Renewal Assessment Report

Dimethenamid-P

BAS 830 01 H

Volume 3 – B.2 Physical and chemical properties

Rev. 0 - 10 August 2016

Rapporteur Member State: Germany

Co-Rapporteur Member State: Bulgaria

Version history

When	What
10 August 2016	First version submitted to EFSA

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B Summary, evaluation and assessment of the data and information

B.2 Physical and chemical properties

Product name: BAS 830 01 H (containing 333 g/L dimethenamid-P and 167 g/L quinmerac, SE)

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.1 Appearance (CP 2.1)						
Appearance	Visual assessment	BAS 830 01 H Batch: 451009	Light brown free-flowing homogeneous liquid of medium viscosity; slightly aromatic odour	acceptable	Y	Morgan (2013) (BVL no. 2630722)
B.2.2 Explosive and oxidising properties (CP 2.2)						
Explosive properties	OECD 113	BAS 830 01 H Batch: 451009	The preparation BAS 830 01 H has no explosive properties.	not according to EC A.14 However, because of the composition of the formulation further tests are not required.	Y	Achhammer (2013) (BVL no. 2630734)
Oxidising properties	EC A.21	BAS 830 01 H Batch: 451009	The preparation BAS 830 01 H has no oxidising properties.	acceptable	Y	Smeykal (2014) (BVL no. 2630737)
B.2.3 Flammability and auto-flammability (CP 2.3)						
Flash point	EC A.9	BAS 830 01 H	The preparation BAS 830 01 H has no flash point up	acceptable	Y	Achhammer (2013)

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
		Batch: 451009	to 100 °C.			(BVL no. 2630738)
Flammability						
Self-heating	EC A.15	BAS 830 01 H Batch: 451009	Auto ignition temperature: 454 °C	acceptable	Y	Achhammer (2013) (BVL no. 2630738)
B.2.4 Acidity/alkalinity and pH value (CP 2.4)						
Acidity or alkalinity and pH	CIPAC MT 191	BAS 830 01 H Batch: 451009	3.34 % (calculated as H_2SO_4)	acceptable	Y	Morgan (2013) (BVL no. 2630739)
pH of a 1 % aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	BAS 830 01 H Batch: 451009	3.6 (1 % in deionised water at 22 °C) 3.7 (1 % in CIPAC D water at 22 °C)	acceptable	Y	Morgan (2013) (BVL no. 2630739)
B.2.5 Viscosity and surface tension (CP 2.5)						
Viscosity	CIPAC MT 192 OECD 114	BAS 830 01 H Batch: 451009	681 mPa s at 20 °C and a shear rate of 10 s^{-1} 173 mPa s at 20 °C and a shear rate of 100 s^{-1} 455 mPa s at 40 °C and a shear rate of 10 s^{-1} 135 mPa s at 40 °C and a shear rate of 100 s^{-1}	acceptable	Y	Morgan (2013) (BVL no. 2630740)
Surface tension	EC A.5 OECD 115	BAS 830 01 H Batch: 451009	35.5 mN/m (0.375 % in deionised water at 24 °C) 36.1 mN/m (1.5 % in deionised water at 24 °C) According to EEC A5 the preparation should be regarded as surface-active.	acceptable	Y	Morgan (2013) (BVL no. 2630740)

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.6 Relative density and bulk density (CP 2.6)						
Relative density	EC A.3 OECD 109 CIPAC MT 3.3.2	BAS 830 01 H Batch: 451009	D^{20}_4 = 1.130	acceptable	Y	Morgan (2013) (BVL no. 2630741)
Bulk density (pour and tap)			Not relevant as the preparation is a (SE).			
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	BAS 830 01 H Batch: 451009	Stable for 14 days at 54 °C in the original packaging (HDPE)		acceptable	Y	Morgan (2013) (BVL no. 2630742)
		Before storage	After storage			
	(Analytical method AFL0879/01, see Volume 3, B.5)	331 g/L dimethenamid-P 169 g/L quinmerac	333 g/L dimethenamid-P 168 g/L quinmerac			
	Visual assessment	Light brown free-flowing homogeneous liquid of medium viscosity; slightly aromatic odour	Light brown free-flowing homogeneous liquid of medium viscosity; slightly aromatic odour			
	CIPAC MT 192 OECD 114 (Viscosity)	681 mPa s at 20 °C and a shear rate of 10 s^{-1} 173 mPa s at 20 °C and a shear rate of 100 s^{-1}	593 mPa s at 20 °C and a shear rate of 10 s^{-1} 174 mPa s at 20 °C and a shear rate of 100 s^{-1}			
	EC A.3 OECD 109	D^{20}_4 = 1.130	D^{20}_4 = 1.131			

Study	Method	Test material	Results		Conclusion/ Comment	GLP	Reference
	(Relative density)						
	CIPAC MT 191 (acidity or alkalinity)		3.34 % (calculated as H_2SO_4)	3.23 % (calculated as H_2SO_4)			
	CIPAC MT 75.3 (pH)		5.6 (1 % in deionised water at 22 °C) 3.7 (1 % in CIPAC D water at 22 °C)	5.8 (1 % in deionised water at 22 °C) 3.6 (1 % in CIPAC D water at 22 °C)			
	CIPAC MT 47.2 (Persistent foaming)		0.375 % v/v in CIPAC water D: after 10 sec 24 mL after 1 min 10 mL after 3 min < 2 mL after 12 min < 2 mL 1.5 % v/v in CIPAC water D: after 10 sec 4 mL after 1 min < 2 mL after 3 min < 2 mL after 12 min < 2 mL < 2: peripheral bubbles only	0.375 % v/v in CIPAC water D: after 10 sec 20 mL after 1 min 8 mL after 3 min 8 mL after 12 min 4 mL 1.5 % v/v in CIPAC water D: after 10 sec < 1 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL			
	CIPAC MT 180 (Dispersion stability)		<u>0.375 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL top oil/cream 0 mL	<u>0.375 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment < 0.5mL top oil/cream 0 mL			

Study	Method	Test material	Results		Conclusion/ Comment	GLP	Reference
			re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL <u>1.5 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL top oil/cream 0 mL re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL	re-dispersibility: initial: sediment < 0.5 after 30 min 0 mL sediment 0 mL top oil/cream 0 mL <u>1.5 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL top oil/cream 0 mL re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL			
	CIPAC MT 185 (Wet sieve)		Wet sieve test: Residue on a 75 µm sieve: < 0.01 %	Wet sieve test: Residue on a 75 µm sieve: < 0.01 %			
	CIPAC MT 187 (Particle size distribution)		≤ 10 % retained on a 0.5 µm sieve ≤ 50 % retained on a 1.1 µm sieve ≥ 90 % retained on a 2.8 µm sieve	≤ 10 % retained on a 0.7 µm sieve ≤ 50 % retained on a 1.6 µm sieve ≥ 90 % retained on a 4.5 µm sieve			

Study	Method	Test material	Results		Conclusion/ Comment	GLP	Reference
	CIPAC MT 148 (Pourability)		Residue: 2.22 % Rinsed residue:0.22 %	Residue: 2.97 % Rinsed residue:0.16 %			
Effect of low temperatures on stability			Stable for 7 d at 0 °C		acceptable	Y	Morgan (2013) (BVL no. 2630742)
			Before storage	After storage			
	CIPAC MT 191 (acidity or alkalinity)		3.34 % (calculated as H_2SO_4)	3.30 % (calculated as H_2SO_4)			
	CIPAC MT 180 (dispersion stability)		<u>0.375 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL top oil/cream 0 mL re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL <u>1.5 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL	<u>0.375 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment 0 mL top oil/cream 0 mL re-dispersibility: initial: sediment < 0.5 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL <u>1.5 % v/v in CIPAC water A and D</u> initial: sediment 0 mL top oil/cream 0 mL after 30 min sediment <0.05 mL			

Study	Method	Test material	Results		Conclusion/ Comment	GLP	Reference
			top oil/cream 0 mL re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL	top oil/cream 0 mL re-dispersibility: initial: sediment < 1 mL after 30 min 0 mL sediment 0 mL top oil/cream 0 mL			
	CIPAC MT 185 (Wet sieve)		Wet sieve test: Residue on a 75 µm sieve: < 0.01 %	Wet sieve test: Residue on a 75 µm sieve: < 0.01 %			
Shelf life following storage at ambient temperature			A 3 yr ambient shelf life study on BAS 830 01 H is ongoing, but could not be submitted at the time of dossier submission. The 2 yr interim report is completed and can be submitted on request of the authority.		A 2-year shelf life study is required.		
Shelf life in months (if less than 2 years)							
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 (SE).				

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.8.2 Persistent foaming (CP 2.8.2)						
Persistent foaming	CIPAC MT 47.2	BAS 830 01 H Batch: 451009	see B.2.7	acceptable	Y	Morgan (2013) (BVL no. 2630743)
B.2.8.3 Suspensibility, spontaneity and dispersion stability (CP 2.8.3)						
Suspensibility						
Spontaneity of dispersion						
Dispersion stability	CIPAC MT 180	BAS 830 01 H Batch: 451009	see B.2.7	acceptable	Y	Morgan (2013) (BVL no. 2630744)
B.2.8.4 Degree of dissolution and dilution stability (CP 2.8.4)						
Degree of dissolution			Not relevant as the preparation is a (SE).			
Dilution stability			Not relevant as the preparation is a (SE).			
B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability (CP 2.8.5)						
Particle size distribution	CIPAC MT 185	BAS 830 01 H Batch: 451009	Wet sieve test: Residue on a 75 µm sieve: < 0.01 %	acceptable	Y	Morgan (2013) (BVL no. 2630745)
	CIPAC MT 187		Size distribution of particles:			

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
			≤ 10 % retained on a 0.5 µm sieve ≤ 50 % retained on a 1.1 µm sieve ≥ 90 % retained on a 2.8 µm sieve			
Dust content			Not relevant as the preparation is a (SE).			
Attrition			Not relevant as the preparation is a (SE).			
Hardness and integrity			Not relevant as the preparation is a (SE).			
B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability (CP 2.8.6)						
Emulsifiability						
Re-emulsifiability						
Emulsion stability						
B.2.8.7 Flowability, pourability and dustability (CP 2.8.7)						
Flowability						
Pourability	CIPAC MT 148	BAS 830 01 H Batch: 451009	Residue: 2.22 % Rinsed residue: 0.22 %	acceptable	Y	Morgan (2013) (BVL no. 2630746)
Dustability following accelerated storage						

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
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	ASTM E1518-05	BAS 830 01 H Batch: 451003	Mixtures of BAS 830 01 H (in total eleven mixtures) with the plant protection products Butisan S, Focus Ultra, Dash, Teridox, Lontrel 100, Roundup, Effigo, Ikarus, Caramba, Carax, Devrinol, and Novall were tested. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping, no flocculation occurred. The mixtures appeared to be homogeneous. Therefore BAS 830 01 H is apparently physically compatible with the tested products.	acceptable	N	Reimann (2013) (BVL no. 2630748)
Chemical compatibility of tank mixes	ASTM E1518-05	BAS 830 01 H Batch: 451003	Dimethenamid-P and quinmerac, the active substances of BAS 830 01 H, are stable in diluted aqueous conditions. Therefore none of the functional groups are likely to react under normal tank mix conditions. Butisan S, Focus Ultra, Dash, Teridox, Lontrel 100, Roundup, Effigo, Ikarus, Caramba, Carax, Devrinol, and Novall are approved commercial product for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed. Therefore BAS 830 01 H is apparently chemically compatible with the tested products.	acceptable	N	Reimann (2013) (BVL no. 2630748)

Study	Method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.10 Adherence and distribution to seeds (CP 2.10)						
Distribution (seed treatment)			Not relevant as the preparation is a (SE).			
Adherence (seed treatment)			Not relevant as the preparation is a (SE).			
B.2.11 Other studies (CP 2.11)						
Other studies	RLA 11799	BAS 830 01 H Batch: 451009	<table><tr><td></td><td>Homogeneity</td></tr><tr><td>Initial</td><td>Completely homogenous</td></tr><tr><td>2 w 54 °C</td><td>Completely homogenous</td></tr></table>	No comment	Y	Morgan (2013) (BVL no. 2630749)

B.2.12 References relied on

Data Point EU as of 2014	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	Previously submitted Y/N If yes, old data point
KCP 2.1/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630722	N	Y	New data for AIR3 renewal	BASF	N III A 2.1
KCP 2.2/1	Achhammer G.	2014	Evaluation of physical and chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008) 2013/1123436 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. GLP, unpublished BVL no. 2630734	N	Y	New data for AIR3 renewal	BASF	N III A 2.2
KCP 2.2/2	Smeykal H.	2014	BAS 830 01 H - determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008) - Oxidising properties of liquids (EC A.21.) 2014/1031624 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. GLP, unpublished BVL no. 2630737	N	Y	New data for AIR3 renewal	BASF	N III A 2.2
KCP 2.3/1	Achhammer G.	2014	Evaluation of physical and chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008) 2013/1123436 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. GLP, unpublished BVL no. 2630738	N	Y	New data for AIR3 renewal	BASF	N III A 2.3

Data Point EU as of 2014	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	Previously submitted Y/N If yes, old data point
KCP 2.4/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630739	N	Y	New data for AIR3 renewal	BASF	N III A 2.4
KCP 2.5/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630740	N	Y	New data for AIR3 renewal	BASF	N III A 2.5
KCP 2.6/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630741	N	Y	New data for AIR3 renewal	BASF	N III A 2.6
KCP 2.7/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630742	N	Y	New data for AIR3 renewal	BASF	N III A 2.7
KCP 2.8.2/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630743	N	Y	New data for AIR3 renewal	BASF	N III A 2.8.2

Data Point EU as of 2014	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	Previously submitted Y/N If yes, old data point
KCP 2.8.3/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630744	N	Y	New data for AIR3 renewal	BASF	N III A 2.8.3
KCP 2.8.5.1/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630745	N	Y	New data for AIR3 renewal	BASF	N III A 2.8.6
KCP 2.8.7/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630746	N	Y	New data for AIR3 renewal	BASF	N III A 2.8.8
KCP 2.9/1	Reimann S.	2013	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 830 01 H 2013/1286244 BASF SE Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep. Not GLP, unpublished BVL no. 2630748	N	Y	New data for AIR3 renewal	BASF	N III A 2.9
KCP 2.11/1	Morgan L.	2013	Physical and chemical properties of BAS 830 01 H: Accelerated storage stability up to 2 weeks at 54 °C stored in a high-density polyethylene (HDPE) bottle 2013/1252863 Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom GLP, unpublished BVL no. 2630749	N	Y	New data for AIR3 renewal	BASF	N