

Renewal Assessment Report

beta-cyfluthrin

Bulldock EC 25

Volume 3 – B.5 Methods of analysis

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Rapporteur Member State: Germany

Co-Rapporteur Member State: Hungary

Version history

When	What

Table of contents

B.5	Methods of analysis.....	4
B.5.1	Methods used for the generation of pre-authorisation data	4
B.5.1.1	Analysis of the plant protection product.....	4
B.5.1.1.1	Methods for the determination of the active substance in the plant protection product	4
B.5.1.1.2	Methods for the determination of relevant impurities and formulants in the plant protection product	4
B.5.1.2	Methods for the determination of residues	5
B.5.2	Methods for post-authorisation control and monitoring purposes	5
B.5.3	References relied on.....	6

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

B.5.1.1.1 Methods for the determination of the active substance in the plant protection product

Reference:

Ricau (2012), Validation of the analytical method for the determination of beta-cyfluthrin in BULLDOCK 25 EC, report no 12-909007-011, IVP (BVL no 2633419)

Principle of the method:

After homogenisation, the technical material is dissolved in 1,4-dioxane and the volume was made up with n-heptane. Beta-cyfluthrin is determined by reverse phase high performance liquid chromatography (HPLC) on basis of the CIPAC method 482/EC/M/3. Quantification is made by comparison of the peak area with an external standard.

Column: Supelco LC-Si, 25 cm x 4.6 mm, 5.0 µm
Mobile phase: n-heptane/TBME 975/25 v/v
Detector wavelength: 235 nm

Findings:

Table B.5.1-1: Validation data for the determination of beta-cyfluthrin in the plant pro

	Specificity/ interferences	Linearity (R ²)	Accuracy (n = 4)		Repeatability (% RSD) (n = 5)
			fortification level (%)	mean recovery (%)	
Beta-cyfluthrin (HPLC)	demonstrated; no interferences	0.9997 (402 mg/L - 1209 mg/L)	2.86	100.5	1.2 (mean content 2.6 %)

The specificity of the method was demonstrated by retention time match with reference standard.

Conclusion:

The method is acceptably validated and allows the determination of beta-cyfluthrin in the plant protection product.

CIPAC method:

CIPAC method [482/EC/M/-] is suitable for the determination of beta-cyfluthrin in EC formulations.

B.5.1.1.2 Methods for the determination of relevant impurities and formulants in the plant protection product

The preparation Bulldock 25 EC does not contain relevant impurities formed during manufacturing or storage of the product of toxicological, ecotoxicological or environmental significance. Therefore, no

methods are presented.

There are no co-formulants of toxicological, ecotoxicological or environmental concern used in the preparation. Therefore, no further analytical method is provided.

B.5.1.2 Methods for the determination of residues

Concerning physical and chemical properties tests please refer to B.5.1.1.1

The need and suitability of analytical methods for the determination of residues is discussed in Vol. 3 CA, B.5.1.2 of the active substance dossier. All methods have been included in the active substance dossier.

B.5.2 Methods for post-authorisation control and monitoring purposes

Concerning analytical methods for the determination of the active substance in the formulation, reference is made to B.5.1.1.

The need and suitability of analytical methods for post-authorisation control and monitoring purposes is discussed in Vol. 3 CA, B.5.2 of the active substance dossier. All methods have been included in the active substance dossier.

B.5.3 References relied on

Annex point/ reference number	Author(s)	Year	Title Report No. Source (where different from company) GLP status (where relevant) published or not BVL registration number	Vertebrate study	Data protection claimed	Justification	Owner
KCP 5.1.1/01	Ricau, H.	2012	Validation of the analytical method for the determination of beta-cyfluthrin in Bulldock 25 EC Report No.: 12-909007-011 Edition No: R-30587 Defitraces, 69126 Brindas, France GLP not published 2633419	N	Y	new method has been developed and validated	IRV

IRV = Irvita Plant Protection, Curacao – a member of Makhteshim Agan Holding B.V., The Netherlands