ANNEX B

Metconazole

B.1 Identity

B.1.1 Identity of the active substance (Annex IIA 1)

B.1.1.1 Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)

BASF Agro B.V., Wädenswil Branch
Steinacherstrasse 101
CH-8820 Wädenswil

Contact person : Dr. Isabelle Herrmann
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e-mail : isabelle.02.herrmann@basf-ag.de

B.1.1.2 Manufacturer(s) of the active substance (Annex IIA 1.2)

Metconazole is manufactured for : BASF Agro B.V., Wädenswil Branch
Steinacherstrasse 101
CH-8820 Wädenswil

by : Kureha Chemical Industry Company Ltd.
1-9-11 Nihonbashi Horidome-cho
Chuo-ku
Tokyo 103, Japan

at currently two toll manufacturers :

1) Japan : Ibaraki Kasei Chemicals Co., Ltd.
Isohara 1309-2
Isohara-cho
Kitaibaraki-city
Ibaraki Pref., Japan

2) India : Rallis India, Ltd.
Agrochemical Division
Plot No. 3301
GIDC Estate
Ankleshwar 393 022, India

Contact person : Dr. Isabelle Herrmann
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B.1.1.3 ISO common name and synonyms (Annex IIA 1.3)

Metconazole

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC nomenclature : (1*RS*,5*RS*:1*RS*,5*SR*)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol

CA nomenclature : 5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol

B.1.1.5 Manufacturer's development code number(s) (Annex IIA 1.5)

Active substance : BAS 555 F; AC 900768; CL 900,768; WL 148271; KNF-S-474M
cis-isomer : CL 354801; trans-isomer : CL 354802

Formulation Metconazole 60 g/L SL : BAS 555 00 F ; SF 09381

B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number : 125116-23-6 (unstated stereochemistry)

EEC number : not assigned

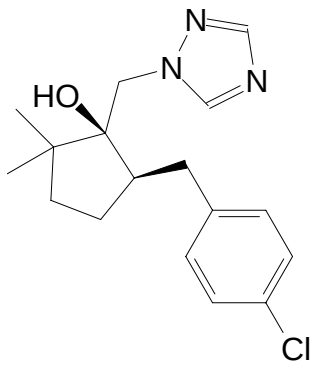
CIPAC number : 706

B.1.1.7 Molecular formula, molecular mass and structural formula (Annex IIA 1.7)

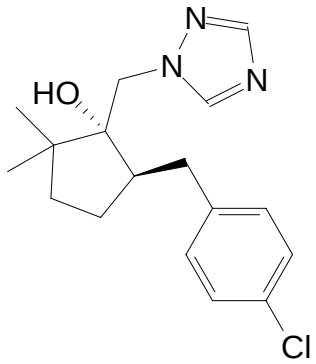
Molecular formula : $C_{17}H_{22}ClN_3O$

Molecular mass : 319.8 g/mol

Structural formula :



cis-isomer
CL 354801



trans-isomer
CL 354802

The active ingredient of Metconazole is a mixture of 4 diastereomers : CL 354801 (“cis-metconazole”) is a mixture of S(OH), R and R(OH), S diastereomers, whereas CL 354802 (“trans-metconazole”) is a mixture of S(OH), S and R(OH), R diastereomers.

B.1.1.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C

B.1.1.9 Specification of purity of the active substance (Annex IIA 1.9)

min. 940 g/kg (sum of *cis*- and *trans*-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not more than 950 g/kg

B.1.1.10 Identity of isomers, impurities and additives (Annex IIA 1.10)

Confidential information, see Annex C

B.1.1.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C

B.1.2 Identity of the plant protection product (Annex IIA 3.1; Annex IIIA 1)

B.1.2.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Trade name : Caramba 60 SL ®

Code number : Metconazole 60 g/L SL; BAS 555 00 F ; SF 09381

B.1.2.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

Manufacturer of the preparation : BASF Agro B.V., Wädenswil Branch
Steinacherstrasse 101
CH-8820 Wädenswil

Manufacturing site : BASF Agri-Production SAS
Z.I. Lyon Nord
Rue Jacquard – BP 73
F-69727 GENAY Cedex
France

Manufacturer of the active substance : Kureha Chemical Industry Company Ltd.
1-9-11 Nihonbashi Horidome-cho
Chuo-ku
Tokyo 103, Japan

Manufacturing sites : 1) Japan
Ibaraki Kasei Chemicals Co., Ltd.
Isohara 1309-2
Isohara-cho
Kitaibaraki-city
Ibaraki Pref., Japan

2) India
Rallis India, Ltd.
Agrochemical Division
Plot No. 3301
GIDC Estate
Ankleshwar 393 022, India

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B.1.2.3 Type of the preparation and code (Annex IIIA 1.5)

Soluble concentrate (SL)

B.1.2.4 Function (Annex IIIA 1.6)

Fungicide

B.1.2.5 Composition of the preparation (Annex IIIA 1.4)

Table B.1.2.5-1 : Composition of Caramba 60 SL ®

Component	**Content (g/L)**	**Function**
Metconazole - pure a.s. - technical a.s. (min. purity : 94%)	 60 63.8	Active substance
Other components	Confidential information, see Annex C	

B.1.3 References relied on

Annex point(s)	**Author(s)**	**Year**	**Title** **Source** **BASF Document No.** **GLP or GEP status** **Published or not**	**Data Protection Claimed Y/N**	**Owner**
Document J II A 1.8/1	Searfass M.T.	1998	Description of materials used to produce the product and description of production process as applied to Caramba technical Metconazole American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-140-006 No unpublished	N	BASF
Document J II A 1.8/2	Harrington P.	1999	Production process information for technical Metconazole American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-140-007 No unpublished	N	BASF
EG:AIIA-1.8	Ohnsorge, U.	2002a	Process of Manufacture and Beginning Materials (Ibaraki Kasai, Japan) 2002/1008816 no unpublished	Y	BASF
EG:AIIA-1.8	Ohnsorge, U.	2002b	Process of Manufacture and Beginning Materials (Rallis India, India) 2002/1008817 no unpublished	Y	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
Document J II A 1.9/1	Huang L.Y.	2000	The analytical profile for representative manufacturing batches of CL 900768 (Metconazole) TGAI and minimum and maximum content of each component for the reregistration of CL 900768 (Metconazole) TGAI with the EU American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-380-014 No (Yes for report in annex) unpublished	N	BASF
Document J II A 1.10/1	Huang L.Y.	2000	The analytical profile for representative manufacturing batches of CL 900768 (Metconazole) TGAI and minimum and maximum content of each component for the reregistration of CL 900768 (Metconazole) TGAI with the EU American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-380-014 No (Yes for report in annex) unpublished	N	BASF
EG:AIIA-1.10	Ohnsorge, U.	2002c	Composition of the Technical Active Ingredient (Rallis India, India) 2003/1013956 no unpublished	Y	BASF
EG:AIIA-1.10	Ohnsorge, U.	2003a	Comparison of Material from Alternate Sources (Ibaraki Kasai, Japan and Rallis India, India) 2003/1013955 no unpublished	Y	BASF
EG:AIIA-1.10	Ohnsorge, U.	2003b	Metconazole TC: Nomenclature of A.I. and potential impurities 2003/1016615 no unpublished	Y	BASF
EG:AIIA-1.10	Yang, H.	1997	Screening of Metconazole Technical Grade Samples for N-Nitrosamines American Cyanamid, U.S.A. MK-390-017 yes unpublished	Y	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
DocumentJ II A 1.11/1	Huang L.Y.	2000	The analytical profile for representative manufacturing batches of CL 900768 (Metconazole) TGAI and minimum and maximum content of each component for the reregistration of CL 900768 (Metconazole) TGAI with the EU American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-380-014 No (Yes for report in annex) unpublished	N	BASF
EG:JII-1.11	Ahuja, E.S.	1998	Additional Information for the Registration of CARAMBA, (Containing Metconazole) Technical Grade Active Ingredient Requested by the Pesticides Safety Directorate (PSD) of the United Kingdom's Ministry of Agriculture, Fisheries, and Food American Cyanamid, Agricultural Products Research Division, Princeton, U.S.A. MK-380-007 Yes Unpublished	Y	BASF
EG:JII-1.11	Ahuja, E.S.	1998	Raw Data of MK-380-007 (APBR 848) (RTP Archive Object # 81293): *'Additional Information for the Registration of CARAMBA, (Containing Metconazole) Technical Grade Active Ingredient Requested by the Pesticides Safety Directorate (PSD) of the United Kingdom's Ministry of Agriculture, Fisheries, and Food'* American Cyanamid, Agricultural Products Research Division, Princeton, U.S.A. Raw Data of MK-380-007 Yes Unpublished	**Y**	BASF
EG:AIIA-1.11	Evans, F.	2002	Compositional Analysis of Metconazole (AC 900768, BAS 555 F) Technical Grade Active Ingredient Manufactured at Rallis India Ltd for the Kureha Chemical Industry Company, Tokyo, Japan in Support of Registration with World-Wide Regulatory Authorities (Rallis India Ltd., India) BASF Agro Research Princeton, U.S.A. MK-380-015 yes unpublished	**Y**	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
EG:AIIA-1.11	Tagawa, Y. and Ohzeki, T.	2003	BAS 555 F - certificate issued by Ibarakikasei Chemicals Japan to confirm origin of five batches as analysed in MK-380-014 2003/1016760 no unpublished	Y	BASF
EG:JII-1.11	Thomson, M.	2002	Raw Data of MK-380-015 (APBR 1215) (RTP Archive Object # 105505): '*Compositional Analysis of Metconazole (AC 900768, BAS 555 F) Technical Grade Active Ingredient Manufactured at Rallis India Ltd for the Kureha Chemical Industry Company, Tokyo, Japan in Support of Registration with World-Wide Regulatory Authorities*' BASF Agro Research, Princeton, U.S.A. Raw Data of MK-380-015 yes unpublished	Y	BASF
EG:JII-1.11	Wang, Ch.	1999	RTP Archive Object # 88178, Lot: AC 9339-114, Secondary Standard Analyses and COAs Re-Certifications and Analytical Raw Data / Chromatograms: APBR # 99-Sep-15-5, Report numbers 94-ASA-0256, 96-ASA-0149, 99-ASA-0275, '*Analytical Standard – Retired Lot # AC 9339-114*' American Cyanamid, Process and Analytical Research, Princeton, U.S.A. Raw Data of RTP Archive Object # 88178 Yes Unpublished	Y	BASF