

Renewal Assessment Report

beta-cyfluthrin

Bulldock EC 25

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: Bulldock EC (containing 25 g/L beta-cyfluthrin, emulsifiable concentrate).

Bulldock EC has been the representative formulation in the original DAR. However, the product has been transferred to ADAMA Agricultural Solutions Limited (formerly Maktheshim Agan Holding B.V.) and the composition of the preparation has been altered completely in the meantime. Therefore, only the new studies are described here.

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.1 Appearance (CP 2.1)						
Appearance	Visual assessment	Bulldock 25 EC (Batch: 92110454)	Physical state: liquid Colour: colourless limpid	acceptable	Y	Demangel (2013) (BVL no. 2633389)
B.2.2 Explosive and oxidising properties (CP 2.2)						
Explosive properties	EC A.14	Bulldock 25 EC (Batch: 92110454)	The preparation Bulldock EC has no explosive properties (shock and heat)	acceptable	Y	Grevin (2013) (BVL no. 2633391)
Oxidising properties	EC A.21	Bulldock 25 EC (Batch: 92110454)	The preparation Bulldock EC has no oxidising properties.	acceptable	Y	Grevin (2013) (BVL no. 2633391)
B.2.3 Flammability and auto-flammability (CP 2.3)						
Flash point	EC A.9	Bulldock 25 EC (Batch: 92110454)	62.0 °C	acceptable	Y	Grevin (2013) (BVL no. 2633394)

Flammability			Not relevant as the preparation is a liquid formulation.			
Self-heating	EC A.15	Bulldock 25 EC (Batch: 92110454)	Auto ignition temperature: 436 °C	acceptable	Y	Grevin (2013) (BVL no. 2633394)
B.2.4 Acidity/alkalinity and pH value (CP 2.4)						
Acidity or alkalinity and pH	CIPAC MT 75.3	Bulldock 25 EC (Batch: 92110454)	Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).	acceptable	Y	Demangel (2013) (BVL no. 2633397)
pH of a 1 % aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Bulldock 25 EC (Batch: 92110454)	1 % in CIPAC water D: 7.16 at 19.8 °C after 1 min 6.99 at 19.9 °C after 2 min 6.30 at 20.1 °C after 10 min	acceptable	Y	Demangel (2013) (BVL no. 2633397)
B.2.5 Viscosity and surface tension (CP 2.5)						
Viscosity	OECD 114 (viscometer)	Bulldock 25 EC (Batch: 92110454)	Dynamic viscosity: 1.89 mPa s at 20 °C and a shear rate of 61 - 196 s ⁻¹ 1.35 mPa s at 40 °C and a shear rate of 61 - 147 s ⁻¹ The test item was considered to have Newtonian behaviour. Kinematic viscosity (calculated from dynamic viscosity with density = 0.901 g/mL): 2.1 x 10 ⁻⁶ m ² /s at 20 °C 1.5 x 10 ⁻⁶ m ² /s at 40 °C	acceptable	Y	Grevin (2013) (BVL no. 2633398)
Surface tension	EC A.5	Bulldock 25 EC (Batch: 92110454)	28.0 mN/m (1.4 % v/v in water at 25 °C) The preparation is regarded as surface active	acceptable	Y	Grevin (2013) (BVL no. 2633398)

B.2.6 Relative density and bulk density (CP 2.6)							
Relative density	OECD 109	Bulldock 25 EC (Batch: 92110454)	0.901 at 21.8 °C		acceptable	Y	Grevin (2013) (BVL no. 2633399)
Bulk density (pour and tap)			Not relevant as the preparation is a liquid formula- tion.				
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	Bulldock 25 EC (Batch: 92110454)	Stable for 14 days at 54 °C in the original packaging (HDPE).		acceptable	Y	Demangel (2013) (BVL no 2633402)
			Before storage:	After storage:			
	CIPAC method 482/EC/M/3 (HPLC)		25.8 g/L beta-cyfluthrin	25.5 g/L beta-cyfluthrin			
	Visual assess- ment		Colourless limpid liquid	Colourless limpid liquid			
	CIPAC MT 47.2 (Persistent foaming)		1.4 % v/v in CIPAC water D: after 10 sec 23 mL after 1 min 21 mL after 3 min 21 mL after 12 min 17 mL	1.4 % v/v in CIPAC water D: after 10 sec 23 mL after 1 min 23 mL after 3 min 21 mL after 12 min 15 mL			
	CIPAC MT 75.3 (pH)		1 % in CIPAC water D: 7.16 after 1 min 6.99 after 2 min 6.30 after 10 min	1 % in CIPAC water D: 6.87 after 1 min 6.72 after 2 min 5.41 after 10 min			
	CIPAC MT 173 (stability of dilute		0.1 % v/v at 25 °C: 70 % (CIPAC water A)	0.1 % v/v at 25 °C: 79 % (CIPAC water A)			

	emulsions)		92 % (CIPAC water D) 1.4 % v/v at 25 °C: 61 % (CIPAC water A) 89 % (CIPAC water D)	89 % (CIPAC water D) 1.4 % v/v at 25 °C: 79 % (CIPAC water A) 97 % (CIPAC water D)			
Stability after storage for other periods and/or temperatures			Not relevant as the formulation is stable at 54 °C.				
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	Bulldock 25 EC (Batch: 92110454)	Stable for 7 days at 0 °C. The test item should be shaken before use.		Acceptable	Y	Grevin (2013) (BVL no. 2633403)
			Before storage:	After storage:			
			Colourless limpid liquid	Colourless limpid liquid with a cloudy inferior phase of about 0.9 mL			
Shelf life following storage at ambient temperature	GIFAP Mono-graph 17	Bulldock 25 EC (Batch: 92110454)	Stable for two years at 20 °C in the original packaging (HDPE)		acceptable	Y	Demangel (2014) (BVL no. 2962745)
			Before storage:	After storage:			
	CIPAC method 482/EC/M/3 (HPLC)		2.58 % beta-cyfluthrin	2.54 % beta-cyfluthrin			
	Visual assessment		Colourless limpid liquid	Colourless limpid liquid			
	CIPAC MT 47.2 (Persistent foaming)		1.4 % v/v in CIPAC water D: after 10 sec 23 mL after 1 min 21 mL after 3 min 21 mL after 12 min 17 mL	1.4 % v/v in CIPAC water D: after 10 sec 28 mL after 1 min 18 mL after 3 min 12 mL after 12 min 9 mL			
	CIPAC MT 75.3		1 % in CIPAC water D:	1 % in CIPAC water D:			

	(pH)		7.16 after 1 min 6.99 after 2 min 6.30 after 10 min	6.48 after 1 min 6.39 after 2 min			
	CIPAC MT 36.3 (Emulsion characteristics)		The emulsions at 0.1 and 1.4 % /v in standard water A and D at 30 °C were considered to be stable.	The emulsions at 0.1 and 1.4 % /v in standard water A and D at 30 °C were considered to be stable.			
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 emulsifiable concentrate.				
B.2.8.2 Persistent foaming (CP 2.8.2)							
Persistent foaming	CIPAC MT 47.2	Bulldock 25 EC (Batch: 92110454)	1.4 % v/v in CIPAC water D: after 10 sec 23 mL after 1 min 21 mL after 3 min 21 mL after 12 min 17 mL		acceptable	Y	Demangel (2013) (BVL no. 2633407)

B.2.8.3 Suspensibility, spontaneity and dispersion stability (CP 2.8.3)						
Suspensibility			Not relevant as the preparation is a emulsifiable concentrate.			
Spontaneity of dispersion			Not relevant as the preparation is a emulsifiable concentrate.			
Dispersion stability			Not relevant as the preparation is a emulsifiable concentrate.			
B.2.8.4 Degree of dissolution and dilution stability (CP 2.8.4)						
Degree of dissolution			Not relevant as the preparation is a emulsifiable concentrate.			
Dilution stability			Not relevant as the preparation is a emulsifiable concentrate.			
B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability (CP 2.8.5)						
Particle size distribution			Not relevant as the preparation is a emulsifiable concentrate.			
Dust content			Not relevant as the preparation is a emulsifiable concentrate.			
Attrition			Not relevant as the preparation is a emulsifiable concentrate.			
Hardness and integrity			Not relevant as the preparation is a emulsifiable concentrate.			

B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability (CP 2.8.6)						
Emulsifiability, re-emulsifiability, emulsion stability	CIPAC MT 36.3	Bulldock 25 EC (Batch: 92110454)	The emulsions at 0.1 and 1.4 % /v in standard water A and D at 30 °C were considered to be stable.	acceptable	Y	Demangel (2013) (BVL no. 2633410)
	CIPAC MT 173	Bulldock 25 EC (Batch: 92110454)	70 % (0.1 % v/v in CIPAC water A at 25 °C) 92 % (0.1 % v/v in CIPAC water D at 25 °C) 61 % (1.4 % v/v in CIPAC water A at 25 °C) 89 % (1.4 % v/v in CIPAC water D at 25 °C)	additional information	Y	Demangel (2013) (BVL no. 2633409)
B.2.8.7 Flowability, pourability and dustability (CP 2.8.7)						
Flowability			Not relevant as the preparation is a emulsifiable concentrate.			
Pourability			Not relevant as the preparation is a emulsifiable concentrate.			
Dustability following accelerated storage			Not relevant as the preparation is a emulsifiable concentrate.			
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, required data will be submitted on country level according to national requirements.			
Chemical compatibility of tank mixes			Not applicable, required data will be submitted on country level according to national requirements.			

B.2.10 Adherence and distribution to seeds (CP 2.10)						
Distribution (seed treatment)			No seed dressing formulation.			
Adherence (seed treatment)			No seed dressing formulation.			
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 Report No. Source (where different from company) GLP status (where relevant) published or not BVL registration number	Vertebrate study	Data protection claimed	Justification	Owner
KCP 2.1/02 2.4/03 2.7/04 2.8.2/03 2.8.6/02	Demangel, B.	2013a	Physico-chemical tests and analysis before and after an accelerated storage procedure for 14 days at 54 ± 2 °C on Bulldock 25 EC. Report No: 12-909007-009 Edition No: R-30588 Defitraces, 69126 Brindas, France GLP not published 2633389 / 2633397 / 2633402 / 2633407 / 2633409	N	Y	replacement [REDACTED]	IRV
KCP 2.2/02 2.3/03 2.5/03 2.6/02 2.7/05	Grevin, P.	2013	Physico chemical tests on BULLDOCK 25 EC Report No: 12-909007-008 Edition No: R-30590 Defitraces, 69126 Brindas, France GLP not published 2633391 / 2633394 / 2633398 / 2633399 / 2633403	N	Y	replacement [REDACTED]	IRV
KCP 2.7	Demangel, B.	2014	Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 ± 2 °C on BULLDOCK 25 EC R-30589!12-909007-010 DEFITRACES (Anadiag) GLP: Y, published: N 2962745	N	Y		ADAMA

Annex point/ reference number	Author(s)	Year	Title Report No. Source (where different from company) GLP status (where relevant) published or not BVL registration number	Vertebrate study	Data protection claimed	Justification	Owner
KCP 2.8.6/03	Demangel, B.	2013b	Emulsion characteristics and re-emulsification properties on Bulldock 25 EC Report No: 13-909007-002 Edition No: R-30616 Defitraces, 69126 Brindas, France GLP not published 2633410	N	Y	replacement [REDACTED] [REDACTED]	IRV

IRV = Irvita Plant Protection, Curacao – a member of Makhteshim Agan Holding B.V., The Netherlands

BCS = Bayer CropScience AG, Monheim, Germany

Studies submitted for the Annex I inclusion of beta-cyfluthrin and already evaluated at EU level are listed in grey (owner Bayer CropScience, license Irvita Plant Protection B.V.).

Studies submitted for the first time in support of the renewal approval of beta-cyfluthrin are listed in black.