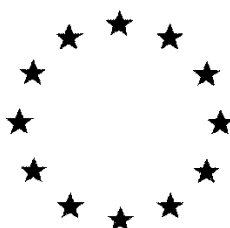


# ***European Commission***



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

**TRITICONAZOLE**

**Volume 3 – B.5 (PPP) – Premis 25 FS**

Rapporteur Member State: Austria  
Co-Rapporteur Member State: United Kingdom

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### Version History

When	What
2003/September	Initial DAR, first version
2018/July	DRAR

## Table of contents

<b>B.5. METHODS OF ANALYSIS.....</b>	<b>4</b>
<b>B.5.1. METHODS USED FOR THE GENERATION OF PRE-AUTHORISATION DATA.....</b>	<b>4</b>
B.5.1.1. Analysis of the plant protection product .....	4
B.5.1.2. Methods for the determination of residues.....	4
<b>B.5.2. METHODS FOR POST-APPROVAL CONTROL AND MONITORING PURPOSES .....</b>	<b>5</b>
<b>B.5.3. REFERENCES RELIED ON.....</b>	<b>6</b>

## B.5. METHODS OF ANALYSIS

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

Premis 25 FS, BAS 595 01 F (former code EXP 80472 B (FS)) is used for the active substance triticonazole.

#### B.5.1.1. Analysis of the plant protection product

##### B.5.1.1.1. Active substance

The method T-864-01-01 (determination of the active substance content by reversed phase HPLC with U.V. detection in formulation BAS 595 01 F (formerly EXP80472B (FS)) was submitted and peer-reviewed in the Annex I Registration process and is still valid. The method is reported here for completeness.

<b>Reference:</b>	<b>Determination of the active substance content by reversed phase HPLC with U.V. detection in formulation EXP80472B (FS) T-864-01-01</b>
Author(s), year:	Le Gren, 2001
Report/Doc. number:	C011474
Guideline(s):	--
GLP:	Yes

##### Principle of the method:

Active ingredient is extracted from the formulation using a mixture of Milli Q water and methanol (10/90), then analysed by isocratic reversed phase HPLC with UV detection at 280 nm. Eluent: acetonitrile/water (60/40); column: Nucleosil 100-5 C18 5µm, 125 x 3 mm.

##### Validation:

Matrix	Analyte	Specificity	Linearity	Accuracy	Precision
Formulation EXP80472B (FS) (Premis 25 FS)	Triticonazole	No interferences	Range (g/L): 0.06 to 0.6 $r^2 = 0.999$	Analysis of 6 independent solutions of triticonazole analytical standard: average recovery: 99.0 % RSD = 1.5 %	Analysis of 6 independent preparations of the formulation: RSD = 0.4 %

##### B.5.1.1.2. Relevant impurities

An analytical method has been developed for the determination of the impurity methanol in the formulation BAS 595 01 F containing triticonazole.

<b>Reference:</b>	<b>Analytical method AFL0939/01 - Determination of Methanol in BAS 595 01 F by means of headspace GC</b>
Author(s), year:	Bacher R., 2016 a
Report/Doc. number:	2016/1222103
Guideline(s):	-
GLP:	no

<b>Reference:</b>	<b>Validation of an analytical method for the determination of Methanol in BAS 595 01 F by means of GC</b>
Author(s), year:	Bacher R., 2016 b
Report/Doc. number:	2016/1222104
Guideline(s):	SANCO/3030/99, EPA 830.1800
GLP:	yes

**Principle of the method**

The method is based on headspace gas chromatography on a medium polar trifluoropropylmethylpolysiloxane GC column (RTx-200, 60 m x 0.32 mm ID, 1.5 µm film) and FID detection. Quantification of methanol was carried out on the basis of peak areas ratios applying the internal standard ethanol and using linear regression calculation. GC/MS was used as confirmatory method to demonstrate the identity of the analyte and to test the specificity of the method.

**Validation**

Analyte	Specificity	Linearity	Assay Accuracy from standard addition experiments	Assay Precision from standard addition experiments (% RSDr according to Horwitz)	LOQ
Methanol fortified to blank formulation	No interferences were observed	Range (mg/L): 7.5 to 1000 (n = 8)	level 75 mg/kg (n = 5): 80% level 750 mg/kg (n = 5): 89%	level 75 mg/kg (n = 5): 1.67% (5.60) level 750 mg/kg (n = 5): 1.72% (3.96)	75 mg/kg
Methanol fortified to BAS 595 01 F			level 75 mg/kg (n = 5): 83% level 750 mg/kg (n = 5): 87%	level 75 mg/kg (n = 5): 1.63% (5.60) level 750 mg/kg (n = 5): 1.36% (3.96)	

**Conclusion**

The method for the determination of methanol in formulation BAS 595 01 F is acceptable.

**B.5.1.2. Methods for the determination of residues**

Please refer to Triticonazole\_DRAR\_07\_Volume\_3CA\_B-5.

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

Please refer to Triticonazole\_DRAR\_07\_Volume\_3CA\_B-5.

**B.5.3. REFERENCES RELIED ON**

Data point(s) EU as of 2014)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Vertebrate study	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N  If yes, old Data point
KCP 5.1.1	Le Gren I.	2001a	Triticonazole - Determination by HPLC analysis in formulation EXP80472B (FS) Aventis CropScience; Lyon; France C011747 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 5.1.1	Le Gren I.	2001a	Triticonazole - Determination by HPLC analysis in formulation EXP80472B (FS) Aventis CropScience; Lyon; France C011747 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 5.1.1/1	Bacher R.	2016 a	Analytical method AFL0939/01 - Determination of Methanol in BAS 595 01 F by means of headspace GC 2016/1222103 EAG Laboratories PTRL Europe, Ulm, Germany Fed.Rep. no Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 5.1.1/2	Bacher R.	2016 b	Validation of an analytical method for the determination of Methanol in BAS 595 01 F by means of GC 2016/1222104 EAG Laboratories PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	New data for AIR3 renewal	BASF	No