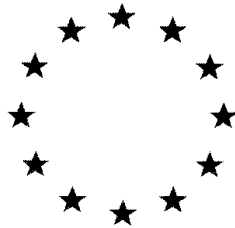


European Commission



List of Endpoints

- *Flutolanil* -

Rapporteur Member State: The Netherlands

June 2018

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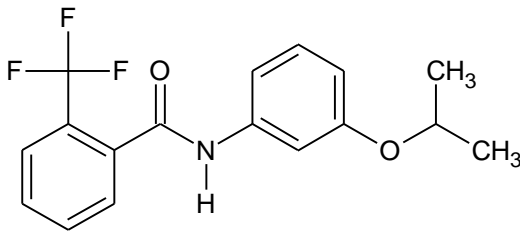
Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	June 2018	Flutolanil

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Flutolanil
Function (<i>e.g.</i> fungicide)	Fungicide
Rapporteur Member State	The Netherlands
Co-rapporteur Member State	UK

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	α,α,α -trifluoro-3'-isopropoxy-o-toluanilide
Chemical name (CA)	<i>N</i> -[3-(1-methylethoxy)phenyl]-2-(trifluoromethyl)benzamide
CIPAC No	524
CAS No	66332-96-5
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	Not allocated
Minimum purity of the active substance as manufactured	975 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities have been identified
Molecular formula	C ₁₇ H ₁₆ F ₃ NO ₂
Molar mass	323.2 g/mol
Structural formula	

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	103.9 – 105.2 °C (99.8%)
Boiling point (state purity)	Decomposition at boiling point
Temperature of decomposition (state purity)	300 °C (99.8%)
Appearance (state purity)	White powder (99.8%)
Vapour pressure (state temperature, state purity)	4.1×10^{-7} Pa at 20 °C (99.8%)
Henry's law constant (state temperature)	1.65×10^{-5} Pa m ³ mol ⁻¹ at 20 °C (calculation)
Solubility in water (state temperature, state purity and pH)	8.01 mg/L at 20 °C (pH neutral) (99.8%)
Solubility in organic solvents (state temperature, state purity)	in g/L at 20 °C (99.3%) Acetone 606 Acetonitrile 334 Dichloromethane 378 Ethyl acetate 365 n-hexane 0.39 Methanol 322 n-octanol 42 Toluene 35
Surface tension (state concentration and temperature, state purity)	71.3 mN/m at 20 °C (90 % saturated solution) (99.8%)
Partition coefficient (state temperature, pH and purity)	log P _{OW} = 3.17 at °C (pH neutral, unbuffered water) (100%)
Dissociation constant (state purity)	Structure of flutolanil has no acidic or basic substituents which could dissociate
UV/VIS absorption (max.) incl. ε (state purity, pH)	99.8% purity Neutral solution (methanolic): λ_{\max} (nm); ε (L mol ⁻¹ cm ⁻¹) 208.5 ; 11709 292.0 ; 33109 Acidic solution (methanolic) : λ_{\max} (nm); ε (L mol ⁻¹ cm ⁻¹) 248.0 ; 10739 212.5 ; 32126
Flammability (state purity)	Not flammable (99.3%) No auto-ignition before melting
Explosive properties (state purity)	Not explosive (99.3%)
Oxidising properties (state purity)	Not oxidising (99.3%)

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Month and year

Active Substance (Name)

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

PPP (product name/code)	Moncut 40SC / 40SC(EU) [without dye]	Formulation Type	Suspension Concentrate (SC)
Active Substance	Flutolanil	Conc. of as	460 g/L
Safener	None	Conc. of safener	Not applicable
Synergist	None	Conc. of synergist	Not applicable
Applicant	Nihon-Nohyaku		
Zone	Northern, Central and Southern Zones	professional use <input checked="" type="checkbox"/>	
		non-professional use <input type="checkbox"/>	

Verified by MS: yes

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	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		
Potato Seed tuber treatment (ware, seed and starch potatoes)	NL & BE	Moncut 40 SC	F I	Rhizoctonia solani	SC	460 g/l	In store treatment Canopied hydraulic or spinning disc equipment	BBCH 00 – 03 (before planting)	1	---	4.6	--	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha. Use appropriate water volumes – 2 L water/t tubers
Potato Seed tuber treatment (ware, seed and starch potatoes)	NL & BE	Moncut 40 SC	F	Rhizoctonia solani	SC	460 g/l	On planter treatment as tuber falls into furrow	BBCH 00 – 03 (at planting)	1	---	0.46 – 0.613	60 - 80	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	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		
Potato Seed tuber treatment (ware, seed and starch potatoes)	NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	In planter treatment before catching up by planting chains.	BBCH 00 – 03 (at planting)	1	---	4.6 – 9.2	4 - 8	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha
Tulip, Iris	NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	Broadcast application with boom sprayer, followed by soil incorporation.	BBCH 00 Oct - Dec	1	---	0.69 – 1.84	150 - 400	2.76	---	Incorporation into the soil, 10 – 15 cm

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Intended uses supported in the EU for which data have been provided

PPP (product name/code)	Moncut 40 SC / 40SC(EU-D) [with dye]	Formulation Type	Suspension Concentrate (SC)
Active Substance	Flutolanil	Conc. of as	460 g/L
Safener	None	Conc. of safener	Not applicable
Synergist	None	Conc. of synergist	Not applicable
Applicant	Nihon-Nohyaku		
Zone	Northern, Central and Southern Zones	professional use	<input checked="" type="checkbox"/>
		non-professional use	<input type="checkbox"/>

Verified by MS: yes

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	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		
Potato Seed tuber treatment (ware seed and starch potatoes)	EU except NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	In store treatment Canopied hydraulic or spinning disc equipment	BBCH 00 – 03 (before planting)	1	---	4.6	--	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha. Use appropriate water volumes – 2 L water/t tubers
Potato Seed tuber treatment (ware seed and starch potatoes)	EU except NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	On planter treatment as tuber falls into furrow	BBCH 00 – 03 (at planting)	1	---	0.46 – 0.613	60 - 80	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha
Potato Seed tuber treatment (ware seed and starch potatoes)	EU except NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	In planter treatment before catching up by planting chains.	BBCH 00 – 03 (at planting)	1	---	4.6 – 9.2	4 - 8	0.368*	---	0.2L product/t *Based on a planting rate of 4 t tubers/ha

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Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	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		
Tulip, Iris	EU except NL & BE	Moncut 40 SC	F	<i>Rhizoctonia solani</i>	SC	460 g/l	Broadcast application with boom sprayer followed by soil incorporation.	BBCH 00 Oct - Dec	1	---	0.69 – 1.84	150 - 400	2.76	---	Incorporation into the soil, 10 – 15 cm

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)

Regulation (EC) N° 1107/2009 Article 8.1(g)

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

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Active Substance (Name)

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PPP (product name/code)	Moncut 70DF	Formulation Type	Water dispersible granule (WG)
Active Substance	Flutolanil	Conc. of as	700 g/KG
Safener	None	Conc. of safener	Not applicable
Synergist	None	Conc. of synergist	Not applicable
Applicant	Nihon-Nohyaku		
Zone	Northern, Central and Southern Zones	professional use	<input checked="" type="checkbox"/>
		non-professional use	<input type="checkbox"/>

Verified by MS: yes

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	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		
Potatoes In furrow-treatment at planting	N/S-EU	Proposed Moncut 70DF	F	<i>Rhizoctonia solani</i>	WG	700 g	Tractor mounted planter -directed hydraulic sprayer	BBCH 00 – 03 at planting	1	Not relevant	0,84-2,8	75 - 250 l/ha	2.100	Not relevant	In furrow application directed at soil

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

planting density of potatoes can vary by EU member state or whether the potato is being grown for consumption as ware potatoes or for the generation of seed potatoes, the representative use in potatoes supported for the renewal of flutolanil is at a planting rate of 4 tonnes potatoes/ha.

Especially for seed potatoes which are often planted at higher densities the proposed GAP is unlikely to be realistic for all member states, as several member states report higher planting densities of up to 5 or 7 tons per hectare, planting densities compatible with the proposed GAP also occur. The GAP is realistic for ware and starch potatoes, which is the majority of the potato acreage.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The uses in the GAP are supported with regard to crop safety.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The uses in the GAP are supported no unacceptable unintended effects are expected.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	HPLC-UV (230 nm)
Impurities in technical a.s. (analytical technique)	HPLC-UV Confirmation of impurity identity is required
Plant protection product (analytical technique)	HPLC-UV (240 nm) RP-18 column

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin	Flutolanil
Food of animal origin	Poultry: Flutolanil Ruminants: Sum of flutolanil, metabolite M-4 (free and conjugated), expressed as flutolanil
Soil	Flutolanil
Sediment	Flutolanil
Water surface	Flutolanil
drinking/ground	Flutolanil
Air	Flutolanil
Body fluids and tissues	Flutolanil

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MSD, 0.01 mg/kg flutolanil (potatoes) HPLC-MS/MS (m/z 324.1/242.0; 324.1/262.0) LOQ 0.01 mg/kg for matrices with low water content, high fat content and high acid content.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS, LOQ 0.01 mg/kg for flutolanil, M-4 and conjugated M-4 in milk, liver, kidney, muscle and fat. LC-MS/MS, LOQ 0.01 mg/kg for flutolanil in chicken liver, muscle, fat and eggs.
Soil (analytical technique and LOQ)	GC-MSD, 0.01 mg/kg flutolanil
Water (analytical technique and LOQ)	LC-MS/MS (m/z 324/262; 324/282) LOQ 0.1 µg/L (surface water) ILV available

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Air (analytical technique and LOQ)

HPLC-UV, 2.7 µg/m³ flutolanil, confirmation by GC-MS (173 m/z)

Body fluids and tissues (analytical technique and LOQ)

Body fluid: LC-MS/MS (m/z 324/242; 324/262)
LOQ 0.05 mg/L
Body tissue: LC-MS/MS (m/z 324/242; 324/262)
LOQ 0.01 mg/kg

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance

Flutolanil

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹:

None

Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008:

None

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	70 % (based on urinary (%) and biliary (%) excretion within 48 h) based on repeated dose administration and 50% for single dose administration
Toxicokinetics	<p><u>C_{max}</u>: 4.18 µg flutolanil equivalent/ml by 20 mg/kg dosing 12.48 µg flutolanil equivalent/ml by 100 mg/kg dosing</p> <p><u>T_{max}</u>: 2 hr in low and high dose groups</p> <p><u>T_{1/2}</u>: 6-8 hr</p>
Distribution	Widely distributed (mainly in liver and kidney)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Rapid and extensive (app. 95 % within 72 h), mainly via urine (appr. 70%) and faeces (appr. 30%) as metabolites
Metabolism in animals	Extensively metabolised (> 95 %); main metabolite M-2 and M-4; metabolism by modification in the aniline ring either by hydroxylation to metabolite M2 or cleavage of the isopropyl moiety leading to metabolite M4
<i>In vitro</i> metabolism	The metabolic pathway of flutolanil in human, mouse, rabbit and dog are qualitatively comparable to the metabolism determined for the rat.
Toxicologically relevant compounds (animals and plants)	Flutolanil and metabolites (M2, M4 M-101)
Toxicologically relevant compounds (environment)	Flutolanil

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD ₅₀ oral	> 10000 mg/kg bw (rat) > 10000 mg/kg bw (mouse)	
Rat LD ₅₀ dermal	> 5000 mg/kg bw	
Rat LC ₅₀ inhalation	LC ₅₀ > 5.98 mg/L/4h (body) LC ₅₀ > 2 mg/L/4h (snout)	
Skin irritation	Non-irritant	

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Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	April 2018	Flutolanil

Section 2 Mammalian Toxicology

Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising (Magnusson & Kligman)	
Phototoxicity	Not phototoxic	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Increased weight of liver (rat, dog, mouse) and thyroid/parathyroid (rat) and histopathological alterations in liver (dog)	
Relevant oral NOAEL	90-day, dog: 80 mg/kg bw per day 90-day rat: 37 mg/kg bw per day Mouse: 680 mg/kg per day	
Relevant dermal NOAEL	21-day, rat: > 1000 mg/kg bw per day	
Relevant inhalation NOAEL	No data - not required	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	Negative in bacterial and mammalian gene mutation assays. Negative in bacterial and mammalian gene mutation assay. Weak positive in one in vitro chromosome aberration, negative in the second.	
<i>In vivo</i> studies	Negative	
Photomutagenicity	Not required	
Potential for genotoxicity	Flutolanil is unlikely to be genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Histological changes in spleen (rat) Histological alterations in liver (male mouse) Clinical signs (emesis, salivation, excretion of soft faeces) (dog)	
Relevant long-term NOAEL	8.7 mg/kg bw/d (2-yr rat), 32 mg/kg bw/day (79-wk mouse), 50 mg/kg bw/d (2-yr dog)	
Carcinogenicity (target organ, tumour type)	No carcinogenic potential	
Relevant NOAEL for carcinogenicity	Not required	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental: increased liver weight Reproduction and offspring: no effects up to the highest dose	
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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Relevant parental NOAEL	157 mg/kg bw per day	
Relevant reproductive NOAEL	> 1614 mg/kg bw per day	
Relevant offspring NOAEL	> 1614 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Maternal: no effect up to the highest dose (rat and rabbit) Foetal: positive trend of resorptions and deaths (rabbit)	
Relevant maternal NOAEL	Rat: > 1000 mg/kg bw per day Rabbit: > 1000 mg/kg bw per day	
Relevant developmental NOAEL	Rat: > 1000 mg/kg bw per day Rabbit: 40 mg/kg bw per day	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	NOAEL > 2000 mg/kg bw per day (rat)	
Repeated neurotoxicity	NOAEL > 1000 mg/kg bw per day (rat)	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data available – not required	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	4-week dietary T cell-dependent antibody assay with flutolanil; the dose-related reduction in overall spleen cell count and viable cells/ spleen might indicate a potential immune suppression. NOAEL: 61.1 mg/kg/day (male rat) and 74.6 mg/kg/day (female rat)
Endocrine disrupting properties	USEPA EDSP studies, ToxCast and literature review: Based on a weight of evidence approach flutolanil does not show endocrine disrupting effects.

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

2 (trifluoromethyl)-benzamide (coded M-101):

Acute oral toxicity

LD50: 300-2000 mg/kg bw (rat)

28-day study

NOAEL 4.2 mg/kg bw (rat)

Genotoxicity studies

Ames, mammalian gene mutation and chromosome aberration studies are negative.

2-(trifluoromethyl)-benzoic acid (coded M-102):

Acute oral toxicity

LD50: > 2000 mg/kg bw (rat)

28-day study

NOAEL 252 mg/kg bw (rat)

Genotoxicity studies

Ames and chromosome aberration studies are negative. The mammalian gene mutation tests gave positive results in the absence of S9 but the effect was not observed in a complementary study.

M2 and M4:

The metabolites M2 and M4 are considered as being the main rat metabolites. Formation of metabolite M2 and M4 in the metabolism of flutolanil was found to be >10% and therefore it can be concluded that the toxicological studies with flutolanil provide adequate information to cover for M2 and M4.

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Based on medical surveillance from manufacturing plants, there have been no incidences or indications (including sensitization) related to flutolanil.

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

Flutolanil

Acceptable Daily Intake (ADI)

Acute Reference Dose (ARfD)

Acceptable Operator Exposure Level (AOEL)

Value (mg/kg bw (per day))	Study	Uncertainty factor
0.09	rat, 2-year	100
0.4	Rabbit, developmental study	100
0.26	rat, 90-day	100*

³ If available include also reference values for metabolites

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Acute Acceptable Operator Exposure Level (AAOEL)

0.28	Rabbit, developmental study	100*
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* Including correction for limited oral absorption/bioavailability (70 %).

M-101

Acceptable Daily Intake (ADI)

0.002	Rat, 28-day	1800
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Acute Reference Dose (ARfD)

-	Not applicable	-
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Acceptable Operator Exposure Level (AOEL)

-	Not applicable	-
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Acute Acceptable Operator Exposure Level (AAOEL)

-	Not applicable	-
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M-102

Acceptable Daily Intake (ADI)

0.14	Rat, 28-day	1800
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Acute Reference Dose (ARfD)

-	Not applicable	-
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Acceptable Operator Exposure Level (AOEL)

-	Not applicable	-
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Acute Acceptable Operator Exposure Level (AAOEL)

-	Not applicable	-
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Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (*indicate name, type e.g. EC and concentration of active substance*)

Concentrate: 25 %

Spray dilution: 70%

Dermal absorption values are based on the default values according to the EFSA guidance on dermal absorption (2012). For the spray dilution, the oral absorption of 70% is considered representative for the dermal absorption.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

MONCUT 40SC

Use: tulip, iris – tractor mounted boom sprayer application to low crops, 2.76 kg a.s./ha

Exposure estimates (model): % of AOEL

EFSA AOEM

Without PPE: 456

PPE (gloves): 23

Use: potatoes - conventional canopied hydraulic or

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Section 2 Mammalian Toxicology

	<p>spinning disc equipment, 0.368 kg a.s./ha</p> <p><u>Exposure estimates (model):</u> <u>% of AOEL</u></p> <p><u>Operator exposure study</u></p> <p>Without PPE: 727</p> <p>PPE (gloves): 69</p>
Workers	<p><u>Use:</u> tulip, iris – tractor mounted boom sprayer application to low crops, 2.76 kg a.s./ha</p> <p>Not relevant since re-entry is not considered necessary shortly after spraying.</p> <p><u>Use:</u> potatoes - conventional canopied hydraulic or spinning disc equipment, 0.368 kg a.s./ha</p> <p>There is no acceptable model available to estimate the exposure of workers to this type of activity. Based on the outcomes of an study the following exposure estimates were made:</p> <p><u>Exposure estimates (model):</u> <u>% of AOEL</u></p> <p>Without PPE: 696</p> <p>PPE (gloves): 23</p>
Bystanders and residents	<p><u>Residents (EFSA AOEM)</u></p> <p>Adult: 75% of AOEL</p> <p>Child: 182% of AOEL</p> <p>Applying vehicle mounted drift reduction results in an acceptable exposure for children (41% of the AOEL).</p>

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance:	Flutolanil
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ⁴ :	No current harmonised classification

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

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Section 2 Mammalian Toxicology

Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

No classification

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) OECD Guideline 501	Crop groups	Crop(s)	Application(s)	DAT (days)
	Fruit crops	-	-	
	Root crops	Potato	Seed treatment:	131
			1x 120 mg/kg	
			1x 360 mg/kg	52
			1x 92 g/ton	,
			In furrow treatment:	
			1x 4.5 kg as/ha	131
			1x 2.5 kg as/ha	90, 122
	Leafy crops	Cabbage	1x 8 kg as/ha (soil application) 2x 0.9 kg as/ha (foliar)	56, 97 7
Metabolism of flutolanil is qualitatively similar in the different crop groups. Flutolanil and its metabolite M-4 (free and conjugated) and metabolite M-101 are the most important metabolites in primary crops				
Rotational crops (metabolic pattern) OECD Guideline 502	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops	Radish	30, 120, 366	
	Leafy crops	Lettuce	30, 148, 366	
	Cereal (small grain)	Oat	30, 148	
		Sorghum	366	
	Root/tuber crops	Radish	30, 120, 270	
	Leafy crops	Lettuce	30, 120, 270	
	Cereal (small grain)	Wheat	30, 120, 270	
	Root/tuber crops	Radish	30, 120, 270	
	Leafy crops	Lettuce	30, 120, 270	
	Cereal (small grain)	Wheat	30, 120, 270	

List of end points

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Section 3 Residues

Rotational crop and primary crop metabolism similar?	Yes, with exception of forming metabolite trifluoroacetic acid (TFA). TFA was only identified in rotational crops. Parent compound flutolanil is extensively metabolised in rotational crops. Metabolites M-2, M-4 (free and conjugated), M-101 and M-102 are the major metabolites in rotational crops.				
Processed commodities (standard hydrolysis study) OECD Guideline 507	Conditions	Flutolanil (%AR)			
	20 min, 90°C, pH 4	101.9			
	60 min, 100°C, pH 5	106.7			
	20 min, 120°C, pH 6	102.4			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes It was noted by RMS that no hydrolysis studies with metabolite M-4 and metabolite M-101 are available.				
Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Flutolanil				
Plant residue definition for risk assessment (RD-RA)	1. Sum of flutolanil and its metabolite M-4 (free and conjugated), expressed as flutolanil 2. M-101				
Conversion factor (monitoring to risk assessment)	Potatoes CF _{sum of flutolanil and metabolite M-4 free and conjugated, expressed as flutolanil} : 2				

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	0.035, 1	4	2,2N; 62.N (broiler)
		0.78	14	49N (broiler)
	Goat/Cow	0.61	4	12,4 N (ram/ewe)
		0.27	5	
	Pig	-		
	Fish	-mg/kg DM		
From all available metabolism studies in livestock it can be concluded that flutolanil is mainly hydroxylated to metabolites M-4 and M-2, followed by formation of their corresponding glycoside or sulfate conjugates. In hens, flutolanil is also further degraded to the metabolite M-101 by cleavage at the carboxamide, followed by its hydrolysis to M-102.				
Time needed to reach a plateau concentration in milk and eggs (days)	Eggs: 7 to 14 days Milk: 2-3 days and within 1 day			
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Poultry: flutolanil Ruminants: Metabolite M-4 (free and conjugated)			

List of end points

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Section 3 Residues

Animal residue definition for risk assessment (RD-RA)	Poultry: 1. Flutolanil, 2. Metabolite M-101 Ruminants: Sum of flutolanil and metabolite M-4 (free and conjugated), expressed as flutolanil
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) (FAO, 2009)	Yes (based on metabolism and livestock feeding studies)

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502	In general, the metabolic pathway seems qualitatively comparable with the metabolism of the primary crops apart from additional identification of TFA. main metabolites with a high concentration in all the rotational crops were metabolite M-101, metabolite M-102 (free and conjugated) and TFA (trifluoroacetic acid).
Field rotational crop study OECD Guideline 504	No residues in rotational crops are expected after potato seed treatment following the proposed cGAP. After in-furrow treatment application rate, residues of flutolanil and its metabolites M-4 (free and conjugated), M-101 and M-102 have been found above the LOQ in rotational crops, especially leafy crops (spinach) leafy part of the crop (radish leaf) and in cereals, including grain (metabolite M-102). Hence, residues in rotational crops cannot be excluded.

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Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Months)			
			Flutolanil	M-4	M-101	
High water content	spinach	-18	12	12	12	
High oil content	rape	-18	18	-		
High protein content	-	-	-	-	-	
High starch content	potato, wheat grain	-18	67	12	12	
High acid content	-	-	-	-	-	
(up to 250 characters)						
Animal	Animal commodity	T (°C)	Stability (Month)			
			Flutolanil	M-4	M-101	
Bovine/ chicken	Muscle	-20	4	14	2.5	
Chicken/ Bovine	Liver	-20	4	14	3	
Bovine	Kidney	-20	2.5	2.5	2.5	
Bovine	Milk	-20	3	3	3	
Chicken	Egg	-20	4	4	14	
(up to 250 characters)						

List of end points

Rapporteur Member State

The Netherlands

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Active Substance (Name)

Flutolanil

Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) [OECD Guideline 509](#), [OECD Guidance, series on pesticides No 66](#) and [OECD MRL calculator](#)

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Potato: seed treatment	NEU outdoor	Mo: 5x <0.01; <0.022; 0.01; 2x 0.014; 2x 0.02; 0.022; 2x 0.03; 0.035; 0.05; 0.09 RA: 1. Sum of flutolanil and metabolite M-4 (free and conjugated) 5x <0.02; 0.02; 2x 0.03; 0.04; 0.06; 0.1 2. Metabolite M-101: 11x <0.01	OECD calculations	0.15	1) 0.1 (0.09) 2) 0.01	1) 0.02 (0.02) 2) 0.01
	SEU outdoor	Mo: 7x <0.01; 2x 0.01; 2x 0.03; 0.04 RA: 1. Sum of flutolanil and metabolite M-4 (free and conjugated) 7x <0.02; 2x 0.02; 2x 0.04; 0.05 2. Metabolite M-101: 12x <0.01	OECD calculations	0.06	1) 0.05 (0.04) 2) 0.01	1) 0.02 (0.01) 2) 0.01

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MRL application						
Potato: in furrow treatment	NEU outdoor	Mo: 6x <0.01; 0.03; 0.04; 0.08; 0.09; 0.1; 0.11 RA: 1. Sum of flutolanil and metabolite M-4 (free and conjugated) 6x <0.02; 0.04; 0.05; 0.1; 0.11; 2x0.13; 2. Metabolite M-101: 12x <0.01	OECD calculations	0.20	1) 0.13 (0.11) 2) 0.01	1) 0.03 (0.02) 2) 0.01
	SEU outdoor	Mo: 3x<0.01; 0.01; 4x 0.02; 0.03; 0.04; 0.09; 0.13 RA: 1. Sum of flutolanil and metabolite M-4 (free and conjugated): 3x <0.02; 0.02; 4x 0.03; 0.04; 0.06; 0.12; 0.18 2. Metabolite M-101: 10x <0.01; 0.012; 0.018	OECD calculations	0.20	1) 0.18 (0.13) 2) 0.018	1) 0.03 (0.02) 2) 0.01
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	Region	Residue data (mg/kg)	Recommendations/comments			
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			

(a): NEU or SEU for northern or southern outdoor trials in EU member states (N+SEU if both zones), Indoor for glasshouse/protected crops, Country if non-EU location.

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Section 3 Residues

- (b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR_{Mo}).

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Section 3 Residues**Inputs for animal burden calculations: Flutolanil**

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses: sum of flutolanil and metabolite M-4 (free and conjugated), expressed as flutolanil				
Potato	0.02	STMTR	0.1	HR
Potato (process waste)	0.4	STMTR*default PF (0.02*20)	n/a	Only STMTR apply
Potato (dried pulp)	0.76	STMTR*default PF (0.02*38)	n/a	Only STMTR apply

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Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.036	Ram/Ewe	0.049	Breeding	0.021	Broiler	0.016	Carp	no data
	Dairy cattle	0.044	Lamb	0.033	Finishing	0.013	Layer	0.012	Trout	no data
							Turkey	0.007	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw Feeding study submitted	Yes		Yes		Yes		Yes		Yes/No	
	Yes		Yes		No		Yes		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level 1 0.120	Beef: 3.4 N Dairy: 2.7N	Level 0.120	Lamb: 3.7N Ewe: 2.4 N	Level	N rate Breed/Finish	Level 0.076	B or T: 4.8N Layer: 6.2N	Level	N rate Carp/Trout
	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals
Muscle	0.033	0.033*	0.033		n.a	n.a	0.01	0.01*		
Fat	0.033	0.033*	0.033		n.a	n.a	0.01	0.01*		
Meat ^(b)					n.a					
Liver	0.033	0.033*	0.033		n.a	n.a	0.01	0.01*		
Kidney	0.043	0.05	0.043		n.a	n.a	-	-		
Milk ^(a)	0.033	0.033*	0.033							
Eggs							0.01	0.01*		
Method of calculation ^(c)										

^(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).

^(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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Section 3 Residues

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey			
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N
Muscle	0.033	0.033	0.033	0.033			0.01	0.01		
Fat	0.033	0.033	0.033	0.033			0.01	0.01		
Meat ^(a)							0.01	0.01		
Liver	0.033	0.033	0.033	0.033			0.01	0.01		
Kidney	0.013	0.013	0.013	0.013			-	-		
Milk	0.033	0.033	0.033	0.033						
Eggs							0.01	0.01		
Method of calculation ^(c)										

^(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

^(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by interpolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Plant products

Table to be deleted if not relevant (RD-Mo = RD-RA)

Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials ^(a) OECD Guidance, series on Pesticides No 66								
PHI ^(b) (days)	N/A							Comments
Representative uses and MRL application								
Potato	2							A CF of 2 from RD-Mo to RD-RA is proposed for potatoes only, based on the available residue data. PHI is not applicable at the proposed cGAP (BBCH 00-03)
Comments (up to 250 characters):								

^(a): CF calculated at the supported PHI are underlined.

^(b): 0-/0+ for samples collected just before/after the last application

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Section 3 Residues

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies ^(a)	Processing Factor (PF)		Conversion Factor (CF _p) for RA ^(b)
		Individual values	Median PF	
Representative uses (row to be deleted if not relevant)				
MRL application (row to be deleted if not relevant)				

^(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

^(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI

Flutolanil: 0.09 mg/kg bw per day

M-101: 0.002 mg/kg bw per day

TMDI according to EFSA PRIMo

Highest TMDI Flutolanil: 3.8% ADI (NL child)

Highest TMDI M-101: 4.9% ADI (NL child)

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

ARfD

Flutolanil: 0.4 mg/kg bw

Not set for M-101

IESTI (% ARfD), according to EFSA PRIMo

Highest IESTI flutolanil: 15.4% ARfD (potato)

NESTI (% ARfD), according to (to be specified)

Factors included in IESTI and NESTI

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

To be deleted if not relevant

Metabolite(s)

ADI (mg/kg bw per day)

Intake of groundwater metabolites (% ADI)

WHO Guideline (WHO, 2009)

Adult (60 kg bw, 2 L): XX % ADI

Child (10 kg bw, 1 L): XX % ADI

Infant (5 kg bw, 0.75 L): XX % ADI

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Section 3 Residues

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code ^(a)	Commodity/Group	MRL/Import tolerance ^(b) (mg/kg) and Comments	
Plant commodities			
Representative uses			
	Potato (seed treatment)	0.15	Sufficient trial data are available. The proposed MRL is higher than the existing MRL.
MRL application			
	Potato (in-furrow treatment)	0.2	Sufficient trial data are available. The proposed MRL is higher than the existing MRL.
Animal commodities			

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

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Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	EU soils 2.9 - 10% after 105d, [aniline ring-U-14C]-label (n= 4) US soil 27.5% after 365d, [aniline ring-U-14C]-label (n= 1) JPN soils 0.4 – 3.0% after 180d [aniline-U-14C]-label (n=3) EU soil 1.2% after 120d (n= 1)
Non-extractable residues after 100 days	EU soils 9.4 – 27.9 % after 105 d, [aniline ring-U-14C]-label (n= 4) US soil 26.7 % after 365 d, [aniline ring-U-14C]-label (n= 1) JPN soils 9.2 - 12.3% after 180d [aniline-U-14C]-label (n=3) EU soil 3.7% after 120d, [phenyl-U-14C]-label (n7= 1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	None (the only metabolite appearing over 5 % was CO ₂)

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	Stable 1.3 % after 333 d, [aniline ring-U-14C]-label (n= 2) 1.15 % after 119 d, [phenyl-U-14C]-label (n= 1)
Non-extractable residues after 100 days	10 % after 333 d, [aniline ring-U-14C]-label (n= 2) 4.9 % after 30 d, [phenyl-U-14C]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none
Mineralisation at study end (100d)	<0.3 % after 25 d, [14C-X]-label (n= x) <0.3 % after 25d, [phenyl-U-14C]-label (n=1)
Non-extractable residues at study end (100d)	9.6 % after 30 d, [aniline ring-U-14C]-label (n= 1) 1.5 % after 25 d, [phenyl-U-14C]-label (n= 1)

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Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

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Section 4 Environmental fate and behaviour

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Soil			Dark aerobic conditions.						
Name	Type	Year	pH (method)	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa)	St. (χ ²)	Method of calculation
Morgenroth, U. (1993),									
Speyer 2.2	loamy sand	1986	6.0 KCl	20 ± 2°C 100% of the field capacity.	115 / 383	-	115	1.75	SFO
Breda	sandy loam	1986	7.1 KCl	20 ± 2°C 100% of the field capacity.	383 / 1270	-	383	1.08	SFO
Westmaas	loam	1986	7.2 KCl	20 ± 2°C 100% of the field capacity.	151 / 502	-	151	0.873	SFO
St. Maartensbrug	sand	1986	7.4 KCl	20 ± 2°C 100% of the field capacity.	400 / 1330	-	400	2.04	SFO
Swanson, M. (1996)									
Wonder Lake / Millington Loam Bottom Soil	sandy loam	1993	7.4 unknown	25 ± 1°C 75% of the 1/3 bar field moisture capacity	116 / 820	-	442	3.81	DFOP (k1 = 0.02891 k2 = 0.00225 g=0.3683)
Takahashi, Y. (2015)									
F2.2 (Phenyl)	Loamy sand	2014	5.5 CaCl ₂	20°C ± 2°C (40.2-59.8% of MWHC).	569 / 1890	-	not used in geometric mean calculation	1.51	SFO
F2.2 (Aniline)					547 / 1820	-		2.18	SFO
F2.2 (Aggregated Rep)					560 / 1860	-	560	1.70	SFO
Aizawa, H. (1982)									
Saitama (upland)	Loam	1981	4.8 KCl	30°C 60% MWHC	1000 / >1000	-	1000 ^a	0.234	FOMC (α: 0.08438 β: 23.25) (persistence) SFO (modelling)
Okayama (upland)	Sandy loam	1981	5.3 KCl	30°C 60% MWHC	531 / 1770	-	1000 ^a	2.55	SFO
Geometric mean (n=8)							400		
Arithmetic mean						-			
pH dependence					No (R ² < 0.5)				

^a normalisation to 20°C and pF2 resulted in a degradation rate > 1000 days. The default maximum of 1000 days was applied.

List of end points

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Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Soil									
Name	Type	Year	pH method	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa	St. (X ²)	Method of calculation
Wicks, R. (1999)									
Manningtree (tuber)	Sandy loam	1997	5.2 water	-	283 / 940	-	137	8.47	SFO
Ottersum (tuber)	Sandy loam	1997	7.0 water	-	342 / 1140	-	171	10.7	SFO
Goch (tuber)	Silt loam	1997	6.5 water	-	184 / 1050	-	125	4.95/ 5.08	DFOP (k ₁ = 0.01156 k ₂ = 0.001748 g = 0.3719) (persistence) SFO (modelling)
Niederkirchen (tuber)	Sandy loam	1997	7.6 water	-	259 / 859	-	166	14.6	SFO
Manningtree (spray)*	Sandy loam	1997	5.2 water	-	127 / 421	-	67.6	12.7	SFO
Ottersum (spray)	Sandy loam	1997	7.0 water	-	211 / 701	-	116	16.3	SFO
Ginzburg, N & Hardy, I. (2007)									
Amstenrade (FA-26-05-01/02)	Silt loam	2005	8.0 unknown	-	104 / 347	-	66.3	15.0	SFO
Ubachsberg (FA-26-05-01/01)	Loam	2005	7.7 unknown	-	86.0 / 286	-	60.4	15.7	SFO
Geometric mean (n=8)							105**		
Arithmetic mean						-			
pH dependence					No				

* excluding day 0.

** Tuber and spray application field DT₅₀ values are combined. However, based on comments of the co-RMS and applicant it was verified that these populations are statistically different (geomean tuber treatments is 148.5 days and geomean spray treatments is 74.9 days). Implications for exposure modelling are not yet addressed.

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Not applicable. The normalised field studies show shorter DegT50 than the laboratory studies.

List of end points

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Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Plateau concentration of 0.812 mg/kg reached after 20 years (based on calculation)

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Soil			Dark anaerobic conditions.						
Name	Type	Year	pH (water)	t. °C / % MWHC (during aerobic phase)	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa)	St. (χ ²)	Method of calculation
Mallipudi, N. & Cooke, L. (2013)									
Loamy sand 1	Loamy sand	2011	6.2	Soil not included because of aerobic conditions					
Sandy clay loam	Sandy clay loam	2011	6.9	20°C / 40%	2310 / 7675	-	1439	-	SFO
Loamy sand 2	Loamy sand	2011	5.9	20°C / 40%	2310 / 7675	-	1774	-	SFO
Clay loam	Clay loam	2011	5.8	Soil not included because of low microbial biomass					
Roohi, A. (2016)									
Speyer 2.2	loamy sand	2015	5.9	20°C / pF2	> 1000	-	> 1000	-	-
Geometric mean (n=6)							> 1000		
Arithmetic mean						-			
pH dependence					No				

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Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Parent	Soil photolysis
No measurable degradation of flutolanil occurred under the conditions of the study in dark and irradiated samples. No metabolites were found in irradiated samples exceeding 2% AR.	

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Soil ID	Texture	pH (water)	OC [%]	Adsorption			Desorption		
				K _f [mL/g]	K _{oc} [mL/g]	1/n	K _f [mL/g]	K _{oc} [mL/g]	1/n
Williams, M., (1992a)									
#110 Loam	loam	8.0	0.47	2.76	594	0.835	3.86	830	0.892
#90 Clay loam	clay loam	7.4	2.85	13.0	457	0.744	18.8	659	0.726
#86 Clay loam	clay loam	6.2	0.64	4.02	628	0.904	5.71	892	0.714
#126 Loamy sand	loamy sand	4.8	1.57	15.8	1005	0.926	20.8	1327	0.936
Geometric mean (n=4)	-	-	-	-	643	-	-	897	-
Arithmetic mean (n=4)	-	-	-	-	-	0.9*	-	-	0.9*

* no acceptable Freundlich exponent (1/n) could be derived and therefore the default values are proposed by RMS. This default of 0.9 is set when Tier 3 OECD 106 has been performed, but no reliable endpoint could be determined (page 40 FOCUS GW guidance, v2.2).

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Soil adsorption transformation product M4 (Desisopropylflutolanil) (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Soil ID	Texture	pH (water)	OC [%]	Adsorption			Desorption		
				K _f [mL/g]	K _{oc} [mL/g]	1/n	K _f [mL/g]	K _{oc} [mL/g]	1/n
Williams, M., (1992b)									
#110 Loam	loam	8.0	0.47	1.36	293	0.859	1.74	375	0.702
#90 Clay loam	clay loam	7.4	2.85	11.3	396	0.750	14.9	522	0.756
#126 Loamy sand	loamy sand	4.8	1.57	4.98	317	0.752	8.27	527	0.684
Geometric mean (n=3)	-	-	-		333			469	
Arithmetic mean (n=3)	-	-	-	-	-	0.9*	-	-	0.9*

* no acceptable Freundlich exponent (1/n) could be derived and therefore the default values are proposed by RMS. This default of 0.9 is set when Tier 3 OECD 106 has been performed, but no reliable endpoint could be determined.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Elution (mm): 200 mm
Time period (d): 2 d
Leachate: < 0.24 % total residues/radioactivity in leachate.
The radioactivity of soil column was not analysed. After 8 months of aging flutolanil still accounted for 84 % of the extracted radioactivity. Thus, it was considered inappropriate to continue the experiment and the study was found unnecessary.

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

No metabolites required further consideration.
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Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

Not considered necessary.

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Hydrolytically stable at all pH

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

DT50 : >231 d
Xenon lamp
No relevant metabolites
Estimated DT50 at 30-50°N 476-701 days

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

Not applicable

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable
(yes/no)

No (the change of BOD/28 days was 0 %)

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Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed ^{a)}	t. °C ^{b)}	DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test)		St. (χ^2)	DT ₅₀ /DT ₉₀ Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalise d to x °C ^{c)}		At study temp	Norma lised to x °C ^{c)}		
Fresh water (100 µg/mL)	8.24	-	20	-	-	-	> 1 yr	-	-	SFO
Fresh water (10 µg/mL)	8.24	-	20	-	-	-	> 1 yr	-	-	SFO

No metabolites formed under aerobic conditions

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Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Fresh water (100 µg/mL)	8.24	-	<1% AR after 90 d (end of study)	^{a)} -	^{a)} -
Fresh water (10 µg/mL)	8.24	-	<1% AR after 90 d (end of study)	^{a)} -	^{a)} -

a) Not relevant as pelagic test systems

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution (max in water 96.8-97.8% after 0.25 d. Max. sed 34.0-68.7 % after 30 d)									
<u>Persistence</u>										
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ^2)	DT ₅₀ /DT ₉₀ water	St. (χ^2)	DT ₅₀ /DT ₉₀ sed	St. (χ^2)	Method of calculation system/water/sediment
Calwich Abbey	7.5	7.0	20	391/1390	1.0 1	32.9/151	3.3 4	1000 (default)/-	-	HS / HS / -
Swiss Lake	6.8	5.7	20	413/1480	2.4 3	50.4/>1000 0	1.3 7	1000 (default)/-	-	HS / HS / -
Pond	8.3	7.3	20	88.7/295	3.1 3	28.1/181	3.9 6	91.9/305	6.5 3	SFO / DFOP / SFO
Ditch	7.2	6.7	20	236/868	1.0 1	4.49/86.2	4.4 6	427/1420	0.2 3	HS / HS / SFO
Geometric mean at 20°C				-		-		-		

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution (max in water 96.8-97.8% after 0.25 d. Max. sed 34.0-68.7 % after 30 d)									
<u>Modelling</u>										
Water / sediment system	pH water phase	pH sed	t. °C	DegT ₅₀ /DegT ₉₀ whole sys.	St. (χ^2)	DisT ₅₀ /DisT ₉₀ water	St. (χ^2)	DisT ₅₀ /DisT ₉₀ sed	St. (χ^2)	Method of calculation system/water/sediment
Calwich Abbey	7.5	7.0	20	346/1150	1.8 3	38.4/128	4.0 1	1000 (default)/-	-	SFO / SFO / -
Swiss Lake	6.8	5.7	20	354/1180	1.9 2	67.8/225	5.7 6	1000 (default)/-	-	SFO / SFO / -

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Pond	8.3	7.3	20	88.7/295	3.1 3	65.8/-	3.9 6	91.9/305	6.5 3	SFO / DFOP / SFO
Ditch	7.2	6.7	20	233/774	2.7 5	53.5/-	4.4 6	427/1420	0.2 3	SFO / HS / SFO
Geometric mean at 20°C				224/n.c.		55/n.c.		445/n.c.		

n.c. not calculated

Metabolite M-4	
Max in total system 6.8 % after 61 days. Max in water 5.2%	

Metabolite M-11	
Max in total system 8.3 % after 61 days. Max in water 6.9%	

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Calwich Abbey	7.5	7.0	0.4% after 98 d	3.2% after 59 d	0.1% after 98 d
Swiss Lake	6.8	5.7	0.2% after 98 d	1.2% after 59 d	<0.1% after 98 d
Pond	8.3 ¹ - 7.0 ²	7.3	5.2% after 105 d	26.3% after 105 d	26.3 % after 105 d
Ditch	7.2 ¹ - 6.5 ²	6.7	3.7% after 105 d	15.1% after 105 d	15.1 % after 105 d

1 = before study start

2 = study end

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air

No data available (flutolanil has a low vapour pressure, 4.7×10^{-8} , and as such its concentration in the atmosphere is likely to be negligible)

Photochemical oxidative degradation in air

DT50 of 0.072 days derived by the Atkinson model (version 1.70). OH (12 h) concentration assumed = $1.5 \times 10^6 \text{ cm}^3$

Volatilisation

No data available (flutolanil has a low vapour pressure, 4.7×10^{-8} , and as such its volatilisation is likely to be negligible)

No data available (flutolanil has a low vapour pressure, 4.7×10^{-8} , and as such its volatilisation is likely to be negligible)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Metabolites

No metabolites required further consideration.

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

Soil:	flutolanil
Surface water:	flutolanil, M-4, M-11
Sediment:	flutolanil, M-4, M-11
Groundwater:	flutolanil
Air:	flutolanil

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

No data provided

Surface water (indicate location and type of study)

Public data available from national monitoring programs in The Netherlands, 321 locations, 2132 samples, in 2014.
No exceedance of environmental quality standards (authorisation threshold ($0.1 \times \text{NOEC}_{\text{fish}}$) 23.3 µg/L and MPC 22 µg/L)

Ground water (indicate location and type of study)

Public data available from national monitoring programs in the United Kingdom and The Netherlands
UK: dataset 1992-2009, 3963 sites, 10301 samples, two detects of flutolanil. Maximum 0.17 µg/L (depth unknown)
NL: dataset 2006, 771 wells, one finding of flutolanil in shallow groundwater (measured concentration >0.1 µg/L) and one finding of flutolanil in deeper groundwater (measured concentration >LOD but <0.1 µg/L)

Air (indicate location and type of study)

No data provided

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent

Method of calculation

DT50 (d): 342 days (Worst case field study, tuber applied)
Kinetics: SFO

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Application data

Crop: potato, flower bulbs
 Depth of soil layer: 5 cm & 10 cm
 Soil bulk density: 1.5 g/cm³
 % plant interception: BBCH 00
 Number of applications: 1
 Interval (d): N/A
 Application rate(s): 368 g a.s./ha potatoes, 2760 g a.s./ha flower bulbs

PECs (mg/kg)		Flutolanil					
		Potato (5 cm)		Tulip & iris (5 cm)		Tulip & iris (10 cm)	
Appl. Rate (g a.s./ha)		368		2760		2760	
Days after maximum		PEC	PEC _{TWA}	PEC	PEC _{TWA}	PEC	PEC _{TWA}
Initial	0	0.491	-	3.680	-	1.840	-
Short term	1	0.490	0.490	3.673	3.676	1.836	1.838
	2	0.489	0.490	3.665	3.673	1.833	1.836
	4	0.487	0.489	3.650	3.665	1.825	1.833
Long term	7	0.484	0.487	3.628	3.654	1.814	1.827
	14	0.477	0.484	3.577	3.628	1.789	1.814
	21	0.470	0.480	3.527	3.603	1.763	1.801
	28	0.464	0.477	3.477	3.578	1.738	1.789
	50	0.443	0.467	3.325	3.500	1.663	1.750
	100	0.401	0.444	3.005	3.331	1.502	1.666
PEC _{S,plateau}		0.112	-	0.840	-	0.840	-
PEC _{S,peak accum}		0.603	-	4.520	-	2.641	-

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PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –
 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
 Model(s) used: FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS MACRO (v 5.5.4)
 Crop: potatoes and onions (surrogate for bulb flowers)
 Molar mass: 323.3 (g/mol)
 Crop uptake factor: 0
 Water solubility (mg/L): 8.01 water and 20°C
 Vapour pressure (Pa): 4.1E-07
 Geometric mean parent DT_{50field} 105 days (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
 KOC (mL/g): 643 arithmetic mean 1/n= 0.9
 Henry Coefficient (J/mol): 1.65E-05
 Metabolites: No metabolites

Application rate

Application rate: potatoes 386 g/ha 10cm incorporation / injection, flower bulbs 2760 g/ha 15cm incorporation
 Crop growth stage: At planting
 Canopy interception %: n/a
 No. of applications: 1

Time of application

Potatoes: relative application date 15 days prior to emergence
 Bulb flowers : 1st of November

FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil potato incorporation 0.1 m. Values in bold exceed the 0.1 µg/L criterion.

Scenario	Flutolanil		
	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001
Hamburg	0.004	0.001	n.a.
Jokioinen	<0.001	<0.001	n.a.
Kremsmuenster	0.002	0.001	n.a.
Okehampton	0.003	0.003	n.a.
Piacenza	0.003	0.002	n.a.
Porto	<0.001	<0.001	n.a.
Sevilla	<0.001	<0.001	n.a.
Thiva	<0.001	<0.001	n.a.

n.a.= not assessed

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FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil potato injection 0.1 m. Values in bold exceed the 0.1 µg/L criterion.

Scenario	Flutolanil		
	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	n.a.	n.a.
Hamburg	0.012	n.a.	n.a.
Jokioinen	<0.001	n.a.	n.a.
Kremsmuenster	0.007	n.a.	n.a.
Okehampton	0.009	n.a.	n.a.
Piacenza	0.009	n.a.	n.a.
Porto	<0.001	n.a.	n.a.
Sevilla	<0.001	n.a.	n.a.
Thiva	<0.001	n.a.	n.a.

n.a.= not assessed

FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil flower bulbs incorporation 0.15 m (onion used as a surrogate crop). Values in bold exceed the 0.1 µg/L criterion.

Scenario	Flutolanil		
	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]
Chateaudun	0.005	<0.001	<0.001
Hamburg	0.345	0.001	n.a.
Jokioinen	<0.001	<0.001	n.a.
Kremsmuenster	0.216	0.001	n.a.
Okehampton	n.a.	n.a.	n.a.
Piacenza	n.a.	n.a.	n.a.
Porto	0.025	<0.001	n.a.
Sevilla	n.a.	n.a.	n.a.
Thiva	<0.001	<0.001	n.a.

n.a.= not assessed

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent flutolanil

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: 3.2
Molecular weight (g/mol): 323.3
Water solubility (mg/L): 8.01
KOC/KOM (mL/g): 643
DegT50 soil (d): 105 days field. In accordance with FOCUS SFO
DT50 water/sediment system (d): 224 d

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Parameters used in FOCUSsw step 3	<p>DT50 water (d): 224</p> <p>DT50 sediment (d): 224</p> <p>Crop interception (%): n/a</p> <p>Crop scenario: potato and onions (surrogate for bulb flowers)</p>
	<p>Version control no.'s of FOCUS software: FOCUS tool SWASH (v 5.3), including the operational models FOCUS-MACRO (v 5.5.4), FOCUS-PRZM (v 4.3.1) and FOCUS-TOXSWA (v 4.4.3)</p> <p>Water solubility (mg/L): 8.01 water at 20°C</p> <p>Vapour pressure: 4.1E-07 Pa at 20°C</p> <p>Field DegT50 soil: 105 days</p> <p>Koc/Kom (mL/g): 643/373</p> <p>1/n: 0.9</p> <p>Q10=2.58, Walker equation coefficient 0.7</p> <p>Crop uptake factor: 0</p> <p>DegT50 water (days) 224 / 1000</p> <p>DegT50 sediment (days) 1000 / 224</p> <p>Crop scenario: potato and bulb vegetables (surrogate for bulb flowers)</p>
Application rate	<p>Crop and growth stage: BBCH 00</p> <p>Number of applications: 1</p> <p>Interval (d): n/a</p> <p>Application rate: 368 g a.s./ha (potatoes), 2760 g a.s./ha (flower bulbs)</p> <p>Application window: see table below</p>

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Crop scenario	Scenario	Application window		
		Emergence day	Start of application window	End of application window
Potato 1x368 g a.s/ha	D3	10 May (130)	10 April (100)	10 May (130)
	D4	22 May (142)	21 April (111)	22 May (142)
	D6	10 April (100)	11 March (70)	10 April (100)
	D6	5 August (217)	6 July (187)	5 August (217)
	R1	5 May (125)	5 April (95)	5 May (125)
	R2	15 March (74)	13 February (44)	15 March (74)
	R3	10 April (100)	11 March (70)	10 April (100)
Flower bulbs 1x2760 g a.s/ha	D3	25 April	1 October (274)	31 December (365)
	D4	23 April	1 October (274)	31 December (365)
	D6	10 May	1 October (274)	31 December (365)
	D6	20 October	1 October (274)	31 December (365)
	R1	20 April	1 October (274)	31 December (365)
	R2	28 February	1 October (274)	31 December (365)
	R3	1 March	1 October (274)	31 December (365)
	R4	1 March	1 October (274)	31 December (365)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Metabolite M-4

Parameters used in FOCUSsw step 1, 2 & 3

Molecular weight: 281.2
 Soil or water metabolite: water (major), soil (minor)
 Koc/Kom (mL/g): 333/193
 1/n: 0.9
 DT50 soil (d): 1000 days
 DT50 water/sediment system (d): 1000 d
 DT50 water (d): 1000 d
 DT50 sediment (d): 1000 d
 Crop interception (%): n/a
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 6.8%
 Soil: 3.0%
 Q10=2.58
 Walker equation coefficient 0.7
 Crop uptake factor: 0

Metabolite M-11

Parameters used in FOCUSsw step 1, 2 & 3

Molecular weight: 353.3
 Soil or water metabolite: water (major), soil (minor)
 Koc/Kom (mL/g): 1 (Worst-case for water compartment)
 1/n: 1.0
 DT50 soil (d): 1000 days
 DT50 water/sediment system (d): 1000 d
 DT50 water (d): 1000 d
 DT50 sediment (d): 1000 d
 Crop interception (%): n/a
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 8.3%
 Soil: 4.9%
 Q10=2.58
 Walker equation coefficient 0.7
 Crop uptake factor: 0

Application rate

see parent

Main routes of entry

Drainage

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Maximum PEC_{sw} and PEC_{sed} values for Flutolanil, M4 and M11 (FOCUS Steps 1-2, and SWASH (Step 3))

Crop Usage	Scenario	Flutolanil		M4		M11	
		PEC _{sw}	PEC _{sed}	PEC _{sw}	PEC _{sed}	PEC _{sw}	PEC _{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Potato 368 g a.s./ha No interception Spring (Mar. - May)	Step 1	66.04	424.67	2.22	7.38	5.36	0.05
	Step 2	25.73	165.44	0.88	2.94	2.14	0.02
	Step 3	0.091	0.224	0.013	0.088	2.795	1.994
Tulip & iris 2760 g a.s./ha No interception Spring (Mar. - May)	Step 1	495.33	3.18E+03	16.63	55.37	40.16	0.40
	Step 2	192.97	1.24E+03	6.63	22.09	16.02	0.16
	Step 3	25.25	33.74	0.163	1.009	20.74	14.89

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 4 Environmental fate and behaviour

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

Data not provided, not requested.

PEC

Maximum concentration

Data not provided, not requested.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Test species	Time scale	Test material	Endpoint [95% CI, lower - upper]	Data point Author, year
Birds				
Bobwhite quail (<i>Colinus virginianus</i>)	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 Fairley C., 1987a
Mallard duck (<i>Anas platyrhynchos</i>)	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 Fairley C., 1987b
Bobwhite quail (<i>Colinus virginianus</i>)	Short-term dietary (5-days)	Flutolanil Technical	LD ₅₀ > 5243 ppm LD ₅₀ > 819.8 mg/kg bw/d	CA 8.1.1.2-01 Fairley, C., 1987c
Mallard duck (<i>Anas platyrhynchos</i>)	Short-term dietary (5-days)	Flutolanil Technical	LD ₅₀ > 5243 ppm LD ₅₀ > 929.3 mg/kg bw/d	CA 8.1.1.2-02 Fairley, C., 1987d
Bobwhite quail (<i>Colinus virginianus</i>)	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 Beavers <i>et al.</i> , 1993a CA 8.1.1.3-03. Palmer, D.A., 2016
Mallard duck (<i>Anas platyrhynchos</i>)	Long-term	Flutolanil Technical	NOEC = 267mg a.s./kg bw/day NOEC _{biologically relevant} = 687.2 mg a.s./kg bw/day EC ₁₀ = ND EC ₂₀ = ND EC ₅₀ = ND	CA 8.1.1.3-02 Beavers <i>et al.</i> , 1996 CA 8.1.1.3-03. Palmer, D.A., 2016
Other terrestrial vertebrates				
Rat	Acute oral	Flutolanil 40SC	LD ₅₀ > 2000 mg/kg bw	CP 7.1.1/01 Horiuchi, K (2007a)
Rat	Acute oral	Flutolanil Technical	LD ₅₀ > 2000 mg/kg bw	CA 5.2.1-03 Toga, T, 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 Tsuchiya, 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 Atkinson, 1986a

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Test species	Time scale	Test material	Endpoint [95% CI, lower - upper]	Data point Author, year
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 Aughton, 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 Atkinson, 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 Schroeder, R.E., 1991 CA 8.1.2.2-01 Thomas, G.D., Myers, D.P., 2016
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 Lambert, 1987, as amended 1992 CA 8.1.2.2-01 Thomas, G.D., Myers, D.P., 2016
Rabbit	Developmental 6-18 days gestation	Flutolanil Technical	NOAEL = 40 mg/kg bw/d (resorptions and deaths occurring in 5 different litters (out of 13 litters))	CA 5.6.2/02 Tauchi, K (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 Mizoguchi, 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 Tsukushi, M (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 Tsukushi, M (2012)
Metabolite M-102				

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Test species	Time scale	Test material	Endpoint [95% CI, lower - upper]	Data point Author, year
Rat	Acute oral	2- (trifluoromethyl)- benzoic acid (M-102)	LD ₅₀ > 2000 mg metabolite/kg bw	CA 5.8.1/07 Serizawa, H (2016)
Rat	Short term oral 28 days	2- (trifluoromethyl)- benzoic acid (M-102)	NOAEL ♂ = 252 mg metabolite/kg bw/d	Inagaki, K (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

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Bulb flowers, early post-emergence weeds, at 2760 g a.s./ha x 1; potatoes

Scenario	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
Potatoes	Small omnivorous	Acute	58.4	34.2	10
Bare soils	Small granivorous		69.8	28.6	
Presence of weeds	Small omnivorous		438.3	4.56	
Potatoes	Small omnivorous	Long-term	12.7	19.6	5
Bare soils	Small granivorous		16.8	14.9	
Presence of weeds	Small omnivorous		94.79	2.61	
Tier 1 (Birds)					
leaf development BBCH 10-19	Medium herbivorous/ granivorous	Acute	153.18	13.06	10
BBCH 10 - 19	Small insectivorous	Acute	73.97	27.04	10
leaf development BBCH 10-19	Medium herbivorous/ granivorous	Long-term	15.47	12.93	5
BBCH 10 - 19	Small insectivorous	Long-term	7.47	26.77	5
Potato-eating bird					
All	Crane	Acute	25.59	> 78.14	10
		Long-term		9.7	5
Screening Step (Mammals)					
Potatoes	Small herbivorous mammal	Acute	43.6	45.9	10
Bare soils	Small granivorous mammal		39.7	50.3	
Presence of weeds	Small herbivorous mammal		376.5	5.31	
Potatoes	Small herbivorous mammal	Long-term	9.420432	4.25	5
Bare soils	Small granivorous mammal		9.65448	4.14	
Presence of weeds	Small herbivorous mammal		105.76	0.38	

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Scenario	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Mammals)					
All season	Large herbivorous	Acute	96.9	20.6	10
BBCH 10-49	Small omnivorous	Acute	47.5	41.6	10
All season	Large herbivorous	Long-term	20.92	1.9	5
BBCH 10-49	Small omnivorous	Long-term	11.41	3.5	5
Potato-eating mammals					
All	Wild boar	Acute	15.708	> 637	10
		Long-term		2.55	5
Metabolites: The risk assessment for dietary exposure to relevant plant metabolites was acceptable for birds but the potential risk from M-4 in weeds in the treated field was not acceptable in the long-term risk assessment for mammals.					
Higher tier (Mammals): A higher tier refinement is required for the chronic risk to small omnivorous and large herbivorous mammals from the proposed use in flower bulbs. A refined risk assessment is also required to address the chronic risk to potato-eating mammals.					
Risk from bioaccumulation and food chain behaviour [indicate when not relevant i.e if Log kow≤3]					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	4.02	62	5
Earthworm-eating mammals		Long-term	4.91	8	5
Fish-eating birds		Long-term	1.02	244	5
Fish-eating mammals		Long-term	0.91	44	5
Higher tier: None necessary.					
Risk from consumption of contaminated water					
Puddle scenario, Screening step					
Application rate (2760g a.s./ha)/2000 = 1.4 <3000 (koc≥500 L/kg), TER calculation not needed.					
Application rate (2760g a.s./ha)/247.8 = 11 <3000 (koc≥500 L/kg), TER calculation not needed.					
Application rate (2760g a.s./ha)/2000 = 1.4 <3000 (koc≥500 L/kg), TER calculation not needed.					
Application rate (2760g a.s./ha)/40 = 69 <3000 (koc≥500 L/kg), TER calculation not needed.					
Endocrine disruption					
There is no indication of endocrine disruption potential in the mammalian data set. The fish short term reproduction assay indicates the potential for endocrine disruption (anti-androgenic) in fish. A data gap is recommended, requesting further information to address the risk for endocrine disruption in fish, including a medaka extended one generation assay.					

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

*This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Species	Test substance	Time-scale (Test type)	End point	Data point Author, year
Toxicity to Fish				

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Species	Test substance	Time-scale (Test type)	End point		Data point Author, year
<i>Oncorhynchus mykiss</i> 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 Bowman, J.H, 1987a
<i>Lepomis macrochirus</i> (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 Bowman, J.H,1987b
<i>Pimephales promelas</i> (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 Bowman, J.H, 1990
<i>Pimephales promelas</i> (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 Rhodes, J.E & Muckerman, M, 1995 CA 8.2.2.1-02 Palmer, D.A., 2016
Toxicity to aquatic invertebrates					
<i>Daphnia magna</i> (Water flea)	Flutolanil Technical	Acute, 48h (static)	EC ₅₀	> 6.8 mg/L (m.m.)	CA 8.2.4.1-01 Forbis, A.D. <i>et al.</i> , 1990
<i>Daphnia magna</i> (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
<i>Mysidopsis bahia</i> (Shrimp)	Flutolanil	Acute, 48h (static)	LC ₅₀	0.13³ (0.087-0.16) mg/L (m.m.)	CA 8.2.4.2-01 Forbis, A.D., 1991
<i>Mysidopsis bahia</i> (Shrimp)	Flutolanil	Life-cycle, 28 days (flow-through)	NOEC EC ₁₀ (95% CI) Survival production young/female growth (dry weight) EC ₂₀ (95% CI) Survival production young/female growth (dry weight) EC ₅₀ (95% CI) Survival production young/female growth (dry weight)	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.) 0.115 (0.0812-0.237) mg/L (m.m.)	CA 8.2.5.2-01 Boeri, R.L., Kowalski, P.L., Ward, T.J., 1995

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Species	Test substance	Time-scale (Test type)	End point		Data point Author, year
<i>Chironomus riparius</i> (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					
<i>Pseudokirchneriella subcapitata</i> ² (Green algae)	Flutolanil Technical	Chronic, 72h (static)	E _r C ₁₀ E _r C ₂₅ E _r C ₅₀ E _b C 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 (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation (Flutolanil 40 SC); a.s.: active substance

² Formerly known as *Salmo gairdneri*

³ Formerly known as *Selenastrum capricornutum*

ND: Could not be determined

CI: Confidence Intervals

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	M-4	M-11
logP _{O/W}	3.17	-	-
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	100 ± 35*	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)			
Annex VI Trigger for the bioconcentration factor	100 (for not readily biodegradable substances)	-	-
Clearance time (days) (CT ₅₀)	0.46 d	-	-
(CT ₉₀)	-	-	-
Level and nature of residues (%) in organisms after the 14-day depuration phase	-	-	-
Higher tier study			
-			

* based on total ¹⁴C or on specific compounds

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

PEC/RAC ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} step 1-3 – PEC/RAC ratios for flutolanil – potatoes at 368 g a.s./ha (1 application)

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	ErC ₅₀	NOEC
		4800 µg/L	233 µg/L	130 µg/L	3.97 µg/L	> 3200 µg/L	1000 µg/L
AF		100	10	100	10	10	10
RAC (µg/L)		48	23.3	1.3	0.397	> 320	100
FOCUS Step 1							
	66.04	1.38	2.83	50.8	166	< 0.21	0.66
FOCUS Step 2							
North Europe	12.86	0.27	0.55	9.89	32.4	-	-
South Europe	25.73	0.53	1.10	19.8	64.8	-	-
FOCUS Step 3*							
D3_Ditch	< 0.000001	-	< 0.01	< 0.01	< 0.01	-	-
D4_Pond	0.027	-	< 0.01	0.02	0.07	-	-
D4_Stream	0.048	-	< 0.01	0.04	0.12	-	-
D6_Ditch (E)	0.035	-	< 0.01	0.03	0.09	-	-
D6_Ditch (L)	0.091	-	< 0.01	0.07	0.22	-	-
R1_Pond	< 0.000001	-	< 0.01	< 0.01	< 0.01	-	-
R1_Stream	< 0.000001	-	< 0.01	< 0.01	< 0.01	-	-
R2_Stream	< 0.000001	-	< 0.01	< 0.01	< 0.01	-	-
R3_Stream	< 0.000001	-	< 0.01	< 0.01	< 0.01	-	-

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - PEC/RAC ratios for flutolanil – Tulip and Iris at 2760 g a.s./ha (1 application)

Scenario	PEC global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
		4800 µg/L	233 µg/L	130 µg/L	3.97 µg/L	>3200 µg/L	1000 µg/L
AF		100	10	100	10	10	10
RAC (µg/L)		48	23.3	1.3	0.397	> 320	100
FOCUS Step 1							
	495.33	10.3	21.3	381	1248	< 1.55	4.95
FOCUS Step 2							
North Europe	96.49	2.01	4.14	74.2	243	< 0.30	0.96
South Europe	192.97	4.02	8.28	148	482	< 0.60	1.93
FOCUS Step 3*							
D3_Ditch	24.99	0.52	1.07	19.2	10.0	-	0.25
D4_Pond	2.242	0.05	0.096	1.72	5.61	-	0.02
D4_Stream	14.95	0.31	0.64	11.5	37.4	-	0.15
D6_Ditch (E)	25.25	0.53	1.09	19.4	63.1	-	0.26
D6_Ditch (L)	25.25	0.53	1.09	19.4	63.1	-	0.26
R1_Pond	2.763	0.06	0.12	2.13	6.91	-	0.03
R1_Stream	12.51	0.26	0.54	9.62	31.3	-	0.13
R2_Stream	16.53	0.34	0.71	12.7	41.3	-	0.17
R3_Stream	17.49	0.36	0.75	13.5	43.7	-	0.17
R4_Stream	13.81	0.29	0.59	10.6	34.5	-	0.14

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - PEC/RAC ratios for M-4 – potatoes at 368 g a.s./ha (1 application)

Scenario	PEC global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
		417 µg/L**	20.27 µg/L**	11.3 µg/L**	0.35 µg/L**	>278.3 µg/L**	86.98 µg/L**
AF		100	10	100	10	10	10
RAC (µg/L)		4.17	2.03	0.11	0.03	> 27.83	8.698
FOCUS Step 1							
	2.22	0.53	1.09	19.6	64.3	< 0.08	0.26
FOCUS Step 2							
North Europe	0.44	-	0.22	4.00	14.7	-	-
South Europe	0.88	-	0.43	7.78	25.5	-	-
FOCUS Step 3*							
D3_Ditch	< 0.000002	-	-	< 0.01	< 0.01	-	-
D4_Pond	0.013	-	-	0.24	0.78	-	-
D4_Stream	0.014	-	-	0.42	1.39	-	-
D6_Ditch (E)	0.011	-	-	0.03	1.01	-	-
D6_Ditch (L)	0.012	-	-	0.81	2.63	-	-
R1_Pond	< 0.000001	-	-	< 0.01	< 0.01	-	-
R1_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-
R2_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-
R3_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**Metabolite endpoint calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - PEC/RAC ratios for M-4 – Tulip and Iris at 2760 g a.s./ha (1 application)

Scenario	PEC global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
		417 µg/L**	20.27 µg/L**	11.3 µg/L**	0.35 µg/L**	>278.3 µg/L**	86.98 µg/L**
AF		100	10	100	10	10	10
RAC (µg/L)		4.17	2.03	0.11	0.03	> 27.83	8.698
FOCUS Step 1							
	16.63	3.99	8.19	147	482	< 0.60	1.91
FOCUS Step 2							
North Europe	3.32	0.80	1.64	30.2	111	-	0.38
South Europe	6.63	1.59	3.27	58.6	192	-	0.76
FOCUS Step 3*							
D3_Ditch	0.001	< 0.01	< 0.01	< 0.01	0.29	-	-
D4_Pond	0.163	0.04	0.08	1.44	4.72	-	-
D4_Stream	0.158	0.04	0.08	1.40	4.57	-	-
D6_Ditch (E)	0.097	0.02	0.05	0.86	2.81	-	-
D6_Ditch (L)	0.097	0.02	0.05	0.86	2.81	-	-
R1_Pond	0.008	< 0.01	< 0.01	0.71	0.23	-	-
R1_Stream	0.014	< 0.01	< 0.01	0.12	0.41	-	-
R2_Stream	0.01	< 0.01	< 0.01	0.09	0.29	-	-
R3_Stream	0.021	< 0.01	0.01	0.19	0.61	-	-
R4_Stream	0.013	< 0.01	< 0.01	0.12	0.38	-	-

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**Metabolite endpoint calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - PEC/RAC ratios for M-11 – potatoes at 368 g a.s./ha (1 application)

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
		525 µg/L**	25.46 µg/L**	14.2 µg/L**	0.43 µg/L**	>350 µg/L**	109 µg/L**
AF		100	10	100	10	10	10
RAC (µg/L)		5.25	2.55	0.14	0.04	> 34.97	10.93
FOCUS Step 1							
	5.36	1.02	2.10	37.3	124	< 0.15	0.49
FOCUS Step 2							
North Europe	1.07	0.20	0.42	7.64	26.8	-	-
South Europe	2.14	0.41	0.84	15.1	49.3	-	-
FOCUS Step 3*							
D3_Ditch	1.814	-	-	12.8	41.8	-	-
D4_Pond	2.795***	0.53	1.10	19.7	64.4	< 0.08	0.26
D4_Stream	1.174	-	-	8.26	27.1	-	-
D6_Ditch (E)	1.256	-	-	8.84	29.0	-	-
D6_Ditch (L)	1.277	-	-	8.90	29.4	-	-
R1_Pond	< 0.000001	-	-	< 0.01	< 0.01	-	-
R1_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-
R2_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-
R3_Stream	< 0.000001	-	-	< 0.01	< 0.01	-	-

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**Metabolite endpoint calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis

***Value is higher than FOCUS Step 2 (Southern) PEC_{sw}

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - PEC/RAC ratios for M-11 – Tulip and Iris at 2760 g a.s./ha (1 application)

Scenario	PEC global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
		525 µg/L**	25.46 µg/L**	14.2 µg/L**	0.43 µg/L**	>350 µg/L**	109 µg/L**
AF		100	10	100	10	10	10
RAC (µg/L)		5.25	2.55	0.14	0.04	> 34.97	10.93
FOCUS Step 1							
	40.16	7.65	15.7	283	926	< 1.15	3.67
FOCUS Step 2							
North Europe	8.01	1.53	3.14	57.2	200	< 0.23	0.73
South Europe	16.02	3.05	6.28	113	369	< 0.46	1.47
FOCUS Step 3*							
D3_Ditch	12.75	2.43	5.00	89.8	294	-	1.167
D4_Pond	20.74	3.95	8.13	146	478	-	1.898
D4_Stream	8.33	1.59	3.27	58.6	192	-	0.762
D6_Ditch (E)	7.209	1.37	2.83	50.7	166	-	0.660
D6_Ditch (L)	7.209	1.37	2.83	50.7	166	-	0.660
R1_Pond	0.011	< 0.01	0.004	0.08	0.25	-	0.001
R1_Stream	0.045	< 0.01	0.018	0.32	1.04	-	0.004
R2_Stream	0.096	0.018	0.038	0.68	2.21	-	0.009
R3_Stream	0.055	0.010	0.022	0.39	1.27	-	0.005
R4_Stream	0.056	0.011	0.022	0.39	1.29	-	0.005

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**Metabolite endpoint calculated assuming 10 times higher toxicity from the active substance and corrected on molecular basis

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

FOCUS_{sw} step 4 - TERs [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]

[Fate experts should also be asked to review this table to check if it is in line with their assessments]

Organisms Indicate species:

Toxicity endpoint: x.xx µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)	PEC _{sw} (x.xx µg/L)	TER	Trigger
FOCUS Step 4*					
D3 / ditch					
D4 / pond					
D4 / stream					
D5 / pond					
D5 / stream					
R1 / pond					
R1 / stream					
R2 / stream					
R3 / stream					
R4 / stream					

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

*This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time-scale (Test type)	Endpoint	Toxicity	Data point /Author, year
Honey bee (<i>Apis mellifera</i> L.)	Flutolanil Technical	48h, Acute oral	LD ₅₀	> 208.7 µg a.s./bee	CA 8.3.1.1.1-01
		48h, Acute contact	LD ₅₀	> 200 µg a.s./bee	Schmitzer, S., 2001
	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
	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
	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

Potential for accumulative toxicity: <i>unknown</i>
Semi-field test (Cage and tunnel test) 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.
Field tests <i>None.</i>

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Risk assessment for – bulb flowers at 2760 g a.s./ha x 1

Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i> L.	a.s.	HQcontact	13.8	> 85
<i>Apis mellifera</i> L.	a.s.	ETRacute adult oral	0.140	0.2
<i>Apis mellifera</i> L.	Flutolanil 40 SC	ETRchronic adult oral	0.031	0.03
<i>Apis mellifera</i> L.	Flutolanil 40 SC	ETRlarvae	0.09	0.2

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Toxicity
<i>Typhlodromus pyri</i>	EXP10066A	Mortality, LR ₅₀	> 4500 g a.s./ha
		Reproduction, ER ₅₀	> 4500 g a.s./ha
<i>Aphidius rhopalosiphi</i>	EXP10066A	Mortality, LR ₅₀	> 4500 g a.s./ha
		Reproduction, ER ₅₀	> 4500 g a.s./ha

First tier risk assessment for – tulip/iris at 2760 g a.s./ha x 1

Test substance	Species	Effect (LR ₅₀ g a.s./ha)	HQ in-field	HQ off-field ¹	Trigger
EXP10066A	<i>Typhlodromus pyri</i>	> 4500	< 0.613	< 0.017	2
EXP10066A	<i>Aphidius rhopalosiphi</i>	> 4500	< 0.613	< 0.017	2

¹indicate distance assumed to calculate the drift rate

Further laboratory tests, extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	Endpoint	% effect	LR/ER ₅₀
<i>Poecilus cupreus</i>	Adult	EXP10066A (quartz sand)	14 d	450 4500 (active substance, initial residues)	Mortality	0 6.7	LR ₅₀ > 4500 g a.s./ha

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	Endpoint	% effect	LR/ER ₅₀
<i>Pardosa sp.</i>	Subadult and adult	EXP10066A (animals and quartz sand)	14 d	450 4500 (active substance, initial residues)	Mortality	0 6.7	LR ₅₀ > 4500 g a.s./ha
<i>Aleochara bilineata</i>	Adult (1-3 days old)	EXP10066A (quartz sand)	91 days (28-day exposure period followed by 63-day extraction period)	450 4500 (active substance, initial residues)	Reproduction	2.2 42.7	ER ₅₀ > 4500 g a.s./ha NOEC = 650 g a.s./ha
<i>Aleochara bilineata</i>	Adult (1-4 days old)	EXP10066A (quartz sand)	86 days (28-day exposure followed by 58-day extraction period)	4500 7800 11200	Reproduction	20.3 15.2 21.9	ER ₅₀ > 11200 g a.s./ha NOEC = 11200 g a.s./ha

Risk assessment for – flower bulbs at 2760 g a.s./ha based on further laboratory tests, extended lab test or aged residue tests

Species	LR ₅₀ /ER ₅₀ (g/ha)	In-field rate	Off-field rate
<i>Poecilus cupreus</i>	> 4500	2760	76.5 (distance of 1m, 2D)
<i>Pardosa sp.</i>	> 4500	2760	76.5 (distance of 1m, 2D)
<i>Aleochara bilineata</i>	> 4500	2760	76.5 (distance of 1m, 2D)
<i>Aleochara bilineata</i>	> 11200	2760	76.5 (distance of 1m, 2D)

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM	Time scale	Endpoint	Toxicity
Earthworms					
<i>Eisenia fetida</i>	EXP10066A	Mixed into soil / 10%	Chronic	Growth, reproduction, behaviour	NOEC = 12.9 mg a.s./kg soil dw

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

The Netherlands	April 2018	Flutolanil (Moncut 40 SC)
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Section 5 Ecotoxicology

Test organism	Test substance	Application method of test a.s./ OM		Time scale	Endpoint	Toxicity
<i>Eisenia fetida</i>	EXP10066A	Mixed into soil / 5%		Chronic	Growth, reproduction, behaviour	NOEC 25 (corr. 12.5) mg a.s./kg soil dw
Other soil macro-organisms						
<i>Folsomia candida</i>	EXP100066A	Treated surface / 10%		Chronic	Mortality, reproduction	LC ₅₀ could not be determined NOEC _{survival} < 10.4 mg a.s./kg soil dw NOEC _{reproduction} = 37.6 (corr. 18.8) mg a.s./kg soil dw
<i>Hypoaspis aculeifer</i>	EXP100066A	Mixed into soil / 5%		Chronic	Mortality, reproduction	LC ₅₀ > 407 mg a.s./kg soil dw NOEC = 407 (corr. 203.5) mg a.s./kg soil dw

Field studies:

1. Effect of EXP10066A on decomposition of the organic matter was investigated. First application was conducted in arable field (mustard) in Germany with 15000 g a.s./ha, followed by second application with 11300 g a.s./ha. At the test termination after 244 days, 22.6 to 30% decomposition reduction was observed.

2. Effect of Moncut 40SC on decomposition of the organic matter was investigated. The product was applied on bare soil at a dose rate of 670.5 g a.s./ha. Test duration was 616 days. Moncut 40SC induced significant decomposition reduction only at a second sampling date (90 days, 11.6 % reduction).

Nitrogen transformation	EXP10066A	0.71% effect at day 42 at 2.09 mg a.i./kg soil (1392 g a.i./ha)
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Toxicity/exposure ratios for soil organisms

Potato and flower bulbs at 368 and 2760 (5 and 10 cm incorporation depth) g a.s./ha, respectively.

Test organism	Test substance	Time scale	Soil PEC _{peak, accum} mg a.s./kg dry soil	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	EXP100066A	Chronic	0.603 (potato) 2.680 (bulbs)	20.7 4.66	5
Other soil macroorganisms					
<i>Folsomia candida</i>	Preparation	Chronic	0.603 (potato) 2.680 (bulbs)	31.2 7.01	5
<i>Hypoaspis aculeifer</i>	Preparation	Chronic	0.603 (potato) 2.680 (bulbs)	337 75.9	5
Microorganisms					
Nitrogen transformation	Preparation	Chronic	0.603 (potato) 2.680 (bulbs)	Risk from use in potato is acceptable since the exposure is 3.5 times lower than the threshold of 2.09 mg a.s./kg soil dw. However, unacceptable risk is concluded for use in flower bulbs as the threshold is exceeded by 1.28 times.	

Effects on terrestrial non-target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Application of EXP10066A at a rate of 11200 g a.s./ha did not cause significant effects on plant growth (tested on six terrestrial non-target plant species representing six plant families). NOER was determined to be 11200 kg a.s./ha.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	Endpoint
Activated sludge	EC ₅₀ > 1000 mg a.s./L.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

Compartment	
soil	Flutolanil
water	Flutolanil, M-4, M-11
sediment	Flutolanil, M-4, M-11
groundwater	Flutolanil

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Flutolanil
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ⁶ :	No harmonised classification
Peer review proposal ⁷ for harmonised classification according to Regulation (EC) No 1272/2008:	H410, P273, P391, P501

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2018	Flutolanil (Moncut 40 SC)

Appendix**Used compounds code(s)**

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula

* The compound code / trivial name in bold is the name used in the list of endpoints.