primary representative product for the BAS workforce was Duplosan KV containing 600 g/L Mecoprop-P (AKA BAS 037 29 H). Note that studies conducted on Optica and Duplosan KV are applicable to the product Mecoprop-P K 600 g/L, as identified by the RMS in Volume 3 CP B.2 of this renewal assessment report.

Mecoprop (racemic) is a mixture of 2 enantiomeric isomers of mecoprop; the D-form is known as mecoprop-P and is the herbicidally active version. It is also known as mecoprop-P (D form), MCPP-P or it can exist in a dimethylamine salt form, referred to as MCPP-P (DMAS), or (DMA Salt). As the active substance in the case of this renewal assessment report is confirmed as the herbicidally active MCPP-P, endpoints from studies with the racemic mixture or with the DMA Salt are suitable for generation of relevant data with the active substance, but all endpoints should be expressed in terms of MCPP-P content for use in the regulatory risk assessments.

The proposed GAP for the representative product is summarised in Table B.9-01

Table B.9-01: Summary of the proposed uses of 'Mecoprop-P K 600 g/L'

Target crop	Crop growth stage at application (range)	Number of applications	Application interval [days]	Maximum application rate (L product/ha)	Maximum individual rate, (kg a.s./ha)
Winter Cereals Wheat (including durum and spelt), Barley, Rye, Oats,	BBCH 20-32 (spring applied 01/03 onwards)	1	N/A	2.0	1.2

Triticale					
Spring Cereals Wheat (including durum and spelt), Barley, Rye, Oats, Triticale	BBCH 13-32 (spring applied 01/03 onwards)	1	N/A	2.0	1.2

Table B.9-02: Potentially ecotoxicologically relevant metabolites

Compartment	Residue Definition
Soil	Mecoprop-P
Groundwater	Mecoprop-P
Surface water	Mecoprop-P; O-cresol
Sediment	Mecoprop-P
Air	Mecoprop-P

Analytical verification if studies submitted for renewal

For the purposes of active substance review under the new data requirements for EU Regulation 1107/2009 (as outlined in Regulation 283/2013 and Regulation 284/2013) it is a requirement to present the details and supporting validation data for pre-registration methods. Such methods are evaluated for the studies submitted in support of the renewal of Mecoprop-P in Volume 3 section B.5.1.2.6 of the active substance (CA) and product (CP) Assessment Reports.

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES**B.9.1.1. Effects on birds**

The avian toxicity data are summarised in table B.9.1.1-01. The associated active substance studies are provided in summary form in the Volume 3 CA – B.9 (AS) Renewal Assessment Report, section B.9.1.1.1.

Table B.9.1.1-01: Toxicity endpoints for birds

Test substance	Endpoint	Species	Toxicity	Reference
Mecoprop-P	Acute LD ₅₀	<i>C.virginianus</i>	>500 mg a.s./kg bw	██████ (1986a)
Mecoprop-P	Acute LD ₅₀	<i>C.virginianus</i>	500 mg a.s./kg bw	██████ (1987)
Mecoprop-P DMAS	Acute LD ₅₀	<i>C.virginianus</i>	602 mg a.s./kg bw (as DMAS) 497 mg a.s./kg bw (as MCPP-P)	██████ (1992a)
Mecoprop-P	Acute LD ₅₀	<i>C.virginianus</i>	648 mg a.s./kg bw	██████ (1995)
Mecoprop-P DMAS	Dietary LD ₅₀	<i>C.virginianus</i>	>861.5 mg a.s./kg bw/day (as DMAS) >712.2 mg a.s./kg bw/day (as MCPP-P)	██████ (1992b)
Mecoprop-P DMAS	Dietary LD ₅₀	<i>A. platyrhynchos</i>	>1051.7 mg a.s./kg bw/day (as DMAS) >876.4 mg a.s./kg bw/day (as MCPP-P)	██████ (1996)
Mecoprop-P DMAS	Reproductive NOEL	<i>C.japonica</i> ¹	85.8 mg a.s./kg bw/day (as DMAS) 70.9 mg a.s./kg bw/day (as MCPP-P)	██████ (1999)

¹Lower endpoint from male and female birds reported as relevant endpoint from study

Choice of acute endpoint for use in the risk assessment

There are 4 available acute toxicity studies with valid endpoints reported in terms of Mecoprop-P (acid). All four studies were conducted with the same avian species, and utilised the same test guideline; US EPA 71-1. As such it is appropriate to make use of a geometric mean acute endpoint from the four studies, in accordance with the EFSA Bird and Mammal Risk Assessment Guidance Document¹. The Geometric mean acute LD₅₀ is calculated to be 532.7 mg a.s./kg bodyweight, expressed in terms of Mecoprop-P.

As mortality occurred in the limit dose tested in some of the available acute avian studies it is not appropriate to extrapolate this acute endpoint. Although dietary toxicity is not directly considered in the current EFSA (2009) avian risk assessment scheme it may be used in a case-by-case higher tier assessment. The above available dietary toxicity studies do not indicate any greater toxicity to birds over that assessed in the acute studies.

Choice of Reproductive endpoint for use in the risk assessment

A single avian reproductive study is available (■■■■■■■■■■ 1999) and was originally considered in the first review of Mecoprop-P. Based on the original RMS conversion of the tested concentrations in food to be expressed in terms of pure DMA salt and MCP-P (acid), the RMS confirms the study endpoint in terms of substance per kg bodyweight per exposure day to be:

- 99.6 mg a.s./kg bw/day (males); 85.8 mg a.s./kg bw/day (females), as DMA salt
- 82.3 mg a.s./kg bw/day (males); 70.9 mg a.s./kg bw/day (females), as MCP-P

If the acute LD₅₀ endpoint when divided by a factor of 10 is lower than the reproductive endpoint then this should be used in preference to the NOEL in the avian reproductive risk assessment. The agreed LD₅₀ is confirmed to be 532.7 mg a.s./kg bw, so divided by 10 this would become 53.3 mg a.s./kg bw and hence should be used in place of the available NOEL from the reproductive study.

The relevant acute and reproductive endpoints for use in the risk assessment according to EFSA (2009) are therefore confirmed as follows:

Table B.9.1.1-02: Relevant avian endpoints for use in the risk assessment

Test substance	Endpoint	Species	Toxicity
Mecoprop-P	Acute LD ₅₀	<i>C.virginianus</i>	532.7 mg a.s./kg bw
Mecoprop-P	Acute LD ₅₀ / 10	<i>C.virginianus</i>	53.3 mg a.s./kg bw

B.9.1.2. Effects on terrestrial vertebrates other than birds

The mammalian toxicity data are summarised in table B.9.1.2-01 and -02. The associated active substance study data are provided in summary form in the Volume 3 – B.5 (AS) Renewal Assessment Report.

¹ Guidance of EFSA : Risk Assessment for Birds and Mammals: EFSA Journal 2009; 7(12):1438

Table B.9.1.2-01: Acute toxicity endpoints for mammals

Test substance	Species	Endpoint	Toxicity	Reference
D-Isomer (Mecoprop-P)	Rat	Acute LD ₅₀	1050 mg a.s./kg bw	██████ (1983a)
D-Isomer (Mecoprop-P)	Rat	Acute LD ₅₀	431 mg a.s./kg bw	██████ (1994a)
D-Isomer (Mecoprop-P)	Rat	Acute LD ₅₀	775 mg a.s./kg bw	██████ (1990a)
D-Isomer (Mecoprop-P)	Rat	Acute LD ₅₀	>700 ¹ mg a.s./kg bw	██████ (1995)
D-Isomer (Mecoprop-P)	mouse	Acute LD ₅₀	>3393 ² mg a.s./kg bw	██████ (2009)

¹ Acute exposure neurotoxicity study. No mortalities at highest tested dose of 700 mg/kg bw

² In an acute dietary study, mice were given diet containing 20000 ppm Mecoprop-P (3393 mg/kg b.w) over the duration of 1 day, rather than receiving a single gavage dose. Under the conditions of the study there were no mortalities. The median lethal dietary dose (LDD50) to female mice of Mecoprop-P a single dietary dose is >3393 mg Mecoprop-P/kg.

There are 4 available acute oral toxicity studies with the rat, all testing mecoprop-P. It is therefore considered appropriate to take a geometric mean of these endpoints to derive an overall LD₅₀ for use in the acute mammalian risk assessment. **The geometric mean LD₅₀ = 703.9 mg a.s./kg bw.** The provided acute dietary mouse study (██████, 2009) is considered as supplementary information to indicate that the a.s. is not of increased acute toxicity to this species.

Table B.9.1.2-02: Long-term/reproductive toxicity endpoints for mammals, as reported by mammalian toxicology

Test substance	Species	Endpoint *	Toxicity (mg a.s./kg bw/day as mecoprop-P)	Reference
Mecoprop (racemic)	Rat	NOAEL LOAEL	4.4/4.8 (male/female) 35.2/38.0	██████ (1986) 7-week oral study
Mecoprop (racemic)	Rat	NOAEL LOAEL	< 18.4 15.6/18.4 (male/female)	██████ (1979) 3-month oral study
Mecoprop-P	mouse	NOAEL LOAEL	< 30 30 (female)	██████ (1993) 3-month oral study
Mecoprop-P	Rat	NOAEL LOAEL	53.7/60.6 (male/female) 82.9/88.8 (male/female)	██████ (2003) 1-gen study
Mecoprop (racemic)	Rat	NOAEL LOAEL	8.0 (reproductive) 40.0 (reproductive)	██████ (1992) 2-gen study
Mecoprop-P	Rat	NOAEL LOAEL	50 100	██████ (1993a) Teratogenicity study
Mecoprop-P	Rabbit	NOAEL LOAEL	50/20 (parental/foetal) 50	██████ (1993b) Teratogenicity study

*As reported in the volume 3, B.6 of the renewal assessment report

Below consideration of each relevant mammalian toxicology study to define an ecotoxicologically-relevant endpoint is made by the RMS. The endpoints that are considered relevant for reproductive performance, as listed below:

- NOAEL for body weight change, behavioural effects and systemic toxicity;
- NOAEL for indices of gestation, litter size, pup and litter weight;
- NOAEL for indices of viability, pre- and post-implantation loss;
- NOAEL for embryo/foetal toxicity including teratological effects;
- NOAEL for number aborting and number delivering early;
- NOAEL for systemic toxicity and effects on adult body weight;
- NOAEL for indices of post-natal growth⁴, indices of lactation and data on physical landmarks;
- NOAEL for survival and general toxicity up to sexual maturity

In conjunction with evaluating the effects parameters themselves the extent of an effect will be considered and its possibility of resulting in a ‘real world’ effect on wild populations, which are the focus if the ecotoxicological risk assessment.

7-week oral study: [REDACTED] (1986)

At the toxicology-defined LOAEL dose of 35.2/38.0 mg mecoprop-P/kg body weight/day (for males and females, respectively), there was an observed increased kidney weight of 8% in males and females as well as some “marginal” clinical chemistry effects (creatinine, calcium, cholesterol). The change in kidney weight was not accompanied by and adverse renal histopathology. It is proposed that these effects would be of no/negligible biological and ecological impact to wild mammals. As such **the ecotoxicologically relevant NOAEL from this study is determined to be 35.2 mg a.s./kg bw/day, expressed as mecoprop-P.** The corresponding LOAEL is therefore > 35.2 mg a.s./kg bw/day, by virtue of the NOAEL being the highest tested dose.

3-month oral study: [REDACTED] (1979)

At the toxicology-defined LOAEL dose of 15.6/18.4 mg a.s./kg bw/day there was an observed 8% increase in male kidney weight as the only parameter of statistically significant change versus the corresponding control group.

At the next highest dose (as mecoprop-P) there was an observed statistically significant effect on male kidney weight (+ 14%) and female body weight (a decrease of only 2.7% versus control females). The dose group corresponds to mecoprop-P intakes of 31.9 and 37.8 mg a.s./kg bw/day for males and females.

In the dose group (as mecoprop-P) of 67.6 and 75.8 mg a.s./kg bw/day (males and females) there was again an observed effect on kidney weight in males - a 9% increase relative to the control group. Also female body weight was observed to decrease compared to the corresponding control group by 4.3%.

It is proposed by the RMS evaluator that none of the described effects seen in the above tested doses could constitute a biologically or ecologically adverse effect on mammals, due to either the extent of the effects (for body weight symptoms) or for their isolation from any other adverse symptoms (kidney weight increase in males only).

It is noted that at the next dose group of 146.4/170.1 mg mecoprop-P/kg bw/day there were significant reductions in both male and female bodyweight of 9.4 and 12%, respectively.

As such the RMS sets **the ecotoxicologically relevant NOAEL from the study as 67.8 mg a.s./kg bodyweight/day, as mecoprop-P.** Corresponding LOAEL = 146.4 mg a.s./kg bw/day, based on the relevant bodyweight decreases seen.

3-month oral study: [REDACTED] (1993)

The study tested mecoprop-P at 3 widely spaced doses of 20/30, 220/330 and 740/930 mg a.s./kg bw/day (male/female dose intakes).

In the lowest dose group no NOEL could be set for toxicology purposes due to minor clinical chemistry observations on females only (increased urea). No effects were seen in males at this tested dose. As such there is considered to be no ecotoxicologically relevant effects in this tested dose group of 20/30 mg a.s./kg bw/day

In the next dose group male bodyweight was reduced by a statistically significant 8%. Although not identified as statistically significant there was a corresponding female bodyweight reduction of 9.2%. These effects are considered to be potentially relevant with regards to protecting populations of wild mammals, further noting that they were equally present at the next dose group with equal/increased magnitude.

As such **the ecotoxicologically defined NOAEL from the study is 20 mg a.s./kg/bw/day as mecoprop-P.** The associated LOAEL = 220 mg a.s./kg bw/day.

1-generation study: [REDACTED] 2003)

A one generation study was performed with Mecoprop-P as the test compound. This included an assessment of the effect on selected offspring over a four week period after weaning. The test substance intake of the pups was limited by decreasing the dietary inclusion rate by a factor of one

third during the lactation and early weaning phases. The achieved doses to males and females as mecoprop-P were as follows (taken from study summary CA 5.6.1/01):

Table B.9.1.2-03: Achieved daily doses of mecoprop-P in the 1-generational study. (2003)

Sex and study phase (if applicable)	Mean dose received mg Mecoprop-P/kg/day		
	500 ppm (in feed)	800 ppm (in feed)	1200 ppm (in feed)
F0 Males, pre-pairing	34.5	53.7	82.9
F0 Females, pre-pairing	41.0	64.7	98.4
F0 Females, gestation	38.2	60.6	88.8
F0 Females, lactation	48.1	85.8	130.2
F0 Mean female	42.4	70.4	105.8
F1 Males	59.6	98.0	148.4
F1 Females	61.1	101.5	147.7
F1 Sexes combined	60.4	99.8	148.1

In the study conduction the actual concentration of mecoprop-P provided in the food was reduced by a factor of about 1/3 due to noted increased female food consumption in this period. The conclusions of the RMS toxicology evaluation are as follows: “At 500 and 800 ppm (reduced to 300 and 530 ppm), there were marginal effects on adult and pup weight gain and food intake”. These "marginal" effects are further discussed within the study summary but are justified as of low concern due to comparison versus the historical control range, as concluded by the RMS toxicologist. As such the ecotoxicologically relevant NOAEL can be set as the lowest of the F0 and F1 achieved doses (as effects were seen on both parent and first-gen offspring at the highest tested group). **The NOAEL from the study is therefore 53.7 mg a.s./kg bw/day.** The corresponding LOAEL is therefore 82.9 mg a.s./kg bw/day.

2-generational study with rat: (1992)

The NOAEL was set at 100 ppm based on a reduced survival rate of 1 to 4 day old pups, as well as reduced pup bodyweight gain, which was evident at 500 ppm. The achieved dose rates in the study are confirmed as follows (taken from study summary in B.5.6.1.1):

Table B.9.1.2-04: Achieved daily doses of mecoprop-P in the 2-generational study. 1992)

Sex and study phase (if applicable)	20 ppm	100 ppm	500 ppm
	Achieved daily dose (mg a.s./kg bw/day)		
F ₀ males	2.0	9.8	49.0
F ₀ females (premating)	2.1	10.6	52.5
F ₀ females (F _{1a} litter) - gestation period - lactation period*	1.7	8.7	42.8
	2.9	14.4	72.6
F ₀ females (F _{1b} litter) - gestation period - lactation period*	1.6	8.0	40.0
	2.6	13.2	67.3
F ₁ males	1.8	9.3	47.3

F ₁ females (prematuring)	2.0	10.3	50.7
F ₁ females (F ₂ litter)			
- gestation period	1.6	8.5 ¹	41.6 ²
- lactation period*	2.5	13.3	67.5

¹ lowest NOAEC related to parameters and study phases of concern – see below discussion

² lowest LOEAC related to parameters and study phases of concern – see below discussion

In the 500 ppm group in both F1a and F2 generation there were effects on pup death. Along with a statistically significant ($P = 0.05$) adverse effect on pup weight gain (estimated at 6% on days 7-14 in the F1a generation, 8-11% in the F2 generation over days 4-14 post-partum) the RMS cannot exclude these effects as not biologically significant. Such effects were not seen in the F1b generation pups, noting that the achieved maternal doses were slightly lower. Therefore the RMS would set the NOAEL as 100 ppm. The effects were reported in the toxicology study summary by the notifier as *"reflected poor maternal care. 100 ppm is equivalent to approximately 10 mg/kg b.w/day in adult rats in this study. Maternal food consumption increases almost two fold in early lactation, with no increase in bodyweight. Thus, the effective dose-rate for lactating dams and neonatal pups is very much higher than that in non-lactating adults. This is the likely cause of the poor maternal care seen at the high dose"*. However, RMS mammalian toxicology evaluation concluded that although the achieved maternal dose increased during lactation, the observed effects on pup mortality could also be due to effects of exposure in the womb (i.e. during gestation).

The NOAEL set for the ecotoxicological purposes is therefore 8.5 mg a.s./kg bw/day, based on no effects to the pups from the F1a and F2 generations and lowest calculated female dose intake during gestation or pup care for these litters. The LOAEL for ecotoxicology purposes is conservatively set at 41.6 mg a.s./kg bw/day, the lowest dose during gestation or maternal care period for any of the pup litters in which the effects on pup survival or bodyweight gain were seen.

Teratogenicity studies with the rat and rabbit: [REDACTED] 1993a+b)

In the teratogenicity study with the Himalayan rabbit [REDACTED] 1993b) the only significant developmental effect was an increased number of late reabsorptions in the highest tested dose of 50 mg a.s./kg bw/day. In the same treatment group there were no adverse effects on the ecologically relevant endpoints of number live foetuses per female, live foetal weight and implantation success. **As such the NOAEL can be considered to be 50 mg a.s./kg bw/day for ecotoxicology purposes.** The LOAEL cannot be defined but is > 50 mg a.s./kg bw/day

In the corresponding rat study there were effects on foetal weight only at the highest tested group of 100 mg a.s./kg bw/day, as well as rib and sternbrae effects. At the next group of 50 mg a.s./kg bw/day there were no adverse findings on the observed developmental endpoints. **As such the NOAEL for this teratogenicity study is also 50 mg a.s./kg bw/day**, for ecotoxicology purposes. The corresponding ecotoxicological LOAEL is 100 mg a.s./kg bw/day.

Overall, the ecotoxicologically-relevant long-term/reproductive endpoints for consideration in the mammalian risk assessment according to EFSA (2009) are as follows:

Table B.9.1.2-05: Ecotoxicologically relevant long-term/reproductive toxicity endpoints for mammals

Test substance	Species	Endpoint	Toxicity (mg a.s./kg bw/day as mecoprop-P)	Reference
Mecoprop (racemic)	Rat	NOAEL LOAEL	35.2 >35.2	██████ (1986) 7-week oral study
Mecoprop (racemic)	Rat	NOAEL LOAEL	67.8 146.4	██████ (1979) 3-month oral study
Mecoprop-P	mouse	NOAEL LOAEL	20 220	██████ (1993) 3-month oral study
Mecoprop-P	Rat	NOAEL LOAEL	53.7 82.9	██████ (2003) 1-gen study
Mecoprop (racemic)	Rat	NOAEL LOAEL	8.5 41.6	██████ (1992) 2-gen study
Mecoprop-P	Rat	NOAEL LOAEL	50 >50	██████ (1993a) Teratogenicity study
Mecoprop-P	Rabbit	NOAEL LOAEL	50 100	██████ (1993b) Teratogenicity study

The 2 reproductive studies ██████ and ██████ (1992) both measured several key endpoints for parental and offspring toxicity. There was a difference in the number of rats per dose group, due to the design of the ██████ (2003) 1-generational study as a preliminary test, which was considered by the RMS toxicologist as sufficient alongside the 1992 Hellwig 2-generation study to demonstrate reproductive toxicity. This is concluded in section B.6.6 of the renewal assessment report: “*The preliminary study on Mecoprop-P demonstrated comparable toxicity to that seen in the existing 2-generations study on racemic Mecoprop (██████ 1992). In the interests of preventing unnecessary testing on animals it was decided not to run the 2 generation study on Mecoprop-P and instead refer to the racemic study which was previously accepted in the review for Mecoprop-P*”. The 2 OECD guidelines followed in the ██████ (2003) and ██████ (1992) studies were OECD 415 and 416, respectively. Other than the continuation to a 2nd generation the methodologies are otherwise mainly comparable. As such on the basis of the above discussion it is considered as appropriate by the RMS to combine the datasets as outlined in the Guidance of EFSA on the Risk Assessment for Birds and Mammals (section 2.4.3). The approach has had the input and confirmation from the RMS mammalian toxicology specialist.

In ██████ (1992) the NOAEL is set as 100ppm, based on observed reduced pup survival and bodyweight gain in the F1a and F2 generations. As this could not be confirmed as solely due to poor maternal care during the lactation phase (when maternal dose consumption was increased, without a corresponding bodyweight increase) the NOAEL as daily dose was defined using the lowest maternal intake from either gestation or lactation, for the generations in question. This was confirmed as 8.5 mg a.s./kg bw/day, based on maternal intake during gestation of the F2 generation pups. The corresponding LOAEL was 41.6, based on lowest maternal dose intake during gestation of the F1a or F2 generations. Confirmation of the achieved doses in the various study phases is given in above table B.9.1.2-04.

In the ██████ (2003) 1-generation study with the rat the NOAEL was set at 800 ppm, based on maternal bodyweight effects at higher doses. The corresponding daily dose for this NOAEL would be 53.7 mg a.s./kg/bw, based on male food intake in the study. At the next tested concentration down there were also no effects on adult body weight, or other parameters of ecotoxicological relevance. The daily dose associated with this tested group is 34.5/38.2 mg a.s./kg/bw/day, based on lowest male/female food intake during the study (see table B.9.1.2-03).

As discussed, it is considered permissible to combine these 2 datasets due to the comparability of the study design, test organism (both studies used Wistar rats) and observed parameters. This is done below, following the guidance of EFSA (2009), section 2.4.3:

Table B.9.1.2-05: Combined 1 and 2-generation mammalian dataset ordered by daily dose consumed to define overall NOAEL.

Study	██████ (1992)	██████ 003)	██████ (1992)	██████ (2003)
Dose (ppm in food)	100	500	500*	800
Dose (mg a.s./kg bw/day)	8.5	34.5/38.2 (male/female)	41.6*	53.7/60.6 (male/female)

*significant effects seen on pub survival and pup bodyweight gain

On the basis of the above it is therefore concluded that **the relevant overall NOAEL from the 2 mammalian reproductive studies be set as 34.5 mg a.s./kg bw/day**, which is protective of any observed maternal and offspring effects. Although the NOAEL is set based on a dose group from the 1-generational study, it is lower than the achieved dose at which any adverse effects were seen in the corresponding 2-generational study.

2 long-term studies with the rat ████████ are available. In the ████████ (1986) study the NOAEL was set as the highest dose group, meaning no significant adverse effects were seen at 35.2 mg a.s./kg bw/day. In ████████ (1979) rats showed ecotoxicologically relevant effects on male and female bodyweight, with reductions of 9.4% and 12%, respectively. Due to the Reinert study being of a longer duration it could be considered that the endpoints derived are more representative of long-term exposure to mecoprop-P. Neither NOAEL from these 2 long-term studies is lower than the overall reproductive NOAEL identified on the basis of the 1-generation and 2-generation studies considered above.

The third long-term study – a 3-month oral dosing with the mouse (██████) used very wide dose spacing and so does little to refine an overall mammalian endpoint based on long-term adult effects. Although a NOAEL was set as 20 mg a.s./kg bw/day, at this dose there were no effects of ecotoxicological relevance on male or female mice. At the next dose group; confirmed to be 220/300 mg a.s./kg bw/day for males and females, respectively, there was a statistically significant 8% reduction in male bodyweight. At the corresponding 330 mg a.s./kg bw/day female dose there was a non-significant 9.2% reduction in bodyweight. Given the extent of these effects (i.e. < 10% versus the corresponding control group) and the achieved daily dose at which they were seen (> 6 times higher than the NOAEL set from the reproduction studies) it is proposed by the RMS that a NOAEL set based on the reproductive studies would be protective of any effects seen in this 3-month oral study with the mouse. This position is further supported by the fact that in the 3-month rat study (Reinert, 1979), there were greater effects seen on adult rats: Both male and female bodyweight reductions of 9.4 and 12%, at a LOAEL dose lower than those used to set the mouse 3-month LOAEL (146.4 versus 220 mg a.s./kg bw/day, respectively).

No significant toxicity was seen in th ████████ (1993a) teratogenicity study with the rat, and in the corresponding study with the rabbit effects on foetal weight were seen only at the highest dose group of 100 mg a.s./kg bw/day, with the NOAEL set at 50 mg a.s./kg bw/day which is only marginally below the reproductive NOAEL set. The reproductive study NOAEL of 34.5 mg a.s./kg bw/day is therefore also considered to be protective of any biologically and/or ecologically relevant toxicity seen in the 2 teratogenicity studies summarised ████████ 1993 a+b).

Overall, based on above detailed consideration of the available long-term and reproductive dataset with mammalian species, the RMS defines **the NOAEL for use in the ecotoxicology risk assessment**

to be 34.5 mg a.s./kg bw/day as mecoprop-P. At this exposure dose no biologically or ecologically significant long-term or reproductive effects are expected to occur in wild mammals.

B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.2.1. Risk assessment for birds

The following risk assessment is performed in line with current guidelines (EFSA guidance for birds and mammals, 2009 7(12), 1438).

An initial screening step is undertaken, considering worst-case scenario ‘indicator species’ associated with general crop groups. The relevant avian indicator species for the representative uses of mecoprop-P (as ‘Mecoprop-P K 600 g/L’) are as follows

Table B.9.2.1-01: Relevant indicator species for risk assessment on screening level acc. to EFSA GD (2009).

EFSA Crop Group	Indicator species	Shortcut value	
		Acute risk assessment	Reproductive risk assessment
Cereals	Small omnivorous bird	158.8	64.8

Acute risk assessment

The avian risk assessment has been performed to the notifier’s GAP (see table B.9-01.). The screening step for acute toxicity is summarised in table B.9.2.1-01. The acute toxicity endpoint has been selected based on available active substance data and the current guidance of EFSA (2009).

The acute DDD (daily Dietary Dose) is the predicted daily exposure of birds to residues of the active substance following the proposed representative uses. It is calculated using the following formula:

$$\text{DDD} = \text{Application rate (kg a.s./ha)} \times \text{shortcut value} \times \text{MAF}_{90}$$

Where:

Shortcut value = as indicated in table B.9.2.1-01 for acute assessment

MAF₉₀ = Multiple application factor (90th percentile) required to account for accumulation of residues following > 1 application. As only a single application of ‘Mecoprop-P K 600 g/L’ is proposed a MAF of 1 is applicable

Table B.9.2.1-02: Screening level acute risk assessment for birds.

Crop	Indicator species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
Cereals (winter, spring) BBCH 13-32	Small omnivorous bird	1.2	158.8	1	190.56	532.7	2.8	10

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

The TER value calculated in the screening level acute risk assessment for birds is below the Annex VI trigger value of 10 for the representative uses on cereals. Thus, the acute risk to birds requires further consideration under the first tier considerations of EFSA (2009).

Table B.9.2.1-03: Relevant generic focal species for risk assessment at first tier, according to EFSA GD (2009).

Crop	Scenario*	Generic focal species	Shortcut value	
			Acute risk assessment	Reproductive risk assessment
Cereals	BBCH 10-29	Small omnivorous bird “lark”	24.0	10.9
Cereals	BBCH 30-39	Small omnivorous bird “lark”	12.0	5.4

*Note that the large herbivorous bird “goose” scenario is not triggered as only spring applications are proposed for the representative uses

Table B.9.2.1-04: First tier acute risk assessment for birds.

Crop + scenario	Generic focal species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
Cereals BBCH 10-29	Small omnivorous bird	1.2	24.0	1	28.8	532.7	18.5	10
Cereals BBCH 30-39			12.0		14.4		37.0	

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

The TER values calculated in the above first tier acute risk assessment for birds are in excess of the Annex VI trigger value of 10. Thus, the acute risk to birds can be concluded a low for the representative uses on winter and spring cereals (spring application only).

Reproductive risk assessment

The avian risk assessment has been performed to the notifier's GAP (see table B.9-01). The screening step for reproduction is summarised in table B.9.2.1-05. The appropriate toxicity endpoint for use in the assessment is the acute LD₅₀ divided by a factor of 10, as this is lower than the NOEL from the available reproductive study.

The reproductive DDD (daily Dietary Dose) is the predicted daily exposure of birds to residues of the active substance following the proposed representative uses. It is calculated using the following formula:

$$\text{DDD} = \text{Application rate (kg a.s./ha)} \times \text{shortcut value} \times \text{MAF}_{\text{mean}} \times f_{\text{TWA}}$$

Where:

Shortcut value = as indicated in table B.9.2.1-01 for acute assessment

MAF_{mean} = Multiple application factor (mean value) required to account for accumulation of residues following > 1 application. As only a single application of 'Mecoprop-P K 600 g/L' is proposed a MAF of 1 is applicable

f_{TWA} is the Time-Weighted Averaged factor and is to account for the 21-day average residue exposure to the substance, assuming that any toxic effects are the result of long-term exposure (LTE). The standard f_{TWA} for use in the screening step and first tier risk assessments is 0.53

Table B.9.2.1-05: Screening level reproductive risk assessment for birds.

Crop	Indicator species	DDD				DDD	NOAEL [mg a.s./kg bw/d]*	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _m	MAF _m	f _{TWA}				
Cereals (winter, spring) BBCH 13-32	Small omnivorous bird	1.2	64.8	1	0.53	41.2	53.3	1.3	5

f_{twa} = time-weighted average factor (average concentration during a certain time interval compared to the initial concentration after single respective last application)

MAF = multiple application factor (concentration immediately after the last application compared to a single application)

DDD = daily dietary dose

*LD₅₀ / 10

The TER value calculated in the screening level reproductive risk assessment for birds is below the Annex VI trigger value of 5 for the representative uses on cereals. Thus, the reproductive risk to birds requires further consideration under the first tier considerations of EFSA (2009). The relevant first tier scenarios, generic focal species and associated shortcut values are provided above in table B.9.2.1-03. The first tier reproductive risk assessment for birds is in below table B.9.2.1-06.

Table B.9.2.1-06: First tier reproductive risk assessment for birds.

Crop + scenario	Generic focal species	DDD				DDD	NOAEL [mg a.s./kg bw/d]*	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _{mean}	MAF _m	f _{TWA}				
Cereals BBCH 10-29	Small omnivorous bird	1.2	10.9	1	0.53	6.93	53.3	7.7	5
Cereals BBCH 30-39			5.4			3.43		15.5	

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

f_{twa} = time-weighted average factor (average concentration during a certain time interval compared to the initial concentration after single respective last application)

* LD₅₀ / 10

The TER values calculated in the above first tier reproductive risk assessment for birds are in excess of the Annex VI trigger value of 5. Thus, the reproductive risk to birds can be concluded a low for the representative uses on winter and spring cereals (spring application only).

Metabolites

In accordance with the guidance of EFSA (2009) it must be identified if any metabolites are likely to be formed in avian food items which may then be consumed by relevant focal species. Consideration if these metabolites occur in food items at higher concentrations than seen in corresponding animal metabolism studies needs to be made and, if so, then specific consideration of the risk to birds from the metabolite in question should be made.

The formation percentage of mecoprop-P and identifiable metabolites in wheat plants is given below (Taken from study Cooper J.L.D., Jones M.K. Lowdon P. and Parsons R., 1998, Vol.3 B.7.2.1):

Table B.9.2.1-07: Maximum metabolite percentage formation in wheat plants treated at 1 x 1.41 kg MCPP-P/ha

Matrix	HMCPP ⁽¹⁾	CCPP ⁽²⁾
Whole plants	14.9%	9.9%
Grain	not detected	6.1%
Straw	12%	14.3%

⁽¹⁾ 2-hydroxymethyl-4-chloro-phenoxypropionic acid

⁽²⁾ 2-carboxy-4-chloro-phenoxypropionic acid

No corresponding hen metabolism study was conducted in support of mecoprop-P approval, and as such it cannot be confirmed whether avian studies with the active substance would also have reflected toxicity caused by these food item metabolites.

As such a first-tier avian risk assessment will be conducted for these 2 most prevalent plant metabolites. Conservatively assuming ten times parental toxicity, and the maximum percent formation in edible plant tissues based on the above referenced metabolism study.

Both of these identified metabolites have a calculated log Pow of < 3: HMCPP = 1.47; CCPP = 1.93. As such a low risk to birds from these metabolites via secondary poisoning would be expected and no further assessment of the risk is required. The acute risk assessment for these metabolites is presented below in table B.9.2.1-08, and the reproductive risk in table B.9.2.1-09.

Table B.9.2.1-08: First tier acute risk assessment for birds – metabolites in plant food items.

Table B.9.2.1-08. First tier acute risk assessment for birds – metabolites in plant food items.								
Crop + scenario	Generic focal species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
HMCPP								
Cereals BBCH 10-29	Small omnivorous bird	0.179 ¹	24.0	1	4.30	53.3 ³	12.4	10
Cereals BBCH 30-39			12.0		2.15		24.8	
CCPP								
Cereals BBCH 10-29	Small omnivorous bird	0.172 ²	24.0	1	4.13	53.3 ³	12.9	10
Cereals BBCH 30-39			12.0		2.06		25.9	

¹ Assuming max. 14.9% residue formation (whole plant)

² Assuming max. 14.3% residue formation (straw)

³ Assuming 10 times parental toxicity

A low acute risk to birds is therefore expected from the plant metabolites of mecoprop-P, even conservatively assuming they are ten times more toxic than the active substance itself.

Table B.9.2.1-09: First tier reproductive risk assessment for birds – metabolites in plant food items.

Food items.

Crop + scenario	Generic focal species	DDD				DDD	NOAEL [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _m	MAF _m	Ftwa				
HMCPP									
Cereals BBCH 10-29	Small omnivorous bird	0.179 ¹	10.9	1	0.53	1.03	5.33 ³	5.2	5
Cereals BBCH 30-39			5.4			0.51		10.5	
CCPP									
Cereals BBCH 10-29	Small omnivorous bird	0.172 ²	10.9	1	0.53	0.99	5.33 ³	5.4	5
Cereals BBCH 30-39			5.4			0.50		10.7	

¹ Assuming max. 14.9% residue formation (whole plant)

² Assuming max. 14.3% residue formation (straw)

³ Assuming 10 times parental toxicity

A low reproductive risk to birds is therefore expected from the plant metabolites of mecoprop-P, even conservatively assuming they are ten times more toxic than the active substance itself.

Risk to birds via contaminated drinking water

The avian risk from exposure to mecoprop-P via drinking water is considered below. According to EFSA Guidance document for birds and mammals, (2009) drinking water sources through which birds might be exposed are:

- puddles on the ground
- reservoirs held in the axils of leaves

As a generic approach, the EFSA Guidance Document states that no specific calculations are required for the puddle scenario when the ratio of effective application rate (in g a.s./ha) to relevant toxicity endpoint (mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg). The mean K_{oc} for mecoprop-P is 21. The results are shown in Table B.9.2.1-10. For the crops under assessment in this evaluation (cereals) the leaf scenario is not considered relevant. All values are below the value of 50 proposed in the EFSA (2009), indicating an acceptable risk. Further consideration is not required. The acute risk via drinking water is considered to also be addressed, as the toxicity endpoint is greater and effective application rate is unchanged (so ratio would be lower than long-term assessment below).

Table B.9.2.1-10: Long-term avian risk assessment for drinking water

Crop	K_{oc} [L/kg]	Application rate [g a.s./ha]	NOAEL* [mg a.s./ kg bw/d]	Ratio	Trigger	Conclusion
cereals	21	1200	53.7	22.1	50	No concern

*Surrogate value $LD_{50} / 10$ conservatively used to represent reproductive toxicity

Risk to birds via secondary poisoning

Bioconcentration is defined as the net result of uptake, distribution and elimination of a substance in an organism. It is directly associated with lipophilicity and as such is only expected to have the potential to occur with substances with a log K_{ow} of ≥ 3 .

- Mecoprop-P has a log K_{ow} (at pH 7) of -0.19
- Plant tissue metabolite HMCPP has a calculated log K_{ow} of 1.47
- Plant tissue metabolite CCPP has a calculated log K_{ow} of 1.93

As such a low risk to birds is expected via secondary poisoning.

The conclusions of mecoprop-P from the Human health assessment and available metabolism studies indicate that the active substance has a low potential for bioaccumulation. As such no further consideration with regards to biomagnification in birds is required.

B.9.2.2. Risk assessment for vertebrates other than birds

The following risk assessment is performed in line with current guidelines (EFSA guidance for birds and mammals, 2009 7(12), 1438).

An initial screening step is undertaken, considering worst-case scenario ‘indicator species’ associated with general crop groups. The relevant mammalian indicator species for the representative uses of mecoprop-P (as ‘Mecoprop-P K 600 g/L’) are as follows

Table B.9.2.2-01: Relevant indicator species for risk assessment on screening level acc. to EFSA GD (2009).

EFSA Crop Group	Indicator species	Shortcut value	
		Acute risk assessment	Reproductive risk assessment
Cereals	Small herbivorous mammal	118.4	48.3

Acute risk assessment

The mammalian risk assessment has been performed to the notifier's GAP (see table B.9-01.). The screening step for acute toxicity is summarised in table B.9.2.1-01. The acute toxicity endpoint has been selected based on available active substance data and the current guidance of EFSA (2009).

The acute DDD (daily Dietary Dose) is the predicted daily exposure of mammals to residues of the active substance following the proposed representative uses. It is calculated using the following formula:

$$\text{DDD} = \text{Application rate (kg a.s./ha)} \times \text{shortcut value} \times \text{MAF}_{90}$$

Where:

Shortcut value = as indicated in table B.9.2.2-01 for acute assessment

MAF₉₀ = Multiple application factor (90th percentile) required to account for accumulation of residues following > 1 application. As only a single application of 'Mecoprop-P K 600 g/L' is proposed a MAF of 1 is applicable

Table B.9.2.2-02: Screening level acute risk assessment for mammals.

Crop	Indicator species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
Cereals (winter, spring) BBCH 13-32	Small herbivorous mammal	1.2	118.4	1	142.08	703.9	5.0	10

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

The TER value calculated in the screening level acute risk assessment for mammals is below the Annex VI trigger value of 10 for the representative uses on cereals. Thus, the acute risk to mammals requires further consideration under the first tier considerations of EFSA (2009).

Table B.9.2.2-03: Relevant generic focal species for risk assessment at first tier, according to EFSA GD (2009).

Crop	Scenario	Generic focal species	Shortcut value	
			Acute risk assessment	Reproductive risk assessment
Cereals	BBCH 10-19	Small insectivorous mammal "shrew"	7.6	4.2
Cereals	BBCH ≥20	Small insectivorous mammal "shrew"	5.4	1.9
Cereals	Early (shoots)	Large herbivorous mammal "lagomorph"	42.1	22.3
Cereals	BBCH 10-29	Small omnivorous mammal "mouse"	17.2	7.8
Cereals	BBCH 30-39	Small omnivorous mammal "mouse"	8.6	3.9

Table B.9.2.2-04: First tier acute risk assessment for mammals.

Crop + scenario	Generic focal species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
Cereals BBCH 10-19	Small insectivorous mammal “shrew”	1.2	7.6	1	9.12	703.9	77.2	10
Cereals BBCH ≥20			5.4		6.48		108.6	
Cereals early (shoots)	Large herbivorous mammal “lagomorph”		42.1		50.52		13.9	
Cereals BBCH 10-29	Small omnivorous mammal “mouse”		17.2		20.64		34.1	
Cereals BBCH 30-39			8.6		10.32		68.2	

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

The TER values calculated in the above first tier acute risk assessment for mammals are in excess of the Annex VI trigger value of 10. Thus, the acute risk to mammals can be concluded a low for the representative uses on winter and spring cereals (spring application only).

Reproductive risk assessment

The mammalian risk assessment has been performed to the notifier’s GAP (see table B.9-01). The screening step for reproduction is summarised in table B.9.2.2-05 The appropriate toxicity endpoint for use in the assessment is a NOAEL of 34.5 mg a.s./kg bw/day, on the basis of the discussion under point B.9.1.2.

The reproductive DDD (daily Dietary Dose) is the predicted daily exposure of mammals to residues of the active substance following the proposed representative uses. It is calculated using the following formula:

$$\text{DDD} = \text{Application rate (kg a.s./ha)} \times \text{shortcut value} \times \text{MAF}_{\text{mean}} \times f_{\text{TWA}}$$

Where:

Shortcut value = as indicated in table B.9.2.2-01 for reproductive assessment

MAF_{mean} = Multiple application factor (mean value) required to account for accumulation of residues following > 1 application. As only a single application of ‘Mecoprop-P K 600 g/L’ is proposed a MAF of 1 is applicable

f_{TWA} is the Time-Weighted Averaged factor and is to account for the 21-day average residue exposure to the substance, assuming that any toxic effects are the result of long-term exposure (LTE). The standard f_{TWA} for use in the screening step and first tier risk assessments is 0.53

Table B.9.2.1-05: Screening level reproductive risk assessment for mammals.

Crop	Indicator species	DDD				DDD	NOAEL [mg a.s./kg bw/d]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _m	MAF _m	f _{TWA}				
Cereals (winter, spring) BBCH 13-32	Small herbivorous mammal	1.2	48.3	1	0.53	30.72	34.5	1.1	5

f_{twa} = time-weighted average factor (average concentration during a certain time interval compared to the initial concentration after single respective last application)

MAF = multiple application factor (concentration immediately after the last application compared to a single application)

DDD = daily dietary dose

The TER value calculated in the screening level reproductive risk assessment for mammals is below the Annex VI trigger value of 5 for the representative uses on cereals. Thus, the reproductive risk requires further consideration under the first tier considerations of EFSA (2009). The relevant first tier scenarios, generic focal species and associated shortcut values are provided above in table B.9.2.2-03. The first tier reproductive risk assessment is in below table B.9.2.2-06.

Table B.9.2.2-06: First tier reproductive risk assessment for mammals.

Crop + scenario	Generic focal species	DDD				DDD	NOAEL [mg a.s./kg bw/d]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _{mean}	MAFm	f _{TWA}				
Cereals BBCH 10-19	Small insectivorous mammal “shrew”	1.2	4.2	1	0.53	2.67	34.5	12.9	5
Cereals BBCH ≥20			1.9			1.21		28.5	
Cereals early (shoots)	Large herbivorous mammal “lagomorph”		22.3			14.18		2.4	
Cereals BBCH 10-29	Small omnivorous mammal “mouse”		7.8			4.96		7.0	
Cereals BBCH 30-39			3.9			2.48		13.9	

MAF = multiple application factor

DDD = daily dietary dose

SV = Shortcut value

f_{TWA} = time-weighted average factor (average concentration during a certain time interval compared to the initial concentration after single respective last application)

Under first tier risk assessment considerations according to EFSA (2009) there is a low reproductive risk to small insectivorous and small omnivorous mammals following the representative use of mecoprop-P on cereals. However, due to the early post-mergence application timing of BBCH 13+, exposure to the large herbivorous “lagomorph” scenario is also relevant. The TER for this scenario is below the trigger of 5 for long-term risk, meaning an outstanding risk is identified.

An outstanding risk to the large herbivorous “lagomorph” is identified following the representative use of mecoprop-P on winter and spring cereals.

Metabolites

In accordance with the guidance of EFSA (2009) it must be identified if any metabolites are likely to be formed in vertebrate food items which may then be consumed by relevant focal species. Consideration if these metabolites occur in food items at higher concentrations than seen in corresponding animal metabolism studies needs to be made and, if so, then specific consideration of the risk from the metabolite in question should be made.

The formation percentage of mecoprop-P and identifiable metabolites in wheat plants is given in above table B.9.2.1-07 (Taken from study Cooper J.L.D., Jones M.K. Lowdon P. and Parsons R., 1998, Vol.3 B.7.2.1). The identified metabolites were HMCCP and CCPP (present at maximums in wheat plants of 14.9% and 14.3%, respectively). Both of these identified metabolites have a calculated log Pow of < 3: HMCCP = 1.47; CCPP = 1.93. As such a low risk to mammals from these metabolites via secondary poisoning would be expected and no further assessment of the risk is required.

Under point B.7.2.3, the RMS has concluded the following with regards to the presence of these metabolites in mammalian tissues: *“The mecoprop-P dairy cow feeding study evaluated in section B.7.4.2. dosed with mecoprop-P only, but demonstrated that no residues of HMCCP (or CCPP) were observed in any matrix destined for human consumption. Furthermore intakes of HMCCP are lower than those of CCPP and the similarity in structure suggests HMCCP metabolite will behave in a*

similar manner to CCPP and significant residues will not arise in ruminant tissue.” Similarly neither metabolite was identified in the goat metabolism study evaluated in the assessment report.

Under volume 3 (CA) B.6.1.3 of the Assessment Report it is confirmed in the toxicology summary that mecoprop-P is largely excreted by the parent. In the supporting absorption, distribution, metabolism and excretion study in the rat (■■■■■ 1997) it was reported that the majority of radiolabelled substance in urine was the parent mecoprop-P (66 and 83% in males and females respectively). One metabolite was identified also at significant levels: *“and one major metabolite - up to 32.6 % of the radioactivity in male urine, considerably less in urine from females. This metabolite was identified by mass spectrometry as a hydroxylated mecoprop-P, and the 13C-NMR spectrum confirmed hydroxylation of the 2-methyl moiety of mecoprop-P.”* the report further confirms that *“One more metabolite was identified in female urine-pools by HPLC and MS - at a level of 0.05 % in low dose animals and 0.07 % in high dose animals - the carboxy-mecoprop-P which is a known metabolite of mecoprop-P in plants.”*

As such it is considered that studies conducted with the active substance on mammalian species would likely also have included exposure to the metabolite hydroxymethyl-mecoprop-P (AKA HMCCP) and so the risk to mammals from this metabolite is considered to be addressed in the risk assessment for the parent mecoprop-P.

However, a first-tier risk assessment will be conducted for the other prevalent plant metabolite Carboxy-mecoprop-P (CCPP), as this was found to be formed in plant tissue at much higher percentages than detected in mammalian species metabolism studies. This requirement of further assessment is supported by the toxicology section which states *“Due to the low levels of this metabolite, the toxicity studies on mecoprop-P are not sufficient to determine the toxicity of carboxy-mecoprop-P.”*

Conservative assumptions made for this assessment of CCPP risk are ten times parental toxicity, and the maximum percent formation in edible plant tissues based on the above referenced plant metabolism study. No consideration of the mammalian scenario small insectivorous “shrew” is made, as the metabolism data is only relevant for plant food items.

Table B.9.2.2-07: First tier acute risk assessment for mammals – metabolites in plant food items.

tems.

Crop + scenario	Generic focal species	DDD			DDD	LD ₅₀ [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀				
CCPP								
Cereals early (shoots)	Large herbivorous mammal “lagomorph”	0.172 ¹	42.1	1	7.24	70.4 ²	9.7	10
Cereals BBCH 10-29	Small omnivorous mammal “mouse”		17.2		2.96		23.8	
Cereals BBCH 30-39			8.6		1.48		47.6	

¹ Assuming max. 14.3% residue formation (straw)

² Assuming 10 times parental toxicity

Under the conservative assumption that the metabolites are ten times as toxic as the parent, MCPP-P, there is an outstanding acute risk to the large herbivorous “lagomorph”. A low risk from the plant metabolites to the small omnivorous “mouse” is demonstrated under these highly conservative assumptions of metabolite toxicity.

Table B.9.2.2-08: First tier reproductive risk assessment for mammals – metabolites in plant food items.

Plant food items:									
Crop + scenario	Generic focal species	DDD				DDD	NOAEL [mg a.s./kg bw]	TER	Trigger
		Appl. rate [kg a.s./ha]	SV _m	MAF _m	Ftwa				
CCPP									
Cereals early (shoots)	Large herbivorous mammal “lagomorph”	0.172 ¹	22.3	1	0.53	2.03	3.45 ²	1.7	5
Cereals BBCH 10-29	Small omnivorous mammal “mouse”		7.8			0.71		4.9	
Cereals BBCH 30-39			3.9			0.36		9.6	

¹ Assuming max. 14.3% residue formation (straw)² Assuming 10 times parental toxicity

Under the conservative assumption that the metabolites are ten times as toxic as the parent, MCPP-P, there is an outstanding long-term risk to the large herbivorous “lagomorph”, as well as the small omnivorous “mouse” at BBCH 10-29.

A low risk from the plant metabolites to the small omnivorous “mouse” at BBCH 30-39 is demonstrated under these highly conservative assumptions of metabolite toxicity.

Risk to mammals via contaminated drinking water

The mammalian risk from exposure to mecoprop-P via drinking water is considered below. According to EFSA Guidance document for birds and mammals, (2009) drinking water sources through which birds might be exposed are:

- puddles on the ground
- reservoirs held in the axils of leaves

As a generic approach, the EFSA Guidance Document states that no specific calculations are required for the puddle scenario when the ratio of effective application rate (in g a.s./ha) to relevant toxicity endpoint (mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg). The mean K_{oc} for mecoprop-P is 21. The results are shown in Table B.9.2.2-09. For the crops under assessment in this evaluation (cereals) the leaf scenario is not considered relevant. All values are below the value of 50 proposed in the EFSA (2009), indicating an acceptable risk. Further consideration is not required. The acute risk via drinking water is considered to also be addressed, as the toxicity endpoint is greater and effective application rate is unchanged (so ratio would be lower than long-term assessment below).

Table B.9.2.2-09: Long-term mammalian risk assessment for drinking water

Crop	K _{oc} [L/kg]	Application rate [g a.s./ha]	NOAEL [mg a.s./kg bw/d]	Ratio	Trigger	Conclusion
cereals	21	1200	53.7	22.3	50	No concern

Risk to mammals via secondary poisoning

Bioconcentration is defined as the net result of uptake, distribution and elimination of a substance in an organism. It is directly associated with lipophilicity and as such is only expected to have the potential to occur with substances with a log of ≥ 3 .

- Mecoprop-P has a log Kow (at pH 7) of -0.19
- Plant tissue metabolite HMCPP has a calculated log Kow of 1.47
- Plant tissue metabolite CCPP has a calculated log Kow of 1.93

As such a low risk to mammals is expected via secondary poisoning.

The conclusions of mecoprop-P from the Human health and available metabolism studies are that the active substance has a low potential for bioaccumulation. As such no further consideration with regards to biomagnification is required.

B.9.3. EFFECTS ON AQUATIC ORGANISMS

B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Report:	CP10.2.1/01
Title	<p>██████████ (2014a) Mecoprop-p K 600 g/L (CA3015): Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-Hour Test</p> <p>Testing Laboratory: ██████████</p> <p>Study Number: ██████████</p> <p>Date: 13 January 2014</p>
Guidelines:	EEC C.1 OECD 203
GLP	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

Test material

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	587.3 g/L
Storage conditions:	At room temperature at 20±5°C, in the dark.

Test system

Organism (<i>Species</i>):	<i>Oncorhynchus mykiss</i> (Rainbow trout)
Source:	██
Body weight:	Mean = 0.82 g at initiation
Body Length:	Mean = 4.79 cm at initiation

Acclimatisation:	1 week under test conditions
Study Type:	Acute toxicity laboratory study
Duration of study:	96 hours
Parameters measured:	Mortality, visual abnormalities
Test water:	Local tap water (non chlorinated well water of drinking quality) was used, reduced for hardness by ion exchange (water hardness = 193 mg/L as CaCO ₃).
Environmental conditions	
Water temperature:	13°C
Photoperiod:	16 hour light - 8 hour dark. 30 min transition period.
Light intensity:	130-490 Lux
Test water pH:	8.4 – 8.5
Test water dissolved oxygen:	9.2 – 9.5 mg/L (equivalent to 87-90% saturation at 13°C)
Feed:	During acclimatisation, until one day prior to test start, the fish were fed with a commercial fish diet (HOKOVIT 502, 1.2 mm supplied by H.U. Hofmann AG, Switzerland).

B STUDY DESIGN AND METHODS

In life dates:	15 th July 2013 – 07 th August 2013
Experimental treatment:	At the start of the test, a concentrated stock solution was prepared by mixing 1.7501 g of the test item in 3.5 litres of test water under intense stirring for 15 minutes at room temperature. This stock solution was then diluted with the test water to prepare the test medium at the nominal concentration of 100 mg/L. The test medium was freshly prepared just before introduction of the fish.
Study design:	At the start of exposure 7 fish were introduced into each 15L test vessel, containing the test medium, in a random order and held under static conditions for 96 hours. The loading rate was 0.38 g fish wet weight per litre test medium. Thus the requirement for a loading rate not exceeding 1 g fish/L was fulfilled. Observations of mortality and other effects were made at 3, 24, 48, 72 and 96 hours. Water samples for analysis were taken at 0 and 96 hours from each vessel and analysed via HPLC-UV.
Statistics:	No statistical assessment was required as no effect of the product Mecoprop-P K 600 was observed at the nominal test concentration of 100 mg/L.
Deviations from study plan:	A new certificate of analysis with a revised analysed content of the active ingredient within the test item was provided by the sponsor after the laboratory work had been carried out. The analysed content of the active ingredient was changed from 595.8 g/L to 587.3 g/L. This deviation to study plan is not considered to have an impact on the outcome of the study.

II. RESULTS AND DISCUSSION

- Dosing:** The measured concentration of the active ingredient mecoprop-P of the formulation Mecoprop-P K 600 (CA3015) in the test medium at the concentration of 100 mg/L was 89% of the nominal value at the start and end of test. Thus the concentration was confirmed and biological results can be based upon the nominal concentration.
- Biological Results:** The test item CA3015 had no acute toxic effects on rainbow trout up to the nominal concentration of 100 mg/L under the specified test conditions. Also no remarkable observations were made concerning the appearance of the test medium, which was clear throughout the entire test duration. It can therefore be determined that the NOEC is 100 mg/L and the LC₅₀ is > 100 mg/L as the formulation Mecoprop-P K 600 (CA3015). Table B.9.3.1-01- displays the biological results.
- Validity:** The test was considered to be valid, based on fulfilment of the below criteria as per OECD 203:
- Control mortality did not exceed 10% = 0%
 - Constant conditions were maintained as far as possible
 - Dissolved oxygen content did not drop below 60% = minimum of 87%
 - Test item stability was demonstrated to remain within 80-120% of nominal concentrations

Table B.9.3.1-01: Mortality and Visible Abnormalities Observed in the Test Fish

Nominal test item concentration (mg/L)	No of abnormal and dead fish/ number of dead fish			
	3 hours	24 hours	72 hours	96 hours
Control	0/0	0/0	0/0	0/0
100	0/0	0/0	0/0	0/0

III. CONCLUSIONS

The test item Mecoprop-P K 600 had no acute toxic effects on juvenile rainbow trout up to the nominal concentration of 100 mg/L under the conditions of the test. The endpoints are concluded below:

96-hour LC₅₀: >100 mg CA3015/L

96-hour NOEC: 100 mg CA3015/L

RMS comments:

Study was well conducted and reported in accordance with OECD guideline 203, with all validity criteria met. The study is considered to be valid and acceptable. Agreed endpoints are as follows:

96-hour LC₅₀ = > 100 mg CA3015/L, based on nominal tested concentrations.
>58.7 mg a.s./L as mecoprop-P

Ref.: IIIA. 10.2.1. Bias, 1988: Determination of the acute toxicity of Duplosan KV (BAS 037 29 H) to the waterflea *Daphnia magna*.

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The acute toxicity of Duplosan KV (BAS 037 29 H) to the waterflea *Daphnia magna* was studied in a 48 hour static test according to 79/831/EEC Annex V, C.2.

Duplosan KV contained mecoprop-P DMA with a purity of 726 g/l as salt and 600 g/l as acid. The test substance was added directly to the vessels at concentrations of 0, 62.5, 125, 250, 500 and 1000 mg Duplosan KV/l. Twenty daphnids less than 24 hours old were used in each group in 4 replicates of 5 animals/200 ml test volume. During the study, pH varied in the solutions between 7.88 and 8.04, the oxygen content between 9.02 and 9.27 mg O₂/l, and the temperature was 21°C. The measured concentrations were close to nominal concentrations.

Results

At the highest concentration 45% was immobilized after 48 hours.

EC₅₀ was > 1000 mg Duplosan KV/l. NOEC (48h) was 500 mg Duplosan KV/l.

nominal conc. (mg/l)	without daphnids 0 h (mg/l)	without daphnids 48 h (mg/l)	with daphnids 48 h (mg/l)
1000	971	987,6	990,4
500	512	499,3	499,8
250	245	248,7	250,7
125	126	121,8	125,7
62,5	61,7	63,6	67,61
0	0	0	0
1000	977	999,9	994,5
500	516	499,4	502,9
250	244	249,2	256,2
125	123	124,1	126,4
62,5	61,3	62,8	62,85
0	0	0	0

Comments

The study was acceptable. Recalculating to MCP-P DMA content the EC₅₀ is > 643 mg/l and NOEC(48h) 321 mg/l. Based on the acid concentration, EC₅₀ is > 531 mg MCP-P/l and NOEC 265 mg MCP-P/l.

RMS comments (renewal):

The RMS has revisited the study for the purposes of active substance renewal and concludes that it is valid and acceptable for use. Reported concentrations of the test item were within 80-120% of nominal and validity criteria were met in accordance with OECD no.202. The confirmed endpoints are:

48-hr EC₅₀ > 1000 mg formulation/L, equivalent to > 600 mg a.s./L (as mecoprop-P) based on nominal concentrations of the test item.

Ref.: IIIA. 10.2.1. Memmert & Knoch, 1993 b: Acute toxicity of Marks Optica MP n to *Daphnia magna* (48-hour immobilization test).

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The acute toxicity of Marks Optica MP n to the waterflea *Daphnia magna* was studied in a 48 hour static test according to 92/69/EEC C.2 and OECD 202.

Marks Optica MPn contained mecoprop-P DMA with a purity of 728 g/l as DMA salt and 602 g/l as acid (specific gravity = 1.136). The test substance was added directly to the stock solution and prepared in the test vessels at the nominal concentrations of 0, 25, 50, 100, 200, 400 and 1000 mg Marks Optica MPn/l. Twenty daphnids less than 24 hours old were used in each group in 4 replicates of 5 animals/50 ml test volume. During the study, pH varied in the solutions between 7.8 and 8.0, the oxygen content between 8.2 and 8.4 mg O₂/l, and the temperature was 21.6°C. The measured concentrations varied between 101.1 and 104.3% of the nominal concentrations.

Results

At the highest concentration 100% of the daphnids were immobilized after 48 hours.

EC₅₀ was calculated to be 272 mg Marks Optica MPn/l with the 95% confidence limits 242-306 mg/l.

NOEC (48h) was 200 mg Marks Optica MPn/l.

Comments

The study is acceptable. Based on the acid concentration, EC₅₀ is 147 mg MCPP-P/l and NOEC 108 mg MCPP-P/l.

RMS comments (renewal):

The RMS has revisited the study for the purposes of active substance renewal and concludes that it is valid. Reported concentrations of the test item were within 80-120% of nominal and validity criteria were met in accordance with OECD no.202.

48-hr EC₅₀ = 272 mg formulation/L, equivalent to 186 mg a.s./l as mecoprop-P, based on nominal concentrations, a specific gravity for the formulation of 1.136 and a Mecoprop-P content of 602 g/L

Report:	CP 10.2.1/02
Title	Liedtke, A (2014b) Mecoprop-p K 600 g/L (CA3015): Acute Toxicity to <i>Daphnia magna</i> in a 48-Hour Immobilization Test Testing Laboratory: Harlan Laboratories Ltd. Study Number: D76033 Date: 13 January 2014
Guidelines:	EEC C.2 OECD 202
GLP	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

Test material

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	587.3 g/L
Storage conditions:	At room temperature at 20±5°C, in the dark.

Test system

Organism (<i>Species</i>):	Daphnia magna Straus (clone 5)
Source:	Original clone supplied by University of Sheffield, UK in 1992. Since acquired the daphnids have been bred at Harlan Laboratories.
Age of test organism:	6-24 hrs at the start of the test
Number of individuals per dose group:	20
Study Type:	Acute toxicity laboratory study, static
Duration of study:	48 hour
Parameters measured:	Immobilization of daphnids
Test water:	Reconstituted test water according to ISO 6341 was used in the study. It consisted of analytical grade salts dissolved in purified water. The test water was aerated prior to start of the study until oxygen saturation was reached.

Environmental conditions

Water temperature:	21 °C
Photoperiod:	16 hr light / 8 hr dark. 30 minute transition period.
Light intensity:	390 to 560 Lux
Test water pH:	7.7
Test water dissolved oxygen:	8.3 – 8.4 mg/L
Feed:	The daphnids were not fed during the test.

B STUDY DESIGN AND METHODS

In life dates:	25 June to 30 July 2013
Experimental treatment:	The test medium was prepared by mixing 100.2 mg of the test item into 1000 mL of test water under intense stirring for 15 minutes. The

test medium was prepared prior to the introduction of daphnids.

Study design:

The test was performed in 100 mL glass beakers filled with 50 mL of test medium. The test vessels were covered with glass plates to reduce the loss of water by evaporation and to avoid the entry of dust into the solutions.

For each treatment, 20 daphnids were used divided into four replicates of five daphnids each. The volume of test solution provided for each daphnid was 10 mL. Thus, the requirement of the test guidelines for the minimum volume of 2 mL test medium per daphnid was fulfilled. The daphnids were randomly distributed to the test vessels at initiation of the test. Observation of immobility and other toxic signs were made at 24 and 48 hours. Samples of the test media were taken for analysis to confirm concentrations at 0 and 48 hours. Analysis was via HPLC-UV.

Statistics:

No statistical assessment was required as no effect of the product Mecoprop-P K 600 was observed at the nominal test concentration of 100 mg/L

Deviations from study plan:

A new certificate of analysis with a revised analysed content of the active ingredient within the test item was provided by the sponsor after the laboratory work had been carried out. The analysed content of the active ingredient was changed from 595.8 g/L to 587.3 g/L. This deviation to study plan is not considered to have an impact on the outcome of the study.

II. RESULTS AND DISCUSSION

Dosing:

The measured concentration of Mecoprop-P K 600 (CA3015) in the test medium at the single tested concentration of 100 mg/L was 102% at test start and 101% at test end, based upon the content of the active substance Mecoprop-P. Thus the concentration was confirmed and the biological results were based upon the nominal concentration.

Biological Results:

In the control and at the test concentration of 100 mg/L, no immobilized test organisms were observed during the test period of 48 hours. The test item CA3015 had no acute toxic effect on *Daphnia*. It can therefore be determined that the NOEC is 100 mg/L and the LD₅₀ is > 100 mg/L as the formulation Mecoprop-P K 600 (CA3015). Table B.9.3.1-02 displays the biological results.

Validity:

The test was considered valid, since the criteria according to OECD 202 were met as follows:

- Control immobility was < 10% = 0% and no signs of stress.
- Dissolved oxygen was maintained ≥ 3 mg/L = 8.3 – 8.4 mg/L.

Table B.9.3.1-02: Immobilization of *Daphnia* exposed to Mecoprop-P K 600 (CA3015)

Nominal test item concentration (mg/L)	No. of daphnids tested	Immobility at the time point (%)	
		24 hours	48 hours
Control	20	0	0
100	20	0	0

III. CONCLUSIONS

The test item CA3015 had no acute toxic effects on *Daphnia magna* up to the nominal concentration of 100 mg/L under the conditions of the test. The endpoints are concluded below:

48-hour EC₅₀: >100 mg CA 3015/L

48-hour NOEC: 100 mg CA3015/L

In a separate test with reference item potassium dichromate the 48-hr EC₅₀ was found to be 0.73 mg/L, within the range 0.6 – 2.1 mg/L expected according to OECD 202.

RMS comments:

Study was well conducted and reported in accordance with OECD guideline 202, with all validity criteria met. Testing of a reference item with organisms from the same source demonstrated appropriate organism sensitivity. The study is considered to be valid and acceptable. Agreed endpoints are as follows:

48 hour EC₅₀ > 100 mg CA3015/L, based on nominal test concentrations
Equivalent to > 58.7 mg a.s./L as mecoprop-P

Ref.: IIIA. 10.2.1. Memmert & Knoch, 1993 c: Toxicity of Marks Optica MPn to *Pseudokirchneriella subcapitata* (algae growth inhibition test).

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The effect on algae of Marks Optica MP containing MCPP-P DMA salt with a purity of 728 g/l as DMA salt and 602 g/l as acid was studied on the green alga *Pseudokirchneriella subcapitata* using a 72-hour growth inhibition test according to 92/69/EEC C3 and OECD 201.

The test was performed at the concentrations 0, 28, 60, 130, 280 and 600 mg preparation/l using a final volume of 50 ml in three replicates each inoculated with algae at an initial cell concentration of about 3×10^4 cells/ml. The culture flasks were placed in an incubator at 23°C at continuous illumination at 8133 Lux and kept in suspension by constant shaking. The cell densities were measured by a photometer.

Results

Using the nominal concentrations the effect levels were obtained by calculation:

based on biomass $E_b C_{50}$ (0-72h) = 204 mg Marks Optica MP/l
 $NOE_b C$ (72h) = 28 mg/l Marks Optica MP/l
 based on growth rate $E_r C_{50}$ (0-72h) = > 600 mg Marks Optica MP/l

The mean measured values ranged 80.3 to 99.7% of nominal concentrations.

Table B.9.3.1-03: Results on biomass calculations and growth rates.

	Mean values at the nominal concentration (mg/l)					
	0	28	60	130	280	600
Cell density ($\times 10^4$)						
24 h	9.25	8.62	8.26	7.77	6.17	3.64
48 h	43.54	39.68	39.70	37.36	28.47	12.83
72 h	329.00	305.67	186.33	160.00	140.78	95.56
Area	5155	4767	3327	2943	2461	1482
% inhibition	0.0	7.5	35.5	42.9	52.3	71.2
Growth rate						
24 h	2.22	2.15	2.11	2.05	1.82	1.29
48 h	1.89	1.84	1.84	1.81	1.67	1.28
72 h	1.93	1.91	1.74	1.69	1.65	1.52
Average	2.01	1.97	1.90	1.85	1.71	1.36
% inhibition	0	2.2	5.6	8.0	14.8	32.2

Comments

The study is performed according to the guideline and is acceptable.

RMS comments (renewal)

Modern validity criteria can be confirmed from the study report. The below modern study by Liedtke (2013a) is considered more appropriate to meet the data requirement of an algal inhibition study with the representative formulation, further noting that other algal species are shown to be more sensitive to the active substance than that used in this study.

Report:	CP 10.2.1/03
Title:	Liedtke, A (2013a) Mecoprop-p K, 600 g/L (CA3015): Acute Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 72-hour algal growth inhibition test Testing Laboratory: Harlan Laboratories Ltd. Study Number: D76044 Date: 30 October 2013
Guideline:	OECD 201 (2006) EC C.3
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

Test material

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	587.3 g/L
Storage conditions:	At room temperature at 20±5°C in the dark
Test system	
Organism (<i>Species</i>):	Pseudokirchneriella subcapitata, Strain No. 61.81 SAG
Source:	SAG, institute for Plant Physiology, University of Göttingen, Germany
Study Type:	Growth parameters toxicity laboratory study, static exposure.
Duration of study:	72 hours
Parameters measured:	Biomass was measured (as surrogate parameter fluorescence) and the shape and size of the algal cells was visually inspected.
Test water:	Reconstituted test water (AAP Medium) prepared according to the test guidelines was used for algal cultivation and testing.
Environmental conditions	
Water temperature:	25°
pH	7.3 – 9.5
Photoperiod:	Constant illumination by fluorescent tubes
Light intensity:	6390-7670 Lux

B STUDY DESIGN AND METHODS

In life dates:	21/06/2013- 03/08/2013
Experimental treatment:	The test medium of the highest nominal concentration of 100 mg/L was prepared by dissolving 100.18 mg of the test item in 1000 mL of test water using intense stirring for 15 minutes at room temperature. This test medium was then used in a series of dilution with test water to prepare the lower test concentrations of 50, 25, 12.5 and 6.25 mg/L. A media-only control was tested in parallel.
Study design:	Each replicate consisted of a 50 mL Erlenmeyer flask with 15 mL of test medium. The test vessels were covered with

glass dishes and incubated in a water bath in a randomized order. They were labelled with the study number and all necessary additional information to ensure unique identification.

The test design included three replicates per test concentration and six replicates of the control. Continuous agitation of the vessels was applied.

The test was started using a nominal algal cell density of 5000 cells/mL. The initial cell density was selected according to the recommendations of the test guideline. The Algal cell density in the pre-culture was determined by an electronic particle counter (Coulter Counter, Model Z2). A static test design was applied.

At the end of the test, a sample was taken from the control and from the test concentration of nominal 100 mg/L to determine a potential influence of the test item on the algal cells. The shape and size of the algal cells were visually inspected.

The sensitivity of the organisms to a known reference item – Potassium dichromate was tested periodically in the lab as a separate study.

Statistics:

The 72-hour EC_{10} and EC_{20} values for the inhibition of average growth rate and yield and their 95% confidence intervals were calculated as far as possible by Probit Analysis using linear maximum likelihood regression.

For the determination of the LOEC and NOEC, the average growth rate and yield at the test concentrations were compared to the control values by Williams t-test.

Deviations from study plan:

A new certificate of analysis with a new analysed content of the active ingredient within the test item was provided by the sponsor after the laboratory work had been carried out. The analysed content of the active ingredient was changed from 595.8 g/L to 587.3 g/L. This deviation to study plan is not considered to have an impact on the outcome of the study.

II. RESULTS AND DISCUSSION

Dosing:

The measured concentrations of Mecoprop-P K 600 (based on the active ingredient Mecoprop-P) in the media of the test concentrations 12.5 to 100 mg/L were 99% of the nominal values at the start of the test and between 98 and 99% at the end of the test. Thus, the correct dosing of the test item CA3015 was confirmed.

Biological Results:

The test item had a statistically significant inhibitory effect on the growth rate of the algae after the test period of 72 hours at the concentration of 25 mg/L and at all higher test concentrations

The yield Y of the algae was also statistically significantly reduced at the test concentration of 25 mg/L.

The microscopic examination of the algal cells at the end of the test showed no difference between the algae growing at the nominal test concentration of 100 mg/L and the algal cells in the control. The shape and size of the algal cells were obviously not affected by the test item up to at least this concentration.

The biological results can be seen in Table B.9.3.1-04 and Table B.9.3.1-05.

Validity:

In the control, the biomass increased by a factor of 301 over 72 hours. The validity criterion of increase of biomass by at least a factor of 16 within three days was fulfilled. The mean coefficient of variation of the daily growth rates in the control during 72 hours was 11%. According to the OECD test guideline, the mean coefficient of variation must not be higher than 35%. Thus, the validity criterion was fulfilled. The coefficient of variation of the average specific growth rates in the replicates of the control after 72 hours was 0.6%. According to the OECD test guideline, the coefficient of variation must not be higher than 7%. Thus, the validity criterion was fulfilled.

Table B.9.3.1-04: Average growth rate (μ) of algae after application of CA3015

Nominal test item concentration [mg/L]	Average growth rate μ (day ⁻¹) and inhibition of μ (I_r)					
	0-24 h		0-48 h		0-72 h	
	μ	I_r [%]	μ	I_r [%]	μ	I_r [%]
Control	2.12	0.0	1.93	0.0	1.90	0.0
6.25	2.11	0.6	1.90	1.2	1.90	0.2
12.5	2.03*	4.3	1.88	2.6	1.89	0.4
25	1.80*	15.0	1.74*	9.6	1.83*	3.7
50	1.90*	10.2	1.77*	8.2	1.83*	3.6
100	1.67*	21.3	1.59*	17.5	1.71*	10.1

*: mean value statistically significantly lower than in the control (according to Williams t-test, one-sided smaller, $\alpha = 0.05$)

Table B.9.3.1-05: Yield (Y) of algae after application of CA3015

Nominal test item concentration [mg/L]	Yield Y (x10 ³) and inhibition of Y (I_y)					
	0-24 h		0-48 h		0-72 h	
	Y	I_y [%]	Y	I_y [%]	Y	I_y [%]
Control	4.2	0.0	26.3	0.0	170.8	0.0
6.25	4.1	1.4	25.2	4.2	169.4	0.8
12.5	3.8*	9.8	23.8	9.4	166.7	2.4
25	2.9*	30.8	18.1*	31.3	138.4*	19.0
50	3.3*	22.2	19.1*	27.5	138.8*	18.7
100	2.5*	41.1	13.2*	49.9	95.7*	44.0

*: mean value statistically significantly lower than in the control (according to Williams t-test, one-sided smaller, $\alpha = 0.05$)

In a separate reference test with potassium dichromate conducted by the same laboratory, the 72-hour ErC_{50} was found to be 1.3 mg a.s./L.

III. CONCLUSIONS

The biological results can be found summarised below (based on nominal concentrations of the test item CA3015).

Table B.9.3.1-06: Calculated endpoints for inhibition of CA3015 on algal cell growth rate and yield

Parameter (0-72hr)	NOEC	EC ₁₀	EC ₂₀	EC ₅₀
Growth rate	12.5	>100	>100	>100
Yield	12.5	19	38	>100

RMS comments:

The study was well reported and conducted in good adherence with the OECD guideline 201 (2006 version). All corresponding validity criteria were met. It is noted that the pH range for some tested rates, including the control group, increased by greater than 1.5 units which is the maximum recommended by the OECD guideline. However, all control validity criteria were met and no morphological abnormalities were observed in the algal cells under microscopic assessment at 72-hours. It is known that exponential cell growth in algae can cause an increase in media pH due to the gaseous exchange involved. As such this deviation is not considered to adversely impact the study. Overall the study is considered to be valid and acceptable for risk assessment purposes. The agreed endpoints are as follows:

- 72-hour NOEC = 12.5 mg CA3015/L
- 72-hour EC₁₀ = 19 mg CA3015/L (yield), > 100 mg CA3015/L (growth rate)
- 72-hour EC₅₀ > 100 mg CA3015/L, equivalent to > 58.7 mg a.s./L, as mecoprop-P

Report:	CP 10.2.1/04
Title:	Liedtke, A (2013b) Mecoprop-p K, 600 g/L (CA3015): Toxicity to the Aquatic Higher Plant <i>Lemna gibba</i> in a 7-Day Growth Inhibition Test Testing Laboratory: Harlan Laboratories Ltd. Study Number: D76055 Date: 07 November 2013
Guideline:	OECD 221 (2006) EC C.26
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

Test material

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	587.3 g/L
Storage conditions:	Room temperature at 20±5°C, in the dark.

Test system

Organism (<i>Species</i>):	<i>Lemna gibba</i> G3 (duckweed)
Source:	Original culture obtained from Bayer CropScience AG, 40789 Monheim, Germany in 2007. The culture has been maintained at Harlan Laboratories since that time.
Study Type:	Acute toxicity laboratory study, static exposure
Acclimatisation period:	7 days
Parameters measured:	Frond and colony numbers and change in appearance. Also total dry weight.
Test water:	Reconstituted test water (20X AAP growth medium prepared according to the OECD test guideline) was used for cultivation and testing.

Environmental conditions

Water temperature:	25°C
Water pH range:	7.7 – 8.9
Photoperiod:	Continuous illumination with fluorescent tubes.
Light intensity:	7120-7780 Lux

B STUDY DESIGN AND METHODS

In life dates:	26/06/2013 – 15/08/2013
Experimental treatment:	The test medium of the highest nominal concentration of 100 mg/L was prepared by completely dissolving 100.51 mg of the test item in 1000 mL of test water using intense stirring (15 minutes at room temperature). The test medium was used in a series of dilution with test water to prepare the test media of the lower test concentrations of 32, 10, 3.2, 1.0 and 0.32 mg/L. A parallel control group was tested (20xAAP media only) and a reference item (3,5-dichlorophenol) was tested as a separate study to confirm organism sensitivity.

Study design:

The plants were exposed to the test item for a period of seven days in a static test.

At the start of the test, *Lemna* colonies were transferred aseptically from the pre-culture into the different test vessels in a randomized order. The test was started with three randomly selected colonies per vessel (12 fronds/3 colonies). Each replicate vessel was a 250 mL glass dish containing 150 mL of appropriate media. 3 replicates were prepared per concentration and control group. A sub-sample of 12 culture fronds was dried and the starting dryweight therefore determined.

On Days 2 and 5 and at the end of the test on Day 7, the number of fronds and colonies of the *Lemna* plants were counted. Fronds visibly projecting over the edge of the mother frond were counted as separate fronds. On the same dates, the plants were inspected for changes in appearance (e.g., discoloration, sinking, root length, or other abnormalities).

At the test termination, the dry weight of the plants of each test vessel was determined. The plants were dried at about 60 °C in a laboratory vacuum oven for 48 hours (sufficient to reach a constant weight).

Statistics:

The EC₁₀, EC₂₀ and EC₅₀ values for the inhibition of the growth rate and yield based on frond numbers and dry weight and their 95% confidence limits were calculated as far as possible by Probit Analysis

The NOEC and the LOEC for the different growth parameters were determined by testing the parameters at the test concentrations for statistically significant differences to the control values using multiple Dunnett t-test

Deviations from study plan:

The test water (20x AAP medium) was prepared using K₂HPO₄ with a final concentration of 20.9 mg/L instead of K₂HPO₄·3H₂O (30 mg/L) as mentioned in the Study Plan.

A new certificate of analysis with a new analysed content of the active ingredient within the test item was provided by the sponsor after the laboratory work had been carried out. The analysed content of the active ingredient was changed from 595.8 g/L to 587.3 g/L. Both deviations to study plan are not considered to have an impact on the outcome of the study.

II. RESULTS AND DISCUSSION

Dosing:

The measured concentrations of CA3015 (based on the active ingredient Mecoprop-P) in the test media of the test concentrations of 0.32 to 100 mg/L were between 104 and 108% of the nominal values at the start of the test and between 102 and 105% at the end of the test. Thus, the correct dosing of the test item CA3015 was confirmed and results were expressed in term of nominal test item

concentrations.

Biological Results:

The test item CA3015 had a statistically significant inhibitory effect on the growth of *Lemna gibba* (yield based on frond number and growth rate and yield based on dry weight) after the exposure period of 7 days at the concentration of 1.0 mg/L and at all higher test concentrations

No abnormalities in appearance of the test plants were recorded in the control and the test concentrations of 0.32 and 1.0 mg/L. At the concentrations of 10 to 100 mg/L the roots of the plants were shorter compared to the control based on visual assessment and the fronds were slightly upwards curved on Day 5. At the concentrations of 3.2 to 100 mg/L (Day 7), the roots of the plants were shorter compared to the control based on visual assessment and the fronds showed gibbosity.

Validity:

The test was considered to be valid, since; Lemna growth was satisfactory under the test conditions, with frond doubling time calculated as 2.0 days (criteria ≤ 2.5 days)

Also the pH of the test media and the control did not exceed the 1.5 variation limit and the water temperature was maintained at 25°C during the test period.

Table B.9.3.1-07: Average growth rate (μ) of Lemna based on frond numbers after application of CA3015

Nominal test item concentration [mg/L]	Average growth rate μ (day ⁻¹) and inhibition of μ (I_r)					
	Days 0-2		Days 0-5		Days 0-7	
	μ	I_r [%]	μ	I_r [%]	μ	I_r [%]
Control	0.162	0.0	0.349	0.0	0.344	0.0
0.32	0.144	11.1	0.336	3.7	0.329	4.5
1.0	0.133	17.7	0.324	7.2	0.324	5.9
3.2	0.153	5.2	0.315*	9.7	0.310*	9.8
10	0.111	31.5	0.277*	20.5	0.261*	24.1
32	0.122	24.4	0.202*	42.2	0.175*	49.2
100	0.112	31.0	0.206*	41.0	0.163*	52.7

* Mean value significantly lower than in the control (according to Dunnett t-test, one-sided smaller, $\alpha = 0.05$)

Table B.9.3.1-08: Yield Y of Lemna based on frond numbers after application of CA3015

Nominal test item concentration [mg/L]	Yield Y and inhibition of Y (I_y)					
	Days 0-2		Days 0-5		Days 0-7	
	Y	I_y [%]	Y	I_y [%]	Y	I_y [%]
Control	4.7	0.0	56.7	0.0	122.0	0.0
0.32	4.0	14.3	52.3	7.6	108.0	11.5

1.0	3.7	21.4	48.7*	14.1	104.0*	14.8
3.2	4.3	7.1	46.0*	18.8	93.3*	23.5
10	3.0	35.7	36.0*	36.5	62.7*	48.6
32	3.3	28.6	21.0*	62.9	29.0*	76.2
100	3.0	35.7	21.7*	61.8	25.7*	79.0

*Mean value significantly lower than in the control (according to Dunnett t-test, one-sided smaller, $\alpha = 0.05$)

Table B.9.3.1-09: Average growth rate (μ) of Lemna based on dry weights

Nominal test item concentration [mg/L]	Average growth rate μ (day ⁻¹) and inhibition of μ (I_r)	
	Days 0-7	
	μ	I_r [%]
Control	0.365	0.00
0.32	0.354	3.01
1.0	0.345*	5.48
3.2	0.349	4.38
10	0.332*	9.04
32	0.311*	14.79
100	0.261*	28.49

* Mean value significantly lower than in the control (according to Dunnett t-test, one-sided smaller, $\alpha = 0.05$)

Table B.9.3.1-10: Yield Y of Lemna based on dry weights after application of CA3015

Nominal test item concentration [mg/L]	Yield Y and inhibition of Y (I_y)	
	Days 0-7	
	Y	I_y [%]
Control	15.0	0.00
0.32	13.8	8.00
1.0	12.9*	14.00
3.2	13.3	11.33
10	11.6*	22.67
32	9.9*	34.00
100	6.6*	56.00

* Mean value significantly lower than in the control (according to Dunnett t-test, one-sided smaller, $\alpha = 0.05$)

III. CONCLUSIONS

The biological results can be summarised as follows (based on nominal concentrations of the test item CA3015):

Table B.9.3.1-11: Summary of endpoints for toxicity of Mecoprop-P K 600 (CA3015) to the macrophyte *Lemna gibba*

EC values [mg/L]	Frond numbers		Dry weight of the plants	
	Growth rate	Yield	Growth rate	Yield
7-day EC ₅₀	59	11	>100	88
7-day EC ₂₀	6.2	1.6	47	6.0
7-day EC ₁₀	1.9	0.61	11	1.5
7-day NOEC	1.0	0.32	0.32	0.32
7-day LOEC	3.2	1.0	1.0	1.0

RMS comments:

The study was well reported and conducted in close adherence with OECD 221. The validity criteria were met as required, and there were no significant deviations from the referenced guideline. As such the study is considered valid and acceptable for risk assessment purposes. The agreed study endpoints are as follows:

EC values [mg CA3015/L]	Growth rate	Yield
7-day EC ₅₀	59	11
7-day EC ₁₀	1.9	0.61
7-day NOEC	1.0	0.32

All endpoints are for inhibition of frond number (the most sensitive parameter) and are expressed in terms of nominal test item concentrations.

Report:	CP 10.2.1/05
Title:	Gonsoir, G. (2015) Mecoprop-p K, 600 g/L: Growth inhibition of <i>Myriophyllum spicatum</i> in a water/sediment system. Testing Laboratory: Eurofins Agrosience Services EcoChem GmbH Study Number: S13-04889 Date: 25 June 2015
Guideline:	OECD Draft Guideline: Water-Sediment <i>Myriophyllum</i> sp Toxicity Test based on Draft AMRAP Method: Growth Inhibition Test for the Rooted Aquatic Macrophyte, <i>Myriophyllum</i> sp. Submitted to OECD for Evaluation, 22 July 2013.
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

Test material

Test item: Mecoprop-P K 600 g/L, AKA CA3015

Description: Brown liquid

Lot No./Batch No: 33-01-119

Active ingredient content: 601.4 g/L

Storage conditions: Room temperature at 20±2°C, in the dark.

Vehicle and/or positive control: Test medium: Smart and Barko
Positive control: None reported

Test system

Organism (*Species*): Rooted aquatic macrophyte, *Myriophyllum spicatum* L., belonging to the family *Haloragaceae*

Source: Laboratory stock culture, used to provide uniform plants throughout the year. The stock culture plants were held under the same environmental conditions as used in the test.

Acclimatisation period: 8 days (7-days in stock sediment, then 1 day in test vessels).

Test water: SMART AND BARKO medium

Test sediment: Artificial sediment according to OECD 219.

Environmental conditions

Water temperature: 19.2 ± 0.6 °C

Water pH: 8.06 ± 0.65

Photoperiod: 16 hour day length

Light intensity: 130 – 160 µE*m⁻²*s⁻¹

B STUDY DESIGN AND METHODS

In life dates: 28 November 2013 – 19 December 2013

Experimental treatment: Mecoprop-p K 600 g/L, Batch No.: 33-01-119, Active ingredient: Mecoprop, Content of a.s. (analysed): 601.4 g/L, Test species: *Myriophyllum spicatum*. Five replicates per test item concentration and ten replicates for the control (Smart and Barco media only) were used. Each replicate consisted of a single shoot of uniform size (± 10%) rooted in artificial sediment (350 g wet weight per vessel) and overlaid with 1.5L of appropriately prepared test media. The duration of the test was 14 days. The test was performed under static test

conditions. The nominal concentrations of the test item during the test were 1.91, 6.10, 19.5, 62.5 and 200 µg/L and control. This is equivalent to 0.917, 2.93, 9.37, 30.0 and 96.1 µg/L active ingredient. The test item was spiked to the water.

Test item concentrations in the definitive test were verified by analysis of Mecoprop-p at all concentration levels by analysing the overlying water at test start and test end and wet sediment at test termination on day 14.

Observations:

On day 14 plants were harvested from each treatment group for assessment of shoot length, plant fresh weight, plant dry weight and number and length of side shoots. Additionally the main shoot length was measured by use of a ruler on days 0, 7 and 14 during the test.

Endpoints reported are the EC50 for yield (EyC50) and growth rate (ErC50) based on the increase in total shoot length and biomass respectively after 14 days of exposure. The NOEC and LOEC for yield and growth rate were also determined. Temperature, pH and oxygen saturation [%] of the test solutions, measured after 0, 7 and 14 days, are reported.

Deviations from study plan:

None

II. RESULTS AND DISCUSSION

Analytical Results:

The measured concentration of the test item based on the Mecoprop-p content in the test vessels at test start ranged between 102 and 111 % of nominal in the overlying water. After 14 days mean Mecoprop-p concentrations in the overlying water were 87-107% of nominal. As the mean contents of Mecoprop-p were between 80 and 120 % of nominal at test start all toxicological endpoints were evaluated using nominal concentrations of the test item. Day 14 analysis of the sediment resulting in mecoprop-P recoveries that could be quantified in only nominally tested concentrations of 62.5 and 200 µg/L, both of which had sediment containing 7% of nominal concentrations.

Biological Results:

The results of the main test are summarised below:

Table B.9.3.1-12: Mean total shoot length including side shoots (cm)

Nominal test item concentration [µg/L]	Days after application		yield [cm]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0 ¹⁾	14				
Control	6.7	39.0	32.3	-	0.1250	-
1.91	6.7	34.6	27.9	13.6	0.1171	6.3
6.10	6.7	32.7	26.0*	19.5*	0.1129	9.7
19.5	6.7	31.7	25.0*	22.6*	0.1107	11.4
62.5	6.7	15.8	9.1*	71.8*	0.0594*	52.5*
200	6.7	11.1	4.4*	86.4*	0.0341*	72.7*

* significantly different reduction compared to the control

¹⁾ based on 15 additional plants, representative of those used in the test**Table B.9.3.1-13: Mean total plant fresh weight (g)**

Nominal test item concentration [µg/L]	Days after application		yield [g]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0 ¹⁾	14				
Control	0.2315	1.269	1.0375	-	0.1199	-
1.91	0.2315	1.1173	0.8858	14.6	0.1120	6.6
6.10	0.2315	0.9988	0.7673*	26.0*	0.1043	13.0
19.5	0.2315	0.9833	0.7518*	27.5*	0.1021	14.8
62.5	0.2315	0.6151	0.3836*	63.0*	0.0691*	42.4*
200	0.2315	0.4700	0.2385*	77.0*	0.0493*	58.9*

* significantly different reduction compared to the control

¹⁾ based on 15 additional plants, representative of those used in the test

Table B.9.3.1-14: Mean total plant dry weight (g)

Nominal test item concentration [µg/L]	Days after application		yield [g]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0 ¹⁾	14				
Control	0.0384	0.0912	0.0528	-	0.0601	-
0.191	0.0384	0.0857	0.0473	10.4	0.0558	7.2
0.610	0.0384	0.0775	0.0391	25.9	0.0499	17.0
1.95	0.0384	0.0821	0.0437	17.2	0.0535	11.0
6.25	0.0384	0.0862	0.0478	9.5	0.0575	4.3
20.0	0.0384	0.0737	0.0353	33.1	0.0457	24.0

¹⁾ based on 15 additional plants, representative of those used in the test

Visual abnormalities were observed at the tested concentrations of nominally 62.5 and 200 µg/L, where hanging leaves, deformation of shoots, reduced root number and reduced root length (200 µg/L only) were seen. The extent of these observations was not recorded.

III. CONCLUSIONS

The biological results can be summarised as follows (based on nominal concentrations of the test item):

Table B.9.3.1-15: Summary of endpoints for toxicity of Mecoprop-P K 600 to the macrophyte *Myriophyllum spicatum*

	µg/L					
	14 day ErC ₅₀		14 day EyC ₅₀		14 day NOEC	
	Mecoprop-p *	Mecoprop-p K 600 g/L	Mecoprop-p *	Mecoprop-p K 600 g/L	Mecoprop-p *	Mecoprop-p K 600 g/L
Shoot length	26.9	56.1	9.41	19.6	0.917	1.91
Biomass (fresh weight)	53.3	111	12.0	24.9	0.917	1.91
Biomass (dry weight)	>96.1¹⁾	>200 ¹⁾	>96.1¹⁾	>200 ¹⁾	96.1	200

1) no effect >50% could be observed, therefore the EC₅₀ was estimated to be estimated to be >200 µg/L Mecoprop-p K 600 g/L or >96.1 µg/L Mecoprop-p *Based on active substance content of 601.4 g/l and density 1.252

RMS comments:

The study was well reported and appears to have been conducted in good adherence with both the draft and finalised OECD guideline (no. 239; Water sediment toxicity test). Validity criteria were met in line with the finalised guideline as follows:

- Doubling time for shoot length and fresh weight did not exceed 14-days: 5.5 days and 5.8 days achieved, respectively.

- The C of V for control replicate fresh weight did not exceed 35%: 14% achieved.

It is noted that no reference item testing was included in the study report, despite the long-term maintenance of the organism cultures at the performing laboratory. Given the date of the study, and reference given to the draft OECD guideline, toxicity data with the reference item 3, 5-dichlorophenol should be available, as this was used in the ring-testing used prior to drafting said guideline.

The agreed endpoints from the study are as follows:

EC values [µg CA3015/L / µg a.s./L)	Growth rate	Yield
14-day EC ₅₀	56.1 / 26.9	19.6 / 9.41
14-day EC ₁₀	3.12 / 1.50	1.15 / 0.552
14-day NOEC	19.15 / 9.37	1.91 / 0.917

All endpoints are expressed in terms of nominal concentrations and are with regards to total shoot length inhibition; the most sensitive measured parameter

Report:	CP 10.2.1/06
Title	Seeland-Fremer, A and Mosch, W (2015) Toxicity of Mecoprop-p K 600 g/L to the Aquatic Plant <i>Myriophyllum spicatum</i> in a Static Growth Inhibition Test with Prior Rooting Phase Testing Laboratory: IBACON, Germany. Study Number: 91411215 Date: 05 March 2015
Guidelines:	OECD Guideline: New Test Guideline 239: Water-Sediment <i>Myriophyllum spicatum</i> Toxicity Test (20-May-2014)
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A. MATERIALS

- Test materials:** MCPP-p K 600 g/L, AKA CA3015
Description: Brown liquid
Lot/Batch #: 18-32-122
Purity: 582.9 g/L
- Test Organism**
Species: Rooted aquatic macrophyte, *Myriophyllum spicatum*
Age/growth stage: 6±1 cm shoots at initiation

Source: The sterile plants introduced in the test were taken from IBACON's in-house laboratory culture.

Holding conditions The plants of the stock culture (shoot segments with two whorls without a shoot tip) were maintained in modified Andrews' medium containing 3 % sucrose under sterile conditions for 36 days to initiate the development of side shoots. They are cultured at 3470 lux and a temperature range of 20 °C. 6 days prior to study initiation plants were rinsed and transferred to the test medium and held under approximate test conditions.

Medium: Water: Smart and Barko

Substrate: Artificial according to OECD 219

3. Environmental conditions

Temperature: 19-21 °C

pH: 7.9 – 9.8

Light intensity: 8250-9890 Lux

Photoperiod: 16 hours light / 8 hours dark

B. STUDY DESIGN

1. In-life dates:

10 July 2014 – 08 August 2014

2. Test conditions

Preparation of test organisms:

New initiated side shoots were washed for 30 minutes in deionised water to remove the whole culture medium. For approximately 6 days the plants are maintained in Smart and Barko medium until the test start at a light intensity of 8380 lux (16 hours photoperiod daily) and temperature conditions of 23°C to remove all plant stored sucrose.

The side shoots, which were used in the static growth inhibition test, had a length of 6 ± 1 cm before introducing them into the test.

Test units:

Small plant pots (approx. 8.5 cm diameter, 7 cm high and with a volume of approx. 400 mL) were used as containers for potting the plants into the sediment.

Test beakers of 2000 mL volume (approx. 11.5 cm diameter, 24 cm high) with approximately 1800 mL test medium were used to provide an overlaying water depth of minimum 12 cm. 5 replicates were prepared per tested concentration, while 10 replicates were prepared for the control group (Smart and Barko medium only). Each replicate consisted of a single plant.

3. Experimental treatments

Before the exposure period a concentrated stock solution of 20 mg/L was prepared by dispersing 27.4 mg test item in 1370 mL test water by intense stirring for 20 minutes. Each treatment group was spiked with a defined volume of the stock solution in order to obtain the desired test concentrations.

The nominal concentrations of the test item during the test were 1000, 316, 100, 31.7 and 10 µg/L and control. This is equivalent to 474, 150, 47.4, 15.0 and 4.74 µg/L active ingredient (Mecoprop-P).

The concentrations of the active ingredient Mecoprop-P in the test item Mecoprop-p K 600 g/L were analysed in the duplicate test media samples from all test concentrations on Days 0 and 14. From the control media duplicate samples were also analysed from both sampling times.

There were five replicates per test item concentration and ten replicates for the control were used. After a pre-rooting phase of 7 days, one plant per replicate was exposed for 14 days under static conditions. The shoot length was determined at test start and day 14. Sub-lethal parameters were assessed at test start, once during the test (day 8) and at test end. At test start and end fresh and dry weight of each replicate was determined. Fresh and dry weight at day 0 was assessed using a representative sample of surplus plants.

Endpoints reported are for yield (EyC10, EyC20 and EyC50) and growth rate (ErC10, ErC20 and ErC50) based on the increase in total shoot length and biomass respectively after 14 days of exposure. The NOEC and LOEC for yield and growth rate were also determined. Temperature, pH and oxygen saturation [%] of the test solutions, were measured after 0, 7 and 14 days.

II. RESULTS AND DISCUSSION

A. OBSERVATIONS

The pH-value at day 0 and day 14 was determined to be between 8.0-8.1 and 7.8-9.8 respectively. The temperature was measured to be 19-21 °C and the oxygen saturation was determined to be between 7.6-8.6 mg/l at day 0 and 8.1-16.4 at day 14.

Analysis of the test media on day 0 and 14 by HPLS-MS/MS resulted in recovered concentrations of Mecoprop-P at 103-113% of nominal (day 0), and 89-100% nominal (day 14). Thus biological endpoints are expressed in terms of nominal tested concentrations

Sub-lethal effects were recorded for all test concentration groups except of the lowest. Beginning with 31.7 mg test item/L all plants had shorter and distorted leaves in comparison to the control after 8 and 14 days of exposure. At 100 - 1000 µg test item/L the leaves were laid to the stem and they were shorter as well after eight and 14 days of exposure.

All plants developed roots. Beginning with 31.7 µg test item/L only a few roots were developed and they were shorter.

Side shoots frequently occurred in the control and the lower concentration ranges but their numbers decreased with increasing test item concentrations.

Table B.9.3.1-16: Mean total shoot length including side shoots (cm)

Nominal test item concentration [µg/L]	Days after application		yield [cm]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0	14				
Control	7.3	73.8	66.8	--	0.166	--
10	6.6	64.2	57.6	13.8*	0.162	2.1
31.7	8.1	53.8	45.7	31.6*	0.136	17.9*
100	7.2	23.9	16.7	74.9*	0.085	48.6*
316	7.3	21.3	13.9	79.2*	0.076	54.1*
1000	7.2	18.3	11.1	83.4*	0.066	59.9*

* Significantly different reduction compared to the control

Table B.9.3.1-17: Mean total plant fresh weight (mg)

Nominal test item concentration [µg/L]	Days after application		yield [g]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0 ¹⁾	14				
Control	257.8	1454	1195.9	--	0.122	--
10	257.8	1079	821.6	31.3*	0.102	16.8*
31.7	257.8	787	527.0	55.9*	0.079	35.3*
100	257.8	416	158.6	86.7*	0.029	76.7*
316	257.8	452	193.8	83.8*	0.038	68.3*
1000	257.8	533	275.4	77.0*	0.050	58.8*

* Significantly different reduction compared to the control

¹⁾ based on additional plants, representative of those used in the test

Table B.9.3.1-18: Mean total plant dry weight (mg)

Nominal test item concentration [µg/L]	Days after application		yield [g]	reduction in yield [%]	growth rate [1/day]	reduction in growth rate [%]
	0 ¹⁾	14				
Control	70.8	142	71.2	--	0.049	--
10	70.8	121	50.6	28.9*	0.038	22.0
31.7	70.8	120	49.4	30.6*	0.036	26.8
100	70.8	81.2	10.4	85.4*	0.007	86.3*
316	70.8	86.2	15.4	78.4*	0.013	73.5*
1000	70.8	81.4	10.6	85.1*	0.009	81.5*

*Significantly different reduction compared to control

¹⁾ Based on additional plants, representative of those used in the test

The test fulfils the criteria of validity, since:

- Mean control shoot length and fresh weight at least doubled by the end of the test = 10.1 and 6.54-fold increase, respectively
- The mean coefficient of variation for growth rate and yield based on measurements of total plant fresh weight (i.e. from test initiation to test termination) in the control cultures did not exceed 35% = 23.1%

III. CONCLUSIONS

Table B.9.3.1-19: Summary of toxicity of MCP-P K 600 (as MCP-P acid) to *Myriophyllum spicatum*

	µg MCP-P acid/L		
	Shoot length	Biomass (fresh weight)	Biomass (dry weight)
ErC ₁₀	< 4.74	< 4.74	< 4.74
EyC ₁₀	< 4.74	< 4.74	< 4.74
ErC ₂₀	12.5	< 4.74	< 4.74
EyC ₂₀	6.13	< 4.74	< 4.74
ErC ₅₀	133	38.9	32.9
EyC ₅₀	27.7	10.6	22.3
LOErC	15	4.74	47.4

LOEyC	4.74	4.74	4.74
NOErC	4.74	<4.74	15
NOEyC	<4.74	<4.74	<4.74

RMS comments:

The study was well reported and appears to have been conducted in good adherence with the finalised OECD guideline (no. 239; Water sediment toxicity test). Validity criteria were met in line with the finalised guideline. Unlike the previous study (Gonsoir, G. 2015), no analysis of the sediment took place. However the results from the analysis of test media on days 0 and 14 confirmed that partition between the water and sediment was likely to be roughly similar in both tests. Stability of the nominal test concentrations in the aqueous media was demonstrated.

It is noted that no reference item testing was included in the study report, despite the long-term maintenance of the organism cultures at the performing laboratory. Given the date of the study, and reference given to the finalised OCED guideline, toxicity of the reference item 3, 5-dichlorophenol is available, as this was used in the ring-testing used to draft said guideline.

The agreed critical endpoints from the study are as follows:

EC values [µg CA3015/L / mg a.s./L)	Growth rate	Yield
14-day EC ₅₀	69.4 / 32.9 ³⁾	22.4 / 10.6 ²⁾
14-day EC ₁₀	< 10 / < 4.74 ^{1,2,3)}	< 10 / < 4.74 ^{1,2,3)}
14-day NOEC	< 10 / < 4.74 ²⁾	< 10 / < 4.74 ^{1,2,3)}

- 1) Shoot length inhibition
- 2) Wet weight inhibition
- 3) Dry weight inhibition

All endpoints are expressed in terms of nominal concentrations.

B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No additional data is provided in support of the representative formulation for the purposes of renewal.

B.9.3.3. Further testing on aquatic organisms

No additional data is provided in support of the representative formulation for the purposes of renewal.

B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS

A summary of the available toxicity data from testing with aquatic organisms is provided in below table B.9.4-01. Only those studies considered valid under the renewal assessment of the active substance are included and only the most sensitive, or most relevant endpoint parameter for the purposes of risk assessment are included. For further agreed endpoints from the available data reference is made to both the List of End Points section of the renewal assessment report, as well as the individual study summaries.

Table 9.4-01: Summary of aquatic toxicity endpoints for use in the risk assessment with Mecoprop-P and the representative formulation

Organism	Test substance	Time-scale	End point	Toxicity as mecoprop-P (unless otherwise noted)	References
Fish					
<i>S.gairdneri</i>	Mecoprop (racemic)	Acute	96-hr LC ₅₀	171 mg a.s./L (m m)	████ (1984b)
<i>L.macrochirus</i>	Mecoprop-P	Acute	96-hr LC ₅₀	>100 mg a.s./L (nom)	████ (1989)
<i>O.mykiss</i>	Mecoprop (DMA salt)	Acute	96-hr LC ₅₀	>93 mg a.s./L (nom)	████ (1992a)
<i>L.macrochirus</i>	Mecoprop (DMA salt)	Acute	96-hr LC ₅₀	>93 mg a.s./L (nom)	████ (1992b)
<i>O.mykiss</i>	Mecoprop-P K 600 g/L	Acute	96-hr LC ₅₀	>100 mg form'n/L >58.7 mg a.s./L (nom)	████ (2014a)
<i>O.mykiss</i>	Mecoprop-P	Chronic	21-day adult NOEC	50 mg a.s./L (nom)	████ (1993)
<i>O.mykiss</i>	Mecoprop-P	Chronic	89-day NOEC	11.1 mg a.s./L (m m)	████ (2015)
Aquatic invertebrates					
<i>D.magna</i>	Mecoprop-P	Acute	48-hr EC ₅₀	>91 mg a.s./L (m m)	Bell (1994)
<i>D.magna</i>	Mecoprop-P	Acute	48-hr EC ₅₀	>100 mg a.s./L (m.m)	Elendt-Schneider (1991)
<i>D.magna</i>	Mecoprop-P K 600 g/L	Acute	48-hr EC ₅₀	> 100 mg form'n/L >58.7 mg a.s./L (nom)	Liedtke (2014b)
<i>D.magna</i>	Duplosan KV	Acute	48-hr EC ₅₀	>1000 mg form'n/L > 600 mg a.s./L (nom)	Bias (1988)
<i>D.magna</i>	Optica MP	Acute	48-hr EC ₅₀	272 mg form'n/L (nom) 186 mg a.s./L (nom)	Memmert and Knoch (1993b)
<i>D.magna</i>	Mecoprop-P	Chronic	21-day NOEC	50 mg a.s./L (nom)	Dohmen (1993a)
<i>D.magna</i>	Mecoprop-P	Chronic	21-day NOEC	22.2 mg a.s./L*	Mullerschön (1990)
<i>C. gigas</i>	Mecoprop-P	Chronic	36-hr EC ₁₀	50.49 mg a.s./L (nom)	Mottier et al (2014)
Algae					
<i>P.subcapitata</i>	Mecoprop-P	Growth	72-hr E _b C ₅₀ 72-hr E _r C ₅₀	270 mg a.s./L (nom) >729 mg a.s./L (nom)	Dohmen (1993b)
<i>A.flos-aquae</i>	Mecoprop (DMA salt)	Growth	72-hr E _b C ₅₀ 72-hr E _r C ₅₀	16.2 mg a.s./L (m m) 23.9 mg a.s./L (m.m)	Armstrong (2000)
<i>N.pelliculosa</i>	Mecoprop (DMA salt)	Growth	72-hr E _b C ₅₀ 72-hr E _r C ₅₀	57.8 mg a.s./L (m m) 105 mg a.s./L (m m)	Jenkins (2007)
<i>S.costatum</i>	Mecoprop (DMA salt)	Growth	72-hr E _b C ₅₀ 72-hr E _r C ₅₀	84 mg a.s./L (m.m) 102 mg a.s./L (m m)	Burke (2007)
<i>P.subcapitata</i>	Mecoprop-P K 600 g/L	Growth	72-hr E _b C ₅₀ 72-hr E _r C ₅₀	>100 mg form'n/L >100 mg form'n/L >58.7 mg a.s./L (nom)	Liedtke (2013a)
Aquatic macrophytes (AKA higher plants)					
<i>L.gibba</i>	Mecoprop-P (DMA salt)	Growth	14-day EC ₅₀ (frond number)	1.6 mg a.s./L (m.m)	Hoberg and Witting (1992)
<i>L.gibba</i>	Mecoprop-P K 600 g/L	Growth	7-day E _b C ₅₀ (frond number) 7-day E _r C ₅₀ (frond number)	11 mg form'n/L 6.46 mg a.s./L (nom) 59 mg form'n/L 34.7 mg a.s./L (nom)	Liedtke (2013b)
<i>M.spicatum</i>	Mecoprop-P K 600 g/L	Growth	14-day E _y C ₅₀ (shoot length) 14-day E _r C ₅₀ (shoot length)	19.6 µg form'n/L 9.41 µg a.s./L (nom) 56.1 µg form'n/L 26.9 µg a.s./L (nom)	Gonsoir (2015)

Organism	Test substance	Time-scale	End point	Toxicity as mecoprop-P (unless otherwise noted)	References
<i>M.spicatum</i>	Mecoprop-P K 600 g/L	Growth	14-day E _y C ₅₀ (wet weight) 14-day E _r C ₅₀ (dry weight)	22.4 µg form'n/L 10.6 µg a.s./L (nom) 69.4 µg form'n/L 32.9 µg a.s./L (nom)	Seeland-Fremer and Mosch (2015)
Other relevant studies					
<i>L.macrochirus</i>	Mecoprop (racemic)	bioconcentration	BCF (whole fish)	3.0	Ellgehausen (1986)

Bold endpoints – critical endpoint for organism group considered in initial risk assessments

*Study could not be confirmed as valid by RMS, conservatively retained as lower endpoint than valid study for same data requirement

Acute fish endpoint with the active substance

With regards to the acute risk to fish from the active substance, there are a total of 4 valid studies, spanning 2 species. Two of the 4 endpoints are unbound 'greater than' values, indicating that the defined concentration causing 50% mortality lies above the tested concentrations. The highest LC₅₀ after 96-hours is a bound endpoint of 171 mg a.s./L. The studies are all comparable in terms of duration, observed parameters and approximate methodology. As such it is proposed as suitable to derive a geometric mean acute fish endpoint from the available dataset, treating any unbound 'greater than' values as bound endpoints. This is in accordance with the 2013 Guidance of EFSA². A geometric mean for each species is first derived, and then an overall geometric mean acute LC₅₀ for fish. This is calculated to be **110.3 mg a.s./L, which is suitable for use in the risk assessment**. This will be applied to the aquatic risk assessment, should the critical (i.e. lowest) acute fish toxicity endpoint not result in a low risk at FOCUS steps 1-3.

Long-term fish endpoint with the active substance

It should be noted that the original DAR included 2 prolonged fish toxicity studies, conducted according to OECD guideline no.204. Under modern active substance data requirements this test type is no longer suitable to define long-term toxicity to fish, due to its failure to assess the various life stages of this organism which may be of heightened sensitivity to substances. The 2 studies in question are retained in the renewal assessment report (CA B.9.2.2) in the original summary form from the DAR, but have not been revisited by the RMS at renewal for the above reasons. It should be noted that a valid ELS study endpoint (from ████████ 2015) is available to address the long-term toxicity to fish data requirement and that the endpoint from that study is lower than was originally concluded for either of the prolonged toxicity tests from the original DAR. As such **the long-term fish toxicity endpoint relevant for use in the renewal risk assessment of mecoprop-P is 11.1 mg a.s./L**.

Acute invertebrate endpoint with the active substance

There are 2 valid studies giving a 48-hour EC₅₀ for *Daphnia magna* for exposure to mecoprop-P. Both are unbound 'greater than' values of a similar level (>91 and >100 mg a.s./L). In both studies there was minimal observed immobility after 48-hours of 5 and 10%, respectively. As such it is appropriate to utilise an **acute EC₅₀ of >100 mg a.s./L in the aquatic invertebrate risk assessment**.

Chronic invertebrate endpoint with the active substance

There are 2 studies available which provide a 21-day NOEC for *Daphnia magna* exposure to mecoprop-P. At renewal on one of these studies: Dohmen (1993a) was provided by the notifier in support of Mecoprop-P and was re-evaluated as valid by the RMS. However, the other available study: Mullerschön (1990) resulted in a lower endpoint, but could not be re-evaluated by the RMS to confirm its reliability for use. To ensure that the risk to this group is sufficiently and conservatively assessed, **the following risk assessment for chronic exposure to aquatic invertebrates considers**

² Guidance on tiered risk assessment for edge-of-field surface waters: EFSA Journal 2013;11(7):3290

both the validated NOEC of 50 mg a.s./L, as well as the lower but un-validated NOEC of 22.2 mg a.s./L.

Algal endpoint with the active substance

In accordance with the 2013 guidance of EFSA for aquatic organisms in edge-of-field surface waters, preference is given to the use of growth rate (i.e. E_rC_{50}) toxicity endpoints with algae and aquatic plants. There are valid endpoints expressed in terms of mecoprop-P for a total of 4 algal species, all of which are based on the critical study duration of 72-hours. 96-hour endpoints were higher, where the duration of the study allowed for their calculation. As such it is considered suitable to calculate a geometric mean algal E_rC_{50} for use in the risk assessment, in accordance with the 2013 guidance of EFSA (see section 2.1.4.1), which can be applied should the lowest endpoint available not result in a low risk at FOCUS steps 1-3. The **geometric mean algal E_rC_{50} is calculated to be 116.9 mg a.s./L**, which is not more than an order of magnitude above the lowest species endpoint of 23.9 mg a.s./L.

Aquatic plant endpoint with the active substance

Data with the species *L.gibba* only is available with the active substance. Accompanying data on the same species from testing with the representative formulation does not indicate increased toxicity over the active substance alone, and this is further supported by consideration of the co-formulants within Mecoprop-P K 600 g/L (see Vol.4 of the renewal assessment report for further detail of the constituents of the representative formulation). As such it is considered appropriate to also consider the formulated product toxicity endpoints for this group, expressed in terms of active substance content. There were 2 equivalent studies conducted with a second aquatic plant species: *Myriophyllum spicatum*, with both studies giving approximately comparable endpoints. In the study by Gonsoir (2015), the lowest 14-day E_rC_{50} was 26.9 µg a.s./L, while the lowest E_rC_{50} in the second study by Seeland-Fremer and Mosch (2015) was 32.9 µg a.s./L. As the 2 studies are considered to be equivalent in regards to the guideline followed, test item, duration, etc. **then a geometric mean E_rC_{50} from the 2 studies is appropriate for use in the risk assessment. This is calculated to be 29.7 µg a.s./L**, and will be applied in the risk assessment should the critical endpoint not result in a low risk at FOCUS steps 1-3. Due to the clear difference in sensitivity of *Lemna* and *Myriophyllum* to the test item (by a factor of ca 60), it is not considered appropriate to combine the 2 species' datasets.

Toxicity of metabolite O-cresol

A submitted position paper (Simmons, 2015) was evaluated by the RMS and is summarised under (CA) 8.2.8/01. The paper compiled available toxicity data with the o-cresol metabolite as well as generating predicted toxicity based on structure using QSAR analysis. The lower endpoint from the available methods is proposed for use to conduct a quantitative risk assessment for the metabolite with regards to the aquatic environment. The endpoints for use are confirmed as follows:

Table 9.4-02: Summary of aquatic toxicity endpoints for use in the risk assessment with Mecoprop-P metabolite O-cresol

Aquatic organism group + species (if provided)	Endpoint type	Toxicity of O-cresol (mg/L)
Fish acute (<i>S.trutti</i>)	96-hr LC_{50}	6.2 ¹
Fish chronic	Not given assumed NOEC	1.7 ²
Daphnid acute	48-hr EC_{50}	5.2 ²
Daphnid chronic	Not given assumed NOEC	1.0 ²
Green algae	96-hr EC_{50}	23.9 ²
Aquatic plant <i>Lemna</i>	7-day EC_{50}	11.9 ²

¹ study data via REACH database

² QSAR-predicted toxicity

It is noted that no data, study generated or modelled is available with the aquatic plant group *Myriophyllum spp.* With regards to the active substance this group was the most sensitive, more so than the other aquatic plant species test; *Lemna gibba*, by about a factor of 1000. However, it was the conclusion of the notifier that this metabolite does not retain the toxophores responsible for the

herbicidal activity of mecoprop-P. Input from the RMS Efficacy branch confirms this: Phenoxy herbicides (such as mecoprop-P) mimic the plant growth regulator indol-3- acetic acid (IAA), or auxin in plants. Auxins must have an aromatic ring and a carboxylic acid group, and it is this carboxylic group which, crucially, is absent in the metabolite compound o-cresol. As such the metabolite would not be expected to be of any greater toxicity to this group than the a.s. Also the PEC_{sw} of o-cresol is much lower than that of mecoprop-P, meaning that the risk assessment for the group *Myriophyllum spp.* for the active substance will also address any risk to this group from o-cresol. It is additionally noted that the toxicity of the metabolite to the aquatic plant *Lemna* is no greater than that of the active substance, further supporting this conclusion.

Toxicity of the representative formulation

Unless otherwise discussed in the above, the representative formulation risk to aquatic organisms will be assessed separately. Endpoints will be expressed in terms of the active substance content (as mecoprop-P) and compared to the Predicted Environmental Concentrations in Surface Water (PEC_{sw}) for the active substance at FOCUS steps 1-4 as appropriate.

Exposure

The PEC_{sw} values for the active substance Mecoprop-P are detailed in section (CP) B.8.5 of the renewal assessment report. There is only one identified metabolite as potentially relevant in the aquatic environment: O-cresol, which was found at a maximum of 30.4% in the available aqueous photolysis study. PEC_{sw} values were calculated in accordance with FOCUS modelling. Distinct values for applications to winter and spring cereals have been produced, due to the differences in proposed earliest growth stage. Refer to table B.9-01 for detail on the representative uses of mecoprop-P considered for renewal purposes.

Subsequent risk assessments for the aquatic environment are conducted in accordance with SANCO 3268/2002³. In the first instance the critical (i.e. lowest relevant) toxicity endpoint per organism group and timescale is considered. Should this not result in a demonstrated low risk at FOCUS step 3, consideration will be given to the refined toxicity endpoints as discussed above. Should an outstanding risk to any group remain at FOCUS step 3, then further assessment under FOCUS step 4 modelled exposures (considering mitigation methods to reduce exposure in surface water) shall be considered.

B.9.4.1. FOCUS step 1

Table B.9.4.1-01: TERs for aquatic organisms at FOCUS Step 1 for applications to winter and spring cereals (spring application only) at 1 x 2L/ha.

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)	TER	Trigger
a.s.	Fish	Acute	>93 000	400.14	232	100
O-cresol	Fish	Acute	6200	1.68	3690	100
Mecoprop-P K 600 g/L	Fish	Acute	>58 700	400.14	147	100
a.s.	Fish	Chronic	11 100	400.14	28	10
O-cresol	Fish	Chronic	1700	1.68	1012	10
a.s.	Aquatic invertebrate	Acute	>91 000	400.14	227	100
O-cresol	Aquatic invertebrate	Acute	5200	1.68	3095	100
Mecoprop-P K 600 g/L	Aquatic invertebrate	Acute	>58 700	400.14	147	100
a.s.	Aquatic invertebrate	Chronic	50 000	400.14	125	10
a.s.	Aquatic invertebrate	Chronic	22 200	400.14	55	10
O-cresol	Aquatic invertebrate	Chronic	1000	1.68	595	10
a.s.	Algae	Growth	23 900	400.14	60	10

³ Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)	TER	Trigger
O-cresol	Algae	Growth	23 900	1.68	14226	10
Mecoprop-P K 600 g/L	Algae	Growth	>58 700	400.14	147	10
a.s.	Aquatic plant (<i>Lemna</i>)	Growth	1600	400.14	4	10
O-cresol	Aquatic plant (<i>Lemna</i>)	Growth	11 900	1.68	7083	10
Mecoprop-P K 600 g/L	Aquatic plant (<i>Lemna</i>)	Growth	34 700	400.14	87	10
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	26.9	400.14	0.07	10

At FOCUS step 1 the calculated TERs for most substances and for most organism groups are above the regulation-defined trigger values, indicating a low risk to these groups following the representative uses of Mecoprop-P on winter and spring cereals. The only groups and substances with an outstanding risk, requiring further assessment at FOCUS step 2 are as follows:

- Risk to *Lemna* from the active substance.
- Risk to *Myriophyllum* from the representative formulation (also considered to address the risk to this group from the active substance).

B.9.4.2. FOCUS step 2

Table B.9.4.2-01: TERs for aquatic organisms at FOCUS Step 2 for applications to spring cereals (spring application only) at 1 x 2L/ha.

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)	TER	Trigger
a.s.	Aquatic plant (<i>Lemna</i>)	Growth	1600	56.47 (N.EU)	28	10
				102.32 (S.EU)	16	
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	26.9	56.47 (N.EU)	0.48	10
				102.32 (S.EU)	0.26	

Table B.9.4.2-02: TERs for aquatic organisms at FOCUS Step 2 for applications to winter cereals (spring application only) at 1 x 2L/ha.

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)	TER	Trigger
a.s.	Aquatic plant (<i>Lemna</i>)	Growth	1600	45.01 (N.EU)	36	10
				79.39 (S.EU)	20	
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	26.9	45.01 (N.EU)	0.60	10
				79.39 (S.EU)	0.34	

At FOCUS step 2 (considering both Northern and Southern Europe maximum PEC_{sw} values) the TER values with regards to the active substance and the aquatic plant group *Lemna spp.* are greater than 10 for both representative uses of mecoprop-P. As such a low risk to this group can be concluded.

With regards to the aquatic plant *Myriophyllum* all step 2 calculated PEC_{sw} values result in a TER less than 10. As such an outstanding risk to this group exists and requires further risk assessment at FOCUS step 3.

B.9.4.3. FOCUS step 3**Table B.9.4.3-01: TERs for aquatic organisms at FOCUS Step 3 for applications to spring cereals (spring application only) at 1 x 2L/ha.**

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)		TER	Trigger
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	26.9	D1 ditch	13.363	2.0	10
				D1 stream	8.276	3.3	
				D3 ditch	7.599	3.5	
				D4 pond	0.263	102.3	
				D4 stream	6.304	4.3	
				D5 pond	0.262	102.7	
				D5 stream	5.958	4.5	
				R4 stream	32.316	0.8	

As demonstrated in the risk assessment in above table B.9.4.3-01, the TERs for *Myriophyllum* are below the regulatory trigger of 10 for most scenarios. Hence there is an unresolved risk for the following FOCUS step 3 scenarios following application of mecoprop-P to spring cereals:

- D1 ditch
- D1 stream
- D3 ditch
- D4 stream
- D5 stream
- R4 stream

Table B.9.4.3-02: TERs for aquatic organisms at FOCUS Step 3 for applications to winter cereals (spring application only) at 1 x 2L/ha.

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)		TER	Trigger
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	26.9	D1 ditch	158.372	0.2	10
				D1 stream	98.801	0.3	
				D2 ditch	184.278	0.1	
				D2 stream	116.438	0.2	
				D3 ditch	7.583	3.5	
				D4 pond	0.263	102.3	
				D4 stream	6.187	4.3	
				D5 pond	0.262	102.7	

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)		TER	Trigger
				D5 stream	5.978	4.5	
				D6 ditch	8.127	3.3	
				R1 pond	0.662	40.6	
				R1 stream	19.599	1.4	
				R3 stream	44.152	0.6	
				R4 stream	5.012	5.4	

As demonstrated in the risk assessment in above table B.9.4.3-02, the TERs for *Myriophyllum* are below the regulatory trigger of 10 for most scenarios. Hence there is an unresolved risk for the following FOCUS step 3 scenarios following application of mecoprop-P to winter cereals:

- D1 ditch
- D1 stream
- D2 ditch
- D2 stream
- D3 ditch
- D4 stream
- D5 stream
- D6 ditch
- R1 stream
- R3 stream
- R4 stream

As discussed earlier in the summary of aquatic toxicity endpoints, in accordance with the guidance of EFSA (2013) it is permissible to utilise the geometric mean toxicity endpoint from the 2 available studies with *Myriophyllum spicatum*. The geometric mean ErC₅₀ of 29.7 µg a.s./L is therefore used in a further risk assessment at FOCUS step 3:

Table B.9.4.3-03: TERs for aquatic organisms at FOCUS Step 3 for applications to spring cereals (spring application only) at 1 x 2L/ha – Using Geometric mean endpoint.

Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)		TER	Trigger
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	29.7	D1 ditch	13.363	2.2	10
				D1 stream	8.276	3.6	
				D3 ditch	7.599	3.9	
				D4 pond	0.263	112.9	
				D4 stream	6.304	4.7	
				D5 pond	0.262	113.4	
				D5 stream	5.958	5.0	
				R4 stream	32.316	0.9	

As demonstrated in the risk assessment in above table B.9.4.3-03, the TERs for *Myriophyllum* are below the regulatory trigger of 10. Hence there is an unresolved risk for the following FOCUS step 3 scenarios following application of mecoprop-P to spring cereals:

- D1 ditch
- D1 stream
- D3 ditch
- D4 stream
- D5 stream
- R4 stream

Table B.9.4.3-04: TERs for aquatic organisms at FOCUS Step 3 for applications to winter cereals (spring application only) at 1 x 2L/ha – Using geometric mean endpoint.

cereals (spring application only) at 1 x 2L/ha Using geometric mean endpoint.							
Test substance	Organism group	Time scale	Toxicity end point (µg a.s./L)	PEC _{sw,max} Global max (µg a.s./L)		TER	Trigger
Mecoprop-P K 600 g/L	Aquatic Plant (<i>Myriophyllum</i>)	Growth	29.7	D1 ditch	158.372	0.2	10
				D1 stream	98.801	0.3	
				D2 ditch	184.278	0.2	
				D2 stream	116.438	0.3	
				D3 ditch	7.583	3.9	
				D4 pond	0.263	112.9	
				D4 stream	6.187	4.8	
				D5 pond	0.262	113.4	
				D5 stream	5.978	5.0	
				D6 ditch	8.127	3.7	
				R1 pond	0.662	44.9	
				R1 stream	19.599	1.5	
				R3 stream	44.152	0.7	
				R4 stream	5.012	5.9	

As demonstrated in the risk assessment in above table B.9.4.3-04, the TERs for *Myriophyllum* are below the regulatory trigger of 10. Hence there is an unresolved risk for the following FOCUS step 3 scenarios following application of mecoprop-P to winter cereals:

- D1 ditch
- D1 stream
- D2 ditch
- D2 stream
- D3 ditch
- D4 stream
- D5 stream
- D6 ditch
- R1 stream

- R3 stream
- R4 stream

The risk to this group of organisms from the representative formulation (also addressing the risk from the active substance alone) will be further assessed at FOCUS step 4, making use of the geometric mean toxicity endpoint of 29.7 µg a.s./L.

B.9.4.4. FOCUS step 4

Under FOCUS step 4 the surface water exposure modelling still considers the individual Drainage (D) and Runoff (R) scenarios as per step 3, but varying methods of risk mitigation are also included in the modelling. As such a great variety of PEC_{sw} values are generated for each FOCUS scenario, each considering a specific applied mitigation measure. To aid interpretation of the impact of these mitigations on the aquatic risk assessment each resulting PEC_{sw} will be directly compared with the Regulatory Acceptable Concentration (RAC) for the aquatic environment. The RAC is a concentration below which a low risk to the aquatic environment may be concluded. The RAC is calculated by the critical organism group endpoint divided by the regulatory trigger value.

From the above FOCUS steps 1-3 risk assessment undertaken the aquatic plant *Myriophyllum spicatum* is clearly defined as the most sensitive group, and is the only group with an outstanding risk at FOCUS step 3. The geometric mean toxicity endpoint with this species is 29.7 µg a.s./L so, with the applied trigger value of 10, **the Regulatory Acceptable concentration (RAC) is set as 2.97 µg a.s./L**. Any PEC_{sw} values modelled as below this concentration are therefore defined as of low risk to the aquatic environment. FOCUS step 4 risk assessment is provided in below tables B.9.4.4-01 (spring cereals use) and B.9.4.4-02 (winter cereals).

Table B.9.4.4-01: Comparison of Regulatory Acceptable Concentration of Mecoprop-P for aquatic plants with FOCUS step 4 PEC_{sw} values – spring cereals use

FOCUS scenario	FOCUS step 4 PEC _{sw} and modelled mitigation type (µg a.s./L)										
	5m NSB Z	10m NSB Z	5m VFS	10m VFS	20m VFS	50% DRT	75% DRT	95% DRT	5m NSBZ + 5m VFS	10m NSBZ + 5m VFS	10m NSBZ + 10m VFS
D1 (Ditch)	13.36	13.36	N/A	N/A	N/A	13.36	13.36	13.36	13.36	13.36	13.36
D1 (Stream)	8.28	8.28	N/A	N/A	N/A	8.28	8.28	8.28	8.28	8.28	8.28
D3 (Ditch)	2.06	1.09	N/A	N/A	N/A	3.80	1.90	0.49	2.06	1.09	1.09
D4 (Pond)	0.26	0.19	N/A	N/A	N/A	0.17	0.11	0.06	0.26	0.20	0.19
D4 (Stream)	2.33	1.25	N/A	N/A	N/A	3.19	1.62	0.37	2.33	1.26	1.25
D5 (Pond)	0.26	0.19	N/A	N/A	N/A	0.17	0.11	0.06	0.26	0.20	0.19
D5 (Stream)	2.19	1.17	N/A	N/A	N/A	3.00	1.51	0.32	2.19	1.17	1.17
R4 (Stream)	32.32	32.32	5.03	14.62	7.64	32.32	32.32	32.32	1.84	0.98	14.62

Bold values – RAC exceeded = high risk to aquatic plants

NSBZ – No spray buffer zone

VFS – Vegetative filter strip

As demonstrated in the above table, for the representative use of mecoprop-P on spring cereals, a low risk to the aquatic plant *Myriophyllum spicatum* (identified as the critical organism group for the aquatic risk assessment) can be concluded for most FOCUS scenarios (4/5 complete scenarios) when a 5m no spray buffer zone and 5m vegetative filter strip are applied as mitigation. However there is 1 outstanding complete scenario which cannot be addressed via the assessed mitigation measures:

- D1 ditch + stream

The D1 ditch scenario has drainage entry as its main route of surface water contamination, while the D1 stream scenario is attributed as an “upstream boundary” – See study CP 9.2.5/03, Simmons K (2015).

Ultimately the decision of risk mitigation and scenario relevance should be made by individual Member States at product registration level.

Table B.9.4.4-02: Comparison of Regulatory Acceptable Concentration of Mecoprop-P for aquatic plants with FOCUS step 4 PEC_{sw} values – winter cereals use

FOCUS scenario	FOCUS step 4 PEC _{sw} and modelled mitigation type (µg a.s./L)										
	5m NSB Z	10m NSB Z	5m VFS	10m VFS	20m VFS	50% DRT	75% DRT	95% DRT	5m NSBZ + 5m VFS	10m NSBZ + 5m VFS	10m NSBZ + 10m VFS
D1 (Ditch)	158.37	158.37	N/A	N/A	N/A	158.37	158.37	158.37	158.37	158.37	158.37
D1 (Stream)	98.80	98.80	N/A	N/A	N/A	98.80	98.80	98.80	98.80	98.80	98.80
D2 (Ditch)	184.28	184.28	N/A	N/A	N/A	184.28	184.28	184.28	184.28	184.28	184.28
D2 (Stream)	116.44	116.44	N/A	N/A	N/A	116.44	116.44	116.44	116.44	116.44	116.44
D3 (Ditch)	2.06	1.09	N/A	N/A	N/A	3.79	1.90	0.52	2.06	1.09	1.09
D4 (Pond)	0.27	0.20	N/A	N/A	N/A	0.20	0.15	0.12	0.27	0.20	0.20
D4 (Stream)	2.31	1.24	N/A	N/A	N/A	3.15	1.61	0.37	2.31	1.27	1.24
D5 (Pond)	0.27	0.20	N/A	N/A	N/A	0.19	0.13	0.07	0.27	0.20	0.20
D5 (Stream)	2.21	1.18	N/A	N/A	N/A	3.02	1.53	0.33	2.21	1.18	1.18
D6 (Ditch)	2.59	1.64	N/A	N/A	N/A	4.33	2.45	1.11	2.59	1.64	1.64
R1 (Pond)	0.67	0.61	0.26	0.40	0.32	0.60	0.55	0.50	0.27	0.21	0.35
R1 (Stream)	19.60	19.60	5.03	8.87	5.03	19.60	19.60	19.60	1.84	1.83	8.87
R3 (Stream)	44.15	44.15	7.04	20.08	10.52	44.15	44.15	44.15	2.57	1.36	20.08
R4 (Stream)	1.83	0.97	5.01	5.01	5.01	2.51	1.25	0.25	1.83	0.97	0.97

Bold values – RAC exceeded = high risk to aquatic plants

NSBZ – No spray buffer zone

VFS – Vegetative filter strip

As demonstrated in the above table, for the representative use of mecoprop-P on winter cereals, a low risk to the aquatic plant *Myriophyllum spicatum* (identified as the critical organism group for the aquatic risk assessment) can be concluded for most FOCUS scenarios (7/9 complete scenarios) when a 5m no spray buffer zone and 5m vegetative filter strip are applied as mitigation. However there are 2 outstanding complete scenarios which cannot be addressed via the assessed mitigation measures:

- D1 ditch + stream
- D2 ditch + stream

The D1 and D2 ditch scenarios have drainage entry as its main route of surface water contamination, while the D1 and D2 stream scenarios are attributed as an “upstream boundary” – See study CP 9.2.5/03, Simmons K (2015).

Ultimately the decision of risk mitigation and scenario relevance should be made by individual member states at product registration level.

Overall the RMS has concluded a low risk to the aquatic environment for 6/8 relevant scenarios for spring cereals use, and 10/14 scenarios for winter cereals use, when a 5m no spray buffer zone and a 5m vegetative filter strip are implemented to mitigate exposure.

B.9.4.5. Relevance of surface water metabolites

A single surface water metabolite was identified as potentially relevant for the ecotoxicological risk assessment. O-cresol was found at a maximum of 30.4% in the aqueous photolysis study and hence triggered risk assessment for the aquatic environment.

On the basis of the submitted position paper CA 8.2.8/01, Simmons, K. (2015) it was established that the metabolite did not retain the toxophore of the active substance mecoprop-P. Aquatic toxicity data was also provided from existing studies available on the ECHA (European CHemicals Agency) website and from QSAR modelling. The lowest of these available endpoints per organism group were applied in the above FOCUS risk assessments and a low risk was established at FOCUS step 1. In contrast, the active substance mecoprop-P required risk assessment at up to FOCUS step 4.

It is noted that no metabolite data, study generated or modelled is available with the aquatic plant group *Myriophyllum spp.* With regards to the active substance this group was the most sensitive, more so than the other aquatic plant species test; *Lemna gibba*, by about a factor of 1000. However, it was the conclusion of the notifier that this metabolite does not retain the toxophores responsible for the herbicidal activity of mecoprop-P. As such the metabolite would not be expected to be of any greater toxicity to this group than the a.s. Also the PEC_{sw} of o-cresol is much lower than that of mecoprop-P, meaning that the risk assessment for the group *Myriophyllum spp.* for the active substance will also address any risk to this group from o-cresol. It is additionally noted that the toxicity of the metabolite to the aquatic plant *Lemna* is no greater than that of the active substance, further supporting this conclusion.

In accordance with the definition provided by the SANCO aquatic guidance document⁴ and ecotoxicologically relevant metabolite is “a metabolite which poses a higher or comparable risk to aquatic organisms as the active substance”. By this definition and considering the above discussion it is concluded that the metabolite O-cresol is not of ecotoxicological relevance in surface water, being of lower risk to aquatic life than the active substance. No metabolites of potential relevance were identified in groundwater.

B.9.4.6. Risk assessment for Groundwater

The ground water fate modelling in the Environmental fate section B.8.3 has identified no metabolites that occur in ground water. The critical concentrations of mecoprop-P in Groundwater (PEC_{GW}) are as follows (taken from RMS conclusions in (CP) B.8.3):

- Spring cereals representative use: 0.056 µg a.s./L (PELMO model, Okehampton scenario)
- Winter cereals representative use: 0.115 µg a.s./L (PELMO model, Okehampton scenario)

The Regulatory Acceptable Concentration for mecoprop-P with regards to aquatic life has previously been identified as 2.97 µg a.s./L, based on toxicity to the most sensitive organism *Myriophyllum spicatum*. As the critical PEC_{GW} values do not exceed this RAC then a low risk from groundwater can be concluded.

⁴ Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC.

B.9.4.7. Environmental Hazard Classification and Labelling**Classification of the active substance for environmental effects according to Regulation (EC) No 1272/2008:**

The lowest relevant LC/EC₅₀ value used in support of the active substance is the E_rC₅₀ from testing with the aquatic plant *Myriophyllum spicatum* (Study Gonsoir, 2015). Although this study was conducted with the formulated product it has been used (expressed in terms of mecoprop-P content) to address the a.s. data requirement for testing with a second aquatic plant species. The E_rC₅₀ is 0.0269 mg a.s./L. This is lower than the trigger for acute classification of 1.0 mg/L, meaning that the classification Acute category 1 (H400) - 'Very toxic to aquatic life' is triggered. The related acute M-factor is 10.

In addition, the lowest NOEC value, also from the above study, is 0.00937 mg a.s./L (growth rate inhibition). According to the environmental fate data the active substance is classified as readily biodegradable. As this lowest NOEC is less than 0.01 mg a.s./L and the substance is readily biodegradable the classification Chronic category 1 (H410) 'very toxic to aquatic life with long lasting effects' is triggered. The related chronic M-factor is 1.

Pictogram : GHS09

Signal word: 'Warning'

Hazard statement : H400 - 'Very toxic to aquatic life' (M-factor 10)

H410 - 'Very toxic to aquatic life with long lasting effects' (M-factor 1)

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/container to ...

... in accordance with local/regional/national/international regulation (to be specified).

Classification of the representative formulation 'Mecoprop-P K 600 g/L' (AKA CA3015) for environmental effects according to Regulation (EC) No 1272/2008:

The lowest relevant LC/EC₅₀ value used in support of the formulation is the E_rC₅₀ from testing with the aquatic plant *Myriophyllum spicatum* (Study Gonsoir, 2015). The E_rC₅₀ is 0.0561 mg form'n/L. This is lower than the trigger for acute classification of 1.0 mg/L, meaning that the classification Acute category 1 (H400) - 'Very toxic to aquatic life' is triggered.

In addition, the lowest NOEC value, also from the above study, is 0.01915 mg form'n/L (growth rate inhibition). According to the environmental fate data the active substance is classified as readily biodegradable. As this lowest NOEC is between 0.01 – 0.1 mg/L and the substance is readily biodegradable the classification Chronic category 2 (H411) 'Toxic to aquatic life with long lasting effects' is triggered.

Pictogram : GHS09

Signal word: 'Warning'

Hazard statement : H400 - 'Very toxic to aquatic life'

H411 - 'Toxic to aquatic life with long lasting effects'

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/container to ...
... in accordance with local/regional/national/international regulation (to be specified).

B.9.5. EFFECTS ON ARTHROPODS

B.9.5.1. Effects on bees

Ref.: IIIA. 10.4.1. Altmann, 1984: Results of the registration study on toxicity to bees (BAS 037 29H).

Ref.: IIIA. 10.4.1. Stute, 1984: Results of the registration study on toxicity to bees (BAS 037 29H).

Ref.: IIIA. 10.4.1. Stute, 1986: Results of the registration study on toxicity to bees (BAS 037 29H).

Ref.: IIIA. 10.4.1. Vorwohl, 1984: Results of the registration study on toxicity to bees (BAS 037 29H).

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The toxicity to bees was studied using BAS 037 29 H (Duplosan KV) containing 600 g mecoprop-P DMA/l according to BBA VI, 23-1.

The honey bees *Apis mellifera* were exposed to the test substance by oral, contact, topical and inhalative exposure at 3x10 bees/route of application and one replicate per route of exposure. The concentration of the test substance was 2-3%. The oral testing was performed using 100 µg/bee in a single administration. Contact toxicity was tested by exposing bees to filter paper soaked in test substance. Topical application was tested by spraying bees with the test substance. Inhalative exposure was performed by exposing caged bees to the vapour from test substance solutions. Observations were made during 72 hours.

Results

The results are summarised in the table below.

Table B.9.5.1-01: Toxicity to bees. Results in % mortality / after hours of observation)

Test substance	Oral (100 µg/bee)	Topical	Contact	Inhalation	Reference
BAS 037 29 H (2%) Control	40% / 24 h N.A.	13% / 72 h 0% / 72 h	13% / 72 h 0% / 72 h	0% / 72 h 0% / 72 h	Altmann 1984
BAS 037 29 (2%) Control	53% / 24 h 7% / 24 h	7% / 72 h 10% / 72 h	3% / 72 h 7% / 72 h	3% / 72 h 3% / 72 h	Stute 1984
BAS 037 29 H (3%) Control	80% / 24 h 7% / 72 h	13% / 72 h 10% / 72 h	7% / 72 h 7% / 72 h	3% / 72 h 3% / 72 h	Stute 1986
BAS 039 29 H (2%) Control	54% (30-77)/ 24 h 5% / 72 h	3% / 72 h 7% / 72 h	23% / 72 h 43% / 72 h	33% / 72 h 10% / 72 h	Vorwohl 1984

Comments

Oral exposure revealed some toxicity at high levels of 100 µg/bee. However, the resulting classification was stated to be “not hazardous to honey bees”.

RMS comments (renewal):

Study not suitable for renewal purposes. Report deficient in key information to confirm validity and suitable conduction. No LD₅₀ derivation possible. There is sufficient other data on mecoprop-P for this evaluation.

B.9.5.2. Effects on non-target arthropods other than bees

Report:	CP 10.3.2.2/01
Title:	<p>Stevens, J (2014b) Mecoprop-P K 600 g/L – A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae)</p> <p>Testing Laboratory: Mambo-Tox Ltd.</p> <p>Study Number: NUF-14-3</p> <p>Date: 9th September 2014</p>
Guideline:	Mead-Briggs <i>et al.</i> (2009). An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) (Hymenoptera, Braconidae).
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS**A MATERIALS****Test material**

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	582.9 g Mecoprop-P/L
Vehicle and/or positive Control	Purified water (control) Perfekthion (400 g/L Dimethoate) (positive control)

Test system

Organism (Species):	<i>Aphidius rhopalosiphi</i> , females only
Age:	Adult, < 48 hours old at initiation
Source:	In house culture, established with wasps initially obtained from Katz Biotech AG, Baruth, Germany
Acclimatisation period:	None (in house culture)

Environmental conditions

Temperature:	21°C
Humidity:	72-74%
Photoperiod:	16 hours light / 8 hours dark
Light intensity:	1550 Lux (mortality phase), 4407 Lux (reproduction phase)
Food:	10% fructose solution (applied to mortality phase plants).

B STUDY DESIGN AND METHODS

In life dates: 9 July 2014 – 18 August 2014

Experimental treatment: 5 adult *Aphidius rhopalosiphi* parasitoids were exposed to fresh residues of Mecoprop-P K 600 applied to Barley plants that were 8-9 days old with two leaves (BBCH12) and approx. 10cm in height. The test units consisted of clear acrylic cylinders (8cm x 20cm), the tops of which were covered with nylon netting that contained an access hole for the introduction of the parasitoids and was sealed with a cotton wool bung

Test groups prepared were: A control (purified water), Mecoprop-P applied at rates equivalent to 2500, 1250, 625 and 312.5 mL product/ha and, Perfekthion at 10 mL/ha(a.s. = Dimethoate as positive control). There were 6 replicates per treatment (i.e. 30 wasps in total per treatment group). The treatments were administered using a laboratory track sprayer which had been calibrated in advance.

For the reproductive assessments 15 female wasps were confined individually over pots containing approximately 15 barley seedlings (*Hordeum vulgare*). The plants were untreated and had been infected with >100 host aphids prior to the test. The wasps were confined over the pots using clear cylinders with tops being covered in nylon netting for ventilation. Females were retained for a period of 24 hours before being removed and the reproductive vessels were incubated under test conditions for a further 10 days in order to allow *Aphidius* 'mummy' development.

Observations: The condition of the wasps was assessed at approximately 3, 24 and 48 hours after their introduction and the insects were classed as being:

Live	Alive and apparently unaffected
Affected	Upright, attempting to walk but with reduced coordination.
Moribund	on their back or side, twitching slightly
Dead	not moving

To determine whether fresh residues of the test product were repellent, observations on the position of the individual wasps were made, with each wasp being described as being on the:

Plant	On the treated plants
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Cylinder On the walls or ceiling of the test arena

Sand On the sand below the plants

Wasps that were moribund, dead or unseen were omitted from this assessment

For the reproduction assessment the reproductive vessels were kept under the specified conditions for 10 days, after which the number of mummies that developed on each plant was recorded.

Statistics:

The mortality in each treatment at 48 hours was compared to that in the control using Fisher's Exact Test ($\alpha = 0.05$).

For the reproduction assessments, the data was compared to the control by Mann-Whitney *U*-test ($\alpha=0.05$) but there were no significant differences.

Deviations from study plan:

None

II. RESULTS AND DISCUSSION

Biological Results: Results are shown in the tables below.

Table B.9.5.2-01: Percentage Mortality of *Aphidius rhopalosiph* after 48 hours of exposure

Treatment	Rate (mL product/ha)	% mortality ^{a)}	Corrected % mortality ^{b)}
Control	-	0.0	-
Mecoprop-P K 600 g/L	2500	13.3	13.3
	1250	6.7	6.7
	625	0.0	0.0
	312.5	3.3	3.3
Toxic reference	10	83.8*	83.3

^{a)} Results for individual treatments compared to control using Fisher's Exact Test ($\alpha = 0.05$). Values marked with an asterisk (*) differed significantly.

^{b)} Calculated using Abbott's formula.

Table B.9.5.2-02: Summary of wasp fecundity assessments in the definitive test

Treatment	Rate (mL product/ha)	Mean number mummies/female	% Inhibition
Control	-	27.5	--
Mecoprop-P K 600 g/L	2500	26.2	4.6
	1250	29.3	-6.7
	625	27.0	1.8
	312.5	N/A	N/A
Toxic reference	10	N/A	N/A

^{a)} Treatments were compared to control by Mann-Whitney u-test ($\alpha = 0.05$). Values marked with an asterisk (*) differed significantly

During the initial 3 h of the definitive bioassay, the percentage of observations where wasps were settled on the treated plants was 42.7% in the control, compared with 30.7%, 34.0%, 40.0% and 35.3% in the 2500, 1250, 625 and 312.5 mL product/ha treatment rates of Mecoprop-p K 600 g/L, respectively, and 22.0% in the toxic-reference treatment. Relative to the control, the settling rate during the initial 3 h was not significantly reduced for any of the test-item treatments ($\alpha = 0.05$).

Validity criteria were met in accordance with the Mead-Briggs et al guideline (2009) as follows:

- Control group 48-hr mortality did not exceed 10% = 0%
- Control group mean fecundity was at least 5.0 mummies/female = 27.5/female
- No more than 2 control females produced zero mummies = 0/15
- The reference item tested at 5-20 mL/ha resulted in 50-100% organism mortality = 83.3% at 10 mL/ha.

III. CONCLUSIONS

In an extended laboratory test to determine the effects of Mecoprop-p K 600 g/L on the parasitic wasp, the 48 hour median lethal rate (LR50) was >2500 mL product/ha, the highest tested. Based on statistical comparisons with the control, the no-observed-effects (NOER) rate for mortality was 2500 mL product/ha. In addition the reproductive capacity of surviving wasps was not significantly affected by the test item at treatment rates up to and including 2500 mL product/ha. Therefore 50% reproductive effects would be expected to occur at > 2500 mL product/ha.

RMS comments:

The study was well reported and conducted in close adherence with the referenced guideline, with all validity criteria met and no significant deviations. The study is considered valid and acceptable for risk assessment use. The agreed endpoints are as follows:

48-hour adult mortality = 13.3% at 2500 mL CA3015/ha (1457 g a.s./ha)

Effects on reproduction = 4.6% at 2500 mL CA3015/ha (1457 g a.s./ha)

Active substance endpoints based on tested batch content of 582.9 g Mecoprop-P/L

Report:	Vaughan, R. (2015)
Title:	Mecoprop-P K 600 g/L – An extended laboratory test to evaluate the effects of fresh residues on the green lacewing, <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Testing Laboratory: Mambo-Tox Ltd. Study Number: NUF-14-4 Date: 20 th January 2015
Guideline:	Vogt <i>et al.</i> (2000) Laboratory method to test effects of plant protection product on larvae of <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae).
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

1. Test material

Test item: Mecoprop-P K 600 g/L, AKA CA3015

Description: Brown liquid

Lot No./Batch No: 18-32-122

Active ingredient content: 582.9 g Mecoprop-P/L

2. Vehicle and/or positive Control Control: Purified water

Positive control: Dimethoate (Perfekthion, 400 g/L dimethoate); tested at 80 mL/ha

Test system

Organism (Species): *Chrysoperla carnea* Steph.

Age: Larvae, 2-3 days old at initiation

Source: Synchronised cohort of eggs from in house culture, originally sourced from Biological Crop Protection, UK.

Environmental conditions

Temperature: 24.0-25.6°C

Relative humidity: 64-79%

Photoperiod: 16 hours light / 8 hours dark

Light intensity: 2900-4400 lux

Food: Larvae: UV light-killed eggs of *Sitotroga cerealella*, *ad libitum* (obtained from AMW Nützlinge, Germany)

Adults: An artificial diet according to Vogt et al.

A 1:2-1:3 honey/water solution was also provided.

B STUDY DESIGN AND METHODS

1. In life dates: 29 October 2014 –5 December 2014

2. Test system

Protocol deviations: None reported

Test concentrations: 0, 1.25, 2.5 L Mecoprop-P K 600/ha, plus reference item at 80 mL Perfekthion/L

Parameters measured: Pre-imaginal mortality, reproduction (number of eggs and egg viability)

3. Methodology

Test arenas:

Arenas for larval mortality assessments:

When residues had dried, the treated leaves (treated surface facing upwards) were used to line the floor of a simple test arena. Each arena comprised a square glass plate (7.5cm x 7.5cm), a Perspex supporting plate of a similar size, with a 5cm diameter hole cut through it and an acrylic cylinder (44mm internal diameter, ca. 2.5cm tall). The petiole of the leaf was wrapped in wet cotton wool, which was draped into a water trough. A ventilated lid, covered with 0.5mm x 0.5mm mesh nylon netting, was placed over each cylinder to ensure that larger larvae could not climb out.

Arenas for pupal development assessments:

As lacewing pupae developed they were transferred to large plastic storage boxes (27cm x 27cm x 14cm). Treatments were kept in separate boxes.

Arenas for reproduction assessments:

As adult lacewings emerged, they were transferred to polystyrene boxes (15cm x 27cm x 10cm) with close fitting lids. A sheet of fibrous tissue was placed under the lid of each box to act as an oviposition site.

Arenas for egg viability assessments:

The fibrous tissue used as an oviposition site was transferred to additional boxes of the same dimensions as the reproductive arenas.

Test item application:

Treatments were applied to recently detached leaves (dwarf French bean plants, *Phaseolus vulgaris* L.) using a Schachter laboratory track-sprayer. The spray pressure was 3 bar and the moving spray boom was fitted with a single 80° flat-fan nozzle. The sprayer was calibrated prior to application, using purified water, to confirm a deposition rate at the target level, equivalent to 200 L/ha.

Replicates:

There were 40 individually confined larvae per treatment. For the reproduction assessments, insects from each treatment group were grouped in 2 boxes, but were considered as a single replicate per treatment for statistical purposes.

Experimental procedure:Pre-imaginal mortality:

One larva was introduced into each test arena unit. Larvae were assigned to treatments impartially and only ones with healthy appearance were used.

Reproduction:

Emerging adults from the individual treatments were transferred to polystyrene oviposition boxes. The sex of the lacewings was determined by eye, based on the shape of the abdomen. This was then confirmed at the end of the test

	using a binocular microscope, when the adults were killed in a freezer.
Assessments:	<p><u>Pre-imaginal mortality:</u></p> <p>The condition of larvae was assessed every 1-3 days until they pupated. They were categorised as follows:</p> <ul style="list-style-type: none"> -alive = apparently healthy and unaffected -abnormal pupa = larvae pupating without spinning a cocoon or appearing different from the norm -dead = no longer moving -pupated = larvae having pupated <p>Any larvae that escaped or were accidentally killed were noted and excluded from data analysis.</p> <p>The number of adult lacewings that emerged successfully from pupae was also recorded every 1-3 days.</p> <p><u>Reproduction:</u></p> <p>Assessments commenced 7 days after the majority (>75%) of the adult lacewings had emerged, which was 9 days after egg laying had first been noted in the individual boxes. The following assessments were made:</p> <ul style="list-style-type: none"> -number of eggs laid in each box were recorded for two 24-hour periods within one week. -the viability of the eggs was determined. Having counted the number of eggs they were transferred to new boxes, with food available. Once the larvae started to emerge the oviposition sheets were removed daily to remove the larvae. After 6 days the number of unhatched eggs was recorded.
Statistics:	The pre-imaginal mortality in each treatment was compared with the control using Fisher's Exact Test ($\alpha = 0.05$).

II. RESULTS AND DISCUSSION

Validity criteria:	<p>All criteria were met.</p> <ul style="list-style-type: none"> -Pre-imaginal mortality was <20% in the control treatment = 10% -Mean egg production was > 15 eggs per female per day = 26.1 -Mean viability of the eggs in the control was >70% = 94.4% -Mortality in the toxic reference treatment was >50% = 97.5%
Pre-imaginal mortality:	There was no significant difference in pre-imaginal mortality observed with either application rates of Mecoprop-P K 600, when compared with the control. The toxic reference exhibited nearly total mortality, as was expected of the substance at the rate applied. The below table details the mortality results.

Table B.9.5.2-03: Summary of pre-imaginal mortality results

Test item	Rate (mL product/ha)	% pre-imaginal mortality	Corrected % pre-imaginal mortality ^{a)}
Control	-	10.0	-
Mecoprop-P K 600 g/L	2500	12.5	2.8
	1250	17.5	8.3
Toxic reference	80	97.5*	97.2

a) Derived using Abbott's formula

* Statistically significantly different, when compared with the control

Reproduction: There was no significant difference in reproductive capacity observed with either application rates of Mecoprop-P K 600, when compared with the control. Table B.9.5.2-04 details the mortality results.

Table B.9.5.2-04: Summary of reproduction results

	Rate (mL product/ha)	Mean [#] no. ^{a)}	Mean % egg viability ^{b)}	Mean [#] no. viable	Effects on reproduction ^{c)}
Control	-	26.1	94.4	24.6	-
Mecoprop-P K 600 g/L	2500	27.0	95.3	25.7	-4.5
	1250	26.7	96.0	25.6	-4.1

a) Based on two 24-hour assessments made for each box in each treatment.

b) Based on all eggs laid on the fibrous tissue sheet of each oviposition box.

c) % change in mean number of viable eggs per female, relative to the control. A positive value indicates a decrease and a negative value an increase.

Mean as eggs per female per day

III. CONCLUSIONS

In an extended laboratory test to determine the effects of Mecoprop-P K 600 on the green lacewing, *Chrysoperla carnea*, there were no harmful effects on the insect's survival at treatment rates up to and including 2.5 L product/ha (the maximum tested).

Effects on lacewing reproduction are assessed on the basis of triggers. There should be ≥ 15 eggs per female per day and the egg hatching rate should be $\geq 70\%$ for a treatment to be deemed harmless. There were no harmful effects on reproduction after treatment with Mecoprop-P K 600 at rates up to and including 2.5 L product/ha.

RMS comments:

The study was well reported and conducted in close adherence with the referenced guideline. Only minor deviations from the guideline were noted and these were due to the use of a natural substrate (leaves) as opposed to an inert glass plate substrate described in Vogt et al. All validity criteria were met in accordance with the referenced guideline, although the tested reference item rate (80 L/ha) was in excess of the recommended range of 30-40 mL. This is not considered to be problematic, as the recommended range is with regards to application on an inert substrate where exposure to residues of the reference item would be higher. Application to a natural substrate such as the detached leaves used in this test would be expected to result in lower average residues and so application of the reference

item at an increased rate is logical. Overall the study is considered as valid and acceptable for risk assessment use. The agreed endpoints are as follows:

Effects of pre-imaginal mortality = 2.8% at 2500 mL CA3015/ha (1457 g a.s./ha)

Effects on reproduction (viable eggs) = -4.5% at 2500 mL CA3015/ha (1457 g a.s./ha)

Active substance endpoints based on tested batch content of 582.9 g Mecoprop-P/L

Reference

Ufer A (1996): Effect of BAS 037 29 H on the parasitoid *Aphidius rhopalosiphi* in an extended laboratory test.

Previous evaluation:	Included in Addendum II to DAR (July 2002) for original a.s. approval
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Methods

Effect of BAS 037 29 H was studied on the aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) in an extended laboratory test performed according to test guideline by Polger L, IOBC/WPRS 1988, and an unpublished test protocol by Mead-Briggs 1994.

The test substance was BAS 037 29 H containing 600 g mecoprop-P/l. It was tested in a concentration of 1.5 ml BAS 037 29 H/200 ml water at 4 µl/cm², equivalent to 3 l/ha in 400 l water/ha. The test plants were 7 days old wheat seedlings in the leaf stage 1-2 with 15 seedlings/pot, each 8 cm in diameter.

The aphids was used as adults lesser than 48 hours after emergence in an equal sex ratio. 5 animals per replicate were used in 3 replicates in the toxicity test and one female wasp in 10 replicates in the fecundity test. Dimethoate was used as reference substance. In the toxicity test mortality and behaviour assessments were made after 1, 2, 24 and 48 hours. Additional behaviour assessment of the position and activity of the wasps was made 0.5 and 2 hours after exposure. In the fecundity test, female wasps were confined in enclosed pots and exposed to a dry spray deposit on wheat seedlings infested with >100 aphids/pot for 24 hours and the total number of parasitized aphids was assessed after 12 days.

Results

The observations on mortality and behaviour (activity and positioning) and fecundity are summarised in the table below.

Table B.9.5.2-05: Summary of mortality behaviour and fecundity

	Control		BAS 037 29 H		Reference substance	
Mortality, total after 48 hours	0%		0%		100%	
Behaviour (activity, %)	After 0.5 h	after 2 h	After 0.5 h	after 2 h	After 0.5 h	after 2 h
Walking	38	18	10	29	5	40
Resting	58	55	83	68	95	58
Grooming	4	4	0	0	0	0
Feeding	0	22	7	3	0	3
Affected	0	0	0	0	0	0
Behaviour (position, %)						
Plants	30	56	37	21	75	47.5
Cylinder wall	70	44	63	79	25	50
Sand	0	0	0	0	0	2.5
Fecundity	22.2	SD 9.95	20.5	SD 11.9	-	

No mortality was observed after 48 hours in control nor exposed wasps. In the fecundity test the average number of parasitized aphids was 22.2 in the control and 20.5 per female in the mecoprop-P exposed wasps. The results did not differ significantly (t-test alpha = 0.05). The overall effect calculated as a combination of mortality and reproduction was E=7.7%:

$$E (\%) = 100 - ((100 - M) \times R)$$

M = mortality

R = reproduction rate where $R = R_t/R_c$

R_t = mean of parasitized aphids per exposed female

R_c = mean of parasitized aphids per female in control

It was concluded that mecoprop-P had no effect on adults of *Aphidius* and was classified as harmless (W1 according to BBA classification ($E < 30\%$)) at a rate up to 3 l/ha.

Comments

The dried residues of mecoprop-P on plants had no significant effects on mortality and fecundity of the parasitoid wasp *Aphidius rhopalosiphi*. Of behavioural activities less grooming and feeding in the mecoprop-P and reference substance was observed. Also a weak repellence of 79% on wall against 21% on exposed plants, whereas plants in control and reference groups showed almost equal distribution. These could be interpreted as minor effects.

The tested dosage is equivalent to 1.8 kg/ha mecoprop-P – The highest intended dosage.

RMS comments (renewal):

Study not revisited. Endpoints of study confirmed as follows from above summary:

0% mortality (48-hr) at 1800 g a.s./ha

7.7% effect on reproduction (mummies produced) at 1800 g a.s./ha

Ref.: IIIA. 10.5.1. Klepka & Petto, 1994: *Effects of Optica MPK on Poecilus cupreus* L. (Coleoptera, Carabidae) in laboratory.

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The effects of Optica MPK on the mortality and consumption of *Poecilus cupreus* (Coleoptera,

Carabidae) were studied in a laboratory test according BBA-guideline VI 23-2.1.9, 1991.

The formulation Optica MPK contained 627 g/l mecoprop-P K salt (532 g/l MCPP-P acid/l). The test substance was used at the maximum rate of application 2 l/ha in 400 l spraying solution (5 ml/l), corresponding to 12.54 µg MCPP-P K salt/cm². The test, reference substance (E 605 forte containing 500 g/l parathion, 5 g/ha) and control groups each comprised 5 replicates with six beetles. The beetles, 5-7 weeks old, were fed fly pupae (*Musca domestica*) and the numbers eaten were counted and used in the estimation of feed consumption. The beetles were observed for 28 days. The study was performed in test cages containing 250 g quartz sand moistened to 70% of the water capacity. The surface of the sand was 170.5 cm². The temperature was 22°C.

Results

The mortality was increased by 22.7% when compared to the control. The food consumption was not affected during exposure to the test substance. According to IOBC/WPRS this would result in Optica MPK to be assessed as harmless.

IOBC Classification scheme:

Mortality/reduction in beneficial capacity:

<30%:	Category 1 = harmless
30-79%:	Category 2 = slightly harmful
80-99%:	Category 3 = moderately harmful
>99%:	Category 4 = harmful

The mortality was 100% in the reference substance after 3 day of exposure.

Table B.9.5.2-06: Mortality and feeding performance values from 5 replicates.

Criteria	Control	Test substance	Reference subst.
Mortality % ± SD	26.7 ±14.9	43.3 ±14.9	100%
Pupae eaten	227	215	4
Pupae eaten/beetle	8.4	8.5	0.1

Comments

The study was acceptable.

RMS comments (renewal):

Study not valid due to high control mortality (validity criterion under Heimbach et al = max. 6.7%)

Ref.: IIIA. 10.5.1. Petto, 1994: *Effects of Optica MPK on Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the laboratory.

Previous evaluation:	Included in DAR (1998) for original a.s. approval
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Methods

The effects of Optica MPK on the reproduction/life cycle of *Aleochara bilineata* (Coleoptera, Staphylinidae) was studied in the laboratory according to IOBC/WPRS guidelines.

The formulation Optica MPK contained 627 g/l mecoprop-P K salt (532 g/l MCPP-P acid/l). The test substance was used at the maximum rate of application 2 l/ha in 600 l spraying solution, corresponding to 12.54 µg MCPP-P K salt/cm².

The adult *A.bilineata* are polyphagous predators whereas the larvae develop in the pupae of flies, especially cabbage root fly *Delia brassicae* or the onion fly *Delia antiqua*.

The test, reference (Perfekthion containing 400 g/l dimethoate, 160 g/ha) and control groups each comprised 5 replicates with six beetles. The rove beetles, 3 days old, were fed frozen fly larvae and sex was identified by copulation behaviour. Round glass beakers with the diameter 14 cm served as test cages. The beakers were half filled (4 cm) with sand moistened to 10% v/v with water. Ten pairs of beetles/test cage were placed in a hole dug in the sand just before spray application. The test substance was applied at 6 mg/cm² (corresponding to 600 l/ha). The study lasted until hatching of the new F1-generation after about 11 weeks. The test was performed in three replicates with 10 pairs of beetles each for control, test substance and positive control. At days 8, 15 and 22, respectively 434, 506 and 611 onion fly pupae per cage were introduced into the sand. After four weeks, the newly hatched beetles were counted up to week 11 were no further beetles hatched. The temperature was 20°C.

Results

No behavioural abnormalities or intoxication symptoms of the exposed beetles were observed. Hatching of the new generation started after 6 weeks. Hatching in exposed groups was not significantly different from control by a Kruskal-Wallis test ($p = 0.023$). Exposure to Optica MPK resulted in a reproduction of 97.2% as compared to control. According to IOBC/WPRS, this would result in Optica MPK could be assessed as harmless.

The hatching was 65% in the reference substance.

Table B.9.5.2-07: Parasitation efficiency and average hatching from 3 replicates.

Criteria	Control	Test substance	Reference subst
Fly pupae (%):			
parasitized	47	45	31
not parasitized	13	13	28
not hatched	37	38	36
not ascertainable	3	4	4
Hatched No. \pm SD	714 \pm 29	693 \pm 5	462 \pm 56
Hatching compared to control	100%	97.2%	64.6%

Comments

The study was acceptable.

RMS comments (renewal):

Study not revisited in detail. It is noted that the reference item had an effect within the guideline-recommended rate (guideline: Grimm et al, 2000). Endpoints confirmed as follows:

Mortality data not reported

2.8% effect on reproduction (successfully hatched F1 generation beetles) at 2 L form'n/ha (1064 g a.s./ha)

Based on tested batch mecoprop-P content of 532 g a.s./L

B.9.6. RISK ASSESSMENT FOR ARTHROPODS**B.9.6.1. Risk assessment for bees**

A summary of the available toxicity data from testing with bees is provided in below table B.9.6.1-01. Only those studies considered valid under the renewal assessment of the active substance are included and only the most sensitive or most relevant endpoint parameters for the purposes of risk assessment are included. For further agreed endpoints from the available data reference is made to both the List of End Points section of the renewal assessment report, as well as the individual study summaries.

Table 9.6.1-01: Toxicity of Mecoprop-P and the representative formulation to bees

Test substance	Organism	Exposure route	Toxicity (as MCPP-P)	Reference
Mecoprop-P DMAS	Honeybee (adults)	Acute contact Acute oral	48-hr LD ₅₀ > 83 µg/bee 48-hr LD ₅₀ > 83 µg/bee	Weyman (1999)
Mecoprop-P	Honeybee (larvae)	Acute dosed diet	72-hr LC ₅₀ = 2.636 g/kg food 72-hr LC ₁₀ = 1.29 g/kg food 72-hr NOEC = 1.463 g/kg food 72-hr LD ₅₀ = 89.4 µg/bee 72-hr LD ₁₀ = 43.7 µg/bee 72-hr NOED = 49.6 µg/bee	Kleebaum (2014)
Mecoprop-P K 600 g/L	Honeybee (brood study)	Field study via treated diet	After 27-days: No adverse effects on brood parameters at 0.15 g/hive No statistically significant effects on brood parameters at 3.75 g/hive	Franke (2013)

Acute adult honeybee toxicity and risk assessment

No valid acute toxicity testing with the representative formulation is available, and originally submitted (equivalent) formulation studies are deemed by the RMS as not fit for purpose. However on consideration of the constituents of the representative formulation; Mecoprop-P K 600 g/L it is proposed that no increased toxicity to bees is expected over the active substance alone. As such any risk assessment conducted using data with mecoprop-P is also considered to address the risk to bees from the representative formulation and visa versa. For detailed information on the composition of Mecoprop-P K 600 g/L please refer to Volume 4 of the Renewal Assessment Report.

The acute risk to adult honeybees is assessed in accordance with the SANCO Terrestrial guidance document⁵. The critical acute contact and oral LD₅₀ values are compared with the maximum individual application rate for the representative uses to derive a Hazard Quotient (HQ) for each exposure route. HQ values of ≤ 50 indicate a low acute risk to honey bees.

Table B.9.6.1-02: Acute risk assessment for exposure of honeybees to Mecoprop-P

Test substance	Exposure	Application rate	LD50	Hazard quotient	trigger
Mecoprop-P DMAS	Oral	1200 g a.s./ha	> 83 µg a.s./bee	<14.5	50
Mecoprop-P DMAS	Contact	1200 g a.s./ha	> 83 µg a.s./bee	<14.5	50

⁵ Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC - SANCO/10329/2002

As all HQ values are below the regulatory trigger value of 50 a low acute risk to honeybees can be concluded following the representative uses of mecoprop-P on winter and spring cereals.

Acute toxicity to honeybee larvae

In line with the data requirements for active substances (EU) 283/2013, an acute toxicity study with honeybee larvae has been conducted and is summarised under (CA) B.9.3.1.2. The study endpoints are summarised in above table B.9.6.1-01. As no EU-agreed risk assessment scheme is in place to utilise this endpoint no further action is taken.

Chronic toxicity and risk to honeybees

The notifier submitted a bee brood study conducted with the representative formulation under field conditions according to the Oomen et al (1992) guideline. The study is evaluated under (CA) B.9.3.1.3 and was concluded to be valid by the RMS. The parameters measured in the study included adult mortality and sub-lethal (behavioural) effects, as well as overall colony health (size) and various brood development parameters. In lieu of a finalised study guideline to meet data requirement 8.3.1.2 – chronic toxicity to bees at the time of dossier submission, it is considered that the submitted bee brood study (Franke, 2013) fulfils the 2 subsequent data requirements for 283/2013: Effects on honeybee development and other life stages (8.3.1.3) and Sub-lethal effects (8.3.1.4), both of which encompass assessment for sub-lethal effects.

The two exposure doses chosen for the bee brood study were based on either scientific rationale on expected maximal residues in food, or else on advice in the test guideline followed. The low dose of 0.15 g a.s./L food was chosen based on a precursor study (Mack, 2012) of residues in food items (nectar, honey) and larvae following a single application of a similar phenoxy herbicide (2, 4-D) to an attractive flowering plant. The maximum residues formed following an application of 1 x 750 g a.s./ha was 75.3 mg a.s./kg (in nectar). As the representative GAP for mecoprop-P is approximately double the study-applied rate (1 x 1200 g a.s./ha) The concentration of active substance in dosed food in the brood study was therefore double the measured residues; 150 mg a.s./L (an assumption of food density of approximately 1 is made). The study summary for this precursor residues trial (Mack, 2012) is provided under (CA) B.9.3.1.3. At this low dose of 0.15 g a.s./L food there were no observed adverse effects on any measured parameters in the bee brood field study, compared to the corresponding control group. As such it can be concluded with confidence that at exposure to honeybees of residues of mecoprop-P in food of up to 0.15 g a.s./L no adverse sub-lethal or brood development effects will occur. It is appreciated however, that the preliminary residue data relied on to select this dose was not generated with mecoprop-P itself (rather an similar phenoxy herbicide) and extrapolation to the active substance in question creates some uncertainty.

The high dose in the study was 3.75 g a.s./L food. This was calculated based on the guidance of the bee brood study (Oomen et al, 1992) which recommends a concentration based on the high volume use of the representative formulation. With regards to Mecoprop-P K 600 g/L this means a proposed application rate of mecoprop-P at 1500 g a.s./ha (note the actual proposed use rate for the purposes of renewal is 1200 g a.s./ha), and a maximum application volume of 400L/ha is proposed. As such, according to the “high volume spray strength” calculation the concentration to be tested (and representing a theoretical 100% exposure to the in-use concentration) would be 3.75 g a.s./L. At this tested dose in food there were no statistically significant effects on any measured parameter compared to the control group. However, it was noted that there was a definite effect on brood development area (-24% versus pre-dose area, compared to control performance of +9%), and also a noticeable increase in the termination of young larvae (18.67% versus 7.67% in the control group). Detailed discussion of these observed effects are provided in the RMS comments of the study summary. Overall, at a concentration of 3.75 g a.s./L food it cannot be comprehensively concluded that mecoprop-P will not cause any biologically adverse brood effects.

In lieu of any EU-agreed approach to assessing the chronic risk to honeybees, each substance and supporting data should be considered on a case-by-case basis. With regards to the renewal of

mecoprop-P, it is not an insect growth regulator and does not have an insecticidal mode-of-action. Due to the lack of an EU-agreed risk assessment scheme and the difficulty relating exposure in this study to mecoprop-P exposure in the field, the risk to bee brood has not been considered further.

B.9.6.2. Risk assessment for non-target arthropods other than bees

A summary of the available toxicity data from testing with non-target arthropods other than bees is provided in below table B.9.6.2-01. Only those studies considered valid under the renewal assessment of the active substance are included and only the most sensitive or most relevant endpoint parameters for the purposes of risk assessment are included. For further agreed endpoints from the available data reference is made to both the List of End Points section of the renewal assessment report, as well as the individual study summaries.

Table B.9.6.2-01: Toxicity of Mecoprop-P and the representative formulation to non-target arthropods other than bees

arthropods other than bees				
Species	Test Substance	End point	Toxicity (g a.s./ha)	Reference
First tier studies				
<i>Aphidius rhopalosiphi</i>	Mecoprop-P K 600 g/L	Mortality, LR ₅₀	447.6	Stevens (2014a)
		Reproduction	-9.5% at 293.7	
<i>Typhlodromus pyri</i>	Mecoprop-P K 600 g/L	Mortality, LR ₅₀	>1468	Fallowfield (2014)
		Reproduction	28.1% at 1468	
Additional species/testing				
<i>Aphidius rhopalosiphi</i>	Mecoprop-P K 600 g/L	<u>3D natural substrate:</u> Mortality	13.3% at 1457	Stevens (2014b)
		Reproduction	4.6% at 1457	
<i>Chrysoperla carnea</i>	Mecoprop-P K 600 g/L	<u>2D natural substrate:</u> Mortality	2.8% at 1457	Vaughan (2015)
		Reproduction	-4.5% at 1457	
<i>Aphidius rhopalosiphi</i>	BAS 037 29 H (Duplosan KV)*	<u>3D natural substrate:</u> Mortality	0% at 1800	Ufer (1996)
		Reproduction	7.7% at 1800	
<i>Aleochara bilineata</i>	Optica MPK*	<u>Artificial substrate:</u> Mortality	Not reported	Petto (1994)
		Reproduction	2.8% at 1064	

*Deemed equivalent in composition to Mecoprop-P K 600 g/L – refer to introduction section (CP) B.9

The risk to non-target arthropods other than bees will be assessed using the Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods from the ESCORT 2 workshop (Candolphi *et al*, 2000), which uses the following equations to calculate hazard quotients for in-field and off-field exposure scenarios. The risk assessment was carried out in accordance with ESCORT II (2000); the effect for in-field and off-field scenarios were calculated as follows

$$\text{In-field HQ} = \frac{\text{Application rate} \times \text{MAF}}{\text{LR}_{50}}$$

$$\text{Off-field HQ} = \frac{\text{Application rate} \times \text{MAF} \times (\text{drift factor/VDF}) \times \text{correction factor}}{\text{LR}_{50}}$$

Where:

- MAF: Multiple Application Factor. For more than a single application of a substance it is expected that some level of accumulation of residues will occur. The MAF is utilised to predict expected peak residues for the assessed use pattern. As only a single application is proposed as the representative use of mecoprop-P on cereals a MAF of 1 is relevant.
- Drift factor: Following an in-field use of a substance spray applied, the percentage of the applied substance is expected to drift onto field-adjacent vegetation. The percentage of substance expected to do so is dependent on the distance of application from the field edge, as well as the target crop. The tables in Appendix IV of the ESCORT II guidance document (Candolfi et al) stipulate the default drift factors to be utilised in the risk assessment. For the proposed single application of mecoprop-P to cereals ('field crop') a drift factor of 0.0277 (i.e. 2.77% of applied substance in-field) is relevant.
- VDF: Vegetation Distribution Factor. It is expected that drift onto off-crop plants will be intercepted and distributed across the whole 3-dimensional structure of the plant itself, as opposed to the downward spray application utilised in standard lab studies to 2-D target substrates, where a particular surface receives the whole application rate applied. To account for this difference a factor of 10 is applied when the assessed toxicity endpoint is derived from a study using a 2-Dimensional target substrate. Where the toxicity study utilised whole plants at application a VDF of 1 is applicable.
- Correction factor: A factor of 10 is applied to the off-field risk assessment to account for the expected greater species variability compared to the in-field, and extrapolated from only 2 indicator species' data.

Tier I risk assessment

Based on the aforementioned equations, the HQ values for the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* based on the first tier laboratory studies are summarised in below tables B.9.6.2-2 (in-field) and B.9.6.2-03 (off-field):

Table B.9.6.2-02: Tier I in-field risk assessment for Mecoprop-P representative uses on cereals

Species	Test substance	Application rate (g a.s./ha)	MAF	PER (g a.s./ha)	LR ₅₀ (g a.s./ha)	HQ*	Trigger
<i>A.rhopalosiphi</i>	Mecoprop-P	1200	1	1200	447.6	2.7	2
<i>T.pyri</i>	K 600 g/L				>1468	<0.82	2

*bold values are higher than the trigger value.

Table B.9.6.2-03: Tier I off-field risk assessment for Mecoprop-P representative uses on cereals

Species	Test substance	Application rate (g a.s./ha)	MAF	Drift factor	CF	VDF	PER (g a.s./ha)	LR ₅₀ (g a.s./ha)	HQ	Trigger
<i>A.rhopalosiphi</i>	Mecoprop-P K 600 g/L	1200	1	0.0277	10	10	33.24	447.6	0.07	2
<i>T.pyri</i>						10	33.24	>1468	<0.03	2

On the basis of the above tier I risk assessments a low risk to off-field populations of non-target arthropods can be concluded for the representative uses of mecoprop-P.

A low risk to in-field populations cannot be concluded, due to the calculated HQ value for indicator species *Aphidius rhopalosiphi* being above the regulatory trigger of 2. As such a higher tier in-field risk assessment is undertaken.

Higher tier risk assessment

In accordance with the guidance of ESCORT II (Candolfi et al), where an indicator species fails the tier I in-field risk assessment, further testing is required with that species, and at least one further species. As detailed in table B.9.6.2-01, an extended laboratory study with *A.rhopalosiphi* is provided, testing exposure on natural substrates (whole plant). There is also data available with 2 further species; *C.carnea* (foliar dwelling green lacewing) and ground dwelling rove beetle *A.bilineata*.

The exposure in-field ($PER_{in-field}$) is calculated using the same equation as at tier I. At higher tier both lethal and sub-lethal effects are considered directly against the predicted exposure, with a threshold of 50% adverse effects at the $PER_{in-field}$ defining a low/high risk.

Table B.9.6.2-04: Higher tier in-field risk assessment for representative uses of Mecoprop-P

Species	Test substance	Application rate (g a.s./ha)	MAF	$PER_{in-field}$ (g a.s./ha)	Rate with <50% effects (g a.s./ha)	Risk acceptable?
<i>A.rhopalosiphi</i>	Mecoprop-P K 600 g/L	1200	1	1200	1457	yes
<i>C.carnea</i>	Mecoprop-P K 600 g/L				1457	yes
<i>A.rhopalosiphi</i>	BAS 037 29 H				1800	yes
<i>A.bilineata</i>	Optica MPK				1064	no

As shown in above table B.9.6.2-04, a low in-field risk is demonstrated for the species *Aphidius rhopalosiphi* and *Chrysoperla carnea*. However, available data from the original DAR with *A.bilineata* does not result in an acceptable risk, due to the limit tested rate of the study not exceeding the $PER_{in-field}$ for the representative uses of mecoprop-P.

The RMS proposes that a low risk to in-field populations of non-target arthropods can still be concluded based on the following:

- A low risk was shown with the indicator species failing the tier I risk assessment plus the required 1 additional species.
- At the limit tested rate in the previous study with *Aleochara bilineata* there was only a 2.8% reduction in reproductive output (as successfully hatched F1 generation). Given that this is such a minor variation from the control group, and the small difference in tested rate from the maximum $PER_{in-field}$ it is likely that no adverse effects to this species in excess of the 50% threshold would occur at exposure to the $PER_{in-field}$.
- Only a single application of Mecoprop-P per year is proposed. The DT_{50} of the active substance in soil is 10.12 days (as used to calculate PEC_{soil}), and a default foliar DT_{50} of 10 days can be conservatively assumed. On this basis it would be expected that in-field residues of Mecoprop-P would drop below the tested 1064 g a.s./ha shown to have negligible effects on *A.bilineata* well within the maximum of 1 year allowed for recolonisation of the in-field according to ESCORT II. As a low risk to off-field populations of non-target arthropods is also demonstrated there would be an available reservoir of individuals to begin the recolonisation process.

No further consideration of the risk to non-target arthropods other than bees is therefore made.

B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA**B.9.7.1. Earthworms**

No data submitted with the representative formulation.

B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms)

Report:	McCormac, A (2015)
Title:	Mecoprop-P K 600 g/L – A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) Testing Laboratory: Mambo-Tox Ltd. Study Number: NUF-14-6 Date: 5 th March 2015
Guideline:	OECD (2009). OECD Guidelines for testing of chemicals, No. 232. Collembolan reproduction test in soil ISO 11267: Soil quality – Inhibition of reproduction of Collembola (<i>Folsomia candida</i>) by soil pollutants.
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS**A MATERIALS****1. Test material**

Test item:	Mecoprop-P K 600 g/L, AKA CA3015
Description:	Brown liquid
Lot No./Batch No:	18-32-122
Active ingredient content:	582.9 g Mecoprop-P/L
Product density:	1.248 g/mL
2. Vehicle and/or positive Control	Control: Purified water Positive control: Betosip 114 (114 g/L phenmedipham)
Test system	
Organism (<i>Species</i>):	<i>Folsomia candida</i> (Willem)
Age:	Juvenile, 10 day old at initiation
Source:	In house culture originally sourced from Syngenta Ltd.,

Jealott's Hill International Research Centre, Bracknell, UK.

Environmental conditions

Temperature:	18.3-21.1°C
Photoperiod:	12 hours light / 12 hours dark
Light intensity:	520-780 lux
Food:	dried granulated baker's yeast was provided on day 0+14 of test.

B STUDY DESIGN AND METHODS

1. In life dates: 15 September 2014 – 18 February 2015

2. Test system

Duration of study:	28 days
Protocol deviations:	None
Test concentrations:	0, 16.3, 29.4, 52.9, 95.3, 171.5, 308.6, 555.6, 1000 mg Mecoprop-P/kg soil dry weight Equivalent to 0, 35, 63, 113, 204, 367, 661, 1190, 2141 mg CA3015/kg soil dry weight Reference item tested at 200 mg product/kg soil dry weight.

Parameters measured: Mortality, reproduction (number of progeny per replicate)

3. Methodology

Obtaining test species: To obtain a synchronised cohort for testing, egg clusters from the breeding containers were transferred to 9-cm-diameter plastic Petri dishes. Once hatching had started, any unhatched eggs and the associated filter papers were transferred to a fresh Petri dish and the remaining juveniles were provided with approximately 2 mg of food. This was carried out on consecutive days during the hatching period so that all juveniles in a single Petri dish were of the same age in days.

Test arenas and substrate: The test arenas were 125-mL capacity glass jars (4.5cm diameter), with screw-top lids.

The substrate within the arenas was an artificial soil prepared in accordance with OECD 232 (5% peat content). Soil pH during the test was in the range 6.01 – 6.45.

Test item application: The test item and reference item were diluted in purified water and then sufficient amounts of the solutions added to the artificial soil to achieve 50% WHC. For the control purified water alone was added. Once treated, 30 g (final prepared weight) of appropriately treated soil was transferred into each replicate vessel.

Replicates: For the definitive test there were 8 replicate arenas for the control, 5 for the toxic reference and 4 for each of the test item treatments. Each arena was set up with 10 organisms.

Experimental procedure:	<p>On D 0 and D 14 granulated bakers yeast was added to each vessel as a food source.</p> <p>On D 0, 14 and 28 each vessel was weighed in order to track any moisture loss. On D 14 any weight loss was replenished as purified water.</p> <p>Each vessel was aerated every 2-3 days throughout the test.</p> <p>On D 28 the number of surviving adults and juveniles produced was assessed.</p>
Assessments:	<p>The number of surviving adults and F1 progeny in each test arena was assessed on 28 DAT (definitive test). To conduct this assessment the soil was placed into a tray (approx 11cmx17cm, 6cm depth). Water (approx. 150 - 200 mL) was then added to the substrate and stirred gently and frequently, so that the soil sank and the springtails floated to the surface. Any adult springtails floating on the water were counted and removed. The water-filled arenas were left for a period of > 2 h and any further adult springtails that had surfaced were recorded. Black ink was then added to the water and the numbers of any nymphs (smaller in size to adults) left in each arena were assessed. The ink darkened the water so that it contrasted with the light-coloured springtails floating on the water surface.</p>
Statistics:	<p>Derivation of the LOEC and NOEC (mortality):</p> <p>Mortality data were compared with that of the control using Fisher's Exact Test ($\alpha = 0.05$).</p> <p>Derivation of the LOEC and NOEC (reproduction):</p> <p>Reproduction data were checked for normality using Shapiro-Wilk test ($\alpha = 0.05$) and for homogeneity of variance using Levene's test ($\alpha = 0.05$). The dataset was then compared with the control using a t-test for unmatched pairs ($\alpha = 0.05$)</p>

II. RESULTS AND DISCUSSION

Validity criteria:	<p>All criteria were met.</p> <ul style="list-style-type: none"> -Control treatment mortality did not exceed 20% = 9% -Mean number of juvenile recorded in the control was greater than 100 per replicate = mean of 776/replicate -The coefficient of variation did not exceed 30% = 9.7% -The efficiency of the method used to extract mites was >95% = 98.3%
Mortality:	Table 1 summarises the mortality results.

Table B.9.7.2-01: Summary of mortality results

Test item	Concentration (mg a.s./kg soil dry weight)	% mortality ^{a)}	Corrected % mortality ^{b)}
Control	0	9	-
Mecoprop-P K 600 g/L	1000	40*	34
	555.6	20	12
	308.6	3	0
	171.5	8	0
	95.3	18	10
	52.9	0	0
	29.4	10	1
	16.3	15	7
Betosip 114	200	58*	54

a) Mortality amongst mites originally introduced

b) Derived using Abbott's formula (negative results given as zero)

* Statistically significantly different, when compared with the control

Reproduction: Table B.9.7.2-02 summarises the reproduction results.**Table B.9.7.2-02: Summary of reproduction results**

Test item	Concentration (mg a.s./kg soil dry weight)	Mean no. Progeny per replicate	% change relative to the control ^{a)}
Control	0	776	-
Mecoprop-P K 600 g/L	1000	2*	100
	555.6	47*	94
	308.6	267*	66
	171.5	392*	50
	95.3	475*	39
	52.9	697	10
	29.4	687	12
	16.3	749	4
Betosip 114	200	1*	100

a) A positive value indicates a decrease and a negative value indicates an increase in reproduction, relative to the control.

* Statistically significantly different, when compared with the control

III. CONCLUSIONS

In a laboratory test in which the springtail *Folsomia candida* was exposed to Mecoprop-p K 600 g/L in an artificial soil substrate (5% peat content), the 28-day EC₅₀ for reproductive capacity was calculated to be 160.8 mg a.s./kg soil dry weight, with 95% confidence limits of 127.8 and 201.1 mg a.s./kg soil dry weight. Based on statistical comparisons with the control, the LOEC for reproduction was 95.3 mg a.s./kg soil dry weight and the NOEC was 52.9 mg a.s./kg soil dry weight. Probit regression analysis indicated that the EC₅₀, EC₂₀ and EC₁₀ values were 160.8, 68.6 and 44.0 mg a.s./kg soil dry weight, respectively.

For assessments of mortality, the LOEC was 1000 mg a.s./kg soil dry weight and the NOEC was 555.6 mg a.s./kg soil dry weight. The 28-day LC₅₀ was > 1000 mg a.s./kg soil dry weight.

RMS comments:

The study was well reported and conducted in close adherence with OECD 232, with all validity criteria met. The reference item produced a significant reduction in juvenile numbers at a tested concentration within the range (in terms of active ingredient; phenmedipham) stated in ISO 11267 (2014). Overall the study can be considered as valid and acceptable for risk assessment use. The agreed endpoints are as follows:

28-day NOEC = 113 mg CA3015/kg soil dry weight, equivalent to 52.9 mg a.s./kg soil dry weight.

EC₁₀ for reproduction = 44.0 mg a.s./kg

EC₂₀ for reproduction = 68.6 mg a.s./kg

Report:	Vinall, S. (2015)
Title:	Mecoprop-P K 600 g/L – A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) Testing Laboratory: Mambo-Tox Ltd. Study Number: NUF-14-5 Date: 6 th January 2015
Guideline:	OECD (2008). OECD Guidelines for testing of chemicals, No. 226. Predatory mite (<i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i>) reproduction test in soil.
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A MATERIALS

1. Test material

Test item: Mecoprop-P K 600 g/L, AKA CA3015

Description: Brown liquid

Lot No./Batch No: 18-32-122

Active ingredient content:	582.9 g Mecoprop-P/L
Product density:	1.248 g/mL
2. Vehicle and/or positive Control	Control: Purified water Positive control: Dimethoate (BASF Perfekthion, 400 g/L diemthoate); tested at 14 mg a.s./kg soil dry weight
Test system	
Organism (<i>Species</i>):	<i>Hypoaspis aculeifer</i> , females only
Age:	Adult (7-14 days at adult stage)
Source:	In house culture, originally sourced from ECT Oekotoxicologie GmbH, Germany.
Environmental conditions	
Temperature:	19.9-20.7°C
Photoperiod:	16 hours light / 8 hours dark
Light intensity:	655-740 lux
Food:	Cheese mites (<i>Tyrophagus putrescentiae</i>) and juvenile springtails (<i>Folsomia candida</i>) provided <i>ad libitum</i>

B STUDY DESIGN AND METHODS

1. In life dates:	1 September 2014 – 27 November 2014
2. Test system	
Duration of study:	14 days
Protocol deviations:	None reported
Test concentrations:	Definitive test: 95.3, 171.5, 308.6, 555.6, 1000 mg Mecoprop-P/kg soil dry weight Test concentrations were selected based upon the results of a range-finding test conducted at 1000, 100, 10 and 1 mg Mecoprop-P/kg soil dry weight.
Parameters measured:	Mortality, reproduction (number of progeny per replicate)
3. Methodology	
Obtaining test species:	To obtain a cohort for the test, female mites were transferred to several new pots containing fresh substrate. After 2 days the eggs were removed and transferred to a new pot of fresh substrate. After a further 2 days the eggs began to hatch and they were used 28 days (range-finding) and 31 days (definitive) after start of egg laying (approximately 7-14 days from becoming adult).
Test arenas and substrate:	The test arenas were 60-mL capacity glass jars (5.5cm tall x 5.2cm outer diameter, 4.4cm inner diameter), with screw-top lids. An 8mm diameter hole was made in the lid for ventilation, which was covered with fine nylon netting (80 micron mesh).

The substrate within the arenas was an artificial soil, prepared according to OECD 226 (5% peat content) and adjusted to 50% WHC. Measured pH during test = 5.61 – 6.08.

Test item application:	The test item and reference item were diluted in purified water and then sufficient amounts of the solutions added to the artificial soil to achieve 50% WHC. For the control purified water alone was added. Once treated 20 g (dry weight equivalent) of the soil was transferred into each replicate arena.
Replicates:	For the definitive test there were 8 replicate arenas for the control, 5 for the toxic reference and 4 for each of the test item treatments. Each arena was set up with 10 adult female mites.
Experimental procedure:	<p>Within an hour of the soil being treated, 10 female <i>Hypoaspis aculeifer</i> were placed into each arena.</p> <p>Food was provided <i>ad libitum</i> every 3-4 days.</p> <p>Vessels were weighed on D 0, 7 and 14. At 7 DAT, the arenas were weighed and if the change in weight was >2%, purified water was carefully added to the soil to re-establish the original soil moisture.</p> <p>Counts of adult and juvenile numbers were made after 14-days</p>
Assessments:	The number of surviving adults and F1 progeny in each test arena was assessed at 14 DAT. To conduct this assessment the soil was placed into Tullgren funnel apparatus. Over a 2 day period, the heat of a bulb above the funnel dried the soil from the top. This forced the <i>H. aculeifer</i> to move downwards until they fell from the base of the funnels into collecting vials placed beneath. The vials contained 70% v/v methyl alcohol in which the mites were drowned and preserved. The number of adult and juvenile <i>H. aculeifer</i> could then be counted using a binocular microscope.
Statistics:	<p>Derivation of the LOEC and NOEC (mortality):</p> <p>Mortality data were compared with that of the control using Fisher's Exact Test ($\alpha = 0.05$).</p> <p>Derivation of the LOEC and NOEC (reproduction):</p> <p>Reproduction data were checked for normality using Shapiro-Wilk test ($\alpha = 0.05$) and for homogeneity of variance using Levene's test ($\alpha = 0.05$). The dataset was then compared with the control using a t-test for unmatched pairs ($\alpha = 0.05$)</p>

II. RESULTS AND DISCUSSION

Validity criteria:

All criteria were met.

-Control treatment mortality did not exceed 20% = 4%

-Mean number of juvenile recorded in the control was greater than 50 per replicate = 287

-The coefficient of variation did not exceed 30% = 10.5%

-The efficiency of the method used to extract mites was >95% = 99.2%

Mortality:

Table B.9.7.2-03 summarises the mortality results.

Table B.9.7.2-03: Summary of mortality results

Test item	Concentration (mg a.s./kg soil dry weight)	% mortality ^{a)}	Corrected % mortality ^{b)}
Control	0	4	-
Mecoprop-P K 600 g/L	1000	3	0
	555.6	0	0
	308.6	0	0
	171.5	10	7
	95.3	3	0
Pefekthion	14	100*	100

a) Mortality amongst mites originally introduced

b) derived using Abbott's formula (negative results given as zero)

* Statistically significantly different, when compared with the control

Reproduction:

Table B.9.7.2-04 summarises the reproduction results.

Table B.9.7.2-04: Summary of reproduction results

Test item	Concentration (mg a.s./kg soil dry weight)	Mean no. Progeny per replicate	% change relative to the control ^{a)}
Control	0	287	-
Mecoprop-P K 600 g/L	1000	311	-8
	555.6	301	-5
	308.6	291	-2
	171.5	301	-5
	95.3	312	-9
Pefekthion	14	2*	99

a) A positive value indicates a decrease and a negative value indicates an increase in reproduction, relative to the control.

* Statistically significantly different, when compared with the control

III. CONCLUSIONS

In a laboratory test in which the soil mite *Hypoaspis aculeifer* was exposed to Mecoprop-P K 600 in an artificial soil substrate, no significant effects were seen on either mite survival or reproductive capacity, when compared with a control. As a result the NOEC for both mortality and reproduction was determined to be 1000 mg Mecoprop-P/kg soil dry weight (the highest concentration tested). No LOECs could be determined as no effects were seen. Additionally LC₅₀, LC₂₀, LC₁₀ (mortality) and EC₅₀, EC₂₀ and EC₁₀ (reproduction) values could not be determined, but can all be deemed to be > 1000 mg Mecoprop-P/kg soil dry weight.

RMS comments:

The study was well reported and conducted in close adherence with OECD guideline 226, with all related validity criteria met. The reference item results do not allow for direct confirmation of acceptable test system sensitivity, as only a single concentration was tested, and this was greater than the recommended range to result in an EC₅₀ for the substance tested (dimethoate, expected EC₅₀ range = 3.0 – 7.0 mg a.s./kg). However, the sensitivity demonstrated at the tested rate is considered by the RMS to support the suitability of the test system. The study is considered to be valid and acceptable for risk assessment use. Agreed endpoints are as follows:

14-day NOEC = 1000 mg a.s./kg soil dry weight, equivalent to 2141 mg CA3015/kg soil dry weight.

The EC₁₀ and EC₂₀ could not be defined but are considered to be > 1000 mg a.s./kg soil dry weight

B.9.8. RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA

A summary of the available toxicity data from testing with soil meso- and macrofauna is provided in below table B.9.8-01. Only those studies considered valid under the renewal assessment of the active substance are included and only the most sensitive or most relevant endpoint parameters for the purposes of risk assessment are included. For further agreed endpoints from the available data reference is made to both the List of End Points section of the renewal assessment report, as well as the individual study summaries.

Table B.9.8-01: Summary of soil meso- and macrofauna toxicity endpoints for use in the risk assessment with Mecoprop-P and the representative formulation

Test substance	Organism	Timescale	Endpoint	Toxicity (mg a.s./kg soil dw)	Reference
Mecoprop-P	<i>Eisenia fetida</i>	Chronic	Reproduction NOEC Reproduction EC ₁₀	10.8 9.0	Stojanowitsch (2014)
Mecoprop-P K 600 g/L	<i>Folsomia candida</i>	Chronic	Reproduction NOEC Reproduction EC ₁₀	52.9 44.0	M ^c Cormac (2015)
Mecoprop-P K 600 g/L	<i>Hypoaspis aculeifer</i>	Chronic	Reproduction NOEC Reproduction EC ₁₀	1000 >1000	Vinall (2015)

No correction of soil organism endpoints is required, as the log Pow of the active substance mecoprop-P is < 2 (-0.19 at pH 7).

Metabolites

There are no identified soil metabolites formed from the active substance. As such only exposure in soil to the active substance and representative formulation require consideration.

The risk assessment for soil meso- and macrofauna is conducted in accordance with the SANCO terrestrial guidance document⁶. Toxicity endpoints expressed in terms of the active substance are

⁶ Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC - SANCO/10329/2002

compared against the initial Predicted Environmental Concentration of the active substance in soil (PEC_{soil}). Due to the short half-life of mecoprop-P in soil (10.12 days) no accumulation in soil following year-on-year application is anticipated for the representative uses. An acute regulatory trigger of ≥ 10 , and a chronic trigger of ≥ 5 indicate a low risk to this organism group.

Table B.9.8-02: Risk assessment for soil meso- and macro-organisms following the representative uses of Mecoprop-P on cereals

Test organism	Test substance	Timescale	Toxicity (mg a.s./kg)	Soil PEC ³ (mg a.s./kg)	TER	Trigger
Earthworms						
<i>E.fetida</i>	Mecoprop-P	Chronic	10.8 ¹	1.600	6.8	5
			9.0 ²	1.600	5.6	
Other soil macro-organisms						
<i>F.candida</i>	Mecoprop-P K 600 g/L	Chronic	52.9 ¹	1.600	33	5
			44.0 ²	1.600	28	
<i>H.aculeifer</i>	Mecoprop-P K 600 g/L	Chronic	1000 ¹	1.600	625	5
			>1000 ²	1.600	>625	

¹ NOEC

² EC₁₀

³ Maximum initial PEC_{soil} for representative uses

When consideration is given to either the NOEC or EC₁₀ endpoint for sub-lethal effects on earthworms and other soil macro-organisms, the chronic TER values are greater than the regulatory trigger of 5. A low risk to these organisms can therefore be concluded following the representative uses of mecoprop-P on winter and spring cereals as detailed in table B.9-01.

B.9.9. EFFECTS ON SOIL NITROGEN TRANSFORMATION

No additional studies provided. A study on the effects of mecoprop-P on nitrogen transformation (Todt, 1989) was reviewed during the 91/414/EC Review for mecoprop-P (SANCO/3065/99 dated 14 April 2003) and has been revisited by the RMS for the purposes of renewal. Please refer to Volume 3, (CA) point B.9.5 of this renewal assessment report for the summary and RMS comments of this study.

B.9.10. RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION

Only a single study on nitrogen transformation to address data requirement 8.5 of 283/2013 is provided in support of the renewal of mecoprop-P, and is summarized under (CA) B.9.5 of the Renewal Assessment Report. The conclusion of the RMS at renewal is that the study is not suitable for regulatory purposes.

As such no risk assessment for this group is possible. **A data gap should be set for the notifier to submit a test to provide sufficient data to evaluate the impact of the active substance on soil microbial activity, in terms of nitrogen transformation.** The recommended OECD guideline for such as test design is OECD Test No. 216: Soil Microorganisms: Nitrogen Transformation Test

B.9.11. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

B.9.11.1. Summary of screening data

No additional studies submitted for the purpose of renewal.

B.9.11.2. Testing on non-target plants

Report:	CP 10.6.2/01
Title:	Siemoneit, S (2002) A toxicity test to determine the effects of BAS 037 32 H on vegetative vigour of 2 terrestrial plants. Staatliche Lehr- und Forschungsanstalt für Landwirtschaft (SLFA) Report Number: 137 392 Published: No
Guidelines:	OECD 208 B (Draft, 2000)
GLP:	Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS**A. MATERIALS**

Test material:	BAS 037 32 H 600 g/L Mecoprop-P (596.1 g/L analysed content)
Batch:	09-5196
Description:	Liquid, Brown, SL Formulation
Density:	1.251 g/mL
Vehicle and/or positive control:	Material was diluted in water prior to spraying.
Test species	
Species:	Oilseed rape (<i>Brassica napus</i>) Pea (<i>Pisum sativum</i>)
Soil:	<u>Oilseed rape:</u> Silty sand (Clay 5.0%, Silt 22.5%, Sand 72.5%) pH 7.5 Organic Carbon 1.3% <u>Pea:</u> Silty sand (Clay 3.9%, Silt 26.4%, Sand 69.7%) pH 8.0 Organic Carbon 0.6%
Environmental conditions	
Temperature:	19 - 27°C
Humidity:	31 - 99%
Photoperiod:	16 Hours light, 8 hours dark

Illumination:	> 5 k lux in both test periods
Watering:	Bottom watered pots according to consumption
Fertilisers:	1 g/L 'Flory 9' Fertiliser as required (approx. 1/week).

B. STUDY DESIGN AND METHODS

In Life dates:	30-May-2001 to 12-Sept-2001
Test System:	

Table B.9.11.2-01: Study replication of organisms

Test Plant	Oilseed rape	Pea
Number of replicates per rate	6	6
No. plants per Replicate	3	4
Replicate description	Plastic, 7.5 cm diameter	Plastic, 13 cm diameter
Soil/replicate (g dry wt.)	220 ± 1	910
Growth stage at application [BBCH]	12	12

The application rates for each species as shown below:

Table B.9.11.2-02: Tested rates for each species

Test Item [ml/ha]	a.s. [g/ha]	Amount of Water [L/ha]	Tested Plant Species
0	0	200	Oilseed rape, pea
23.4	14.1	200	Oilseed rape
46.9	28.1	200	Oilseed rape, pea
93.8	56.3	200	Oilseed rape, pea
188	113	200	Oilseed rape, pea
375	225	200	Oilseed rape, pea
750	450	200	Oilseed rape
1500	900	200	Oilseed rape, pea
3000	1800	200	Pea

Methodology: Solutions of the test item were prepared in deionised water, via serial dilution from a concentrated stock solution (also used to treat plants at the highest tested rate of 3000 mL/ha). Application of solutions to plants was made at a volume of 200 L/ha using a calibrated laboratory sprayer. After application all plants were moved to greenhouse conditions for the duration of the test.

Observations: Plants were assessed for symptoms of phytotoxicity at 7, 14 and 21 days after application. Phytotoxicity was rated

as % affected plant compared to the control (0% = all plants healthy – 100% = all plants dead).

At 21 days the plants were cut directly above the ground and their height (longest shoot) and fresh weight were determined

Statistics:

From observations mean values and standard deviations were calculated.

The following were used for plant height and fresh weight:

1. Kolmogorof-Smirnov-Test – normal distribution,
2. Cochran's test – homogeneity of variance,
3. ANOVA in case of homogeneity of variance between treatments with a Generalized Linear Model (GLM),
4. Dunnett test applied to determine NOEC.

II. RESULTS AND DISCUSSION

A. RESULTS

The results for phytotoxicity, plant height and fresh weight are shown in Tables CP 10.6.2-1 and CP 10.6.2-2.

The NOER, ER₅₀ and ER₂₅ values are shown in Table CP 10.6.2-3.

Table B.9.11.2-03: Oilseed Rape: Effects of application of BAS 037 32 H

Rate mL product/ha	0	23.4	46.9	93.8	188	375	750	1500
Phytotoxicity [%]								
Day 7	0	13	23	37	47	57	67	77
Day 14	0	7	20	32	45	71	68	77
Day 21	0	13	25	33	62	88	86	92
Plant Height [cm]								
Day 21	49.6	44.3*	41.0*	36.8*	29.2*	24.6*	23.1*	23.1*
Fresh Weight [g]								
Day 21	56.62	43.01*	42.47*	26.5*	10.11*	1.93*	3.36*	2.36*

*significantly different from controls (Dunnett test, $p \leq 0.05$).

At day 21 phytotoxic symptoms observed were plant deformation, growth reductions and some plant death (plant death seen at rates of 188 mL/ha and above).

Table B.9.11.2-04: Pea: Effects of application of BAS 037 32 H

Rate mL product/ha	0	47	94	188	375	750	1500	3000
	Phytotoxicity [%]							
Day 7	0	0	0	7	22	35	48	50
Day 14	0	0	0	5	20	30	47	60
Day 21	0	0	0	5	20	30	52	68
	Plant Height [cm]							
Day 21	98.7	97.5	100.7	96.0	91.5	89.9	72.0*	49.9*
	Fresh Weight [g]							
Day 21	24.40	25.19	29.42	22.44	21.20	24.15	16.78	8.24*

*significantly different from controls (Dunnett test, $p \leq 0.05$).

At day 21 phytotoxic symptoms observed were plant deformation and growth reduction.

Validity criteria (according to modern guideline OECD 227) were met as follows:

- Seedling emergence is at least 70%: This is not reported. However the plants were pre-grown prior to study use and enough plants of suitable robustness to meet other control validity criteria (see below criteria) were available.
- Control plants do not exhibit visual phytotoxic effects: Met; all control phytotoxic scores were reported as 0%, with no abnormalities recorded.
- Mean control plant survival in the study duration is at least 90%: Met; although not explicitly reported, any incidences of plant death were recorded as phytotoxic observations. As such it can be concluded with confidence that there was no control plant death for either tested species.
- Environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix from the same source: Met; As detailed in the above summary, each species was grown and maintained in a single soil of known characteristics, with a consistent dry weight used per vessel, which was also consistent in size per species. All plants were maintained under equal environmental conditions (temperature, lighting, humidity).

Table B.9.11.2-05: BAS 037 32 H: NOER, ER₁₀, ER₂₅ and ER₅₀ values (mL/ha) of the plant at 21 Days

Test Species	Oilseed rape	Pea
	Phytotoxicity [%]	
NOER	<23.4	93.8
	Plant Height [cm]	
NOER	<23.4	750
ER ₁₀	5.9	NC
ER ₂₅	60.7	1348
ER ₅₀	621	2519
	Plant Fresh Weight [g]	
NOER	<23.4	750
ER ₁₀	24.3	NC
ER ₂₅	45.6	1325
ER ₅₀	85.5	2189

NC – not calculated

III CONCLUSION

Based on the results of this study it can be concluded that BAS 037 32 H may cause adverse effects to oilseed rape and pea. Pea is clearly less sensitive than oilseed rape. The critical ER₅₀ after 21 days is 85.5 mL/ha, with regards to plant fresh weight reduction in oilseed rape.

RMS comment:

Although conducted to the older, draft non-target terrestrial plant guideline the study was generally well reported and conducted in good adherence with the modern OECD guideline equivalent (OECD 227). With the exception of the non-reporting of seed batch germination success all validity criteria were considered to be met. The study is considered as valid and acceptable for risk assessment purposes. It should be noted however that the test item is not the representative formulation chosen to support renewal of active substance mecoprop-P. As such the study should be used with care, and endpoints should be expressed in terms of active substance content to aid its use.

The agreed endpoints from the study are:

21-day ER₅₀ = 85.5 mL product/ha, equivalent to 50.97 g mecoprop-P/ha (fresh wt. reduction to oilseed rape).

21-day ER₅₀ = 2189 mL product/ha, equivalent to 1304.9 g mecoprop-P/ha (fresh wt. reduction to pea).

B.9.11.3. Extended laboratory studies on non-target plants

No additional studies submitted for the purpose of renewal

B.9.11.4. Semi-field and field tests on non-target plants

Report:	CP 10.6.4/01
Title:	Oberwalder, C (2002a) BASF 037 32 H: A Toxicity test to determine the effects on

	Vegetative Vigour of Pea (<i>Pisum sativum</i>) under field conditions. BASF Aktiengesellschaft. Report Number: 2002/1004662 (70847-2) Published: No
Guidelines:	OPPTS 850 4300 (Draft), 1996
GLP:	No; GEP: Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I MATERIALS AND METHODS

A. MATERIALS

Test material:	BAS 037 32 H 596.1 g/L Mecoprop-P
Batch:	09-5196
Description:	Liquid, Brown, SL Formulation
Vehicle and/or positive control:	Material was diluted in water prior to spraying.
Test species	
Species:	Pea (<i>Pisum sativum</i>)
Variety:	Miami
Test Site	
Location:	67459 Boehl-Iggelheim; Rheinland Pfalz. GERMANY, 105m above sea level.
Soil:	Sandy Loam (10% clay, 33% loam, 57% sand) pH = 7.1 Soil organic carbon = 1.5%
Slope:	0%

B. STUDY DESIGN AND METHODS

In Life dates:	08-May-2000 to 31-July-2000
Test System	Study design:

Table B.9.11.4-01: Trial replication

No. of trials	1
Treatment per trial	7
Replicates per treatment	4
Trial design	Randomised block design
Plot (replicate) size	9.2m ²

Table B.9.11.4-02: Tested rates of test item

Rate Product [ml/ha]	Rate a.s. [g/ha]	Water Volume [L/ha]	Growth Stage [BBCH]
0	0	0	13-14
47	28.2	250	13-14
94	56.4	250	13-14
188	113	250	13-14
375	225	250	13-14
750	450	250	13-14
1500	900	250	13-14

Application was made using a calibrated plot sprayer with a 30cm height above the target plants. On the day of application the temperature was 27°C, with 8/10 cloud cover and 2 m/s wind speed.

Plants were assessed for symptoms of phytotoxicity at 7, 21 and 42 days after application. Phytotoxicity was assessed as % plant affected compared to the control.

At study termination (84 Days after application) plants were harvested and biomass (as gran dry weight/ha) was determined per plot.

Statistics

From observations mean values and standard deviations were calculated.

The following were also used:

For metric parameters (grain weight) analysis of variance (ANOVA) was done.

Homogeneity of variance tested by the Barlett-test ($\alpha=0.05$).

NOAER determined by Dunnett's test ($\alpha= 0.05$).

ERx was determined by non-linear regression.

II. RESULTS AND DISCUSSION

A. RESULTS

The results for phytotoxicity, shoot weight are shown in Table B.9.11.4-03.

Table B.9.11.4-03: Pea: Effects of application of Mecoprop-P as BAS 037 32 H

Rate (g a.s./ha)	0	28.2	56.4	113	225	450	900
	Mean Phytotoxicity [%]						
Day 7	0	0	0	1	4	6	10
Day 21	0	0	0	0	0	0	10
Day 42	0	0	0	0	0	0	0
	Mean Grain Weight [g/ha]						
Day 84	26.1	23.3	24.0	23.3	21.9	21.3	24.0
	Mean Grain Weight [% relative to control]						
Day 84	100	89	92	89	84	81	92

*significantly different from controls (Dunnett test, $p \leq 0.05$).

III CONCLUSION

Based on the results of this study BAS 037 32 H has no impact on the grain weight of peas grown under field conditions when applied at the maximum rate of 900 g a.s./ha. After 42 days there were also no visual effects on pea plants treated at up to 900 g a.s./ha.

RMS comments:

The study was only sparsely reported, with little detail on the methodology followed for visual phytotoxicity observations, or handling of the harvested grain to determine dry weight for each replicate. Although no numerical environmental data was provided, reported graphical data indicate a high temperature range as expected for a European day-night cycle at the time of year of the study. It is further noted that the study is not GLP-compliant; despite aspects likely to have been laboratory conducted (test solution preparation, dry weight analysis of harvested plants).

As such this study should not be utilised in any quantitative risk assessment and may be relied on for supportive information only.

Report:	CP 10.6.4/02
Title:	Oberwalder, C (2002b) BASF 037 32 H: A Toxicity test to determine the effects on Vegetative Vigour of flax (<i>Linum usitatissimum</i>) under field conditions. BASF Aktiengesellschaft. Number: 2002/1004663 (70847-3) Published: No
Guidelines:	OPPTS 850 4300 (Draft), 1996
GLP:	No; GEP: Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A. MATERIALS

Test material:	BAS 037 32 H 56.1 g/L Mecoprop-P
Batch:	09-5196
Description:	Liquid, Brown, SL Formulation
Vehicle and/or positive control:	Material was diluted in water prior to spraying.
Test species	
Species:	Flax (<i>Linum usitatissimum</i>)
Variety:	Mikael
Test Site	
Location:	67459 Boehl-Iggelheim; Rheinland Pfalz. GERMANY, 104m above sea level
Soil:	Sandy Loam (10% clay, 33% loam, 57% sand) pH = 7.1 Soil organic carbon = 1.5%
Slope:	0%

B. STUDY DESIGN AND METHODS

In Life dates: 15-May-2000 to 29-Jun-2000

Test System: **Table B.9.11.4-04: Study design**

No. of trials	1
Treatment per trial	7
Replicates per treatment	4
Trial design	Randomised block design
Plot size	9.2m ²

Table B.9.11.4-05: Treatment rates

Rate Product [ml/ha]	Rate a.s. [g/ha]	Water Volume [L/ha]	Growth Stage [BBCH]
0	0	-	07-12
47	28.2	250	07-12
94	56.4	250	07-12
188	113	250	07-12
375	225	250	07-12
750	450	250	07-12

1500	900	250	07-12
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Application was made using a calibrated plot sprayer with a 30cm height above the target plants. On the day of application the temperature was 25°C, with 2/10 cloud cover and 2 m/s wind speed. Relative humidity was 70%.

Plants were assessed for symptoms of phytotoxicity at 7, 21 and 42 days after application. Phytotoxicity was assessed as % plant affected compared to the control.

At study termination (45 Days after application) plant biomass was determined per plot. Plants were harvested directly above ground and shoot fresh weight immediately determined.

Statistics:

From observations mean values and standard deviations were calculated.

The following were also used:

For metric parameters (grain weight) analysis of variance (ANOVA) was done.

Homogeneity of variance tested by the Barlett-test ($\alpha=0.05$).

NOAER determined by Dunnett's test ($\alpha=0.05$).

ERx was determined by non-linear regression.

II. RESULTS AND DISCUSSION

A. RESULTS

The results for phytotoxicity, shoot weight are shown in Table CP 10.6.4-3.

Table B.9.11.4-06: Flax: Effects of application of BAS 037 32 H

Rate ml/ha	0	28.2	56.4	113	225	450	900
	Mean Phytotoxicity [%]						
Day 7	0	0	0	1	11	21	31
Day 21	0	0	0	6	24	41	73
Day 42	0	0	0	5	14	33	60
	Mean Grain Weight [g]						
Day 45	121.9	111.4	136.1	129.4	119.4	106.4	94.4
	Mean Grain Weight [% relative to control]						
Day 45	100	91	112	106	98	89	77

*significantly different from controls (Dunnett test, $p \leq 0.05$).

III. CONCLUSION

Based on the results of this study BAS 037 32 H has no impact on the shoot weight of flax grown under field conditions when applied at the maximum rate of 900 g a.s./ha.

RMS comments:

The study was only sparsely reported, with little detail on the methodology followed for visual phytotoxicity observations. Although no numerical environmental data was provided, reported graphical data indicate a high temperature range as expected for a European day-night cycle at the time of year of the study. It is further noted that the study is not GLP-compliant; despite aspects likely to have been laboratory conducted (test solution preparation, fresh weight analysis of harvested plants).

As such this study should not be utilised in any quantitative risk assessment and may be relied on for supportive information only.

Report:	CP 10.6.4/03
Title:	Oberwalder, C (2003) BASF 037 32 H: A Toxicity test to determine the effects on Vegetative Vigour of Poppy (<i>Papaver somniferum</i>) under field conditions. BASF Aktiengesellschaft. Report Number: 2003/1006346 (70847-5) Published: No
Guidelines:	OPPTS 850 4300 (Draft), 1996
GLP:	No; GEP: Yes

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 844/2012
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I. MATERIALS AND METHODS

A. MATERIALS

Test material:	BAS 037 32 H 600 g/L Mecoprop-P
Batch:	09-5196
Description:	Liquid, Brown, SL Formulation
Vehicle and/or positive control:	Material was diluted in water prior to spraying.
Test species	
Species:	Poppy (<i>Papaver somniferum</i>)

Test Site

Location: 67117 Limburgerhof, Rheinland Pfalz. GERMANY

Soil: Loamy sand (7% clay, 12% loam, 81% sand)
pH = 5.8
Soil organic carbon = 1.2%

Slope: 0%

B. STUDY DESIGN AND METHODS

In Life dates: July-2000 to August-2000

Test System:

Table B.9.11.4-07: Study design

No. of trials	1
Treatment per trial	7
Replicates per treatment	4
Trial design	Randomised block design
Plot size	8m ²

Table B.9.11.4-08: Treatment rates

Rate Product [ml/ha]	Rate a.s.[g/ha]	Water Volume [L/ha]	Growth Stage [BBCH]
0	0	0	
47	28.2	400	16-18
94	56.4	400	16-18
188	113	400	16-18
375	225	400	16-18
750	450	400	16-18
1500	900	400	16-18

Application was made using a calibrated plot sprayer with a 30cm height above the target plants. On the day of application the temperature was 27°C, with 75% cloud cover and 1 m/s wind speed. Relative humidity was 70%.

Plants were assessed for symptoms of phytotoxicity at 7, and 28 days after application. Phytotoxicity was assessed as % plant affected compared to the control.

At study termination (29 Days after application) shoot weight was determined per plot. Due to a reported high variability in the crop, only a single replicate per rate was sampled and weighed, and for some treatment groups (56.4 and 450 g a.s./ha) no replicate plots were weighed.

Statistics:

From observations mean values and standard deviations were calculated.

The following were also used:

For metric parameters (grain weight) analysis of variance (ANOVA) was done.

Homogeneity of variance tested by the Barlett-test ($\alpha=0.05$).

NOAER determined by Dunnett's test ($\alpha=0.05$).

ERx was determined by non-linear regression.

II. RESULTS AND DISCUSSION

A. RESULT

The results for phytotoxicity, shoot weight are shown in Table CP 10.6.4-4.

Table B.9.11.4-09: Poppy: Effects of application of BAS 037 32 H

Rate ml/ha	0	28.2	56.4	113	225	450	900
	Mean Phytotoxicity [%]						
Day 7	0	0	0	3	1	14	23
Day 28	0	0	3	6	23	42	83
	Mean Grain Weight [g]						
Day 29	604.3	718.0	-	505.3	359.0	-	28.0
	Mean Grain Weight [% relative to control]						
Day 29	100	119	-	84	59	-	5*

*significantly different from controls (Dunnett test, $\alpha=0.05$).

III. CONCLUSION

Based on the results of this study BAS 037 32 H has no impact on the shoot weight of poppy grown under field conditions if applied at a rate of 56.4 g a.s./ha.

RMS comments:

The study was only sparsely reported, with little detail on the methodology followed for visual phytotoxicity observations. It is further noted that the study is not GLP-compliant, despite aspects likely to have been laboratory conducted (test solution preparation, fresh weight analysis of harvested plants). Only one replicate (of 4 set up in the study) was analysed for plant fresh weight, and some tested rates (56.4 and 450 g a.s./ha) were not analysed at all. This was reported as due to uneven growth of plants, speculated as caused by a form of stem rot. This demonstrates that the test system was not suitable to derive robust conclusions. The statistical power of the study is also questioned, as the control data was such that a 41% inhibitory effect on plant fresh weight (as seen at the tested rate of 225 g a.s./ha) could not be defined as statistically significant.

On the basis of the above deficiencies the RMS concludes that this study is unsuitable for use and should not be relied on.

Reference

Oberwalder C (2001): BAS 037 32 H. A toxicity test to determine the effects on vegetative vigour of oilseed rape (*Brassica napus* L.) under field conditions. BASF Study no 70 847-1. BASF Doc ID 2001/1005989.

Previous evaluation:	Included in Addendum II to DAR (July 2002) for original a.s. approval
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Methods

The toxicity (vegetative vigour) to oilseed rape (*Brassica napus*) under field conditions was studied using BAS 037 32 H containing nominal 600 g/l Mecoprop-P and measured to 596.1 g/l mecoprop-P. The study was performed according to the US-EPA guideline OPPTS 850.4300, 1996. The study was performed in Southwest Germany at Rheinland Pfalz.

The test substance was applied at 6 concentrations in 4 replicates (0, 47, 94, 188, 375, 750, 1500 ml/ha of BAS 037 32 H equivalent to the nominal concentrations 0, 28.2, 56.4, 113, 225, 450, 900 g mecoprop-P/ha) in a randomised block design. Each replicate was a plot of 10 m² size. The seedling rate was 5 kg/ha with a seedling depth of 3 cm. The test substance was applied post-emergence at growth stage 13-14 (BBCH scale) of the test plant. The damage was assessed day 7, 21 and 42 after application. Shoot weight was determined at study termination day 44. The data was analysed with ANOVA followed by Dunnetts test (p=0.05) and non-linear regression analysis.

Table B.9.11.4-10: Characterisation of soil.

Soil type	pH	Sand (>63 µm)	Silt (2-63 µm)	Clay (<2 µm)	Organic Carbon
Sandy loam	7.1	57%	33%	10%	1.5%

The observed symptoms of phytotoxicity were e.g. scorch, stunting and deformations and were rated in % affected plant volume compared to control. The plant biomass (weight) was determined after 44 days.

Results

Damages were observed in the lowest treatment group 7 days after the application but the damages completely disappeared at study termination 42 days after application. Moderate damages were observed in the 56.4 g a.s./ha group but the group was recovered before study termination. Above 56 g a.s./ha severe visible effects were observed in all groups and the damages only recovered slightly or worsened up to study termination. At the two highest application rates the plants were completely destroyed.

In the shoot weight, statistically significant differences (Dunnett's test, $p \leq 0.05$) to control were observed in all application groups except the 28.2 g a.s./ha group.

Table B.9.11.4-11: Summary of results in % of control.

Species	Common name	Effect	BAS 037 32 H (ml/ha)	0	47	94	188	375	750	1500
			Nominal concentration (g a.s./ha)	0	28.2	56.4	113	225	450	900
<i>Brassica napus</i>	Oilseed rape	Damage (%)	Day 7	0	15	44	61	71	79	88
			Day 21	0	5	44	83	89	93	97
			Day 42	0	0	5	65	83	99	100
		Shoot weight	(dt/ha)	752.	604.	556.	290.	80.6	0	0
			Standard deviation, dt/ha	5	0	9	0	30.4	0	0
		Mean weight	(% of control)	87.0	16.1	56.7	71.3			
				100	80	74	39	11	0	0

Table B.9.11.4-12: Effect levels summarised from the results.

Plant damage	NOEC	28.2 g a.s./ha	equivalent to:	47 ml BAS 037 32 H/ha
Shoot weight	EC ₅₀	88.5 g.a.i/ha	equivalent to:	147.5 ml BAS 037 32 H/ha
	EC ₂₅	48.2 g a.s./ha		80.3 ml BAS 037 32 H/ha
	NOEC	28.2 g a.s./ha		47 ml BAS 037 32 H/ha

Comments

The field study on effects to terrestrial plants was performed on a plant which was observed sensitive in the greenhouse experiments. The field results for oilseed rape confirms the greenhouse tests on the same test substance applied post emergence where the plant was exposed at the same growth stage. The study made it possible to derive an EC₅₀ and a NOEC level. The study confirmed that the greenhouse experiments could be used as representative for field study at least for oilseed rape.

RMS comments (renewal):

Study not revisited by RMS at renewal of active substance, noting the above previous conclusion by the original RMS: *“The study confirmed that the greenhouse experiments could be used as representative for field study at least for oilseed rape.”*

B.9.12. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS

A summary of the toxicity data for vegetative vigour and seedling emergence of non-target plants exposed to the representative formulations of mecoprop-P is presented in Table B.9.12-1. As this Assessment Report is concerned with the renewal of active substance mecoprop-P, all representative formulation endpoints provided are expressed in terms of mecoprop-P content for ease of comparison. Only the most sensitive species and measured parameter per study is reported in the below table, and only the endpoint to be utilised in the regulatory risk assessment. Further details of the non-target plant studies including additional species and endpoints are provided in the study summaries under the relevant study summaries in the relevant sections of Volume 3 (CA) and (CP) of the Renewal Assessment Report.

Table B.9.12-01: Summary of the most sensitive species end points from laboratory dose response tests

Test substance	Exposure	Most sensitive species	ER ₅₀ (g a.s./ha)	Study reference
Mecoprop-P (3% aqueous solution)	Pre-emergence	<i>Brassica napus</i> (oilseed rape)	19.2	Eley (2009a)
Mecoprop-P (3% aqueous solution)	Post-emergence	<i>Cucumis stativa</i> (cucumber)	19.9	Eley (2009b)
BAS 037 32 H	Post-emergence	<i>Brassica napus</i> (oilseed rape)	50.97	Siemoneit (2002)
BAS 037 32 H	Pre-emergence	<i>Brassica napus</i> (oilseed rape)	266	Frank (2001)
BAS 037 32 H	Pre-emergence	<i>Papaver somniferum</i> (poppy)	294	Frank (2001)

Bold – Lowest pre- and post-emergence exposure endpoints for use in the deterministic risk assessment

Following the recommendations of the terrestrial guidance document SANCO/10329/2002 rev.2 a tiered approach consisting of 3 steps is recommended for assessing the risk to non-target plants: Tier 1 is an initial decision on the likelihood of terrestrial plant effects. Given mecoprop-P's use as an effective herbicide this initial step is skipped. At tier 2 consideration of ER₅₀ endpoints for pre- and post-emergence effects on terrestrial plant species are compared against predicted off field exposure to the substance in question.

Effects on non-target plants are of concern in the off-field environment, where plants may be exposed to spray drift from pesticide applications. The amount of formulated product reaching off-crop habitats via spray drift is calculated according to SANCO/13029/2002, using the percentile estimates, depending on the number of applications and target crop group, derived by the *BBA (2000)* from the spray-drift predictions of *Ganzelmeier & Rautmann (2000)*. The proposed uses for the representative formulation of mecoprop-P are presented in Table B.9-01 at the start of this Volume 3 (CP) section for ecotoxicology. The predicted off-field exposures arising from the representative uses are calculated in the below table.

Table B.9.12-02: Predicted off-field exposure to non-target terrestrial plants following the representative uses of Mecoprop-P K 600 g/L

Substance	Crop use	Maximum single application rate (g a.s./ha)	Maximum number applications	Drift distance (m)	% Drift	Drift rate (PER _{off-field}) (g a.s./ha)
Mecoprop-P K 600 g/L	Winter and spring cereals BBCH 13-32	1200	1	1	2.77	33.2
				5	0.57	6.84
				10	0.29	3.48

Tier II deterministic approach

Using a deterministic approach firstly, the lowest ER₅₀ is divided by the predicted off-field exposure rate (PER_{off-field}) to calculate a TER. TERs of ≥ 5 demonstrate a low risk to non-target plants. The tier 2 deterministic risk assessments from pre-and post-emergence exposure of non-target terrestrial plants to mecoprop-P are provided below in table B.9.12-3.

Table B.9.12-03: Tier II deterministic risk assessment for terrestrial non-target plants exposed to Mecoprop-P pre- and post-emergence

Substance	Species (most sensitive)	Exposure	ER ₅₀ (g a.s./ha)	Exposure (g a.s./ha)	TER	Trigger
Mecoprop-P K 600 g/L	<i>Brassica napus</i> (oilseed rape)	Pre-emergence	19.2	33.2 (1m)	0.58	5
				6.84 (5m)	2.80	
				3.48 (10m)	5.52	
Mecoprop-P K 600 g/L	<i>Cucumis stativa</i> (cucumber)	Post-emergence	19.9	33.2(1m)	0.60	
				6.84 (5m)	2.91	
				3.48 (10m)	5.72	

As demonstrated in the above tier II deterministic risk assessment for non-target terrestrial plants, the pre-and post-emergence TER values are both above the regulatory trigger of 5, when consideration is given to a 10m spray application distance, or equivalent mitigation.

Tier II Probabilistic approach

In accordance with current EU guidance for terrestrial ecotoxicology (SANCO/10329/2002 rev 2), a *probabilistic* approach is considered suitable if data on 6-10 species is available. This approach utilises a species sensitivity distribution (SSD) to calculate an ER₅₀ for 5% of species (HC₅) which is then compared to the predicted environmental exposure. If exposure is lower than the calculated median HC₅ the risk is considered acceptable.

The totality of the available valid data with mecoprop-P from pre- and post-emergence laboratory studies is summarised in below tables B.9.12-04 and B.9.12-05 for pre- and post-emergence ER₅₀ endpoints, respectively. Discussion and calculation of a HC₅ for each exposure route is presented under each table.

Table B.9.12-04: Summary of all valid species ER₅₀ end points from laboratory pre-emergence tests (for most sensitive parameter – plant weight)

Test substance	Species	ER ₅₀ (g a.s./ha)	Study reference
Mecoprop-P (3% aqueous solution)	<i>L.perenne</i> (ryegrass)	678	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>T.aestivum</i> (wheat)	421	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>Z.mays</i> (maize)	754	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>A.ceph</i> (onion)	40.9	Eley (2009a)
BAS 037 32 H		>900	Frank (2001)
Mecoprop-P (3% aqueous solution)	<i>C.sativa</i> (cucumber)	159	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>R.sativus</i> (radish)	82.7	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>L.sativa</i> (lettuce)	68	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>L.esculentum</i> (tomato)	431	Eley (2009a)
Mecoprop-P (3% aqueous solution)	<i>B.napus</i> (oilseed rape)	19.2	Eley (2009a)
BAS 037 32 H		266	Frank (2001)
BAS 037 32 H	<i>L.usitatissimum</i> (Flax)	>900	Frank (2001)
BAS 037 32 H	<i>P.sativum</i> (Pea)	>900	Frank (2001)
BAS 037 32 H	<i>P. somniferum</i> (Poppy)	278.3	Frank (2001)
BAS 037 32 H	<i>A.sativa</i> (oats)	>900	Frank (2001)

Bold – endpoints excluded from HC₅ calculation. See below discussion

Across the 2 valid seedling emergence studies with representative formulations of mecoprop-P there is data available from a total of 13 distinct terrestrial plant species. In the interests of retaining an accurate and conservative HC₅ value any unbound ‘greater than’ endpoint generated with a tested species will not be included in the HC₅ calculation. It is noted that this would still retain 2 endpoints for the sensitive species *Brassica napus* (oilseed rape). As the difference between the 2 endpoints (both for the parameter plant weight inhibition) is so great (> a factor of 10) it is considered by the RMS to utilize only the lower of the 2 endpoints for the derivation of a pre-emergence HC₅. Therefore a total of 10 distinct species endpoints are used to model a pre-emergence HC₅.

Utilising the publicly available DEFRA ‘Webfram’ software⁷ goodness-of-fit tests (Kolmogorov Smirnov, Camer von Mises, Anderson Darling) on the pre-emergence data set were all accepted at 0.1, 0.05, 0.025 and 0.01 levels. The resultant calculated pre-emergence HC₅ (with 90% confidence intervals to determine the upper and lower limits) is presented below:

Median pre-emergence HC₅ = 19.8 g a.s./ha (4.34 – 46.8)

⁷ Pesticide Risk Assessment Tool - Framework for Addressing Uncertainty and Variability in Pesticide Risk Assessment; www.webfram.com

Table B.9.12-05: Summary of all valid species ER₅₀ end points from laboratory post-emergence tests (for most sensitive parameter – plant weight)

Test substance	Species	ER ₅₀ (g a.s./ha)	Study reference
Mecoprop-P (3% aqueous solution)	<i>L.perenne</i> (ryegrass)	> 800	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>T.aestivum</i> (wheat)	> 800	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>Z.mays</i> (maize)	126	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>A.cepa</i> (onion)	881	Eley (2009b)
BAS 037 32 H		1407	Frank (2001)
Mecoprop-P (3% aqueous solution)	<i>C.sativa</i> (cucumber)	19.9	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>R.sativus</i> (radish)	89.2	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>L.sativa</i> (lettuce)	459	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>L.esculentum</i> (tomato)	89.7	Eley (2009b)
Mecoprop-P (3% aqueous solution)	<i>B.napus</i> (oilseed rape)	129.2	Eley (2009b)
BAS 037 32 H		< 159	Frank (2001)
BAS 037 32 H		85.5	Siemoneit (2002)
BAS 037 32 H	<i>L.usitatissimum</i> (Flax)	601	Frank (2001)
BAS 037 32 H	<i>P.sativum</i> (Pea)	991	Frank (2001)
BAS 037 32 H		2189	Siemoneit (2002)
BAS 037 32 H	<i>P. somniferum</i> (Poppy)	294	Frank (2001)
BAS 037 32 H	<i>A.sativa</i> (oats)	> 1800	Frank (2001)

Bold – endpoints excluded from HC₅ calculation. See below discussion

Across the 3 valid vegetative vigour studies with representative formulations of mecoprop-P there is data available from a total of 13 distinct terrestrial plant species. In the interests of retaining an accurate and conservative HC₅ value any unbound ‘less than’ or ‘greater than’ endpoints generated with a tested species will not be included in the HC₅ calculation. It is noted that this would still retain 2 endpoints for the species *Brassica napus* (oilseed rape), *Pisum sativum* (pea) and *Alium cepa* (onion). Although the unbound ‘less than’ endpoint for oilseed rape is not utilized, the 2 remaining bound endpoint values support the result of < 159 g a.s./ha. With regards to both pea and onion species the 2 available endpoints are not conflicting, differing by no more than a factor of 2.2. This is considered to be within the realms of inter-study variability and so a geometric mean ER₅₀ for each of these species will be utilized for the HC₅ calculation. This gives a geometric mean ER₅₀ for pea of 1473 g a.s./ha, and for onion 1113 g a.s./ha. Likewise a geometric mean of the 2 bound endpoints for oilseed rape can be calculated to be 105.1 g a.s./ha. Overall a total of 10 distinct species are used to model the post-emergence HC₅.

Utilising the publicly available DEFRA ‘Webfram’ software⁸ goodness-of-fit tests (Kolmogorov Smirnov, Camer von Mises, Anderson Darling) on the pre-emergence data set were all accepted at 0.1, 0.05, 0.025 and 0.01 levels The resultant calculated post-emergence HC₅ (with 90% confidence intervals to determine the upper and lower limits) is presented below:

⁸ Pesticide Risk Assessment Tool - Framework for Addressing Uncertainty and Variability in Pesticide Risk Assessment; www.webfram.com

Median post-emergence HC₅ = 22.6 g a.s./ha (4.49 – 56.6)

Following the *probabilistic* approach outlined in EU guidance SANCO/10329/2002, the media HC₅ value is compared directly to the predicted environmental exposure (i.e. a TER of ≥ 1 indicates acceptable risk to non-target plant populations). The probabilistic risk assessments for the representative uses of mecoprop-P are given in below table B.9.12-06.

Table B.9.12-06: Tier II probabilistic risk assessment for terrestrial non-target plants exposed to Mecoprop-P pre- and post-emergence

Substance	Exposure	HC ₅ (g a.s./ha)	Exposure (g a.s./ha)	TER	Trigger
Mecoprop-P	Pre-emergence	19.8	33.2 (1m)	0.60	1
			6.84 (5m)	2.89	
Mecoprop-P	Post-emergence	22.6	33.2 (1m)	0.68	
			6.84 (5m)	3.30	

As demonstrated in the above tier II probabilistic risk assessment for non-target terrestrial plants, the pre- and post-emergence TER values are both above the regulatory trigger of 5, when consideration is given to a 5m spray application distance, or equivalent mitigation.

B.9.13. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

No further studies submitted with the representative product to address this data requirement. Please refer to Point (CA) B.9.8 of the Assessment report for relevant studies with the active substance.

B.9.14. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

Results of a single OECD 209 test (Falk, 2013) indicate that technical mecoprop-P is of low toxicity to aerobic waste water bacteria, having an estimated EC₅₀ value of 319 mg/L. Since the maximum predicted worst case concentration of mecoprop-P in water courses adjacent to where this compound is used is 184.278 µg a.s./L (critical scenario at FOCUS step 3) the risk to sewage treatment plants is considered to be low.

Metabolites


O-cresol is the only major metabolite likely to occur in sediment/water systems. No specific studies have been presented to demonstrate the toxicity of this metabolite to aerobic waste water bacteria. It is possible that the metabolite would have been produced in the test provided, however its presence was not confirmed by analysis and it is unlikely to have reached peak concentrations in such a short time period. There is no evidence to suggest that o-cresol is of any greater toxicity to other forms of wildlife than the parent mecoprop-P. Based on this fact plus the high safety margin for the parent compound, the risk to sewage treatment plants from o-cresol is considered to be low.

B.9.15. REFERENCES RELIED ON

The literature review related to ecotoxicology has been assessed. See the active substance dossier (Volume 3 (AS) section B.9.11.1) for the RMS consideration of the search process.

References relied on, by data requirement according to (EU) 284/2013:

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
IIIA 10.2.1		2014a	Mecoprop-p K 600 (CA3015): Acute toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-Hour Test  GLP Not published	Y	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.2.1	<i>Bias</i>	1988	<i>Determination of the acute toxicity of Duplosan KV (BAS 037 29 H) to the waterflea Daphnia magna. 88/10037 GLP Not published</i>	<i>N</i>	<i>N</i>	<i>N/A</i>	<i>MCPP- P Task Force</i>	<i>In DAR (1998)</i>
IIIA 10.2.1	<i>Memmert, U & Knoch, E</i>	1993b	<i>Acute toxicity of Marks Optica MP n to</i>	<i>N</i>	<i>N</i>	<i>N/A</i>	<i>MCPP- P Task Force</i>	<i>In DAR (1998)</i>

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>Daphnia magna</i> (48-hour immobilization test). RCC Umweltchemie GMBH & Co. RCC 409198 (93/11635) GLP Unpublished					
IIIA 10.2.1	Liedtke, A	2014b	Mecoprop-p K 600 (CA3015): Acute Toxicity to <i>Daphnia magna</i> in a 48-Hour Immobilization Test D76033 Harlan Laboratories Ltd, Switzerland GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.2.1	Liedtke, A	2013a	Mecoprop-p K 600 (CA3015): Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 72-hour algal growth inhibition test D76044 Harlan Laboratories Ltd, Switzerland	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			GLP Not published					
IIIA 10.2.1	Liedtke, A	2013b	Mecoprop-p K 600 (CA3015): Toxicity to the Aquatic Higher Plant <i>Lemna gibba</i> in a 7- day Growth Inhibition Test D76055 Harlan Laboratories Ltd, Switzerland GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.2.1	Gonsoir, G	2015	Mecoprop-p K, 600 g/L: Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sedimen t System S13-04889 Eurofins Agroscience Services GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.2.1	Seeland- Fremer, A & Mosch, W	2015	Toxicity of Mecoprop-p K 600 g/L to the Aquatic Plant <i>Myriophyllum spicatum</i> in a Static Growth Inhibition Test with Prior	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			Rooting Phase 91411215 IBACON GLP Not published					
IIIA 10.3.2.2	Stevens, J	2014b	Mecoprop-p K 600 g/L – A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae) NUF-14-3 Mambo-Tox Ltd, UK GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.3.2.2	Vaughan, R	2015	Mecoprop-p K 600 g/L – An extended laboratory test to evaluate the effects of fresh residues on the green lacewing <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) NUF-14-4 Mambo-Tox Ltd, UK GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA	Ufer, A	1996	Effect of BAS	N	N	N/A	MCPP-	In 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
10.3.2.2			037 29 H on the parasitoid <i>Aphidius rhopalosiphii</i> in an extended laboratory test. BASF study code 33161. Reg. Doc # BASF 96/10592. GLP Not published				P Task Force	Addendum II (July 2002)
IIIA 10.3.2.2	Petto, R	1994	Effects of Optica MPK on <i>Aleochara bilineata</i> Gyll. (Coleoptera, Staphylinidae) in the laboratory. RCC Umweltchemie GmbH & Co. 94/11750 GLP Not published	N	N	N/A	MCCP- P Task Force	In DAR (1998)
IIIA 10.4.2.1	McCormac , A	2015	Mecoprop-p K 600 g/L – A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) NUF-14-6 Mambo-Tox Ltd, UK GLP Not published	N	Y	New data submitted	Nufarm	Submitted for purpose of renewal
IIIA 10.4.2.1	Vinall, S	2015	Mecoprop-p K	N	Y	New data	Nufarm	Submitted for purpose

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
			600 g/L – A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculifer</i> (Acari, Laelapidae) NUF-14-5 Mambo-Tox Ltd, UK GLP Not published			submitted		of renewal
IIIA 10.6.2	Siemonheit , S	2002	Toxicity test to determine the effects of BAS 037 32 H on the vegetative vigour of 2 terrestrial plants 137 392 SLFA, Germany GLP Not published	N	N	N/A	MCPP- P Task Force	Submitted for purpose of renewal