European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

24-EPIBRASSINOLIDE

Volume 3 – B.5 (PPP) – Sunergist

Rapporteur Member State: Austria

Version History

When	What
2018/05	Initial DAR

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B.5. METHODS OF ANALYSIS

B.5.1. METHODS USED FOR THE GENERATION OF PRE-AUTHORISATION DATA

No risk assessment methods for the product Sunergist were evaluated. Methods for post-approval control and monitoring purposes

B.5.2. METHODS FOR POST-APPROVAL CONTROL AND MONITORING PURPOSES

B.5.2.1. Analysis of the plant protection product (CP 5.1.1)

B.5.2.1.1. Method for the determination of Active substance in the preparation

An analytical method has been developed for the determination of 24-Epibrassinolide in the preparation.

Reference:	**KCP 5.1.1/01, Validation of analytical methodology for the assay of active ingredient of Epibrassinolide 0.01% SL**
Author(s), year:	Gao J. (2016)
Report/Doc. number:	NC-2015-044
Guideline(s):	SANCO/3030/99, rev.4.
GLP:	yes

Material and methods:

Test material:

Sunergist

Analytes:

24-Epibrassinolide

Principle of the method:

Active substance content is determined after dissolving the test item in Methanol and derivatization by adding Phenyboronic acid. The separation is achieved using HPLC with UV detection (at 220 nm).

HPLC Conditions: Agilent ZORBAX Eclipse XDB-C18 150 x 4.6 mm, 5 µm i.d., Acetonitrile, water 78/22; static mode

Findings:

- Specificity: The specificity of the analytical method was verified by checking the retention time of the active substance. It was separated from the co-formulants. No interference was detected.
- Calibration (Linearity): The linearity was checked with solutions of different concentrations (6 different concentrations). The results were found to be linear.
- Accuracy (Recovery): Samples were spiked with different amounts of active substance (see Table 5.2.1-1). 3 samples of each Fortification level were analysed. All results were within the recommended range of 90-110 %.
- Precision (Repeatability): 6 samples of Sunergist were analysed for the active substance content. The RSD is inside the recommended values (modified Horwitz values RSD_r).

Validation Data are available in Table 5.2.1-1

Conclusion:

The method is acceptable and allows the determination of 24-Epibrassinolide in the formulation Sunergist.

B.5.2.1.2. Methods for the determination of degradation products in the preparation

There is no decrease of the content in the active substance in the preparation after storage. Therefore an analytical method and validation is not needed.

B.5.2.1.3. Methods for the determination of relevant impurities identified in the technical material or which may be formed during manufacture of the preparation or from degradation of the preparation during storage

Methods are not required for impurities as no toxicologically, ecotoxicologically or environmentally relevant impurities will be formed in the technical material, or during manufacture of the plant protection product or from degradation of the plant protection product during storage.

B.5.2.1.4. Methods for the determination of relevant co-formulants or components of co-formulants, where required by the national competent authorities.

With respect to toxicological, eco-toxicological or environmental aspects the product does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

B.5.2.1.5. Applicability of existing CIPAC methods

A CIPAC method is not available for 24-Epibrassinolide formulated as a soluble liquid.

Table 5.2.1-1: Validation data for the determination of active substance in Sunergist

Reference	Analyte	Accuracy			Precision			Calibration	Specificity /Interference
		Fortification lvl [%w/w]	mean recovery [%]	n	RSD [%]	RSD_r [%] (Horwitz)	n		
Gao (2016)	24-Epibrassinolide	0.005 0.010 0.015	103 102 98	3 3 3	0.85	5.30	6	0.005 – 0.015 %w/w (49-148 %) n=6, R > 0.99	No interfering peaks.

B.5.3. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny 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	Previous evaluation
KCP 5.1.1/01	Gao, J.	2016	VALIDATION OF ANALYTICAL METHODOLOGY FOR THE ASSAY OF ACTIVE INGREDIENT OF EPIBRASSINOLIDE 0.01 % SL Report No.: NC-2015-044 (421-001) Nutrichem Laboratory Co., Ltd., Beijing, China GLP, unpublished	N	Y	New study necessary for the approval of 24-Epibrassinolide	Suntton GmbH	N