



EPOXICONAZOLE

List of Annex II studies which were considered
as relied upon for the evaluation with a view to
Annex I inclusion
and for which the main submitter has claimed
data protection

Version 2 - final

Rapporteur Member State: Germany

2 October 2008

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B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports¹ on previous use in granting national authorisations
AIIA-1.8	Ohnsorge, U.	2002	Epoxiconazole TC, Process of Manufacture and Beginning Materials. 2002/1007071 not GLP, unpublished CHE2002-527	
AIIA-1.10	Ohnsorge, U.	2004	Epoxiconazole TC, Composition of the Techn. Active Ingredient, Certified Limits and Rationale. 2004/1015112 not GLP, unpublished CHE2004-963	
AIIA-1.11	Genari, G.	1987	Wirkstoffanteil und Nebenkomponenten in Wirkstoff 205259 Nachlieferung 33, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep., BASF DocID 1987/1000504 GLP, unpublished CHE2006-1882	
AIIA-1.11	Genari, G.	1988	Wirkstoffanteil und Nebenkomponenten in Wirkstoff 205259 Nachlieferung 73, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep., BASF DocID 1988/1000627 GLP, unpublished CHE2006-1883	

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AIIA-1.11	Genari, G.	1990	Determination of active ingredient and impurities in 205259 batch CP2341 BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep., BASF DocID 1990/1000624 GLP, unpublished CHE2006-1884	
AIIA-1.11	Westphalen, K.O.	2002	BAS 480 F: Summary on content of parent and of technical impurities of epoxiconazole batches, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep., BASF DocID 2002/1014183 not GLP, unpublished CHE2006-1885	
AIIA-2.1.1; AIIA-2.1.3	Daum, A.	2004	Subject: Physical and chemical properties of Epoxiconazole, Ref.: Annex IIA - point 2.1, melting point BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 2004/1027228! not GLP, unpublished	
AIIA-2.14	Kroehl, T.	2006	Epoxiconazole (BAS 480 F, Reg.No. 205 259): Surface tension of the pure active ingredient, BASF, DocID 2006/1030462 GLP, unpublished CHE2006-188	
AIIA-3.7	Gerlach H.	2002	Safety data sheet - Epoxiconazol Techn. 2002/1014095 not GLP, unpublished CHE2003-1247	
AIIA-4.2.1; AIIIA-5.2.1	Lehmann, A. and Mackenroth, C.	2001	Validation of BASF method no. 445/0: Determination of BAS 480 F in following plant matrices: Wheat plant without root, grain and straw, sugar beet, oilrape seed and orange; . 2000/1012401! 78591 GLP, unpublished MET2001-277	
AIIA-4.2.1	Lehmann A.; Mackenroth, C.	2002	Validation of BASF method No. 504/0: Determination of BAS 480 F in wheat grain. 2001/1015027! 133243 GLP, unpublished MET2003-475	

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AIIA-4.2.1	Reinhard K.	1996	Extractability of ¹⁴ C-Epoxiconazole (BAS 480 F) residues from banana peel and pulp with aqueous methanol (according to method No. 309/1). 1996/10930! 13580 GLP, unpublished MET2003-484	
AIIA-4.2.1 AIIIA-5.2.1	Lehmann, A. Mackenroth C.	2007	Validation of BASF Method No. 535/1 in plant matrices Study code 246631, BASF DocID 2006/1039427 GLP, unpublished RIP2007-463	
AIIA-4.2.1	Bacher R.	2005	Epoxiconazol (BAS 480 F): Validation of an analytical confirmatory method for the determination of BAS 480 F in animal matrices Study Code 212410, Doc ID 2005/1006485 GLP, unpublished MET2006-173	
AIIA-4.2.4	Zangmeister W.	2004	Validation of analytical method 367/2: Determination of BAS 480 F (Reg.No. 205 259) in air by GC-ECD 2004/1015204! GLP, unpublished BVL-No.1209509	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports² on previous use in granting national authorisations
AIIA-5.4.1.1	Fabian E., Landsiedel R.	2006	Stability analysis of BAS 480 F (Epoiconazole) in DMSO. BASF DocID 2006/1037429, GLP, unpublished. TOX2007-357	
AIIA-5.7	Mellert, W.;	2000	Reg. No. 205 259: Subchronic oral neurotoxicity study in wistar rats - Administration in the diet for 3 months - (Amendment No. 1 to the report). 2000/1017248 ! 1996/10713 ! 50S0195/91170 GLP, unpublished TOX2003-1856	
AIIA-5.7	Mellert, W. ; Kaufmann, W. ; Hildebrand, B. ;	1996	Reg.No. 205 259: Subchronic oral neurotoxicity study in wistar rats - Administration in the diet for 3 months. 1996/10713 ! 50S0195/91170 GLP, unpublished TOX2003-1854	
AIIA-5.7	Mellert, W. ; Kaufmann, W. ; Hildebrand, B. ;	1996	Reg.No. 205 259: Acute oral neurotoxicity study in wistar rats. 1996/10736 ! 20S0195/91174 GLP, unpublished TOX2003-1853	
AIIA-5.8.2	Mellert, W. and Hildebrand, B.	1999	Determination of hormone concentrations in wistar rats treated with Reg.No. 205 259 - Amendment No. 1 to the interim report.: 1999/11334 ! 92/10715 ! 99S0959/88120 not GLP, unpublished TOX2003-1858	
AIIA-5.8.2	Wuttke, W. ;	1995	Reg.No. 205 259 (triazole): In vitro investigations into the effects of triazole on the production of ovarian and adrenal steroids and of the pituitary hormone prolactin. 1995/11377 ! 13B0959/889041 not GLP, unpublished TOX2003-1861	

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B.7 Residues

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorisations
AIIA-6.0; AIIA-6.3	Funk, H.; Mackenroth, C.	2001	Investigation of the stability of residues of BAS 480 F in plant matrices under normal storage conditions. 2001/1015032! 58237 GLP, unpublished RIP2003-1533	
AIIA-6.3	Balluff, M.	2001	Field residue study for the determination of residues of the active ingredient(s) after the maximum number of applications under open field conditions with BAS 480 27 F in winter cereals in southern Europe, 2000. 2001/1009088! 20003013/E1-FPWC GLP, unpublished RIP2003-1529	
AIIA-6.3	Beck, J. et al.	2003	Study on the residue behaviour of Epoconazole in winter wheat after application of BAS 480 27 F under field conditions in France (S), Germany, United Kingdom and Spain, 2002. 2002/1008783! 134503 GLP, unpublished RIP2003-1528	
AIIA-6.3	Beck, J. et al.	1995	Study on the residue behaviour of BAS 481 03 F in cereals under field conditions in Germany, 1992. 1995/10661! DE/FR/01/92 GLP, unpublished RIP2003-1527	
AIIA-6.3	Jones, S.	2003	Study on the residue behaviour of BAS 480 F in wheat and barley after application of BASF 480 27 F under field conditions in France (South) and Spain, 2002. 2002/1014334! 141736 GLP, unpublished RIP2003-1531	
AIIA-6.3	Jones S.	2002	Study on the residue behaviour of BAS 480 F in cereals after application of BAS 480 27 F under field conditions in France (S), Italy, 2001. 2001/1006146! 4890! 58241 GLP, unpublished RIP2003-1530	

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AIIA-6.3.1	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in barley after treatment with BAS 480 31 F under field conditions in Germany, Denmark, England, Northern and Southern France, 2004 SGS Institut Fresenius GmbH, Taunusstein, Germany unpublished BASF RegDoc# 2006/1018053 RIP2006-2759	
AIIA-6.3.1	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in barley after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Southern France and Northern France, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany unpublished BASF RegDoc# 2006/1029385 RIP2006-2760	
AIIA-6.3.1	Perny, A.	2004	Study on the residue behaviour of fenpropimorph and epoxiconazole on sugar beets after application of BAS 480 08 F under field conditions in Greece and Spain, 2003 BASF AG; unpublished BASF DocID 2004/1024749 RIP2006-2761	
AIIA-6.3.1	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Northern and Southern France and Italy, 2004 SGS Institut Fresenius GmbH, Taunusstein, Germany unpublished BASF RegDoc# 2006/1018052 RIP2007-465	
AIIA-6.3.1	Schulz H.	2007	1st addendum to report 1/2: Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Northern and Southern France and Italy, 2004 SGS Institut Fresenius GmbH; Taunusstein; Germany Fed. Rep. Unpublished BASF RegDoc# 2007/1009641	

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AIIA-6.3.1	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Denmark, England and Northern France, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Unpublished BASF RegDoc# 2006/1029386 RIP2007-469	
AIIA-6.3.1	Schroth E.	2005	Study on the residue behavior of Epoxiconazole on sugar beets after application of BAS 480 31 F under field conditions in Spain and Greece, 2004 Agrologia SL; Palomares; Spain Unpublished BASF RegDoc# 2004/1032625	
AIIA-6.5.1	Goetz, N. von	1999	Hydrolysis of BAS 480 F at 90°C, 100°C, and 120°C. 1999/11790! 58236 GLP, unpublished RIP2003-1535	
AIIA-6.5.2; AIIIA-8.4	Renner, G.	2003	Determination of the residues of BAS 510 F and Epoxiconazole in winter wheat processing products following double application of BAS 549 KA F in Germany. 2003/1000945! 02 10 47 003 GLP, unpublished RIP2003-1536	
AIIA-6.5.2; AIIIA-8.4	Schulz, H.	2003	Determination of the residues of Epoxiconazole and BAS 510 F in barley and processed products following treatment with BAS 549 KA F under field conditions in Germany 2002. 2003/1000946! IF-02/00006864! IPMIS 104369 GLP, unpublished RIP2003-1532	
AIIA-6.6	Veit, P.	2003	Confined rotational crop study with 14C-BAS 480 F. 2003/1000950! 58242 GLP, unpublished RIP2003-1537	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports³ on previous use in granting national authorisations
AIIA-7.1.1.1.1	Regetta R.C., Zogorski W.J.	1992	A random soil survey for 1,2,4-Triazole content in California. 1992/1000816 GLP, unpublished BOD2003-406	
AIIA-7.1.1.1.1	Scholz K.	1990	Metabolism of (3,5- ¹⁴ C) 1,2,4-Triazole in soil under aerobic conditions. 1990/1000709 not GLP, unpublished BOD2003-405	
AIIA-7.1.1.1.2; AIIA-7.1.1.2; AIIA-7.1.1.2.1	Bayer H.	2003	The anaerobic soil metabolism of ¹⁴ C-BAS 480 F (14C-Epoxiconazole). 2002/1007743 GLP, unpublished BOD2003-408	
AIIA-7.1.1.1.2; AIIA-7.1.1.2; AIIA-7.1.1.2.1	Goetz N. von	2002	Soil photolysis of BAS 480 F. 2002/1005313 GLP, unpublished BOD2003-407	
AIIA-7.1.1.2; AIIA-7.1.1.2.1	Hauck, T.	2002	Standardisation of laboratory half-lives of BAS 480 F - epoxiconazole to reference conditions according to the recommendations of FOCUS. 2002/1005315 not GLP, unpublished BOD2003-159	
AIIA-7.1.1.2.1	Platz K.	2004	Report amendment No. 1 to final report: Standardization of laboratory half-lives of BAS 480 F - Epoxiconazole to reference conditions according to the recommendations of FOCUS BASF DocID 2004/1022528 Not GLP, unpublished	
AIIA-7.1.1.2.1	Tilting N.	2006	Standardization of laboratory half-lives of BAS 480 F-epoxiconazole to reference conditions according to the recommendations of FOCUS BASF DocID 2006/1024626 No, not subject to GLP regulations Unpublished BOD2006-819	

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AIIA-7.1.1.2; AIIA-7.1.1.2.2; AIIIA-9.1.3	Platz, K.	2002	Standardisation of field dissipation rates of BAS 480 F - epoxiconazole. 2002/1005317 not GLP, unpublished BOD2003-163	
AIIA-7.1.1.2.1; AIIIA-9.1.2.1	Slangen P.J.	2000	Degradation of 1,2,4-Triazole in three soils under aerobic conditions. 2000/1021117 GLP, unpublished BOD2003-411	
AIIA-7.1.1.2.2	Kellner O. et al.	2002	Field soil dissipation of BAS 480 F (Formulation BAS 480 27 F) on bare soil in Spain 2000 - 2001. 2002/1000202 GLP, unpublished BOD2003-412	
AIIA-7.1.1.2.2	Tilting N.	2007	Predicted environmental concentrations in soil for BAS 480 F (Epoxiconazole) according to FOCUS recommendations BASF DocID 2007/1005103 not GLP, unpublished	
AIIA-7.1.1.2.2	Tilting N.	2007	Predicted environmental concentrations in soil for BAS 480 F (Epoxiconazole) according to FOCUS recommendations BASF DocID 2007/1018878 (Report Amendment No. 1 to Final Report BASF DocID 2007/1005103) not GLP, unpublished BOD2007-153	
AIIA-7.1.2	Hawkins, D.R.	1988	Soil adsorption and desorption of 1,2,4-Triazole. 34S-88-27 ! 1988/1000655 GLP, unpublished BOD2003-422	
AIIA-7.1.2	Seher, A.	2002	Soil adsorption / desorption study of BAS 480 F (epoxiconazol). 2002/1004272 GLP, unpublished BOD2003-164	
AIIA-7.1.3.2	Ackermann I.B.	1986	Laboratory leaching study of 1,2,4 Triazole aged residues through soil columns. 1986/1000532 not GLP, unpublished BOD2003-424	

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AIIA-7.2.1.1; AIIIA-9.2.1	Spare W.C.	1983	Determination of the hydrolysis rate constants of 1,2,4-H-Triazole. 1983/1000500 not GLP, unpublished WAS2003-239	
AIIA-7.2.1.2	Miller G.C.	1983	Sunlight photolysis of 1,2,4-H-Triazole in distilled water and humic acid solutions. 1983/1000501 not GLP, unpublished LUF2003-61	
AIIA-7.2.1.3.2	Schnoeder F.	2003	Degradation of BAS 480 F (Epoiconazole) in water/sediment systems under aerobic conditions. 2003/1001015 GLP, unpublished WAS2003-243	
AIIA-7.2.2	Krohn J.	2001	Water solubility and Henry law constant of 1,2,4-Triazole. 2001/1021183 not GLP, unpublished LUF2003-62	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports⁴ on previous use in granting national authorisations
AIIA-8.1.1	Zok S.	2003	Reg.No. 137 281 (metabolite of BAS 480 F, Epoxiconazole) - Avian single-dose oral LD50 on the Bobwhite Quail (<i>Colinus virginianus</i>). 2003/1004105 GLP, unpublished AVS2003-234	
AIIA-8.1.2	Beavers B., Jaber M.	1983	A dietary LC50 in the bobwhite with CGA-131013. 1983/1000462 not GLP, unpublished AVS2003-235	
AIIA-8.1.2	Beavers J.B.	1983	A dietary LC50 in the mallard with CGA-131013. 1983/1000463 not GLP, unpublished AVS2003-236	
AIIA-8.2.1	Rufli H.	1983	Report on the test for acute toxicity CGA 98032 to rainbow trout. 1983/1000494 not GLP, unpublished WAT2003-593	
AIIA-8.2.2.1	Dorgerloh M., Sommer H.	2002	1,2,4-Triazole - Juvenile growth test, fish (<i>Oncorhynchus mykiss</i>). 2002/1007850 GLP, unpublished WAT2003-594	
AIIA-8.2.2.3	Schäfers, Ch.	2003	Zebrafish (<i>Danio rerio</i>), static full life test with sediment, Epoxiconazole, technical. BASF 2003/1004101 ! -014/4-61 GLP, unpublished WAT2003-368	
AIIA-8.2.2.3	Zok, S. (a)	2003	BAS 480 F - Life cycle study in fathead minnow (<i>Pimephales promelas</i>). 2003/1001115 GLP, unpublished WAT2003-369	
AIIA-8.2.3	Seiferlein M.	2003	Bioaccumulation and metabolism of (14C)-BAS 480 F (Epoxiconazole) in rainbow trout. 2002/1000001 GLP, unpublished WAT2003-595	

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AIIA-8.2.4	Bell G.	1995	Fluquinconazole technical material 100.8% w/w 1,2,4-Triazole: Acute toxicity to <i>Daphnia magna</i> . 1995/1001851 GLP, unpublished WAT2003-596	
AIIA-8.2.6	Palmer S.J. et al.	2001	1,2,4-Triazole: A 96-hour toxicity test with the freshwater alga (<i>Selenastrum capricornutum</i>). 2001/1022266 GLP, unpublished WAT2003-597	
AIIA-8.2.7	Funk M.	2003	Effect of Reg.No. 226 215 (metabolite of BAS 480 F) on the development of sediment dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system. 2003/1001108 GLP, unpublished WAT2003-559	
II A 8.2.8/2	Hoffmann, F.	2006	Effect of BAS 480 F (Reg. No. 205259) on the growth of <i>Lemna gibba</i> BASF DocID 2006/1031717 GLP Unpublished WAT2006-872	
AIIA-8.4; AIIIA-10.6	Anonym	1993	Physico-chemical properties of 1,2,4 Triazole (CGA 71 019). 1993/1000502 not GLP, unpublished ARW2004-234	
AIIA-8.4.1	Heimbach F.	1986	Acute toxicity of 1,2,4-Triazole (technical) to earthworms. 1986/1000651 not GLP, unpublished ARW2003-202	
AIIA-8.4.2; AIIIA-10.6; AIIIA-10.6.1	Ehlers H.A.	2003	Effects of 1,2,4-triazole on reproduction and growth of earthworms <i>Eisenia fetida</i> (Savigny 1826) in artificial soil. 7781022 ! 2000/1021862 GLP, unpublished ARW2003-203	

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AIIA-8.4.2	Moser T., Scheffczyk A.	2002	1,2,4-Triazole: Acute and reproduction toxicity to the collembolan species <i>Folsomia candida</i> according to the ISO guideline 11267 Soil quality - Inhibition of reproduction of collembola (<i>Folsomia candida</i>) by soil pollutants (1999). 2002/1007851 GLP, unpublished ARW2003-204	
AIIA-8.5	Voelkel W.	2000	The effects of CGA71019 on soil respiration and nitrification. 2000/1021861 GLP, unpublished BMF2003-94	