



## **SULCOTRIONE**

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 2.0

**Rapporteur Member State: Germany**

**March 2009**

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Version 2.0 - (23.03.2009)

**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**

<b>Author(s)</b>	<b>Annex point/ reference number</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>
Bogdoll, B.	AIIA-1.11	2004	Certificate of Analysis: AE F104238 00 1D91 0001. AZ 11846 ! MO-04-007713 GLP, unpublished CHE2004-2206	
Feucht, G.	AIIA-1.11	2004	Certificate of Analysis: AE F104238 00 1D93 0001. AZ 11973 ! MO-04-009346 GLP, unpublished CHE2004-2207	
Feucht, G.	AIIA-1.11	2004	Analytical profile of five typical production batches - AE F104238 (Sulcotrione) - (Technical grade active ingredient). PA04/053 ! MO-04-008021 GLP, unpublished CHE2004-2205	
Shipp, E.	AIIA-1.11	2004	Sulcotrione - Toxicological assessment of maximum levels of ICIA0051-Deschloro-analogue, ICIA0051-Benzo-CHD, and ICIA0051-Bromo-analogue in technical Sulcotrione compared to toxicologically tested technical sulcotrione. MO-04-009595 not GLP, unpublished CHE2004-2208	
Moffatt, F.	AIIA-2.9.3	1994	ICIA0051: Quantum yield and environmental half-life for direct phototransformation in aqueous solution. RJ1657B ! MO-01-010617 GLP, unpublished CHE2004-2216	

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Schneider, K revised by Le Gren, I., Haack K.-J	AIIA-1.9 AIIA-1.10 AIIA-1.11	2008	Tier 2 Summary of the Identity of the Active Substance Sulcotrione, document no. M-089884-02-1 not GLP, unpublished BVL no. 1746257	
Billian, P.	AIIA-4.2.1	2004	Enforcement method 00847 for the determination of residues of sulcotrione and CMSBA in/on plant material by HPLC-MS/MS. 00847 ! MO-04-001880 GLP, unpublished MET2004-958	
Billian, P.	AIIA-4.2.1	2003	Supplement E001 to the analytical method 00730 for the determination of residues of sulcotrione and CMSBA in/on ryegrass (green material) by HPLC-MS/MS. 00730/E001 ! MO-03-009090 GLP, unpublished MET2004-957	
Brumhard, B.	AIIA-4.2.1	2004	Independent laboratory validation of method 00847 for the determination of residues of sulcotrione and CMSBA in/on matrices of plant origin by HPLC-MS/MS. MR-027/04 ! MO-04-007146 GLP, unpublished MET2004-960	
Brumhard, B.	AIIA-4.2.1	2003	Independent laboratory validation of the enforcement method 00730 for the determination of residues of sulcotrione and CMSBA in/on matrices of plant origin by HPLC-MS/MS. MR-386/02 ! MO-03-003949 GLP, unpublished MET2004-959	
Ernst-Diefenbach, R.	AIIA-4.1.2	2004	Determination of the total cyanide content of sulcotrione (AE F104238) - Batches DEBG059026, DEBG059495, DEBG059720, DEBG060562 and DEBG061427. MO-04-008026 ! PA04/053 GLP, unpublished CHE2004-2225	
Feucht, G. and Ruppmann, G.	AIIA-4.1.2	2004	Analytical method - Determination of Toluene (AE F125577) and Triethylamine (AE 0171388) in technical grade and pure Sulcotrione (AE F104238) by gas chromatography (GC). AM003104FP1 ! MO-04-008040 GLP, unpublished CHE2004-2224	

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Feucht, G. and Ruppmann, G.	AIIA-4.1.2	2004	Analytical method - Determination of impurities in technical grade and pure sulcotrione (AE F104238) by high performance liquid chromatography (HPLC). AM002804FP2 ! MO-04-008034 not GLP, unpublished CHE2004-2222	
Feucht, G. and Ruppmann, G.	AIIA-4.1.2	2004	Analytical method - Determination of impurities in technical grade and pure sulcotrione (AE F104238) by high performance liquid chromatography (HPLC). AM002804FP1 ! MO-04-008031 not GLP, unpublished CHE2004-2220	
Feucht, G. and Ruppmann, G.	AIIA-4.1.3	2004	Validation of GC- method AM003104FP1 - Determination of Toluene (AE F125577) and Triethylamine (AE 0171388) in technical grade and pure Sulcotrione (AE F104238) by gas chromatography (GC). AF04/025 ! MO-04-008041 not GLP, unpublished CHE2004-2230	
Feucht, G. and Ruppmann, G.	AIIA-4.1.3	2004	Validation of HPLC-method AM002804FP1 - Determination of impurities in technical grade and pure Sulcotrione (AE F104238) by high performance liquid chromatography (HPLC). AF04/021 ! MO-04-008037 not GLP, unpublished CHE2004-2227	
Graney, R.	AIIA-4.2.1	2004	Erklaerung zur Unabhaengigkeit der Laboratorien bei der Durchfuehrung von ILV und Methodvalidierung. MO-04-012315 GLP, unpublished MET2004-961	
Harris, R.	AIIA-4.2.3	1997	Residue analytical method for the analysis of ICIA0051 and CMBA in water. RAM 203/04 ! MO-01-018563 not GLP, unpublished MET2004-968	
Muehlen, U. zur	AIIA-4.1.1	2003	Sulcotrione Assay of technical grade active ingredient ; HPLC - internal standard. 2005-0012401-02 ! MO-02-015581 not GLP, unpublished CHE2004-2219	

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Muehlen, U. zur	AIIA-4.1.2	2003	Sulcotrione ICIA 0051-CHD in technical grade active ingredient - HPLC - external standard. 2005-0013701-03 ! MO-03-006444 not GLP, unpublished CHE2004-2223	
Muehlen, U. zur	AIIA-4.1.2	2003	Sulcotrione Byproducts - HPLC - external standard. 2005-0014301-03 ! MO-03-006436 not GLP, unpublished CHE2004-2221	
Muehlen, U. zur	AIIA-4.1.3	2003	Validation of HPLC-method 2005-0014301-03 - Sulcotrione - byproducts in technical grade active ingredient. VB1-2005-0014301 ! MO-03-006443 not GLP, unpublished CHE2004-2228	
Muehlen, U. zur	AIIA-4.1.3	2003	Validation of HPLC-method 2005-0013701-02 - ICIA 0051-CHD in technical grade active ingredient. VB1-2005-0013701 ! MO-03-006445 not GLP, unpublished CHE2004-2229	
Muehlen, U. zur	AIIA-4.1.3	2003	Validation of HPLC-method 2005-0012401-02 - Sulcotrione Assay of technical grade active ingredient. VB1-2005-0012401 ! MO-03-006435 not GLP, unpublished CHE2004-2226	
Neuss, B.	AIIA-4.2.1	2003	Analytical method for sulcotione (ICI0051) in animal tissues. PFNUB01 ! MO-03-006127 GLP, unpublished MET2004-962	
Newcombe, A.	AIIA-4.2.2	1995	Residue analytical method for the analysis of ICIA0051 and CMBA in soil. RAM 202/02 ! MO-01-017521 not GLP, unpublished MET2004-965	
Newcombe, A.	AIIA-4.2.2	1997	Residue analytical method for the analysis of ICIA0051 and CMBA in soil. RAM 202/03 ! MO-01-017528 not GLP, unpublished MET2004-966	

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Sur, R.	AIIA-4.2.1	2002	Analytical method 00730 for the determination of residues of sulcotrione and CMSBA in/on corn by HPLC-MS/MS. 00730 ! MO-02-006049 GLP, unpublished MET2004-956	

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## B.6 Toxicology and metabolism

Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations
Callander, R.D.	AIIA-5.4.1	1992	ICIA 0051: An evaluation of mutagenic potential using <i>S. typhimurium</i> and <i>E. coli</i> . CTL/P/3739 ! MO-01-010945 GLP, unpublished TOX2004-2844	
Callander, R.D.	AIIA-5.8.1	1991	CMSBA: An evaluation of mutagenic potential using <i>S. typhimurium</i> and <i>E. coli</i> . CTL/P/3293 ! MO-01-010898 GLP, unpublished TOX2004-2858	Submitted in NL before application for Annex I inclusion
Cameron, D.M.	AIIA-5.1	1995	<sup>14</sup> C-R44520: Metabolism in lactating goats - In-life study. ISN342/950674 ! MO-01-010201 GLP, unpublished TOX2004-2827	
Clay, P.	AIIA-5.8.1	1997	CMSBA: (2-chloro-4-methanesulfonyl benzoic acid): L5178Y TK mouse lymphoma mutation assay. CTL/P/5446 ! MO-01-010903 GLP, unpublished TOX2004-2859	
Diesing, L.	AIIA-5.7	2003	Is it necessary to test sulcotrione for a specific neurotoxic potential? MO-03-006325 not GLP, unpublished TOX2004-2854	
Earl, V.L. and Long, P.B.	AIIA-5.1	1995	2-chloro-4-methylsulfonyl benzoic acid (R44520): Metabolism in lactating goats following dosing at 10 mg kg <sup>-1</sup> in the diet - Nature of the residues in milk and tissues. RJ1919B ! MO-01-010212 GLP, unpublished TOX2004-2825	Submitted in NL before application for Annex I inclusion
Griffiths, K. and Mackay, J.M.	AIIA-5.4.2	1992	ICIA0051: An evaluation in the mouse micronucleus test. CTL/P/3820 ! MO-01-010951 GLP, unpublished TOX2004-2850	Submitted in NL before application for Annex I inclusion
Kilgour, J.D.	AIIA-5.8.1	1999	CMSBA: 28 day inhalation toxicity study in the rat (nose only exposure). CTL/P/6148 ! MO-01-010663 GLP, unpublished TOX2004-2857	

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Kroetlinger, F.	AIIA-5.3.3	2003	ICIA0051 (Sulcotrione): Study for subacute dermal toxicity in rats (four-week application). AT00431 ! MO-03-006553 GLP, unpublished TOX2004-2843	
Kroetlinger, F.; Hartmann, E.; Hildebrand, H. and Schmidt, U.	AIIA-5.3.2	2003	ICIA 0051: Subchronic mechanistic study in rats on the causal relationship between increased levels of tyrosine and effects on liver and kidney. AT00590 ! MO-03-009076 not GLP, unpublished TOX2004-2830	
Majeska, J.B.	AIIA-5.4.1	1985	SC-0051: Mutagenicity evaluation in <i>salmonella typhimurium</i> . T-11964 ! MO-01-010997 not GLP, unpublished TOX2004-2846	
Majeska, J.B.	AIIA-5.4.1	1984	SC-0051: Mutagenicity evaluation in <i>salmonella typhimurium</i> . T-11960 ! MO-01-010979 not GLP, unpublished TOX2004-2845	
Majeska, J.B.	AIIA-5.4.2	1986	SC-0051 technical: Mutagenicity evaluation in bone marrow micronucleus. T-12775 ! MO-01-010906 GLP, unpublished TOX2004-2851	
Moxon, M.E.	AIIA-5.3.2	1992	ICIA0051: 16 week oral toxicity study in dogs. CTL/L/4380 ! MO-01-011635 not GLP, unpublished TOX2004-2834	
Parr-Dobrzanski, R.J.;	AIIA-5.8.1	1995	CMSBA: 4-hour acute inhalation toxicity study in the rat. CTL/P/4624 ! MO-01-010592 GLP, unpublished TOX2004-2856	
Peffer, R.C.	AIIA-5.1	1990	ICIA0051: Pharmacokinetics/metabolism probe in the monkey. T-13223 ! MO-01-010632 GLP, unpublished TOX2004-2824	
Peffer, R.C.	AIIA-5.1	1990	ICIA0051 metabolism study in rats: Intravenous and repeated dose. T-13011B ! MO-01-010891 GLP, unpublished TOX2004-2823	

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Rattray, N.J.	AIIA-5.8.1	1997	CMSBA: One generation study in the rat. CTL/P/5496 ! MO-01-010847 GLP, unpublished TOX2004-2863	

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**B.7 Residues**

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Billian, P.	AIIA-6.0	2004	Storage stability of the herbicide sulcotrione (A.S.) and its metabolite 2-chloro-4-methylsulfonylbenzoic acid (CMSBA) in/on corn for 24 months. MR-079/03 GLP, unpublished RIP2004-2397	
Cameron, D.M.	AIIA-6.2	1995	<sup>14</sup> C-R44520 - Metabolism in lactating goats - In-life study. ISN342/950674 GLP, unpublished RIP2004-2398	
Clarke, D.M.; Atger, J.C. and Butters, C.	AIIA-6.3	1999	Residue levels in sweet maize from trials carried out in southern France during 1998. RJ2751B GLP, unpublished RIP2004-2404	
Earl, V.L. and Long, P.B.	AIIA-6.2; AIIA-6.9	1995	2-chloro-4-methylsulfonyl benzoic acid (R44520) - Metabolism in lactating goats following dosing at 10 mg kg <sup>-1</sup> in the diet - Nature of the residues in milk and tissues. RJ1919B GLP, unpublished RIP2004-2400	
Sur, R.	AIIA-6.3	2002	Determination of residues of sulcotrione and CMSBA in/on corn following spray application of Mikado 300 SC in Greece. RA-2195/01 GLP, unpublished RIP2004-2406	
Tummon, O.J.; Earl, M. and Alevra, E.	AIIA-6.3	1996	ICIA0051: Residue levels in maize from a trial carried out in Greece during 1994. RJ2080B GLP, unpublished RIP2004-2405	

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**B.8 Environmental fate and behaviour**

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Moffatt, F.	AIIA-7.2.1.2	1994	ICIA0051: Quantum yield and environmental half life for direct phototransformation in aqueous solution. RJ1657B GLP, unpublished LUF2004-156	Submitted in NL before application for Annex I inclusion
Reinken, G.	AIIA-7.1.1.2.1	2003	Kinetic evaluation of the degradation behaviour of sulcotrione under aerobic laboratory soil conditions. MEF-179/03 not GLP, unpublished BOD2004-930	
Reinken, G. and Meyer, H.	AIIA-7.1.1.2.2; AIIIA-9.1.3	2004	Kinetic evaluation of the dissipation of sulcotrione and its metabolite CMBA under European field conditions. MEF-162/03 not GLP, unpublished BOD2004-932	
Reinken, G.; Meyer, H. and Kaune, M.	AIIA-7.1.3.3	2004	Predicted environmental concentrations of sulcotrione and its metabolite CMBA in groundwater (PEC <sub>gw</sub> ). Use on maize in Europe. MEF-04/127 not GLP, unpublished BOD2004-936	
Reinken, G., Hellpointner, E.	AIIA-7.1.1.2.2	2007	Use of FOCUS normalised DT50 values for exposure and risk assessments of MIKADO® or other sulcotrione containing products in the Netherlands Report No.: MEF-07/402, Edition Number: M-294962-01-1 Not GLP, unpublished BVL no. 1754082	
Runnalls, J.K. and Earl, M.	AIIA-7.1.1.2.2	1997	ICIA0051 and CMBA: Storage stability in frozen soil. RJ2163B GLP, unpublished BOD2004-933	
Simmonds, M. and Early, E.	AIIA-7.1.2	2004	[ <sup>14</sup> C]-Sulcotrione: Adsorption to and desorption from five soils. CX/03/062 GLP, unpublished BOD2004-934	

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Stupp, H.P.	AIIA-7.1.1.1.2	2002	Photolysis of sulcotrione on soil surface. MR-032/02 GLP, unpublished BOD2004-929	
Stupp, H.P.	AIIA-7.1.1.1.2	2003	Anaerobic soil metabolism of sulcotrione. MR-474/02 GLP, unpublished BOD2004-928	

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## B.9 Ecotoxicology

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Barfknecht, R.	AIIA-8.1.2	2003	ICIA 0051-CMSBA techn. as: 5-day-dietary LC <sub>50</sub> to mallard duck ( <i>Anas platyrhynchos</i> ). BAR/LC 013 GLP, unpublished AVS2004-433	
Barfknecht, R.	AIIA-8.1.3	2004	Comment on Report No. 200355 (Study No. SU740801): Effects of technical sulcotrione on mallard reproduction. BAR/COM 001 GLP, unpublished AVS2004-435	
Bätscher, R.	AIIA-8.2.8	2002	Toxicity of sulcotrione-CMSBA to the aquatic higher plant <i>Lemna gibba</i> in a 7-day static growth inhibition test. 843567 GLP, unpublished WAT2004-1089	
Bätscher, R.	AIIA-8.2.8	2002	Toxicity of sulcotrione to the aquatic higher plant <i>Lemna gibba</i> in a 7-day static growth inhibition test. 826007 GLP, unpublished WAT2004-1088	
Bowers, L. M.	AIIA-8.1.3	2003	Effect of technical sulcotrione on mallard reproduction. 200355 GLP, unpublished AVS2004-434	
Bowers, L.M.	AIIA-8.1.3	2004	Effects of technical sulcotrione on mallard reproduction - six-week dietary exposure. 200694 GLP, unpublished AVS2004-436	
Caspers, N.	AIIA-8.7	2002	ICI A0051 - Toxicity to bacteria. 1139 A/01 B GLP, unpublished WAT2004-1090	
Dorgerloh, M.	AIIA-8.2.5	2001	Influence of ICIA0051 (techn.) on the reproduction rate of water fleas in a static renewal laboratory test system. DOM 21048 GLP, unpublished WAT2004-1085	

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Grimes, J.; Hoxter, K.A.; Smith, G.J., Jaber, M. and Lynn, S.P.	AIIA-8.1.2	1991	ICIA 0051: A dietary LC <sub>50</sub> study with the mallard. PROJ.NO. 144-142/T-13092 GLP, unpublished AVS2004-432	
Hoberg, J. R.	AIIA-8.6	1996	CMSBA - Determination of effects on seedling emergence and plant weight of three plant species. 96-3-6435 GLP, unpublished PFL2004-195	
Jackson, D. and Bembridge, J.D.	AIIA 8.4.1	1996	CMSBA: Toxicity of technical material to the earthworm <i>Eisenia fetida</i> in an artificial soil test. RJ2058B GLP, unpublished ARW2004-280	Submitted in NL before application for Annex I inclusion
Kent, S.J., Morris, D.S., Williams, N.J. and Shearing, J.M.	AIIA-8.2.5	1995	CMSBA: Chronic toxicity to <i>Daphnia magna</i> . BL5495/B GLP, unpublished WAT2004-1086	
Kent, S. J., Morris, D.S. and Wallace, S.J.	AIIA-8.2.2.1	1995	CMSBA: The 28 day LC <sub>50</sub> to rainbow trout ( <i>Oncorhynchus mykiss</i> ). BL5470/B GLP, unpublished WAT2004-1081	
Lührs, U.	AIIA-8.4.2	2002	ICIA0051-CMSBA: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. 12512022 GLP, unpublished ARW2004-281	
McMurray, A.	AIIA-8.5	2001	A laboratory assessment of the effects of CMBA (2-chloro-4-methylsulfonyl benzole acid), a metabolite of sulcotrione, on soil microflora respiration and nitrogen transformation according to OECD guidelines. ENV5086 GLP, unpublished BMF2004-142	

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Meister, A.	AIIA-8.6	2002	ICIA0051-CMSBA: Effects on reproduction of the collembola <i>Folsomia candida</i> in artificial soil. 12511016 GLP, unpublished PFL2006-35	
Morris, D.S. and Latham, M.	AIIA-8.7	1996	CMSBA (2-chloro-4-methylsulphonyl benzoic acid): determination of toxicity to <i>Pseudomonas putida</i> . BL5678/B GLP, unpublished WAT2004-1091	Submitted in NL before application for Annex I inclusion
Seyfried, B.	AIIA-8.2.6	2002	Toxicity of sulcotrione to <i>Anabaena flos-aquae</i> (Cyanophyta) in a 72-hour algal growth inhibition test. 816276 GLP, unpublished WAT2004-1087	
Shillabeer, N.	AIIA-8.7	1994	CMSBA: Activated sludge respiration inhibition. RIC0705 not GLP, unpublished WAT2004-1093	
Shillabeer, N.	AIIA-8.7	1998	CMSBA: Activated sludge respiration inhibition. RIC6906 not GLP, unpublished WAT2004-1092	

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