

European Commission



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

Metconazole

Volume 3 – B.1 (PPP) – BAS 555 01 F

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

Version History

When	What
January 2004	Initial DAR Draft Assessment Report (DAR) – prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC. Various addenda were issued in August 2004, January and September 2005.
2018-01-31	Draft Renewal Assessment Report (DRAR) – prepared in the context of the application for renewal of approval of the a.s. according to Reg (EU) No EU 844/2012. <i>Note: The RAR is a stand-alone document containing the evaluations already displayed in the original DAR, as well as the new assessments. The revision of the initial DAR has been done in accordance with SANCO/10180/2013 rev.1 (March 2013), with changes to the original text – resulting from assessment of new studies (or reconsideration of old studies or studies that were not yet previously peer-reviewed) – being highlighted by means of yellow shading. However, for the renewal of the a.s., a new formulation is proposed as representative formulation. Data submitted on the formulation 'BAS 555 01 F' were therefore not evaluated in the initial DAR and are presented and evaluated in this document.</i>

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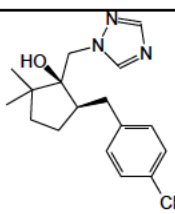
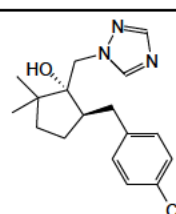
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B.1. IDENTITY

B.1.1. IDENTITY OF THE PLANT PROTECTION PRODUCT

B.1.1.1. Applicant	<p>BASF Agro BV Arnhem (NL) - Freienbach Branch Huobstrasse 3 8088 Pfäffikon SZ Switzerland</p> <p>(a) Contact:</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>(b) Alternative:</p> <p>Dr. Martin Dust</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
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<p>B.1.1.2. Producer of the plant protection product</p>	<p><u>Manufacturer of the Plant Protection Product (legal entity)</u></p> <p>BASF Agro BV Arnhem (NL) - Freienbach Branch Huobstrasse 3 8088 Pfäffikon SZ Switzerland</p> <p><u>Affiliates or representatives:</u></p> <p>BASF SE Crop Protection Division P.O. Box 120 67114 Limburgerhof Germany</p> <p>Contact person: [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p> <p><u>Location of the manufacturing site of the Plant Protection Product</u></p> <p>CONFIDENTIAL information – Vol. 4.</p> <p><u>Manufacturer of the metconazole (legal entity)</u></p> <p>BASF Agro BV Arnhem (NL) - Freienbach Branch Huobstrasse 3 8088 Pfäffikon SZ Switzerland</p> <p><u>Affiliates or representatives:</u></p> <p>BASF SE Crop Protection Division P.O. Box 120 67114 Limburgerhof Germany</p> <p>Contact person: [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p> <p><u>Location of the manufacturing plant:</u></p> <p>CONFIDENTIAL information – Vol. 4.</p>
<p>B.1.1.3. Trade name or proposed trade name and producer's development code number of the plant protection product</p>	<p>Code number: BAS 555 01 F</p> <p>Trade names: CARAMBA® 90 JUVENTUS® 90 CARAMBA STAR® CINCH® PRO SUNORG® PRO CARAMBA®</p>

B.1.1.4. Detailed quantitative and qualitative information on the composition of the plant protection product		
B.1.1.4.1. Composition of the plant protection product	Pure active substance	
	Content of pure a.s. metconazole:	90 g/L
	Limits (±10%):	81.00 – 99.00 g/L
	8.60 % w/w *	
	7.74 – 9.46 % w/w *	
	Technical active substance	
Content of technical a.s. metconazole:	95.74 g/L	9.15 % w/w *
Limits (±10%):	86.17 – 105.32 g/L	8.24 – 10.07 % w/w *
* contents are calculate with a product density of 1.046g/cm³		
Sum of cis- and trans- isomers min. 940g/kg		
cis metconazole (CL 35801) min. 800g/kg		
max. 950g/kg		
Safeners, synergists and co-formulants		
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B.1.1.4.2. Information on the active substances	Type	Name/Code Number
	ISO common name	METCONAZOLE
	IUPAC name	(1RS,5RS;1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol
	CA name	5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol
	CAS No	125116-23-6 (unstated stereochemistry)
	EC No	Not assigned
	CIPAC No	706
	Molecular formula	C ₁₇ H ₂₂ ClN ₃ O
	Structural formula	<div><div></div><div></div></div> <div><div>cis-isomer CL 354801</div><div>trans-isomer CL 354802</div></div> <p>The active substance Metconazole is a mixture of 4 diastereomers: CL 354801 (“cis-metconazole”) is a mixture of <i>S</i>(OH), <i>R</i> and <i>R</i>(OH), <i>S</i> diastereomers, whereas CL 354802 (“trans-metconazole”) is a mixture of <i>S</i>(OH), <i>S</i> and <i>R</i>(OH), <i>R</i> diastereomers</p>
	Molecular mass	319.8 g/mol
	Salt, ester anion or cation present	The active is not in the form of a salt, ester, anion or cation.
	B.1.1.4.3. Information on safeners, synergists and co-formulants	
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B.1.1.5. Type and code of the plant protection product	<p>Nature : Emulsifiable Concentrate [Code: EC]</p> <p>At the beginning the formulation type of BAS 555 01 F was described as SL (Soluble Concentrate). Due to the intrinsic physico-chemical properties of metconazole this classification is not appropriate. In fact this product is best described as an emulsifiable concentrate (EC).</p> <p>There has been no change in the composition of BAS 555 01 F formulation. Therefore, the physical-chemical properties of the formulation will remain unchanged as will the toxicological and ecotoxicological endpoints and consequently the (eco-) toxicological classification. All existing studies performed with BAS 555 01 F will remain valid. The properties and benefits for the customers remain exactly the same.</p>
B.1.1.6. Function	Fungicide; Plant Growth Regulator
B.1.1.7. Field of use envisaged	Crops
B.1.1.8. Effects on harmful organisms	Fungicide - not systemic in plants

B.1.2. REFERENCES RELIED ON

There are no references submitted with this section.