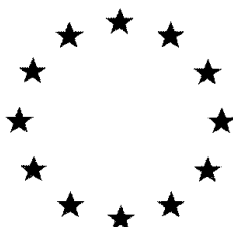


European Commission



VOLUME 3 – Annex B (PPP)

- *Flutolanil* -

B.3 Data on application and efficacy

Rapporteur Member State: The Netherlands

June 2018

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

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B.3 Data on application and efficacy

B.3.1 Field of use envisaged

The representative formulation of Flutolanil, 'MONCUT 40SC' is to be used as a fungicide in agricultural situations (as a potato tuber treatment) and in horticultural situations as a soil treatment for the growing of tulip and iris bulbs.

Please refer to the GAP in paragraph B.3.3 for an overview of the intended uses.

B.3.2 Effects on harmful organisms

'MONCUT 40SC' contains 460 g/L flutolanil. Flutolanil is a systemic benzanilide fungicide with protective and curative actions. It acts through the inhibition of succinate dehydrogenase complex of the mitochondrial respiratory chain in susceptible fungi. Flutolanil is in Fungicide Resistance Action Committee group 7.

B.3.3 Details of intended use

The intended use pattern is summarised in the GAP table in document D and this is copied below; with separate GAP tables for the dyed and un-dyed versions of the product. It is intended that flutolanil will be used to treat potato tubers pre-planting (BBCH 00 – 03) in stores using canopied hydraulic sprayer or spinning disc equipment on a roller table or at planting (BBCH 00 – 03) with on-planter or in-planter equipment. The other intended use is as a soil treatment with broadcast spray equipment and incorporated into the soil pre-planting with iris and tulip bulbs (BBCH 00).

It should be mentioned that 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 since this is considered representative of the majority of intended EU uses.

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 tonnes 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.

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	<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)	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

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 sucking 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. fluoroxypr). **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

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

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. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-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

B.3.4 Application rate and concentration of the active substance

'MONCUT 40SC' contains 460 g/L flutolanil. The application rate to potato tubers is intended to be 200 mL product/tonne of potato. This equates to 92 g flutolanil/tonne of potato. The product is made up in water to 2 L/tonne of potato to achieve better coverage. On the basis of a planting rate of 4 tonne tubers/ha, this is equivalent to a field rate of 0.368 kg flutolanil/ha. Whilst it is acknowledged that the 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 since this is considered representative of the majority of intended EU uses.

The use on flower bulbs is at a field rate of 2.76 kg flutolanil/ha in 150 – 400 L water/ha, equivalent to 0.69–1.84 kg as/hL.

B.3.5 Method of application

For seed potatoes in stores, 'MONCUT 40SC' is applied using canopied hydraulic sprayer or spinning disc equipment on a roller table. For treatment of potatoes at planting, 'MONCUT 40SC' is applied as an in or on planter treatment. For the use on flower bulbs, 'MONCUT 40SC' is applied to bare soil with broadcast spray equipment and incorporated into the soil pre-planting.

As the application techniques for the seed treatment use on potato tubers are somewhat unusual, further information and clarification is provided. The in-store treatment of potatoes takes place using canopied roller table equipment such as that depicted in figure 3.4-1.

Figure 3.4-1: Canopied roller table equipment used for the seed treatment of potato tuber



The potatoes tubers to be treated are loaded onto a conveyer belt (to the left in the figure). When they enter the enclosed canopy (centre), the potato tubers are treated by being sprayed with a dilution in water of the product using either hydraulic nozzles or spinning disc equipment such as that depicted in figure 3.4-2.

Figure 3.4-2: Hydraulic nozzles sprayer (left) and spinning disc sprayer (right) in a canopied roller table equipment.



Following treatment, the treated tubers exit the enclosed canopy and drop into crates or bags for storage prior to planting (to the right and rear in the figure).

The on-planter treatment consists of spray equipment mounted integrally to the tractor mounted potato sowing equipment. The potato tubers are sprayed with the dilute product as they fall through the equipment and into the soil. Photographs of examples of two such models of equipment are presented in figure 3.4-3.

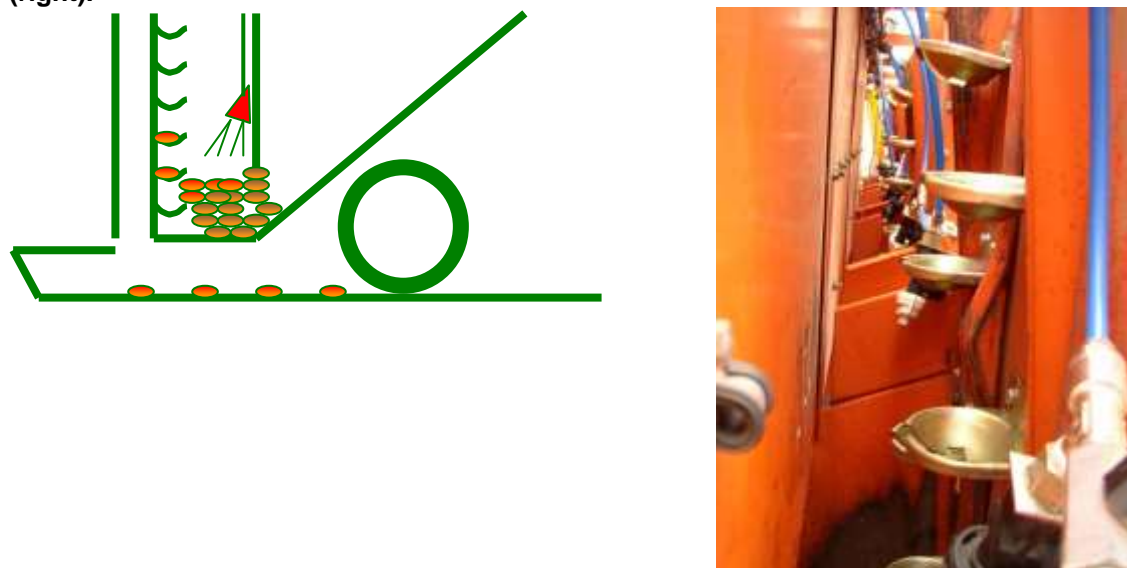
Figure 3.4-3: Examples of two on-planter spray equipment for the seed treatment of potato tubers at the time of sowing.





The in-planter treatment consists of spray equipment mounted inside the potato hopper of the tractor mounted planting equipment. The potatoes are sprayed directly just before they are taken up by the planting chains and to be sown into the ground. This is illustrated in figure 3.4-4.

Figure 3.4-4: In-planter potato tuber treatment equipment. Schematic (left) and photograph (right).



Since the nozzles are placed very near the potato and in the hopper where the potatoes are stored on the planting machine, there is minimal risk for contamination of the soil.

B.3.6 Number and timing of application and duration of protection

For the potato tuber treatment, there is a single application per crop pre-planting or at the time of planting (BBCH 00 – 03). For the iris and tulip bulb treatment, there is a single application per crop pre-planting (BBCH 00). This provides season-long protection.

B.3.7 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

No waiting periods or other precautions are proposed since 'MONCUT 40SC' is not phytotoxic to succeeding crops (i.e. cereals, tubers, beans, fruit vegetables, leafy crops, root vegetables, fruits, pasture and flowers).

B.3.8 Proposed instruction for use

The GAP in paragraph B3.3 has an overview of the proposed representative uses and dose rates.

B.3.9 Effectiveness

Flutolanil is a systemic benzanilide fungicide with protective and curative actions. Flutolanil acts through the inhibition of succinate dehydrogenase complex of the mitochondrial respiratory chain in susceptible fungi.

Considering that the substance is approved and that the extant authorisations of plant protection products containing flutolanil have already been evaluated according to the Uniform Principles, no other efficacy information is considered to be necessary at this time.

B.3.10 Information on the development of resistance

Flutolanil (chemical group: phenylbenzamides) belongs to the group of succinate dehydrogenase inhibitors ("SDHI"), a fungicide group with a vast number of different active substances (table 3.7-The FRAC code is 7).

The risk for development of resistance of the major target disease was analysed following EPPO guideline PP1/213(4).

Table 3.7-1: Overview of SDHI active substances (source: <http://www.frac.info/working-group/sdhi-fungicides>)

FRAC Code	Target site of action	Group name	Chemical group	Common name	Comments
7	Complex II; succinate-dehydrogenase	SDHI (Succinate dehydrogenase inhibitors)	Phenyl benzamides	Benodanil Flutolanil Mepronil	Resistance known for several fungal species in field populations and lab mutants. Target site mutations in <i>sdh</i> gene, e.g. H/Y (or H/L) at 257* or P225L**. Medium-high risk. Resistance management required
			phenyl-oxo-ethyl thiophene amide	Isofetamid	
			Pyridinyl-ethyl-benzamide	Fluopyram	
			Furan-carboxamides	Fenfuram	
			Oxathiin-carboxamides	Carboxin Oxycarboxin	
			Thiazole-carboxamides	Thifluzamide	
			Pyrazole-carboxamides	Benzovindiflupyr Bixafen Fluxapyroxad Furametpyr Isopyrazam Penflufen Penthiopyrad Sedaxane	
			Pyridine-carboxamides	Boscalid	

* *Ustilago maydis*, homolog to 267 in *Zymoseptoria tritici* and 272 in *Botrytis cinerea*.

** *B. cinerea*

Basic properties of this group such as persistent activity and single-site mode of action indicate a medium – high risk of development of resistance. This is also the general conclusion of the FRAC working group on SDHI fungicides (Table 3.7-1). The proposed representative use is control of *Rhizoctonia solani*, this pathogen is not listed among the fungi that have developed resistance against FRAC group 7.

Table 3.7-2: List of cases of SDHI resistant fungal plant pathogen species, their origin, and mutations found conferring SDHI resistance. Table reflects the list published on the FRAC webpage (status July 2014) with some updates based on BASF, unpublished data. (source: <http://www.frac.info/working-group/sdhi-fungicides>)

Species name		Reported from host	Origin	Resistance mechanism (Subunit-mutation)
<i>Ustilago maydis</i>	a	(Laboratory)	Lab	B-H257L
<i>Aspergillus oryzae</i>	b	(Laboratory)	Lab	B-H249Y/L/N, C-T90I, D-D124E
<i>Zymoseptoria tritici</i>	c	(Laboratory)	Lab	B-N225I, B-H267Y/R/L, B-I269V, C-A84V, C-H152R, C-T79I, C-N86K, C-G90R, D-H129E, and several others
<i>Zymoseptoria tritici</i>	d	Wheat	Field	B-N225T, C-T79N, C-W80S, C-N86S
<i>Pyrenophora teres</i>	e	Barley	Field	B-H277Y, C-N75S, C-G79R, C-H134R, C-S135R, D-D124N/E, D-H134R, D-D145G
<i>Botrytis cinerea</i>	f	Various	Field	B-P225L/T/F, B-H272Y/R/L/V, B-N230I, D-H132R, C-A85V
<i>Botrytis elliptica</i>	g	Lilies	Field	B-H272Y/R
<i>Alternaria alternata</i>	h	Pistachio	Field	B-H277Y/R, C-H134R, D-D123E, D-H133R
<i>Alternaria solani</i>	i	Potatoes	Field	B-H277Y/R, D-H133R
<i>Corynespora cassiicola</i>	j	Cucurbits	Field	B-H278Y/R, C-S73P, D-S89P, D-G109V
<i>Didymella bryoniae</i>	k	Cucurbits	Field	B-H277R/Y
<i>Podosphaera xanthii</i>	l	Cucurbits	Field	B-H->Y (homologous to H272 in <i>B. cinerea</i>)
<i>Sclerotinia sclerotiorum</i>	m	Oilseed rape	Field	B-H273Y, C-H146R, D-H132R
<i>Stemphylium vesicarium</i>	n	Asparagus	Field	B-P225L, H272Y/R
<i>Venturia inaequalis</i>	o	Apple	Field	C-H151R

This is confirmed by the practical experience obtained with flutolanil in Europe after more than 20 years of use as a seed/soil treatment vs. *Rhizoctonia solani* in potatoes.

So, the inherent risk of resistance development of *Rhizoctonia solani* to flutolanil may be considered as LOW-MEDIUM. Supporting factors are:

- Typically, only 1 treatment per season vs. the target disease (some exemptions in case of a tuber + soil treatment strategy)
- No significant use of other fungicides with the same mode of action (as of October 2016)
- Significant number of other fungicides with a different mode of action available
- Potatoes (a major host) of *Rhizoctonia solani* is cultivated in a wide crop rotation (at least 3 years). Occurrence of *Rhizoctonia solani* in rotational crops (e.g. cereals, maize, oilseed rape) is much less important respectively there is no (or only limited) use of fungicides to control this disease.
- No known cases of resistance after decades of use

The proposed gap is found to be realistic for the representative use concerning resistance risk and management.

Occurrence or possible occurrence of the development of resistance and appropriate management strategies will need to be further evaluated in the dossier for product renewal or registration.

B.3.11 Adverse effects on treated crops

The active substance is approved and extant authorisations of plant protection products containing flutolanil have already been evaluated according to the Uniform Principles. No unacceptable adverse effects on treated crops are known at currently registered rates. No additional information is needed.

B.3.12 Observations on other undesirable or unintended side-effects

The active substance is approved and extant authorisations of plant protection products containing flutolanil have already been evaluated according to the Uniform Principles. No unacceptable unintended side-effects are known at currently registered rates. No additional information is needed.

B.3.13 References relied on

No studies were submitted for this section.