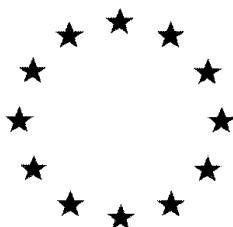


# **European Commission**



**Addendum**  
**VOLUME 3 – Annex B (A12115I)**

**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

**TABLE OF CONTENTS – VOLUME 3 B.1-B.5**

B.5	Methods of analysis.....	4
B.5.1	Methods used for the generation of pre-authorisation data.....	4
B.5.2	References relied on .....	5

## **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
----------------------	-----------	------	---	---	---	-----