European Commission

Addendum

VOLUME 3 – Annex B (A12115l)

Abamectin

B.2 Physical and chemical properties

Rapporteur Member State: The Netherlands

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

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B.2 Physical and chemical properties

B.2.1 B.2.1 Physical and chemical properties of the active stubstance

No new studies submitted. Not applicable for this application.

B.2.2 B.2.2 Physical and chemical properties of the plant protection product

In the table below, the physical and chemical properties of the representative product are summarised. The product is a suspension concentrate (SC) with the development code A12115I.

Based on the information in section B.3.4, the product is applied at 5L/ha, with 10000 – 20000L water/ha, which results in an in-use concentration of 0.05 – 0.1%v/v.

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Colour, odour and Physical state (IIIA 2.1)	Visual and organoleptic test	19 g/L abamectin SC (A12115I)	Colour: black/red Physical state: liquid Odour: no particular odour	**Acceptable**	Y	Kalt R. 2009
Explosive properties (IIIA 2.2.1)	EEC A.14	19 g/L abamectin SC (A12115I)	Not explosive.	**Acceptable** The product is not sensitive to heat, friction or shock. It is considered acceptable to use the outcome of the test to support that the product does not need to be classified as explosive under Regulation (EC) 1272/2008.	Y	Jackson W.A. 2009

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Oxidizing properties (IIIA 2.2.2)	EEC A.21	19 g/L abamectin SC (A12115I)	Not oxidising.	**Acceptable** Considering the product does not contain any component with the functional groups associated with oxidising behaviour, the conclusion that the product is not oxidising is sufficiently supported for classification according to Regulation (EC) 1272/2008 as well.	Y	Jackson W.A. 2009
Flash point (IIIA 2.3.1)	EEC A.9	19 g/L abamectin SC (A12115I)	Not detected below 102 ºC.	**Acceptable**	Y	Jackson W.A. 2009
Flammability (IIIA 2.3.2)			Not classified in terms of its flashpoint.			
Auto-flammability (IIIA 2.3.3)	EEC A.15	19 g/L abamectin SC (A12115I)	630 °C ± 15 ºC	**Acceptable**	Y	Jackson W.A. 2009
pH and pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.1)	CIPAC MT 75.3	19 g/L abamectin SC (A12115I)	pH of a 1% suspension in water: 7.5 pH undiluted: 7.8	**Acceptable** The measurements were performed at 25°C.	Y	Kalt R. 2009
Acidity or alkalinity and pH (IIIA 2.4.2)	CIPAC MT 191	19 g/L abamectin SC (A12115I)	0.16% (calculated as NaOH)	**Acceptable**	Y	Kalt R. 2009
Kinematic viscosity (IIIA 2.5.1)			Not relevant (formulation not intended for Ultra Low Volume (ULV) use)			
Dynamic viscosity (IIIA 2.5.2)	CIPAC MT 192	19 g/L abamectin SC (A12115I)	At 20°C: 436 - 106 mPa.s Shear rate range: 10 s^{-1} to 200 s^{-1} At 40°C : 336 - 70.0 mPa.s	**Acceptable** The viscosity indicates the product does not need to	Y	Kalt R. 2009

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
			Shear rate range: 10 s^{-1} to 200 s^{-1} A12115I is not a Newtonian liquid.	considered for classification as an aspiration hazard (H304).		
Surface tension (IIIA 2.5.3)	EEC A 5	19 g/L abamectin SC (A12115I)	σ = 35.4 mN/m 1.7 % w/w at 20 °C σ = 38.8 mN/m 0.2 % w/w at 20 °C σ = 40.9 mN/m 0.1 % w/w at 20 °C σ = 37.2 mN/m undiluted at 20 °C	**Acceptable** The surface tension should be determined at 25°C. Deviation is acceptable in this case considering the surface tension is not relevant to classification and labelling. The surface tension indicates the product is surface active.	Y	Kalt R. 2009
Relative density (IIIA 2.6.1)	OECD 109	19 g/L abamectin SC (A12115I)	At 20°C, the density is 1.198 g/cm^3	**Acceptable**	Y	Kalt R. 2009
Bulk or tap density (IIIA 2.6.2)			Not applicable, the formulation is a liquid.			
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46.3	19 g/L abamectin SC (A12115I)	The formulation is physically and chemically stable after storage for two weeks at 54°C in the following packaging materials: - High density polyethylene pack (HDPE) - Polyethylene terephthalate (PET)	**Acceptable**	N N	Kalt R. 2009a Kalt R. 2009b
			Summary Kalt R. 2009a (HDPE)			
				Initial	**After storage**	
			Active substance content	19.0 g/L	18.8 g/L	
			Appearance	Black red liquid with no particular odour	Black red liquid with no particular odour	

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings		Comments	GLP Y/N	Reference
			pH (1%, CIPAC MT75.3)	7.5	7.5		
			Density (OECD 109)	1.198 g/cm^3	1.199 g/cm^3		
			Wet sieve residue (CIPAC MT185)	< 0.01% residue on a 75µm sieve	< 0.01% residue on a 75µm sieve		
			Foam persistence (CIPAC MT47.2)	1.7% in CIPAC D: 0mL foam after 1 minute.	1.7% in CIPAC D: 0mL foam after 1 minute.		
			Pourability (CIPAC MT148)	Pour residue 1.9% Rinsed residue 0.2%	Pour residue 2.2% Rinsed residue 0.1%		
			Suspensibility (CIPAC MT184, assay)	1.7% in CIPAC D: 99% 0.2% in CIPAC D: 98%	1.7% in CIPAC D: 99% 0.2% in CIPAC D: 98%		
			Spontaneity of dispersion (CIPAC MT160, assay)	5% in CIPAC D water: 100%	5% in CIPAC D water: 97%		
			Packaging	-	No changes, weight loss 0.03%		
			Summary Kalt R. 2009b (PET)				
				Initial	**After storage**		
			Active substance content	19.0 g/L	18.8 g/L		
			Appearance	Black red liquid with no particular odour	Black red liquid with no particular odour		
			pH (1%, CIPAC MT75.3)	7.5	7.4		
			Density (OECD 109)	1.198 g/cm^3	1.200 g/cm^3		
			Wet sieve residue (CIPAC MT185)	< 0.01% residue on a 75µm sieve	< 0.01% residue on a 75µm sieve		
			Foam persistence (CIPAC MT47.2)	1.7% in CIPAC D: 0mL foam after 1 minute.	1.7% in CIPAC D: 0mL foam after 1 minute.		

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings		Comments	GLP Y/N	Reference
			Pourability (CIPAC MT148)	Pour residue 1.9% Rinsed residue 0.2%	Pour residue 2.2% Rinsed residue 0.1%		
			Suspensibility (CIPAC MT184, assay)	1.7% in CIPAC D: 99% 0.2% in CIPAC D: 98%	1.7% in CIPAC D: 99% 0.2% in CIPAC D: 99%		
			Spontaneity of dispersion (CIPAC MT160, assay)	5% in CIPAC D water: 100%	5% in CIPAC D water: 99%		
			Packaging	-	No changes, weight loss 0.42%		
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)			Not relevant as the formulation is stable at 54°C.				
Minimum content after heat stability testing (IIIA 2.7.3)			Not required as there is no decomposition.				
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3 CIPAC MT 185 CIPAC MT 184 CIPAC MT 160	19 g/L abamectin SC (A12115I)	After 7 days storage at 0°C: no trace of separation After 24 hours at room temperature after 1 inversion: no trace of separation Tests performed using the material from the low temperature stability storage: Wet sieve: less than 0.01 % was retained on a 75µm sieve Suspensibility (gravimetric assay) 99.0 % (1.7 % w/v in CIPAC water D at 30°C after 30 minutes) 104 % (0.2 % w/v in CIPAC water D at 30°C after 30 minutes) Spontaneity of dispersion (gravimetric assay) 100 % (5% v/v in CIPAC water D at 30°C		**Acceptable**	N	Kalt R. 2009c

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
			after 5 minutes)			
Ambient temperature shelf life (IIIA 2.7.5)	GIFAP Monograph 17	19 g/L abamectin SC (A12115I)	The formulation is physically and chemically stable after storage for two years at 25°C in the following packaging materials: - High density polyethylene pack (HDPE) - Polyethylene terephthalate (PET)	**Acceptable**	N N	Kalt R. 2011 Kalt R. 2011a
			Summary Kalt R. 2011 (HDPE)			

	Initial	**After storage**
Active substance content	19.0 g/L	19.1 g/L
Appearance	Black red liquid with no particular odour	Black red liquid with no particular odour
pH (CIPAC MT75.3, 1%)	7.5	7.4
Density (OECD 109)	1.198 g/cm^3	1.199 g/cm^3
Wet sieve residue (CIPAC MT185)	< 0.01% residue on a 75µm sieve	< 0.01% residue on a 75µm sieve
Foam persistence (CIPAC MT47.2)	1.7% in CIPAC D: 0mL foam after 1 minute.	1.7% in CIPAC D: 0mL foam after 1 minute.
Pourability (CIPAC MT148)	Pour residue 1.9% Rinsed residue 0.2%	Pour residue 2.2% Rinsed residue 0.1%
Suspensibility (CIPAC MT184, assay)	1.7% in CIPAC D: 99% 0.2% in CIPAC D: 98%	1.7% in CIPAC D: 100% 0.2% in CIPAC D: 99%
Spontaneity of dispersion (CIPAC MT160, assay)	5% in CIPAC D water: 100%	5% in CIPAC D water: 100%
Packaging	-	No changes, weight loss 0.04%
Summary Kalt R. 2011a (PET)		

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
			Initial / **After storage** Active substance content: 19.0 g/L / 19.4 g/L Appearance: Black red liquid with no particular odour / Black red liquid with no particular odour pH (CIPAC MT75.3, 1%): 7.5 / 7.4 Density (OECD 109): 1.198 g/cm^3 / 1.202 g/cm^3 Wet sieve residue (CIPAC MT185): < 0.01% residue on a 75µm sieve / < 0.01% residue on a 75µm sieve Foam persistence (CIPAC MT47.2): 1.7% in CIPAC D: 0mL foam after 1 minute. / 1.7% in CIPAC D: 0mL foam after 1 minute. Pourability (CIPAC MT148): Pour residue 1.9% Rinsed residue 0.2% / Pour residue 2.5% Rinsed residue 0.1% Suspensibility (CIPAC MT184, assay): 1.7% in CIPAC D: 99% 0.2% in CIPAC D: 98% / 1.7% in CIPAC D: 100% 0.2% in CIPAC D: 99% Spontaneity of dispersion (CIPAC MT160, assay): 5% in CIPAC D water: 100% / 5% in CIPAC D water: 100% Packaging: - / No changes, weight loss 0.04%			
Shelf life in months (if less than 2 years) (IIIA 2.7.6)			Not relevant			
Wettability (IIIA 2.8.1)			Not applicable, the formulation is a liquid.			
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	19 g/L abamectin SC (A12115I)	Concentration 1.7 % w/v in CIPAC water D: after 10 sec 6 ml	**Acceptable** The tested concentration well exceeds the highest	N	Kalt R. 2009c

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
			after 1 min 0 ml after 3 min 0 ml after 12 min 0 ml	in-use concentration (0.1%v/v) and is therefore considered acceptable.		
Suspensibility (IIIA 2.8.3.1)	CIPAC MT 184	19 g/L abamectin SC (A12115I)	Gravimetric assay 99 % (1.7% w/v in CIPAC D at 30°C after 30 minutes) 102 % (0.2% w/v in CIPAC D at 30°C after 30 minutes) Chemical assay 99 % of abamectin (1.7% w/v in CIPAC D at 30°C after 30 minutes) 98 % of abamectin (0.2% w/v in CIPAC D at 30°C after 30 minutes)	**Acceptable** The highest in-use concentration is 0.1%, but CIPAC MT184 specifically states that if the in-use concentration is lower than 0.2%, the test should be performed at 0.2%.	N	Kalt R. 2009c
Spontaneity of dispersion (IIIA 2.8.3.2)	CIPAC MT 160	19 g/L abamectin SC (A12115I)	Gravimetric assay 100 % (5% v/v in CIPAC D at 30°C after 5 minutes) Chemical assay 100 % of abamectin (5% v/v in CIPAC D at 30°C after 5 minutes)	**Acceptable**	N	Kalt R. 2009c
Dilution stability (IIIA 2.8.4)			Not applicable (preparation is not water soluble).			
Dry sieve test (IIIA 2.8.5.1)			Not applicable, the formulation is a liquid.			
Wet sieve test (IIIA 2.8.5.2)	CIPAC MT 185	19 g/L abamectin SC (A12115I)	0.01 % was retained on a 75µm sieve	**Acceptable**	N	Kalt R. 2009c
Particle size distribution (IIIA 2.8.6.1)	CIPAC MT 187 (laser diffraction)	19 g/L abamectin SC (A12115I)	The three characteristics values of the cumulative undersize volume distribution were determined: d10 : 10 % of particles < 0.73 µm d50 : 50 % of particles < 1.65 µm d90 : 90 % of particles < 3.41 µm	**Acceptable**	Y	Kalt R. 2009
Nominal size range of granules			Not applicable, the formulation is a liquid.			

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
(IIIA 2.8.6.2)						
Dust content (IIIA 2.8.6.3)			See IIIA 2.8.6.2			
Particle size of dust (IIIA 2.8.6.4)			See IIIA 2.8.6.2			
Friability and attrition (IIIA 2.8.6.5)			See IIIA 2.8.6.2			
Emulsifiability (IIIA 2.8.7.1)			Not relevant, the formulation is not an emulsion.			
Emulsion stability (IIIA 2.8.7.2)			See 2.8.7.1			
Re-emulsifiability (IIIA 2.8.7.3)			See 2.8.7.1			
Stability of dilute emulsions (IIIA 2.8.7.4)			See 2.8.7.1			
Stability of emulsions (IIIA 2.8.7.5)			Not relevant, not an EW formulation			
Flowability (IIIA 2.8.8.1)			Not applicable, the formulation is a liquid.			
Pourability (including rinsed residue) (IIIA 2.8.8.2)	CIPAC MT 148	19 g/L abamectin SC (A12115I)	Pour residue: 1.9 % Rinse residue: 0.2 %	**Acceptable**	N	Kalt R. 2009c
Dustability following accelerated storage (IIIA 2.8.8.3)			Not applicable, the formulation is a liquid.			
Physical compatibility of tank mixes (IIIA 2.9.1)			Information will be provided separately if the commercial need for specific, mandatory tank mixing is confirmed.			
Chemical compatibility of tank mixes (IIIA 2.9.2)			Information will be provided separately if the commercial need for specific, mandatory tank mixing is confirmed.			
Adhesion to seeds			Not applicable as not a seed treatment.			

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
(IIIA 2.10.1)						
Distribution to seed (IIIA 2.10.2)			Not applicable as not a seed treatment.			
Miscibility (IIIA 2.11)	ABNT-Norm NBR 13240	19 g/L abamectin SC (A12115I)	1.7 % in CIPAC water A at 30 °C Test results : Appearance after 1 hour: black red homogeneous liquid Due to the appearance after 1 hour, the test sample was assessed to be miscible. 1.7 % in methanol at 30 °C Test results : Appearance after 1 hour: black red liquid with solid separation Due to the appearance after 1 hour, the test sample was assessed to be not miscible. 1.7 % in toluene at 30 °C Test results : Appearance after 1 hour: colorless liquid with pearl like separation Due to the appearance after 1 hour, the test sample was assessed to be not miscible.	This study is not an EC data requirement. Therefore, the RMS has not evaluated this study in detail.	Y	Kalt R. 2009
Dielectric breakdown (IIIA 2.12)			This is not an EC data requirement.			
Corrosion characteristics (IIIA 2.13)	ASTM G 31-72 (2004)	19 g/L abamectin SC (A12115I)	tin plate: corrosion, corrosion rate: 0.20 g/m^2h galvanized sheet metal: corrosion, corrosion rate: 0.50 g/m^2h sheet steel: corrosion, corrosion rate: 0.34 g/m^2h	This study is not an EC data requirement. Therefore, the RMS has not evaluated this study in detail.	Y	Kalt R. 2009

Test or study & Annex point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
			stainless steel: no corrosion			
Container material (IIIA 2.14)			This is not an EC data requirement.			
Other/special studies (IIIA 2.15)			This is not an EC data requirement.			

B.2.3 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	Owner
KIIIA1 2.1 / 01 & KIIIA1 2.4.1 / 01 & KIIIA1 2.4.2 / 01 & KIIIA1 2.5.2 / 01 & KIIIA1 2.5.3 / 01 & KIIIA1 2.6.1 / 01 & KIIIA1 2.8.6.1 / 01	Kalt R.	2009	A12115I - Physical properties of batch SMU9EP004 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120109 GLP, not published Syngenta File No A12115I_10005	N	Y	SYN
KIIIA1 2.2.1 / 01 & KIIIA1 2.2.2 / 01 & KIIIA1 2.3.1 / 01 & KIIIA1 2.3.3 / 01	Jackson W.	2009	A12115I - Physical and chemical properties Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT09/241 GLP, not published Syngenta File No A12115I_10013	N	Y	SYN
KIIIA1 2.7.1 / 01	Kalt R.	2009a	A12115I - Storage stability and shelf life statement (2 weeks 54°C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Not GLP, not published Syngenta File No A12115I_10009	N	N	SYN
KIIIA1 2.7.1 / 02	Kalt R.	2009b	A12115I - Storage stability and shelf life statement (2 weeks 54°C) in packaging made of PET Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Not GLP, not published Syngenta File No A12115I_10010	N	N	SYN
KIIIA1 2.7.4 / 01 & KIIIA1 2.8.2 / 01 & KIIIA1 2.8.3.1 / 01 & KIIIA1 2.8.3.2 / 01 &	Kalt R.	2009c	A12115I - Technical properties of batch SMU9EP004 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120251 Not GLP, not published Syngenta File No A12115I_10004	N	N	SYN

KIIIA1 2.8.5.2 / 01 & KIIIA1 2.8.8.2 / 01						
KIIIA1 2.7.5 / 01 & KIIIA1 4.1.3 / 01	Kalt R.	2011	A12115I - Storage stability and shelf life statement (2 years 25°C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10478696 Not GLP, not published Syngenta File No A12115I_10039	N	N	SYN
KIIIA1 2.7.5 / 02 & KIIIA1 4.1.3 / 02	Kalt R.	2011a	A12115I - Storage stability and shelf life statement (2 years 25°C) in packaging made of PET Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10478743 Not GLP, not published Syngenta File No A12115I_10040	N	N	SYN
KIIIA1 3.3.1 / 01	Briswalter C.	2011	A12115I GAP Syngenta Crop Protection AG, Basel, Switzerland, Not GLP, not published Syngenta File No A12115I_10042	N	N	SYN