European Commission

Addendum

VOLUME 3 – Annex B (A12115l)

Abamectin

B.5 Methods of analysis

Rapporteur Member State: The Netherlands

April 2015

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

Version history page

Date	Version history
April 2015	Initial version

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B.5 Methods of analysis

B.5.1 Methods used for the generation of pre-authorisation data

B.5.1.1 Analysis of the plant protection product

Study 1 Determination of MK936 in A12115I
IIIA 5.2.1/01, Dos Santos Alves A.M. (2009)

Method

The method SF-328/1 is based on the analysis of avermectin B1a and avermectin B1b by HPLC-UV with external standardisation.

Weigh 1125 – 1375 mg product in a 50mL volumetric flask. Add 25mL solvent (methanol) and sonicate for about 5 minutes, then make up to volume with solvent.

Conditions

Chromatograph	Merck Hitachi L7100		
Detector	Merck Hitachi UV Detector L7400		
Column	Inertsil C8 (5µm), 250mm, 4.6mm i.d.		
Column temperature	Room temperature		
Sample size	10µl of reference/test solution		
Flow	1.5 mL/minute		
Duration	approx. 29 min		
Gradient	t (min)	methanol [%]	0.1% aqueous phosphoric acid [%]
	0	65	35
	20	90	10
	21	100	0
	25	100	0
	25.1	65	35
	29	65	35

Specificity

See study 2. IIIA 5.2.1/01 does not contain validation data.

Linearity

See study 2. IIIA 5.2.1/01 does not contain validation data.

Accuracy

See study 2. IIIA 5.2.1/01 does not contain validation data.

Precision

See study 2. IIIA 5.2.1/01 does not contain validation data.

Conclusion

The study contains a description of the proposed method only. See study 2 for validation data.

Study 2 Validation of analytical method SF-328/1
IIIA 5.2.1/02, Heintz K. (2009)

Method

See study 1.

Conditions

See study 1.

Specificity

No interference based on representative chromatograms (standard, blank formulation and spiked formulation).

Linearity

Avermectin B1a	r = 0.99999	Y = 1.000X + 2.570
Avermectin B1b	r = 0.99993	Y = 1.047X + 0.005

Accuracy

The accuracy was determined at 3 three levels with 2 determinations each (75% - 125% declared content).

Avermectin B1a	100.6%
Avermectin B1b	104.7%

Precision

Precision was determined with 10 injections of formulation.

	Mean (%w/w)	Precision (%RSD)
Avermectin B1a	1.57	0.510
Avermectin B1b	0.03	0.000

Conclusion

The method SF-328/1 was successfully validated for determination of the abamectin content in the representative formulation (A12115I).

B.5.2 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 5.2.1 / 01	Dos Santos Alves A.	2009	Determination of MK936 in A12115I Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, SF-328/1 Not GLP, not published Syngenta File No A12115I_10017	N	N	SYN

KIIIA1 5.2.1 / 02	Heintz K.	2009	A12115I - Validation of analytical method SF-328/1 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120106 GLP, not published Syngenta File No A12115I_10018	N	Y	SYN