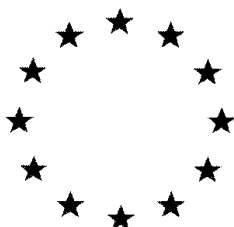


# **European Commission**



**VOLUME 3 – Annex B (PPP)**

**- *Flutolanil* -**

**B.2 Physical and chemical properties**

**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.2 Physical and chemical properties**

For the renewal of flutolanil the nominated representative formulated product is 'MONCUT 40SC', an SC formulation containing 460 g/L flutolanil. This is the same product that was the representative product considered in the original review of flutolanil for inclusion in Annex I of Dir 91/414/EEC. However, the formulation composition of 'MONCUT 40SC' has been revised over time.

In the original review of flutolanil in the DAR, a single 'MONCUT 40SC' composition was supported and was known by the code name "40SC". Following inclusion in Annex I of Dir 91/414/EEC a major formulation change took place and as such no formulation physicochemical data from the original flutolanil review are relied upon at renewal. The revised formulation was available without a dye, code "40SC (NPE free)" and with a dye "40SC (EU-D)"; both formulations were supported by physicochemical properties data that have been evaluated to uniform principles for national product authorisations and some of these data are relied upon at renewal. The formulation composition supported in this renewal dossier represents a further minor formulation change with respect to that of the authorised formulation; the formulation at renewal is available without a coloured dye, code "40SC (EU)" and with a dye "40SC (EU-D)". New accelerated and cold storage stability and physicochemical properties data are provided at renewal specific to the latest formulation composition; these data have not been previously evaluated. Ambient storage stability studies for the latest formulation composition are ongoing, but the data that is relied upon that was obtained with the currently authorised formulation are deemed to be sufficient to support the revised formulation at renewal. Seed adhesion and loading data were determined using the currently authorised formulation. The respective iterations of the 'MONCUT 40SC' formulation composition are discussed further in the confidential section (Volume 4).

Data that have previously been evaluated to uniform principles are displayed in grey. It is also made clear as to when the physicochemical tests were performed with the most recent iteration of the formulation recipe as supported at renewal and which tests were performed on the previous recipe which is the recipe that is currently authorised. In all cases it is considered that these formulations are only minor changes with respect to each other and thus data obtained with one recipe supports the other.

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
<b>B.2.1 Appearance</b>						
	OPPTS 830.6303 OPPTS 830.6302 OPPTS 830.6317 OPPTS 830.6304	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	Opaque, white, free-flowing medium viscosity homogeneous liquid. No discernible odour.  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.1/01: Weatherhead, P. (2015) (PC-3115) CP 2.1/02: Goldsmith, A E (2015) (PC-3117)
	OPPTS 830.6303 OPPTS 830.6302 OPPTS 830.6317 OPPTS 830.6304	'MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	Opaque, purple, free-flowing medium viscosity homogeneous liquid. No discernible odour.  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.1/03: Weatherhead, P. (2015a) (PC-3116) CP 2.1/04: Goldsmith, A E (2015a) (PC-3118)
<b>B.2.2 Explosive and oxidising properties</b>						
	Dir 92/69/EEC Method A14 Dir 92/69/EEC Method A21	'MONCUT 40SC' (without dye) "40SC (NPE-free)" 40% w/w nominal flutolanil Batch: 030605	Explosive properties: Expert statement, 'Flutolanil 40SC' is not explosive.  Oxidising properties: Expert statement, 'Flutolanil 40SC' has no oxidising properties.  'Flutolanil 40SC' is not classified for explosive and oxidising properties.  Note, these expert statements refer to a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal	<b>Acceptable</b>  The changes to the formulation are not considered to have an effect on the explosive or oxidising properties of the formulation.	Y  Y	CP 2.2/01* van der Baan-Treur, J. (2004) (PC-3036) CP 2.2/02* van der Baan-Treur, J. (2004a) (PC-3037)

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
	Dir 92/69/EEC Method A14 Dir 92/69/EEC Method A21	'MONCUT 40SC' (with dye) "40SC (EU-D)" 397 g/kg flutolanil Batch: 7AE8902F	Explosive properties: Expert statement, 'Flutolanil 40SC' is not explosive.  Oxidising properties: Expert statement, 'Flutolanil 40SC' has no oxidising properties.  'Flutolanil 40SC' is not classified for explosive and oxidising properties.  Note, these expert statements refer to a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal.	<b>Acceptable</b>  The changes to the formulation are not considered to have an effect on the explosive or oxidising properties of the formulation.	Y	CP 2.2/03* Selditz, U. (2007) (PC-3065)
	Dir 92/69/EEC Method A14 Dir 92/69/EEC Method A21	'MONCUT 40SC' (with dye) "40SC (EU-D)" 40% w/w flutolanil nominal Batch: 5AE9401F	Explosive properties: 'Flutolanil 40SC' was not found to be explosive when subject to physical tests involving physical shock and heat.  Oxidising properties: 'Flutolanil 40SC' was not found to be oxidising when subject to a physical test.  'Flutolanil 40SC' is not classified for explosive and oxidising properties. These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.2/04 Younis, S (2015)
<b>B.2.3 Flammability and self-heating</b>						
	Dir 92/69/EEC Method A9 Dir 92/69/EEC Method A15	'MONCUT 40SC' (without dye) "40SC (NPE-free)" 40% w/w nominal flutolanil Batch: 030605	Flammability properties: Expert statement, 'Flutolanil 40SC' is not flammable.  Self-heating properties: Expert statement, 'Flutolanil 40SC' has no self-heating properties.  'Flutolanil 40SC' is not classified for flammability and self-heating properties.	See Younis 2015 (CP 2.3/04)		CP 2.3/01* van der Baan-Treur, J. (2004b) (PC-3038) CP 2.3/02* van der Baan-Treur, J. (2004c) (PC-3039)

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
			Note, these expert statements refer to a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal.			
	Dir 92/69/EEC Method A9 Dir 92/69/EEC Method A15	'MONCUT 40SC' (with dye) "40SC (EU-D)" 397 g/kg flutolanil Batch: 7AE8902F	<p>Flammability properties: Expert statement, 'Flutolanil 40SC' is not flammable.</p> <p>Self-heating properties: Expert statement, 'Flutolanil 40SC' has no self-heating properties.</p> <p>'Flutolanil 40SC' is not classified for flammability and self-heating properties.</p> <p>Note, these expert statements refer to a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal.</p>	See Younis 2015 (CP 2.3/04)		CP 2.3/03* Selditz, U. (2007) (PC-3065)
	Dir 92/69/EEC Method A9 Dir 92/69/EEC Method A15	'MONCUT 40SC' (with dye) "40SC (EU-D)" 40% w/w flutolanil nominal Batch: 5AE9401F	<p>Flammability properties: 'Flutolanil 40SC' was not found to have a flash point prior to boiling.</p> <p>Self-heating properties: 'Flutolanil 40SC' was found to have an auto-ignition temperature of 461°C.</p> <p>'Flutolanil 40SC' is not classified for flammability and self-heating properties. These data were obtained using the representative formulation at renewal.</p>	<p><b>Acceptable</b></p> <p>Considering the difference between the formulations with and without dye, the results for the EU-D formulation can be considered representative for the formulation.</p>	Y	CP 2.3/04 Younis, S (2015)

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
<b>B.2.4 Acidity/alkalinity and pH value</b>						
	CIPAC MT 75.3	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	pH of neat formulation at 21.5°C: 8.7 pH of a 0.1% dilution in deionised water at 22.0°C: 7.7 pH of a 1.0% dilution in deionised water at 22.0°C: 8.5 pH of a 20% dilution in deionised water at 22.5°C: 8.7  'Flutolanil 40SC' is not classified for corrosive properties. An acidity / alkalinity test according to CIPAC MT 191 is not triggered.  These data were obtained using the representative formulation at renewal.	Acceptable	Y	CP 2.4/01: Weatherhead, P. (2015) (PC-3115) CP 2.4/02: Goldsmith, A E (2015) (PC-3117)
	CIPAC MT 75.3	'MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	pH of neat formulation at 22.0°C: 7.0 pH of a 0.1% dilution in deionised water at 22.5°C: 7.4 pH of a 1.0% dilution in deionised water at 22.5°C: 7.3 pH of a 20% dilution in deionised water at 21.0°C: 7.1  'Flutolanil 40SC' is not classified for corrosive properties. An acidity / alkalinity test according to CIPAC MT 191 is not triggered.  These data were obtained using the representative formulation at renewal.	Acceptable	Y	CP 2.4/03: Weatherhead, P. (2015a) (PC-3116) CP 2.4/04: Goldsmith, A E (2015a) (PC-3118)
<b>B.2.5 Viscosity and surface tension</b>						
	CIPAC MT 192 (OECD 114)  Dir 92/69/EEC Method A5 (OECD 115)	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	Viscosity at 20°C: 111 mPa.s with a shear rate of 100 s <sup>-1</sup> . 416 mPa.s with a shear rate of 10 s <sup>-1</sup> .  Viscosity at 40°C: 93 mPa.s with a shear rate of 100 s <sup>-1</sup> . 381 mPa.s with a shear rate of 10 s <sup>-1</sup> .  Surface tension at 20°C:	Acceptable	Y	CP 2.5/01: Weatherhead, P. (2015) (PC-3115) CP 2.5/02: Goldsmith, A E (2015) (PC-3117)



Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
			Neat formulation: 31.9 mNm <sup>-1</sup> 0.1% dilution: 35.5 mNm <sup>-1</sup> 20% dilution: 24.7 mNm <sup>-1</sup>  ‘Flutolanil 40SC’ is a non-Newtonian liquid and is thixotropic.  These data were obtained using the representative formulation at renewal.			
	CIPAC MT 192 (OECD 114)	‘MONCUT 40SC’ (with dye) “40SC (EU-D)” 464.6 g/L flutolanil Batch: 5AE9401F	Viscosity at 20°C: 112 mPa.s with a shear rate of 100 s <sup>-1</sup> . 419 mPa.s with a shear rate of 10 s <sup>-1</sup> .  Viscosity at 40°C: 111 mPa.s with a shear rate of 100 s <sup>-1</sup> . 455 mPa.s with a shear rate of 10 s <sup>-1</sup> .  Surface tension at 20°C: Neat formulation: 32.3 mNm <sup>-1</sup> 0.1% dilution: 34.1 mNm <sup>-1</sup> 20% dilution: 30.6 mNm <sup>-1</sup>  ‘Flutolanil 40SC’ is a non-Newtonian liquid and is thixotropic.  These data were obtained using the representative formulation at renewal.	Acceptable	Y	CP 2.5/03: Weatherhead, P. (2015a) (PC-3116) CP 2.5/04: Goldsmith, A E (2015a) (PC-3118)
<b>B.2.6 Relative density and bulk density</b>						
	Dir 92/69/EEC Method A3 (OECD 109)	MONCUT 40SC’ (without dye) “40SC (EU)” 465.7 g/L flutolanil Batch: 5AE9301F	Relative density: D <sub>4</sub> <sup>20</sup> = 1.133  These data were obtained using the representative formulation at renewal.	Acceptable	Y	CP 2.6/01: Weatherhead, P. (2015) (PC-3115) CP 2.6/02: Goldsmith, A E (2015) (PC-3117)
	Dir 92/69/EEC Method A3	‘MONCUT 40SC’ (with dye) “40SC (EU-D)”	Relative density: D <sub>4</sub> <sup>20</sup> = 1.136  These data were obtained using the representative	Acceptable	Y	CP 2.6/03: Weatherhead, P. (2015a) (PC-3116)

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference			
	(OECD 109)	464.6 g/L flutolanil Batch: 5AE9401F	formulation at renewal.			CP 2.6/04: Goldsmith, A E (2015a) (PC-3118)			
B.2.7 Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product									
	Storage stability: The test item was stored in a 0.5 L HDPE container for 14 days at 54°C or 7 days at 0°C.	MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	Results after storage for 14 days at 54°C:		Acceptable	Y	CP 2.7/01: Weatherhead, P. (2015) (PC-3115) CP 2.7/02: Goldsmith, A E (2015) (PC-3117)  CP 2.7/05* van der Baan-Treur, J. (2006) (PC-3051) CP 2.7/06* Brands, Ir C (2004) (PC-3034)		
			Data point	Method				Results after storage	
			Appearance	As CP 2.1				Opaque, white free flowing medium viscosity liquid with <1% clear supernatant separation and no sediment. The sample was completely homogeneous after 3 inversions of the pack. No discernible odour.	
			Active substance content	Method XG/15/018/1				Initial: 470 g/L After storage: 470 g/L (0% change)	
			pH	As CP 2.4				Neat formulation (23°C): 8.5 0.1% dilution (23°C): 9.0 1.0% dilution (23°C): 8.2 20% dilution (23°C): 8.5	
			Persistent foam	As CP 2.8.2				0.1% dilution in CIPAC water D:	
								Time	Vol. of foam
								10 sec	14 mL
								1 min	6 mL
								3 min	4 mL
12 min	2 mL								
20% dilution in CIPAC water D:									
Time	Vol. of foam								
10 sec	66 mL								
1 min	32 mL								
3 min	20 mL								
12 min	4 mL								
Spontaneity of dispersion	As CP 2.8.3	5% dilution in CIPAC water D: Flutolanil 98%.							
Suspensibility	As CP 2.8.3	0.1% dilution in CIPAC water D: Flutolanil 95%							

Data point	Guideline and method	Test material purity and specification	Results			Comment	GLP Y/N	Reference
		'MONCUT 40SC' (without dye) "40SC (NPE-free)" 40% w/w nominal flutolanil			20% dilution in CIPAC water D: Flutolanil 100%	Acceptable	Y	
			Wet sieve	As CP 2.8.5.1	0.02% retained on a 75 µm sieve.			
			Pourability	As CP 2.8.7	Non-rinsed residue: 2.39% Rinsed residue: 0.11%			
			Pack appearance / weight change	Observation	Initial: 0.5 L HDPE bottle with ratcheted screw cap. Pack in good condition with no sign of corrosion. After storage: -.0.03% weight loss. No deformation, leakage or staining. No corrosion. Screw cap intact.			
			These data were obtained using the representative formulation at renewal.					
			Results after storage for 7 days at 0°C:					
			Data point	Method	Results after storage			
			Appearance	As CP 2.1	Opaque, white free flowing medium viscosity liquid. No discernible odour.			
			Spontaneity of dispersion	As CP 2.8.3	5% dilution in CIPAC water D: Flutolanil 99%.			
			Suspensibility	As CP 2.8.3	0.1% dilution in CIPAC water D: Flutolanil 98% 20% dilution in CIPAC water D: Flutolanil 98%			
			Wet sieve	As CP 2.8.5.1	0.02% retained on a 75 µm sieve.			
			These data are obtained on the representative formulation at renewal.					
			Results after storage for 2 years under ambient conditions:					
			Data point	Method	Results after storage			
			Appearance	Observation	Initial: Opaque liquid with a milky white colour and without any characteristic odour.			

Data point	Guideline and method	Test material purity and specification	Results			Comment	GLP Y/N	Reference																
	packaging) for 2 years under ambient conditions.	Batch: 030605			After storage: Phase separation was observed with a dark-coloured upper layer. Inverting the container 10 times resulted in a visually homogeneous liquid which was opaque and milky white and without any characteristic odour.																			
			Active substance content	HPLC UV method from Notox Project 391084 (PC-3034)	Initial: 41.9 % w/w After storage: 40.5% w/w (-3.3% change)																			
			pH	CIPAC MT 75	pH of 1% w/v dispersion in water at 20°C Initial: pH 7.2 After storage: pH 7.3																			
			Persistent foam	CIPAC 47.2	10% (v/v) dilution in CIPAC water C: Initial <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>46 mL</td></tr><tr><td>1 min</td><td>0 mL</td></tr><tr><td>12 min</td><td>0 mL</td></tr></table> After storage <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>32 mL</td></tr><tr><td>1 min</td><td>6 mL</td></tr><tr><td>12 min</td><td>0 mL</td></tr></table>				Time	Vol. of foam	10 sec	46 mL	1 min	0 mL	12 min	0 mL	Time	Vol. of foam	10 sec	32 mL	1 min	6 mL	12 min	0 mL
									Time	Vol. of foam														
									10 sec	46 mL														
									1 min	0 mL														
12 min	0 mL																							
Time	Vol. of foam																							
10 sec	32 mL																							
1 min	6 mL																							
12 min	0 mL																							
Suspensibility	CIPAC MT 161 with chemical assay	1% (v/v) dilution in CIPAC water C Initial: Flutolanil 99% After storage: Flutolanil 99% 10% (v/v) dilution in CIPAC water C Initial: Flutolanil 97% After storage: Flutolanil 96%																						
Wet sieve	CIPAC MT 59.3	Residue retained on a 75 µm sieve.																						

Data point	Guideline and method	Test material purity and specification	Results			Comment	GLP Y/N	Reference
					Initial: None After storage: None			
			Pourability	CIPAC 148	Non-rinsed residue Initial: 4.44% After storage: 4.92% Rinsed residue Initial: 0.48% After storage: 0.24%			
			Pack appearance / weight change	Observation	After storage: No visual changes were observed in the packaging material and no significant change in weight (<0.1%) was measured.			
			These data were obtained using a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal. Shelf life studies on the representative formulation at renewal are ongoing.					
	Storage stability: The test item was stored in a 0.5 L HDPE container for 14 days at 54°C or 7 days at 0°C.	MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	Results after storage for 14 days at 54°C:			Acceptable	Y	CP 2.7/03: Weatherhead, P. (2015a) (PC-3116)  CP 2.7/04: Goldsmith, A E (2015a) (PC-3118)  CP 2.7/07* Selditz, U (2009) (PC-3086)  CP 2.7/08* Selditz, U. (2007) (PC-3065)
			Data point	Method	Results after storage			
			Appearance	As CP 2.1	Opaque, purple free flowing medium viscosity liquid with 1% clear purple supernatant separation and no sediment. The sample was completely homogeneous after 3 inversions of the pack. No discernible odour.			
			Active substance content	Method XG/15/018/1	Initial: 470 g/L After storage: 468 g/L (-0.43% change)			
			pH	As CP 2.4	Neat formulation (23°C): 6.9 0.1% dilution (23°C): 7.2 1.0% dilution (23°C): 7.2 20% dilution (23°C): 7.0			
			Persistent foam	As CP 2.8.2	0.1% dilution in CIPAC water D:			
					Time	Vol. of foam		

Data point	Guideline and method	Test material purity and specification	Results				Comment	GLP Y/N	Reference
					10 sec	14 mL	Acceptable	Y	
					1 min	8 mL			
					3 min	8 mL			
					12 min	6 mL			
					20% dilution in CIPAC water D:				
					Time	Vol. of foam			
					10 sec	76 mL			
					1 min	40 mL			
					3 min	8 mL			
					12 min	4 mL			
			Spontaneity of dispersion	As CP 2.8.3	5% dilution in CIPAC water D: Flutolanil 102%.				
			Suspensibility	As CP 2.8.3	0.1% dilution in CIPAC water D: Flutolanil 94% 20% dilution in CIPAC water D: Flutolanil 99%				
			Wet sieve	As CP 2.8.5.1	<0.01% retained on a 75 µm sieve.				
			Pourability	As CP 2.8.7	Non-rinsed residue: 2.29% Rinsed residue: 0.11%				
			Pack appearance / weight change	Internal method	Initial: 0.5 L HDPE bottle with ratcheted screw cap. Pack in good condition with no sign of corrosion. After storage: -.005% weight loss. No deformation, leakage or staining. No corrosion. Screw cap intact.				
			These data were obtained using the representative formulation at renewal.						
			Results after storage for 7 days at 0°C:						
			Data point	Method	Results after storage				
			Appearance	As CP 2.1	Opaque, purple free flowing medium viscosity liquid. No discernible odour.				
			Spontaneity of	As CP 2.8.3	5% dilution in CIPAC water D:				

Data point	Guideline and method	Test material purity and specification	Results			Comment	GLP Y/N	Reference				
	Shelf life: The test item was stored in a white HDPE bottle (commercial packaging) for 2 years under ambient conditions.	'MONCUT 40SC' (with dye) "40SC (EU-D)" 397 g/kg flutolanil Batch: 7AE8902F	dispersion		Flutolanil 100%.	Acceptable	Y					
			Suspensibility	As CP 2.8.3	0.1% dilution in CIPAC water D: Flutolanil 96% 20% dilution in CIPAC water D: Flutolanil 100%							
			Wet sieve	As CP 2.8.5.1	<0.01% retained on a 75 µm sieve.							
			These data were obtained using the representative formulation at renewal.									
			Results after storage for 2 years under ambient conditions:									
			Data point	Method	Results after storage							
			Appearance	OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304	Initial: Opaque magenta liquid without any characteristic odour. After storage: Opaque magenta liquid without any characteristic odour.							
			Active substance content	HPLC UV method from Notox Project 485413 (PC-3065)	Initial: 39.7% w/w After storage: 41.0% w/w (+3.3% change)							
			pH	CIPAC MT 75.3	pH of 1% w/v dispersion in water at 20°C Initial: pH 7.6 After storage: pH 7.5 pH of neat formulation at 20°C Initial: pH 7.5 After storage: pH 7.5							
			Persistent foam	CIPAC 47.2	10% (v/v) dilution in CIPAC water D: Initial <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>67 mL</td></tr><tr><td>1 min</td><td>61 mL</td></tr><tr><td>3 min</td><td>18 mL</td></tr><tr><td>12 min</td><td>11 mL</td></tr></table>				Time	Vol. of foam	10 sec	67 mL
Time	Vol. of foam											
10 sec	67 mL											
1 min	61 mL											
3 min	18 mL											
12 min	11 mL											

Data point	Guideline and method	Test material purity and specification	Results				Comment	GLP Y/N	Reference
					After storage				
					Time	Vol. of foam			
					10 sec	68 mL			
					1 min	55 mL			
					3 min	16 mL			
					12 min	14 mL			
			Suspensibility	CIPAC MT 161 with chemical assay	1% (v/v) dilution in CIPAC water D Initial: Flutolanil 98% After storage: Flutolanil 96% 10% (v/v) dilution in CIPAC water D Initial: Flutolanil 95% After storage: Flutolanil 94%				
			Wet sieve	CIPAC MT 185	Residue retained on a 75 µm sieve. Initial: 0.4% After storage: 0.4%				
			Pourability	CIPAC 148.1	Non-rinsed residue Initial: 5.3% After storage: 4.8%				
			Pack appearance / weight change	Observation	After storage: No visual changes were observed in the packaging material and no significant change in weight (<0.1%) was measured.				
These data were obtained using a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal. Shelf life studies on the representative formulation at renewal are ongoing.									
B.2.8 Technical characteristics of the plant protection product									
B 2.8.1 Wettability			Not relevant for an SC formulation						
B 2.8.2 Persistence of	CIPAC MT 47.2	'MONCUT 40SC' (without dye)	0.1% dilution in CIPAC water D				Acceptable	Y	CP 2.8.2/01: Weatherhead, P.



Data point	Guideline and method	Test material purity and specification	Results		Comment	GLP Y/N	Reference																			
foaming		“40SC (EU)” 465.7 g/L flutolanil Batch: 5AE9301F	<table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>16 mL</td></tr><tr><td>1 min</td><td>8 mL</td></tr><tr><td>3 min</td><td>8 mL</td></tr><tr><td>12 min</td><td>6 mL</td></tr></table>	Time	Vol. of foam	10 sec	16 mL	1 min	8 mL	3 min	8 mL	12 min	6 mL				(2015) (PC-3115) CP 2.8.2/02: Goldsmith, A E (2015) (PC-3117)									
			Time	Vol. of foam																						
10 sec	16 mL																									
1 min	8 mL																									
3 min	8 mL																									
12 min	6 mL																									
<p>20% dilution in CIPAC water D</p> <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>100 mL</td></tr><tr><td>1 min</td><td>50 mL</td></tr><tr><td>3 min</td><td>28 mL</td></tr><tr><td>12 min</td><td>4 mL</td></tr></table> <p>These data were obtained using the representative formulation at renewal.</p>	Time	Vol. of foam	10 sec	100 mL	1 min	50 mL	3 min	28 mL	12 min	4 mL																
Time	Vol. of foam																									
10 sec	100 mL																									
1 min	50 mL																									
3 min	28 mL																									
12 min	4 mL																									
		‘MONCUT 40SC’ (with dye) “40SC (EU-D)” 464.6 g/L flutolanil Batch: 5AE9401F	<p>0.1% dilution in CIPAC water D</p> <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>20 mL</td></tr><tr><td>1 min</td><td>12 mL</td></tr><tr><td>3 min</td><td>10 mL</td></tr><tr><td>12 min</td><td>10 mL</td></tr></table> <p>20% dilution in CIPAC water D</p> <table><tr><td>Time</td><td>Vol. of foam</td></tr><tr><td>10 sec</td><td>78 mL</td></tr><tr><td>1 min</td><td>62 mL</td></tr><tr><td>3 min</td><td>36 mL</td></tr><tr><td>12 min</td><td>4 mL</td></tr></table> <p>These data were obtained using the representative formulation at renewal.</p>	Time	Vol. of foam	10 sec	20 mL	1 min	12 mL	3 min	10 mL	12 min	10 mL	Time	Vol. of foam	10 sec	78 mL	1 min	62 mL	3 min	36 mL	12 min	4 mL	<b>Acceptable</b>  For the 20% dilution, the amount of foam after 1 minute exceeds 60 mL. Instructions for use should include directions to prevent the formation of foam.	Y	CP 2.8.2/03: Weatherhead, P. (2015a) (PC-3116) CP 2.8.2/04: Goldsmith, A E (2015a) (PC-3118)
Time	Vol. of foam																									
10 sec	20 mL																									
1 min	12 mL																									
3 min	10 mL																									
12 min	10 mL																									
Time	Vol. of foam																									
10 sec	78 mL																									
1 min	62 mL																									
3 min	36 mL																									
12 min	4 mL																									

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
<b>B 2.8.3</b> <b>Suspensibility, spontaneity and dispersion stability</b>	Spontaneity of dispersion: CIPAC MT 160 with chemical assay	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	5% dilution in CIPAC water D: Flutolanil 102%  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.3/01: Weatherhead, P. (2015) (PC-3115) CP 2.8.3/02: Goldsmith, A E (2015) (PC-3117)
		'MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	5% dilution in CIPAC water D: Flutolanil 101%  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.3/03: Weatherhead, P. (2015a) (PC-3116) CP 2.8.3/04: Goldsmith, A E (2015a) (PC-3118)
	Suspensibility: CIPAC MT 184 with chemical assay	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	0.1% dilution in CIPAC water D: Flutolanil 97% 20% dilution in CIPAC water D: Flutolanil 98%  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.3/01: Weatherhead, P. (2015) (PC-3115) CP 2.8.3/02: Goldsmith, A E (2015) (PC-3117)
		'MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	0.1% dilution in CIPAC water D: Flutolanil 97% 20% dilution in CIPAC water D: Flutolanil 100%  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.3/03: Weatherhead, P. (2015a) (PC-3116) CP 2.8.3/04: Goldsmith, A E (2015a) (PC-3118)
<b>B 2.8.4 Degree of dissolution and dilution stability</b>			Not relevant for an SC formulation			
<b>B 2.8.5 Particle size distribution, dust content, attrition and</b>						

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
<b>mechanical stability</b>						
<b>B 2.8.5.1 Particle size distribution</b>	Wet sieve test: CIPAC MT 185	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	0.01% retained on a 75 µm sieve  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.5.1/01: Weatherhead, P. (2015) (PC-3115) CP 2.8.5.1/02: Goldsmith, A E (2015) (PC-3117)
		'MONCUT 40SC' (with dye) "40SC (EU-D)" 464.6 g/L flutolanil Batch: 5AE9401F	0.01% retained on a 75 µm sieve  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.5.1/03: Weatherhead, P. (2015a) (PC-3116) CP 2.8.5.1/04: Goldsmith, A E (2015a) (PC-3118)
<b>B 2.8.5.2 Dust content</b>			Not relevant for an SC formulation			
<b>B 2.8.5.3 Attrition</b>			Not relevant for an SC formulation			
<b>B 2.8.5.4 Hardness and integrity</b>			Not relevant for an SC formulation			
<b>B 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability</b>			Not relevant for an SC formulation			
<b>B 2.8.7 Flowability, pourability and dustability</b>	Pourability: CIPAC MT 148	'MONCUT 40SC' (without dye) "40SC (EU)" 465.7 g/L flutolanil Batch: 5AE9301F	Non-rinsed residue: 3.67% Rinsed residue: 0.24%  These data were obtained using the representative formulation at renewal.	<b>Acceptable</b>	Y	CP 2.8.7/01: Weatherhead, P. (2015) (PC-3115) CP 2.8.7/02: Goldsmith, A E (2015) (PC-3117)
		'MONCUT 40SC' (with dye) "40SC (EU-D)"	Non-rinsed residue: 4.18% Rinsed residue (1 <sup>st</sup> rinse): 0.31% Rinsed residue (2 <sup>nd</sup> rinse): 0.09%	<b>Acceptable</b>	Y	CP 2.8.7/03: Weatherhead, P. (2015a) (PC-3116)

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference																								
		464.6 g/L flutolanil Batch: 5AE9401F	These data were obtained using the representative formulation at renewal.			CP 2.8.7/04: Goldsmith, A E (2015a) (PC-3118)																								
B.2.9 Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised																														
			No data are provided since no tank mixes are specified in the GAP	Acceptable																										
B.2.10 Adherence and distribution to seeds																														
	An internal method comparable to CIPAC MT 175 and MT 194 was used.	<p>'MONCUT 40SC' (with dye) "40SC (EU-D)" 399 g/kg flutolanil Batch: 061221-3</p> <p>'RhiNo' (without dye) "40SC (NPE-free)" 407 g/kg flutolanil Batch: A4C05</p>	<p>Potato tubers (525 kg per lot, cv. King Edward) were treated with 'MONCUT 40SC' or 'RhiNo' according to commercial practice using a roller table mounted spray applicator at a rate equivalent to 92 g flutolanil/tonne potatoes diluted in water to achieve a spray volume of 2 L/tonne tubers. Treated tubers were stored under conditions representative of a commercial seed store. Samples of 5 kg potatoes were taken after 0, 3 and 6 months storage for analysis of retention of active substance content. For analysis of uniformity of loading, 101 individual tubers were taken from each treatment and analysed.</p> <p>Potatoes were analysed for surface residues of flutolanil according to Agrisearch Method Flutolanil/Potato/NG/04/1 (GC-MS/MS &amp; GM-NPD). Concurrent procedural recoveries at 0.046 g/kg and 0.092 g/kg gave an overall mean recovery of 89% and RSD of 9.2% (n=6). The method is considered to be acceptably validated.</p> <p>Accuracy of loading to treated potatoes:</p> <table><tr><th rowspan="2">Day after application</th><th colspan="2">Treatment with 'MONCUT 40SC' (92 g flutolanil/tonne)</th><th colspan="2">Treatment with 'RhiNo' (92 g flutolanil/tonne)</th></tr><tr><th>Mean rate determined (g/flutolanil/tonne)</th><th>Mean % of nominal</th><th>Mean rate determined (g/flutolanil/tonne)</th><th>Mean % of nominal</th></tr><tr><td>1</td><td>73.8</td><td>80</td><td>64.2</td><td>70</td></tr><tr><td>91</td><td>78.1</td><td>85</td><td>55.8</td><td>61</td></tr><tr><td>182</td><td>63.9</td><td>69</td><td>53.4</td><td>58</td></tr></table> <p>Uniformity of loading: Treatment with 'MONCUT 40SC' (92 g flutolanil/tonne): RSD = 57%</p>	Day after application	Treatment with 'MONCUT 40SC' (92 g flutolanil/tonne)		Treatment with 'RhiNo' (92 g flutolanil/tonne)		Mean rate determined (g/flutolanil/tonne)	Mean % of nominal	Mean rate determined (g/flutolanil/tonne)	Mean % of nominal	1	73.8	80	64.2	70	91	78.1	85	55.8	61	182	63.9	69	53.4	58	Acceptable  As the treatment of potato tubers or flower bulbs is not regarded to be seed treatment, this information is regarded to be additional only	Y	CP 2.10/01: Harrison, C. & Partington, K. (2007) (R-3205)
Day after application	Treatment with 'MONCUT 40SC' (92 g flutolanil/tonne)		Treatment with 'RhiNo' (92 g flutolanil/tonne)																											
	Mean rate determined (g/flutolanil/tonne)	Mean % of nominal	Mean rate determined (g/flutolanil/tonne)	Mean % of nominal																										
1	73.8	80	64.2	70																										
91	78.1	85	55.8	61																										
182	63.9	69	53.4	58																										

Data point	Guideline and method	Test material purity and specification	Results	Comment	GLP Y/N	Reference
			<p>Treatment with 'RhiNo' (92 g flutolanil/tonne): RSD = 41%</p> <p>These data were obtained using a previous iteration of the 'Flutolanil 40SC' formulation recipe but are considered acceptable to extrapolate to the representative formulation recipe supported at renewal.</p>			
<b>B.2.11 Other studies</b>						
			No additional studies are provided			

## B.2.12

## References relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 2.1/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG/15/017/1 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.1/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.1/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/018/2 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

CP 2.1/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.2/01	van der Baan-Treur, J	2004	STATEMENT ON THE EXPLOSIVE PROPERTIES OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 391275 Nihon Nohyaku Co. Ltd code: PC-3036 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.2/02	van der Baan-Treur, J	2004a	STATEMENT ON THE OXIDIZING PROPERTIES OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 391286 Nihon Nohyaku Co. Ltd code: PC-3037 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.2/03	Selditz, U.	2007	DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 485413 Nihon Nohyaku Co. Ltd code: PC-3065 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.2/04	Younis, S.	2015	Physical Hazards Testing on a Sample of Flutolanil 40% w/w SC (EU-D) (aqueous) Report No.: GLP113769/C/R1V1/2015	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

			Nihon Nohyaku Co. Ltd code: GLP: Yes Published: No				
CP 2.3/01	van der Baan-Treur, J	2004b	DETERMINATION OF THE FLASH POINT OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 391297 Nihon Nohyaku Co. Ltd code: PC-3038 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.3/02	van der Baan-Treur, J	2004b	DETERMINATION OF THE AUTO-IGNITION TEMPERATURE (LIQUID) OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 391308 Nihon Nohyaku Co. Ltd code: PC-3039 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.3/03	Selditz, U.	2007	DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES OF FLUTOLANIL 40SC NOTOX B.V. Report No.: 485413 Nihon Nohyaku Co. Ltd code: PC-3065 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.3/04	Younis, S.	2015	Physical Hazards Testing on a Sample of Flutolanil 40% w/w SC (EU-D) (aqueous) Report No.: GLP113769/C/R1V1/2015 Nihon Nohyaku Co. Ltd code: GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.4/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F	N	Y	Article 59(1) & (2) of Regulation	Nihon Nohyaku



			Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No			(EC) 1107/2009 applies	Co. Ltd
CP 2.4/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.4/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.4/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.4/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

			GLP: Yes Published: No				
CP 2.5/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.5/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.5/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.5/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.6/01	Weatherhead,	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of	N	Y	Article 59(1) & (2)	Nihon

	P		data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No			of Regulation (EC) 1107/2009 applies	Nohyaku Co. Ltd
CP 2.6/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.6/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.6/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

			Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No				
CP 2.7/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/05	van der Baan-Treur, J	2006	DETERMINATION OF THE STABILITY OF FLUTOLANIL 40SC OVER 2 YEARS UNDER AMBIENT CONDITIONS NOTOX B.V. Report No.: 391422 Nihon Nohyaku Co. Ltd code: PC-3051 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

CP 2.7/06	Brands, Ir. C.	2004	DETERMINATION OF THE CONTENT OF FLUTOLANIL IN FLUTOLANIL 40SC NOTOX B.V. Report No.: 391084 Nihon Nohyaku Co. Ltd code: PC-3034 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/07	Selditz, U.	2009	DETERMINATION OF THE STABILITY OF FLUTOLANIL 40SC (EU-D) OVER 2 YEARS UNDER AMBIENT CONDITIONS NOTOX B.V. Report No.: 485432 Nihon Nohyaku Co. Ltd code: PC-3086 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.7/08	Selditz, U.	2007	DETERMINATION OF THE PHYSICO-CHEMICAL PROPERTIES OF FLUTOLANIL 40 SC (EU-D) NOTOX B.V. Report No.: 485413 Nihon Nohyaku Co. Ltd code: PC-3065 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.2/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.2/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd.	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

			Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No				
CP 2.8.2/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.2/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.3/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.3/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd

			Published: No				
CP 2.8.3/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.3/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.5.1/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.5.1/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.5.1/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F	N	Y	Article 59(1) & (2) of Regulation	Nihon Nohyaku

			Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116 GLP: Yes Published: No			(EC) 1107/2009 applies	Co. Ltd
CP 2.8.5.1/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.7/01	Weatherhead, P	2015	Certificate of Analysis for Flutolanil 40SC EU; generation of data for batch 5AE9301F Battelle UK Ltd. Report No.: XG150171 Nihon Nohyaku Co. Ltd code: PC-3115 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.7/02	Goldsmith, A E	2015	Physical and Chemical Properties of Flutolanil 40SC (EU): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/017/2 Nihon Nohyaku Co. Ltd code: PC-3117 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.8.7/03	Weatherhead, P	2015a	Certificate of Analysis for Flutolanil 40SC EU-D; generation of data for batch 5AE9401F Battelle UK Ltd. Report No.: XG15/0182 Nihon Nohyaku Co. Ltd code: PC-3116	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd



			GLP: Yes Published: No				
CP 2.8.7/04	Goldsmith, A E	2015a	Physical and Chemical Properties of Flutolanil 40SC (EU-D): Accelerated Storage Stability for 2 weeks at 54°C and 7 days at 0°C stored in high-density polyethylene (HDPE) bottles Battelle UK Ltd. Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: PC-3118 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd
CP 2.10/01	Harrison, C. & Partington, K.	2007	FINAL REPORT ON PROJECT AP/11343/CZ: To determine the post application loading, uniformity and retention following longer term storage, of flutolanil on the surface of tubers following post-harvest application of 061-221, compared to that of RhiNo, to seed grade potatoes in the UK Eurofins Agrisearch Report No.: XG/15/018/3 Nihon Nohyaku Co. Ltd code: R-3205 GLP: Yes Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co. Ltd