

PENCONAZOLE

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: DE

31 August 2009

PENCONAZOLE

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 (31 August 2009)

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	Reports ¹ on previous use in granting national authorisations
AIIA-2.3.1	Krohn, J.	2001	Vapour pressure curve of 1,2,4-triazole. MO-01-002793 !0049 ! 100415 not GLP, unpublished CHE2004-2268	
AIIA-2.3.1	Widmer, H.	2001	Vapour pressure of CGA 179944. CGA179944/0003! 2001WI03 GLP, unpublished CHE2004-2269	
AllA-2.3.1	Geoffroy, A	2006	Penconazole - Vapour pressure Extra information Solvias AG, Physical Chemistry, Not published BVL-No. 1646825	
AllA-2.6	Das, R.	2001	Water solubility of CGA 179944. CGA179944/0002 ! 107339 GLP, unpublished CHE2004-2274	
AllA-2.8	Das, R.	2001	Octanol / water partition coefficient of CGA 179944. CGA179944/0004! 107340 GLP, unpublished CHE2004-2277	
AllA-2.9.1	van der Gaauw, A.	2002	Hydrolysis of ¹⁴ C-phenyl Labelled Penconazole (CGA71818) at Four Different pH Values. CGA71818/4397! 841774 GLP, unpublished CHE2004-2278	

¹ Entries are based on information received from the main data submitter and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

		· · · · · · · ·
31	August	2009

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 ¹ on previous use in granting national authorisations
AIIA-4.2.1	Gill, J. P.	2004	Penconazole (CGA 71818) - Validation of Residue Analytical Method REM 107.10 for the Determination of Residues in Crops. CGA71818/4520! RJ3494B GLP, unpublished MET2004-998	
AIIA-4.2.1	Weeren, R., Pelz, S.	2001	Penconazole: Independent Laboratory Validation of the DFG Method S 19 (extended Version) for the Determination of Residues of Penconazole (CGA 71818) in Milk, Meat and Egg. CGA71818/4372! NOV-0004V! Az. G00-0092 GLP, unpublished MET2004-1000	
AIIA-4.2.2	Tummon, O. J.	2004	Penconazole: Validation of an Analytical Method for the Determination of Residues of Penconazole and CGA179944 in Soil. CGA71818/4523! RJ3507B! RAM 429/1 GLP, unpublished MET2004-1002	

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	Reports on previous use in granting national authorisations
AIIA-5.3.2	Milburn, G.;	2002	Penconazole: 90-day preliminary carcinogenicity study in mice. CGA71818/4393! CTL/PM1235/TEC/REPT GLP, unpublished TOX2004-2909	
AIIA-5.5	Milburn, G.;	2004	CGA 71818: 80-week carcinogenicity study in mice. CGA71818/4518! PM1239 GLP, unpublished TOX2004-2918	

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-6.1	Stingelin, J.	2001	Behaviour and metabolism of [triazole-(u)- ¹⁴ C] CGA 71818 in field grown tomato plants. CGA71818/4373 ! 97JS25 GLP, unpublished RIP2003-771	
AIIA-6.1	Stingelin, J.	2001	Behaviour and metabolism of [phenyl-(u)- ¹⁴ C] CGA 71818 in field grown tomato plants. CGA71818/4374! 97JS26 GLP, unpublished RIP2003-768	
AllA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (South). CGA71818/4385! 0111901 GLP, unpublished RIP2004-2445	
AllA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (South). CGA71818/4386! 0111701 GLP, unpublished RIP2004-2444	
AllA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (North). CGA71818/4389! 0111502 GLP, unpublished RIP2004-2455	
AllA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (North). CGA71818/4390! 0111501 GLP, unpublished RIP2004-2456	
AllA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4387! 0111801 GLP, unpublished RIP2004-2439	
AIIA-6.3	Pointurier, R.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4388! 0111601 GLP, unpublished RIP2004-2438	
AIIA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melon in Spain. CGA71818/4404! 2067/01 GLP, unpublished RIP2004-2468	

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
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4413! 2068/01 GLP, unpublished RIP2004-2469	
AliA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4415! 2069/01 GLP, unpublished RIP2004-2470	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4406 ! 2062/01 GLP, unpublished RIP2004-2471	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4407 ! 2063/01 GLP, unpublished RIP2004-2472	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4399! 2066/01 GLP, unpublished RIP2004-2467	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in Greece. CGA71818/4408 ! 2023/01 GLP, unpublished RIP2004-2460	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in Spain. CGA71818/4405 ! 2065/01 GLP, unpublished RIP2004-2462	
AIIA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4410 ! 2061/01 GLP, unpublished RIP2004-2465	
AIIA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4409! 2060/01 GLP, unpublished RIP2004-2466	

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-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in Italy. CGA71818/4402 ! 2064/01 GLP, unpublished RIP2004-2461	
AIIA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in Italy. CGA71818/4401 ! 2101/01 GLP, unpublished RIP2004-2449	
AllA-6.3	Ryan, J.	2002	Residue Study with Penconazole (CGA 71818) in or on Grapes in Italy. CGA71818/4400 ! 2100/01 GLP, unpublished RIP2004-2448	
AllA-6.3	Simon, P.	2002	Determination of Residues of Penconazole in White Wine Grape Berries in Germany. CGA71818/4392 ! ggr62801 GLP, unpublished RIP2004-2437	
AllA-6.3	Simon, P.	2002	Determination of Residues of Penconazole in Red Wine Grape Berries in Germany. CGA71818/4391! ggr52801 GLP, unpublished RIP2004-2436	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4471! 847455! 02-2150 GLP, unpublished RIP2004-2441	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4485 ! 847456 ! 02-2151 GLP, unpublished RIP2004-2442	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (South). CGA71818/4512! 847449! 02-2146 GLP, unpublished RIP2004-2446	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (South). CGA71818/4511! 847450! 02-2147 GLP, unpublished RIP2004-2447	

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-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in Italy. CGA71818/4468 ! 847462 ! 02-2144 GLP, unpublished RIP2004-2450	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in Italy. CGA71818/4503 ! 847463 ! 02-2145 GLP, unpublished RIP2004-2451	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4476! 847521!02-2024 GLP, unpublished RIP2004-2474	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4506! 847522!02-2025 GLP, unpublished RIP2004-2475	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4502 !847473 ! 02-2107 GLP, unpublished RIP2004-2476	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Melons in Italy. CGA71818/4504!847474!02-2108 GLP, unpublished RIP2004-2477	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Summer Squash in Spain. CGA71818/4456! 847505!02-2017 GLP, unpublished RIP2004-2452	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Summer Squash Spain. CGA71818/4457! 847506! 02-2018 GLP, unpublished RIP2004-2453	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Summer Squash in Italy. CGA71818/4508! 847483! 02-2100 GLP, unpublished RIP2004-2454	

Annex point/ reference number	Author(s) Wolf, S.	Year 2003	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number Residue Study with Penconazole (CGA 71818)	Reports on previous use in granting national authorisations
AllA-0.3	Woll, 3.	2003	in or on Cucumbers in France (North). CGA71818/4487 ! 0847486 ! 02-2071 GLP, unpublished RIP2004-2457	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (North). CGA71818/4473! 847487! 02-2072 GLP, unpublished RIP2004-2458	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (North). CGA71818/4472!847490!02-2073 GLP, unpublished RIP2004-2459	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (South). CGA71818/4478! 847488! 02-2142 GLP, unpublished RIP2004-2463	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Cucumbers in France (South). CGA71818/4479! 847489! 02-2143 GLP, unpublished RIP2004-2464	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Melons in Spain. CGA71818/4475! 847520!02-2023 GLP, unpublished RIP2004-2473	
AllA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4486! 847457!02-2152 GLP, unpublished RIP2004-2443	
AIIA-6.3	Wolf, S.	2003	Residue Study with Penconazole (CGA 71818) in or on Grapes in France (North). CGA71818/4489! 847453! 02-2149 GLP, unpublished RIP2004-2440	
AIIA-6.5.1	Crawford, N.	2002	[Triazole-(U)- ¹⁴ C] CGA 71818 (Penconazole), Aqueous Hydrolysis at 90, 100 & 120 ℃. CGA71818/4411! 02JH008 GLP, unpublished RIP2004-2478	

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-6.5.2	Wolf, S.	2003	Processing Study with Grapes from France (North) containing Penconazole (CGA 71818). CGA71818/4509 ! 847459 ! 02-2153 GLP, unpublished RIP2004-2480	
AIIA-6.5.2	Wolf, S.	2003	Processing Study with Grapes from France (South) containing Penconazole (CGA 71818). CGA71818/4510!847451!02-2148 GLP, unpublished RIP2004-2479	

B.8 Environmental fate and behaviour

	A (1 ()		= 1.1	
Annex	Author(s)	Year	Title	Reports on .
point/			Source (where different from company)	previous use in
reference			Report no.	granting national
number			GLP or GEP status (where relevant)	authorisations
			Published or not	
			BVL registration number	
AllA-7.1.1.1;	Völkl, S.	2002	¹⁴ C-Triazole Labelled Penconazole	
AIIA-7.1.1.2.1			(CGA71818): Degradation and metabolism in	
			two Soils incubated under Aerobic Conditions.	
			CGA71818/4403	
			GLP, unpublished	
			BOD2004-950	
AllA-7.1.1.1.1;	Völkl, S.	2002	¹⁴ C-Triazole Labelled CGA 179944:	
AIIA-7.1.1.2.1			Degradation in Three Soils incubated under	
			Aerobic Conditions.	
			CGA179944/0013	
			GLP, unpublished	
			BOD2004-951	
AIIA-7.1.1.1.2;	Mamouni, A.	2003	(14C)-CGA 71019: Anaerobic soil degradation.	
AIIA-7.1.1.2.1			798660 ! CGA71019/0062	
			GLP, unpublished	
			BOD2004-83	
AIIA-7.1.1.2.2	Emburey, S. N.	2004	Residue Stability Study for Penconazole	
			(CGA71818) and its Metabolite CGA179944 in	
			Soil under Freezer Storage Conditions - Interim	
			Report.	
			CGA71818/4522	
			GLP, unpublished	
			BOD2004-964	
AIIA-7.1.2	Mamouni, A.	2003	Adsorption/Desorption of ¹⁴ C-CGA179944 on	
			four different soils.	
			CGA179944/0015	
			GLP, unpublished	
			BOD2004-966	
AIIA-7.2.1.1	Mamouni, A.	2002	¹⁴ C-CGA179944: Hydrolysis at three different	
			pH values.	
			CGA179944/0014	
			GLP, unpublished	
			WAS2004-401	
AIIA-7.2.1.1	van der Gaauw,	2002	Hydrolysis of ¹⁴ C-phenyl Labelled Penconazole	
	A.		(CGA71818) at Four Different pH Values.	
			GA71818/4397	
			GLP, unpublished	
			WAS2004-399	

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	Reports on previous use in granting national authorisations
AIIA-8.2.1	Swarbrick, R.and Woodyer, J.M.	2001	Acute toxicity to fathead minnow (Pimephales promelas). CGA179944/0009 GLP, unpublished WAT2004-1101	
AllA-8.2.2.1	Dorgerloh, M. and Sommer, H.	2002	1, 2, 4 - Triazole - Juvenile growth test, fish (Oncorhynchus mykiss). DOM21060! MO-02-000959! CGA 71019/ 0052 GLP, unpublished WAT2002-498	
AIIA-8.2.4	Swarbrick, R. and Woodyer, J.M.	2001	Acute Toxicity to Daphnia magna. CGA179944/0011 GLP, unpublished WAT2004-1103	
AIIA-8.2.6	Desjardins, D. et al.	2001	A 96-Hour Growth Inhibition Test of CGA-71818 Tech. to the Green Alga, Selenastrum capricornutum. CGA71818/4378 GLP, unpublished WAT2004-1105	
AIIA-8.2.6	Palmer, S.J., Kendall, T.Z. and Krueger, H.O.	2001	1,2,4-Triazole: A 96-hour toxicity test with the freshwater alga (Selenastrum capricorntum). 528A-101! CGA71019/0044 GLP, unpublished WAT2004-102	
AIIA-8.2.6	Swarbrick, R. and Woodyer, J.	2001	Toxicity to the green alga Selenastrum capricornutum. CGA179944/0010 GLP, unpublished WAT2004-1106	
AIIA-8.4; AIIIA-10.6.2	Förster, B. and Baumann, J.	2002	CGA71818 formulated as EC100 (A6209G); Effects on the Decomposition of Organic Material in the Field. CGA71818/4395 GLP, unpublished ARW2004-290	
AIIA-8.4.1	Bätscher, R	2002	Acute Toxicity of CGA 179944 (Metabolite of CGA 71818) to the Earthworm Eisenia fetida in a 14-day Test. CGA179944/0012 GLP, unpublished ARW2004-287	

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-8.4.2	Ehlers, H.A.	2000	Effects of 1,2,4-triazole on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil. 7781022 ! 2000/1021862 ! 2003637 ! CGA 64250/ 4385 GLP, unpublished ARW2003-203	
AIIA-8.4.2; AIIIA-10.6.1.2	Gillham, A.M.	2002	Determination of effects on reproduction of Penconazole EC formulation (A6209G) in the Earthworm (Eiseneia foetida foetida). CGA71818/4381 GLP, unpublished ARW2004-288	
AllA-8.5	Völkel, W.	2001	The Effects of CGA 179944 (Metabolite of CGA 71818) on Soil Respiration and Nutrification. CGA179944/0008 GLP, unpublished BMF2004-147	
AllA-8.5	Völkel, W.	2000	The effect of CGA71019 on soil respiration and nitrification. 763367 ! CGA71019/0042 GLP, unpublished BMF2004-18	
AllA-8.6	Barth, M.	2001	CGA 71818 EC100 (A-6209 G): Effects on the reproduction of the Collembola Folsomia candida. CGA71818/4376 GLP, unpublished PFL2004-200	
AllA-8.6	Förster, B. and Baumann, J.	2002	CGA71818 formulated as EC100 (A6209G); Effects on the Decomposition of Organic Material in the Field. CGA71818/4395 GLP, unpublished PFL2004-201	
AIIA-8.6; AIIIA-10.8	Moser, Th. and Scheffczyk, A.	2002	1,2,4-Triazole: Acute and Reproduction Toxicity to the Collembolan species Folsomia candida. CGA71019/0053 GLP, unpublished PFL2004-202	