

# **Renewal Assessment Report**

**beta-cyfluthrin**

**Montur Forte FS 230**

**Volume 3 – B.5 Methods of analysis**

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**Rapporteur Member State: Germany**

**Co-Rapporteur Member State: Hungary**

## Version history

When	What

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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

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

###### Reference:

Zitzmann (2006), Determination of Imidacloprid and Beta-Cyfluthrin in formulations - Assay - HPLC, external standard, report no AM008706MF1, BAY (BVL no 2633238)

Kienow, Seidel (2010), Validation of HPLC-method AM008706MF1 - Determination of beta-cyfluthrin and imidacloprid in formulations - beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L), report no VB4-AM008706MF1, BAY (BVL no 2633239)

Michel (2014), Statement for analytical method - Applicability of CIPAC Method 482 - Determination of Beta-Cyfluthrin in FS-Formulations, report no M-480760-01-1, BAY (BVL no 2633240)

###### Principle of the method AM008706MF1:

After homogenisation, the technical material is dissolved in acetonitrile. Beta-cyfluthrin and imidacloprid are determined by reverse phase high performance liquid chromatography (HPLC). Quantification is made by comparison of the peak area with an external standard.

Column: XBridge-Phenyl, 50 mm x 4.6 mm, 2.5 µm  
Mobile phase: 0.5 % sulphuric acid in water/ acetonitrile (gradient)  
Detector wavelength: 245 nm

###### Findings:

**Table B.5.1-1: Validation data for the determination of beta-cyfluthrin and imidacloprid in the plant protection product**

	Specificity/ interferences	Linearity (R <sup>2</sup> )	Accuracy (n = 6) mean recovery (%)	Repeatability (% RSD) (n = 5)
Beta-cyfluthrin (HPLC)	demonstrated; no interferences	0.99998 (77.1 mg/L – 226 mg/L)	100.2	0.28 (mean content 7.0 %)
Imidacloprid (HPLC)	demonstrated; no interferences	0.99997 (138 mg/L – 410 mg/L)	100.2	0.39 (mean content 13.1 %)

The specificity of the method was demonstrated by retention time match and by comparison of the UV-spectra with reference standard. The accuracy was determined with six different concentrations and statistical assessment of the recovery results.

###### Conclusion:

The method is acceptably validated and allows the determination of beta-cyfluthrin and imidacloprid in the formulation 'CYB+IMD FS 230 (80+150) G'

###### CIPAC method:

No CIPAC method is available for the determination of beta-cyfluthrin in FS formulations. However,

it was demonstrated by chromatograms that CIPAC method [482/EC/M/-] is applicable for the determination of beta-cyfluthrin in the formulation 'CYB+IMD FS 230 (80+150) G'.

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

The preparation 'CYB+IMD FS 230 (80+150) G' does not contain any relevant impurities formed during manufacturing or storage of the product.

With respect to toxicological, ecotoxicological or environmental aspects the preparation 'CYB+IMD FS 230 (80+150) G' does not contain any relevant formulants. Therefore, a special analytical method and validation are not needed.

#### **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 Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 /01	Zitzmann, W.	2006	Determination of Imidacloprid and beta-cyfluthrin in formulations ; assay - HPLC, external standard Bayer CropScience, Report No.: AM008706MF1, Edition Number: M-278633-01-2 Date: 2006-10-11 GLP/GEP: no, unpublished 2633238	N	N		Bayer CropScience
KCP 5.1.1 /02	Kienow, A. ; Seidel, E.	2010	Validation of HPLC-method AM008706MF1 - Determination of beta-cyfluthrin and imidacloprid in formulations - beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) Bayer CropScience, Report No.: VB4-AM008706MF1, Edition Number: M-395934-01-1 Date: 2010-11-25 GLP/GEP: no, unpublished 2633239	N	N		Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies  
Black Studies indicate Supplementary Dossier Studies

<b>Annex point / reference num- ber</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Source</b> <i>(where different from company)</i> <b>Company name, Report No., Date, GLP status</b> <i>(where</i> <i>relevant)</i> , <b>published or not</b> <b>BVL registration number</b>	<b>Verte- brate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.1.1 /03	Michel, A.	2014	Statement for analytical method - Applicability of CI- PAC Method 482 - Determination of beta-cyfluthrin in FS-Formulations Bayer CropScience, Report No.: M-480760-01-1, Edition Number: M-480760-01-1 Date: 2014-03-21 GLP/GEP: no, unpublished 2633240	N	N		Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies  
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