



Tebufenpyrad

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

31 March 2009

TEBUFENPYRAD

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 March 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-1.8	Cevasco, A.A.	2001	Description of the beginning materials and manufacturing process for tebufenpyrad. TB-140-006 not GLP, unpublished CHE2004-2103	
AIIA-1.9; AIIA-1.10	Johnson, J.	2001	Certificate of analysis tebufenpyrad technical. TB-380-013 GLP, unpublished CHE2004-2104	
AIIA-1.10	Wilson, L.A.	1997	Structural identification of the minor components and residual solvents in AC 801,757 (tebufenpyrad) Technical Grade Active Ingredient (TGA). TB-380-010 GLP, unpublished CHE2004-2105	
AIIA-2.1.2; AIIA-2.1.3; AIIA-2.11.1; AIIA-2.11.2	Teeter, D.	1997	Tebufenpyrad: Determination of boiling temperature, flammability and autoflammability. TB-304-001 GLP, unpublished CHE2004-2067	
AIIA-2.6	Daum, A.	2003	Determination of the water solubility of Reg. No. 4 110 691 (metabolite of BAS 318 I, identical with CL# 810721) in deionised water at 20 °C. 2003/1009693 GLP, unpublished CHE2004-2076	

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AIIA-2.6	Daum, A.	2003	Determination of the water solubility of Reg. No. 4 110 693 (metabolite of BAS 318 I, identical with CL# 810729) in deionised water at 20 °C. 2003/1012711 GLP, unpublished CHE2004-2075	
AIIA-2.8	Daum, A.	2003	Determination of the octanol/water-partition coefficient of Reg.No. 4 110 691 (metabolite of BAS 318 I, identical with CL-No. 810721). 2003/1009460 GLP, unpublished CHE2004-2079	
AIIA-2.8	Daum, A.	2003	Determination of the octanol/water-partition coefficient of Reg.No. 4 110 693 (metabolite of BAS 318 I, identical with CL-No. 810729). 2003/1009459 GLP, unpublished CHE2004-2078	
AIIA-2.9.4	Daum, A.	2003	Determination of the dissociation constant of Reg. No. 4 110 691 (metabolite of BAS 318 I, identical with CL# 810721) in deionised water at 20 °C. 2003/1009694 GLP, unpublished CHE2004-2081	
AIIA-2.9.4	Daum, A.	2003	Determination of the dissociation constant of Reg.No. 4 110 693 (metabolite of BAS 318 I, identical with CL# 810729) in deionised water at 20 °C. 2003/1012608 GLP, unpublished CHE2004-2080	
AIIA-2.9.4	Stockton, G.W.	1999	Calculated acid base dissociation constants for tebufenpyrad (AC 801,757). TB-311-001 not GLP, unpublished CHE2004-2085	
AIIA-2.10	Mangels, G.	2000	Tebufenpyrad (AC 801757): Estimation of the photochemical oxidation rate in the atmosphere. TB-321-001 GLP, unpublished CHE2004-2086	

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AIIA-2.11.1	Teeter, D.	1997	Tebufenpyrad: Determination of boiling temperature, flammability and autoflammability. TB-304-001 GLP, unpublished CHE2004-2068	
AIIA-2.11.2	Teeter, D.	1997	Tebufenpyrad: Determination of boiling temperature, flammability and autoflammability. TB-304-001 GLP, unpublished CHE2004-2069	
AIIA-3.9	Schenk, W.	2003	Possible procedures for the decontamination of water from BAS 318 I. 2003/1009315 GLP, unpublished CHE2004-2090	
AIIA-4.2.1	Class, T.	2001	BAS 318 I (Tebufenpyrad): Independent Laboratory Validation (ILV) of the multi-residue method DFG S19 for the determination of tebufenpyrad in foodstuff of animal origin (milk, muscle, fat, liver, egg). 2001/5003680 GLP, unpublished MET2004-841	
AIIA-4.2.1	Class, T.	2001	BAS 318 I (Tebufenpyrad): Independent laboratory validation (ILV) of the multiresidue method DFG S19 for the determination of tebufenpyrad in apples, grapes and rape seed oil. TB-240-005 GLP, unpublished MET2004-840	
AIIA-4.2.1	Cook, J.	1991	AC 801,757: The validation of the analytical method for the determination of residues in apples and grapes. TB-123-123 GLP, unpublished MET2004-842	
AIIA-4.2.1	Jones, J.E.	2003	Validation of method: Method for the determination of BAS 318 I and its metabolites (CL 810,720 and CL 810,721) residues in lactating dairy cow tissues milk and chicken egg using LC/MS/MS. 2002/5004464 GLP, unpublished MET2004-853	

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AIIA-4.2.1	Pelz, S. and Steinhauer, S.	2001	BAS 318 I (Tebufenpyrad): Validation of DFG Method S 19 for the determination of residues of Tebufenpyrad in apples, grapes, oilseed rape, and dried hop cones. TB-240-004 GLP, unpublished MET2004-839	
AIIA-4.2.1	Smalley, R.	2003	Validation of GLC method RLA 11893V to include the analysis of BAS 318 I in apples and their processing commodities. 2003/1010652 GLP, unpublished MET2004-838	
AIIA-4.2.3	Genari, G.	2002	Validation of analytical method CP 382: Bestimmung von BAS 318 I (Tebufenpyrad) in Wasser mittels HPLC. 2002/1004022 GLP, unpublished MET2004-858	
AIIA-4.2.3	Genari, G.	2006	Analysenmethode CP-Nr. 382. Bestimmung von BAS 318 I (Tebufenpyrad) in Wasser mittels HPLC and GC/MS. 2001/1019743 not GLP, unpublished MET2006-418	
AIIA-4.2.3	Wolf, S.	2006	Development and validation of a residue analytical method for tebufenpyrad in surface water. 2006/1028268 GLP, unpublished MET2006-419	
AIIA-4.2.4	Dacunha, A. and Kukel, C.	2002	BAS 318 I (CL 801757, tebufenpyrad): Laboratory validation of GC/MS methods M 3449.01 for the determination of BAS 318 in air. 2002/5003813 GLP, unpublished MET2004-865	

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-5.2	Lorenz, C.	2006	Tebufenpyrad (BAS 318 I) Discussion of the acute oral toxicity (classification). 2006/1024078 GLP, unpublished TOX2006-1591	
AIIA-5.8.1	Engelhardt, G.	2004	<i>Salmonella typhimurium</i> / <i>Escherichia coli</i> reverse mutation assay (Standard plate test and preincubation test) with Reg.No. 411 0693 (metabolite of BAS 318 I) - Amendment No. 1 to the Report. 2004/1027671 ! 2002/1011923 ! 40M0403/014185 GLP, unpublished TOX2005-2682	
AIIA-5.8.1	Engelhardt, G. and Hellwig, J.	2002	<i>Salmonella typhimurium</i> / <i>Escherichia coli</i> reverse mutation assay (Standard plate test and preincubation test) with Reg.No. 411 0693 (metabolite of BAS 318 I). 2002/1011923 40M0403/014185 GLP, unpublished TOX2004-2544	
AIIA-5.8.1	Engelhardt, G. and Leibold, E.	2002	<i>Salmonella typhimurium</i> / <i>Escherichia coli</i> reverse mutation assay (standard plate test and preincubation test) with Reg.No. 4110691 (metabolite of BAS 318 I, tebufenpyrad). 2002/1013892 40M0404/014189 GLP, unpublished TOX2004-2543	
AIIA-5.8.1	Gamer, A.O. and Leibold, E.	2002	Reg.No. 4110693 (metabolite of BAS 318 I): Acute oral toxicity study in Wistar rats. 2002/1014162 10A0403/011112 GLP, unpublished TOX2004-2542	
AIIA-5.8.1	Gamer, A.O. and Leibold, E.	2002	Reg.No. 4110691 (metabolite of BAS 318 I, tebufenpyrad): Acute oral toxicity study in Wistar rats. 2002/1014161 10A0404/011113 GLP, unpublished TOX2004-2541	

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AIIA-5.8.1	Gamer, A.O. and Leibold, E.	2004	Reg.No. 4110693 (metabolite of BAS 318 I): Acute oral toxicity study in Wistar rats - Amendment No. 1 to the Report. 2004/1025740 ! 2002/1014162 ! 10A0403/011112 GLP, unpublished TOX2005-2681	
AIIA-5.8.1	Schulz, M.	2005	Chromosome aberration test in human lymphocytes <i>in vitro</i> with CL 810,721 (metabolite of tebufenpyrad, BAS 318 I). 2004/1027065 GLP, unpublished TOX2006-1554	
AIIA-5.8.1	Wollny, H.E.	2005	Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells with CL 810,721 (metabolite of tebufenpyrad, BAS 318 I). 2004/1027066 GLP, unpublished TOX2006-1553	
AIIA-5.8.2	Anonymous	2006	Rapid bioassay for liver carcinogenesis in rats. 2006/1026801 not GLP, unpublished TOX2006-2138	
AIIA-5.8.2	Hess, F.G.	1999	Tebufenpyrad MASAI response to Austrian authorities regarding the classification categorisation of tebufenpyrad's carcinogenic potential. TB-428-002 not GLP, unpublished TOX2004-2545	
AIIA-5.9.1	Berdondini, R.	1997	Masai 20 % Tebufenpyrad 20 % WP: Worker exposure data. TB-445-002 not GLP, unpublished TOX2004-2548	
AIIA-5.9.1	Mizoguchi, M.	1998	Health surveillance information on the manufacture of tebufenpyrad technical by Mitsubishi. TB-445-001 not GLP, unpublished TOX2004-2546	
AIIA-5.9.1	Uematsu, Y.	2003	Re: Tebufenpyrad surveillance data on workers. 2003/1004364 not GLP, unpublished TOX2004-2547	

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	Reports³ on previous use in granting national authorisations
AIIA-6.3	Rawle, N.W.	2004	Freezer storage stability of BAS 318 I (Tebufenpyrad) in apples, apple pomace, apple juice and apple sauce. 2004/1021076 GLP, unpublished RIP2004-2156	
AIIA-6.3	Skorzynski, S.	1994	CL 801,757: Freezer storage stability of CL 801,757 residues in apples. TB-326-015 GLP, unpublished RIP2004-2155	
AIIA-6.5.1	McCraken, B.	2003	BAS 318 I (tebufenpyrad): Effects of processing on the nature of the residues due to hydrolysis. 2002/5004594 GLP, unpublished RIP2004-2158	
AIIA-6.5.2	Smalley, R.	2003	Processing study on the residue behaviour of BAS 318 I in apples after application of BAS 318 00 I under field conditions in France (N and S), Germany and Italy, 2001. 2003/1004354 GLP, unpublished RIP2004-2159	

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B.8 Environmental fate and behaviour

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AIIA-7.1.1.2.2	Edwards, J.	2004	Freezer storage stability of BAS 318 I (tebufenpyrad) and metabolites CL 810,729 and CL 810,721 in soil. 2004/1019798 GLP, unpublished BOD2004-844	
AIIA-7.1.1.2.2	Smalley, R.	2003	Field soil dissipation of BAS 318 I in the formulation BAS 318 00 I on bare soil in France (S) and Spain, 2001 - 2002. 2003/1004350 GLP, unpublished BOD2004-843	
AIIA-7.1.2	Hatzenbeler, C.	2001	Tebufenpyrad (BAS 318 I): Adsorption/desorption on soils. TB-620-014 GLP, unpublished BOD2004-846	
AIIA-7.1.2	Voelkel, W.	2004	Adsorption/Desorption of CL 810,728 (metabolite of tebufenpyrad, BAS 318 I) on soils. 2004/1007842 GLP, unpublished BOD2004-848	
AIIA-7.2.1.1	McCracken, B. and Rice, P.	2003	BAS 318 I (tebufenpyrad): Effects of processing on the nature of the residues due to hydrolysis. 2002/5004594 GLP, unpublished WAS2004-356	
AIIA-7.2.1.2	David, M.D.	2003	Natural water photolysis of BAS 318 I (tebufenpyrad). 2002/5004589 GLP, unpublished LUF2004-140	
AIIA-7.2.2	Mangels, G.	2000	Tebufenpyrad (AC 801,757): Estimation of the photochemical oxidation rate in the atmosphere. TB-321-001 GLP, unpublished LUF2004-139	

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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	Reports⁵ on previous use in granting national authorisations
AIIA-3.4	Langewald, J.	2006	Screening tests to evaluate the potential insecticidal activity of CL 810 721 (Metabolite of Tebufenpyrad, BAS 318 I) to different insect species 2006/1002558 not GLP, unpublished BIO2007-1479	
AIIA-8.2.1	Peither, A.	2004	Acute toxicity of tebufenpyrad (BAS 318 I) to Zebra fish (<i>Brachydanio rerio</i>) in a 96-hour flow-through test. 2004/1011094 GLP, unpublished WAT2004-1003	
AIIA-8.2.1	Peither, A.	2004	Acute toxicity of tebufenpyrad (BAS 318 I) to Rice fish (<i>Oryzias latipes</i>) in a 96-hour flow-through test. 2004/1011096 GLP, unpublished WAT2004-1002	
AIIA-8.2.1	Peither, A.	2004	Acute toxicity of tebufenpyrad (BAS 318 I) to Fathead minnow (<i>Pimephales promelas</i>) in a 96-hour flow-through test. 2004/1011095 GLP, unpublished WAT2004-1001	
AIIA-8.2.1	Zok, S.	2002	BAS 318 I - Acute toxicity study on the Bluegill sunfish (<i>Lepomis macrochirus</i>) in a flow through sytem over 96 hours. 2002/1005256 GLP, unpublished WAT2004-999	
AIIA-8.2.3	Chapleo, S.	2003	Bioaccumulation and metabolism of [¹⁴ C]-tebufenpyrad in Rainbow trout (OECD guidelines for the testing of chemicals, document 305). 2003/1009445 GLP, unpublished WAT2004-1006	

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AIIA-8.2.4	Jatzek, H.-J.	2003	Reg.No. 411 069 1 (metabolite of BAS 318 I, tebufenpyrad) - Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> Straus. 2003/1004530 GLP, unpublished WAT2004-1008	
AIIA-8.2.4	Jatzek, H.-J.	2003	BAS 318 I - Determination of the acute effect on the swimming ability of the Water flea <i>Daphnia magna</i> Straus. 2003/1004531 GLP, unpublished WAT2004-1007	
AIIA-8.2.6	Jatzek, H.-J.	2003	Reg.No. 411 069 1 (metabolite of BAS 318 I, tebufenpyrad) - Determination of the inhibitory effect on the cell multiplication of unicellular green algae. 2003/1004549 GLP, unpublished WAT2004-1009	
AIIA-8.3.1.1	Strnad, S.P. and Mulligan, E.	2002	Acute toxicity of technical tebufenpyrad (AC 801,757) to the Honey bee, <i>Apis mellifera</i> . 2002/5003794 GLP, unpublished BIE2004-185	
AIIA-8.4.1	Schmidt, T.	2004	Acute toxicity of CL 810,728 (metabolite of tebufenpyrad, BAS 318 I) to the earth-worm, <i>Eisenia fetida</i> , in a 14-day test. 2004/1011093 GLP, unpublished ARW2004-246	
AIIA-8.4.1	Staebler, D.	2003	Acute toxicity of CL 810,729 (metabolite of BAS 318 I) on earthworms, <i>Eisenia fetida</i> , using an artificial soil test. 2003/1004520 GLP, unpublished ARW2004-245	
AIIA-8.4.1	Staebler, D.	2003	Acute toxicity of CL 810,721 (metabolite of BAS 318 I) on earthworms, <i>Eisenia fetida</i> , using an artificial soil test. 2003/1004521 GLP, unpublished ARW2004-244	

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AIIA-8.5	Koelzer, U.	2003	Effects of CL 810,729 (metabolite of BAS 318 I) on the activity of the soil microflora, nitrogen transformation test. 2003/1004509 GLP, unpublished BMF2004-116	
AIIA-8.5	Koelzer, U.	2003	Effects of CL 810,729 (metabolite of BAS 318 I) on the activity of the soil microflora, carbon transformation test. 2003/1004510 GLP, unpublished BMF2004-115	
AIIA-8.5	Koelzer, U.	2003	Effects of CL 810,721 (metabolite of BAS 318 I) on the activity of the soil microflora, nitrogen transformation test. 2003/1004511 GLP, unpublished BMF2004-114	
AIIA-8.5	Koelzer, U.	2003	Effects of CL 810,721 (metabolite of BAS 318 I) on the activity of the soil microflora, carbon transformation test. 2003/1004512 GLP, unpublished BMF2004-113	