

Chlorothalonil

NOTIFICATION OF AN ACTIVE SUBSTANCE UNDER COMMISSION REGULATION (EU) 844/2012

DOCUMENT L-CA, Section 5 Supplement Reference List

TOXICOLOGICAL AND METABOLISM STUDIES ON THE ACTIVE SUBSTANCE

Updated 24 August 2015

Updated 14 December 2015

Updated 19 January 2016

Updated 8 March 2016

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
21/8/15	CA 5.8.1: Inclusion of new metabolite data (all changes highlighted in yellow)	7 March 2015 updated 24/8/15
14/12/15	CA 5.8.1: Inclusion of new metabolite data (all changes highlighted in green)	7 March 2015 updated 24/8/15 and 14/11/15
19/01/16	CA 5.8.2 : Inclusion of report references cited in the assessments for immunotoxicity and endocrine disruption as requested by RMS (all changes highlighted in blue)	7 March 2015 updated 24/8/15, 14/12/15 and 19/01/16

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report.

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| Art. 33
(3) c | Justifications of steps taken to avoid animal testing and duplication of such testing | Justification: There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines or because they were necessary to comply with regulatory requirements outside of EU28. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable. |
| Art. 33
(3) d | Reasons for necessity for submission of tests and study reports | Reason: since this active substance was previously registered there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain re-approval new tests and study reports are provided. |

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Reference List, by Data Point**15 February 2015****KCA Section 5, Toxicological and metabolism studies on the active substance**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.1.1 / 01	Hassler S.	2007	[14C] Chlorothalonil: Disposition of [14C] Chlorothalonil in the Rats After Multiple Oral Administration Vischim Srl, Milano, Italy RCC Ltd., Itingen, Switzerland, B21205 GLP not published Syngenta File No R044686_11301	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Oxon Italia SpA **
KCA 5.1.1 / 02	Punlet M.	2013	Chlorothalonil - Biotransformation of [14C]- chlorothalonil in the rat Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 32633 GLP not published Syngenta File No R044686_11027	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
KCA 5.2.1 / 01	Moore GE	2000	Chlorothalonil Technical: Acute Oral Toxicity Study in Rats Zeneca Agrochemicals, Jealott's Hill, United Kingdom Product Safety Labs, East Brunswick, USA, CTL/C/3974 GLP not published Syngenta File No R44686/0080	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN

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KCA 5.2.2 / 01	Johnson IR	2000	Chlorothalonil Technical: Acute Dermal Toxicity Study in Rats Zeneca Agrochemicals, Jealott's Hill, United Kingdom , CTL/CR3537/REG/REPT GLP not published Syngenta File No R44686/0078	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.2.4 / 01	Johnson IR	2000a	Chlorothalonil Technical: Skin Irritation Study in Rabbits Zeneca Agrochemicals, Jealott's Hill, United Kingdom , CTL/EB4891/REG/REPT GLP not published Syngenta File No R44686/0079	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.2.7 / 01	Gehrke H.	2014	Chlorothalonil technical - In Vitro 3T3 NRU Phototoxicity Test Syngenta BSL Bioservice Scientific, Planegg, Germany, 143685 GLP not published Syngenta File No R044686_11093	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.6.2 / 01	Farag A., Karkour T., Okazy A.	2006	Embryotoxicity of Oral Administered Chlorothalonil in Mice University of Alexandria, Faculty of Agriculture, Egypt, Birth Defects Research (Part 8) 77:104-109 (2006) Not GLP published Syngenta File No R044686_11260	N	N	-	-
KCA 5.8.1 / 01	Beerens-Heijnen C.	2005	Assessment of Acute Oral Toxicity with SDS-3701 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402479 GLP not published Syngenta File No R182281_10019	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 02	Beerens-Heijnen C.	2005a	Primary Skin Irritation/Corrosion Study with SDS-3701 in the Rabbit Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 411108 GLP not published Syngenta File No R182281_10021	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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KCA 5.8.1 / 03	Verspeek-Rip C.	2004	Evaluation of the Mutagenic Activity of SDS-3701 in the Salmonella Typhimurium Reverse Mutation Assay and the Escherichia Coli Reverse Mutation Assay (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402468 GLP not published Syngenta File No R182281_10022	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 04	Verspeek-Rip C.	2005	Evaluation of the Mutagenic Activity of SDS-3701 in an in vitro Mammalian Cell Gene Mutation Test with L5178y Mouse Lymphoma Cells Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402457 GLP not published Syngenta File No R182281_10020	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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KCA 5.8.1 / 05	Buskens C.	2004	Micronucleus Test in Bone Marrow Cells of the Mouse with SDS-3701 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402446 GLP not published Syngenta File No R182281_10025	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 06	Honarvar N.	2005	in vivo Unscheduled DNA Synthesis in Rat Hepatocytes with SDS 3701 Vischim Srl, Milano, Italy RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 887200 GLP not published Syngenta File No R182281_10024	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 07	van Otterdijk F.	2007	90-Day Oral Toxicity with SDS3701 by Dietary Administration in the Rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481646 GLP not published Syngenta File No R182281_10023	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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KCA 5.8.1 / 08	Hastings TF	1973	Acute Oral LD50 in Sprague-Dawley Rats Using DAC-3701 Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3749 Not GLP not published Syngenta File No R44686/0815	Y	N	-	SYN
KCA 5.8.1 / 09	Wazeter FX	1971	Acute Oral LD50 in Male Albino Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3747 Not GLP not published Syngenta File No R44686/0847	Y	N	-	SYN
KCA 5.8.1 / 10	Ford WH, Killeen JC	1982	A Short-Term Dietary Study in Rats with DS- 3701 Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3491 Not GLP not published Syngenta File No R44686/0822	Y	N	-	SYN

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KCA 5.8.1 / 11	Budny J	1975	DAC-3701: 90-Day feeding study in dogs Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3763 Not GLP not published Syngenta File No R44686/0765	Y	N	-	SYN
KCA 5.8.1 / 12	Wazeter F., Goldenthal E.	1976	Teratology Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3367 Not GLP not published Syngenta File No R44686/0794	Y	N	-	SYN
KCA 5.8.1 / 13	Schroeder RE	1998	SDS-3701: A Developmental Toxicity Study in Rats via Oral Administration Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3921 GLP not published Syngenta File No R44686/2743	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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KCA 5.8.1 / 14	van Huygevoort A.	2005	Assessment of Acute Oral Toxicity with VIS 01 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402547 GLP not published Syngenta File No R417888_10023	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 15	Verspeek-Rip C.	2005a	Evaluation of the mutagenic activity of VIS 01 in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay (with independent repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402536 GLP not published Syngenta File No R417888_10025	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 16	Verspeek-Rip C.	2006	Evaluation of the Mutagenic Activity of VIS 01 in an in vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402525 GLP not published Syngenta File No R417888_10026	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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KCA 5.8.1 / 17	Meerts I.	2005	Micronucleus test in bone marrow cells of the mouse with VIS 01 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402514 GLP not published Syngenta File No R417888_10024	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 18	Honarvar N.	2006	in vivo Unscheduled DNA Synthesis in Rat Hepatocytes with VIS 01 Vischim Srl, Milano, Italy RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 921400 GLP not published Syngenta File No R417888_10028	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 19	van Otterdijk F.	2007a	90-Day Oral Toxicity Study with VIS01 by Dietary Administration in the Rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481602 GLP not published Syngenta File No R417888_10027	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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KCA 5.8.1 / 20	Sokolowski A.	2007	Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with R417888 ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030808 GLP not published Syngenta File No R417888_10020	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Arysta LifeScience
KCA 5.8.1 / 21	Kunz S.	2007	Chromosome Aberration Test in Human Lymphocytes in vitro ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030810 GLP not published Syngenta File No R417888_10022	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Arysta LifeScience

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KCA 5.8.1 / 22	Wollny H.	2007	Cell Mutation Assay at the Thymidine Kinase Locus (TK ⁺ /-) in Mouse Lymphoma L5178Y Cells with R417888 ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030809 GLP not published Syngenta File No R417888_10021	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Arysta LifeScience
KCA 5.8.1 / 23	Sokolowski A.	2015	SYN548708 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677301 GLP not published Syngenta File No SYN548708_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 24	Sokolowski A.	2015a	SYN548708 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677302 GLP not published Syngenta File No SYN548708_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 25	Wollny H.	2015	SYN548708 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677303 GLP not published Syngenta File No SYN548708_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 26	Dunton J.	2015	SYN548708 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10373 GLP not published Syngenta File No SYN548708_10006	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 276	Sokolowski A.	2015b	SYN548765 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678101 GLP not published Syngenta File No SYN548765_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 287	Sokolowski A.	2015c	SYN548765 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678102 GLP not published Syngenta File No SYN548765_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 298	Wollny H.	2015a	SYN548765 - Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678103 GLP not published Syngenta File No SYN548765_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3029	Sokolowski A.	2015d	SYN548766 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678001 GLP not published Syngenta File No SYN548766_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 3130	Sokolowski A.	2015e	SYN548766 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678002 GLP not published Syngenta File No SYN548766_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3234	Wollny H.	2015b	SYN548766 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678003 GLP not published Syngenta File No SYN548766_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3332	Sokolowski A.	2015f	SYN548738 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677901 GLP not published Syngenta File No SYN548738_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 3433	Sokolowski A.	2015g	SYN548738 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677902 GLP not published Syngenta File No SYN548738_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3534	Sokolowski A.	2015h	SYN548738 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677903 GLP not published Syngenta File No SYN548738_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 243536	Sokolowski A.	2015ai	SYN548580 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677501 GLP not published Syngenta File No SYN548580_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 3736	Sokolowski A.	2015j	SYN548580 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677502 GLP not published Syngenta File No SYN548580_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3837	Wollny H.	2015c	SYN548580 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677503 GLP not published Syngenta File No SYN548580_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 3938	Sokolowski A.	2015k	SYN548764 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677401 GLP not published Syngenta File No SYN548764_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 4039	Sokolowski A.	2015l	SYN548764 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677402 GLP not published Syngenta File No SYN548764_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 4140	Wollny H.	2015d	SYN548764 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677403 GLP not published Syngenta File No SYN548764_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 42	Dunton J.	2015a	SYN548764 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10404 GLP not published Syngenta File No SYN548764_10008	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 254143	Beerens-Heijnen C.	2005b	Assessment of Acute Oral Toxicity with SDS-46851 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402558 GLP not published Syngenta File No R611965_10014	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 264244	Beerens-Heijnen C.	2005c	Primary Skin Irritation/Corrosion Study with SDS-46851 in the Rabbit Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 411119 GLP not published Syngenta File No R611965_10015	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 274345	Verspeek-Rip C.	2004a	Evaluation of the Mutagenic Activity of SDS-46851 in the Salmonella Typhimurium Reverse Mutation Assay and the Escherichia Coli Reverse Mutation Assay (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402503 GLP not published Syngenta File No R611965_10018	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

Reference List, by Data Point**15 February 2015****KCA Section 5, Toxicological and metabolism studies on the active substance**

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KCA 5.8.1 / 284446	Verspeek-Rip C.	2005b	Evaluation of the Mutagenic Activity of SDS-46851 in an in vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402492 GLP not published Syngenta File No R611965_10016	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 294547	Buskens C.	2004a	Micronucleus Test in Bone Marrow Cells of the Mouse with SDS-46851 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402481 GLP not published Syngenta File No R611965_10017	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
KCA 5.8.1 / 304648	van Otterdijk F.	2007b	90-Day oral toxicity study by dietary administration with SDS46851 in the rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481624 GLP not published Syngenta File No R611965_10019	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.1 / 314749	Sokolowski A.	2015 ^{em}	R611968 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677801 GLP not published Syngenta File No SYN548651_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 4850	Sokolowski A.	2015 ⁿ	R611968 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677802 GLP not published Syngenta File No SYN548651_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 4951	Wollny H.	2015 ^e	R611968 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677803 GLP not published Syngenta File No SYN548651_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.1 / 52	Dunton J.	2015b	R611968 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10406 GLP not published Syngenta File No SYN548651_10006	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 325053	Sokolowski A.	2015eo	R613636 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677701 GLP not published Syngenta File No R613636_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 5154	Sokolowski A.	2015p	R613636 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677702 GLP not published Syngenta File No R613636_10008	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 55	Wollny H.	2015f	R613636 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1677703 GLP not published Syngenta File No R613636_10012	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 56	Wollny H.	2015g	R613636 - Gene Mutation Assay in Chinese Hamster V79 Cells in vitro (V79/HPRT) Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1711600 GLP not published Syngenta File No R613636_10014	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 57	Dunton J.	2015c	R613636 - Oral (Gavage) Mouse Micronucleus Test Syngenta, Syngenta Sequani Limited, Ledbury, United Kingdom, BF10402 GLP not published Syngenta File No R613636_10010	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 58	Sokolowski A.	2015q	SYN507900 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699301 GLP not published Syngenta File No SYN507900_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 59	Sokolowski A.	2015r	SYN507900 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699302 GLP not published Syngenta File No SYN507900_10008	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 60	Wollny H.	2015h	SYN507900 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699303 GLP not published Syngenta File No SYN507900_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.1 / 61	Dunton J.	2016	SYN507900 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0444 GLP not published Syngenta File No SYN507900_10010	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.1 / 33526162	Parr-Dobrzanski B.	2015	Chlorothalonil: Assessment of Relevance of Predicted Groundwater Metabolites, Derek Report Data Supplement to support Document N4 for AIR3 Syngenta - Jealott's Hill, Bracknell, United Kingdom , Not GLP not published Syngenta File No R044686_11288 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.2 / 01	Akkan Z.	2014	Chlorothalonil Position Statement Concerning Immunotoxicity Potential Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, TK0239123 Not GLP not published Syngenta File No R044686_11224 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force*
KCA 5.8.2 / 02 & KCA 5.8.3 / 13	Wilson NH, Ignatoski JA	1982	Four-Week Dietary Range-Finding Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3261 GLP not published Syngenta File No R44686/0550	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.2 / 03 & KCA 5.8.3 / 14	Wilson NH, Killeen JC, Ignatoski JA	1981	A 90-Day Toxicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , 099-5TX-80-0200-006, CTL/C/3283 GLP not published Syngenta File No R44686/0761	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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KCA Section 5, Toxicological and metabolism studies on the active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.2 / 04 & KCA 5.8.3 / 15	Colley J, Syred LJ, Heywood R	1983	A 13-Week Subchronic Toxicity Study of T-117-11 in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3280 GLP not published Syngenta File No R44686/0729	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.2 / 05 & KCA 5.8.3 / 09	Mizens M	1996	A 21-Day Repeated Dose Dermal Toxicity Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3832 GLP not published Syngenta File No R44686/0562	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.2 / 06 & KCA 5.8.3 / 20	Spencer-Briggs D.	1996	Chlorothalonil - Potential Tumorigenic Effects in Prolonged Dietary Administration in Rats Syngenta Crop Protection AG, Basel, Switzerland Huntingdon Research Centre Ltd., Huntingdon, United Kingdom, VCM 15/943286 GLP not published Syngenta File No R044686_10749	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA Section 5, Toxicological and metabolism studies on the active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.2 / 07 & KCA 5.8.3 / 19	Wilson NH, Kileen JC, Ignatoski JA	1985	A Tumorigenicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3328 GLP not published Syngenta File No R44686/1558	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
KCA 5.8.2 / 08	Wilson NH, Killeen JC	1989	A Tumorigenicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3436 Not GLP not published Syngenta File No R44686/3218	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
KCA 5.8.2 / 09 & KCA 5.8.3 / 25	Lucas F, Benz G	1990	A Two Generation Reproduction Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3438 GLP not published Syngenta File No R44686/0327	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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KCA Section 5, Toxicological and metabolism studies on the active substance

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KCA 5.8.2 / 10 & KCA 5.8.3 / 16	Shults SK, Killeen JC	1983	A 90-Day Feeding Study in Mice with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3403 GLP not published Syngenta File No R44686/0575	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
KCA 5.8.2 / 11 & KCA 5.8.3 / 21	Wilson NH, Killeen JC	1983	A Chronic Dietary Study in Mice with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3355 108-5TX-79-0102-004 GLP not published Syngenta File No R44686/0638	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
KCA 5.8.2 / 12 & KCA 5.8.3 / 22	Wilson NH, Killeen JC	1987	A Tumorigenicity Study of Technical Chlorothalonil in Male Mice - Final Report Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3364 GLP not published Syngenta File No R44686/0511	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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KCA Section 5, Toxicological and metabolism studies on the active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.2 / 13 & KCA 5.8.3 / 17	Fillmore GE, Laveglia J	1993	A 90 Day Toxicity Study in Dogs with Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3284 GLP not published Syngenta File No R44686/0763	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
KCA 5.8.2 / 14 & KCA 5.8.3 / 18	Mizens M, Laveglia J	1994	A Chronic (12-Month) Oral Toxicity Study in Dogs with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3363 GLP not published Syngenta File No R44686/0420	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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KCA Section 5, Toxicological and metabolism studies on the active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.2 / 15	Donald L.	2012	Chlorothalonil - A 28 Day Immunotoxicity Study by Oral (Dietary) Administration in Mice using Sheep Red Blood Cells as the Antigen Syngenta, Arysta LifeScience North America, LLC, Cary, NC, USA, Celsius Property B.V., Amsterdam, Netherlands, IBC Manufacturing Co., Memphis, TN, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, SipcamAdvan, Durham, NC, USA Charles River Laboratories, Edinburgh, United Kingdom, 32994 GLP not published Syngenta File No R044686_10961	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.3 / 01	Green R.	2015	Chlorothalonil - Review for Potential for Endocrine Disruption in Mammalian Species Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP not published Syngenta File No R044686_11145 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force*

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.3 / 02	Willoughby J.	2011	Chlorothalonil - Estrogen Receptor Binding (Rat Uterine Cytosol) Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331ERB GLP not published Syngenta File No R044686_50867	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA Section 5, Toxicological and metabolism studies on the active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCA 5.8.3 / 03	Willoughby J.	2011a	Chlorothalonil - Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLA-9903)) Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V- 100331ERTA GLP not published Syngenta File No R044686_50866	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force

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KCA 5.8.3 / 04	Willoughby J.	2012	Chlorothalonil - Androgen Receptor Binding (Rat Prostate Cytosol) Arysta LifeScience North America, LLC, Cary, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, Syngenta - Jealott's Hill, Bracknell, United Kingdom CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331ARB GLP not published Syngenta File No R044686_50943	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.3 / 05	Wagner H.	2012	Chlorothalonil - H295R Steroidogenesis Assay Arysta LifeScience North America, LLC, Cary, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331STER GLP not published Syngenta File No R044686_50935	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.3 / 06	Wilga P.	2011	Chlorothalonil - Human Recombinant Aromatase Assay Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta - Jealott's Hill, Bracknell, United Kingdom CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331AROM GLP not published Syngenta File No R044686_50865	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.3 / 07	Sawhney Coder P.	2012	Chlorothalonil - Uterotrophic Assay in Ovariectomized Rats Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639140 GLP not published Syngenta File No R044686_10957	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.3 / 08	Sawhney Coder P.	2012a	Chlorothalonil - Hershberger Bioassay in Orchidoepididymectomized Rats Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639141 GLP not published Syngenta File No R044686_10956	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
KCA 5.8.3 / 10	Shults SK, Wilson NH	1986	21-Day Repeated Dose Dermal Toxicity Study in Albino Rabbits with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3418 GLP not published Syngenta File No R44686/0609	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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KCA 5.8.3 / 11	Sawhney Coder P.	2012b	Chlorothalonil - Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats Syngenta, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639143 GLP not published Syngenta File No R044686_10959	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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KCA 5.8.3 / 12	Sawhney Coder P.	2012c	Chlorothalonil - Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats Syngenta, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Arysta LifeScience North America, LLC, Cary, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim Srl, c/o Lewis & Harrison, LLC, Washington, DC, USA WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639142 GLP not published Syngenta File No R044686_10960	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
KCA 5.8.3 / 23	Mizens M, Wilson NH, Killeen JC	1983	A Teratology Study in Rats with Technical Chlrothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3431 GLP not published Syngenta File No R44686/0337	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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KCA 5.8.3 / 24	Wilson NH, Killeen JC	1988	A Teratology Study in Rabbits with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3429 GLP not published Syngenta File No R44686/1014	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.9.5 / 01	Draper A, Cullinan P, Campbell C, Jones M, Taylor A.	2003	Occupational asthma from fungicides fluazinam and chlorothalonil Occupational and Environmental Medicine, vol. 60, no. 1, pp. 76–77. Not GLP published Syngenta File No R044686_11300	N	N	-	-

*Data confidentiality is requested for these data. Disclosure of the information might undermine the company commercial interests by providing access to company specific know-how used to develop unique positions and approaches to risk assessment.

**OXON Italia SpA acquired Vischim S.r.l. in November 2011.

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Akkan Z.	KCA 5.8.2 / 01	2014	Chlorothalonil Position Statement Concerning Immunotoxicity Potential Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, TK0239123 Not GLP not published Syngenta File No R044686_11224 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force*
Beerens-Heijnen C.	KCA 5.8.1 / 01	2005	Assessment of Acute Oral Toxicity with SDS-3701 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402479 GLP not published Syngenta File No R182281_10019	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Beerens-Heijnen C.	KCA 5.8.1 / 02	2005a	Primary Skin Irritation/Corrosion Study with SDS-3701 in the Rabbit Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 411108 GLP not published Syngenta File No R182281_10021	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Beerens-Heijnen C.	KCA 5.8.1 / 254143	2005b	Assessment of Acute Oral Toxicity with SDS-46851 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402558 GLP not published Syngenta File No R611965_10014	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Beerens-Heijnen C.	KCA 5.8.1 / 264244	2005c	Primary Skin Irritation/Corrosion Study with SDS-46851 in the Rabbit Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 411119 GLP not published Syngenta File No R611965_10015	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Budny J.	KCA 5.8.1 / 11	1975	DAC-3701: 90-Day feeding study in dogs Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3763 Not GLP not published Syngenta File No R44686/0765	Y	N	-	SYN

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Buskens C.	KCA 5.8.1 / 05	2004	Micronucleus Test in Bone Marrow Cells of the Mouse with SDS-3701 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402446 GLP not published Syngenta File No R182281_10025	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Buskens C.	KCA 5.8.1 / 294547	2004a	Micronucleus Test in Bone Marrow Cells of the Mouse with SDS-46851 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402481 GLP not published Syngenta File No R611965_10017	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Colley J, Syred LJ, Heywood R	KCA 5.8.2 / 04 & KCA 5.8.3 / 15	1983	A 13-Week Subchronic Toxicity Study of T-117-11 in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3280 GLP not published Syngenta File No R44686/0729	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Donald L.	KCA 5.8.2 / 15	2012	Chlorothalonil - A 28 Day Immunotoxicity Study by Oral (Dietary) Administration in Mice using Sheep Red Blood Cells as the Antigen Syngenta, Arysta LifeScience North America, LLC, Cary, NC, USA, Celsius Property B.V., Amsterdam, Netherlands, IBC Manufacturing Co., Memphis, TN, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, SipcamAdvan, Durham, NC, USA Charles River Laboratories, Edinburgh, United Kingdom, 32994 GLP not published Syngenta File No R044686_10961	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Draper A, Cullinan P, Campbell C, Jones M, Taylor A.	KCA 5.9.5 / 01	2003	Occupational asthma from fungicides fluazinam and chlorothalonil Occupational and Environmental Medicine, vol. 60, no. 1, pp. 76–77. Not GLP published Syngenta File No R044686_11300	N	N	-	-

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Dunton J.	KCA 5.8.1 / 26	2015	SYN548708 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10373 GLP not published Syngenta File No SYN548708_10006	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
Dunton J.	KCA 5.8.1 / 42	2015a	SYN548764 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10404 GLP not published Syngenta File No SYN548764_10008	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
Dunton J.	KCA 5.8.1 / 52	2015b	R611968 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BF10406 GLP not published Syngenta File No SYN548651_10006	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force

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Dunton J.	KCA 5.8.1 / 57	2015c	R613636 - Oral (Gavage) Mouse Micronucleus Test Syngenta, Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0402 GLP not published Syngenta File No R613636_10010	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Dunton J.	KCA 5.8.1 / 61	2016	SYN507900 - Oral (Gavage) Mouse Micronucleus Test Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0444 GLP not published Syngenta File No SYN507900_10010	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Farag A., Karkour T., Okazy A.	KCA 5.6.2 / 01	2006	Embryotoxicity of Oral Administered Chlorothalonil in Mice University of Alexandria, Faculty of Agriculture, Egypt, Birth Defects Research (Part 8) 77:104-109 (2006) Not GLP published Syngenta File No R044686_11260	N	N	-	-

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Fillmore GE, Laveglia J	KCA 5.8.2 / 13 & KCA 5.8.3 / 17	1993	A 90 Day Toxicity Study in Dogs with Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3284 GLP not published Syngenta File No R44686/0763	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
Ford WH, Killeen JC	KCA 5.8.1 / 10	1982	A Short-Term Dietary Study in Rats with DS- 3701 Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3491 Not GLP not published Syngenta File No R44686/0822	Y	N	-	SYN
Gehrke H.	KCA 5.2.7 / 01	2014	Chlorothalonil technical - In Vitro 3T3 NRU Phototoxicity Test Syngenta BSL Bioservice Scientific, Planegg, Germany, 143685 GLP not published Syngenta File No R044686_11093	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN

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Green R.	KCA 5.8.3 / 01	2015	Chlorothalonil - Review for Potential for Endocrine Disruption in Mammalian Species Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP not published Syngenta File No R044686_11145 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force*
Hassler S.	KCA 5.1.1 / 01	2007	[14C] Chlorothalonil: Disposition of [14C] Chlorothalonil in the Rats After Multiple Oral Administration Vischim Srl, Milano, Italy RCC Ltd., Itingen, Switzerland, B21205 GLP not published Syngenta File No R044686_11301	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Hastings TF	KCA 5.8.1 / 08	1973	Acute Oral LD50 in Sprague-Dawley Rats Using DAC-3701 Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3749 Not GLP not published Syngenta File No R44686/0815	Y	N	-	SYN

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Honarvar N.	KCA 5.8.1 / 06	2005	in vivo Unscheduled DNA Synthesis in Rat Hepatocytes with SDS 3701 Vischim Srl, Milano, Italy RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 887200 GLP not published Syngenta File No R182281_10024	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Honarvar N.	KCA 5.8.1 / 18	2006	in vivo Unscheduled DNA Synthesis in Rat Hepatocytes with VIS 01 Vischim Srl, Milano, Italy RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 921400 GLP not published Syngenta File No R417888_10028	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Johnson IR	KCA 5.2.2 / 01	2000	Chlorothalonil Technical: Acute Dermal Toxicity Study in Rats Zeneca Agrochemicals, Jealott's Hill, United Kingdom , CTL/CR3537/REG/REPT GLP not published Syngenta File No R44686/0078	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Johnson IR	KCA 5.2.4 / 01	2000a	Chlorothalonil Technical: Skin Irritation Study in Rabbits Zeneca Agrochemicals, Jealott's Hill, United Kingdom , CTL/EB4891/REG/REPT GLP not published Syngenta File No R44686/0079	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Kunz S.	KCA 5.8.1 / 21	2007	Chromosome Aberration Test in Human Lymphocytes in vitro ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030810 GLP not published Syngenta File No R417888_10022	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Arysta LifeScience
Lucas F, Benz G	KCA 5.8.2 / 09 & KCA 5.8.3 / 25	1990	A Two Generation Reproduction Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3438 GLP not published Syngenta File No R44686/0327	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Meerts I.	KCA 5.8.1 / 17	2005	Micronucleus test in bone marrow cells of the mouse with VIS 01 Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402514 GLP not published Syngenta File No R417888_10024	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA **
Mizens M	KCA 5.8.2 / 05 & KCA 5.8.3 / 09	1996	A 21-Day Repeated Dose Dermal Toxicity Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3832 GLP not published Syngenta File No R44686/0562	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Mizens M, Laveglia J	KCA 5.8.2 / 14 & KCA 5.8.3 / 18	1994	A Chronic (12-Month) Oral Toxicity Study in Dogs with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3363 GLP not published Syngenta File No R44686/0420	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Mizens M, Wilson NH, Killeen JC	KCA 5.8.3 / 23	1983	A Teratology Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3431 GLP not published Syngenta File No R44686/0337	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN
Moore GE	KCA 5.2.1 / 01	2000	Chlorothalonil Technical: Acute Oral Toxicity Study in Rats Zeneca Agrochemicals, Jealott's Hill, United Kingdom Product Safety Labs, East Brunswick, USA, CTL/C/3974 GLP not published Syngenta File No R44686/0080	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN

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Parr-Dobrzanski B.	KCA 5.8.1 / 33526162	2015	Chlorothalonil: Assessment of Relevance of Predicted Groundwater Metabolites, Derek Report Data Supplement to support Document N4 for AIR3 Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP not published Syngenta File No R044686_11288 This is CONFIDENTIAL INFORMATION	N	N	-	Chlorothalonil Task Force
Punlet M.	KCA 5.1.1 / 02	2013	Chlorothalonil - Biotransformation of [14C]-chlorothalonil in the rat Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 32633 GLP not published Syngenta File No R044686_11027	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sawhney Coder P.	KCA 5.8.3 / 07	2012	Chlorothalonil - Uterotrophic Assay in Ovariectomized Rats Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639140 GLP not published Syngenta File No R044686_10957	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sawhney Coder P.	KCA 5.8.3 / 08	2012a	Chlorothalonil - Hershberger Bioassay in Orchidoepididymectomized Rats Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639141 GLP not published Syngenta File No R044686_10956	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
Sawhney Coder P.	KCA 5.8.3 / 11	2012b	Chlorothalonil - Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats Syngenta, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639143 GLP not published Syngenta File No R044686_10959	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force

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Sawhney Coder P.	KCA 5.8.3 / 12	2012c	Chlorothalonil - Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats Syngenta, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Arysta LifeScience North America, LLC, Cary, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim Srl, c/o Lewis & Harrison, LLC, Washington, DC, USA WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639142 GLP not published Syngenta File No R044686_10960	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Schroeder RE	KCA 5.8.1 / 13	1998	SDS-3701: A Developmental Toxicity Study in Rats via Oral Administration Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3921 GLP not published Syngenta File No R44686/2743	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Shults SK, Killeen JC	KCA 5.8.2 / 10 & KCA 5.8.3 / 16	1983	A 90-Day Feeding Study in Mice with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3403 GLP not published Syngenta File No R44686/0575	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Shults SK, Wilson NH	KCA 5.8.3 / 10	1986	21-Day Repeated Dose Dermal Toxicity Study in Albino Rabbits with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3418 GLP not published Syngenta File No R44686/0609	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Sokolowski A.	KCA 5.8.1 / 20	2007	Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with R417888 ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030808 GLP not published Syngenta File No R417888_10020	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Arysta LifeScience

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Sokolowski A.	KCA 5.8.1 / 23	2015	SYN548708 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677301 GLP not published Syngenta File No SYN548708_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 24	2015a	SYN548708 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677302 GLP not published Syngenta File No SYN548708_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 2627	2015b	SYN548765 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678101 GLP not published Syngenta File No SYN548765_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sokolowski A.	KCA 5.8.1 / 2728	2015c	SYN548765 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678102 GLP not published Syngenta File No SYN548765_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 2930	2015d	SYN548766 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678001 GLP not published Syngenta File No SYN548766_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 3031	2015e	SYN548766 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678002 GLP not published Syngenta File No SYN548766_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sokolowski A.	KCA 5.8.1 / 3233	2015f	SYN548738 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677901 GLP not published Syngenta File No SYN548738_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 3234	2015g	SYN548738 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677902 GLP not published Syngenta File No SYN548738_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 3435	2015h	SYN548738 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677903 GLP not published Syngenta File No SYN548738_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sokolowski A.	KCA 5.8.1 / 243536	2015i	SYN548580 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677501 GLP not published Syngenta File No SYN548580_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 3637	2015j	SYN548580 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677502 GLP not published Syngenta File No SYN548580_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 3839	2015k	SYN548764 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677401 GLP not published Syngenta File No SYN548764_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sokolowski A.	KCA 5.8.1 / 3940	2015l	SYN548764 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677402 GLP not published Syngenta File No SYN548764_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 314749	2015bm	R611968 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677801 GLP not published Syngenta File No SYN548651_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 4850	2015n	R611968 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677802 GLP not published Syngenta File No SYN548651_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Sokolowski A.	KCA 5.8.1 / 325053	2015c	R613636 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677701 GLP not published Syngenta File No R613636_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 5154	2015p	R613636 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677702 GLP not published Syngenta File No R613636_10008	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Sokolowski A.	KCA 5.8.1 / 58	2015q	SYN507900 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699301 GLP not published Syngenta File No SYN507900_10004	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Sokolowski A.	KCA 5.8.1 / 59	2015r	SYN507900 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699302 GLP not published Syngenta File No SYN507900_10008	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Spencer-Briggs D.	KCA 5.8.2 / 06 & KCA 5.8.3 / 20	1996	Chlorothalonil - Potential Tumorigenic Effects in Prolonged Dietary Administration in Rats Syngenta Crop Protection AG, Basel, Switzerland Huntingdon Research Centre Ltd., Huntingdon, United Kingdom, VCM 15/943286 GLP not published Syngenta File No R044686_10749	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
van Huygevoort A.	KCA 5.8.1 / 14	2005	Assessment of Acute Oral Toxicity with VIS 01 in the Rat (Acute Toxic Class Method) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402547 GLP not published Syngenta File No R417888_10023	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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van Otterdijk F.	KCA 5.8.1 / 07	2007	90-Day Oral Toxicity with SDS3701 by Dietary Administration in the Rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481646 GLP not published Syngenta File No R182281_10023	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
van Otterdijk F.	KCA 5.8.1 / 19	2007a	90-Day Oral Toxicity Study with VIS01 by Dietary Administration in the Rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481602 GLP not published Syngenta File No R417888_10027	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
van Otterdijk F.	KCA 5.8.1 / 304648	2007b	90-Day oral toxicity study by dietary administration with SDS46851 in the rat Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 481624 GLP not published Syngenta File No R611965_10019	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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Verspeek-Rip C.	KCA 5.8.1 / 03	2004	Evaluation of the Mutagenic Activity of SDS-3701 in the Salmonella Typhimurium Reverse Mutation Assay and the Escherichia Coli Reverse Mutation Assay (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402468 GLP not published Syngenta File No R182281_10022	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA **
Verspeek-Rip C.	KCA 5.8.1 / 04	2005	Evaluation of the Mutagenic Activity of SDS-3701 in an in vitro Mammalian Cell Gene Mutation Test with L5178y Mouse Lymphoma Cells Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402457 GLP not published Syngenta File No R182281_10020	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA **

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Verspeek-Rip C.	KCA 5.8.1 / 15	2005a	Evaluation of the mutagenic activity of VIS 01 in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay (with independent repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402536 GLP not published Syngenta File No R417888_10025	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**
Verspeek-Rip C.	KCA 5.8.1 / 16	2006	Evaluation of the Mutagenic Activity of VIS 01 in an in vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402525 GLP not published Syngenta File No R417888_10026	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA**

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Verspeek-Rip C.	KCA 5.8.1 / 274345	2004a	Evaluation of the Mutagenic Activity of SDS-46851 in the Salmonella Typhimurium Reverse Mutation Assay and the Escherichia Coli Reverse Mutation Assay (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402503 GLP not published Syngenta File No R611965_10018	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA **
Verspeek-Rip C.	KCA 5.8.1 / 284446	2005b	Evaluation of the Mutagenic Activity of SDS-46851 in an in vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells (With Independent Repeat) Vischim Srl, Milano, Italy NOTOX B.V., Hertogenbosch, Netherlands, 402492 GLP not published Syngenta File No R611965_10016	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Oxon Italia SpA **

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Wagner H.	KCA 5.8.3 / 05	2012	Chlorothalonil - H295R Steroidogenesis Assay Arysta LifeScience North America, LLC, Cary, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331STER GLP not published Syngenta File No R044686_50935	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wazeter F., Goldenthal E.	KCA 5.8.1 / 12	1976	Teratology Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3367 Not GLP not published Syngenta File No R44686/0794	Y	N	-	SYN
Wazeter FX	KCA 5.8.1 / 09	1971	Acute Oral LD50 in Male Albino Rats Syngenta Crop Protection AG, Basel, Switzerland CTL/C/3747 Not GLP not published Syngenta File No R44686/0847	Y	N	-	SYN

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Wilga P.	KCA 5.8.3 / 06	2011	Chlorothalonil - Human Recombinant Aromatase Assay Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta - Jealott's Hill, Bracknell, United Kingdom CeeTox, Inc., Kalamazoo, MI, USA, 9047V- 100331AROM GLP not published Syngenta File No R044686_50865	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force

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Willoughby J.	KCA 5.8.3 / 02	2011	Chlorothalonil - Estrogen Receptor Binding (Rat Uterine Cytosol) Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V-100331ERB GLP not published Syngenta File No R044686_50867	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Willoughby J.	KCA 5.8.3 / 03	2011a	Chlorothalonil - Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLA-9903)) Arysta LifeScience North America, LLC, Cary, NC, USA, SipcamAdvan, Durham, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, IBC Manufacturing Co., Memphis, TN, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA CeeTox, Inc., Kalamazoo, MI, USA, 9047V- 100331ERTA GLP not published Syngenta File No R044686_50866	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force

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Willoughby J.	KCA 5.8.3 / 04	2012	Chlorothalonil - Androgen Receptor Binding (Rat Prostate Cytosol) Arysta LifeScience North America, LLC, Cary, NC, USA, Makhteshim Agan of North America Inc, Raleigh, NC, USA, IBC Manufacturing Co., Memphis, TN, USA, SipcamAdvan, Durham, NC, USA, Vischim SrL, c/o Lewis & Harrison, LLC, Washington, DC, USA, Syngenta - Jealott's Hill, Bracknell, United Kingdom CeeTox, Inc., Kalamazoo, MI, USA, 9047V- 100331ARB GLP not published Syngenta File No R044686_50943	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	Chlorothalonil Task Force
Wilson NH, Ignatoski JA	KCA 5.8.2 / 02 & KCA 5.8.3 / 13	1982	Four-Week Dietary Range-Finding Study in Rats with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3261 GLP not published Syngenta File No R44686/0550	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/201 2	SYN

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Author(s)	Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
Wilson NH, Killeen JC, Ignatoski JA	KCA 5.8.2 / 07 & KCA 5.8.3 / 19	1985	A Tumorigenicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3328 GLP not published Syngenta File No R44686/1558	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Wilson NH, Killeen JC	KCA 5.8.2 / 08	1989	A Tumorigenicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3436 Not GLP not published Syngenta File No R44686/3218	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Wilson NH, Killeen JC	KCA 5.8.2 / 11 & KCA 5.8.3 / 21	1983	A Chronic Dietary Study in Mice with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3355 108-5TX-79-0102-004 GLP not published Syngenta File No R44686/0638	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Wilson NH, Killeen JC	KCA 5.8.2 / 12 & KCA 5.8.3 / 22	1987	A Tumorigenicity Study of Technical Chlorothalonil in Male Mice - Final Report Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3364 GLP not published Syngenta File No R44686/0511	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Wilson NH, Killeen JC	KCA 5.8.3 / 24	1988	A Teratology Study in Rabbits with Technical Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , CTL/C/3429 GLP not published Syngenta File No R44686/1014	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN
Wilson NH, Killeen JC, Ignatoski JA	KCA 5.8.2 / 03 & KCA 5.8.3 / 14	1981	A 90-Day Toxicity Study of Technical Chlorothalonil in Rats Syngenta Crop Protection AG, Basel, Switzerland , 099-5TX-80-0200-006, CTL/C/3283 GLP not published Syngenta File No R44686/0761	Y	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN

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Wollny H.	KCA 5.8.1 / 22	2007	Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells with R417888 ARYSTA LIFESCIENCE SAS, Noguères, France RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1030809 GLP not published Syngenta File No R417888_10021	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Arysta LifeScience
Wollny H.	KCA 5.8.1 / 25	2015	SYN548708 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677303 GLP not published Syngenta File No SYN548708_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Wollny H.	KCA 5.8.1 / 2829	2015a	SYN548765 - Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678103 GLP not published Syngenta File No SYN548765_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wollny H.	KCA 5.8.1 / 3132	2015b	SYN548766 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1678003 GLP not published Syngenta File No SYN548766_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wollny H.	KCA 5.8.1 / 3738	2015c	SYN548580 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677503 GLP not published Syngenta File No SYN548580_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Wollny H.	KCA 5.8.1 / 4041	2015d	SYN548764 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677403 GLP not published Syngenta File No SYN548764_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wollny H.	KCA 5.8.1 / 4951	2015e	R611968 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1677803 GLP not published Syngenta File No SYN548651_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wollny H.	KCA 5.8.1 / 55	2015f	R613636 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1677703 GLP not published Syngenta File No R613636_10012	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

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Wollny H.	KCA 5.8.1 / 56	2015g	R613636 - Gene Mutation Assay in Chinese Hamster V79 Cells in vitro (V79/HPRT) Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1711600 GLP not published Syngenta File No R613636_10014	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force
Wollny H.	KCA 5.8.1 / 60	2015h	SYN507900 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1699303 GLP not published Syngenta File No SYN507900_10006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	Chlorothalonil Task Force

*Data confidentiality is requested for these data. Disclosure of the information might undermine the company commercial interests by providing access to company specific know-how used to develop unique positions and approaches to risk assessment.

**OXON Italia SpA acquired Vischim S.r.l. in November 2011.

Listing of Test and Study Reports and published Papers not submitted, by Author**15 February 2015****KCA Section 5, Toxicological and metabolism studies on the active substance**

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None