Document Title

Tier 2 Summary of the Methods of Analysis of the Plant Protection Product for

Sivanto (Flupyradifurone, BYI 2960) SL 200

Specification number

102000021884

Data Requirements

Regulation (EC) No 1107/2009

Regulatory Directive 2003-01/Canada/PMRA
OPPTS guidelines/US/EPA

Annex IIIA
Section 2, Point 5
Document M

According to OECD format guidance for industry data submissions on plant protection products and their active substances

Date

2012-04-13

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OWNERSHIP STATEMENT

TABLE OF CONTENTS

IIIA1 5 Methods of Analysis of the Plant Protection Product

IIIA1 5.1 Analytic standards and samples

IIIA1 5.1.1 Samples of the preparation

Samples will be provided on request

IIIA1 5.1.2 Analytical standards for pure active substance

Samples will be provided on request

IIIA1 5.1.3 Samples of the active substance as manufactured

Samples will be provided on request

IIIA1 5.1.4 Analytical standards for relevant metabolites included DoR

Not relevant

IIIA1 5.1.5 Samples of reference substances for relevant impurities

Not relevant

IIIA1 5.2 Methods for the analysis of plant protection products

IIIA1 5.2.1 Analytical methods for the determination of the a.s. in product

Report:	**KIIIA1 5.2.1/01, Zitzmann, W.; 2009; M-343224-01-1**
Title:	Determination of BYI 02960 in formulations Assay HPLC, external standard
Report No & Document No	AM012609MF1 M-343224-01-1
Guidelines:	
GLP	Non GLP

The HPLC method AM012609MF1 is applicable for the determination of the content of Flupyradifurone (BYI 2960) in formulations (*e.g.* 'Flupyradifurone (BYI 2960) SL 200').

Principle of the method: The active substance (BYI 02960) is separated from formulation constituents by reversed phase chromatography using isocratic elution. After UV detection (280 nm), the quantitative evaluation is carried out by comparing the peak areas with those of reference substances, using an external standard of BYI 02960.

Report:	**KIIIA1 5.2.1/02, Kienow, A; Seidel, E; 2010, M-395374-01-1**
Title:	Validation of HPLC-method AM012609MF1 Determination of BYI 02960 in formulations BYI 02960 SL 200 (200 g/L)
Report No & Document No	VB2-AM012609MF1 M-395374-01-1
Dates of work	2009-06-25
GLP	Non GLP

The HPLC method **AM012609MF1** has been completely validated on the formulation Flupyradifurone (BYI 2960) SL 200, specification number 102000021884, by checking the parameters linearity, precision, accuracy, specificity and interference from excipients.

Linearity	6 concentrations with single injections; range 50 -150%; correlation co-efficient $r_{K:}$ 0.9999; regression equation: y = 73.3404x + 21.4446 Chromatograms are given; the function is linear in the operating range.
Precision	6 samples from one batch; single injection; no outliers; acceptable according to the Horwitz equation; relative standard deviation RSD: 0.31%.
Accuracy	6 samples of laboratory-prepared synthetic formulation; mean recovery: 100.3%, confidence interval of recovery: 100.28 $\pm$ 0.98 the method shows no constant or proportional systematic error.
Specificity	The UV-spectra of active substance and reference substance show no spectral difference; the retention times of active substance and reference substance are identical.
Interference	No interferences are found.

The HPLC method **AM012609MF1**for the determination of Flupyradifurone (BYI 2960) in the formulation Flupyradifurone (BYI 2960) SL 200, specification number 102000021884 is found to be valid.

IIIA1 5.2.2 Suitable method for preparations containing more than 1 a.s.

The preparation 'Flupyradifurone (BYI 2960) SL 200 (200 g/L)' does not contain more than 1 a.s.

IIIA1 5.2.3 Applicability of existing CIPAC methods

Flupyradifurone is a new active ingredient. A CIPAC method for the determination of Flupyradifurone in formulations is not yet available

IIIA1 5.2.4 Analytical methods for relevant impurities in the preparation

The preparation 'Flupyradifurone (BYI 2960) SL 200 (200 g/L)' does not contain relevant impurities formed during manufacturing or storage of the product.

IIIA1 5.2.5 Analytical methods for formulants or their constituents in the product

With respect to toxicological, ecotoxicological or environmental aspects the preparation 'Flupyradifurone (BYI 2960) SL 200 (200 g/L)' does not contain formulants in relevant concentrations. Therefore a special analytical method and validation is not needed.

IIIA1 5.3 Analytical methods for residues, stability of working solutions

IIIA1 5.3.1 Description of analytical methods for the determination of residues

Please refer to KIIA 4.3.

IIIA1 5.3.2 Storage stability of working solutions

Please refer to KIIA 6.1.2.

IIIA1 5.4 Description of methods for analysis of soil (parent and metabolites)

Please refer to KIIA 4.4.

IIIA1 5.5 Description of methods for analysis of sediment

Please refer to KIIA 4.6.

IIIA1 5.6 Description of methods for analysis of water (parent and metabolites)

Please refer to KIIA 4.5.

IIIA1 5.7 Description of methods for analysis of air (parent and metabolites)

Please refer to KIIA 4.7.

IIIA1 5.8 Methods for analysis of body fluid/tissues (parent and metabolites)

Please refer to KIIA 4.8.

IIIA1 5.9 Other/special studies

Please refer to KIIA 4.9.