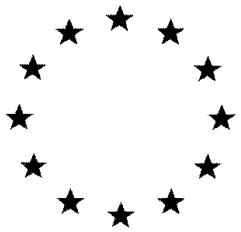
European Commission



VOLUME 3- Annex B (PPP)

- Flutolanil -

B.9 Ecotoxicology data and assessment of risks for non-target species

Rapporteur Member State: The Netherlands

June 2018

Draft Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible approval of flutolanil under Regulation (EC) 1107/2009

Version history page

Date	Version history
June 2018	Initial RAR

TABLE OF CONTENTS – VOLUME 3 B.9

B.9 Ecotoxicology data and assessment of risks for non-target species

Introduction

MONCUT 40 SC is a seed treatment containing 460 g/L flutolanil as the active ingredient. It is used as a fungicide for the control of *Rhizoctonia solani* in potatoes and the flower bulbs of tulips and iris. MONCUT 40 SC is applied once per growing season before sowing. The method of application can vary and it may include indoor application using canopied hydraulic or spinning equipment, on planter treatment on a falling tuber at planting, in planter treatment before catching up by planting chains or a broadcast application using a boom sprayer. This section summarises the ecotoxicological effects of the formulation and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms.

This dossier has been prepared in accordance with guidance document SANCO/10181/2013 – rev 3, dated 12 December 2014 and a full risk assessment is provided which demonstrates that MONCUT 40 SC risks to the environment are acceptable.

This section of the submission provided the EU agreed endpoints or, where relevant, proposals for amended endpoints. Where new guidance documents have been introduced since the first review of flutolanil, an updated evaluation has been included. To adequately assess MONCUT 40 SC according to the new guidance documents, it may have been necessary to provide new data. If so, these are also included.

A set of ecotoxicological studies presented in this dossier has been conducted with a comparable formulation (EXP10066A), containing 460 g/L flutolanil and further information on the detailed composition of the formulation of MONCUT 40 SC can be found in the confidential section of this dossier submission (Document J).

Details of all relevant data from scientific peer reviewed open literature on the active substance, metabolites and breakdown reaction products have been provided in Document M-CA 9; and are discussed in the relevant data point of the associated dossier.

Full details of the proposed use pattern for the EU review of flutolanil are shown in Document D1 of this dossier and are summarised in Table 9-1 below. The critical GAP is application to flower bulbs, however because the indicator species for the application to potato is different to that for flower bulbs a risk assessment for application potato has also been conducted.

Table 9-1 Proposed critical use pattern of MONCUT 40 SC (Flutolanil 460 g/L)

Crop and/or situation	F, G or I	Application				Application rate per treatment			PHI (days)	Remarks:
(a)	(b)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (days)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
Potato Seed tuber treatment	F	On planter treatment on falling tuber at planting	BBCH 00 – 03 (at planting)	1	---	0.46 – 0.613	60 - 80	0.368*	---	0.2L product/t
Tulip, Iris	F	Broadcast application with boom sprayer	BBCH 00 Oct - Dec	1	---	0.69 – 1.84	150 - 400	2.76	---	Incorporation into the soil, 10 – 15 cm

*based on a planting rate of 4 t tubers/ha

Standard exposure scenario

MONCUT 40 SC a suspension-concentrate formulation containing flutolanil as the active ingredient and it is used as seed treatment for potato tubers. As a seed dressing it is applied at a rate of 0.2 L product/tonne tubers (equivalent to 92 g a.s./tonne tubers). MONCUT 40 SC is also used for pre-planting incorporated application for tulips and iris. The surrounding soil is treated by broadcast spray application with boom sprayer and the flower bulbs (iris & tulips) are incorporated into the soil, planting at a depth of 10-15 cm.

Please see Document D1 of this dossier for the supported GAP.

Consideration of metabolites

Flutolanil is not applied directly to plant materials, however, due to its systemic activity, exposure to birds and mammals via plant food items cannot be excluded. Since potato foliage is not palatable to birds and mammals, it was not considered relevant for this scenario. The crop used in the plant metabolism studies which is considered a good surrogate is cabbage, however, in this case the application rate was 8 kg a.s./ha on bare soil. This was taken into account in the exposure to metabolites calculations, in order to reflect the GAP application rate of 2.76 kg a.s./ha.

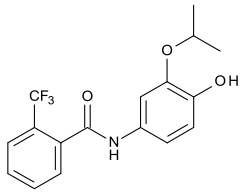
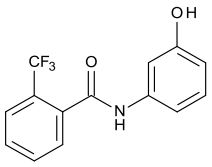
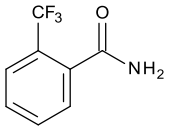
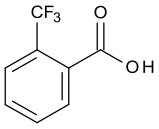
Four degradates of flutolanil were found in the outer leaf of mature cabbage (radiolabel: [Phenyl-U-^{14}C]-Flutolanil):

- M-2 (α,α,α-trifluoro-4'-hydroxy-3'-isopropoxy-o-toluanilide) at 0.16% TRR or 0.131 mg/kg (+ conjugates).
- M-4, (α,α,α-trifluoro-3'-hydroxy-o-toluanilide) at 33.65% TRR or 1.02 mg/kg (+ conjugates).
- M-101 (2-(trifluoromethyl)benzamide) at 1.00% TRR or 0.03 mg/kg.

- M-102 (2-(trifluoromethyl)benzonic acid) at 0.62% TRR or 0.02 mg/kg.

These metabolites are listed in the following table (Table 9.4-2).

Table 9-2 List and molecular structures of metabolites of flutolanil identified in plants

Metabolite Name & Synonyms – Structure	**Chemical name - Relevant compartments**	**Metabolite Name & Synonyms – Structure**	**Chemical name - Relevant compartments**
M-2 HFT  Molecular weight: 339.3 g/mol	α,α,α-trifluoro-4'-hydroxy-3'-isopropoxy-o-toluanilide Found in: Soil (aerobic minor) Rat Crop (potato, cabbage, rice) Livestock (hen, goat)	M-4 DIP  Molecular weight: 281.2 g/mol	α,α,α-trifluoro-3'-hydroxy-o-toluanilide Found in: Soil (aerobic minor) Water sediment systems Crop (rice, potato, peanuts, cabbage) Livestock (hen, goat) Rat
M-101  Molecular weigth: 189.13 g/mol	2-(trifluoromethyl)benzamide Found in: Soil (aerobic minor) Water sediment systems Rat Crop (potato, cabbage, rice) Livestock (hen, goat)	M-102  Molecular weight: 190.12 g/mol	2-(trifluoromethyl)benzonic acid Found in: Soil (aerobic minor) Rat Crop (potato, cabbage, rice) Livestock (hen, goat)

B.9.1 Effects on birds and other terrestrial vertebrates

Table 9.1-1 Summary of toxicity effects on birds and other terrestrial vertebrates

Test species	**Time scale**	**Test material**	**Endpoint [95% CI, lower - upper]**	**Data point Author, year**
Birds				
Bobwhite quail (*Colinus virginianus*)	Acute	Flutolanil Technical	**LD_{50} > 2000 mg a.s./kg bw** NOEL = 2000 mg a.s./kg bw LD_{10} = ND LD_{20} = ND	CA 8.1.1.1-01 [redacted] 1987a
Mallard duck (*Anas platyrhynchos*)	Acute	Flutolanil Technical	LD_{50} > 2000 mg a.s./kg bw NOEL = 2000 mg a.s./kg bw LD_{10} = ND LD_{20} = ND	CA 8.1.1.1-02 [redacted] 1987b
Bobwhite quail (*Colinus virginianus*)	Short-term dietary (5-days)	Flutolanil Technical	LC_{50} > 5243 ppm LD_{50} > 961 mg/kg bw/d	CA 8.1.1.2-01 [redacted] 1987c
Mallard duck (*Anas platyrhynchos*)	Short-term dietary (5-days)	Flutolanil Technical	LC_{50} > 5243 ppm LD_{50} > 1249 mg/kg bw/d	CA 8.1.1.2-02 [redacted] 1987d

Test species	Time scale	Test material	Endpoint [95% CI, lower - upper]	Data point Author, year
Bobwhite quail (*Colinus virginianus*)	Long-term	Flutolanil Technical	**NOEC = 247.8 mg a.s./kg bw/day** EC_{10} * = 525 [ND - 873] mg a.s./kg bw/day EC_{20} = ND EC_{50} = ND	CA 8.1.1.3-01 [redacted] 1993a CA 8.1.1.3-03. [redacted] 2016
Mallard duck (*Anas platyrhynchos*)	Long-term	Flutolanil Technical	NOEC = 267 mg a.s./kg bw/day $NOEC_{ecologically\ relevant}$ = 687 mg a.s./kg bw/day EC_{10} = ND EC_{20} = ND EC_{50} = ND	CA 8.1.1.3-02 [redacted] 1996 CA 8.1.1.3-03. [redacted] 2016
Other terrestrial vertebrates				
Rat	Acute oral	Flutolanil 40SC	LD_{50} > 2000 mg/kg bw	CP 7.1.1/01 [redacted] (2007a)
Rat	Acute oral	Flutolanil Technical	**LD_{50} > 2000 mg/kg bw**	CA 5.2.1-03 [redacted] 2009
Rat	Short term oral 28 days	Flutolanil	NOAEL = 180 mg/kg/day (minor reduction in body weight gain with slight liver weight increase at ≥ 916 mg/kg/day)	CA 5.3.1/01 [redacted] 1977
Rat	Short term oral 90 days	Flutolanil technical	NOAEL = 37 mg/kg/day (increased liver and thyroid/parathyroid weight and increased albumin at ≥ 299 mg/kg/day).	CA 5.3.2/01 [redacted] 1986a
Mouse	Short term oral 90 days	Flutolanil technical	NOAEL = 680 mg/kg/day (reduced weight gain with increased liver weight at 8637 mg/kg/day)	CA 5.3.2/02 [redacted] 1987
Dog	Short term oral 90 days	Flutolanil technical	NOAEL = 80 mg/kg/day (increased liver weight with hepatocyte swelling and pallor at 400 mg/kg/day)	CA 5.3.2/03 [redacted] 1986b
Rat	Reproductive	Flutolanil Technical	**$NOAEL_{parental}$ = 160 mg/kg/d for males, 190 mg/kg/d for females** EC_{10} = ND EC_{20} = ND (increased liver weight) $NOAEL_{pup,\ reproduction}$ = ≥ 1614 mg/kg bw/d	CA 5.6.1-01 [redacted], 1991 CA 8.1.2.2-01 [redacted] 2016

Test species	Time scale	Test material	Endpoint [95% CI, lower - upper]	Data point Author, year
Rat	Developmental 6-15 days gestation	Flutolanil Technical	Maternal: NOAEL ≥ 1000 mg/kg bw/day No LOAEL Embryofetal toxicity: NOAEL ≥ 1000 mg/kg bw/day No LOAEL EC_{10} = ND EC_{20} = ND	CA 5.6.2/01 [redacted], 1987, as amended 1992 CA 8.1.2.2-01 [redacted] 2016
Rabbit	Developmental 6-18 days gestation	Flutolanil Technical	**NOAEL = 40 mg/kg bw/d** (resportions and deaths occurring in 5 different litters (out of 13 litters))	CA 5.6.2/02 [redacted] (1987)
Rabbit	Developmental 6-27 days gestation	Flutolanil	Maternal: NOAEL ≥ 1000 mg/kg bw/day No LOAEL Embryofetal toxicity: NOAEL ≥ 1000 mg/kg bw/day No LOAEL EC_{10} = ND EC_{20} = ND	CA 5.6.2/03 [redacted] 2012
Metabolite M-101				
Rat	Acute oral	2-(trifluoromethyl)-benzamide (M-101)	LD_{50} = > 300 mg metabolite/kg bw and < 2000 mg/kg bw	CA 5.8.1/02 [redacted] (2011)
Rat	Short term oral 28 days	2-(trifluoromethyl)-benzamide (M-101)	NOAEL ♂ = 4.2 mg metabolite/kg bw/d (organ weight changes, clinical chemistry) **NOAEL ecotoxicologically relevant ♂ = 17.6 mg metabolite/kg bw/d** (bodyweight decrease♂)	CA 5.8.1/03 [redacted] (2012)
Metabolite M-102				
Rat	Acute oral	2-(trifluoromethyl)-benzoic acid (M-102)	**LD_{50} > 2000 mg metabolite/kg bw**	CA 5.8.1/07 [redacted] (2016)
Rat	Short term oral 28 days	2-(trifluoromethyl)-benzoic acid (M-102)	**NOAEL ♂ = 252 mg metabolite/kg bw/d**	[redacted] (2010) CA 5.8.1/08

Endpoints in **bold** are the agreed endpoints retained for the risk assessment in line with the EFSA Conclusion (2008, 2013)
ND: could not be determined.
CI: Confidence intervals
* Endpoint not considered reliable

B.9.1.1 Effects on birds

A summary of the avian toxicity endpoints for flutolanil and the formulated product is provided in Table 9.1.1-1 above. The relevant EU endpoints for the effects of flutolanil on birds are also listed in the EFSA (2008) review report (EFSA Journal 2008; 126, 1-63).

Endpoints to be used in the risk assessment

Acute

The acute and short-term oral studies showed no effects at the highest tested dose in all studies. Thus, the endpoint from the acute oral studies **(> 2000 mg/kg bw)** will be used in the risk assessment.

Chronic

As shown in Table 9.1.1-1, above, the lowest ecologically relevant endpoint to be used in the risk assessment is **247.8 mg/kg bw/day**.

B.9.1.2 Effects on terrestrial vertebrates other than birds

A summary of the mammalian toxicity endpoints for flutolanil is provided in the table above. The relevant EU endpoints for the effects of flutolanil on mammals are also listed in the EFSA (2008) review report (EFSA Journal 2008; 126, 1-63). Details and a full description of the toxicity studies used in this risk assessment can be found in Document M-CA 5 of this dossier.

Endpoints to be used in the risk assessment

Acute

Several acute oral studies with the formulation are available. The RMS (toxicology) has requested that the notifier clarify which formulations were tested, as it is not clear from the available test reports. However, both available acute oral tests do not indicate higher toxicity of the formulations, therefore, it is assumed that the risk assessment using the endpoint from the technical active substance covers the potential risk from exposure to the formulation. The endpoint of **> 2000 mg/kg bw** will be used in the risk assessment.

For the metabolites, a toxicity value of 10x lower than that of the parent is used in the risk assessment, except for M-101 and M-102, where toxicity data is available. The toxicity value of M-2 and M-4 will thus be **> 200 mg/kg bw**. For M-101, the acute value is **> 300 mg/kg bw** and for M-102, the acute value is **> 2000 mg/kg bw.**

Chronic

As shown in Table 9.1.1-1, above, there are several long-term endpoints lower than the endpoint from the available 2-generation test, however, most of these are based upon increased organ weights for liver or thyroid. In one developmental toxicity test in rabbit, significant resorptions and fetal deaths were seen in 5 of 13 litters. The RMS (toxicology) has therefore proposed a NOAEL of **40 mg/kg bw/day**. There is a second test in rabbits in which no effects were seen. The RMS (ecotoxicology) will show a risk assessment considering this endpoint, pending a final decision from the toxicology section

on the appropriate developmental endpoint. It should be noted that **based on the currently available data the RMS considers the endpoint of 40 mg/kg bw/day to be the most appropriate endpoint for the wild mammalian risk assessment**.[1]

For the metabolites, a toxicity value of 10x lower than that of the parent is used in the risk assessment, except for M-101 and M-102, where toxicity data is available. The toxicity value(s) of M-2 and M-4 will thus be **> 4 mg/kg bw/d**. For the metabolite M-101, the RMS (toxicology) has set an endpoint based upon effects on organ weight changes at 200ppm, however, the most ecotocologically relevant endpoint would be based on bodyweight changes at 400 ppm, thus the $NOAEL_{ecologically\ relevant}$ would be 200ppm (which the RMS calculates to be **17.6 mg/kg bw/d**, based on a mean bodyweight of 252 g and food intake of 4.43 mg/day). For metabolite M-102, the value of **252 mg/kg bw/d** will be used.

B.9.2 Risk assessment for birds and other terrestrial vertebrates

B.9.2.1.1 Risk from dietary exposure

The following risk assessments have been conducted in line with EFSA's Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438). No short-term risk assessment is required under EFSA (2009) as this is assumed to be covered by the acute and long-term risk assessment and therefore these are conducted in the sections below.

Birds and mammals in the wild may be exposed to flutolanil following broadcast application to the bare soil, by drinking water, secondary poisoning or ingestion of treated potato tubers or contaminated weeds. Both acute and long-term risk assessments have been conducted on the highest application rate, but also using the application rate for potatoes in order to assess the risks to potato-eating birds and mammals. Flutolanil is considered to be a systemic active substance and the exposure of herbivorous and omnivorous species to plants containing residues of flutolanil cannot be excluded. The potential presence of weeds during the pre-emergence application has also been included in the risk assessment, since "pre-emergence" refers to the crop, rather than weeds. Since the "pre-emergence" (bare soil) scenario of EFSA (2009) (EFSA Journal 2009; 7(12):1438) does not include herbivorous or omnivorous species, the RMS uses the early post-emergence scenarios (BBCH 10-19) for herbivorous and omnivorous focal species (with plants in their diets) as a surrogate to cover this potential exposure route in the risk assessment. Therefore, the three scenarios that will be addressed in the risk assessment include the bare soils scenario for potato, the bare soils scenario for bulb flowers and the leafy vegetables scenario, early post-emergence, which henceforth shall be called "presence of weeds".

[1] If the toxicology section should determine that the second developmental toxicity test is more relevant or the first should be excluded for any reason, the endpoint from the 2-generation study could be considered relatively conservative, because the effect seen at the next highest dose was increased liver weight, which is not considered to be ecotoxicologically relevant. However, in the rat 28-day study a NOEAL of 180 mg/kg bw/day was set based on increased liver weight and **slightly decreased bodyweight** at the next highest dose. Thus, in the event that the information from the first developmental toxicity test in rabbits be disregarded by the mammalian toxicology section, the RMS considers the value of **160 mg/kg bw/d** to be appropriate for use in the chronic risk assessment.

Metabolites

In order to assess the risk from metabolites formed in potential food items to birds and mammals, the endpoints derived from the parent were used by applying a safety factor of 10, thus assuming the metabolites are ten times more toxic, unless acceptable specific toxicity data was available.

The exposure to metabolites (on a mass to mass basis) on the food item is used to calculate the concentration of metabolite on the food item:

$EXP_{metabolite}$ = Ftrr x Mole fraction x AR_{EQ}

Ftrr = fraction of metabolite formed (%TRR/100)
Mole fraction = Molecular weight of metabolite / Molecular weight of parent
AR_{EQ} (Equivalent application rate) = Application rate of a.s. (GAP) / Application rate of a.s. (cabbage metabolism study; i.e. 8 kg a.s./ha)

Results of crop residue metabolism studies may be used to determine the fraction of metabolite formed (Ftrr). For metabolites M-2, M-4, M-101, M-102 in cabbage using radiolabelled flutolanil, which is the most relevant crop for the intended use (please refer to MCA6 point CA 6.2.1/04), the Ftrr is reported on a mole % basis and requires conversion to mass %. This is accomplished by multiplying the Ftrr by the mole fraction for the metabolite and this value is used in the risk assessment for the metabolites. The results are shown in the table below.

Table B.9.2.1.1-1 Estimated metabolite exposure levels in bird and mammal food items

	Molecular weight	**Mole fraction**	**%TRR[1]**	**AR_{EQ} (kg a.s./ha)**	**$EXP_{metabolite}$**
Flutolanil	323.3			2.76	
M-2 (+ conjugates)	339.3	1.04949	0.16	0.345	0.000579318
M-4 (+ conjugates)	281.2	0.86978	33.65		0.100998986
M-101	189.1	0.584998	1.00		0.002018245
M-102	190.1	0.588061	0.62		0.001257862

[1] Found in the outer leaf of mature cabbage (radiolabel: [Phenyl-U-^{14}C]-Flutolanil)

The $EXP_{metabolite}$ values are multiplied by the application rate to calculate the hypothetical AR for the various metabolites. Since the metabolites were found at highest levels in cabbage (compared to, for example, peanuts), and since it cannot be accertained whether the metabolites would occur at all on non-plant food items, the RMS considers it worst-case to use these values for all plant and non-plant food items.

B.9.2.1.2 Birds

Screening step

According to the Guidance Document (EFSA, 2009), an 'indicator species' is used in a screening step to eliminate all those substances that clearly pose an acceptable risk to mammals. This 'indicator species' is not a real species but, by virtue of its size and feeding habits, it is considered to have a higher exposure than (i.e. to be protective of) other species that may occur in a particular crop at a particular time.

For application to the crops relevant for this dossier, the small herbivorous mammal and the small granivorous mammal should be considered in the screening step using the relevant shortcut values for acute and long-term risk assessments. The daily dietary dose (DDD) is defined by the food intake rate of the species of concern, its body weight, the concentration of a substance in/on fresh diet and the fraction of diet obtained in the treated area. The above information is combined into a single value for a specific species-crop-combination and termed a 'shortcut value' (SV). The values are presented in the following table (Table 9.2.1.2-1).

Table 9.2.1.2-1 Shortcut values and indicator species

Crop	Crop group for screening step	Indicator Species	Acute assessment		Reproductive assessment	
			SV	MAF_{90}	SV	MAF_m
Potato	Bulbs & onion like crops, cereals fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root & stem vegetables, strawberries, sugar beet and sunflower	Small omnivorous bird	158.8	1	64.8	1
Tulip/Iris	Bare soil	Small granivorous birds	25.3	1	11.4	1
	Bulbs & onion like crops, cereals fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root & stem vegetables, strawberries, sugar beet and sunflower	Small omnivorous bird	158.8	1	64.8	1

SV: Shortcut value MAF: multiple application factor
Note: SV values defined in EFSA 2009 Guidance document for birds and mammals

Acute

In the screening risk assessment, generic focal species are selected relevant to the proposed crops and growth stages. The acute screening step daily dietary doses (DDDs) and associated toxicity exposure ratios (TERs) are presented in Table 9.2.1.2-1 below.

Table 9.2.1.2-2 Avian screening acute assessment for the proposed uses of MONCUT 40 SC

Crop	Indicator Species	Toxicity (mg/kg bw)	Appl. rate (kg/ha)	SV	MAF_{90}	DDD	TER_A	Annex VI trigger
Flutolanil								
Potatoes	Small omnivorous bird	2000	0.368	158.8	1.0	58.4	34.2	10

Bare soil	Small granivorous bird		2.76	25.3		69.8	28.6	
Presence of weeds	Small omnivorous bird			158.8		438.3	**4.56**	
Metabolite M-2								
Bare soil	Small granivorous bird	200	0.0016	25.3	1.0	0.04	4944.05	10
Presence of weeds	Small omnivorous bird			158.8		0.25	787.69	
Metabolite M-4								
Bare soil	Small granivorous bird	200	0.279	25.3	1.0	7.05	28.36	10
Presence of weeds	Small omnivorous bird			158.8		44.27	**4.52**	
Metabolite M-101								
Bare soil	Small granivorous bird	200	0.0056	25.3	1.0	0.14	1419.14	10
Presence of weeds	Small omnivorous bird			158.8		0.88	226.10	
Metabolite M-102								
Bare soil	Small granivorous bird	200	0.0035	25.3	1.0	0.09	2277.02	10
Presence of weeds	Small omnivorous bird			158.8		0.55	362.78	

MAF: multiple application factor TER: Toxicity Exposure Ratio DDD: daily dietary dose
SV: Shortcut value
Note: calculations conducted using unrounded values TER values in **bold** are lower than the trigger value of 10

The screening assessment for the acute risks to birds from exposure to MONCUT 40 SC after use according to the recommended GAP demonstrate that the risks are acceptable, with the exception of the small omnivorous bird exposed to the scenario of the presence of weeds during the pre-emergence application in flower bulbs. The TER_A value was calculated to be less than the Annex VI trigger of 10, indicating a potential acute risk to birds from the exposure of MONCUT 40 SC. In this occasion, a first tier assessment was required.

Chronic

Table 9.2.1.2-3 Avian screening long-term assessment for the proposed uses of MONCUT 40SC

Crop	Indicator Species	Toxicity (mg/kg bw)	Appl. rate (kg/ha)	SV	MAF_m*f_{TWA}	DDD	TER_{LT}	Annex VI trigger
Flutolanil								
Potatoes	Small omnivorous bird	247.8	0.368	64.8	0.53	12.7	19.6	5
Bare soil	Small granivorous bird		2.76	11.4		16.8	14.9	
Presence of weeds	Small omnivorous bird			64.8		94.79	**2.61**	
Metabolite M-2								
Bare soil	Small granivorous bird	24.78	0.0016	11.4	0.53	0.010	2563.0	5
Presence of weeds	Small omnivorous bird			64.8		0.055	451.0	
Metabolite M-4								
Bare soil	Small granivorous bird	24.78	0.279	11.4	0.53	1.69	14.7	5
Presence of weeds	Small omnivorous bird			64.8		9.58	**2.59**	
Metabolite M-101								
Bare soil	Small granivorous bird	24.78	0.0056	11.4	0.53	0.034	732.4	5
Leafy veg.	Small omnivorous bird			64.8		0.192	128.8	
Metabolite M-102								
Bare soil	Small granivorous bird	24.78	0.0035	11.4	0.53	0.021	1171.8	5
Presence of weeds	Small omnivorous bird			64.8		0.120	206.1	

MAF: multiple application factor DDD: daily dietary dose TER: Toxicity Exposure Ratio
SV: Shortcut value
Note: calculations conducted using unrounded values TER values in **bold** are lower than the trigger value of 5

The screening assessment for the long-term risks to birds from exposure to MONCUT 40 SC after use according to the recommended GAP demonstrate that the risks are acceptable, with the exception of the small omnivorous bird exposed to the scenario of the presence of weeds during the pre-emergence application in flower bulbs. The TER_{LT} value was calculated to be less than the Annex VI trigger of 5, indicating a potential chronic risk to birds from the exposure of MONCUT 40 SC. On this occasion, a first-tier assessment was required and presented below.

Tier 1 Risk assessment

Acute

Table 9.2.1.2-4 Avian first tier acute assessment for the proposed uses of MONCUT 40 SC in flower bulbs – presence of weeds scenario

Crop stage	Indicator spp.	Shortcut value	MAF	TWA	Endpoint (mg/kg bw)	DDD (mg/kg bw)	TER
Application rate: 2.76 kg a.s./ha (single, pre-emergence application to flower bulbs)							
leaf development BBCH 10-19	Medium herbivorous/ granivorous bird "pigeon"	55.5	1.0	1.0	2000	153.18	13.06
BBCH 10 - 19	Small insectivorous bird “wagtail”	26.8				73.97	27.04
Metabolite M-4: Application rate: 0.279 kg a.s./ha							
leaf development BBCH 10-19	Medium herbivorous/ granivorous bird "pigeon"	55.5	1.0	1.0	200	15.47	12.93
BBCH 10 - 19	Small insectivorous bird “wagtail”	26.8				7.47	26.77

MAF: multiple application factor TWA: time weighted average factor
DDD: daily dietary dose n.a.: not applicable
Note: calculations conducted using unrounded values; TER values in **bold** are lower than the trigger value of 10

As shown in the Table above, the acute risk to birds from weeds emerging in the treated fields of pre-emergence flower bulbs and potatoes from the proposed use of MONOCUT 40 SC is acceptable. It is noted that the scenario presented above is a surrogate to cover the fact that there is no herbivorous or insectivorous bird present in the bare soils scenario of EFSA (2009). Therefore, the exposure levels calculated may be overly conservative and the focal species may not be entirely appropriate. Nonetheless, since wagtail and pidgeon are both regularly found in field crops, the RMS considers this the most appropriate manner in which to address this potential route of exposure.

Chronic

Table 9.2.1.2-5 Avian first tier long term assessment for the proposed uses of MONCUT 40 SC in flower bulbs – presence of weeds scenario

Crop stage	Indicator spp.	Shortcut value	MAF	TWA	Endpoint (mg/kg bw)	DDD (mg/kg bw)	TER
Application rate: 2.76 kg a.s./ha (single, pre-emergence application to flower bulbs)							
leaf development BBCH 10-19	Medium herbivorous/ granivorous bird "pigeon"	26.7	1.0	0.53	247.8	39.06	7.46
BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3				16.53	15.0
Metabolite M-4: Application rate: 0.279 kg a.s./ha							
leaf development BBCH 10-19	Medium herbivorous/ granivorous bird "pigeon"	22.7	1.0	0.53	24.78	3.94	7.38
BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3				1.67	14.8

MAF: multiple application factor TWA: time weighted average factor
DDD: daily dietary dose n.a.: not applicable
Note: calculations conducted using unrounded values; TER values in **bold** are lower than the trigger value of 5

As shown in the Table above, the chronic risk to birds from weeds emerging in the treated fields of pre-emergence flower bulbs and potatoes from the proposed use of MONOCUT 40 SC is acceptable. It is noted that the scenario presented above is a surrogate to cover the fact that there is no herbivorous or insectivorous bird present in the bare soils scenario of EFSA (2009). Therefore, the exposure levels calculated may be overly conservative and the focal species may not be entirely appropriate. Nonetheless, since wagtail and pigeon are both regularly found in field crops, the RMS considers this the most appropriate manner in which to address this potential route of exposure.

Risk assessment for potato eating birds

Direct exposure of birds to MONCUT 40 SC is unlikely from potato treatment, since the product is sprayed in store treatment or on planter treatment on falling tubers at planting, then which are immediately covered with soil. However, in general, birds may be exposed to residues of flutolanil by the consumption of these treated potato tubers. It is therefore noted that the presented nominal application rate values may be conservative, as some decline of the content on the surface of the potato tubers is expected during application.

The likelihood of exposure is relatively minimal, because treated potatoes are planted into the soil and most will remain buried, only a few, if any, are expected to be on the soil surface and readily available for birds. In addition, potato tubers are not generally an essential part of the food of birds.

The following risk assessment for the effects on birds is conducted in line with the EFSA's Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438). However, according to EFSA (2009), the relevant indicator species for application in seeds are granivorous birds and the standard scenarios do not include treated tubers. Therefore, the existing scenarios were modified to address the risk to potato eating birds more appropriately.

In this risk assessment, the value for FIR/bw (Food Intake Rate/body weight) is not taken from the table in the Appendix A of EFSA (2009), since the FIR/bw of granivorous birds is different when compared to a FIR/bw of a potato eating bird.

In the EFSA (2008) review report on flutolanil it was pointed out that: "*EFSA recommended that the scenario for granivorous birds and mammals should be revised to take into account 'potato eating' birds and mammals. For birds the Common Crane (Grus grus) was selected as relevant focal species to represent potatoes-eating birds.*"

It is therefore considered that the Common Crane (*Grus grus*) is an appropriate indicator species for potato-eating birds. The following risk assessment is based on a comparison of toxicity endpoints and estimated theoretical exposure (ETE) scenarios of wild birds to the active substance.

Calculation of Estimated Theoretical Exposure (ETE)

The Estimated Theoretical Exposure (ETE) can be derived using the following equation, according to EFSA (2009):

The estimated daily exposure, i.e. the uptake of a compound via a single food item, is given by the following equation (Appendix G, EFSA 2009):

$$\mathrm{ETE} = \left(\frac{\mathrm{FIR}}{\mathrm{bw}}\right) \times \mathrm{C} \times \mathrm{PT}$$

Where:

FIR = Food intake rate (g fresh weight/d)

C = Concentration of active substance in fresh diet (mg/kg)

PT = Fraction of diet obtained in treated fields (between 0 and 1)

bw = Body weight (g)

PT is initially assumed to be 1 in a worst case scenario.

Puerta *et al*. (1990)1F[2] reported the mean body mass of 16 adult Common Cranes to be 5500 g ± 129 g. In the present calculation the lower, more conservative value of 5371 g is used. In the final addendum to the DAR (January, 2008) for flutolanil there was a calculation of the food intake rate

[2] Puerta, M.L., Alonso, J.C., Huecas, V., Alonso, J.A., Abelenda, M., Munoz-Pulido, R. (1990): Haematology and blood chemistry of wintering common cranes. The Condor, 92:210-214

(FIR) of the common crane based on Alonso & Alonso (1993)2F[3] that reported the time cranes spent feeding and the net food intake rate, as at that time the EFSA (2009) guidance document (EFSA Journal 2009; 7(12):1438) was not published. Using the data for the time cranes spent feeding in spring (400 min/day) and the mean net intake rate (0.95 g/min) it is possible to estimate the daily dietary intake of cranes:

FIR = 400 min/day x 0.95 g/min = 380 g /day

The corresponding FIR / bw ratio is 380 g / 5371 g = 0.071

However, in this risk assessment the FIR/bw calculation is estimated using values found in EFSA (2009) (Appendix L) for assimilation efficiency in birds of the order *Gruiformes*. These values are 45% for fruits, 59% for herbage and 69% for artificial food type. Thus, an assimilation efficiency of 45% was used. The mean energy content of potatoes is 15.5938 kJ/dry weight and the moisture content of potatoes is 79.34% 3F[4]. This produces a more conservative estimation of FIR/bw compared to the one used in the final addendum to the DAR (January, 2008) with the calculated FIR/bw value being 0.277 (see Table 9.2.1.2-4 below). As a worst-case approach it is assumed that the birds feed exclusively on treated potato tubers (PD = 1).

Table 9.2.1.2-6 Calculation of FIR/bw of potato eating birds

Food type	Energy (KJ/g dry mass)	% moisture	PD	Assimilation efficiency	$FE_{total, fresh}$	DEE	FIR	FIR/bw
Body weight (bw) = 5371 g								
Daily energy expenditure (DEE): logDEE = loga + b x logbw								
Potatoes	15.5938	79.34	1	0.45	1.4497	2160	1489.7	0.277

loga = 0.839 and b = 0.669 (Appendix G in EFSA (2009)) values for non-passerines
$FE_{total, fresh}$ = Energy x (1-(moisture/100)) x Assimilation efficiency
FIR = DEE/$FE_{total, fresh}$ = Daily energy expenditure of the indicator species (kJ/d)/Food energy (kJ/dry g)
FIR/bw = Food intake rate/body weight

The level of flutolanil in the diet will be assumed to be equal to the application rate, i.e. 92.4 mg/kg tuber, though this is likely conservative, as mentioned above. This assumes a 100% adhesion to seed and an even distribution on the seed tubers. It is also assumed that birds will satisfy their entire food demand in the treated area (PT = 1). The ETE and TER values are shown in Table 9.2.1.2-5.

Table 9.2.1.2-7 Exposure estimate of MONCUT 40 SC and acute TER_A values for birds for an application in seed potatoes

Active substance	Relevant potato-eating species	Concentration on potato	PT	FIR/bw	ETE	LD_{50}	TER_A	Trigger value

[3] Alonso, J.A & Alonso, J.C. (1993): Age related difference in time budgets and parental care in wintering common cranes. The Auk, 110, 1: 78-88.

[4] USDA National Nutrient Database for standard Reference Release 27: Basic Report 11352, Potatoes, flesh and skin, raw (http://ndb.nal.usda.gov/ndb/?format=&count=&max=25&sort=&fg=&man=&lfacet=&qlookup=potatoes&offset=75)

Flutolanil	Common crane	92.4	1	0.277	25.59	> 2000	> 78.14	10

ETE = Estimated Theoretical Exposure (mg/kg bw/day) TER = Toxicity Exposure Ratio
PT= Fraction of diet obtained in treated fields
FIR/bw = Food intake rate/body weight

Table 9.2.1.2-8 Exposure estimate of MONCUT 40 SC and chronic TER_L values for birds for an application in seed potatoes

Active substance	Relevant potato-eating species	Concentration on potato	PT	FIR/bw	ETE	NOEL	TER_L	Trigger value
Flutolanil	Common crane	92.4	1	0.277	25.59	247.8	9.7	5

ETE = Estimated Theoretical Exposure (mg/kg bw/day) TER = Toxicity Exposure Ratio
PT= Fraction of diet obtained in treated fields
FIR/bw = Food intake rate/body weight

It is therefore demonstrated that all TER values are found to be above the trigger values of 10 and 5, the risks to birds from exposure to flutolanil from the proposed use of MONCUT 40 SC on potato tubers are considered acceptable.

B.9.2.1.3 Mammals

The following risk assessment for the effects of flutolanil on mammals, is conducted in line with EFSA's Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438).

Mammals in the wild may be exposed to flutolanil following broadcast application on the bare soil, by drinking water, secondary poisoning or ingestion of treated potato tubers or contaminated weeds. Both acute and long-term risk assessments have been conducted on the highest application rate, but also using the potato application rate in order to assess the risk to potato-eating mammals. Flutolanil is considered to be a systemic active substance and the exposure of herbivorous and omnivorous species to plants containing residues of flutolanil cannot be excluded. The potential presence of weeds during the pre-emergence application has also been included in the risk assessment, since "pre-emergence" refers to the crop, rather than weeds. Since the "pre-emergence" (bare soil) scenario of EFSA (2009) (EFSA Journal 2009; 7(12):1438) does not include herbivorous or omnivorous species, the RMS uses the early post-emergence scenarios (BBCH 10-19) for herbivorous and omnivorous focal species (with plants in their diets) as a surrogate to cover this potential exposure route in the risk assessment. Therefore, the three scenarios that will be addressed in the risk assessment include the bare soils scenario for potato, the bare soils scenario for bulb flowers and the leafy vegetables scenario, early post-emergence, which henceforth shall be called the "presence of weeds" scenario.

Screening step

According to the Guidance Document (EFSA, 2009), an 'indicator species' is used in a screening step to eliminate all those substances that clearly pose an acceptable risk to mammals. This 'indicator species' is not a real species but, by virtue of its size and feeding habits, it is considered to have a higher exposure than (i.e. to be protective of) other species that may occur in a particular crop.

For application to the crops relevant for this dossier, the small herbivorous mammal and the small granivorous mammal should be considered in the screening step using the relevant shortcut values for acute and long-term risk assessments. The daily dietary dose (DDD) is defined by the food intake rate of the species of concern, its body weight, the concentration of a substance in/on fresh diet and the fraction of diet obtained in the treated area. The above information is combined into a single value for a specific species-crop-combination and termed a 'shortcut value' (SV). The values are presented in the following table (Table 9.2-1).

Table 9.2.1.3-1 Shortcut values and indicator species

Crop	Crop group for screening step	Indicator Species	Acute assessment		Reproductive assessment	
			SV	MAF_{90}	SV	MAF_m
Potatoes	Bulbs & onion like crops, cereals fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root & stem vegetables, strawberries, sugar beet and sunflower	Small herbivorous mammal	118.4	1	48.3	1
Tulip/Iris	Bare soil	Small granivorous mammal	14.4	1	6.6	1
	Bulbs & onion like crops, cereals fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root & stem vegetables, strawberries, sugar beet and sunflower	Small herbivorous mammal	136.4	1	72.3	1

Acute

Table 9.2.1.3-2 Acute screening assessment based on the exposure of mammals to MONCUT 40 SC

Crop	Indicator Species	Toxicity (mg/kg bw)	Appl. rate (kg/ha)	SV	MAF_{90}	DDD	TER_A	Annex VI trigger
Flutolanil								
Potatoes	Small herbivorous mammal	2000	0.368	118.4	1.0	43.6	45.9	10

Crop	Indicator Species	Toxicity (mg/kg bw)	Appl. rate (kg/ha)	SV	MAF_{90}	DDD	TER_A	Annex VI trigger
Bare soil	Small granivorous mammal		2.76	14.4		39.7	50.3	
Presence of weeds	Small herbivorous mammal			136.4		376.5	**5.31**	
Metabolite M-2								
Bare soil	Small granivorous mammal	200	0.0016	14.4	1.0	0.02	8686.43	10
Presence of weeds	Small herbivorous mammal			136.4		0.22	917.04	
Metabolite M-4								
Bare soil	Small granivorous mammal	200	0.279	14.4	1.0	4.01	49.82	10
Presence of weeds	Small herbivorous mammal			136.4		38.02	**5.26**	
Metabolite M-101								
Bare soil	Small granivorous mammal	300	0.0056	14.4	1.0	0.08064	3720.3	10
Presence of weeds	Small herbivorous mammal			136.4		0.76384	392.8	
Metabolite M-102								
Bare soil	Small granivorous mammal	2000	0.0035	14.4	1.0	0.0504	39682.5	10
Presence of weeds	Small herbivorous mammal			136.4		0.4774	4189.4	

MAF: multiple application factor DDD: daily dietary dose TER: Toxicity Exposure Ratio
SV: Shortcut value Note: calculations conducted using unrounded values

The screening assessment for the acute risks to mammals from exposure to MONCUT 40 SC after use according to the recommended GAP demonstrate that the risks are acceptable, with the exception of the small herbivorous mammal exposed to the scenario of the presence of weeds during the pre-emergence application for the flower bulbs. The TER_A value was calculated to be less than the Annex VI trigger of 10, indicating a potential acute risk to birds from the exposure of MONCUT 40 SC. In this occasion, a first tier assessment was required.

Chronic

Table 9.2.1.3-3 Long-term screening assessment based on the exposure of mammals to MONCUT 40 SC

Crop	Indicator Species	Toxicity (mg/kg bw)	Appl. rate (kg/ha)	SV	MAF_m	DDD	TER_{LT}	Annex VI trigger
Flutolanil								
Potatoes	Small herbivorous mammal	40	0.368	48.3	1.0	9.420432	**4.25**	5
Bare soil	Small granivorous mammal		2.76	6.6		9.65448	**4.14**	
Presence of weeds	Small herbivorous mammal			72.3		105.7604	**0.38**	
Metabolite M-2								
Bare soil	Small granivorous mammal	4	0.0016	6.6	1.0	0.012211	327.6	5
Presence of weeds	Small herbivorous mammal			72.3		0.06131	65.2	
Metabolite M-4								
Bare soil	Small granivorous mammal	4	0.279	6.6	1.0	2.129328	1.88	5
Presence of weeds	Small herbivorous mammal			72.3		10.691	**0.37**	

MAF: multiple application factor DDD: daily dietary dose TER: Toxicity Exposure Ratio
SV: Shortcut value
Note: calculations conducted using unrounded values TER values in **bold** are lower than the trigger value of 5

The screening assessment for the long-term risks to mammals from exposure to MONCUT 40 SC after use according to the recommended GAP does not demonstrate that the risks are acceptable. A Tier 1 assessment is therefore required for all uses.

Tier 1 Risk assessment

Acute

Table 9.2.1.3-4 Mammal first tier acute assessment for the proposed uses of MONCUT 40 SC in flower bulbs – presence of weeds scenario

Crop stage	Indicator spp.	Shortcut value	MAF	TWA	Endpoint (mg/kg bw)	DDD (mg/kg bw)	TER
Application rate: 2.76 kg a.s./ha (single, pre-emergence application to flower bulbs)							
All season	Large herbivorous mammal “lagomorph”	35.1	1.0	1.0	2000	96.9	20.6
BBCH 10-49	Small omnivorous mammal “mouse”	17.2				47.5	41.6

Metabolite M-4: Application rate: 0.279 kg a.s./ha							
All season	Large herbivorous mammal “lagomorph”	35.1	1.0	1.0	200	9.79	20.4
BBCH 10-49	Small omnivorous mammal “mouse”	17.2				4.79	42

MAF: multiple application factor TWA: time weighted average factor
DDD: daily dietary dose n.a.: not applicable
Note: calculations conducted using unrounded values; TER values in **bold** are lower than the trigger value of 10

For the early post-emergence stages of leafy vegetables growth and relevant focal species the calculated acute TER values indicate that the acute risk is acceptable.

Chronic

Table 9.2.1.3-5 Mammal first tier long-term assessment for the proposed uses of MONCUT 40 SC in flower bulbs – presence of weeds scenario

Crop stage	Indicator spp.	Shortcut value	MAF	TWA	Endpoint (mg/kg bw)	DDD (mg/kg bw)	TER
Application rate: 2.76 kg a.s./ha (single, pre-emergence application to flower bulbs)							
All season	Large herbivorous mammal “lagomorph”	14.3	1.0	0.53	40	20.92	**1.9**
BBCH 10-49	Small omnivorous mammal “mouse”	7.8				11.41	**3.5**
Metabolite M-4: Application rate: 0.279 kg a.s./ha							
All season	Large herbivorous mammal “lagomorph”	14.3	1.0	0.53	4	2.11	**1.9**
BBCH 10-49	Small omnivorous mammal “mouse”	7.8				1.15	**3.5**

MAF: multiple application factor TWA: time weighted average factor
DDD: daily dietary dose n.a.: not applicable
Note: calculations conducted using unrounded values; TER values in **bold** are lower than the trigger value of 5

As shown in the table above, a refined risk assessment is required to address the potential for exposure due to weeds in the treated field, both from the parent, flutolanil and the metabolite M-4.

Table 9.2.1.3-6 Mammal first tier long-term assessment for the proposed uses of MONCUT 40 SC in bare soils, potatoes and flower bulbs

Crop stage	Indicator spp.	Shortcut value	MAF	TWA	Endpoint (mg/kg bw)	DDD (mg/kg bw)	TER
Flower bulbs - application rate: 2.76 kg a.s./ha (single, pre-emergence application to flower bulbs)							
BBCH <10	Small omnivorous mammal “mouse”	14.3	1.0	0.53	40	20.9	**1.9**
Potatoes - application rate: 0.368 kg a.s./ha (single, pre-emergence application)							
BBCH <10	Small omnivorous mammal “mouse”	14.3	1.0	0.53	40	2.79	14.3

As shown in the Tables above, only the use in potato is acceptable. For the use in flower bulbs, further refinement is required. It might be considered that the exposure via weeds scenario used by the RMS

is quite conservative, as it is unlikely that sufficient weeds will be present to satisfy a PD or PT of 1, however, regardless of this, a risk remains for the small omnivorous mammal “mouse” in the flower bulbs “bare soil” scenario. A refinement is required for the proposed use in flower bulbs.

Risk assessment for potato eating mammals

Direct exposure of mammals to MONCUT 40 SC is unlikely from the potato treatment, since the product is sprayed in store treatment or on planter treatment on falling tuber at planting, which is then immediately covered with soil. However, in general, mammals may be exposed to residues of flutolanil by the consumption of these treated seed potato tubers. It is noted that the presented nominal application rate values are conservative estimates for residues on potatoes, as some decline of the content on the surface of the potato tubers is expected during application.

The likelihood of exposure is also relatively minimal because treated potatoes are planted into the soil and most will remain buried. Only a few, if any, are expected to be on the soil surface readily available for mammals, though mammals are known to dig for food which is in the top layer of soil. In addition, potato tubers are not usually an essential part of the diet of mammals. Thus, the exposure of mammal populations *per se* is relatively limited.

The following risk assessment for effects on mammals is conducted in line with EFSA’s Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438). However, the standard scenarios defined by EFSA (2009) do not include treated tubers. Therefore, the existing scenarios were modified to address the risk to potato eating mammals more appropriately.

In the EFSA (2008) review report on flutolanil it was pointed out that: “*EFSA recommended that the scenario for granivorous birds and mammals should be revised to take into account ‘potato eating’ birds and mammals. Badger (Meles meles) was used as relevant focal species to represent potatoes-eating mammals.*”

It is therefore assumed that the Badger (*Meles meles*) is an appropriate indicator species for potato eating mammals.

The following risk assessment is based on a comparison of toxicity endpoints and estimated theoretical exposure (ETE) scenarios of wild mammals to the active substance.

Calculation of Estimated Theoretical Exposure (ETE)

The Estimated Theoretical Exposure (ETE) can be derived using the following equation, according to the EFSA (2009):

The estimated daily exposure, i.e. the uptake of a compound via a single food item, is given by the following equation (Appendix G, EFSA 2009):

$$\mathrm{ETE} = \left(\frac{\mathrm{FIR}}{\mathrm{bw}}\right) \times \mathrm{C} \times \mathrm{PT}$$

With

FIR = Food Intake rate (g fresh weight/d)

C = Concentration of active substance in fresh diet (mg/kg)

PT = Fraction of time spent foraging in treated fields (between 0 and 1)

bw = Body weight (g)

PT is initially assumed to be 1 in a worst case scenario.

Calculation of Toxicity Exposure Ratio (TER)

The assessment of the risks to mammals is performed for both acute and long-term exposures using endpoints derived from acute and reproduction studies with mammals.

The calculation of acute and long-term toxicity exposure ratios (TER) is defined as follows:

Acute risk assessment: $$TER_A = \frac{LD_{50}}{DDD}$$

Reproductive risk assessment: $$TER_{LT} = \frac{NOAEL}{DDD}$$

Acute

According to the final addendum to the DAR (January, 2008) for flutolanil, in order to calculate the FIR/bw values for the Badger, data from the open literature were taken to estimate conservative values for the dietary intake rates as at that point the EFSA (2009) guidance document was not available. In addition, a fraction of 55% of animal and 45% vegetable diet was assumed.

The corresponding FIR / bw ratio was calculated to be 0.266 and was then used in the risk assessment.

However, in the current risk assessment, the FIR/bw calculation is conducted based on worst-case assumptions such as:

- the Badger will feed exclusively on treated potato tubers (PD = 1)

The body weight value used for the Badger (10850 g) is in line with the value used in the final addendum to the DAR (January, 2008) for flutolanil (from Crocker et al. (2002)5F5). An assimilation efficiency of 0.74 is used, as was used the final addendum to the DAR (January, 2008) for vegetable material (from Crocker *et al*. (2002)) and is also the value of fruit for mammals (EFSA, 2009 in Appendix G).

For the current calculation, the following values are used, which are found in the open literature: mean energy content of potatoes 15.5938 kJ/dry weight and moisture content of 79.34% 6F[6]. The calculated FIR/bw value is 0.189 (see **Table 9.2.1.3-** below).

[5] Crocker, D., Hart, A., Gurney, J. and McCoy, C. (2002) Project PN0908: methods for estimating daily food intake of wild birds and mammals. Final report. Central Science Laboratory, York.

[6] USDA National Nutrient Database for standard Reference Release 27: Basic Report 11352, Potatoes, flesh and skin, raw

Table 9.2.1.3-7 Calculation of FIR/bw of potato eating mammals

Food type	Energy (kJ/g dry mass)	% moisture	PD	Assimilation efficiency	$FE_{total, fresh}$	DEE	FIR	FIR/bw
Body weight (bw) = 10850 g								
Daily energy expenditure (DEE): logDEE = loga + b x logbw								
Potatoes	15.5938	79.34	1	0.74	2.45	5004	2046	0.189

loga = 0.814 and b = 0.715 (Appendix G in EFSA (2009)) values for mammals

$FE_{total, fresh}$ = Energy x (1-(moisture/100)) x Assimilation efficiency

FIR = DEE/$FE_{total, fresh}$ = Daily energy expenditure of the indicator species (kJ/d)/Food energy (kJ/dry g)

FIR/bw = Food intake rate/body weight

As a conservative approach, the level of flutolanil in the diet will be equal to the application rate, i.e. 92.4 mg/kg tuber. This assumes a 100% adhesion to seed and an even distribution on the seed tubers. It was also assumed that mammals satisfy their entire food demand in the treated area (PT = 1). The ETE and TER values are shown in Table 9.2.1.3-9.

Table 9.2.1.3-8 Exposure estimate of MONCUT 40 SC and acute TER_A values for mammals for an application in seed potatoes

Active substance	Relevant potato-eating species	Concentration on potato	PT	FIR/bw	ETE	LD_{50} (mg/kg bw/d)	TER_A	Trigger value
Flutolanil	Badger	92.4	1	0.189	17.875	> 10000	> 573	10

ETE = Estimated Theoretical Exposure (mg/kg bw/day) TER = Toxicity Exposure Ratio

PT= Fraction of time spent foraging in treated fields

FIR/bw = Food intake rate/body weight

The acute risk to mammals from consumption of treated tubers is considered to be acceptable.

Long-term

The food intake was calculated as presented in the acute toxicity exposure and the same FIR/bw ratios were used.

The lowest NOEL values for flutolanil were used to calculate the TER values in order to provide a worst-case scenario. No time weighted average factor was assumed for the assessment of the long-term risk.

The concentration of flutolanil in the diet is 92.4 mg/kg tubers, being the nominal tuber treatment rate. It was assumed that mammals satisfy their entire food demand in the treated area (PT = 1). The ETE and TER values for are shown in Table 9.2.1.3-10.

(http://ndb.nal.usda.gov/ndb/?format=&count=&max=25&sort=&fg=&man=&lfacet=&qlookup=potatoes&offset=75)

Table 9.2.1.3-9 Exposure estimate of MONCUT 40 SC and long-term TER_L values for mammals for an application in seed potatoes

Active substance	Relevant potato-eating species	Concentration on potato	PT	FIR/ bw	ETE	NOAEL (mg/kg bw/d)	TER_L	Trigger value
Flutolanil	Badger	92.4	1	0.189	17.833	40	**2.29**	5

ETE = Estimated Theoretical Exposure (mg/kg bw/day) TER = Toxicity Exposure Ratio
PT= Fraction of diet obtained in treated fields
FIR/bw = Food intake rate/body weight

Under the conservative assumptions of this tier 1 risk assessment, a risk to the potato eating mammal, badger, from the use in potato cannot be excluded. However, the risk assessment did not consider any residues decline, which is unlikely, and also assumed a PD and PT of 1, which are also considered highly conservative for this scenario.

Furthermore, the potato-eating mammal used in the risk assessment for other RARs, including more recent RARs, has been the wild boar (*Sus scrofa*) (used in the EU risk assessment of pencycuron, penflufen and most recently, toclofos), with a FIR/bw of 0.17, based on the adult female wild boar (*Sus scrofa*)[7] with a body weight (BW) 60 kg and a daily food intake of 9.98 kg/day (FIR/bw: 0.17).

Use of the boar as the relevant potato-eating mammal would result in the following risk assessment.

Table 9.2.1.3-10 Acute TER_A and chronic TER_L values for boars for an application in seed potatoes

Active substance	Relevant potato-eating species	Concentration on potato	PT	FIR/bw	ETE	LD_{50} or NOEL (mg/kg bw/d)	TER_A or TER_L	Trigger value
Flutolanil	Boar	92.4	1	0.17	15.708	> 10000	> 637	10
						40	**2.55**	5

ETE = Estimated Theoretical Exposure (mg/kg bw/day) TER = Toxicity Exposure Ratio
PT= Fraction of time spent foraging in treated fields
FIR/bw = Food intake rate/body weight

Considering this, a more realistic residues level in potatoes and/or other relevant refinements should be presented by the notifier in order to support a finding of no significant long-term risk to potato eating mammals. The RMS considers the wild boar to be the most relevant potato-eating species, and recommends submission of refinements relating to the boar.

[7] A bw of 84 kg and a daily food intake of 7 kg/day were used in the EU risk assessments of pencycuron and penflufen (DAR pencycuron, October 2005), however, a body weight of 60 kg and a daily food intake of 9980 g/day were used in this RAR, in accordance with the more recently finalised RAR of toclofos.

B.9.2.1.4 Risk assessment from exposure via water

Exposure to mammals *via* drinking water is not explicitly included in the above daily dietary dose calculation. Therefore, in line with the EFSA's Bird and Mammal Guidance (2009), the risk to mammals through drinking treated water has been assessed. The 'puddle scenario' is considered relevant for the proposed uses of MONCUT 40 SC in potatoes and the flower bulbs, tulips and iris. This relates to mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in 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} ≥ 500 L/kg).

Flutolanil has a K_{oc} of 652.2 L/kg (arithmetic mean used in the $PEC_{groundwater}$ modelling). The maximum effective rate of use of MONCUT 40 SC is 1 × 2760 g flutolanil/ha (please see Table 9-1). The ratios of effective application rate to relevant endpoints are presented in the following table.

Table 9.2.1.4-1 Drinking water assessment for the proposed worst-case use of MONCUT 40 SC

Time-scale	Crop scenario (Maximum effective application rate)	Endpoint	Ratio	Trigger value
Birds				
Acute	Flower bulb (1 × 2760 g/ha)	LD_{50} > 2000 mg a.s./kg bw	11.1	3000
Long-term		NOEL = 248 mg a.s./kg bw/d	1.38	
Mammals				
Acute	Flower bulb (1 × 2760 g/ha)	LD_{50} > 2000 mg a.s./kg bw	< 1.38	3000
Long-term		NOEL = 160 mg a.s./kg bw/d	17.3	
		NOEL = 40 mg a.s./kg bw/d	69.2	

The above ratios are below the relevant trigger values demonstrating an acceptable acute and long-term risk to mammals *via* drinking water treated from the proposed use of MONCUT 40 SC.

B.9.2.1.5 Secondary poisoning risk assessment

Use of plant protection products containing active substances having a high bioaccumulation potential could theoretically result in risk to mammals as a result of secondary poisoning. In the case of MONCUT 40 SC, which is applied as a plant treatment application and as a broadcast application, this could occur as a result of uptake in small prey organisms e.g. fish, earthworms, small birds and mammals.

According to the EFSA Birds and Mammals Guidance Document (EFSA 2009), the bioaccumulation potential should be evaluated for substances with a log P_{ow} in excess of 3. As the log P_{ow} value of flutolanil is 3.17 an assessment of the risk from secondary poisoning is required.

Earthworm eating birds and mammals

In accordance with the EFSA Guidance (2009), the exposure risk, via the food chain, for earthworm-eating mammals can be assessed based on two approaches; one using dry soil concentrations; and one based on soil pore water concentrations. For flutolanil the dry soil concentration approach has been followed, since the log P_{ow} value is 3.17, indicating that adsorption to soil organic matter would

be expected. In addition, the adsorption coefficient, K_{oc} is 652.2 L/kg and the movement class within the soil was given as medium mobility. Therefore, based on the adsorption and expected mobility within the soil the risk assessment based on dry soil concentrations can be considered more appropriate for assessment of flutolanil exposure and is considered to present a worst-case.

Dry Soil Approach

A bioconcentration factor is calculated for earthworms ($BCF_{earthworm}$), since there are no experimental data for this value. This is defined as the concentration in earthworm related to fresh weight compared to the concentration in soil related to dry weight ($PEC_{worm\ fresh\ weight}/C_{soil\ dry\ weight}$).

$$BCF_{earthworm} = \frac{0.84 + 0.012\ K_{ow}}{f_{oc} \times K_{oc}}$$

Where;

K_{oc} = organic adsorption coefficient

f_{oc} = organic carbon content of soil

K_{ow} = octanol/water partition coefficient

For flutolanil the log K_{ow} is 3.17, giving a K_{ow} of 1479 and the K_{oc} is 652.2 L/kg. The f_{oc} is 0.02 for this assessment, the default value stated in the guidance document.

Residues in earthworms are then calculated by multiplying the $BCF_{earthworm}$ with the appropriate PEC_{soil} value.

$$PEC_{earthworm} = PEC_{soil} \times BCF_{earthworm}$$

A daily dose is then calculated by multiplying the $PEC_{earthworm}$ value with a conversion factor of 1.28 for mammals, which is based on a 10 g mammal eating 12.8 g fresh weight earthworms (fresh) per day. The daily dose is then divided by the bird or mammalian reproduction NOEC to calculate the TER which is compared to the trigger value of 5.

The following table presents the predicted concentration along with earthworms (PEC_{worm}), based on the 21 day twa PEC_{soil} and on the estimated earthworm bioconcentration factor (BCF_{worm}) and the corresponding daily dietary dose (DDD) and the toxicity exposure ratio (TER), following the guidance presented in EFSA (2009).

Table 9.2.1.5-2 Calculation of TER_{LT} for secondary poisoning from flutolanil of earthworm-eating birds and mammals

21 day TWA PEC_{soil}[a] (mg/kg)	2.68	
K_{ow}	1479.1	
f_{oc} (default value)	0.02	
K_{oc}	652.2	
BCF_{worm}	1.43	
PEC_{worm} (mg/kg)	3.83	
DDD (mg/kg bw/d)	4.02	4.91
Endpoint (mg/kg bw/d)	248	40
TER_{LT}	61.6	8.14

[a] For flutolanil the plateau soil $PEC_{accumulation}$ is used (see Document M - CP 9.1.3) for the higher application rate and at 10 cm planting depth)

The above TER is greater than the trigger value of 5, demonstrating an acceptable risk to earthworm-eating mammals from the proposed use of MONCUT 40 SC.

Fish-eating birds and mammals

The food chain exposure risk to fish-eating birds and mammals following consumption of treated fish has been assessed as follows.

A value for residues in fish (PEC_{fish}) is calculated using the 21-d time weighted average (TWA) predicted environmental concentration of flutolanil in surface water at FOCUS step 1 (PEC_{sw} (TWA)) (see **Table B.9.2-2**) multiplied by the fish bioconcentration factor (BCF_{fish}).

$$PEC_{fish} = PEC_{sw} (TWA) \times BCF_{fish}$$

A daily dose (DDD) is then divided by multiplying the PEC_{fish} with a conversion factor of 0.159, based on a 1000 g bird eating 159 g fresh fish/day or with a conversion factor of 0.142, based on a 3000 g mammal eating 425 g fresh fish/day.

$$DDD = PEC_{fish} \times 0.159$$

$$DDD = PEC_{fish} \times 0.142$$

The DDD is then compared with the bird or mammalian reproduction endpoint in order to calculate the TER, which is compared to the trigger value of 5.

The following tables present the predicted concentration in fish (PEC_{fish}), based on the maximum initial PEC_{sw} value and the laboratory fish bioconcentration factor (BCF_{fish}). Based on the PEC_{fish} the daily dietary dose (DDD) and corresponding toxicity exposure ratio (TER) were calculated. The calculations follow the guidance presented in EFSA (2009).

Table 9.2.1.5-3 Calculation of TER_{LT} for secondary poisoning from flutolanil of fish-eating birds and mammals

Max initial PEC_{water} (mg/kg)[a]	0.06394	
BCF_{fish}	100	
PEC_{fish} (mg/kg)	6.394	
DDD (mg/kg bw/d)	1.02	0.91
Endpoint (mg/kg bw/d)	248	40
TER_{LT}	244	44

[a] For flutolanil, maximum initial FOCUS Step 1 PEC_{sw} values have been used (see Document M-CP 9.2.5)

The above TER value is greater than the trigger value of 5, demonstrating an acceptable risk to fish-eating birds and mammals from the proposed use of MONCUT 40 SC. Therefore, no adverse effects as a result of secondary poisoning through eating fish are expected.

B.9.3 Effects on aquatic organisms

The aquatic toxicity endpoints for flutolanil are given in Table 10.2-1. PEC_{sw} values are provided in Document B.8 of this dossier, along with full details of PEC_{sw} calculations. Effects on aquatic

organisms for MONCUT 40 SC and the active ingredient, flutolanil, are evaluated and risk assessments with the proposed pattern are provided here.

Table 9.3-1 Summary of toxicity data on fish, aquatic invertebrates, aquatic algae and macrophytes

Species	Test substance	Time-scale (Test type)	End point		Data point Author, year
Toxicity to Fish					
Oncorhynchus mykiss[1] (Rainbow trout)	Flutolanil Technical	Acute, 96h (static)	LC_{50} NOEC	5.4 mg/L (m.m.) 3.0 mg/L (m.m.)	CA 8.2.1-01 [redacted] 1987a
Lepomis macrochirus (Bluegill sunfish)	Flutolanil Technical	Acute, 96h (static)	LC_{50} NOEC	> 5.4 mg/L (m.m.) 2.5 mg/L (m.m.)	CA 8.2.1-02 [redacted] 1987b
Pimephales promelas (Fathead minnow)	Flutolanil Technical	Acute, 96h (static)	LC_{50} NOEC	**4.8 mg/L (m.m.)** 1.2 mg/L (m.m.)	CA 8.2.1-03 [redacted] 1990
Pimephales promelas (Fathead minnow)	Flutolanil Technical	Long-term, FELS, 30 days (flow-through)	NOEC $EC_{10, wet weight}$ EC_{20} EC_{50} MATC	**0.233 mg/L (m.m.)** 0.601 mg/L (m.m.) ND ND 0.337 mg/L (m.m.)	CA 8.2.2.1-01 [redacted], 1995 CA 8.2.2.1-02 [redacted], 2016
Toxicity to aquatic invertebrates					
Daphnia magna (Water flea)	Flutolanil Technical	Acute, 48h (static)	EC_{50}	> 6.8 mg/L (m.m.)	CA 8.2.4.1-01 Forbis, A.D. *et al*., 1990
Daphnia magna (Water flea)	Flutolanil Technical	Reproduction, 21 days (semi-static)	NOEC EC_{10} (95% CI) EC_{20} (95% CI) EC_{50} (95% CI) MATC	0.29 mg/L (m.m.) 2.03 (1.35-2.45) mg/L (m.m.) 2.37 (1.74-2.75) mg/L (m.m.) 3.18 (2.73-3.58) mg/L (m.m.) 0.76 mg/L (m.m.)	CA 8.2.5.1-01 Blakemore, G.C. & Burgess, D.,1991 CA 8.2.5.1-02 Palmer, D.A., 2016
Mysidopsis bahia (Shrimp)	Flutolanil	Acute, 48h (static)	LC_{50}	**0.13 [3] (0.087-0.16) mg/L (m.m.)**	CA 8.2.4.2-01 Forbis, A.D., 1991
Mysidopsis bahia (Shrimp)	Flutolanil	Life-cycle, 28 days (flow-through)	NOEC EC10 (95%CI) Survial production young/female growth (dry weight) EC20 (95%CI) Survial production young/female growth (dry weight) EC50 (95%CI) Survial production	0.0113 mg/L **0.00397 (0.00241-0.00560) mg/L (m.m.)** 0.0117 (0.0101-0.0129) mg/L (m.m.) 0.0165 (0.0063-0.0252) mg/L (m.m.) 0.00685 (0.00472-0.00896) mg/L (m.m.) 0.0136 (0.0122-0.0147) mg/L (m.m.) 0.0321 (0.0192-0.0430) mg/L (m.m.) 0.0195 (0.0158-0.0238) mg/L (m.m.) 0.0182 (0.0172-0.0191) mg/L (m..m)	CA 8.2.5.2-01 Boeri, R.L., Kowalski, P.L., Ward, T.J., 1995

Species	Test substance	Time-scale (Test type)	End point		Data point Author, year
			young/female growth (dry weight)	0.115 (0.0812-0.237) mg/L (m.m.)	
Chironomus riparius (Chironomid Midge)	Flutolanil	Long-term: Water spiked, 28 days (static)	NOEC EC_{10} EC_{20} EC_{50}	**1.0 mg/L (nom.)** ND ND > 1 mg/L (nom.)	CA 8.2.5.3-01 Desmares-Koopmans, D., 2003
Toxicity to algae					
Pseudokirchneriella subcapitata[2] (Green algae)	Flutolanil Technical	Chronic, 72h (static)	E_rC_{10} E_rC_{25} E_rC_{50} E_bC_{50} NOEC	0.49 mg/L (nom.) 2.30 mg/L (nom.) **> 3.2 mg/L (nom.)** 0.97 mg/L (nom.) 0.18 mg/L (nom.)	CA 8.2.6.1-01 Migchielsen, M.H.J., 2003

[1] Formerly known as *Salmo gairdneri*
[2] Formerly known as *Selenastrum capricornutum*
[3] only for adults, not for juvenile shrimp
ND: Could not be determined
CI: Confidence Intervals
[*] Flutolanil 40 SC is equivalent to the representative formulation MONCUT 40 SC
Note: When more than one endpoints are available for a substance for the same taxonomic group and study type, the lowest endpoint is in **bold** and is the one used in the risk assessment

Summary of the risk assessment for flutolanil on aquatic organisms

First-tier risk assessment for flutolanil on potatoes (dose 0.368 kg a.s./ha)

The FOCUS Step 1 PEC_{sw} value of flutolanil was found to be lower than the acute $RAC_{sw, ac}$ value for the chronic $RAC_{sw, ch}$ values for chironomids and algae, indicating that the chronic risks to chironomids and algae are considered acceptable.

The FOCUS Step 2 PEC_{sw} values of flutolanil was found to be lower than the acute $RAC_{sw, ac}$ value for fish, indicating that the acute risk to fish are considered acceptable.

After assessing all scenarios in FOCUS Step 3, PEC_{sw} values of flutolanil were found to be lower than the chronic $RAC_{sw, ch}$. Therefore, the risk of flutolanil is considered acceptable for the use in potatoes.

First-tier risk assessment for flutolanil on flower bulbs (dose 2.76 kg a.s./ha)

The FOCUS Step 2 PEC_{sw} values of flutolanil were found to be lower than the chronic $RAC_{sw, ch}$ value for algae. The chronic risk to algae is considered acceptable.

The acute and chronic risks for fish and the chronic risks for chironomids were considered acceptable after assessing all scenarios in FOCUS Step 3, except for the chronic risk of flutolanil to fish for the application in flower bulbs for the scenario D3 (ditch) and D6 (ditch), and further for all flower bulb scenarios for the acute and chronic risk of flutolanil to aquatic invertebrates, and therefore, a risk for flutolanil remains for the use in flower bulbs.

Summary of the risk assessment for metabolites on aquatic organisms

First-tier risk assessment for metabolites on potatoes (dose 0.368 kg a.s./ha)

Metabolite M-4

The Step 1 PEC_{sw} value of M-4 was found to be lower than the chronic $RAC_{sw, ch}$ values for chironomids and algae and the acute $RAC_{sw, ac}$ value for fish. The chronic risks to chironomids and algae and the acute risk to fish are considered acceptable.

The FOCUS Step 2 PEC_{sw} values of M-4 were found to be lower than the chronic $RAC_{sw, ac, ch}$ values for fish, indicating that the chronic risk to fish is considered acceptable for the use in potatoes.

After assessing all scenarios in FOCUS Step 3, PEC_{sw} values of M-4 were found to be lower than the acute RAC_{sw} for aquatic invertebrates but not for the chronic RAC_{sw} for the scenarios D4 Stream and D6 Ditch (E and L) for aquatic invertebrates. Therefore, the risk of M-4 is considered unacceptable for the use in potatoes.

Metabolite M-11

The FOCUS Step 1 PEC_{sw} value of M-11 was lower than the chronic $RAC_{sw, ch}$ value for algae and chironomids, indicating that the chronic risk to algae and chironomids is considered acceptable.

The FOCUS Step 2 PEC_{sw} values of M-11 were found to be lower than the acute and chronic risks for fish, indicating that the acute and chronic risk to fish are considered acceptable. However, the FOCUS Step 3 PEC_{sw} for M-11 for scenario D4 pond is higher than PEC_{sw} of FOCUS step 2 which resulted in a chronic risk for fish for the metabolite M-11 for the scenario D4 Pond for the use in potatoes. Comparison of the FOCUS Step 3 PEC_{sw} for the M-11 metabolite with the RAC indicated an unacceptable acute and chronic risk for aquatic invertebrates for the scenarios D3 Ditch, D4 Pond, D4 Stream and D6 Ditch (E and L) for the application in potatoes. Therefore, a risk for M-11 remains for the use in potatoes.

First-tier risk assessment for metabolites on flower bulbs (dose 2.76 kg a.s./ha)

Metabolite M-4

The FOCUS Step 1 PEC_{sw} values of M-4 were found to be lower than the chronic $RAC_{sw, ch}$ value for algae, indicating that the chronic risk to algae is considered acceptable.

The FOCUS Step 2 PEC_{sw} values of M-4 were found to be lower than the chronic $RAC_{sw, ch}$ value for chironomids, indicating that the chronic risk to chironomids is considered acceptable.

The acute and chronic risks for fish and the acute risk for aquatic invertebrates were considered acceptable after assessing all scenarios in FOCUS Step 3 but not for the chronic risk for aquatic invertebrates for the the scenarios D4 Stream and D6 Ditch (E and L). Therefore, the risk of M-4 is considered unacceptable for the use in flower bulbs.

Metabolite M-11

The chronic risk for algae was considered acceptable after assessing all scenarios in FOCUS Step 3, but not for the acute and chronic risks for fish (scenario D3 Ditch, D4 Pond, D4 stream and D6 Ditch (E and L)) and the acute (scenario D3 Ditch, D4 Pond, D4 Stream, D6 Ditch (E and L)) and chronic (all scenario scenarios except R1 Pond) risks for aquatic invertebrates, as well as the chronic risk for chironomids (scenario D3 Ditch, D4 Pond). Therefore, a risk for M-11 remains for the use in flower bulbs.

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

Studies on the toxicity of MONCUT 40 SC (Flutolanil 40 SC/EXP10066A) to fish and aquatic invertebrates have not been conducted. The studies conducted with the active substance of flutolanil adequately predict the toxicity of MONCUT 40 SC (flutolanil 460 g/L).

The formulation of MONCUT 40 SC contains a number of co-formulants (see Doc J), out of which only Proxel GXL has a biocidal function (antimicrobial). The other coformulants are common to many types of formulations and are not known to have significant toxicity to aquatic organisms. Considering the nominal content of Proxel GXL is 0.1% w/w in the current formulation, and the results of the algal growth inhibition study performed with the formulation (see CP 10.2.1-01), where there were no findings of additional toxicity, no additional toxic effects are expected for fish or aquatic invertebrates from the formulation. It is therefore justified to consider the endpoint generated with flutolanil as representative of the formulated product MONCUT 40 SC for invertebrates and fish.

Study CP 10.2.1-01

Report	CP 10.2.1-01 Yaginuma, S., 2007, as amended 2016
Title	Algal growth inhibition test of flutolanil 40SC
Report no	LSRC-E07-045A (N-3029)
Guidelines	OECD 201 (2006)
GLP	Yes (JMAFF and OECD)
Previous evaluation	Addendum 2 to the DAR (2007)
RMS Comment	Considered acceptable for use in risk assessment

Endpoint

Parameter (0 – 72 h)	**Yield y (mg/L)**		**Growth rate r (mg/L)**		**Biomass b (mg/L)**	
	Flutolanil 40SC	**a.s.**	**Flutolanil 40SC**	**a.s.**	**Flutolanil 40SC**	**a.s.**
EC_{10}	0.36	0.15	1.5	0.62	0.39	0.16
95%-confidence limits	0.34-0.39	0.14-0.16	1.4-1.6	0.57-0.66	0.38-0.40	0.16-0.16
EC_{20}	0.73	0.30	4.0	1.6	0.80	0.33
95%-confidence limits	0.69-0.77	0.28-0.32	3.8-4.3	1.6-1.8	0.79-0.83	0.32-0.34
EC_{50}	2.8	1.1	27	11	3.3	1.4
95%-confidence limits	2.7-2.8	1.1-1.1	26-28	11-12	3.2-3.3	1.3-1.4
NOEC	ND	ND	< 1.0	< 0.41	ND	ND

Executive Summary

Three replicate algal suspensions (*Pseudokirchneriella subcapitata*) were each exposed to flutolanil 40SC at nominal concentrations of 1.0, 3.0, 9.0, 27, 81 and 243 mg product/L for 72 hours. Three replicates without test item were used as untreated control. Observations of cell growth were recorded at 24, 48 and 72 hours to determine the potential effect on growth rate (E_rC_{50}) relative to the control and the no observed effect concentration (NOE_rC) after 72 hours exposure.

Analysis of the test solutions (fresh and spent) for the determination of the content of flutolanil was performed in samples taken at 0 and 72 hours after application. The determination of the content of flutolanil in the test solutions showed a recovery between 92.2% and 99.1% in the fresh samples, and

between 85.9% and 98.8% in the spent samples. For each concentration, the measured value did not vary more than 20% from the nominal concentration of flutolanil, therefore the evaluation of effect for flutolanil 40SC was based on the nominal concentrations of flutolanil 40SC.

Growth rate inhibition was observed to increase from 7.3% at the minimum test concentration to 75.1% at the maximum concentration compared to the control after 72 hours of exposure. The growth rate E_rC_{10} E_rC_{20} and E_rC_{50} values for flutolanil 40SC were determined to be 1.6 (0.98-2.2), 4.3 (3.0-5.7), 30 (24-37) mg/L (nominal) respectively (95% confidence intervals). The growth rate NOE_rC values were estimated to be less than 1.0 mg/L (nominal), the lowest concentration tested.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Flutolanil 40SC (Lot. 7AE8802F)

Batch no.: 7AE8802F

A.i content: flutolanil 40.7% (nominal, w/w), 41.0% (determined, w/w)

Description: Off-white viscous suspension liquid

2. Test organism: *Pseudokirchneriella subcapitata*

Strain: ATCC22662

Source: Purchased from American Type Culture Collection in 2004 and cultured in-house.

Initial density: 0.7×10^4 cells/mL

3. Treatment: 0 (untreated control), 1.0, 3.0, 9.0, 27, 81 and 243 mg/L (nominal)

4. Test vessels: Erlenmeyer flasks (200 mL)

Test water: OECD medium (according to testing guidelines)

Shaking: Yes (swirl, 100 rpm)

5. Environmental conditions:

Temperature: 22.2 – 22.5°C

pH: 7.8 – 8.2

Photoperiod: Continuous illumination by fluorescent light (3850 – 3920 lux)

B. STUDY DESIGN AND METHODS

1. In-life phase: Mar 02 to Mar 16, 2007

2. Test organism assignment and treatment

The test started (0 hours) by inoculation of a biomass of about 0.7×10^4 algal cells per mL test medium in each flask. These cells were taken from a pre-culture incubated for three days under the same conditions. The test was performed with three replicates per test concentration and control. The flasks were placed on shakers.

3. Dose preparation

An aliquot of flutolanil 40SC (500 mg) was suspended and filled up to 10 mL with test medium. The obtained stock solution (50,000 mg/L) was further diluted to prepare test solutions at concentrations of 1.0, 3.0, 9.0, 27, 81 and 243 mg/L. Four replicates of 100 mL of test medium without test substance were prepared for the untreated control group and pH measurements.

4. Measurements and observations

The cell density in each replicate was daily assessed during the test period by flow cytometry based on light scattering and self-fluorescence of algal cells derived from chlorophyll. The pH values were measured in the untreated and treated groups at the beginning and at the end of the test. The temperature in the climatic chamber was continuously recorded in a temperature-control vessel.

The analysis of the concentration of flutolanil was performed for each test concentration. The samples were collected from the six test item concentrations and from the control at 0 hours from fresh test solutions and at the end of the test (72 hours) from the aged solutions. Analysis was performed by a sufficiently validated HPLC-UV method (recoveries between 91.2 and 101.4% for concentration range between 0.05 to 5 mg a.s./L).

5. Statistics

The determination of the 72-hours $EC_{10,}$ EC_{20} and EC_{50} values for growth rate was performed using the probit method. Additionally, the data obtained were also statistically evaluated to determine the NOEC values, using a Dunnett's multiple comparison test toward control. The input data refers to the growth data evaluated during 72 hours of exposure at different concentrations.

II. RESULTS AND DISCUSSION

A. Growth inhibition

Mean number of cells and growth rates with the corresponding percent inhibition values are presented in the following tables.

Mean number of cells (cells/mL) at each observation time

Nominal concentration of flutolanil 40SC (mg/L)	Mean number of cells		
	at 24 hrs	at 48 hrs	at 72 hrs

0.0 (control)	39567	264300	1359800
1.0	38100	204700	923833
3.0	39367	167767	781533
9.0	26000	78167	258567
27	17933	40533	72033
81	16333	38000	30667
243	12667	23333	26333

Growth rate 0-72 hours and corresponding inhibition (%) after 72 hours of exposure

Nominal concentration of flutolanil 40SC (mg/L)	**Growth rate 0-72 hours**	
	Mean value	**% inhibition mean value**
0.0 (control)	1.75	-
1.0	1.63**	7.3
3.0	1.57***	10.4
9.0	1.20***	31.5
27	0.78***	55.8
81	0.49***	72.1
243	0.44***	75.1

**: $p < 0.01$, ***: $p < 0.001$, significantly different from the control (Dunnett's multiple comparison test)

B. Analytical verification

The flutolanil content in the test samples showed a mean recovery of 96% in the fresh solutions and a mean recovery of 93% in the spent solutions. For each concentration, the measured value was in the range 20% from the nominal, therefore the evaluation of effect was based on the test item nominal concentrations. The analytical results are reported in the following table.

Measured concentrations of flutolanil during the test

Nominal concentration of flutolanil 40SC (mg/L)	**Nominal concentration of flutolanil (mg/L)**	**Measured flutolanil (mg/L) - Recovery (%)**	
		Sampling (h)	
		0 (fresh)	**72 (spent)**
0.0 (control)	-	Not detectable	Not detectable
1.0	0.41	0.38 – 92.2	0.39 – 95.2
3.0	1.23	1.14 – 92.4	1.19 – 96.6

9.0	3.69	3.60 – 97.5	3.65 – 98.8
27	11.07	10.64 – 96.2	9.81 – 88.6
81	33.21	32.84 – 98.9	28.52 – 85.9
243	99.63	98.69 – 99.1	94.24 – 94.6

C. Toxicity endpoints

The 72-hour toxicity endpoints of flutolanil 40SC for *Pseudokirchneriella subcapitata* are presented in the following table.

72-h toxicity endpoints of the test item flutolanil 40SC

Effect concentration	**Growth rate (mg flutolanil 40SC/L, nominal)**	**Growth rate (mg flutolanil/L, nominal)**
EC_{10} (95% confidence intervals)	1.6 (0.98-2.2)	0.66 (0.40-0.90)
EC_{20} (95% confidence intervals)	4.3 (3.0-5.7)	1.76 (1.23-2.34)
EC_{50} (95% confidence intervals)	30 (24-37)	12.3 (9.84-15.17)
NOEC	< 1.0	< 0.41

III. CONCLUSION

In a growth inhibition test on the green alga *Pseudokirchneriella subcapitata*, 72-h $E_rC_{10,}$ E_rC_{20} and E_rC_{50} values for flutolanil 40SC were 1.6, 4.3 and 30 mg/L (nominal flutolanil 40 SC) for growth rate ($E_rC_{10, 20, 50}$). The growth rate NOE_rC value was estimated to be less than 1.0 mg/L (nominal flutolanil 40 SC), the lowest concentration tested. These values would be equivalent to 0.66, 1.76 and 12.3 mg flutolanil/L for the growth rates ($E_rC_{10,}$ E_rC_{20} and E_rC_{50}) respectively and 0.41 mg flutolanil/L for the growth rate NOE_rC value.

Comments by RMS

The study was conducted according to OECD 201 without deviations. The validity criteria for the controls were met: the biomass in the control cultures was increased by a factor of 194 (> 16) within the 72-hours; the mean coefficient of variation for section-by-section specific growth rates was 8.8% (< 35%) and the coefficient of variation of average specific growth rates during the whole test period was 2.3% (< 7%).

The measured flutolanil concentrations ranged between 92.2-99.1% of nominal at the start and between 85.9 -98.8% of nominal at the end of the test. Effect levels were based on nominal concentrations, which is acceptable.

ECx values for biomass and/or yield were not reported. RMS estimated these endpoints with TOXRAT v.3.2, using probit analysis. Also, ECx values for growth rate were determined and these values were lower and had higher reliabilities than the values of the applicant and are thus reported.

Nominal Flutolanil 40 SC (mg/L)	Yield y and % inhibition of y		Growth rate (r) and % inhibition of r		Biomass b and % inhibition of b	
	72 hours		72 hours		72 hours	
	y	%	r	%	b	%
control	135	-	1.8	-	2319	-
1	92	32	1.6	7.3*	1649	29
3	78	43	1.6	10*	1393	40
9	25	81	1.2	32*	518	78
27	6.5	95	0.78	56*	185	92
81	2.4	98	0.49	72*	125	95
243	1.9	99	0.44	75*	76	97

Parameter (0 – 72 h)	Yield y (mg/L)		Growth rate r (mg/L)		Biomass b (mg/L)	
	Flutolanil 40SC	a.s.	Flutolanil 40SC	a.s.	Flutolanil 40SC	a.s.
EC_{10}	0.36	0.15	1.5	0.62	0.39	0.16
95%-confidence limits	0.34-0.39	0.14-0.16	1.4-1.6	0.57-0.66	0.38-0.40	0.16-0.16
EC_{20}	0.73	0.30	4.0	1.6	0.80	0.33
95%-confidence limits	0.69-0.77	0.28-0.32	3.8-4.3	1.6-1.8	0.79-0.83	0.32-0.34
EC_{50}	2.8	1.1	27	11	3.3	1.4
95%-confidence limits	2.7-2.8	1.1-1.1	26-28	11-12	3.2-3.3	1.3-1.4
NOEC	ND	ND	< 1.0	< 0.41	ND	ND

ND: not determined as these are not relevant for risk assessment and classification

Reliability of endpoints

For the purpose of classification, the NrOEC was < the lowest tested concentration and therefore the reliability of the ErC_{10} value was considered.

To assess the reliability of the estimated EC_x values, two approaches are described in EFSA Supporting publication 2015:EN-924:

- Normalised width of the confidence interval (NW = (upper limit – lower limit) / median estimate); rating of the NW ranges from excellent (<0.2) to bad (>2)
- Relationship between EC_{10} and EC_{20}/EC_{50} confidence intervals: the best case (high certainty of protection level) is achieved when EC_{10} is lower than the lower limit of the EC_{20}; the worst case (low certainty of protection level) occurs when the median EC_{10} is greater than the lower confidence limit for the EC_{50}.

Based on these results, ErC_{10} value had excellent reliability based on the normalized width of CI and a high certainty on the level of protection.

The ErC_{10} was 1.5 mg Flutolanil 40SC/L, corresponding to 0.62 mg a.s./L.

For risk assessment, the ErC_{50} was 27 mg product/L (95% CI 26-28 mg product/L), corresponding to 11 mg a.s./L (95% CI 11-12 mg a.s./L); EyC_{50} was 2.8 mg product/L (95% CI 2.7-2.8 mg product/L), corresponding to 1.1 mg a.s./L (95% CI 1.1-1.1 mg a.s./L); EbC_{50} was 3.3 mg product/L (95% CI 3.2-3.3 mg product/L), corresponding to 1.4 mg a.s./L (95% CI 1.3-1.4 mg a.s./L).

Yaginuma, S.	2007	Algal growth inhibition test of flutolanil 40SC	Report No. LSRC-E07-045A (N-3029)
Reliability			
General information			
Is a guideline method or modified guideline used?*		Yes	
Is the test performed under GLP conditions?*		Yes	
If applicable, are validity criteria fulfilled (e.g. control survival, growth, etc.)?		Yes	
Are appropriate controls performed (e.g. solvent control, negative and/or positive control)?		Yes.	
* these criteria are of minor importance for study reliability, but may support study evaluation			
Test compound			
Is the test substance clearly identified with name or CAS-number? Are test results reported for the appropriate compound?		Yes	
Is the purity of the test substance reported? Or, is the source of the test substance trustworthy?		Yes	
If a formulation is used or if impurities are present: do other ingredients in the formulation		The a.s. content is known. The effects should be considered the result of the formulated product.	

exert an effect? Is the amount of test substance in the formulation known?	
Test organism	
Are the organisms well described (e.g. scientific name, weight, length, growth, age/life stage, strain/clone, gender if appropriate)?	Yes
Are the test organisms from a trustworthy source and acclimatized to test conditions? Have the organisms not been pre-exposed to test compound or other unintended stressors?	Yes
Exposure conditions	
Is the experimental system appropriate for the test substance, taking into account its physicochemical characteristics?	Yes
Is the experimental system appropriate for the test organism? Have conditions been stable during the test?	Yes
If appropriate, were exposure concentrations below the limit of water solubility (taking the use of a solvent into account)? If a solvent is used, is the solvent within the appropriate range and is a solvent control included?	Yes
Is a correct spacing between exposure concentrations applied?	Yes
Is the exposure duration defined?	Yes
If necessary, are chemical analyses adequate to verify concentrations of the test substance over the duration of the study?	Yes
Where applicable, is the biomass loading of the organisms in the test system within the appropriate range?	Yes
Statistical Design and Biological Response	
Is a sufficient number of replicates used? Is a sufficient number of organisms per replicate used for all controls and test concentrations?	Yes

Are appropriate statistical methods used?	Yes
Is a concentration-response curve observed? Is the response statistically significant?	Yes
Are sufficient data available to check the calculation of endpoints and (if applicable) validity criteria (e.g., control data, concentration-response curves)?	Yes
Relevance of the study for Environmental Risk Assessment, appropriateness of study endpoints	
Exposure Relevance	
Is the substance tested representative and relevant for the substance being assessed?	Yes
Is the tested exposure scenario relevant for the substance?	Yes
Is the tested exposure scenario relevant for the species?	Yes
Biological relevance	
Is the species tested relevant for the compartment under evaluation?	Yes
Are the organisms tested relevant for the tested compound?	Yes
Are the reported endpoints appropriate for the regulatory purpose?	Yes
Are the reported endpoints appropriate for the investigated effects or the mode of action of the test substance?	Yes
Is the effect relevant on a population level?	Yes
Is the magnitude of effect statistically significant and biologically relevant for the regulatory purpose (e.g. EC10, EC50)?	Yes
Are appropriate life-stages studied?	Yes
Are the experimental conditions relevant for the tested species?	Yes
Is the exposure duration relevant and appropriate for the studied endpoints and	Yes

species?	
If recovery is studied, is this relevant for the framework for which the study is evaluated?	Not applicable
Concluding weight of evidence/proposed action	Study is reliable without restrictions. Study is relevant without restrictions.
Type of information (Fully acceptable, supporting information, not applicable)	Fully acceptable
Consideration/concluding score	Fully acceptable

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

Chronic studies on the toxicity of MONCUT 40 SC to fish or aquatic invertebrates were not conducted as the studies conducted for the active substance were considered to be fully representative of the formulation.

Please refer to Document B.8 of this dossier for studies on the active substance.

B.9.3.3 Further testing on aquatic organisms

Tests on aquatic plants are not required as MONCUT 40 SC is neither a herbicide nor a plant growth regulator.

B.9.4 Risk assessment for aquatic organisms

The following risk assessment has been conducted in line with the “Guidance of tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Journal 2013; 11(7):3290).

The product MONCUT 40 SC is applied as a dressing to potato tubers before planting. It is also applied to bare soil with a boom sprayer and incorporated into the soil at 10-15 cm depth prior to planting flower bulbs. There is a potential for the compound to reach surface water through spray drift. The product might also reach adjacent water bodies via drift due to the method of application.

Exposure

Aquatic organisms may be exposed to flutolanil and relevant metabolites through spray drift, run-off and drainage from the application site into adjacent water bodies. Exposure of aquatic organisms from these routes was estimated by calculating Predicted Environmental Concentrations in surface water (PEC_{sw}). The PEC_{sw} values for flutolanil following the potato seed tuber treatment and the broadcast spray application of the product MONCUT 40 SC were modelled using a tiered approach as

recommended by FOCUS (FOCUS 2001)7F[8]. The simulations were based on the recommended GAP crops as presented in the following table.

Table 9.4-1 Proposed critical use pattern of MONCUT 40 SC (460 g/L flutolanil)

Crop	Max individual application rate (kg a.s./ha)	Number of applications	Max total application rate (kg a.s./ha)	Application timing
Potato seed tuber treatment	0.368*	1	0.368*	BBCH 00-03 (at planting)
Tulip, Iris	2.76	1	2.76	BBCH 00 Oct – Dec

*based on a planting rate of 4 t tubers/ha

Metabolites

Flutolanil is not applied directly to aquatic systems. However, it might reach water bodies indirectly by spray drift and by surface or drainage run-off. Under biotic conditions, flutolanil degrades with a half-life of 225 days from the whole system, and dissipates from the aqueous phase to sediment with a half-life of 225 days. No major transformation products (≥ 10% AR) were observed in the water or sediment layer. Two major degradates of flutolanil were found in the water M-4, (α,α,α-trifluoro-3'-hydroxy-o-toluanilide) at 6.8% AR, and M-11, 2-[3-(α,α,α-trifluoro-o-toluoylamino) phenoxy] propionic acid) at 8.3% AR. Only very minor transformation products in the sediment were detected which reached maximum concentrations of < 5.0% AR (See B.8 for details).

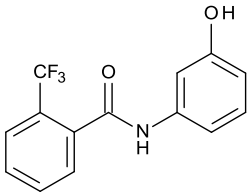
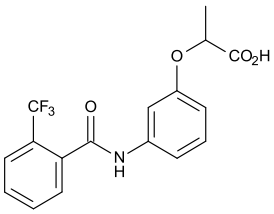
No transformation products > 5% were found in the photolysis studies. Two known degradates M-101 and M-102 were identified as minor degradates, which accounted for 2.6 and 1.3% of AR after 24 days irradiation, several unknown degradates were detected but none of these accounted for greater than 2% of AR.

Metabolites identified as potentially ecologically relevant for the surface water risk assessment are listed in the following table (Table 9.4-2).

Table 9.4-2 List and molecular structures of metabolites of flutolanil identified in the surface water

Metabolite Name & Synonyms – Structure	Chemical name - Relavent compartments	Metabolite Name & Synonyms – Structure	Chemical name - Relavent compartments
M-4	α,α,α-trifluoro-3'-hydroxy-o-toluanilide Found in:	M-11	2-[3-(α,α,α-trifluoro-o-toluoylamino) phenoxy]propionic

[8] FOCUS (2001) FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev 2

 DIP Molecular weight: 281.2 g/mol	Soil (aerobic minor) Water sediment systems Crop (rice, potato, peanuts, cabbage) Livestock (hen, goat) Rat	 Molecular weight: 353.3 g/mol	acid Found in: Soil (aerobic minor) Water sediment systems Rat Crop (rice, peanuts, cabbage; trace amounts)

For the above metabolites there were no experimental toxicity data generated on fish, aquatic invertebrates, or green algae. In line with the decision scheme (EFSA, 2013) for the taxonomic groups where no metabolite toxicity data are available, it can be assumed as a worst-case that the acute and chronic toxicity of each metabolite is equal to ten times the parental toxicity taking into account the lower exposure levels and converting this value on a molar basis for each case.

Is $RAC_{sw,ac}$ and $RAC_{sw,ch}$ (based on parent) > PEC_{sw} (metabolite)? If the PEC/RAC ratio is > 1 then the risk is not acceptable.

FOCUS Steps 1 and 2

FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} values for flutolanil and the metabolites M-4 and M-11 were calculated (see B.8 for details) using FOCUS calculator (v. 2.1) with crop types according to the proposed GAP of 1 × 368 g product/ha and 1 × 2760 g product/ha. A summary of the FOCUS Step 1 and 2 maximum PEC_{sw} values for the proposed uses of MONCUT 40 SC (flutolanil 460 mg/L) are presented in Table 9.4-3, 4 and 5, for flutolanil, M-4 and M-11, respectively.

Table 9.4-3 FOCUS Step 1 and 2 PEC_{sw} for flutolanil

Crop	Step	Scenario	Application rate (g a.s./ha)	PEC_{sw} µg/L
Potato (Mar-May)	1	n/a	Potato: 1 × 368 g a.s./ha	**66.04**
	2	Northern		12.86
	2	Southern		**25.73**
Flower bulbs (Oct-Dec)	1	n/a	Flower bulb: 1 × 2760 g a.s./ha	**495.33**
	2	Northern		96.49
	2	Southern		**192.97**

Note: The PEC_{sw} values in **bold** were the highest values indicating a worst case scenario and therefore were used in the risk assessment

Table 9.4-4 FOCUS Step 1 and 2 PEC_{sw} for metabolite M-4

Crop	Step	Scenario	Application rate (g a.s./ha)	PEC_{sw} µg/L
Potato (Mar-May)	1	n/a	Potato: 1 × 368 g a.s./ha	**2.22**
	2	Northern		0.44
	2	Southern		**0.88**
Flower bulbs (Oct-Dec)	1	n/a	Flower bulb: 1 × 2760 g a.s./ha	**16.63**
	2	Northern		3.32
	2	Southern		**6.63**

Note: The PEC_{sw} values in **bold** were the highest values indicating a worst case scenario and therefore were used in the risk assessment

Table 9.4-5 FOCUS Step 1 and 2 PEC_{sw} for metabolite M-11

Crop	Step	Scenario	Application rate (g a.s./ha)	PEC_{sw} µg/L
Potato (Mar-May)	1	n/a	Potato: 1 × 368 g a.s./ha	**5.36**
	2	Northern		1.07
	2	Southern		**2.14**
Flower bulbs (Oct-Dec)	1	n/a	Flower bulb: 1 × 2760 g a.s./ha	**40.16**
	2	Northern		8.01
	2	Southern		**16.02**

Note: The PEC_{sw} values in **bold** were the highest values indicating a worst case scenario and therefore were used in the risk assessment

FOCUS Step 1 and Step 2 PEC_{sw} were compared with the RAC values (Table 9.4-6 and 7).

Table 9.4-6 FOCUS Step 1: $RAC_{sw, ac}$ and $RAC_{sw, ch}$ values of aquatic organisms compared to $PEC_{sw;max}$ values for flutolanil and metabolites

Test type / Application rate (Crop)	Substance	FOCUS Step 1 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]*	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Acute:					
368 g product/ha	Flutolanil	66.04	4800	48	**1.38**
(Potatoes seed	M-4	2.22	417.49	4.17	0.53
treatment)	M-11	5.36	524.54	5.25	**1.02**
Fish Acute:	Flutolanil	495.33	4800	48	**10.3**
2760 g product/ha	M-4	16.63	417.49	4.17	**3.99**
(Flower bulbs)	M-11	40.16	524.54	5.25	**7.65**
Fish Chronic					
368 g product/ha	Flutolanil	66.04	233	23.3	**2.83**
(Potatoes seed	M-4	2.22	20.27	2.03	**1.09**
treatment)	M-11	5.36	25.46	2.55	**2.10**
Fish Chronic	Flutolanil	495.33	233	23.3	**21.3**
2760 g product/ha	M-4	16.63	20.27	2.03	**8.19**
(Flower bulbs)	M-11	40.16	25.46	2.55	**15.7**
Aquatic invertebrate					
Acute:	Flutolanil	66.04	130	1.30	**50.8**
368 g product/ha	M-4	2.22	11.3	0.11	**19.6**
(Potatoes seed	M-11	5.36	14.2	0.14	**37.7**
treatment)					
Aquatic invertebrate					
Acute:	Flutolanil	495.33	130	1.30	**381**
2760 g product/ha	M-4	16.63	11.3	0.11	**147**
(Flower bulbs)	M-11	40.16	14.2	0.14	**283**
Aquatic invertebrate					
Chronic	Flutolanil	66.04	3.97	0.40	**166**
368 g product/ha	M-4	2.22	0.35	0.03	**64.3**
(Potatoes seed	M-11	5.36	0.43	0.04	**124**
treatment)					

Test type / Application rate (Crop)	Substance	FOCUS Step 1 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]*	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Aquatic invertebrate Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	495.33	3.97	0.40	**1248**
	M-4	16.63	0.35	0.03	**482**
	M-11	40.16	0.43	0.04	**926**
Chironomid Chronic 368 g product/ha (Potatoes seed treatment)	Flutolanil	66.04	1000	100	0.66
	M-4	2.22	86.98	8.698	0.26
	M-11	5.36	109.28	10.93	0.49
Chironomid Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	495.33	1000	100	**4.95**
	M-4	16.63	86.98	8.698	**1.91**
	M-11	40.16	109.28	10.93	**3.67**

Test type / Application rate (Crop)	Substance	FOCUS Step 1 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]*	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC Ratio
Algae Chronic 368 g product/ha (Potatoes seed treatment)	Flutolanil	66.04	> 3200	> 320	< 0.21
	M-4	2.22	> 278.3	> 27.83	< 0.08
	M-11	5.36	> 349.69	> 34.97	< 0.15
Algae Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	495.33	> 3200	> 320	**< 1.55**
	M-4	16.63	> 278.3	> 27.83	< 0.60
	M-11	40.16	> 349.69	> 34.97	**< 1.15**

* Metabolite endpoints calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis, (EFSA, 2013)

Table 9.4-7 FOCUS Step 2: $RAC_{sw, ac}$ and $RAC_{sw, ch}$ values for flutolanil and metabolites compared to $PEC_{sw;max}$ values

Test type / Application rate (Crop)	Substance	FOCUS Step 2 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]*	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Acute: 368 g product/ha (Potatoes seed treatment)	Flutolanil	25.73	4800	48	0.53
	M-11	2.14	524.54	5.25	0.41
Fish Acute: 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	4800	48	**4.02**
	M-4	6.63	417.49	4.17	**1.59**
	M-11	16.02	524.54	5.25	**3.05**
Fish Chronic 368 g product/ha (Potatoes seed treatment)	Flutolanil	25.73	233	23.3	**1.10**
	M-4	0.88	20.27	2.03	0.43
	M-11	2.14	25.46	2.55	0.84
Fish Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	233	23.3	**8.28**
	M-4	6.63	20.27	2.03	**3.27**
	M-11	16.02	25.46	2.55	**6.28**
Aquatic invertebrate Acute: 368 g product/ha (Potatoes seed treatment)	Flutolanil	25.73	130	1.3	**19.8**
	M-4	0.88	11.3	0.11	**7.78**
	M-11	2.14	14.2	0.14	**15.1**
Aquatic invertebrate Acute: 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	130	1.30	**148**
	M-4	6.63	11.3	0.11	**58.6**
	M-11	16.02	14.2	0.14	**113**

Test type / Application rate (Crop)	Substance	FOCUS Step 2 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]*	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Aquatic invertebrate Chronic 368 g product/ha (Potatoes seed treatment)	Flutolanil	25.73	3.97	0.40	**64.8**
	M-4	0.88	0.35	0.03	**25.5**
	M-11	2.14	0.43	0.04	**49.3**
Aquatic invertebrate Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	3.97	0.40	**482**
	M-4	6.63	0.35	0.03	**192**
	M-11	16.02	0.43	0.04	**369**
Chironomid Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	1000	100	**1.93**
	M-4	6.63	86.98	8.698	0.76
	M-11	16.02	109.28	10.93	**1.47**
Algae Chronic 2760 g product/ha (Flower bulbs)	Flutolanil	192.97	> 3200	> 320	< 0.60
	M-11	16.02	> 349.69	> 34.97	< 0.46

SEU: South Europe

* Metabolite endpoints calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis, (EFSA, 2013)

A potential risk for the parent compound in both types of applications was observed for fish, aquatic invertebrates and algae, therefore further PEC_{sw} simulations at FOCUS Step 3 were required.

FOCUS Step 3

Predicted environmental concentrations in surface water and sediment were calculated at FOCUS Step 3 for flutolanil and M-4 and M-11 for the use in potato (Table 9.4-8) and flower bulbs (Table 10.2-10). Worst-case PEC_{sw} values were used as two sets (One evaluation considered a DegT50water 1000 days and DegT50sed 225 days (total system) and the other considered a DegT50water of 225 days (total system) and DegT50sed of 1000 days) evaluations were conducted according to FOCUS requirements (see B.8 for details).

Moreover, the FOCUS Step 3 PEC_{sw} for M-11 for scenario D4 pond (2.795 µg/L) is higher than PEC_{sw} of FOCUS step 2 (2.14 µg/L). This only affects the acute and chronic risk assessment for fish for the use in potatoes: PEC/RAC_{acute} is 0.53, and the risk is considered acceptable, $PEC/RAC_{chronic}$ is **1.10**

and thus, there is a chronic risk for fish for the metabolite M-11 for the scenario D4 Pond in the use in potatoes. This should be addressed by the applicant.

Table 9.4-8 Maximal FOCUS STEP 3 PEC_{sw} and PEC_{sed} values following application of MONCUT 40 SC (flutolanil) to potato (dose 368 g/ha)

Scenario	Flutolanil	Metabolite M-4	Metabolite M-11
	Step 3 PEC_{sw} (µg/L)	Step 3 PEC_{sw} (µg/L)	Step 3 PEC_{sw} (µg/L)
D3_Ditch	< 0.000001	< 0.000002	1.814
D4_Pond	0.027	0.013	2.795*
D4_Stream	0.048	0.014	1.174
D6_Ditch (E)	0.035	0.011	1.256
D6_Ditch (L)	0.091	0.012	1.277
R1_Pond	< 0.000001	< 0.000001	< 0.000001
R1_Stream	< 0.000001	< 0.000001	< 0.000001
R2_Stream	< 0.000001	< 0.000001	< 0.000001
R3_Stream	< 0.000001	< 0.000001	< 0.000001

(E) Early, (L) Late

* Value is higher than FOCUS Step 2 (Southern) PECsw

Table 9.4-9 Maximal FOCUS STEP 3 PEC_{sw} and PEC_{sed} values following application of MONCUT 40 SC (flutolanil) to flower bulbs (dose 2760 g/ha)

Scenario	Flutolanil	Metabolite M-4	Metabolite M-11
	Step 3 PEC_{sw} (µg/L)	Step 3 PEC_{sw} (µg/L)	Step 3 PEC_{sw} (µg/L)
D3_Ditch	24.99	0.001	12.75
D4_Pond	2.242	0.163	20.74*
D4_Stream	14.95	0.158	8.33
D6_Ditch (E)	25.25	0.097	7.209
D6_Ditch (L)	25.25	0.097	7.209
R1_Pond	2.763	0.008	0.011
R1_Stream	12.51	0.014	0.045
R2_Stream	16.53	0.01	0.096
R3_Stream	17.49	0.021	0.055
R4_Stream	13.81	0.013	0.056

(E) Early, (L) Late

* Value is higher than FOCUS Step 2 (Southern) PECsw

FOCUS Step 3 PEC_{sw} for the different scenarios were compared with the RAC values (Table 9.4-10, 11 and 12).

Table 9.4-10 FOCUS Step 3: $RAC_{sw, ac}$ and $RAC_{sw, ch}$ values, compared to $PEC_{sw;max}$ values for flutolanil

Flutolanil Test type/ Application rate	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Acute (application rate 1 × 2760 g/ha)	D3_Ditch	24.99	4800	48	0.52
	D4_Pond	2.242			0.05
	D4_Stream	14.95			0.31
	D6_Ditch (E)	25.25			0.53
	D6_Ditch (L)	25.25			0.53
	R1_Pond	2.763			0.06
	R1_Stream	12.51			0.26
	R2_Stream	16.53			0.34
	R3_Stream	17.49			0.36
	R4_Stream	13.81			0.29
Fish Chronic (application rate 1 × 368 g/ha)	D3_Ditch	< 0.000001	233	23.3	< 0.01
	D4_Pond	0.027			< 0.01
	D4_Stream	0.048			< 0.01
	D6_Ditch (E)	0.035			< 0.01
	D6_Ditch (L)	0.091			< 0.01
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01

Fish Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	24.99	233	23.3	**1.07**
	D4_Pond	2.242			0.096
	D4_Stream	14.95			0.64
	D6_Ditch (E)	25.25			**1.09**
	D6_Ditch (L)	25.25			**1.09**
	R1_Pond	2.763			0.12
	R1_Stream	12.51			0.54
	R2_Stream	16.53			0.71
	R3_Stream	17.49			0.75
	R4_Stream	13.81			0.59
Aquatic invertebrates Acute (application rate 1 × 368 g/ha)	D3_Ditch	< 0.000001	130	1.30	< 0.01
	D4_Pond	0.027			0.02
	D4_Stream	0.048			0.04
	D6_Ditch (E)	0.035			0.03
	D6_Ditch (L)	0.091			0.07
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
Aquatic invertebrates Acute (application rate 1 × 2760 g/ha)	D3_Ditch	24.99	130	1.30	**19.2**
	D4_Pond	2.242			**1.72**
	D4_Stream	14.95			**11.5**
	D6_Ditch (E)	25.25			**19.4**
	D6_Ditch (L)	25.25			**19.4**
	R1_Pond	2.763			**2.13**
	R1_Stream	12.51			**9.62**
	R2_Stream	16.53			**12.7**
	R3_Stream	17.49			**13.5**
	R4_Stream	13.81			**10.6**

Aquatic invertebrates Chronic (application rate 1 × 368 g/ha)	D3_Ditch	< 0.000001	3.97	0.40	< 0.01
	D4_Pond	0.027			0.07
	D4_Stream	0.048			0.12
	D6_Ditch (E)	0.035			0.09
	D6_Ditch (L)	0.091			0.22
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01

Flutolanil Test type/ Application rate	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Aquatic invertebrates Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	24.99	3.97	0.40	**10.0**
	D4_Pond	2.242			**5.61**
	D4_Stream	14.95			**37.4**
	D6_Ditch (E)	25.25			**63.1**
	D6_Ditch (L)	25.25			**63.1**
	R1_Pond	2.763			**6.91**
	R1_Stream	12.51			**31.3**
	R2_Stream	16.53			**41.3**
	R3_Stream	17.49			**43.7**
	R4_Stream	13.81			**34.5**
Chironomid Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	24.99	1000	100	0.25
	D4_Pond	2.242			0.02
	D4_Stream	14.95			0.15
	D6_Ditch (E)	25.25			0.26
	D6_Ditch (L)	25.25			0.26
	R1_Pond	2.763			0.03
	R1_Stream	12.51			0.13
	R2_Stream	16.53			0.17
	R3_Stream	17.49			0.17
	R4_Stream	13.81			0.14

(E) Early, (L) Late

Comparison of the FOCUS Step 3 PEC_{sw} with the RAC indicated an acceptable risk for aquatic organisms except for the chronic risk of flutolanil to fish for the application in flower bulbs for the

scenario D3 (ditch) and D6 (ditch) and for all flower bulb scenarios for the acute and chronic risk of flutolanil to aquatic invertebrates, and therefore, a risk for flutolanil remains for the use in flower bulbs.

Table 9.4-11 FOCUS Step 3: $RAC_{sw, ac}$ and $RAC_{sw, ch}$ values, compared to $PEC_{sw;max}$ values for M-4 metabolite

M-4 Metabolite Test type/ Application rate	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L] *	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Acute (application rate 1 × 2760 g/ha)	D3_Ditch	0.001	417.49	4.17	< 0.01
	D4_Pond	0.163			0.04
	D4_Stream	0.158			0.04
	D6_Ditch (E)	0.097			0.02
	D6_Ditch (L)	0.097			0.02
	R1_Pond	0.008			< 0.01
	R1_Stream	0.014			< 0.01
	R2_Stream	0.01			< 0.01
	R3_Stream	0.021			< 0.01
	R4_Stream	0.013			< 0.01
M-4 Metabolite Test type/ Application rate	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L] *	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	0.001	20.27	2.03	< 0.01
	D4_Pond	0.163			0.08
	D4_Stream	0.158			0.08
	D6_Ditch (E)	0.097			0.05
	D6_Ditch (L)	0.097			0.05
	R1_Pond	0.008			< 0.01
	R1_Stream	0.014			< 0.01
	R2_Stream	0.01			< 0.01
	R3_Stream	0.021			0.01
	R4_Stream	0.013			< 0.01
Aquatic invertebrates	D3_Ditch	< 0.000001	11.3	0.11	< 0.01
	D4_Pond	0.027			0.24

Acute (application rate 1 × 368 g/ha)	D4_Stream	0.048			0.42
	D6_Ditch (E)	0.035			0.03
	D6_Ditch (L)	0.091			0.81
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
	R3_Stream	0.021			0.19
	R4_Stream	0.013			0.12
	R4_Stream	0.013			0.12
Aquatic invertebrate Acute (application rate 1 × 2760 g/ha)	D3_Ditch	0.001	11.3	0.11	< 0.01
	D4_Pond	0.163			**1.44**
	D4_Stream	0.158			**1.40**
	D6_Ditch (E)	0.097			0.86
	D6_Ditch (L)	0.097			0.86
	R1_Pond	0.008			0.71
	R1_Stream	0.014			0.12
	R2_Stream	0.01			0.09
	R3_Stream	0.021			0.19
	R4_Stream	0.013			0.12
	R4_Stream	0.013			0.12
	R4_Stream	0.013			0.12
Aquatic invertebrates Chronic (application rate 1 × 368 g/ha)	D3_Ditch	< 0.000001	0.35	0.03	< 0.01
	D4_Pond	0.027			0.78
	D4_Stream	0.048			**1.39**
	D6_Ditch (E)	0.035			**1.01**
	D6_Ditch (L)	0.091			**2.63**
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
	R3_Stream	0.021			0.61
	R4_Stream	0.013			0.38
	R4_Stream	0.013			0.38
Aquatic invertebrate Chronic (application rate 1 × 2760	D3_Ditch	0.001	0.35	0.03	**0.29**
	D4_Pond	0.163			**4.72**
	D4_Stream	0.158			**4.57**
	D6_Ditch (E)	0.097			**2.81**
	D6_Ditch (L)	0.097			**2.81**

g/ha)	R1_Pond	0.008		0.23
	R1_Stream	0.014		0.41
	R2_Stream	0.01		0.29
	R3_Stream	0.021		0.61
	R4_Stream	0.013		0.38

(E) Early, (L) Late

* Metabolite endpoints calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis, (EFSA, 2013)

Comparison of the FOCUS Step 3 PEC_{sw} for the M-4 metabolite with the RAC indicated an acceptable risk for fish and the acute risk for aquatic invertebrates for the application in potatoes, but not for the acute risk of M4 to aquatic invertebrates for the application in flower bulbs for the scenarios D4 Pond and D4 Stream and for the chronic risk for aquatic invertebrates for the application in potatoes for the scenarios D4 Stream and D6 Ditch (E and L) and for the application in flower bulbs for the scenarios D3 Ditch, D4 Pond, D4 Strean and D6 Ditch (E and L), and therefore, a risk for M-4 remains for the application in potatoes and flower bulbs.

Table 9.4-12 FOCUS Step 3: $RAC_{sw, ac}$ and $RAC_{sw, ch}$ values, compared to $PEC_{sw;max}$ values for M-11 metabolite

M-11 Metabolite Test type/ Application rate	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L] *	$RAC_{sw, ac}$ (= acute endpoint/100) or $RAC_{sw, ch}$ (= chronic endpoint/10)	PEC/RAC ratio
Fish Acute (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	524.54	5.25	**2.43**
	D4_Pond	20.74			**3.95**
	D4_Stream	8.33			**1.59**
	D6_Ditch (E)	7.209			**1.37**
	D6_Ditch (L)	7.209			**1.37**
	R1_Pond	0.011			< 0.01
	R1_Stream	0.045			< 0.01
	R2_Stream	0.096			0.018
	R3_Stream	0.055			0.010
	R4_Stream	0.056			0.011
Fish Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	25.46	2.55	**5.00**
	D4_Pond	20.74			**8.13**
	D4_Stream	8.33			**3.27**
	D6_Ditch (E)	7.209			**2.83**

	D6_Ditch (L)	7.209			**2.83**
	R1_Pond	0.011			0.004
	R1_Stream	0.045			0.018
	R2_Stream	0.096			0.038
	R3_Stream	0.055			0.022
	R4_Stream	0.056			0.022
Aquatic invertebrates Acute (application rate 1 × 368 g/ha)	D3_Ditch	1.814	14.2	0.14	**12.8**
	D4_Pond	2.795*			**19.7**
	D4_Stream	1.174			**8.26**
	D6_Ditch (E)	1.256			**8.84**
	D6_Ditch (L)	1.277			**8.90**
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
Aquatic invertebrate Acute (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	14.2	0.14	**89.8**
	D4_Pond	20.74			**146**
	D4_Stream	8.33			**58.6**
	D6_Ditch (E)	7.209			**50.7**
	D6_Ditch (L)	7.209			**50.7**
	R1_Pond	0.011			0.08
	R1_Stream	0.045			0.32
	R2_Stream	0.096			0.68
	R3_Stream	0.055			0.39
	R4_Stream	0.056			0.39
Aquatic invertebrates Chronic (application rate 1 × 368 g/ha)	D3_Ditch	1.814	0.43	0.04	**41.8**
	D4_Pond	2.795*			**64.4**
	D4_Stream	1.174			**27.1**
	D6_Ditch (E)	1.256			**29.0**
	D6_Ditch (L)	1.277			**29.4**
	R1_Pond	< 0.000001			< 0.01
	R1_Stream	< 0.000001			< 0.01
	R2_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01
	R3_Stream	< 0.000001			< 0.01

M-11 Metabolite	Scenario-route	FOCUS Step 3 PEC_{sw} [µg/L]	Toxicity endpoint [µg/L]	$RAC_{sw, ac}$ (= acute endpoint/100) or	PEC/RAC Ratio

Test type/ Application rate			*	$RAC_{sw, ch}$ (= chronic endpoint/10)	
Aquatic invertebrate Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	0.43	0.04	**294**
	D4_Pond	20.74			**478**
	D4_Stream	8.33			**192**
	D6_Ditch (E)	7.209			**166**
	D6_Ditch (L)	7.209			**166**
	R1_Pond	0.011			0.25
	R1_Stream	0.045			**1.04**
	R2_Stream	0.096			**2.21**
	R3_Stream	0.055			**1.27**
	R4_Stream	0.056			**1.29**
Chironomid Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	109.28	10.93	**1.167**
	D4_Pond	20.74			**1.898**
	D4_Stream	8.33			0.762
	D6_Ditch (E)	7.209			0.660
	D6_Ditch (L)	7.209			0.660
	R1_Pond	0.011			0.001
	R1_Stream	0.045			0.004
	R2_Stream	0.096			0.009
	R3_Stream	0.055			0.005
	R4_Stream	0.056			0.005
Algae Chronic (application rate 1 × 2760 g/ha)	D3_Ditch	12.75	> 349.69	> 34.97	< 0.36
	D4_Pond	20.74			< 0.59
	D4_Stream	8.33			< 0.238
	D6_Ditch (E)	7.209			< 0.206
	D6_Ditch (L)	7.209			< 0.206
	R1_Pond	0.011			< 0.003
	R1_Stream	0.045			< 0.001
	R2_Stream	0.096			< 0.003
	R3_Stream	0.055			< 0.002
	R4_Stream	0.056			< 0.002

(E) Early, (L) Late

* Metabolite endpoints calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis, (EFSA, 2013)

Comparison of the FOCUS Step 3 PEC_{sw} for the M-11 metabolite with the RAC indicated an unacceptable acute and chronic risk for aquatic invertebrates for the scenarios D3 Ditch, D4 Pond, D4 Stream and D6 Ditch (E andL) for the application in potatoes. For the application in flower bulbs the risk for algae is considered acceptable, but not for the acute and chronic risks for fish (scenario D3 Ditch, D4 Pond, D4 stream and D6 Ditch (E and L)) and the acute (scenario D3 Ditch, D4 Pond, D4 Stream, D6 Ditch (E and L)) and chronic (all scenario scenarios except R1 Pond) risks for aquatic invertebrates, as well as the chronic risk for chironomids (scenario D3 Ditch, D4 Pond). Therefore, a risk for M-11 remains for the application in potatoes and flower bulbs.

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees

The available toxicity data for flutolanil on bees are listed in the EFSA (2008) review report (EFSA Journal 2008; 126, 1-63) and summarised in **Table 9.5.1-1** below.

Table 9.5.1-1 Summary of toxicity data on bees

Species	Test substance	Time-scale (Test type)	End point	Toxicity	Data point /Author, year
Honey bee (*Apis mellifera* L.)	Flutolanil Technical	48h, Acute oral	LD_{50}	**> 208.7 µg a.s./bee**	CA 8.3.1.1.1-01 Schmitzer, S., 2001
		48h, Acute contact	LD_{50}	**> 200 µg a.s./bee**	
	Flutolanil 40 SC[1]	10 d, Chronic oral	LDD_{50} (95% CI) LDD_{20} (95% CI) LDD_{10} (95% CI)	**35.1 µg a.s./bee/day** (29.0 – 42.7) 18.3 µg a.s./bee/day (13.2 – 22.7) 13.0 µg a.s./bee/day (8.4-17.0)	CA 8.3.1.2-01 Ruhland, S., 2016, amended 2018
	Flutolanil 40 SC[1]	22 d, Larval toxicity	NOED LD/ED_{10} (95% CI) LD/ED_{20} (95% CI) LD/ED_{50} (95% CI)	**10 µg a.s./larva** 9.4 (6.5-14.0) µg a.s./larva 10.6 (7.1-15.9) µg a.s./larva 11.7 (10.6-13.0) µg a.s./larva	CA 8.3.1.3-01 Scheller, K., 2016, amended 2018
	Monarch 40 SC[1]	8 d, Semi-field	NOEC	> 11200 g in 400 L/ha	CP 10.3.1.6-01 Kling, A., 2003

Note: Endpoints in **bold** are the agreed endpoints retained for the risk assessment in line with the EFSA Conclusion (2008)

[1] Flutolanil 40 SC and Monarch 40 SC are equivalent to the representative formulation MONCUT 40 SC

CI = Confidence Intervals

B.9.5.1.1 Acute oral toxicity to bees

Please refer to Document M-CA 8.3.1.1.1.

B.9.5.1.2 Acute contact toxicity to bees

Please refer to Document M-CA 8. 3.1.1.2.

B.9.5.1.3 Chronic toxicity to bees

Please refer to Document M-CA 8.3.1.2

B.9.5.1.4 Effects on honey bee development and other honey bee life stages

Please refer to Document M-CA 8.3.1.3

B.9.5.1.5 Sub-lethal effects

No data have been submitted. The proposed uses of flutolanil are once per year as pre-emergence fungicide. Therefore, it is considered that bees will not be exposed and any further chronic tests are not required.

B.9.5.1.6 Cage and tunnel tests

No data have been submitted. The proposed uses of flutolanil are once per year as pre-emergence fungicide. Therefore, it is considered that bees will not be exposed and any further chronic tests are not required.

B.9.5.1.7 Field tests with honey bees

Study CP 10.3.1.6-01

Report:	**CP 10.3.1.6-01. Kling, A., 2003**
Title:	Assessment of Side Effects of Monarch 40 SC on the Honey Bee (*Apis mellifera* L.) in the Semi-Field
Report no.:	Project no: 20021306/01-BZEU (N-3027)
Published:	No
GLP:	Yes
Guidelines:	OEPP/EPPO Guideline No. 170(3) (OEPP/EPPO, 2001)
Deviations:	Due to a high infestation with *varroa* in a colony, replicate 3 of the control group was excluded from further evaluations. Minor deviations from the study protocol occurred, with no effect on the validity of the study.
Comment:	Equivalent to OECD 75, 2007. The validity criteria were met and the study is considered acceptable. Although the formulation used in this study is slightly different to the current specification, the results are still considered a valid and acceptable for the assessment of honey bee toxicity of MONCUT 40 SC.
RMS Conclusion	A single treatment of Monarch 40 EC two weeks before full flowering resulted in a slight, statistically significant but transient reduction in flight intensity, but this did not affect survival or brood development.

Executive Summary

The effects of Monarch 40 SC (EXP10066A) containing the active substance flutolanil at nominal 449 g/L, were tested on the honey bee *(Apis mellifera* L.) under semi-field conditions after 8 days of exposure. Separate tents with flowering *Phacelia* (*Phacelia tanacetifolia* Benth) were used for the different treatments of the test (Control, Toxic standard and Monarch 40 SC treatment). The crop was applied with the dose of 11200 g in 400 L water/ha two weeks before introduction of the bee colonies. Each treatment group contained bee colonies; approx. 4000 to 5000 bees in tunnel tents were placed over the plots with flowering *Phacelia tanacetifolia*. The exposure of the bee colonies started on the day of application of the control and the toxic standard at full flowering of the crop.
Mortality, behaviour and foraging activity (number of foraging bees/m^2 flowering *Phacelia*) was assessed after the treatment; condition of the colonies and the development of the bee brood was assessed before and after treatment.
According to the results of this study, a slight effect on the flight intensity was observed during the first 6 days after start of exposure; it was therefore concluded that Monarch 40 SC applied two weeks before full flowering of the *Phacelia* crop at an application rate of 11200 g in 400 L/ha did not have any effects on the mortality, behaviour and brood development of honey bees under semi-field conditions.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Monarch 40 SC (EXP10066A) (Flutolanil 449 g/L)
Batch no.: OP210612
Purity (flutolanil): 452 g/L, analysed (449 g/L nominal)
CAS no.: 66332-96-5
Description: Opaque liquid / white
Date of expiry: 11 May 2003

2. Reference material: Perfekthion (Dimethoate) / BAS 152 11l
Batch: 99-1
Purity: 417.5 g a.s./L (analysed)
Ref. concentration: 650 g product/ha in 400 L water/ha

3. Test organism: Honey bee (*Apis mellifera*) (Hymenoptera, Apidae)
Size of combs: "Zandermaß": 420 mm x 220 mm (containing approx. 4000-5000 bees)

4. Treatment: 0 (control), a toxic standard at a rate of 650 g product/ha in 400 L water/ha and a test substance group at the test rate equivalent to 11200 g/ha in 400 L water/ha

5. Test location: semi-field test located in the south of Germany (near Pforzheim)
Crop used: *Phacelia tanacetifolia* Benth
Test cages: Tents (8m x 5m x 3.5m) covering area 40 m^2 per tent, covered with light plastic gauze (mesh size: 1.5mm)
Replicates: 3 replicates per group, 9 tunnel tents

6. Environmental conditions (at application):
Temperature: 22.4 – 27.8°C
Humidity: 40 – 69%

Wind speed: 0-1 m/s

Clouding: 20%

Precipitation: 0 mm on the day of application, 6.3 mm on the 6th day after application of the treatment; 1.6 mm on the day following application for the control and the toxic standard.

B. STUDY DESIGN AND METHODS

1. In-life phase: Aug 14 to Sept 07, 2002

2. Test organism assignment and treatment

For the test, small healthy colonies with three combs containing approx. 4000 to 5000 bees were used. All nuclei were produced at the same time. The corresponding queens originated from one breeding line in order to guarantee uniform bee material in all treatment groups. Bees were free from Nosema, at least one honey and pollen comb was added and two brood combs containing eggs, larvae and capped cells.

The colonies were introduced into the test cages on the evening before the application of the control and the toxic standard. Spray treatment of the test substance was applied two weeks before full flowering of the *Phacelia* crop. The control and the toxic standard were applied during bee-flight activity in the flowering crop.

Arrangement of the different treatment groups during the semi-field test:

Wooden bee traps (38 cm x 38 cm x 22 cm) with gauze on bottom and on 50% of the top were attached to the entrance of the hives in order to register those dead bees which were carried out of the hives by the bees.

3. Dose preparation

The Monarch 40 SC (Flutolanil 449 g/L) was prepared just before application and was applied using an appropriate sprayer equipment at an application rate of 11200 g in 400 L water/ha. The test substance was applied two weeks before full flowering of the crop *Phacelia tanacetifolia*. At full flowering of the crop a second group was treated with tap water which served as control. As toxic standard "Perfekthion" (dimethoate) was applied at a concentration of 650 g product/ha in 400 L water/ha.

4. Measurements and observations

Mortality, behaviour and foraging activity were assessed after the treatment; condition of the colonies and the development of the bee brood was assessed before and after treatment. At each assessment time the number of bees that were both foraging on flowering *Phacelia* and flying over the crop were counted on a square of 1 m^2 in each tent. The condition of the colonies and the development of the bee brood was checked one day before start of bee exposure in the tents (the day of set-up of the colonies) and 9 days after start of bee exposure. The amount of eggs, larvae and capped brood was estimated in percent of total brood population for each type of brood. Also, in order to assess any effects of the test substance, the following parameters were assessed:

• Strength of the colony (number of combs covered with bees)
• Presence of a healthy queen (presence of eggs, presence of queen cells)
• Estimate of the pollen storage area and area with nectar
• Estimate of the area containing eggs, larvae and capped cells

5. Statistics

The statistical software program SAS version 8 was used for the statistical analysis. The data of flight activity were analysed for significant differences in comparison to the control group. The normality of data was tested following Shapiro Wilk test. If data were normally distributed, differences of the test substance treatment to the control were analysed by using the Dunnett test; if not, they were analysed by the pairwise U-test according to Mann-Whitney. A statistical analysis of the data on mortality was not performed because the values of the test substance treatment were on a lower or similar level compared to the control group on all assessment dates.

II. RESULTS AND DISCUSSION

A. Biological data

The results showed that the mean daily mortality per replicate in the test substance treatment group was either similar or lower compared to the control group indicating no significant effect caused by the test substance. On the start of exposure, a significantly reduced flight intensity was observed in the test substance treatment group compared to the control. No other treatment related significant effects were observed on the honey bees under semi-field conditions.

B. Mortality

Mortality of *Apis mellifera* exposed to Monarch 40 SC (Flutolanil 449 g/L)

Evaluation Day	Mean - Monarch 40 SC[1]		Mean - Control[1]		Mean - Toxic Standard[1]	
	BT	E	BT	E	BT	E
1	2.3	3.7	0.0	6.0	63.3	20.0
2	1.7	9.0	1.5	13.0	270.3	34.7
3	1.0	6.3	4.0	7.5	93.3	22.7
4	1.3	23.0	1.0	26.5	7.7	20.0
5	2.7	12.7	3.0	18.5	15.7	27.0
6	3.3	4.3	10.5	10.0	6.3	25.0
7	1.0	11.3	3.5	11.0	7.0	14.3
8	1.7	8.0	2.5	3.5	0.3	9.0
Mean	**1.9**	**9.8**	**3.3**	**12.0**	**58.0**	**21.6**

[1] Values expressed in mean number of dead bees found in 3 replicates for Monarch 40 SC and the toxic standard, 2 replicates for the control

BT Bee traps; E Edge of the treated *Phacelia* area

C. Bee flight intensity

Mean flight intensity of *Apis mellifera* (mean number of bees / m^2 flowering *Phacelia*)

Evaluation Day	Mean number of bees/m^2 and day		
	Monarch 40 SC[1]	Control[1]	Toxic Standard[1]
1	7.3*	11.5	0.0*
2	6.7	8.0	0.7*
3	1.3	2.0	0.3
4	2.0*	4.0	0.3*
5	4.3	10.0	2.0
6	10.0	13.0	2.7*
7	7.7	6.5	0.7*
8	11.0	10.5	1.3*
Mean	**6.3**	**8.2**	**1.0**

[1] Values expressed in mean number of dead bees found in 3 replicates for Monarch 40 SC and the toxic standard, 2 replicates for the control

* significantly different compared to the control (Dunnett-test; p = 0.05; based on normal distribution)

D. Bee brood

Compared to the brood assessment at the beginning of the test, the strength of the colonies in the different treatment groups remained either on the same level or was slightly increased or decreased until the brood assessment after the exposure period. No test substance related effects on the brood development were observed during this test and the results are presented below.

Mean brood development

Measurement	Mean number from colony replicates for each group[1]		
	Monarch 40 SC	**Control**	**Toxic Standard**
Before exposure			
Colony strength (No. of combs covered by adult bees)	2.7	2.5	2.5
No. of combs containing brood	2.0	2.0	2.0
Average comb area containing eggs (%)	10.8	11.3	15.0
Average comb area containing larvae (%)	13.3	7.5	6.7
Average comb area containing capped brood (%)	14.2	21.3	11.7
After exposure			
Colony strength (No. of combs covered by adult bees)	2.5	2.8	2.2
No. of combs containing brood	2.0	1.5	1.7
Average comb area containing eggs (%)	9.2	6.3	12.5
Average comb area containing larvae (%)	10.8	12.5	12.5
Average comb area containing capped brood	11.7	11.3	8.3

(%)			

[1] Values expressed in mean number from 3 replicates for Monarch 40 SC and the toxic standard groups, 2 replicates for the control group

E. Behaviour of the Bees

No behavioural differences were observed in the Monarch 40 SC treatment group compared to the control group throughout the entire test period.

III. CONCLUSION

Under semi-field conditions, it was concluded that Monarch 40 SC (Flutolanil 449 g/L) applied at a rate of 11200 g in 400 L water/ha two weeks before the full flowering *Phacelia* crop, did not have any effects on the mortality, behaviour and brood development of honey bees (*Apis mellifera*). A slight effect on the flight intensity was observed during the following five days after the start of exposure.

Comments by RMS

The study was conducted in general agreement with the EPPO 170 guideline. A major deviation was the number of replicates evaluated for the control (i.e. 2 instead of at least 3). This was caused by high infestation of the 3rd replicate with *Varroa*, and may have affected the statistical power of the study, but does not invalidate the study as the effect of the treatment was evident. No effects were observed for mortality, behaviour or brood development, but flight intensity (foraging activity) was slightly reduced during the first 6 days (although only statistically significant on day 1 and day 4 only). Flight intensity was lower in all groups on days 3 and 5, which may have been caused by unfavourable weather conditions (i.e. 70-100% cloud cover). The slight and transient effect on flight activity did affect survival or brood development.

In conclusion, a single treatment of Monarch 40 EC two weeks before full flowering resulted in a slight, statistically significant but transient reduction in flight intensity, but this did not affect survival or brood development. The conclusion as stated may be used in risk assessment.

Kling, A.	2003	Assessment of Side Effects of Monarch 40 SC on the Honey Bee (*Apis mellifera* L.) in the Semi-Field	Project no: 20021306/01-BZEU (N-3027)
Reliability			
General information			
Is a guideline method or modified guideline used?*	Yes		
Is the test performed under GLP conditions?*	Yes		
If applicable, are validity criteria fulfilled (e.g. control survival, growth, etc.)?	Yes		
Are appropriate controls performed (e.g. solvent control, negative and/or positive control)?	Yes		

* these criteria are of minor importance for study reliability, but may support study evaluation	
Test compound	
Is the test substance clearly identified with name or CAS-number? Are test results reported for the appropriate compound?	Yes
Is the purity of the test substance reported? Or, is the source of the test substance trustworthy?	Yes
If a formulation is used or if impurities are present: do other ingredients in the formulation exert an effect? Is the amount of test substance in the formulation known?	The effects, if any, may be attributed to the entire product; a.s. content is known.
Test organism	
Are the organisms well described (e.g. scientific name, weight, length, growth, age/life stage, strain/clone, gender if appropriate)?	Yes
Are the test organisms from a trustworthy source and acclimatized to test conditions? Have the organisms not been pre-exposed to test compound or other unintended stressors?	Yes
Exposure conditions	
Is the experimental system appropriate for the test substance, taking into account its physicochemical characteristics?	Yes
Is the experimental system appropriate for the test organism? Have conditions been stable during the test?	Yes
If appropriate, were exposure concentrations below the limit of water solubility (taking the use of a solvent into account)? If a solvent is used, is the solvent within the appropriate range and is a solvent control included?	Not applicable
Is a correct spacing between exposure concentrations applied?	Not applicable
Is the exposure duration defined?	Yes
If necessary, are chemical analyses adequate	Not applicable

to verify concentrations of the test substance over the duration of the study?	
Where applicable, is the biomass loading of the organisms in the test system within the appropriate range?	Not applicable
Statistical Design and Biological Response	
Is a sufficient number of replicates used? Is a sufficient number of organisms per replicate used for all controls and test concentrations?	One of the replicates for the control could not be evaluated due to infestation with *Varroa*, which may have affected the statistical power of the study. However, this was not considered to invalidate the study as the effects of the treatment were evident.
Are appropriate statistical methods used?	Yes
Is a concentration-response curve observed? Is the response statistically significant?	Not applicable
Are sufficient data available to check the calculation of endpoints and (if applicable) validity criteria (e.g., control data, concentration-response curves)?	Yes
Relevance of the study for Environmental Risk Assessment, appropriateness of study endpoints	
Exposure Relevance	
Is the substance tested representative and relevant for the substance being assessed?	Yes
Is the tested exposure scenario relevant for the substance?	Yes
Is the tested exposure scenario relevant for the species?	Yes
Biological relevance	
Is the species tested relevant for the compartment under evaluation?	Yes
Are the organisms tested relevant for the tested compound?	Yes
Are the reported endpoints appropriate for the regulatory purpose?	Yes
Are the reported endpoints appropriate for the investigated effects or the mode of action of the	Yes

test substance?	
Is the effect relevant on a population level?	Yes
Is the magnitude of effect statistically significant and biologically relevant for the regulatory purpose (e.g. EC10, EC50)?	Not applicable
Are appropriate life-stages studied?	Yes
Are the experimental conditions relevant for the tested species?	Yes
Is the exposure duration relevant and appropriate for the studied endpoints and species?	Yes
If recovery is studied, is this relevant for the framework for which the study is evaluated?	Not applicable
Concluding weight of evidence/proposed action	The study is both reliable and relevant without restrictions
Type of information (Fully acceptable, supporting information, not applicable)	Fully acceptable
Consideration/concluding score	Fully acceptable

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

Study CP 10.3.2.1-01

Report:	**CP 10.3.2.1-01 Nienstedt, K.M., 1999c**
Title:	EXP10066A: A Laboratory Acute Toxicity Test with the Ground Beetle, *Poecilus cupreus* L. (Coleoptera: Carabidae)
Report no.:	99-072-1013 (N-3018)
Published:	No
GLP:	Yes (OECD)
Guidelines:	IOBC 1992 & Draft Guideline of the Ring-Testing Group 1996
Deviations:	None reported
Comment:	The study has already been reviewed under Uniform Principles for the first approval of flutolanil under Directive 91/414/EEC. (DAR: B.9.5.1) All validity criteria were met and the study is considered to be acceptable. Although the formulation used in this study is different to the current specification, the results are still considered a valid and acceptable assessment for the ground beetle toxicity assessment of MONCUT 40 SC.
Previous evaluation	In DAR (2006) for original approval.
Remark by RMS	Considered acceptable at the time of original inclusion. The study summary from the DAR is replaced with an updated (extended) version. Evaluation from the DAR is

	copied as a whole without changes.
Conclusion	LR_{50} > 4500 g a.s./ha

Executive Summary

The effects on mortality and behaviour of EXP10066A to the predacious mite, *Poecilus cupreus*, were determined in a laboratory study. Mortality and behaviour were observed following exposure to the test substance as fresh residues. Three pairs (one male and one female per pairs, approximately six weeks old) per replicate were used in a two rate study design comprising two treatment rates and a control. Beetles, substrate and the initial feed were exposed to the test item via spray application for 14 days. Five replicates for the control, and for each treatment rate 450 and 4500 g a.s./ha (nominal) were used. Spray solutions were made up in deionised water and applied at a nominal rate of 400 L/ha. Mortality and behaviour (food consumption) were assessed and compared with corresponding parameters recorded in the untreated group at the end of the test.

No analysis for verification of achieved concentration was undertaken. Effects were reported based on nominal treatment rates. EXP10066A was considered to be harmless to *Poecilus cupreus*.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:** EXP10066A
Lot no.: OP980259
Purity: 464 g/L Flutolanil
Description: White opaque liquid

2. **Test organism:** *Poecilus cupreus*
Age: ~6-week old adults
Source: BTL, Sagerheide, Germany
Feeding: Fly pupae (*Musca domestica*)

3. **Treatment:** 0 (control), 450 and 4500 g a.s./ha (nominal)
Replication: 5 (3 males and 3 females per replicate)
Vehicle: Deionised water
Toxic Reference: Afugan 30 EC (pyrazophos)

4. **Test vessels:** 1L lidded (partially mesh) plastic vessel (17 × 12.5 × 6 cm) with a layer of moistened (45g water) silica sand (250 g)

5. **Environmental conditions**

Temperature: 18.5-21.0°C
Relative humidity: 72-89%
Photoperiod: 16:8 light:dark (730-1500 lux)

B. STUDY DESIGN AND METHODS

1. In-life phase: December 07 to December 21, 1998

2. Test organism assignment and treatment

Three pairs (1 male, 1 female per pair) were impartially introduced to the test units three days before application. All beetles were on the surface at the time of application and a barrier was placed on the inner sides of the test vessel. Beetles, sand and food were subjected to spray application.

Nominal treatment (g a.s./ha)	Number of replicates	Number of males per replicate	Number of females per replicate
0 (control)	5	3	3
450	5	3	3
4500	5	3	3
Afugan 30 EC 1.8L /ha Toxic reference	5	3	3

Beetles were fed one fly pupae per surviving adult at test initiation and on days 2, 4, 7 and 10.

3. Dose preparation

A primary stock solution of 11.25 g a.s./L was prepared. Spray solutions were made up in deionised water and either used directly or following dilution. Spray solutions were applied to test units by a calibrated laboratory sprayer at a nominal rate of 400 L/ha.

4. Measurements and observations

Mortality and behavioural changes were assessed at 2, 4, 6 and 24 hours after treatment and at 2, 4, 7, 10 and 14 days after treatment. Behaviour was recorded as follows:

-Normal behaviour, -Beetles buried in the sand, -Beetles on their backs with quivering legs, -Beetles on their backs with no movement9F[9], -Beetles with blocked mandibles, -Co-ordination problems, -Paralysed hind legs

5. Statistics

Test rate mortality was corrected for control mortality using Abbott's correction. Mortality data was subjected to the Fisher's exact test. Since the feeding rate data was normally distributed, ANOVA was used. Statistical analysis was undertaken using Statistica for Windows (StatSoft Inc.).

The IOBC scheme was used to evaluate the classification of EXP10066A from corrected mortality (M):

M Value	Classification
< 30%	Harmless
30-80%	Slightly harmful
80-99%	Moderately harmful
> 99%	Harmful

II. RESULTS AND DISCUSSION

A. Biological data

The evaluated parameters were mortality and behaviour. Results are presented below.

[9] Beetles found lying on their backs with no movement were moved to a distinct corner of the box. If no movement had occurred by the next observation period, the beetle was considered dead and was removed from the arena

Mortality

Nominal treatment (g a.s./ha)	Mortality (%)									Total Mortality	
	2 h	4 h	6 h	24 h	2 d	4 d	7 d	10 d	14 d	Male	Female
0 (control)	0	0	0	0	0	0	0	0	0	0	0
450	0	0	0	0	0	0	0	0	0	0	0
4500	0	0	0	0	0	0	0	3.3	3.3	6.7	0
Afugan 30 EC 1.8L /ha Toxic reference	0	0	0	3.3	83.3	93.3	93.3	93.3	93.3	86.7	100

Behavior

With the exception of the positive control beetle and the one dead beetle observed at 4500 g a.s./ha, all beetles, at all observations, were classed as “normal” or “buried in sand”.

Food Consumption

The average number of fly pupae consumed per beetle per day is given below.

Nominal treatment (g a.s./ha)	Food consumption (pupae/beetle/day)							
	Days 0-2	Days 2-4	Days 4-7	Days 7-10	Days 10-14	Mean	Total	% reduction
0 (control)	0.117	0.050	0.089	0.056	0.067	0.076	1.033	--
450	0.117	0.100	0.067	0.056	0.092	0.086	1.167	-13.97
4500	0.167	0.083	0.078	0.080	0.070	0.096	1.253	-26.47
Afugan 30 EC 1.8L /ha Toxic reference	0.063	0.000	0.000	0.167	0.000	0.046	0.625	39.34

B. Toxicity endpoint

The 48-day mortality endpoint for EXP10066A to *Poecilus cupreus* is presented in the following table.

Endpoints of the test item EXP10066A

Endpoint	Lethal rate (g a.s./ha)	48 hours
Mortality	LR_{50}	> 4500

III. CONCLUSION

EXP10066A was considered to be harmless to *Poecilus cupreus*.

Evaluation RMS (DAR 2006)

The study was well performed and reported and in compliance with GLP. However performed prior to establishing the current test guideline, the test proposal of BBA (Germany) was followed and the test is considered as acceptable.

Study CP 10.3.2.1-02

Report:	**CP 10.3.2.1-02 Nienstedt, K.M., 1999d**
Title:	Laboratory Toxicity Test with Spiders, *Pardosa* sp. (Araneae: Lycosidae)
Report no.:	10.13.042.272 (N-3019)
Published:	No
GLP:	Yes
Guidelines:	BBA Guideline part VI 1998
Deviations:	Light intensity not stated, no impact to validity Spray volume used 500 L/ha, guideline requires 400 L/ha, no impact to validity No moulting behaviour noted, no impact on validity of study.
Previous evaluation	In DAR (2006) for original approval.
Remark by RMS	Considered acceptable at the time of original inclusion. The study summary from the DAR is replaced with an updated (extended) version. Evaluation from the DAR is copied as a whole without changes.
Endpoint	LR_{50} > 4500 g a.s./ha

Executive Summary

The effects on mortality and behaviour of EXP10066A to the ground-dwelling spider, *Pardosa* sp., were determined in a laboratory study. Mortality and behaviour were observed following exposure to the test substance as fresh residues. Fifteen males and fifteen females were individually housed (a total of 30 replicates per rate) in a two rate study design comprising two treatment rates and a control. Spiders and substrate were exposed to the test item via spray application for 14 days. Thirty replicates for the control, and for each treatment rate 450 and 4500 g a.s./ha (nominal) were used. Spray solutions were made up in deionised water and applied at a nominal rate of 500 L/ha. Mortality and behaviour (food consumption) were assessed and compared with corresponding parameters recorded in the untreated group at the end of the test.

No analysis for verification of achieved concentration was undertaken. Effects were reported based on nominal treatment rates.

EXP10066A applied at 450 and 4500 g a.s./ha did not cause statistically significant effects on mortality and the feeding rate of *Pardosa* sp.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: EXP10066A
Lot no.: OP980259
Purity: 464 g/L Flutolanil
Description: White opaque liquid

2. Test organism: *Pardosa* sp.
Age: Subadult and adult
Source: Field collected in St. Pelagiberg, Switzerland
Collection date: March 03, 1999
Feeding: Wingless *Drosophila* sp.

3. **Treatment:** 0 (control), 450 and 4500 g a.s./ha (nominal)

Replication: 30 (15 males and 15 females replicated indivdually)

Vehicle: Deionised water

Toxic Reference: Karate 5 EC (λ-cyhalothrin)

4. **Test vessels:** Plastic vessel with meshed lid (9.4 × 9.4 × 6 cm) with a layer of moistened (23g water) quartz sand (125 g).

5. **Environmental conditions**

Temperature: 19.0-20.5°C

Relative humidity: 73-90%

Photoperiod: 16:8 light:dark

B. STUDY DESIGN AND METHODS

1. In-life phase: March 15 to March 29, 1999

2. Test organism assignment and treatment

Spiders were weighed and impartially introduced to the test units three days before application with distribution of weight being factored in. Spiders were not fed for this three-day period. A barrier was placed on the inner sides of the test vessel before spraying. Spiders and sand were subject to spray application.

Nominal treatment (g a.s./ha)	Number of replicates	Number of males per replicate	Number of females per replicate
0 (control)	15	1	-
	15	-	1
450	15	1	-
	15	-	1
4500	15	1	-
	15	-	1
2g λ-cyhalothrin /ha Toxic reference	15	1	-
	15	-	1

Spiders were fed five flies per surviving adult 1 day after application and each observation point thereafter.

3. Dose preparation

A primary stock solution of 9.0 g a.s./L was prepared. Spray solutions were made up in deionised water and either used directly or following dilution. Spray solutions were applied to test units by a calibrated laboratory sprayer at a nominal rate of 500 L/ha.

4. Measurements and observations

Mortality and behavioural changes were assessed at 2, 4 and 6 hours after treatment and at 1, 2, 3, 4, 7, 9, 10 and 14 days after treatment. Behaviour was recorded as follows:

Normal behaviour, Co-ordination problems, Alive but affected, Moribund, Dead

Food consumption was recorded 1, 2, 3, 4, 7, 9, 11 and 14 days after exposure.

5. Statistics

Test rate mortality was not corrected for control mortality as no control mortality occurred.

Mortality data was subject to the Fisher's exact test. Food consumption data was compared with Kruskal-Wallis ANOVA. Statistical analysis was undertaken using Statistica for Windows (StatSoft Inc.).

II. RESULTS AND DISCUSSION

A. Biological data

The evaluated parameters were mortality and behaviour. Results are presented below.

Mortality

Nominal treatment (g a.s./ha)	**MALES Mortality (%)**										
	2 h	**4 h**	**6 h**	**1 d**	**2 d**	**3 d**	**4 d**	**7 d**	**9 d**	**11d**	**14 d**
0 (control)	0	0	0	0	0	0	0	0	0	0	0
450	0	0	0	0	0	0	0	0	0	0	0
4500	0	0	0	0	0	0	0	6.7	6.7	6.7	6.7
2g λ-cyhalothrin /ha Toxic ref.	0	0	0	20	33.3	40	40	46.7	46.7	46.7	46.7
Nominal treatment (g a.s./ha)	**FEMALES Mortality (%)**										
	2 h	**4 h**	**6 h**	**1 d**	**2 d**	**3 d**	**4 d**	**7 d**	**9 d**	**11d**	**14 d**
0 (control)	0	0	0	0	0	0	0	0	0	0	0
450	0	0	0	0	0	0	0	0	0	0	0
4500	0	0	0	0	0	0	0	0	0	0	0
2g λ-cyhalothrin /ha Toxic ref.	0	0	0	13.3	26.7	40	40	40	40	40	40

Behavior

With the exception of the positive control spiders, at all observations, were classed as "normal".

Food Consumption

The average number of flies consumed per spider per day is given below.

Nominal treatment (g a.s./ha)	**MALES Food consumption (flies/spider/day)**								**Mean**
	Days 0-1	**Days 1-2**	**Days 2-3**	**Days 3-4**	**Days 4-7**	**Days 7-9**	**Days 9-11**	**Days 11-14**	
0 (control)	3.20	3.20	3.00	2.13	1.33	1.20	1.20	0.70	1.99
450	2.60	2.33	2.87	3.80	1.51	1.40	1.40	0.96	2.11
4500	2.27	2.07	3.00	2.20	1.40	1.21	1.11	0.81	1.74
2g λ-cyhalothrin /ha (Toxic ref.)	0	0	0	1.33	1.00	1.69	1.94	0.96	0.60

Nominal treatment (g a.s./ha)	FEMALES Food consumption (flies/spider/day)								Mean
	Days 0-1	Days 1-2	Days 2-3	Days 3-4	Days 4-7	Days 7-9	Days 9-11	Days 11-14	
0 (control)	2.93	4.00	4.60	4.60	1.67	2.50	2.50	1.67	3.06
450	3.40	3.53	4.33	4.67	1.64	2.50	2.50	1.67	3.03
4500	2.67	3.20	3.93	4.00	1.53	2.40	2.50	1.67	2.74
2g λ-cyhalothrin /ha (Toxic ref.)	0	0.64	2.44	4.00	1.44	2.50	2.44	1.67	1.32

B. Toxicity endpoint

The 14-day mortality endpoint for EXP10066A to *Pardosa* sp. is presented in the following table.

Endpoints of the test item EXP10066A

Endpoint	Lethal rate (g a.s./ha)	48 hours
Mortality	LR_{50}	> 4500

III. CONCLUSION

EXP10066A applied at 450 and 4500 g a.s./ha did not cause statistically significant effects on mortality and the feeding rate of *Pardosa* sp.

Evaluation RMS (DAR 2006)

The study was well performed and reported and in compliance with GLP. However performed prior to establishing the current test guideline, the test proposal of BBA (Germany) was followed and the test is considered as acceptable.

Study CP 10.3.2.1-03

Report:	**CP 10.3.2.1-03 Drexler, A., 2000**
Title:	Effects of EXP10066A on the Reproduction of Rove Beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the Laboratory
Report no.:	IBACON Project: 8412070 (N-3020)
Published:	No
GPL:	Yes
Guidelines:	IOBCWPRS (1992)
Deviations:	-Minimal deviations to test unit, acclimation unit design with no impact to validity -Modification to parental extraction technique: Grimm requires a further week incubation without parental generation to allow existing larvae to find a pupal host. This was not done. - Light intensity not stated, potential deviation (no impact) -Relative humidity deviation (low), no impact to validity -Adult generation mortality not recorded -Possible to calculate ER_{25} -If the calculation in Grimm is used for % reduction, the actual reduction is lower
Previous evaluation	In DAR (2006) for original approval.
Remark by RMS	Considered acceptable at the time of original inclusion. The study summary from the DAR is replaced with an updated (extended) version. Evaluation from the DAR is copied as a whole without changes.
Conclusion	ER_{50} > 4500 g a.s./ha $NOEC_{reporduction}$ = 650 g a.s./ha

Executive Summary

The effects on the reproduction (fecundity) of EXP10066A to the rove beetle, *Aleochara bilineata* were determined in a laboratory study. Ten pairs of adult beetles (male:female) were exposed to treated sand for a period of four weeks. Following this period, the parasitisation rate of *Delia antiqua* pupae was observed over a 9-week extraction period. A two rate study design comprising two treatment rates and a control was used, each rate used four replicates. Treatment rates were 650 and 4500 g a.s./ha (nominal) and were applied as spray solutions made up in deionised water and applied at a nominal rate of 400 L/ha. Fecundity was assessed and compared with corresponding parameters recorded in the untreated group at the end of the test.

No analysis for verification of achieved concentration was undertaken. Effects were reported based on nominal treatment rates. EXP10066A significantly reduced reproduction in *Aleochara bilineata* when applied at 4500 g a.s./ha. The NOEC was therefore determined to be 650 g a.s./ha.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:** EXP10066A
Lot no.: OP200006
Purity: 454 g/L Flutolanil
Description: White opaque liquid

2. **Test organism:** *Aleochara bilineata*
Age: Adult (1-3 days old)
Source: De Groene Vlieg, Duivenwaardsdedijk, The Netherlands
Feeding: Frozen midge larvae *ad libitum*

3. **Treatment:** 0 (control), 600 and 4500 g a.s./ha (nominal)
Replication: 4 (10 male and 10 female beetles per replicate)
Vehicle: Deionized water
Toxic Reference: Perfekthion (Dimethoate)

4. **Test vessels:** Glass beakers (14 cm Ø, 7.5 cm height) covered with watch-glass. Half-filled with quartz sand (800g)

5. **Environmental conditions:**
Temperature: 19-21 (Exposure), 18-22 (Fecundity extraction) °C
Relative humidity: 45-85%
Photoperiod: 16:8 light:dark

B. STUDY DESIGN AND METHODS

1. In-life phase: May 30 to August 30, 2000

2. Test organism assignment and treatment

One day before application, the sex of just emerged (2 days old) beetles was determined by observing copulating pairs. Groups of ten pairs (10 male, 10 female) were housed until introduction to the test units immediately after application.

Mortality Phase			
Nominal treatment (g a.s./ha)	**Number of replicates**	**Number of males per replicate**	**Number of females per replicate**
0 (control)	4	10	10
650	4	10	10
4500	4	10	10
435 g Dimethoate /ha Toxic reference	4	10	10

Once a week, around 500 Delia *Antiqua pupae* were carefully buried in each vessel.

3. Dose preparation

Spray solutions of 3.74 g product/L and 28.05 g product/L were prepared in deionised water and were used directly. Spray solutions were applied to the test units (inner surface protected) by a calibrated laboratory sprayer at a nominal rate of 400 L/ha.

4. Measurements and observations

After 28 days of adult beetle exposure to the test system, the *Delia antiqua* pupae were washed and removed. The number of adults emerging from parasitized fly pupae was recorded three times per week, over 9 weeks by funnel extraction.

5. Statistics

ArcSin transformed data were used. Fecundity data was checked for normality and homogeneity of variance using the Kolmogoroff-Smirnov and Bartletts test. Since the data was normally distributed and homogenous, Student t-test (Pairwise comparison, one sided) was used. Statistical analysis was undertaken using EASEY ASSAY, ©SPiRiT, Version 4.0.

II. RESULTS AND DISCUSSION

A. Biological data

The evaluated parameter was fecundity after 4 week exposure. Results are presented below.

Mean Fecundity

Nominal treatment (g a.s./ha)	**Number of beetles emerged (n = 4)**			**Reduction of reproduction (%)**
	Mean	**Standard deviation**	**Total**	
0 (control)	710	85	2840	--
650	694	63	2777	2.2
4500	407	122	1627	42.7*
435 g Dimethoate /ha Toxic reference	68	60	272	90.4*

* $p < 0.05$

B. Toxicity endpoint

The fecundity endpoint for EXP10066A to *Aleochara bilineata,* following a 4-week exposure period for the parental generation is presented in the following table.

Endpoints of the test item EXP10066A

Endpoint	**Effect rate (g a.s./ha)**	**48 hours**
Fecundity	ER_{50}	> 4500
	NOEC	650

III. CONCLUSION

EXP10066A significantly reduced reproduction in *Aleochara bilineata* when applied at 4500 g a.s./ha. The NOEC was therefore determined to be 650 g a.s./ha.

Evaluation RMS (DAR 2006)

The study was well performed and reported, according to the test guideline and in compliance with GLP. The deviations from the study protocol were clearly reported and acceptable, and it is considered unlikely that the deviations would have affected the outcome or integrity of the study.

Study CP 10.3.2.2-01

Report:	**CP 10.3.2.2-01 Drexler, A., 2001**
Title:	Effects of EXP10066A on the Reproduction of Rove Beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) – Extended laboratory study
Report no.:	IBACON Project 10692071 (N-3021)
Published:	No
GPL:	Yes
Guidelines:	IOBC/WPRS (1992) and current improvements of the ring test group (2000)
Deviations:	Minor environmental
Previous evaluation	In DAR (2006) for original approval.
Remark by RMS	Considered acceptable at the time of original inclusion. The study summary from the DAR is replaced with an updated (extended) version. Evaluation from the DAR is copied as a whole without changes.
Endpoint	ER50 > 11.2 kg a.s./ha $NOEC_{reporduction}$ = 11.2 kg a.s./ha

Executive Summary

The aim of this study was to estimate the reproduction efficiency of the rove beetle *Aleochara bilineata* when exposed to residues of EXP10066A containing the active substance flutolanil at 458 g/L, on a worst case natural soil (LUFA 2.1) and in an extended laboratory experiment, compared to a water treated control and a toxic standard group.

Adult beetles were exposed to the test item for 28 days. There were four replicates per treatment group, each containing 10 test organisms of each gender (10 males and 10 females respectively). The larvae hatched from the eggs laid in the sandy soil by the female beetles parasitized the fly pupae. To assess the effect on reproduction, the number of beetles emerged from the successfully parasitized fly

pupae were counted, 36 days after application. Emerging beetles were counted and removed out of the emergence containers at least 3 times per week; following 3 consecutive days of no beetle emergence it was assumed that no further emergence would occur and the assessment was finished.

The results showed that the test item did not cause significant mortality to adult rove beetles *Aleochara bilineata* after exposure up to 11.2 kg a.s./ha. No test item related behavioural abnormalities were observed in the control and the test substance treated groups. During the reproductive test, the test item caused a reduction in reproduction compared to the controls, which ranged from 15.2 to 21.9% for the test groups, and to 68.1% for the Toxic standard. Therefore, under extended laboratory conditions, EXP10066A caused no statistically significant effects on mortality or reproduction of the rove beetle *Aleochara bilineata*.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: EXP10066A
Lot no.: OP210100
Purity: 458 g/L Flutolanil (analytical)
Description: White opaque liquid
Expiry date: February 01, 2001

2. Toxic Standard: Afugan SC 30
Batch: C07174310
Purity: 30.6% (w/w) Pyrazophos
Ref. concentration: 400 L/ha (corresponding to 4 mg/cm^2)

3. Test organism: *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae)
Age: Adult (*ca*. 1-4 days old)
Source: De groene Vlieg, Duivenwaardsdedijk I; NL- 3244 LG -Nieuwe Tonge
Feeding: Frozen midge larvae (*Chironomus* sp.) *ad libitum*

4. Treatment: 0 (control), 6.92, 11.99 and 17.21 g product/250 mL (nominal spraying dilution) and 2.375 mL Afugan EC 30/250 mL (toxic standard)

Application rate: 4 mg/cm^2 ± 10% (corresponding to 400 L spray liquid/ha)

Replication: 4 replicates (10 male and 10 female beetles per replicate)
Vehicle: Deionized water

5. Test units: plastic boxes (18.3 cm x 13.6 cm x 6 cm; length, width, height), covered with plastic lids, filled with soil (600 mL LUFA 2.1 soil - *ca*. 900 g soil)

6. Environmental conditions:

Temperature: 19-21 (Exposure), 17-25 (post-exposure)°C

Relative humidity: 40-90 % (Exposure), 40-95 % (post-exposure)

Photoperiod: 16:8 light:dark 500-1100 (Exposure), 650-1160 (post-exposure) lux

B. STUDY DESIGN AND METHODS

1. In-life phase: February 28 to May 25, 2001

2. Test organism assignment and treatment

Adult rove beetles *Aleochara bilineata,* were exposed to the test item for 28 days. Test units were sprayed at nominal dose rates of up to 11.2 kg a.s./ha. Additional test units were treated with a toxic standard (Afugan SC 30) and with deionised water as a control treatment. Ten pairs of beetles were introduced into the test units immediately after application. Once a week, *ca*. 750 *Delia antiqua* pupae per container were added on days 7, 14 and 21 to be parasitized by the larvae of the beetles. The pupae were carefully buried into the soil (depth *ca*. 2-3 cm) and homogeneously distributed within the test unit and completely covered with the substrate following 36 days after application the pupae were washed out of the soil and the pupae of each replicate were transferred into a separate emergence container. The emergence of the beetles was observed from day 36 to 86.

3. Dose application

The EXP10066A treatment was prepared in deionised water; using an amount corresponding to a spray of 4 mg/cm^2 ± 10%. The concentration of the test substance was 6.92, 11.99 and 17.21 g product/250 mL. Singular application was performed to the test units filled with the soil according to agricultural practice, with a laboratory-spraying equipment onto the soil surface. The concentration of the toxic standard spraying dilution was 2.375 mL Afugan EC 30/250 mL and the control was sprayed with deionized water.

4. Measurements and observations

The effect on reproduction of *Aleochara bilineata* was assessed by counting the number of beetles of the F1 generation that hatched from the offered fly pupae, until emergence was completed. For the determination of the reduction of reproduction, the mean number of offspring of the treatment group was calculated by averaging the number of offspring in each replicate of that treatment group. Any abnormal behaviour of the beetles was recorded.

5. Statistics

A square root arcsine transformation was used prior to analysis. Reproduction data were tested for normality distribution and homogeneity of variance using Kolmogoroff-Smirnov-Test and Cochran-Test. Because reproduction data were normally distributed and variance homogenous, Dunnett-Test (one sided smaller), $\alpha = 0.05$, was used. The software used to perform the statistical analyses was EASY ASSAY Multiple Testing,© SPiRiT, Version 4.0.

II. RESULTS AND DISCUSSION

A. Biological data

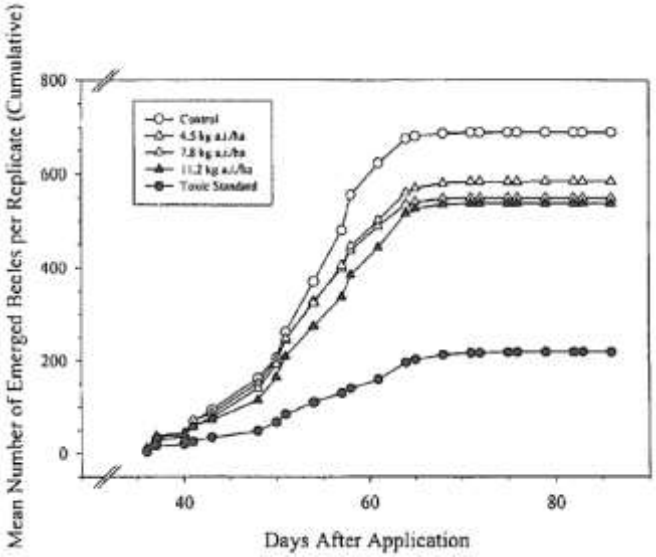
After exposure the number of *Aleochara bilineata* to dried residues of EXP10066A in the rates of 4.5, 7.8 and 11.2 kg a.s./ha, emerged beetles ranged from 538 to 585 (mean values), which resulted in a reduction of reproductive capacity of 15.2 - 21.9% compared to the control group.

No behavioural abnormalities were observed in the control and the test item treatment groups.

In the toxic standard group, 220 beetles emerged (reduction of reproduction of 68.1%).

The mean number of emerged beetles in the control group was calculated to be 30.6% (> 400 beetles per replicate) and the reduction of reproduction in the toxic standard was statistically significant and over 50% (68.1%), therefore the validity criteria of this study were met.

Cumulative emergence (mean number per replicate) of the F1 generation of rove beetles *Aleochara bilineata*



Effects on the rove beetle *Aleochara bilineata* exposed to EXP10066A

Measurement	Test Formulation (kg a.s./ha)				
	Control	**4.5**	**7.8**	**11.2**	**Toxic standard**
Mean number of emerged beetles per replicate	689	549	585	538	220
% reduction in reproduction	n.a.	20.3	15.2	21.9	68.1*

n.a. not applicable
* significant compared to the control, Dunnett-test, α = 0.05

B. Toxicity endpoints

No statistically significant effects (Dunnett-test) on reproduction capacity of rove beetles *Aleochara bilineata* occur after exposure up to 11.2 kg a.s./ha in this extended laboratory study, therefore the endpoints are presented in the following table.

Endpoints of the test item EXP10066A

Endpoint	Effect concentration (kg a.s./ha)	28 days
Reproduction	ER_{50}	> 11.2
	NOEC	11.2

III. CONCLUSION

After 28 days of exposure of the rove beetle *Aleochara bilineata* to EXP10066A under extended laboratory conditions, the test item did not cause statistically significant mortality at the exposure concentration of 11.2 kg a.s./ha. The results of the reproduction test did not show statistically significant adverse effects of the test item at the application rate of up to 11.2 kg a.s./ha in this extended laboratory study.

Evaluation RMS (DAR 2006)

The study was well performed and reported, according to the test guideline and in compliance with GLP.

B.9.6 Risk assessment for arthropods

B.9.6.1 Risk assessment for bees

Methodologies used for the risk assessment for bees

The bee risk assessment by the notifier was conducted in line with the Guidance on Terrestrial Ecotoxicology (SANCO/10329/2002 rev. 2 final) and additionally in line with the revised EPPO Risk Assessment Scheme (OEPP/EPPO 2010), as appropriate based on the data requirements under EU Regulations 283/2013 and 284/2014. The RMS has added a risk assessment according to EFSA (2013) for those areas of the risk assessment where data is available, as per the agreements in PraPer 133. All calculations for the risk assessment according to EFSA, 2013, were performed using the EFSA Bee Tool V.3.

Application scenario

According to the GAP table, MONCUT 40 SC is proposed to be applied in potatoes and flower bulbs (Tulips and Iris) at 0.368 and 2.76 kg a.s./ha (1 application), respectively, during BBCH: 00-03 and BBCH: 00 (Oct-Dec), respectively.

Bees may be exposed to flutolanil mainly as a result of spray drift whilst foraging for food in or in the vicinity of treated crops, and also to flutolanil from contact with or consumption of pollen and nectar in flowering weeds present in the crop.

B.9.6.1.1 Risk assessment in line with (SANCO/10329/2002 rev 2 final)

The acute study performed on bees provides the oral and contact LD_{50} values of the active substance expressed as µg a.s./bee.

The acute risk to honey bees from the use of flutolanil was assessed using the worst-case maximum single application rate for the proposed uses and the LD_{50} values to calculate hazard quotients

according to European Commission Working Document - SANCO/10329/2002 rev 2 Final, 'Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC' as follows:

$$\text{Hazard Quotient } (HQ_O) = \frac{\text{Maximum single application rate (g a.s./ha or g formulation/ha)}}{\text{Acute } LD_{50} \text{ (µg a.s./ha or µg formulation/ha)}}$$

Hazard quotients were calculated for oral exposure (HQ_O) and contact exposure (HQ_C) and were evaluated against a trigger value of 50. Values below 50 are considered to indicate an acceptable risk to bees in the field. The calculated HQ values are presented in **Table 9.6.1.1-1**.

Table 9.6.1.1-1 Hazard quotients for honeybees based on laboratory toxicity studies

Test substance	Route	Toxicity (µg a.s./bee)	Application rate (g a.s./ha)	Hazard quotient	Annex VI Trigger
Flutolanil	Oral	208.7	2760	13.2	50
Flutolanil	Contact	200	2760	13.8	50

The oral and contact hazard quotients for flutolanil are below 50, indicating that the acute exposure risk to bees from flutolanil following the highest application rate according to the proposed uses, is acceptable.

No further consideration is required for this assessment.

B.9.6.1.2 Risk assessment in line with the EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) (EFSA Journal 2013; 11(7):3295)

Acute Risk Assessment

The acute risk to honey bees from the use of flutolanil was assessed using the worst-case maximum single application rate for the proposed uses and the LD_{50} values to calculate the Exposure Toxicity Ratio (ETR) according to EFSA Journal 2013 as follows:

$$ETR_{\text{acute adult oral}} = \frac{\text{Application Rate (AR) (kg a.s./ha)} \times \text{Shortcut Value (SV)}}{\text{Acute } LD_{50} \text{ (µg a.s./bee)}}$$

Exposure Toxicity Ratio (ETR) was calculated for the acute oral exposure and was evaluated against a trigger value of ETR > 0.2. The shortcut value used for this type of spray application to bare soil was 10.6 (side-ward application) as non-emerged crops will be exposed to down-ward spraying of MONCUT 40SC. Values below or equal to the trigger meet the protection goal and are considered to indicate an acceptable risk to bees in the field. The calculated ETR value is presented in **Table 9.6.1.2-1**.

Table 9.6.1.2-1 Exposure toxicity ratios for honeybees based on oral acute laboratory study

Test substance	Route	Toxicity (µg a.s./bee)	Application rate (kg a.s./ha)	SV	ETR	ETR Trigger value
Flutolanil	Oral	208.7	2.76	10.6	0.140	> 0.2

Hazard quotient (HQ) for acute contact exposure of adult honey bees in the field margin was calculated:

$$\text{Hazard Quotient } (HQ_C) = \frac{\text{Maximum single application rate (g a.s./ha)}}{\text{Acute contact } LD_{50} \text{ (µg a.s./ha)}}$$

Table 9.6.1.2-2 Hazard quotient for honeybees based on laboratory acute contact toxicity study

Test substance	Route	Toxicity (µg a.s./bee)	Application rate (g a.s./ha)	Hazard quotient	Trigger value
Flutolanil	Contact	200	2760	13.8	HQ (suw) > 85

HQ(suw) = HQ trigger for sideward/upwards spray application

The oral ETR value and contact hazard quotient for flutolanil are below 0.2 and 85, respectively, indicating that the acute exposure risk to bees from flutolanil following the highest application rate according to the proposed uses, is acceptable.

No further consideration of the acute risk to bees is required.

Chronic Risk Assessment

The chronic adult oral and larval development risks to honey bee will be evaluated in accordance with the EFSA Guidance Document (EFSA Journal 2013; 11(7):3295) These long-term assessments are considered to address potential exposure via nectar and pollen from the treated crop and flowering weeds, and encompass potential exposure from systemic activity. The chronic adult assessment did not pass in the screening step, thus, a tier 1 assessment of the potential chronic risk to bees from the proposed uses is required.

Table 9.6.1.2-3 Tier 1 chronic risk assessment for adult honey bee

category	scenario	BBCH	Honeybee	
			ETR	trigger
Bulb flowers (attractive nectar and pollen)				
chronic	treated crop	< 10	**0.031**	0.03
chronic	weeds	< 10	0.02	0.03
chronic	field margin	< 10	0.00	0.03
chronic	adjacent crop	< 10	0.00	0.03
chronic	next crop	< 10	**0.031**	0.03

Potatoes (only attractive pollen)				
chronic	treated crop	< 10	0.00	0.03
chronic	weeds	< 10	0.00	0.03
chronic	field margin	< 10	0.00	0.03
chronic	adjacent crop	< 10	0.00	0.03
chronic	next crop	< 10	0.00	0.03

As shown in the Table above, the chronic adult risk assessment according to EFSA (2013) indicates a potential chronic risk to adult honey bees from the proposed use of Monocut 40SC in bulb flowers, from the crop itself and from a potential following crop, however, the proposed use in potatoes shows an acceptable risk.

The Tier 1 risk assessment for chronic exposure to adult bees can be refined considering the available field study with Monarch 40 SC, a formulation which is slightly different from Monocut 40 SC, but contains the same a.s. level and the same formulation type. The semi-field test was performed under worst-case circumstances versus the proposed use of Monocut 40SC in blub flowers, as it was applied only two weeks before full flowering and at a rate significantly higher (>4x) than the proposed use rate. There were no effects on mortality of adult bees flying in the crop (*Phacelia*) in the 8 days of observation. Nor were there any effects on the number of adult bees in each of the tested colonies during the entire time of observation. Considering these data, the fact that the application is before flowering and therefore residues levels in nectar in pollen are expected to be low at the time of flowering of the crop, and the fact that the trigger value was very close to acceptable (ratio of 1.03), the RMS considers the chronic risk to honey bees from the proposed use of Monocut 40 SC in bulb flowers acceptable.

Larval Risk Assessment

The chronic adult oral and larval development risks to honey bee will be evaluated in accordance with the EFSA Guidance Document (EFSA Journal 2013; 11(7):3295) These long-term assessments are considered to address potential exposure via nectar and pollen from the treated crop and flowering weeds, and encompass potential exposure from systemic activity. The larval risk assessment did not pass in the screening step for the proposed use in bulb flowers (it did pass for the proposed use in potatoes), thus, a tier 1 assessment of the potential risk to larval bees from the proposed uses is required.

Table 9.6.1.2-4 Tier 1 chronic risk assessment for larval honey bee

category	scenario	BBCH	Honeybee	
			ETR	trigger
Bulb flowers (attractive nectar and pollen)				
larva	treated crop	< 10	0.09	0.2
larva	Weeds	< 10	0.05	0.2
larva	field margin	< 10	0.00	0.2
larva	adjacent crop	< 10	0.00	0.2
larva	next crop	< 10	0.09	0.2

As shown in the Table above, according to the Tier 1 risk assessment (EFSA, 2013), the potential risk to larval honey bees from the proposed uses of Monocut 40SC is acceptable.

Assessment of the risk from exposure via contaminated water

The risk assessment was performed according to EFSA, 2013, wherever data was available. Note that the Fate section does not calculate PECrunoff, as there is no agreed methodology in the Fate section for this calculation. Thus, the PECpuddle was not calculated and no risk assessment could be performed for puddle water. As inputs, the water solubility of flutolanil (8 mg/L, see Table B.9.6-1) and the highest Step 3 PECsw (0.02525 mg/L, see Table 9.4-9) were used. Note that as there was no safe use for bulb flowers using this PEC, it is likely that refinements will be performed, perhaps resulting in a lower PECsw.

According to these inputs the risk to bees from surface water passed in the screening step. The risk to bees from puddle water could not be calculated. The risk to bees from guttation water is presented in a Tier 1 step, as it is not known to what degree guttation water is likely to form on bulb flowers or potatoes during the potential exposure period. The Tier 1 assessment is shown below.

Table 9.6.1.2-5 Tier 1 risk assessment for honey bee exposure via guttation water

	water cons. (µL)	**ETR**	Trigger
acute	11.4	0.00	0.2
chronic	11.4	0.001	0.03
larvae	111	0.06	0.2

As shown in the Table above, the potential risk to honey bees from guttation water is assumed to be low.

Considering the above, the risk to honey bees from exposure via water from the proposed uses of Monocut 40SC is expected to be low.

Assessment of the risk from exposure to metabolites

Only one metabolite is found in plants at TRR >10%, that being metabolite M-4.

	Molecular weight	**Mole fraction**	**%TRR[1]**	**AR_{EQ} (kg a.s./ha)**	**$EXP_{metabolite}$**
Flutolanil	323.3			2.76	
M-2 (+ conjugates)	339.3	1.04949	0.16	0.345	0.000579318
M-4 (+ conjugates)	281.2	0.86978	33.65		0.100998986
M-101	189.1	0.584998	1.00		0.002018245
M-102	190.1	0.588061	0.62		0.001257862

[1] Found in the outer leaf of mature cabbage (radiolabel: [Phenyl-U-^{14}C]-Flutolanil)

The risk assessment for potential exposure to metabolite M-4 was conducted according to EFSA (2013), assuming that the metabolite was 10x more toxic than the parent. This resulted in the following results, shown in Table 9.6.1.2-4, below.

Table 9.6.1.2-6 Tier 1 risk assessment for honey bee exposure to metabolite M-4

category	**scenario**	**BBCH**	**Honeybee**	
			ETR	**trigger**
Bulb Flowers (attractive nectar and pollen)				
acute	treated crop	< 10	0.028	0.2
acute	weeds	< 10	0.014	0.2
acute	field margin	< 10	0.001	0.2

category	scenario	BBCH	Honeybee	
			ETR	trigger
acute	adjacent crop	< 10	0.001	0.2
acute	next crop	< 10	0.028	0.2
chronic	treated crop	< 10	**0.090**	0.03
chronic	weeds	< 10	**0.045**	0.03
chronic	field margin	< 10	0.004	0.03
chronic	adjacent crop	< 10	0.003	0.03
chronic	next crop	< 10	0.085	0.03
larva	treated crop	< 10	0.275	0.2
larva	weeds	< 10	0.137	0.2
larva	field margin	< 10	0.014	0.2
larva	adjacent crop	< 10	0.010	0.2
larva	next crop	< 10	**0.275**	0.2
Potato (attractive pollen only)				
acute	treated crop	< 10	0.000	0.2
acute	weeds	< 10	0.002	0.2
acute	field margin	< 10	0.000	0.2
acute	adjacent crop	< 10	0.000	0.2
acute	next crop	< 10	0.004	0.2
chronic	treated crop	< 10	0.000	0.03
chronic	weeds	< 10	0.006	0.03
chronic	field margin	< 10	0.001	0.03
chronic	adjacent crop	< 10	0.000	0.03
chronic	next crop	< 10	0.011	0.03
larva	treated crop	< 10	0.000	0.2
larva	weeds	< 10	0.018	0.2
larva	field margin	< 10	0.002	0.2
larva	adjacent crop	< 10	0.001	0.2
larva	next crop	< 10	0.037	0.2

As shown in the Table above, the risk to honey bees from exposure to metabolite M-4 is considered acceptable for the proposed use in potato, however, there is a chronic risk to adult bees from use in the crop and from weeds in the treated field, and to larvae from the next crop. However, the results of the semi-field test do not show any significant effects on adult bees, nor any brood effects, despite a worst-case exposure profile in a highly attractive crop. The honey bees in the semi-field study were exposed to the metabolite at higher rates, in the same way they were exposed to flutolanil at higher rates than proposed in the GAP. The assumption of 10x greater toxicity is also considered conservative, as the parent molecule is a fungicide, and is not highly toxic in and of itself.

Considering all the available data, the RMS finds the risk to honey bees from the metabolite, M-4, acceptable.

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

Table 9.6.2-1 Summary of toxicity data to non-target arthropods

Test species Life stage	Time scale - Substrate	Test material	Endpoint - Effect	Data point Author, year
Aphidius rhopalosiphi – Adult females (< 48 hr)	48 h – glass plate	EXP10066A*	Mortality, LR_{50} – > 4500 g a.s./ha Reproduction, ER_{50} – > 4500 g a.s./ha	CA 8.3.2.1-01 Nienstedt, K.M., 1999a
Typhlodromus pyri – 2-day synchronised protonymph	14 d – glass plate	EXP10066A*	Mortality, LR_{50} – > 4500 g a.s./ha Reproduction, ER_{50} – > 4500 g a.s./ha	CA 8.3.2.2-01 Nienstedt, K.M., 1999b
Poecilus cupreus – Adult (~6 weeks old)	14 d – silica sand	EXP10066A*	Mortality, LR_{50} – > 4500 g a.s./ha	CP 10.3.2.1-01 Nienstedt, K.M., 1999c
Pardosa sp. – Subadult and adult	14 d – quartz sand	EXP10066A*	Mortality, LR_{50} – > 4500 g a.s./ha	CP 10.3.2.1-02 Nienstedt, K.M, 1999d
Aleochara bilineata - Adult (1 – 3 days old)	91 d – quartz sand	EXP10066A*	Reproduction 650 g a.s./ha -2.2% 4500 g a.s./ha -42% , ER_{50} > 4500 g a.s./ha	CP 10.3.2.1-03 Drexler, A., 2000
Aleochara bilineata - Adult (1 – 4 days old) (Extended lab study)	86 d – quartz sand	EXP10066A*	Reproduction, ER_{50} – > 11200 g a.s./ha	CP 10.3.2.2-01 Drexler, A., 2001

* EXP10066A is equivalent to the representative formulation MONCUT 40 SC

The risk assessment has been conducted in line with ESCORT 2 (Candolfi *et al*., 2000)[10].

B.9.6.2.1 In-field

Non-target arthropods can be exposed to residues from MONCUT 40 SC by direct contact either as a result of over-spray or through contact with residues on soil or in food items. MONCUT 40 SC is incorporated in the soil to pre planting application for flower bulbs (BBCH 00) at a maximum rate of 1 × 2.76 kg formulated product/ha.

The in-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

In-field PER = Application rate × MAF

The MAF is a generic multiple application factor, which is used to take into account the potential build-up of applied active substances between applications and is based on the application interval, the DT_{50} value on foliage and the number of applications. Based on the worst-case GAP proposed uses,

[10] M.P. Candolfi, K.L. Barrett, P.J. Campbell, R. Forster, N. Grandy, M-C. Huet, G. Lewis, P. A. Oomen, R. Schmuck and H. Vogt (2000) Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From the ESCORT 2 workshop (European Standard Characteristics Of non-target arthropod Regulatory Testing)

the maximum predicted environmental residues (PER) occurring in-field after application of MONCUT 40 SC are presented in Table 9.6.2.1-1.

Table 9.6.2.1-1 In-field PER values for MONCUT 40 SC applied to potatoes and flower bulbs

Test substance	Max single application rate	No. of applications	MAF	In-field PER g a.s./ha
Flutolanil (MONCUT 40 SC)	2760 g a.s./ha	1	1	2760

B.9.6.2.2 Off-field

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent potential natural reservoirs for immigration, emigration and reproduction of arthropod species and provide increased species diversity in the natural community. Exposure of non-target arthropods living in off-field areas to MONCUT 40 SC will mainly be due to spray drift from field applications. Off-field areas are assumed to be densely vegetated, and thus, spray drift is unlikely to reach bare ground.

The off-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

$$\textit{Off-field PER} = \textit{Application rate} \times \textit{MAF} \times \frac{\textit{drift factor}}{\textit{vegetation distribution factor}} \times \textit{correction factor}$$

Vegetation distribution factor: The model used to estimate spray drift was developed for drift onto a two-dimensional water surface and, as such, does not account for interception and dilution by three-dimensional vegetation in off-crop areas. Therefore, a vegetation distribution or dilution factor is incorporated into the equation when calculating PERs to be used in conjunction with toxicity endpoints derived from two-dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2 and will be used within this assessment.

Drift factor: The drift factor value (%) at different distances varies depending on the crop and total number of applications (Appendix VI, ESCORT 2, Candolfi *et al.* 2000). A drift factor at 1m of 2.77 % will be used in this assessment.

Correction factor: For Tier I studies a correction factor of 10 is recommended by ESCORT 2 and is used within this assessment.

The resulting off-field PER values are presented in Table 9.6.2.2-1.

Table 9.6.2.2-1 Off-field PER values for MONCUT 40 SC applied to flower bulbs (the highest application)

Test substance	Max single application rate	Drift factor %	Vegetation distribution factor	Correction factor	MAF	Off-field PER g a.s./ha
Flutolanil (MONCUT 40 SC)	2760 g a.s./ha	2.77	10	10	1	76.45

Calculation of the in-field and off-field Hazard Quotients (HQ)

The risk to non-target arthropods is assessed using the approach recommended in the published *ESCORT 2 document* (Candolfi *et al.* 2001 and SANCO/10329/2002).

The potential risk of MONCUT 40 SC to non-target arthropods was assessed by calculation of the hazard quotient (HQ = exposure/toxicity) using the equation below. The input values were based on the predicted environmental residue (PER) and the lowest lethal rate (LR_{50}) values for two most sensitive species exposed to MONCUT 40 SC.

$$HQ = \frac{PER}{LR_{50}}$$

The HQ values based on Tier I laboratory studies are evaluated against a trigger value of 2. If values are above the trigger a risk to non-target arthropods is indicated and further higher-tier assessment to address the potential risk is required. The resulting $HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for non-target arthropods are presented in Table 9.6.2.2-2.

Table 9.6.2.2-2 In-field and Off-field HQs for non-target arthropods exposed to MONCUT 40 SC on potatoes and flower bulbs

Species	LR_{50} (g a.s./ha)	In-field PER (g a.s./ha)	$HQ_{in\text{-}field}$	Off-field PER (g a.s./ha)	$HQ_{off\text{-}field}$	Trigger
Aphidius rhopalosiphi	> 4500	2760	< 0.613	76.45	< 0.017	2
Typhlodromus pyri	> 4500		< 0.613		< 0.017	2

The in-field and off-field HQ values for non-target arthropods were below the Annex VI trigger value of 2 for *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Therefore, MONCUT 40 SC poses an acceptable in-field and off-field risk following application in accordance with the proposed uses.

Calculation of the in-field and off-field risk to *P. cupreus* and *A. bilineata*

The risk to *P. cupreus* and *A. bilineata* is assessed using the approach recommended in the published ESCORT 2 document *(Candolfi et al. 2001)* and the EC Guidance Document on Terrestrial Ecotoxicology.

The endpoints from the additional species studies and the extended laboratory are compared to the in-field and off-field exposure values in this higher tier risk assessment in the Table 9.6.2.2-3.

Table 9.6.2.2-3 Tier II in-field and Off-field risk to non-target arthropods

Species	LR_{50} (g a.s./ha)	In-field PER (g a.s./ha)	$HQ_{in\text{-}field}$	Off-field PER (g a.s./ha)	$HQ_{off\text{-}field}$	Trigger
Poecilus cupreus	> 4500	2760	< 0.613	76.45	< 0.017	1
Paradosa sp.	> 4500		< 0.613		< 0.017	
Aleochara bilineata Tier I	> 4500		< 0.613		< 0.017	
Aleochara bilineata Extended lab	> 11200		< 0.246		< 0.007	

Based on the results presented in the above table, it is considered that no risk is anticipated for non-target arthropods for the proposed application scenarios of MONCUT 40 SC in flower bulbs or potatoes.

B.9.7 Effects on non-target soil meso- and macrofauna

B.9.7.1 Effects on Earthworms

There are no new studies submitted. The studies from the DAR (2006) were re-evaluated by the RMS. Please see the new summaries and evaluations in Volume 3 CA B.9.4.1.

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

There are no new studies submitted. The studies from the DAR (2006) were re-evaluated by the RMS (where necessary). Please see the new summaries and evaluations in Volume 3 CA B.9.4.2.

B.9.8 Risk assessment for non-target soil meso- and macrofauna

Table 9.8-1 Summary of toxicity data to soil macro-organisms

Test species	Time scale	Test material	Endpoint	Data point Author, year
Eisenia fetida	Long-term 8 w	EXP10066A*	NOEC = 25.0 mg a.s./kg dw soil **$NOEC_{corr}$ [1, 2] = 12.5 mg a.s./kg dw soil**	CA 8.4.1-02 Lührs U., 2001
Eisenia fetida	Long-term 8 w	EXP10066A*	$NOEC_{reproduction}$ = 12.9 mg a.s./kg dw soil	CA 8.4.1-01 Lührs U., 2000
Folsomia candida	Long-term 28 d	EXP10066A*	NOEC = 37.6 mg a.s./kg dw soil **$NOEC_{corr}$ [1, 2] = 18.8 mg a.s./kg dw soil**	CA 8.4.2-01 Meister, A., Lührs, U., 2002
Hypoaspis aculeifer	Long-term 14 d	MONCUT 40 SC	NOEC = 407 mg a.s./kg dw soil **$NOEC_{corr}$ [1, 2] = 203.5 mg a.s./kg dw soil**	CA 8.4.2.1-01 Ganßmann, M., 2015

Note: endpoints in **bold** used in the risk assessment

[1] Endpoint was selected for the risk assessment as it was performed in reduced organic matter and considered closer to natural soil.

[2] Endpoint corrected by a factor of 2 due to log P_{ow} > 2.

* EXP10066A is equivalent to the representative formulation MONCUT 40 SC

B.9.8.1 Risk assessment for earthworms

The risk assessment for earthworms has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).

The maximum predicted environmental concentrations in soil (PEC_{soil}) for flutolanil were calculated following the use of MONCUT 40 SC (EXP10066A) as a soil treatment on potatoes and flower bulbs (tulips and iris), at a maximum rate equivalent to 1 × 2760 g a.s./ha. Details on the predicted environmental concentrations (standard field calculations) in soil (PEC_{soil}) for flutolanil are presented in Document M-CP 9.1.3 of this dossier. The GAP specifies incorporation at 10-15 cm for flower bulbs, thus the risk assessments are performed at a depth of 10cm, noting that this is the worst-case according to the GAP.

Table 9.8.1-1 Maximum accumulated PEC_{soil} values of flutolanil

Crop	Rate per Season [g a.s. /ha]	Soil depth [cm]	$PEC_{s,\ plateau}$ (C_{low}) [mg/kg] *	PEC_{soil} [mg/kg]	$PEC_{s,\ accumulation}$ [mg/kg]
Potatoes	368	5	0.112	0.491	0.603
Bulbs	2760	10	0.840	1.840	2.641

* at 20 cm soil depth

Based on the most sensitive endpoints the TER values were calculated using the following equation:

$$TER_{LT} = \frac{\text{chronic NOEC}}{PEC_{soil}}$$

Long-term toxicity exposure ratio (TER) values for the proposed worst-case uses are presented in the following table.

Table 9.8.1-2 Long term TER values for earthworms exposed to MONCUT 40 SC

Organism	Species	Toxicity endpoint	Appl. rate (g a.s./ha)	PEC_{soil} (mg/kg)	Endpoint [mg/a.s. kg dw soil]	TER_{LT}	Trigger value
Earthworm	*Eisenia fetida*	Long-term	1 × 368 (potatoes)	0.603	12.5	20.7	5
Earthworm	*Eisenia fetida*	Long-term	1 × 2760 (bulbs incorp. to ≥10 cm)	2.641	12.5	**4.73**	5

The long-term TER value is above the trigger of 5 for use in potato, while for bulbs the TER is below the trigger, indicating unacceptable long-term risk to earthworm. The risk requires refinement.

B.9.8.2 Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Long-term toxicity exposure ratio (TER) values for the proposed worst-case uses are presented in the following table.

Table 9.8.2-1 Long term TER values for non-target soil macro-organisms exposed to MONCUT 40 SC (other than earthworms)

Species	Application rate (g a.s./ha)	Toxicity * (mg a.s./kg dw soil)	$PEC_{soil\ accum}$ (mg/kg dw soil)	TER_{LT}	Trigger
Folsomia candida	1 × 368	18.8	0.603	31.2	5
	1 × 2760 (bulbs incorp. to ≥10 cm)	18.8	2.680	7.01	
	1 × 368	> 203.5	0.603	337	
Hypoaspis aculeifer	1 × 2760 (bulbs incorp. to ≥10 cm)	> 203.5	2.680	75.9	5

* Endpoint corrected by a factor of 2 due to log P_{ow} > 2

For *Folsomia candida* the TER_{LT} values for flutolanil are above the trigger value of 5 for use in potato and bulbs, demonstrating an acceptable chronic risk following application in accordance with the proposed uses.

For *Hypoaspis aculeifer* the TER_{LT} values for flutolanil are above the trigger value of 5, demonstrating an acceptable chronic risk following application in accordance with the proposed uses. No further consideration is necessary.

B.9.9 Effects on soil nitrogen transformation

No new data has been submitted. The study from the DAR (2006) was used. Please see Volume 3 CA 9.5 for the full study summary and evaluation.

Report:	CA 8.5-01 Forster, J. 1999
Title:	A laboratory assessment of the effect of EXP10066A (Flutolanil) on soil microflora respiration and nitrogen transformations according to current EU guidelines.
Report no.:	N-3024
Published:	No
GLP:	Yes (UK)
Guidelines:	Directive 96/12/EC, SETAC. EPPO Bulletin 24, 1-16 (1994).
Previous evaluation	In DAR (2006) for original approval.
Remark by RMS	Considered acceptable at the time of original inclusion. Study evaluation from DAR copied as a whole without changes.
Endpoint	0.71% effect at day 42 at 2.09 mg a.i./kg soil (1392 g a.i./ha)

B.9.10 Risk assessment for soil nitrogen transformation

The risk to soil microbial processes has been assessed in accordance with the Terrestrial Guidance Document (SANCO/10329/2002).

The highest $PEC_{S,peak\ accum}$ for potato and tulip/iris (5 and 10 cm soil incorporation) are 0.603 and 2.68 mg a.s./kg soil dw, respectively, while the endpoint value is 2.09 mg a.s./kg soil dw. Therefore, risk from use in potato is acceptable since the exposure is 3.5 times lower than the threshold. However,

unacceptable risk is concluded for use in flower bulbs as the threshold is exceeded by 1.28 times. A data gap has been identified to address the potential risk to soil microorganisms from the proposed use in flower bulbs.

B.9.11 Effects on terrestrial non-target higher plants

B.9.11.1 Summary of screening data

No data submitted.

B.9.11.2 Testing on non-target plants

No new data submitted. The dat from the DAR (2006) were used. Please see Volume 3 CA B.9 9.6.2 for the study summary and evaluation.

B.9.11.3 Extended laboratory studies on non-target plants

No data submitted.

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

No data submitted.

B.9.12 Risk assessment for terrestrial non-target higher plants

Toxicity of MONCUT 40 SC non-target terrestrial plants

Table 9.12-1 Toxicity of MONCUT 40 SC (Flutolanil 460 g/L) to non-target plants

Study Type	Test substance	Species	Endpoint	NOER (g a.s./ha)	Reference
Seedling emergence	EXP10066A*	Tomato, *Lycopersicon esculentum*	Fresh weight	11200	CA 8.6.1-01 Spatz, B., 2002
		Cucumber *Cucumis sativus*	Fresh weight	11200	
		Oat, *Avena sativa*	Fresh weight	11200	
		Soybean, *Glycine max*	Fresh weight	11200	
		Radish, *Raphanus sativus*	Fresh weight	11200	
		Onion *Allium cepa*	Fresh weight	11200	

* EXP10066A is equivalent to the representative formulation MONCUT 40 SC

Risk Assessment for Non-Target Terrestrial Plants

The risk to non-target plants in the off-crop environment from spray drift following application of MONCUT 40 SC has been assessed by calculating the off field TER_{LT} value using the NOER values from the pre-emergence studies (seedling emergence summarised under document M-CA 8.6.1-01) and the $PER_{off\text{-}field}$ based on the drift rate of 2.77% at 1 m, as follows:

$$TER_{LT} = NOER \text{ (g a.s./ha)} / PER_{off\ field} \text{ (g a.s./ha)}$$

The TER_{LT} values are evaluated against the Annex VI trigger value of 5.

The TER_{LT} values based on the proposed uses of MONCUT 40 SC are presented in the following table.

Table 9.12-1 MONCUT 40 SC TER values for non-target plants

Test Substance	Species	NOER (g a.s./ha)	PER (g a.s./ha)	TER_{LT}	Trigger value
EXP10066A* Seedling emergence	Tomato *Solanum lycopersicon*	11200	76.5	146.5	5
	Cucumber *Cucumis sativus*				
	Radish *Raphanus sativus*				
	Soybean *Glycine max*				
	Oat *Avena sativa*				
	Onion *Allium cepa*				

* EXP10066A is equivalent to the representative formulation MONCUT 40 SC

The achieved TER_{LT} values exceed the Annex VI trigger value of 5, based on the application rate resulting from spray drift expected off-field at 1 m from the field edge. This indicates that the risk to plant species in the off-field environment following an in-field application of MONCUT 40 SC in accordance with the proposed uses, is acceptable.

Since flutolanil is not a herbicide or a plant regulator, vegetative vigour testing is not required.

B.9.13 Effects on other terrestrial organisms (flora and fauna)

Tests on the other terrestrial plant species are not available for MONCUT 40 SC. The preliminary screening data with formulation EXP10066A (a very similar formulation to MONCUT 40 SC) shows no adverse effects on plant growth at a rate of 11.2 kg a.s./ha (tested on six terrestrial non-target plant species representing six plant families), which is four times higher than the proposed application rate for MONCUT 40 SC required. Based on this, the risk for this product is considered acceptable.

B.9.14 Risk assessment for other terrestrial organisms (flora and fauna)

For the proposed uses, the exposure to sewage treatment plants is not considered likely since flutolanil will not, under normal circumstances, enter the waste water treatment system. Nevertheless, no adverse effects were seen in the laboratory test with activated sewage sludge at 1000 mg/L and the risk of harmful effects on biological methods of sewage treatment is considered acceptable.

No further consideration is required.

B.9.15 Literature search

A literature search was performed according to to EFSA (2011; 9(2): 2092), and was considered acceptable by the RMS. For more details on the search and RMS assessment, please refer to the CA document, as the search included the formulation name(s) as well as active substance and metabolites.

B.9.16 References relied on

Reference	Author	Year	Title Report No. Test facility GLP [Y/N] / Published [Y/N]	Vertebrate Study [Y/N]	Data Protection claimed [Y/N]	Justification	Owner
CP 10.2.1-01	Yaginuma, S.	2007	Algal growth inhibition test of Flutolanil 40SC Report No: LSRC-E07-045A (N-3029) Performing Lab: Nihon Nohyaku Co., Ltd. GLP: Yes, Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 10.3.1.6-01	Kling, A.	2003	Assessment of Side Effects of Monarch 40 SC on the Honey Bee (*Apis mellifera* L.) in the Semi-Field Report No: 20021306/01 (N-3027) Performing Lab: GAB Biotechnologie GmbH & JFU Umweltanalytik GmbH, Germany GLP: Yes, Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 10.3.2.1-01	Nienstedt, K.M.	1999c	EXP10066A:A laboratory acute toxicity test with the ground beetle, *Poecilus Cupreus* L.(Coleoptera:Carabidae) Report No: 99-072-1013 (N-3018) Performing Lab: Nihon Nohyaku GLP: Yes, Published: No	N	N	-	Nihon Nohyaku Co. Ltd
CP 10.3.2.1-02	Nienstedt, K.M.	1999d	EXP10066A:A laboratory toxicity test with spiders, *Pardosa* sp. (Araneae:Lycosidae) Report No: 10.13.042.272 (N-3019) Performing Lab: Nihon Nohyaku GLP: Yes, Published: No	N	N	-	Nihon Nohyaku Co. Ltd
CP 10.3.2.1-03	Drexler, A.	2000	Effect of EXP10066A on the reproduction of rove beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the laboratory Report No: IBACON Project: 8412070 (N-3020) Performing Lab: IBACON GmbH GLP: Yes, Published: No	N	N	-	Nihon Nohyaku Co. Ltd

CP 10.3.2.2-01	Drexler, A.	2001	Effect of EXP10066A on the reproduction of rove beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) – Extended laboratory study Report No: IBACON Project 10692071 (N-3021) Performing Lab: IBACON GmbH GLP: Yes, Published: No	N	N	-	Nihon Nohyaku Co. Ltd