



2,5-DICHLOROBENZOIC ACID METHYLESTER

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

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Version 2 - (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-1.4; AIIA-2	Frauen, M.; Stähler, O. and Stähler, R.	2004	Determination of the Release of Methyl-2,5-dichlorobenzoate and 8-Hydroxy-quinoline from a fortified Rebwachs WF (ASU 70190 F) Formulation in Water. AB 70190-RU-010 not GLP, unpublished CHE2005-1593	
AIIA-1.6; AIIA-1.7; AIIA-1.9; AIIA-1.10; AIIA-1.11; AIIA-2.5.1; AIIA-2.5.2	Class, T.	2004	2,5-Dichlorobenzoic Acid Methyl Ester: Impurity Profiles and Spectra. B 730 G GLP, unpublished CHE2005-1594	
AIIA-1.8	Stähler, G.	2004	Method of manufacture (synthesis pathway) of the active substance Way of synthesis for methyl-2,5-dichlorobenzoate. not GLP, unpublished CHE2005-1595	
AIIA-1.11	Stähler, G.	2004	Statement: Analytical profile of batches. not GLP, unpublished CHE2005-1596	
AIIA-2.1.1; AIIA-2.4.1; AIIA-2.4.2; AIIA-2.7	Frauen, M., Stähler, O., Stähler, R.	2004	Determination of the physical-chemical Properties of Methyl-2,5-dichlorobenzoate. AB70190-FO-012B GLP, unpublished CHE2005-1597	

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AIIA-2.1.2	Keipert, W.	2004	Determination of the Boiling Temperature of 2,5-Dichlorobenzoic Acid Methyl ester. B026/2004 GLP, unpublished CHE2005-1599	
AIIA-2.2	Fischer, A.	2004	Determination of the Relative Density of 2,5-Dichlorobenzoic acid methyl ester. B027/2004 GLP, unpublished CHE2005-1600	
AIIA-2.3.1	Kiss, G.	2006	Final report Determination of the vapour pressure of Methyl-2,5-Dichlorobenzoate. 06/148-323AN GLP, unpublished CHE2006-1415	
AIIA-2.3.1	Schmid, J.	1991	Untersuchungsbericht - Bestimmung der Dampfdruckkurve gemäß OECD 104 an 2,5-Dichlorbenzoesäuremethylester. 91 50 40 527 GLP, unpublished LUF2002-16	
AIIA-2.3.2	Franke, K.	2004	Calculation of the Henry Constant of Methyl-2,5-dichlorobenzoate using the Tool HENRYWIN v3.10. not GLP, unpublished CHE2005-1602	
AIIA-2.5.1; AIIA-2.14	Dardemann, J., Frauen, M.	2006	Determination of physical-chemical Properties of Methyl-2,5 dichlorobenzoate (UV/VIS-Spectra and Surface Tension). AB 70190-FO-012G ! GLP, unpublished CHE2006-1416	
AIIA-2.6	Frauen, M.	2001	Determination of the Solubility of Methyl-2,5-dichlorobenzoate in Water Final Report. AB70190-PC-051 GLP, unpublished CHE2002-435	
AIIA-2.6; AIIA-2.8; AIIA-2.9.1; AIIA-2.9.4	Dardemann J.	2007	Statement: Requests from the authorities on some physical and chemical properties Methyl 2,5-dichlorobenzoate Unpublished report BVL no 1691654	

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AIIA-2.8	Fischer, A.	2004	Determination of the partition coefficient (n-octanol/water) of 2,5-Dichlorobenzoic acid methylester. B028/2004 GLP, unpublished CHE2005-1603	
AIIA-2.9.1	Stähler, G.	2004	Statement: Hydrolysis of pure active substance, rate, metabolites, DT50. not GLP, unpublished CHE2005-1604	
AIIA-2.9.1	Dardemann J.	2007	Amendment to Final Report AB 70190-PC-052A - Determination of the Hydrolysis of Methyl 2,5-dichlorobenzoate Unpublished report Amendment AB70190-PC-052A BVL no 1691664	
AIIA-2.9.2; AIIA-2.9.3	Stähler, G.	2004	Statement: Photolysis of pure active substance, photochemical DT50, metabolites. not GLP, unpublished CHE2005-1605	
AIIA-2.9.4	Franke, K.	2004	Statement: Dissociation in water of pure active substance (pKa values). not GLP, unpublished CHE2005-1606	
AIIA-2.10	Frauen, M.	2001	Estimation of Photo-Chemical Oxidative Degradation. not GLP, unpublished CHE2005-1588	
AIIA-2.11.1	Keipert, W.	2004	Determination of the Flammability of 2.5-Dichlorobenzoic acid methylester. B029/2004 GLP, unpublished CHE2005-1589	
AIIA-2.11.2	Keipert, W.	2004	Determination of the Relative Self-Ignition Temperature of 2.5-Dichlorobenzoic acid methylester. B031/2004 GLP, unpublished CHE2005-1590	
AIIA-2.12	Kiss, G.	2006	Determination of the Flash Point of Methyl-2,5-dichlorobenzoate. 06/148-352AN GLP, unpublished CHE2006-1417	

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AIIA-2.13	Keipert, W.	2004	Determination of the Explosive Properties of 2.5-Dichlorobenzoic acid methylester. B030/2004 GLP, unpublished CHE2005-1591	
AIIA-2.15	Keipert, W.	2004	Determination of the Oxidizing Properties of 2.5-Dichlorobenzoic acid methylester. B032/2004 GLP, unpublished CHE2005-1592	
AIIA-4.1.1	Dardemann, J. and Frauen, M.	2007	Validation of the analytical method for the determination of the active ingredient methyl-2,5-dichlorobenzoate and the relevant impurities in technical material, GLP, unpublished report, Study no AB70190-GM-003B BVL no 1691651	

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- 5.1	Feser-Zügner, W.	2004	Study on the absorption, distribution, excretion and metabolism (ADME) of ¹⁴ C-labelled 2,5-Dichlorobenzoic Acid Methyl Ester after single or repeated intravenous and oral administration to CD [®] rats Study director: Dr. W. Feser-Zügner (November 2004); Report No.: A&M 04-044. BVL no 1663626	
AIIA-5.2.3	Sebestyén, I.	2005	Acute Inhalation Toxicity of 2,5 Dichlorbenzoesäuremethylester (2,5-DCBME) in Rats; LAB International Research Centre Hungary Ltd., Veszprém, HU, No. 04/922-004P Statement of Hirka, G. BVL no 1663636	
AIIA-5.2.6	Stáhl, J.	2005	Skin Sensitization of Test Item 2,5-DCBME in Guinea Pigs by Magnusson and Kligman; LAB International Research Centre Hungary Ltd., Veszprém, HU, No. 04/922-104T Experimental phase: 17.11. – 11.12.2004 BVL no 1663639	
AIIA-5.3.1	Leuschner, J.	2004	2-week dose-range-finding study for a 28-day subchronic oral toxicity study of 2,5 Dichlorobenzoic acid methylester in rats; LPT Laboratory of Pharmacology and Toxicology KG, Hamburg, Germany, Report No. 16897/03, 12.07.2004 BVL no 1663640	
AIIA-5.3.1	Leuschner, J.	2004	28-day subchronic oral toxicity study of 2,5 Dichlorobenzoic acid methyl ester in rats; LPT Laboratory of Pharmacology and Toxicology KG, Hamburg, Germany, Report No. 16840/03, 24.05.2004 BVL no 1663641	
AIIA-5.3.2 AIIA-5.6.1 AIIA-5.6.2 AIIA-5.7	Stähler, G., Schaefer, M.	2007	Scientifically sound argumentation of the non-submission of the reprotox studies under point 5.3.2, 5.6.1, 5.6.2 and 5.7 BVL no 1690641	

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AIIA-5.4.1	Vértesi, A..	2004	Testing of 2,5-DCBME with Bacterial Reverse Mutation Assay; LAB International Research Centre Hungary Ltd, Study code: 04/842-007M, 27 September 2004 BVL no 1663644	
AIIA-5.4.1	Béres, E.	2004	Testing of 2,5-DCBME with in vitro Mammalian Chromosome Aberration Test; LAB International Research Centre Hungary Ltd, Study code: 04/842-020C, 15 October 2004 BVL no 1663646	
AIIA-5.4.1	Béres, E.	2004	Testing of 2,5-DCBME with CHO/HPRT assay, LAB International Research Centre Hungary Ltd., Study code: 04/842-015C, 24 August 2004 BVL no 1663648	
AIIA-5.4.2	Béres, E.	2004	Testing of Mutagenic Effect of Test Item 2,5-DCBME by Mouse Micronucleus Test, LAB International Research Centre Hungary Ltd., Study code: 04/842-013E BVL no 1663651	

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-6.0	Stähler International Registration Department	2005	Statement to residues and plant metabolism BVL no 1663663	

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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	Reports⁴ on previous use in granting national authorisations
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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	Reports⁴ on previous use in granting national authorisations
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