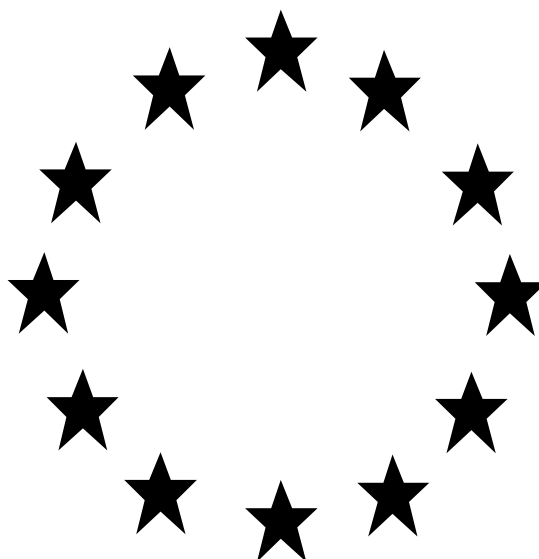




Additional Report to the DAR

- public version -

**Risk assessment provided by the rapporteur Member State
Italy for the existing active substance**

CHLOROPICRIN

**upon resubmission in the framework of the accelerated procedure in
accordance with Commission Regulation (EC) No 33/2008**

Volume 2

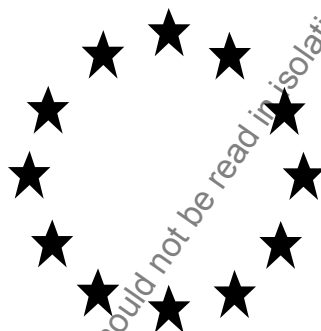
March 2010

Ministry of Health

Rome

Italy

**Addendum to Draft Assessment Report
regarding resubmission of Chloropicrin**



Chloropicrin

Volume 2

**Annex A: List of the tests and studies submitted
and information available**

March 2010

A.1 Identity (Annex IIA 1, 3.1 to 3.4; Annex IIIA 1, 3.1 to 3.7, 3.9 and 11.1)

Active Ingredient - ANNEX II

Not applicable

Plant Protection Product : Chloropicrin 99 - ANNEX III

Not applicable

A.2 Physical and chemical properties (Annex IIA 2; Annex IIIA, 2)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 2.5.1/03	Comb, A.L.	2007a	Chloropicrin: Infrared and Mass Spectra Huntingdon Life Sciences Ltd. Report No. SXC/0003/072428 GLP, Unpublished	Y	European Chloropicrin Group
IIA, 2.15/02	Comb, A.L.	2007b	Chloropicrin: Oxidising Properties Huntingdon Life Sciences Ltd. Report No. SXC/0002/072562 GLP, Unpublished	Y	European Chloropicrin Group

Plant Protection Product : Chloropicrin 99 - ANNEX III

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIIA 2.2.2/02	Comb, A.L.	2007b	Chloropicrin: Oxidising Properties Huntingdon Life Sciences Ltd. Report No. SXC/0002/072562 GLP, Unpublished	Y	European Chloropicrin Group

A.3 Further information (Annex IIA 3; Annex IIIA 3 and 4)

Active Ingredient - ANNEX II

Please refer to the DAR from 2006

Plant Protection Product : Chloropicrin 99 - ANNEX III

Please refer to the DAR from 2006

A.4 Classification, packaging and labelling (Annex IIA 9; Annex IIIA 11.3 and 11.4)

Active Ingredient - ANNEX II

Please refer to the DAR from 2006

Plant Protection Product : Chloropicrin 99 - ANNEX III

Not applicable

A.5 Methods of analysis (Annex IIA, 4; Annex IIIA 5)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 4.2.1/02 ⇒ IIA 1.11/01 Document J	Arndt, T	2009	Analysis and certification of product ingredients in five batches of chloropicrin PTRL West , Inc Report No. 1801W GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.3/03	Todd, M.	2007a	Chloropicrin: Independent Laboratory Validation of methodology for the determination of residues of chloropicrin in tomatoes Huntingdon Life Sciences, Ltd Report No. SXC 0006/072457 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.3/04 ⇒ IIA 6.3.1/05	Zoboli, G.	2009a	Residue Determinations of Chloropicrin in Tomatoes According to the OECD Principles of GLP (Good Laboratory Practice) NEOTRON, S.r.l. Report No. LN93-08 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.3/05 ⇒ IIA 6.3.1/04	Gandhi, J	2009	Gandhi, J., Analysis of Residues of Chloropicrin in Outdoor Grown Tomatoes with Associated Validation in Compliance with Good Laboratory Practice Oxford Analytical Ltd Report No. OA01626 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.3/06	Zoboli, G.	2009b	Determination of Residues of Dichloronitromethane In Tomato. Validation of the Analytical Method NEOTRON, S.r.l. Report No. LN95 (validation) GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.4/01	Todd, M.	2007b	Chloropicrin: validation of methodology for the determination of residues of chloropicrin in two soil types Huntingdon Life Sciences, Ltd Report No. SXC0004/072450 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.5/01	Todd, M.	2007c	Chloropicrin: validation of methodology for the determination of residues of chloropicrin in ground, drinking and surface water)	Y	Chloropicrin Manufacturers Task Force

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
			Huntingdon Life Sciences, Ltd Report No. SCX0007/072387 GLP, Unpublished		
IIA 4.7/01	Todd, M.	2007d	Chloropicrin: validation of methodology for the determination of residues of chloropicrin in air Huntingdon Life Sciences, Ltd Report No. SXC0005/072973 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force
IIA 4.8/02	Airs, D.	2009	Chloropicrin: validation of methodology for the determination of residues of chloropicrin in human blood, porcine muscle and liver) Huntingdon Life Sciences, Ltd Report No. SXC0026 GLP, Unpublished	Y	Chloropicrin Manufacturers Task Force

Plant Protection Product : Chloropicrin 99 - ANNEX III

Not applicable

A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA, 5.1/02	Kidd, G.G., Davidson, J.	2005	[¹⁴ C]-Chloropicrin: Absorption, Distribution, Metabolism and Excretion in the Rat [REDACTED] Report No. 24991 GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.1/03	Sparks, S.E., Quistad, G.B., Casida, J.E.	1997	Chloropicrin: Reactions with Biological Thiols and Metabolism in Mice University of California, Berkeley <i>Chem. Res. Toxicol.</i> , 10, 1001-1007 No GLP, Published	N	-
IIA, 5.1/04	Sparks, S.E., Quistad, G.B., Li, W., Casida, J.E.	1997	Chloropicrin Dechlorination in Relation to Toxic Action University of California, Berkeley <i>J. Biochem. Molecular Toxicology</i> , 14, 1: 26-32 No GLP, Published	N	-

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA, 5.2.6/01	Basketter D. A., Gerberick, G. F. and Kimber I.	1998	Strategies for identifying false positive responses in predictive skin sensitization tests <i>Food and Chemical Toxicology</i> 36, 327-333 No GLP, Published	N	-
IIA, 5.5.2/02	Giknis, M.L.A and Clifford, C.	2004	Compilations of Spontaneous Neoplastic Lesions and Survival in the [REDACTED] Rats from Control Groups [REDACTED] No GLP, Unpublished	Y	-
IIA, 5.5.3/02	Kovatch, R. M.	1996	Pathology peer review of chloropicrin: vapour inhalation oncogenicity study in CD-1 mice Study no. 92N1105 [REDACTED] No GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.5.3/03	Giknis, M.L.A and Clifford, C.	2005	Spontaneous Neoplastic Lesions in the [REDACTED] Mouse in Control Groups from 18 Month to 2 year studies [REDACTED] No GLP, Unpublished	Y	-
IIA, 5.6.10/02	Lang, P. L	1993	Historical control data for developmental and reproductive toxicity studies using the [REDACTED] rat [REDACTED] No GLP, Unpublished	Y	-
IIA, 5.6.10/03	Schardein, J.L.	1994	Letter (refers to IIA, 5.6.10/01) [REDACTED] No GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.8/01	Sparks, S.E., Quistad, G.B. and Casida, J.E.	1997	Chloropicrin: Reactions with Biological Thiols and Metabolism in Mice Department of Environmental Science, Policy and Management, University of California, Berkeley, CA 94720-3112, USA <i>Chem. Res. Toxicol.</i> 10, 1001-1007 No GLP, Published ⇒ IIA, 5.1.1/02	Y	-
IIA, 5.8/02	Sparks, S.E., Quistad, G.B., Li, W. and Casida, J.E.	2000	Chloropicrin Dechlorination in Relation to Toxic Action Department of Environmental Science, Policy and Management, University of California, Berkeley, CA 94720-3112, USA <i>J. Biochem. Molecular Toxicology</i> , 14 (1), 26-32 No GLP, Published ⇒ IIA, 5.1.1/03	Y	-

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA, 5.8/03	Plewa, M.J., Wagner, E.D. and Jazwierska, P.	2004	Halonitromethane Drinking Water Disinfection Byproducts: Chemical Characterization and Mammalian Cell Cytotoxicity and Genotoxicity Department of Crop Science, college of Agricultural, Consumer and Environmental Sciences, University of Illinois at Urbana-Champaign, 1101 West Peabody Drive, Urbana, Illinois 61801, USA National Exposure Research Laboratory, U.S. Environmental Protection Agency, Athens, Georgia 30605, USA CanSyn Chem. Corp. 200 College Street, Toronto, Ontario, M5S 3E5, Canada <i>Environ. Sci. Technol.</i> 38, 62-68 No GLP, Published	Y	
IIA, 5.10/01	Hoffman, G.E.	1999	Chloropicrin: A Sensory Irritation Study in the Mouse via Head-Only Exposure [REDACTED] Report No. 99-5388 GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.10/02	Cain, W.S.	2004	Human Sensory Irritation Testing for Chloropicrin [REDACTED] Report No. PIC-1 GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.10/03	Butala, J. H.	2007	Chloropicrin: use of human sensory irritation data in exposure standard setting Report No. ECG/04/05 No GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.10/04	Butala, J. H.	2009a	Chloropicrin: Respiratory Sensitization Report No. ECG/05/09 No GLP, Unpublished	Y	European Chloropicrin Group
IIA, 5.14/01	Butala, J. H.	2009b	Chloropicrin: Evaluation of the human sensory irritation threshold in relation to animal inhalation toxicity data and determination of safety factors Report No. ECG/05/10 No GLP, Unpublished	Y	European Chloropicrin Group

Plant Protection Product : Chloropicrin 99 - ANNEX III

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIIA 7.3.3/01	Trevisan, M.	2009	Chloropicrin: concentration in air and operators exposure assessment during and after soil application. CERZOO - Centro Ricerche per la Zootechnia e l'Ambiente, Piacenza, Italia. Report-No CZ/08/013/UCSC/CHLAIR/RF. GLP, Unpublished	Y	European Chloropicrin Group

A.7 Residue data (Annex IIA 6; Annex IIIA 8 and 11.2)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 6.1.1/01	Gandhi, J.S.G.	2009	Determination of Residues of Chloropicrin in Samples of Tomato Following One Month Freezer Storage in Compliance with Good Laboratory Practice Oxford Analytical Ltd Report No. OA01656 GLP, Unpublished	Y	European Chloropicrin Group
IIA 6.3.1/03	Couldridge, C.	2009	Residues of Chloropicrin in Outdoor Grown Tomatoes following a Single Application via Drip Irrigation or Shank Fumigation Oxford Agricultural Trials Ltd Report No. 671-08-RIV-TOM GLP, Unpublished	Y	European Chloropicrin Group
IIA 6.3.1/04	Gandhi, J.S.G	2008	Analysis of Residues of Chloropicrin in Outdoor Grown Tomatoes with Associated Validation in Compliance with Good Laboratory Practice Oxford Analytical Ltd Report No. OA01626 GLP, Unpublished	Y	European Chloropicrin Group
IIA 6.3.1/05	Zoboli, G.	2009	Residue Determinations of Chloropicrin in Tomatoes According to the OECD Principles of GLP (Good Laboratory Practice) Neutron S.r.l. Report No. LN93-08 GLP, Unpublished	Y	European Chloropicrin Group
IIA 6.3.1/06	Ferrari D.	2009	Determination of Residues of Chloropicrin and its Metabolite Dichloronitromethane in Protected Grown Tomato at Harvest Following a Single Application (Soil Drip and by Injection) of Chloropicrin 99 – One Trial in Italy – 2008 – 2009 Neutron S.r.l. Report No. LN95 GLP, Unpublished	Y	European Chloropicrin Group

Plant Protection Product : Chloropicrin 99 - ANNEX III

All data are submitted in Annex II

A. 8 Environmental fate and behaviour (Annex IIA 7; Annex IIIA 9)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 7.4.3/02	Shepler, K	2009	Aged Leaching of [¹⁴ C]Chloropicrin in Representative Agricultural Soil. PTRL West Inc. report number 51645W-1. GLP. Unpublished.	Yes	European Chloropicrin Group
IIA 7.4.1/02	Penketh, S.	2008	Chloropicrin Adsorption/Desorption on Five Soils. Huntingdon Life Sciences report number SXC0001. GLP. Unpublished.	Yes	European Chloropicrin Group

Plant Protection Product : Chloropicrin 99 - ANNEX III

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIIA 9.4/01	Moltmann, J.F.	2009	Predicted Environmental Concentrations in Soil (PEC _{soil}) and Ground Water (PEC _{gw}) for Chloropicrin and its Major Metabolite Dichloronitromethane (DCNM) in Preparation of the Planting of Tomatoes. ECT Oekotoxikologie GmbH report number P8054-01-09. Unpublished	Yes	European Chloropicrin Group
IIIA 9.4/01	Moltmann, J.F.	2009	Predicted Environmental Concentrations in Surface Water (PEC _{sw}) and Sediment (PEC _{sed}) for Chloropicrin and its Major Metabolite Dichloronitromethane (DCNM) in Preparation of the Planting of Tomatoes. ECT Oekotoxikologie GmbH report number P8054-02-09. Unpublished	Yes	European Chloropicrin Group

A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)

Active Ingredient - ANNEX II

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 8.1.1/01	Hubbard, P.M., Beavers, J.B.	2009a	Chloropicrin: An Acute Oral Toxicity Study with the Northern Bobwhite Using a Sequential Testing Procedure. [REDACTED] Report no.: 650-101 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.1.1/02	Weinberg, J.T.	2008	A 5-day Whole-Body Inhalation Toxicity Study of Chloropicrin in Northern Bobwhite Quail [REDACTED] Report no.: [REDACTED]-697002. GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.1.2/01	Hubbard, P.M., Martin, K.H., and Beavers, J.B.	2009a	Chloropicrin: A Dietary LC ₅₀ Study with the Mallard [REDACTED] Report no.: 650-106. GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.1.3/01	Hubbard, P. M., Martin, H. K., Beavers, B. J	2009 b	Chloropicrin: A Dietary LC ₅₀ Study With The Northern Bobwhite [REDACTED] Report no. 650-105 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.1.4/01	Frey, L.T., Martin, K.H., Beavers, J.B. and Jaber, M.	2009	Chloropicrin: A Reproduction Study With the Northern Bobwhite [REDACTED] report no.: 650-104. GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.2.4/01	Lee M.R.	2009	Chloropicrin - Early Life-Stage Toxicity Test with Rainbow Trout (<i>Oncorhynchus mykiss</i>) Following OECD Guideline #210 and OPPTS Draft Guideline 850.1400 [REDACTED] Report No. 13939.6100 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.3.2.1/01	Jenkins, C.A.	2009	Chloropicrin Prolonged Toxicity to <i>Daphnia magna</i> , Huntingdon Life Sciences Ltd Report No. SXC0011 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.4/02	Wilby, J.J	2009a	Chloropicrin Algal Growth Inhibition Assay Huntingdon Life Science Ltd. Report no.: SXC0022 GLP, Unpublished	Y	European Chloropicrin Group

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection claimed Y/N	Owner
IIA 8.6/01	Wilby, J.J	2009 b	Chloropicrin Higher Plant (<i>Lemna</i>) Growth Inhibition Test. Huntingdon Life Science Ltd. Report no.: SXC0023 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.7/01	Porch, J et al.	2009	Chloropicrin: An acute vapour exposure toxicity study with the honey bee Wildlife international report no: 650-107 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.9.2/02	Rogers. M.H.	2009 b	Chloropicrin To Determine the Effects of Aged Soil Residues on Reproduction and Growth of the Earthworm, <i>Eisenia fetida</i> . Huntingdon Life Sciences Ltd. GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.10.1/02	Carter, J.N	2008	Chloropicrin: Effects on Soil Non-Target Micro-Organisms: Nitrogen Transformation. Huntingdon Life Sciences Ltd Report No.: SXC0019 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.10.1/03	Carter, J.N	2009	Chloropicrin: Evaluation of Effects on Soil Non-Target Micro-Organisms following Commercial Application of Chloropicrin to Soil in the UK in 2009 Huntingdon Life Sciences Ltd. Report No.: SXC0028 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.12/01	Weinberg, J.T.	2009	Toxicity of Chloropicrin to six plant species: corn, soybean, ryegrass, oilseed rape, cucumber and sunflower. WIL Research Laboratories, Report No.: WIL- 697004. GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.16.1-01	Hubbard P.M., Beavers, J.B	2009 b	A Comparison of Technical Chloropicrin vs Microencapsulated Chloropicrin in an Acute Oral Toxicity Study with the Northern Bobwhite [REDACTED] Report No.: 650-102 GLP, Unpublished	Y	European Chloropicrin Group
IIA 8.16.2/01	Bartolme, J	2009	Chloropicrin: Determination of Residues Levels in Non-Target Insects, Plants and Earthworms Following Commercial Application of Chloropicrin to Soil in the UK in 2009 Huntingdon Life Sciences Report No.: SXC0027 GLP, Unpublished.	Y	European Chloropicrin Group

Plant Protection Product : Chloropicrin 99 - ANNEX III

Please refer to the DAR from 2006

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