

Renewal Assessment Report

beta-cyfluthrin

Montur Forte FS 230

Volume 3 – B.2 Physical and chemical properties

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Version history

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B.2 Physical and chemical properties

Product name: Montur Forte FS 230 (containing 80 g/L beta-cyfluthrin and 150 g/L imidacloprid, flowable concentrate for seed treatment). This product has not been evaluated in the original DAR.

The following batches have been used in the physico-chemical studies:

1. Batch-Number: 2010-003825 (Test substance: beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L))
2. Batch-Number: 06200/0146*5.0 (Test substance: FCR 4545 80 FS NTN 33893 150, AB-number 0266429)
3. Batch-Number: 06200/0252(0193) (Test substance: Montur Forte FS 230, AB-number 0266429)
4. Batch-Number: 06200/0146(0106) (Test substance: Montur Forte FS 230)
5. Batch-Number: 2014-000360 (Test substance: beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L))

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.1 Appearance (CP 2.1)						
Appearance	Visual assessment	Batch: 2010-003825	Physical state: suspension Colour: off-white	acceptable	Y	Guedner, Hoppe (2010) (BVL no. 2633217)
B.2.2 Explosive and oxidising properties (CP 2.2)						
Explosive properties	EC A.14	Batch: 06200/0146*5.0	The preparation Montur Forte FS 230 has no explosive properties.	acceptable	Y	Heinz (2002) (BVL no. 2633218)
Oxidising properties	EC A.21	Batch: 06200/0252(0193)	The preparation Montur Forte FS 230 has no oxidising properties.	acceptable	Y	Heinz (2002) (BVL no. 2633219)

B.2.3 Flammability and auto-flammability (CP 2.3)						
Flash point	EC A.9	Batch: 06200/0146*5.0	The preparation Montur Forte FS 230 has no flash point up to the boiling point (100 °C).	acceptable	Y	Heinz (2002) (BVL no. 2633220)
Flammability			Not relevant as the preparation is a liquid formulation.			
Self-heating	EC A.15	Batch: 06200/0146*5.0	Auto ignition temperature: 395 °C	acceptable	Y	Heinz (2002) (BVL no. 2633220)
B.2.4 Acidity/alkalinity and pH value (CP 2.4)						
Acidity or alkalinity and pH	CIPAC MT 75.3	Batch: 2010-003825	pH: 4.4 (undiluted) Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633221)
pH of a 1 % aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Batch: 2010-003825	5.1 (1 % in deionised water at room temperature)	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633221)
B.2.5 Viscosity and surface tension (CP 2.5)						
Viscosity	CIPAC MT 192	Batch: 2010-003825	Dynamic viscosity 180.6 mPa s at 20 °C and a shear rate of 20 s ⁻¹ 65.79 mPa s at 20 °C and a shear rate of 100 s ⁻¹ 165.9 Pa s at 40 °C and a shear rate of 20 s ⁻¹ 58.19 Pa s at 40 °C and a shear rate of 100 s ⁻¹	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633222)

			Kinematic viscosity (calculated from dynamic viscosity) shear rate 20 s ⁻¹ 1.60·10 ⁻⁴ m²/s at 20 °C 1.49·10 ⁻⁴ m²/s at 40 °C shear rate 100 s ⁻¹ 0.582·10 ⁻⁴ m²/s at 20 °C 0.522·10 ⁻⁴ m²/s at 40 °C				
Surface tension	OECD 115	Batch: 2010-003825	42 mN/m (undiluted at 25 °C) 52 mN/m (1 g of the formulation/L at 20 °C) The preparation is regarded as surface-active.	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633222)	
B.2.6 Relative density and bulk density (CP 2.6)							
Relative density	OECD 109	Batch: 2010-003825	1.130 at 20 °C 1.115 at 40 °C	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633223)	
Bulk density (pour and tap)			Not relevant as the preparation is a liquid formulation.				
B.2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product (CP 2.7)							
Storage stability after 14 days at 54 °C	CIPAC MT 46.3	Batch: 2014-000360	Stable for 14 days at 54 °C in the original packaging (HDPE)		acceptable	Y	Gueldner, Hoppe (2014) (BVL no. 2963410)
	AM008706MF1 (HPLC)		80.54 g/L beta-cyfluthrin 150.0 g/L imidacloprid	80.31 g/L beta-cyfluthrin 148.9 g/L imidacloprid			
	Visual assessment		white suspension	white suspension			
					However a test on adhesion to seeds before and after storage is missing.		

	CIPAC MT 75.3 (pH)		4.5 (undiluted) 5.0 (1 % in deionised water)	4.6 (undiluted) 5.0 (1 % in deionised water)			
	EC A.3 (relative density)		1.128	1.128			
	CIPAC MT 47.3 (persistent foaming)		64 % v/v in CIPAC water D: after 10 sec 5 mL after 1 min 9 mL after 3 min 9 mL after 12 min 8 mL 100 % (undiluted): after 10 sec 0 mL after 1 min 1 mL after 3 min 1 mL after 12 min 2 mL	64 % v/v in CIPAC water D: after 10 sec 6 mL after 1 min 8 mL after 3 min 7 mL after 12 min 4 mL 100 % (undiluted): after 10 sec 0 mL after 1 min 1 mL after 3 min 1 mL after 12 min 3 mL			
	CIPAC MT 184 (suspensibility)		64 % of the preparation in CIPAC-water D: Beta-cyfluthrin: 100 % Imidacloprid: 101 %	64 % of the preparation in CIPAC-water D: Beta-cyfluthrin: 101 % Imidacloprid: 101 %			
	CIPAC MT 185 (wet sieve test)		Residue on a 75 µm sieve: 0.03 %	Residue on a 75 µm sieve: < 0.01 %			
	CIPAC MT 187 (particle size distribution)		d (0.1): 0.47 µm d (0.5): 1.02 µm d (0.9): 2.66 µm	d (0.1): 0.58 µm d (0.5): 1.23 µm d (0.9): 3.05 µm			
	CIPAC MT 148 (pourability)		Residue: 1.93 % Rinsed residue: 0.21 %	Residue: 1.88 % Rinsed residue: 0.16 %			
	Statement		Statement of the applicant regarding the study on storage stability: For the formulation it was shown that the parameters wet sieve test and particle size distribution did not change significantly during storage. Therefore it is considered unnecessary to determine again the "Seed-to-seed distribution acc. to CIPAC		The statement is considered not sufficient to address the missing determination of adhesion to seeds after storage of the	N	Gueidner, Hoppe, Wiese (2013) (BVL no 2963411)

			MT 175” and the “Adhesion to seeds acc. To CIPAC MT 194 of seed treated with formulation after storage of the formulation. From scientific point of view the same results can be expected compared to testing seeds treated with formulation before storage of the formulation.	product.		
Stability after storage for other periods and/or temperatures	CIPAC MT 46.3	Batch: 06200/0146(0106)	Stable for 8 weeks at 40 °C in the original packaging (HDPE)	additional information	Y	Guedner (2005) (BVL no 2633224)
			Before storage:			
	2001-0044501-97 (GC)		7.0 % beta-cyfluthrin (at beginning of the study, content determined within another study: 7.5 % beta-cyfluthrin)			
	2001-0002502-97 (LC)		13.5 % imidacloprid			
	Visual assessment		beige suspension			
	CIPAC MT 75.3 (pH)		4.9 (undiluted) 5.4 (1 % in CIPAC water D)			
	CIPAC MT 185 (wet sieve test)		Residue on a 75 µm sieve: < 0.01 %			
	CIPAC MT 148 (pourability)		Residue: 1.81 % Rinsed residue: 0.14 %			
	CIPAC MT 47.2 (persistent foaming)		18.4 % v/v in CIPAC water D: after 10 sec 24.5 mL after 1 min 5.5 mL after 3 min 4.5 mL after 12 min 2.0 mL			
Minimum content after heat stability testing			Not required, as no decrease in active substance content of greater than 5 % was observed after heat			

			stability testing.				
Effect of low temperatures on stability	CIPAC MT 39.3	Batch: 2014-000360	Stable for 7 days at 0 °C (no visible separation).		acceptable	Y	Gueldner, Hoppe (2014) (BVL no. 2963410)
			Before storage:	After storage:			
	CIPAC MT 185 (wet sieve test)		Residue on a 75 µm sieve: 0.03 %	Residue on a 75 µm sieve: 0.01 %			
Shelf life following storage at ambient temperature	GIFAP Mono-graph 17	Batch: 06200/0146(0106)	Stable for two years at 20 °C in the original packaging (HDPE)		acceptable, However, tests on adhesion to seeds and suspensibility before and after storage are missing.	Y	Gueldner (2005) (BVL no 2633224)
			Before storage:	After storage:			
	2001-0044501-97 (GC)		7.0 % beta-cyfluthrin at beginning of the study (content determined within another study: 7.5 % beta-cyfluthrin)	7.1 % beta-cyfluthrin			
	2001-0002502-97 (LC)		13.5 % imidacloprid	13.4 % imidacloprid			
	Visual assessment		beige suspension	beige suspension			
	CIPAC MT 75.3 (pH)		4.9 (undiluted) 5.4 (1 % in CIPAC water D)	4.8 (undiluted) 5.2 (1 % in CIPAC water D)			
	CIPAC MT 185 (wet sieve test)		Residue on a 75 µm sieve: < 0.01 %	Residue on a 75 µm sieve: < 0.01 %			
	CIPAC MT 148 (pourability)		Residue: 1.81 % Rinsed residue: 0.14 %	Residue: 2.14 % Rinsed residue: 0.12 %			
	CIPAC MT 47.2 (persistent foaming)		18.4 % v/v in CIPAC water D: after 10 sec 24.5 mL after 1 min 5.5 mL after 3 min 4.5 mL after 12 min 2.0 mL	64 % v/v in CIPAC water D: after 10 sec 19 mL after 1 min 5 mL after 3 min 4 mL after 12 min 3 mL			
	Statement		Statement of the applicant regarding the study on		The statement is	N	Gueldner, Hoppe, Wiese

			<p>storage stability: For the formulation it was shown that the parameters wet sieve test and particle size distribution did not change significantly during storage. Therefore it is considered unnecessary to determine again the “Seed-to-seed distribution acc. to CIPAC MT 175” and the “Adhesion to seeds acc. To CIPAC MT 194 of seed treated with formulation after storage of the formulation. From scientific point of view the same results can be expected compared to testing seeds treated with formulation before storage of the formulation.</p>		considered not sufficient to address the missing determination of adhesion to seeds after storage of the product.		(2013) (BVL no 2963411)
		Batch: 2010-003825	Stable for 18 months at ambient temperature (treated seeds)		acceptable	Y	Geldner, Hoppe (2012) (BVL no 2963412)
			Before storage:	After storage:			
	CIPAC MT 175 (Distribution)		Seed type: sugar beet Thousand grain weight: 30.1 g Beta-cyfluthrin: Mean value: 0.086 mg RSD: 15.0 % Seed loading: 103.4 %	Seed type: sugar beet Thousand grain weight: 30.1 g Beta-cyfluthrin: Mean value: 0.080 mg RSD: 16.9 % Seed loading: 97.6 %			
	CIPAC MT 194 (Adherence)		Beta-cyfluthrin: 100.0 % Imidacloprid: 99.9 %	Beta-cyfluthrin: 100.4 % Imidacloprid: 102.8 %			
Shelf life in months (if less than 2 years)			Not relevant				

B.2.8 Technical characteristics of the plant protection product (CP 2.8)						
B.2.8.1 Wettability (CP 2.8.1)						
Wettability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
B.2.8.2 Persistent foaming (CP 2.8.2)						
Persistent foaming	CIPAC MT 47.2	Batch: 2010-003825	64 % v/v in CIPAC water D: after 10 sec 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL 100 % (undiluted): after 10 sec 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633226)
B.2.8.3 Suspensibility, spontaneity and dispersion stability (CP 2.8.3)						
Suspensibility	CIPAC MT 184 (Chemical assay)	Batch: 2010-003825	64 % of the preparation in CIPAC-water D: Beta-cyfluthrin: 100 % Imidacloprid: 101 %	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633227)
Spontaneity of			Not relevant as the preparation is a flowable			

dispersion			concentrate for seed treatment.			
Dispersion stability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
B.2.8.4 Degree of dissolution and dilution stability (CP 2.8.4)						
Degree of dissolution			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Dilution stability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability (CP 2.8.5)						
Particle size distribution	CIPAC MT 185 CIPAC MT 187	Batch: 2010-003825 Batch: 2010-003825	Wet sieve test: Residue on a 75 µm sieve: 0.01 % Size distribution of particles: ≤ 10 % retained on a 0.60 µm sieve ≥ 90 % retained on a 3.65 µm sieve	Acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633228)
Dust content			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Attrition			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Hardness and integrity			Not relevant as the preparation is a flowable concentrate for seed treatment.			

B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability (CP 2.8.6)						
Emulsifiability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Re-emulsifiability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Emulsion stability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
B.2.8.7 Flowability, pourability and dustability (CP 2.8.7)						
Flowability			Not relevant as the preparation is a flowable concentrate for seed treatment.			
Pourability	CIPAC MT 148	Batch: 2010-003825	Residue: 1.49 % Rinsed residue: 0.10 %	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633229)
Dustability following accelerated storage			Not relevant as the preparation is a flowable concentrate for seed treatment.			
B.2.9 Physical compatibility with other products including plant protection products with which its use is to be authorised (CP 2.9)						
Physical compatibility of tank mixes			Not applicable (tank mixtures with other pesticides are not recommended)			
Chemical compatibility of tank mixes			Not applicable (tank mixtures with other pesticides are not recommended)			

B.2.10 Adherence and distribution to seeds (CP 2.10)						
Distribution (seed treatment)	CIPAC MT 175	Batch: 2010-003825	Seed type: sugar beet Thousand grain weight: 30.1 g Beta-cyfluthrin: Mean value: 0.086 mg RSD: 15.0 % Seed loading: 103.4 % Imidacloprid: Mean value: 0.151 mg RSD: 11.5 % Seed loading: 93.4 %	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633230)
Adherence (seed treatment)	CIPAC MT 194	Batch: 2010-003825	Beta-cyfluthrin: 100.0 % Imidacloprid: 99.9 %	acceptable	Y	Gueldner, Hoppe (2010) (BVL no. 2633230)
B.2.11 Other studies (CP 2.11)						
Other studies			No other special studies required.			

B.2.12 References relied on

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 /01 KCP 2.4 /01 KCP 2.5 /01 KCP 2.6 /01 KCP 2.8.2 /01 KCP 2.8.3 /01 KCP 2.8.5.1 /01 KCP 2.8.7 /01 KCP 2.10 /01	Gueldner, W.; Hoppe, M.	2010	Physical, chemical and technical properties of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) Bayer CropScience, Report No.: FM0078(PC00)G01, Edition Number: M-390794-01-1 Date: 2010-09-24 GLP/GEP: yes, unpublished 2633217 / 2633221 / 2633222 / 2633223 / 2633226 / 2633227 / 2633228 / 2633229 / 2633230	N	Y	data not submitted on EU level	Bayer CropScience
KCP 2.2 /01	Heinz, U.	2002	Determination of Safety-Relvant Data of FCR 4545 80 FS NTN 33893 150 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 02/00096, Edition Number: M-080410-01-1 Date: 2002-04-12 GLP/GEP: yes, unpublished 2633218 / 2633220	N	Y	data not submitted on EU level	Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies
Black Studies indicate Supplementary Dossier Studies

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2 /02	Heinz, U.	2004	Determination of Safety-Relevant Data of Imidacloprid + Beta-Cyfluthrin FS 230 - Further code name: Montur Forte FS 230 Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience, Report No.: 04/00410, Edition Number: M-182034-01-1 Date: 2004-12-08 GLP/GEP: yes, unpublished 2633219	N	Y	data not submit- ted on EU level	Bayer CropScience
KCP 2.7 /01	Gueldner, W.	2005	Storage Stability of Montur Forte FS 230 - (Packaging material: HDPE) - Final report Bayer CropScience, Report No.: 06200-0219, Edition Number: M-090776-02-1 Date: 2005-03-31 GLP/GEP: no, unpublished 2633224	N	N		Bayer CropScience
KCP 2.7 /02	Gueldner, W.; Hoppe, M.	2014	Storage stability at elevated temperature and cold stabil- ity of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) - Packaging material: HDPE - Final report (14 days) Bayer CropScience, Report No.: FM0078(ACF01)N01, Edition Number: M-481012-02-1 Date: 2014-04-22 GLP/GEP: no, unpublished 2963410	N	Y		Bayer CropScience

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Black Studies indicate Supplementary Dossier Studies

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7 /03	Gueldner, W.; Hoppe, M.; Wiese, B.	2013	Statement on distribution and adhesion to seeds for assessing application properties of formulations after storage - Statement Bayer CropScience, Report No.: M-446084-02-1, Edition Number: M-446084-02-1 Date: 2013-11-07 GLP/GEP: no, unpublished 2963411	N	Y		Bayer CropScience
KCP 2.7 /04	Gueldner, W.; Hoppe, M.	2012	Determination of seed loading, adherence test and uni- formity of distribution of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) on sugar beet pellets before and after storage Bayer CropScience, Report No.: FM0078(SS96)N01, Edition Number: M-429878-01-1 Date: 2012-04-26 GLP/GEP: no, unpublished 2963412	N	Y		Bayer CropScience

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