



## **ACLONIFEN**

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 1.0

**Rapporteur Member State: Germany**

**November 2008**

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Version 1.0 - (05.11.2008)

**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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not BVL registration number</b>	<b>Reports on previous use in granting national authorizations</b>
AIIA-1.9; AIIA-1.10; AIIA-1.11	Feucht, G.	2005	Amendment 1: Technical aclonifen analysis and certification. C048562 GLP, unpublished CONFIDENTIAL CHE2005-1635	
AIIA-1.9	Riegner, K.	2005	Justification of the Content of Aclonifen in Aclonifen TGAS. C048253 not GLP, unpublished CONFIDENTIAL CHE2005-1634	
AIIA-1.10	Riegner, K.	2005	Justification of the Impurity Contents for RPA403348 and Phenol in Aclonifen TGAS. C048254 not GLP, unpublished CONFIDENTIAL CHE2005-1633	
AIIA-2.3.2	Bogdoll, B. and Lemke, G.	2005	Henry's Law Constant of Aclonifen Code: AE F068300. C048312 not GLP, unpublished CHE2005-1632	
AIIA-2.9.2	Oddy, A. and Jacob, O.	2003	[ <sup>14</sup> C]-aclonifen: Aqueous photolysis at pH 7. C031518 GLP, unpublished CHE2005-65	
AIIA-4.1.1; AIIA-4.1.3.1; AIIA-4.1.3.2; AIIA-4.1.3.3; AIIA-4.1.3.4	Emeric, G.T.	1999	Technical aclonifen HPLC determination of active ingredient. R007417 GLP, unpublished CHE2005-73	

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AIIA-4.1.2; AIIA-4.1.3.1; AIIA-4.1.3.2; AIIA-4.1.3.3; AIIA-4.1.3.4	Emeric, G.T.	1999	Technical aclonifen HPLC determination of methanol. R008574 GLP, unpublished CONFIDENTIAL CHE2005-165	
AIIA-4.1.2; AIIA-4.1.3.1; AIIA-4.1.3.2; AIIA-4.1.3.3; AIIA-4.1.3.4	Feucht, G.	2005	Amendment 1: Technical aclonifen HPLC determination of main impurities Method A-993-03-99. C048561 ! R&D/CRLD/AN/9916193 (99-17) GLP, unpublished CONFIDENTIAL CHE2005-1636	
AIIA-4.1.2	Zöllner, P.	2006	Structure confirmation of impurities in technical aclonifen. M-265413-01-1 not GLP, unpublished CONFIDENTIAL CHE2006-346	
AIIA-4.2.1	Ballesteros, C.	2005	Analytical method 00889 for the determination of residues of aclonifen in/on potato by GC/MS. M-247795-01-1; MR-103/04 GLP, unpublished MET2006-492	
AIIA-4.2.1	Bourgade C., Diot R.	2005	Analytical method 00950 for the determination of residues of aclonifen in/on plants by HPLC-MS/MS M-262314-01-1 GLP, unpublished	
AIIA-4.2.1	Class, T.	1999	Aclonifen: Assessment and Validation of the Multi-Residue Enforcement Method DFG S19 with Modified Extraction for the Determination of Residues of Aclonifen in Cereals (Wheat, Grain and Straw, Barley Grain and Straw, Corn Grain and Silage). R007421 GLP, unpublished MET2005-66	

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AIIA-4.2.1	Davies, P.	2002	Residues at harvest in sunflowers European Union (Northern zone) 2001 Aclonifen water miscible suspension concentrate (SC) 49.59 % w/w (600 g/L) Code: AE F068300 00 SC50 A202. C021765 GLP, unpublished MET2005-65	
AIIA-4.2.1	Guillet M. and Simonin, B.	1990	Aclonifen - Analytical method for the determination of aclonifen residues in sunflower. R001471 not GLP, unpublished MET2005-62	
AIIA-4.2.1	Laporte, F.	2003	Validation of the multi-residue enforcement method DFG S19 (extended revision) for the determination of aclonifen in animal matrices. Code: AE F068300 C031065 GLP, unpublished MET2005-68	
AIIA-4.2.1	Laporte, F.	2003	Validation of the multi-residue enforcement method DFG S19 (extended revision) for the determination of aclonifen in plant matrices. Code: AE F068300 C031064 GLP, unpublished MET2005-67	
AIIA-4.2.1	Maestracci, M.	1997	Aclonifen and oxadiargyl, formulation EXP31443A (SC), Trials Italy 1996-1997, Residues in sunflower (seed, oil and pressed cake). R003246 GLP, unpublished MET2005-64	
AIIA-4.2.2	Craig, A., Pirie, L.M., Doran, A.M. and McGuire, G.M.	2002	Aclonifen: Validation of an analytical method to determine residues of aclonifen in soil. C020037 GLP, unpublished MET2005-72	
AIIA-4.2.3	Fuchsichler, G.	2000	Validation of an Analytical Method for the Determination of Aclonifen in Drinking water. R007422 GLP, unpublished MET2005-73	

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**B.6 Toxicology and metabolism**

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AIIA-5.1	Mackenzie, E.	2008	Aclonifen: A comparison of metabolites observed in plants and the rat VC07023-02, MLCLX020, M-297581-01-1 Not GLP, unpublished ASB2008-539	
AIIA-5.3.3	Chevalier, G.	2002	4-week toxicity study by cutaneous route in rats aclonifen. C021862 GLP, unpublished TOX2005-98	
AIIA-5.5	Pallen, C.	2001	24-Month dietary study in the rat - BASF Project 71S001/8401 LPT Project Statistical evaluation of thyroid C-cell tumors for Austrian official statistical analysis report aclonifen. C013814 not GLP, unpublished TOX2005-109	
AIIA-5.5	Semino, G.	2006	Position paper on the proposed classification with R40. Code: AE F068300 Not GLP, unpublished M-282519-01-1 ASB2008-538	
AIIA-5.5	Wason, S.	2004	Chronic toxicity and carcinogenicity study of aclonifen in the Wistar rat by dietary administration (24-month report). C034454 GLP, unpublished TOX2005-110	
AIIA-5.6.1	Pallen, C.	1997	Aclonifen: Two-generation reproduction toxicity study with CME - 127 in the rat - Project 030644, Document No. 127AD-453-001 (R.C.C) - Statistical analysis report. R007436 not GLP, unpublished TOX2005-114	
AIIA-5.8.2	Herbold, B.	2006	AE F068300 (aclonifen) (tested as aclonifen techn.): Salmonella/Microsome test plate incorporation and preincubation method. T 1076125 ! M-266365-01-1 GLP, unpublished TOX2006-761	

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**B.7 Residues**

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AIIA-6.0	Uceda, L., and Kieken, J.L.	2004	Aclonifen: Storage stability at around -20 degrees Celsius in sunflower seed, pea and tomato. C041932 GLP, unpublished RIP2005-73	
AIIA-6.1	MacKenzie, E.	2008	Aclonifen: A comparison of metabolites observed in plants and the rat M-297581-01-1; VC07023-02 Not GLP, unpublished ASB 2008-539	
AIIA-6.3	Davies, P.	2002	Residues at harvest in sunflowers European Union (Northern zone) 2001 aclonifen water miscible suspension concentrate (SC) 49.59 % w/w (600 g/L) Code: AE F068300 00 SC50 A202. C021765 GLP, unpublished RIP2005-93	
AIIA-6.3	Muller, M.-A.	1992	Aclonifen - Formulation EXP30506 (EW) - Trials France 1990 - Residues in the sunflower (seed). C028701 ! AG/CRLD/AN/9115915 not GLP, unpublished RIP2005-80	
AIIA-6.3	Muller, M.-A.	1991	ACLONIFEN - Formulation EXP30506 (EW) - Essais France 1990 - Residues dans le Tournesol (graine). R007163 ! AG/CRLD/AN/9115915 not GLP, unpublished RIP2005-78	
AIIA-6.3	Muller, M.-A.	1995	Aclonifen - Flurtamone - Formulation EXP30985A (SC) Trials conducted in France 1994 - Residues in sunflowers (seed). C028887 ! R&D/CRLD/AN/bd/9515133 not GLP, unpublished RIP2005-92	
AIIA-6.3	Muller, M.-A.	1994	Aclonifen - Oxadiazon - Formulation EXP30825A (EC) Trials conducted in France 1992 - Residues in sunflowers (seed). C028888 ! R&D/CRLD/AN/bd/9415393 GLP, unpublished RIP2005-88	

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AIIA-6.3	Muller, M.A.	1992	Aclonifen - Oxadiazon - Formulation EXP30825 (EC) Essai France 1991 Residus dans le tournesol. R001869 ! R&D/CRLD/AN/vp/9216956 GLP, unpublished RIP2005-85	
AIIA-6.3	Muller, M.-A.	1992	Aclonifen - Oxadiazon - Formulation EXP30825 (EC) - Trials France 1991 - Residues in the sunflower. C028699 ! R%D/CRLD/AN/vp/9216956 not GLP, unpublished RIP2005-86	
AIIA-6.3	Muller, M.-A.	1995	Aclonifen - Flurtamone - Formulation EXP30985A (SC) Essais France 1994 Residus dans le tournesol (graine). R002544 ! R&D/CRLD/AN/bd/9515133 GLP, unpublished RIP2005-91	
AIIA-6.3	Muller, M.-A.	1994	Aclonifen - Oxadiazon - Formulation EXP30825A (EC) - Essai France 1992 - Residus dans le tournesol (graine). R002376 ! R&D/CRLD/AN/bd/9415393 GLP, unpublished RIP2005-87	
AIIA-6.3	Muller, M.-A.	1992	Aclonifen - Oxadiazon - Formulation EXP30642 (EW) - Trials France 1991 - Residues in the sunflower. C028697 ! R&D/CRLD/AN/vp/9216953 not GLP, unpublished RIP2005-84	
AIIA-6.3	Muller, M.-A.	1992	Aclonifen - Oxadiazon - Formulation EXP30642 (EW) Essai France 1991 Residus dans le tournesol. R001865 ! R&D/CRLD/AN/vp/9216953 GLP, unpublished RIP2005-83	
AIIA-6.3	Muller, M.-A.	1991	Aclonifen - Oxadiazon - Formulation EXP30642 (EW) - Trials France 1990 - Residues in the sunflower. C028702 ! AG/CRLD/AN/9115829 not GLP, unpublished RIP2005-82	

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AIIA-6.3	Muller, M.-A.	1991	Aclonifen - Oxadiazon - Formulation EXP30642 (EW) - Essais France 1990 - residues dans le tournesol. R001561 ! AG/CRLD/AN/9115829 not GLP, unpublished RIP2005-81	
AIIA-6.5.2	Maestracci, M.	1997	Aclonifen and Oxadiargyl Formulation EXP31443A (SC) Trials Italy 1996-1997 Residues in sunflower (seed, oil and pressed cake). R003246 GLP, unpublished RIP2005-97	
AIIA-6.5.2	Maestracci, M.	1998	Aclonifen - Oxadiargyl - Formulation EXP31443A (SC) Trials Italy 1996-1997 Residues in sunflower (seed, oil and pressed cake). R003470 GLP, unpublished RIP2005-98	
AIIA-6.5.2	Maestracci, M.	1998	Aclonifen - Formulation EXP04209E (SC) Trials Italy 1996 Residues in sunflower (seed, oil and pressed cake). C019847 ! R&D/CRLD/AN/dbe/9716867 GLP, unpublished RIP2005-96	
AIIA-6.5.2	Muller, M.-A.	1994	Aclonifen - Flurtamone - Formulation EXP30985A (SC) Trials in France 1993 Residues in sunflowers (oil and oil cake). C035828 ! R&D/CRLD/AN/cb/9416504 not GLP, unpublished RIP2005-95	
AIIA-6.5.2	Muller, M.-A.	1994	Aclonifen - Flurtamone - Formulation EXP30985A (SC) Essais France 1993 - Residues dans le tournesol (huile et tourteau). R007259 ! R&D/CRLD/AN/cb/9416504 GLP, unpublished RIP2005-94	
AIIA-6.6	McEwen, A.	2003	[Aniline-U- <sup>14</sup> C]-aclonifen: A confined Crop Rotation Study. C031669 GLP, unpublished RIP2005-99	

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AIIA-6.6	Muller, M.-A.	1990	Aclonifen Formulation EXP 30506 (EW) French trials 1989 Residues in maize (silage and grain). C035842 not GLP, unpublished RIP2005-101	
AIIA-6.6	Muller, M.-A.	1990	Aclonifen Formulation EXP30506 (EW) Essais France 1989 Residus dans le maïs (ensilage et grain). R007137 ! AG/CRLD/AN/9015939 not GLP, unpublished RIP2005-100	
AIIA-6.6	Anonymous	1983	Berichtsbogen - Report form for residue analysis with plant protection agent - Bandur - Winter wheat (1980 - 1982). C032921 not GLP, unpublished RIP2005-102	

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**B.8 Environmental fate and behaviour**

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AIIA-7.1.1.1.1; AIIA-7.1.1.2.1	Newby, S. and Schanné, C.	1995	1 <sup>st</sup> Amendment to Report - [ <sup>14</sup> C]-aclonifen: Soil degradation under various experimental conditions in accordance with the Danish pesticide registration requirements. R008566 GLP, unpublished BOD2005-34	
AIIA-7.1.1.1.1; AIIA-7.1.1.2.1	Schanné, C.	1994	[ <sup>14</sup> C]-aclonifen: Soil degradation under various experimental conditions in accordance with the Danish pesticide registration requirements. R007085 ! Rep.No. 200857 GLP, unpublished BOD2005-33	
AIIA 7.1.1.1.2	Mackenzie, E.	2007	Extraction efficiency in aclonifen soil studies Report-No.: M-291254-01-1 GLP, unpublished	
AIIA-7.1.1.2.1	Hardy, I.	2006	Aclonifen - Kinetic evaluation of soil laboratory studies. M-266704-01-1 GLP, unpublished BOD2006-202	
AIIA 7.1.1.2.1.2	Hardy, I. and Patel, M.	2008	Kinetic Modelling Analysis of Aclonifen from Aerobic Soil Degradation Studies Normalised to 20 °C and pF2, Report-No. VC/08/016, M-300678-01-1 Not GLP, unpublished	
AIIA-7.1.1.2.2	Duncan, P. and Doran, A.	2003	Aclonifen: Field soil dissipation study in Southern Europe. C032811 ! Rep.No. 680375 GLP, unpublished BOD2005-39	
AIIA-7.1.1.2.2	Hardy, I.	2006	Aclonifen - Re-evaluation of aclonifen field dissipation studies. M-266725-01-1 GLP, unpublished BOD2006-203	
AIIA-7.1.3.3	Cooper, I. and Hardy, I.	2003	Predicted environmental concentrations in groundwater (PEC <sub>gw</sub> ) of aclonifen using the FOCUS groundwater scenarios. C032385 not GLP, unpublished BOD2005-46	

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AIIA-7.2.1.2	Oddy A. and Jacob, O.	2003	[ <sup>14</sup> C]-aclonifen : Aqueous photolysis at pH 7. C031518 ! Rep.No. 38371 GLP, unpublished LUF2005-5	
AIIA-7.2.1.3.1	Voigt, H.	1990	Ready biodegradability of aclonifen with activated sludge (28 days). R003640 ! Rep.No. 443343 GLP, unpublished WAS2005-37	
AIIA 7.2.1.3.2	Hardy, I. and Patel, M.	2008	Aclonifen: Kinetic Modelling Analysis of Data from a Water Sedi-ment Study , Report-No. VC/08/016B, M-300702-01-1 Not GLP, unpublished	

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**B.9 Ecotoxicology**

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AIIA-8.1.2	Barfknecht, R.	2003	5-day-dietary LC <sub>50</sub> for Bobwhite quail ( <i>Colinus virginianus</i> ), aclonifen (tech. as). C038216 GLP, unpublished AVS2005-20	
AIIA-8.2.7	Sewell, I.G. and McKenzie, J.	2004	Sediment-water chironomid toxicity test using spiked sediment aclonifen (AE F068300). C039873 GLP, unpublished WAT2005-36	
AIIA-8.3.2; AIIIA-10.5.1	Jacobs, G.	2002	AE F068300 00 SC50 A203 = EXP04209E (Bandur): Laboratory dose-reponse test to evaluate the effect on survival and reproduction of the predaceous mite <i>Hypoaspis aculeifer</i> Canestrini (Acari, Laelapidae) in standard soil (LUFA 2.1). C029557 GLP, unpublished ANA2005-30	
AIIA-8.3.2; AIIIA-10.5.1	Waltersdorfer, A.	2003	Toxicity to the Predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseidae) in the laboratory aclonifen water miscible suspension concentrate 600 g/L code: AE F068300 00 SC50 A203. C032823 ! CW02/082 GLP, unpublished ANA2005-27	
AIIA-8.5	Eichler	1984	Prüfung des Einflusses von Aclonifen (CME 127) auf die Bodenmikroflora - Endbericht -. C035107 not GLP, unpublished BMF2005-7	
AIIA-8.5	Eichler	1984	Study to determine the effect of aclonifen (CME 127) on soil microflora - Definitive Report Translation C035107. R007411 not GLP, unpublished BMF2005-6	

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AIIA-8.5	Forster, J.	1994	A laboratory assessment of the effects of aclonifen on asymbiotic nitrogen fixation in soils. R007082 GLP, unpublished BMF2005-8	
AIIA-8.6; AIII A-10.8	Spatz, B. and Meinerling, M.	2003	Effects of AE F068300 00 SC50 A2 (EXP04209E) on Terrestrial (Non-Target) Plants - Higher Tier Test with <i>Lactuca sativa</i> . C040615 ! 17192094 GLP, unpublished PFL2004-83	
AIIA-8.6; AIII A-10.8	Spatz, B. and Meinerling, M.	2004	Effects of AE F068300 00 SC50 A2 (EXP04209E) on Terrestrial (Non-Target) Plants - Higher Tier Test with <i>Brassica napus</i> and <i>Lolium perenne</i> . C040617 ! 17191094 GLP, unpublished PFL2004-82	
AIIA-8.7	Watt, S.D.	1993	Bandur EXP04209 - Acute toxicity in bacteria ( <i>Pseudomonas putida</i> ). R007902 GLP, unpublished WAT2005-41	

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