

Cyprodinil

**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**

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
20 May 2016	CA 5.1, 5.4, 5.6, 5.6, 5.8.1, 5.8.2, 5.8.3, and 5.9.2 – additional reports included. Ongoing studies only included in data point list as author not yet known. (All changes highlighted in yellow)	CGA219417_11582 8 October 2015 updated 20/5/16
03 February 2017	CA 5.1, 5.4, 5.8.1 – additional reports included. (All changes are highlighted in green)	CGA219417_11582 8 October 2015 updated 20/5/16, 3/2/17
7 April 2017	CA 5.4, 5.8.1 – additional reports included. (All changes are highlighted in green)	CGA219417_11582 8 October 2015 updated 20/5/16, 3/2/17, 7/4/17
8 June 2017	CA 5.8.1 – 3 additional reports included. (All changes are highlighted in green)	CGA219417_11582 8 October 2015 updated 20/5/16, 3/2/17, 7/4/17, 6/6/17

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 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 Reasons for necessity for submission of tests and (3) d 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. |

Reference List, by Data Point

8 October 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	Thibaut R.	2017	Cyprodinil - In Vitro Comparative Metabolism of 14C-Cyprodinil in Human and Rat Liver Microsomes Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20160331 GLP not published Syngenta File No CGA219417_11769	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.2.7 / 01	Lehmeier D.	2014	Cyprodinil technical - In Vitro 3T3 NRU Phototoxicity Test Syngenta BSL Bioservice Scientific, Planegg, Germany, 142177 GLP not published Syngenta File No CGA219417_11555	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.3.3 / 01	Sommer E	2008	CGA219417 Tech - 28 day dermal toxicity (semi occlusive) study in the Wistar rat Syngenta - Jealott's Hill, Bracknell, United Kingdom RCC Ltd., Itingen, Switzerland, B65485, T004770-07 GLP not published Syngenta File No CGA219417_10986	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

Reference List, by Data Point

8 October 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 5.4.1 / 01	Sokolowski A	2009	Cyprodinil tech. - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta - Jealott's Hill, Bracknell, United Kingdom RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1247000, T009018-08 GLP not published Syngenta File No CGA219417_11373	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.4.1 / 02	Knight A. et al	2009	Evaluation of high-throughput genotoxicity assays used in profiling the US EPA ToxCast TM chemicals Regulatory Toxicology and Pharmacology 55 (2009) 188–199 Not GLP published Syngenta File No NA_13830	N	N	-	-
KCA 5.4.1 / 03	Wollny H.	2017	Cyprodinil - Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT) Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1791000 GLP not published Syngenta File No CGA219417_11767	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

Reference List, by Data Point

8 October 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 5.4.1 / 04	Naumann S.	2017	Cyprodinil - Micronucleus Test in Human Lymphocytes <i>In Vitro</i> . Syngenta Envigo CRS GmbH, Rossdorf, Germany. 1791000 GLP not published Syngenta File No CGA219417_11780	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.4.2 / 01	Fincher K.	2016	The following study is ongoing: Cyprodinil - Oral (Gavage) Proof of Exposure in the Mouse. Syngenta Sequani Limited, Bromyard Road, Ledbury, Herefordshire, HR8 1LH, United Kingdom. Laboratory Report No. BFI0514, GLP Unpublished. Syngenta File No CGA219417_11759	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.6.2 / 01	Sipes N. et al	2011	Predictive Models of Prenatal Developmental Toxicity from ToxCast High-Throughput Screening Data Toxicological Sciences. 124(1), 109-127 Not GLP published Syngenta File No NA_13834	N	N	-	-

Reference List, by Data Point

8 October 2015

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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 5.7 / 01 & KCA 5.8.2 / 07	Coleman M. et al	2012	A Preliminary Investigation into the Impact of a Pesticide Combination on Human Neuronal and Glial Cell Lines In Vitro PLoS ONE 7(8): e42768. doi:10.1371/journal.pone.0042768 Not GLP published Syngenta File No NA_13832	N	N		SYN
KCA 5.8.1 / 01	Manton J. Booth E.	2016	MULTI-(Q)SAR Genotoxicity Assessment of Cyprodinil and Dietary Metabolites Syngenta Not GLP not published Syngenta File No CGA219417_11750	N	N	-	SYN
K-CA 5.8.1/02	Chang S.	2017	The following study is ongoing: NOA422054 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. NOA422054_10002	N	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)
K-CA 5.8.1/03	Naumann S.	2017a	The following study is ongoing: NOA422054 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. NOA422054_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
K-CA 5.8.1/04	Chang S.	2017a	The following study is ongoing: CGA321915 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. CGA321915_10023	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
K-CA 5.8.1/05	Naumann S.	2017b	The following study is ongoing: CGA321915 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. CGA321915_10021	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

Reference List, by Data Point

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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 5.8.1 / 06	Hertner T.	1994	Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 943052 GLP not published Syngenta File No CGA263208/0001	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 07	Hertner T.	1992	Salmonella and escherichia/liver-microsome test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 923050 GLP not published Syngenta File No CA1139/0006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
K-CA 5.8.1/08	Chang S.	2016/2017	The following study is ongoing: CGA263208-CA1139 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany 1781800 GLP Unpublished. Syngenta File No CA1139_10008	N	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 5.8.1 / 09	Hertner T.	1992a	Cytogenetic test on Chinese hamster cells in vitro (EC-conform). Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 923051 GLP not published Syngenta File No CA1139/0007	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 10	Dony E.	2015	Reg.No. 4182909 (Metabolite of BAS 605 F, Pyrimethanil) tested as carbonate salt: Micronucleus Assay in Bone Marrow Cells of the Rat BASF Ltd., Ludwigshafen, Germany Envigo CRS GmbH, Rossdorf, Germany, 06M0319/15X114, 2015/1186908, 789065 GLP not published Syngenta File No CGA263208_10011	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 11	Grauert E., Kamp H.	2015	Reg.No. 4182909 (Metabolite of BAS 605 F, Pyrimethanil) tested as carbonate salt Plasma Analysis for external studies BASF Ltd., Ludwigshafen, Germany BASF Ltd., Ludwigshafen, Germany, 06Y0319/15Y023, 2015/1223832 GLP not published Syngenta File No CGA263208_10010	N	Y	New data; eligible for data protection according to SANCO/12576/2012	BASF (SYN access)

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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 5.8.1 / 1112	Hertner T.	1994a	Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 943054 GLP not published Syngenta File No CGA304075/0002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
K-CA 5.8.1/1213	Chang S.	20162017	The following study is ongoing: CGA304075 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany. 1781600 GLP Unpublished. Syngenta File No CGA304075_10005	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
K-CA 5.8.1/1314	Naumann S.	20162017	The following study is ongoing: CGA304075 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany 1781700 GLP Unpublished. Syngenta File No CGA304075_10003	N	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

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KCA 5.8.1 / 1415	Hartmann H.R.	1994	CGA 263208 tech. (Plant metabolite of CGA 219417) - Acute oral toxicity in the rat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 943051 GLP not published Syngenta File No CGA263208/0002	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 1516	Hartmann H.R.	1992	CA 1139 A - Acute oral toxicity in the rat. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 923045 GLP not published Syngenta File No CA1139/0001	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 1617	Hartmann H.R.	1991	CGA 263208 tech.: Acute Oral Toxicity in the Rat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 911054 GLP not published Syngenta File No CA1059/0001	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 5.8.1 / 1718	Altmann B.	2002	CGA263208 tech. - 90-day oral toxicity study in rats (Administration in food) Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 20013024 GLP not published Syngenta File No CGA263208/0005	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 1819	Khalil S.	2002	Cyprodinil - Prenatal developmental toxicity study in the rat Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 20013025 GLP not published Syngenta File No CGA263208/0006	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.1 / 1920	Schoch M.	1994	Acute oral toxicity in the rat. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 943053 GLP not published Syngenta File No CGA304075/0001	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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8 October 2015

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

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KCA 5.8.2 / 01	Bhandal H.	2015	Cyprodinil - Position Statement Concerning Immunotoxicity Potential Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, TK0223683 Not GLP not published Syngenta File No CGA219417_11652 This is CONFIDENTIAL INFORMATION	N	N	-	SYN*
KCA 5.8.2 / 02	Crittenden P.	2010	Cyprodinil - A 28-Day Dietary Immunotoxicity Study in CD-1 Female Mice Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639075 GLP not published Syngenta File No CGA219417_11448	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 5.8.2 / 03	Shah I. et al	2011	Using Nuclear Receptor Activity to Stratify Hepatocarcinogens <i>PLoS ONE</i> . Vol 6, Issue 2, e14584 Not GLP published Syngenta File No NA_13828	N	N	-	-

Reference List, by Data Point

8 October 2015

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

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KCA 5.8.2 / 04	Judson R.	2010	In Vitro Screening of Environmental Chemicals for Targeted Testing Prioritization: The ToxCast Project <i>Environ Health Perspect</i> 118:485-492 Not GLP published Syngenta File No NA_13831	N	N	-	-
KCA 5.8.2 / 05	Wetmore B. et al	2012	Integration of Dosimetry, Exposure, and High-Throughput Screening Data in Chemical Toxicity Assessment <i>Toxicological Sciences</i> 125(1), 157-174 Not GLP published Syngenta File No NA_13821	N	N	-	-
KCA 5.8.2 / 06	Chorfa A. et al	2014	A variety of pesticides trigger in vitro α synuclein accumulation, a key event in Parkinson's disease <i>Arch Toxicol.</i> DOI 10.1007/s00204-014-1388-2. Not GLP published Syngenta File No NA_13827	N	N	-	-

Reference List, by Data Point

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KCA 5.8.2 / 08	Fang C. et al	2013	Cyprodinil as an activator of aryl hydrocarbon receptor Toxicology 304:32-40 Not GLP published Syngenta File No CGA219417_11675	N	N	-	-
KCA 5.8.2 / 09	Retroff D. et al	2010	Incorporating Human Dosimetry and Exposure into High-Throughput In Vitro Toxicity Screening Toxicological Sciences 117(2), 348–358 Not GLP published Syngenta File No NA_13825	N	N	-	-
KCA 5.8.2 / 10	Retroff D.	2010a	Xenobiotic-metabolizing enzyme and transporter gene expression in primary cultures of human hepatocytes modulated by toxcast chemicals Journal of Toxicology and Environmental Health, Part B: Critical Reviews, 13:2-4, 329- 346, DOI: 10.1080/10937404.2010.483949 Not GLP published Syngenta File No NA_13823	N	N	-	-

Reference List, by Data Point

8 October 2015

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KCA 5.8.3 / 01	Charlton A.	2015	Cyprodinil - Review for Potential for Endocrine Disruption in Mammalian Species Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP not published Syngenta File No CGA219417_11641 This is CONFIDENTIAL INFORMATION	N	N	-	SYN*
KCA 5.8.3 / 02	Reif D., et al.	2010	Endocrine Profiling and Prioritization of Environmental Chemicals Using ToxCast Data <i>Environ. Health Perspec.</i> 118(12) : 1714-1720 Not GLP published Syngenta File No NA_13716	N	N	-	-
KCA 5.8.3 / 03	Rotroff D., et al.	2013	Using in Vitro High Throughput Screening Assays to Identify Potential Endocrine-Disrupting Chemicals <i>Environ. Health Perspec.</i> 121(1) : 7-14 Not GLP published Syngenta File No NA_13717	N	N	-	-

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KCA 5.8.3 / 04	Rotroff D., et al	2014	Predictive Endocrine Testing in the 21st Century Using in Vitro Assays of Estrogen Receptor Signaling Responses <i>Environ. Sci. Technol.</i> 48 : 8706-8716, Not GLP published Syngenta File No NA_13715	N	N	-	-
KCA 5.8.3 / 05	Orton F., Rosivatz E., Scholze M., Kortenkamp A.	2011	Widely Used Pesticides with Previously Unknown Endocrine Activity Revealed as in Vitro Antiandrogens <i>Environ Health Perspect</i> 119 :(6)794–800 Not GLP published Syngenta File No NA_13741	N	N	-	-
KCA 5.8.3 / 06	Orton F. et al	2012	Competitive Androgen Receptor Antagonism as a Factor Determining the Predictability of Cumulative Antiandrogenic Effects of Widely Used Pesticides <i>Environ Health Perspect</i> 120 :1578–1584 Not GLP published Syngenta File No NA_13820	N	N	-	-

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KCA 5.8.3 / 07	Medjakovic S. et al	2013	Effect of Nonpersistent Pesticides on Estrogen Receptor, Androgen Receptor, and Aryl Hydrocarbon Receptor Wiley Online Library (wileyonlinelibrary.com).DOI 10.1002/tox.21852 Not GLP published Syngenta File No NA_13826	N	N	-	-
KCA 5.8.3 / 08	Sipes N. et al	2013	Profiling 976 ToxCast Chemicals across 331 Enzymatic and Receptor Signaling Assays <i>Chem. Res. Toxicol.</i> 26, 878-895 Not GLP published Syngenta File No NA_13822	N	N	-	-
KCA 5.8.3 / 09	Prutner W. et al	2013	Effects of single pesticides and binary pesticide mixtures on estrone production in H295R cells <i>Arch Toxicol.</i> 87:2201–2214 Not GLP published Syngenta File No NA_13824	N	N	-	-

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KCA 5.8.3 / 10	Go R. Choi K.	2014	Antifungal Agents As Agricultural Products, Fenhexamid, Fludioxonil, and Cyprodonil, Induced The Expression of Cytochrome P450 Family and Cell Cycle-Related Genes in Estrogen Receptor Expressing BG-1 Ovarian Cancer Cells Reproduction, Fertility and Development 27(1) 201-201, Not GLP published Syngenta File No NA_13833	N	N	-	-
KCA 5.9.2 / 01	Schummer C., Salquebre G., Briand O., Millet M., Appenzeller B.	2012	Determination of farm workers' exposure to pesticides by hair analysis Toxicology Letters 210;203-210 Not GLP published Syngenta File No NA_13850	N	N	-	-
KCA 5.9.2 / 02	Li Y., Chen L., Chen Z., Coehlo J., Cui L., Liu Y., Lopez T., Sankaran G., Vega H., Krieger R.	2011	Glove accumulation of pesticide residues for strawberry harvester exposure assessment Bull Environ Contam Toxicol. 86:615-620 Not GLP published Syngenta File No NA_13851	N	N	-	-

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KCA 5.9.2 / 03	Hassan A.	2012	Effects reported in farm workers repeatedly exposed to pesticides Abstracts / Toxicology Letters 211S; S43-S216. Meeting Info: 48th Congress of the European Societies of Toxicology Not GLP published Syngenta File No NA_13849	N	N	-	-
KCA 5.9.2 / 04	Appenzeller B., Schummer C., Salquebre G., Millet M., Briand O.	2011	Hair analysis to document human exposure to agricultural and non-agricultural pesticides Abstracts / Toxicology Letters 205S; S60-S179. Meeting Info.: 47 th Congress of the European-Societies-of-Toxicology Not GLP published Syngenta File No NA_13852	N	N	-	-
KCA 5.9.2 / 05	Rapagnani M., Rossi R., Caffarelli V., Mazzini F.	2007	Evaluation of potential health risk for operators in Emilia Romagna region (Italy) using exposure models XIII Symposium Pesticide Chemistry - Environmental Fate & Ecological Effects Not GLP published Syngenta File No NA_13848	N	N	-	-

*Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta's commercial interests by providing access to Syngenta specific know-how used to develop unique positions and approaches to risk assessment.

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Altmann B.	KCA 5.8.1 / 1718	2002	CGA263208 tech. - 90-day oral toxicity study in rats (Administration in food) Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 20013024 GLP not published Syngenta File No CGA263208/0005	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Appenzeller B., Schummer C., Salquebre G., Millet M., Briand O.	KCA 5.9.2 / 04	2011	Hair analysis to document human exposure to agricultural and non-agricultural pesticides Abstracts / Toxicology Letters 205S; S60-S179. Meeting Info.: 47 th Congress of the European-Societies-of-Toxicology Not GLP published Syngenta File No NA_13852	N	N	-	-
Bhandal H.	KCA 5.8.2 / 01	2015	Cyprodinil - Position Statement Concerning Immunotoxicity Potential Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, TK0223683 Not GLP not published Syngenta File No CGA219417_11652 This is CONFIDENTIAL INFORMATION	N	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)
Chang S.	K-CA 5.8.1/02	2017	The following study is ongoing: NOA422054 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. NOA422054_10002	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Chang S.	K-CA 5.8.1/04	2017a	The following study is ongoing: CGA321915 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. CGA321915_10023	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Chang S.	K-CA 5.8.1/08	2016/2017	The following study is ongoing: CGA263208-CA1139 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany 1781800 GLP Unpublished. Syngenta File No CA1139_10008	N	Y	New data; eligible for data protection according to SANCO/12576/2012	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)
Chang S.	K-CA 5.8.1/1213	2016/2017	The following study is ongoing: CGA304075 - Cell Gene Mutation Assay in Chinese Hamster V79 Cells <i>in vitro</i> (V79/HPRT). Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany. 1781600 GLP Unpublished. Syngenta File No CGA304075_10005	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Charlton A.	KCA 5.8.3 / 01	2015	Cyprodinil - Review for Potential for Endocrine Disruption in Mammalian Species Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP not published Syngenta File No CGA219417_11641 This is CONFIDENTIAL INFORMATION	N	N	-	SYN*
Chorfa A. et al	KCA 5.8.2 / 06	2014	A variety of pesticides trigger <i>in vitro</i> α synuclein accumulation, a key event in Parkinson's disease Arch Toxicol. DOI 10.1007/s00204-014-1388-2. Not GLP published Syngenta File No NA_13827	N	N	-	-

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

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)
Coleman M.et al	KCA 5.7 / 01 & KCA 5.8.2 / 07	2012	A Preliminary Investigation into the Impact of a Pesticide Combination on Human Neuronal and Glial Cell Lines In Vitro PLoS ONE 7(8): e42768. doi:10.1371/journal.pone.0042768 Not GLP published Syngenta File No NA_13832	N	N		SYN
Crittenden P.	KCA 5.8.2 / 02	2010	Cyprodinil - A 28-Day Dietary Immunotoxicity Study in CD-1 Female Mice Syngenta WIL Research Laboratories, LLC, Ashland, OH, USA, WIL-639075 GLP not published Syngenta File No CGA219417_11448	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Dony E.	KCA 5.8.1 / 10	2015	Reg.No. 4182909 (Metabolite of BAS 605 F, Pyrimethanil) tested as carbonate salt: Micronucleus Assay in Bone Marrow Cells of the Rat BASF Ltd., Ludwigshafen, Germany Envigo CRS GmbH, Rossdorf, Germany, 06M0319/15X114, 2015/1186908, 789065 GLP not published Syngenta File No CGA263208_10011	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Fang C. et al	KCA 5.8.2 / 08	2013	Cyprodinil as an activator of aryl hydrocarbon receptor Toxicology 304:32-40 Not GLP published Syngenta File No CGA219417_11675	N	N	-	-
Fincher K.	KCA 5.4.2 / 01	2016	The following study is ongoing: Cyprodinil - Oral (Gavage) Proof of Exposure in the Mouse. Syngenta Sequani Limited, Bromyard Road, Ledbury, Herefordshire, HR8 1LH, United Kingdom. Laboratory Report No. BFI0514, GLP Unpublished. Syngenta File No CGA219417_11759	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Go R. Choi K.	KCA 5.8.3 / 10	2014	Antifungal Agents As Agricultural Products, Fenhexamid, Fludioxonil, and Cyprodinil, Induced The Expression of Cytochrome P450 Family and Cell Cycle-Related Genes in Estrogen Receptor Expressing BG-1 Ovarian Cancer Cells Reproduction, Fertility and Development 27(1) 201-201, Not GLP published Syngenta File No NA_13833	N	N	-	-

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Grauert E., Kamp H.	KCA 5.8.1 / 11	2015	Reg.No. 4182909 (Metabolite of BAS 605 F, Pyrimethanil) tested as carbonate salt Plasma Analysis for external studies BASF Ltd., Ludwigshafen, Germany BASF Ltd., Ludwigshafen, Germany. 06Y0319/15Y023, 2015/1223832 GLP not published Syngenta File No CGA263208_10010	N	Y	New data; eligible for data protection according to SANCO/12576/2012	BASF (SYN access)
Hartmann H.R.	KCA 5.8.1 / 1415	1994	CGA 263208 tech. (Plant metabolite of CGA 219417) - Acute oral toxicity in the rat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 943051 GLP not published Syngenta File No CGA263208/0002	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Hartmann H.R.	KCA 5.8.1 / 1516	1992	CA 1139 A - Acute oral toxicity in the rat. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 923045 GLP not published Syngenta File No CA1139/0001	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

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)
Hartmann H.R.	KCA 5.8.1 / 1617	1991	CGA 263208 tech.: Acute Oral Toxicity in the Rat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 911054 GLP not published Syngenta File No CA1059/0001	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Hassan A.	KCA 5.9.2 / 03	2012	Effects reported in farm workers repeatedly exposed to pesticides Abstracts / Toxicology Letters 211S; S43-S216. Meeting Info: 48th Congress of the European Societies of Toxicology Not GLP published Syngenta File No NA_13849	N	N	-	-
Hertner T.	KCA 5.8.1 / 06	1994	Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 943052 GLP not published Syngenta File No CGA263208/0001	N	Y	New data; eligible for data protection according to SANCO/12576/2012	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)
Hertner T.	KCA 5.8.1 / 07	1992	Salmonella and escherichia/liver-microsome test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 923050 GLP not published Syngenta File No CA1139/0006	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Hertner T.	KCA 5.8.1 / 09	1992a	Cytogenetic test on Chinese hamster cells in vitro (EC-conform). Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 923051 GLP not published Syngenta File No CA1139/0007	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Hertner T.	KCA 5.8.1 / 112	1994a	Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 943054 GLP not published Syngenta File No CGA304075/0002	N	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

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)
Judson R.	KCA 5.8.2 / 04	2010	In Vitro Screening of Environmental Chemicals for Targeted Testing Prioritization: The ToxCast Project <i>Environ Health Perspect</i> 118:485-492 Not GLP published Syngenta File No NA_13831	N	N	-	-
Khalil S.	KCA 5.8.1 / 1819	2002	Cyprodinil - Prenatal developmental toxicity study in the rat Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 20013025 GLP not published Syngenta File No CGA263208/0006	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN
Knight A. et al	KCA 5.4.1 / 02	2009	Evaluation of high-throughput genotoxicity assays used in profiling the US EPA ToxCast TM chemicals <i>Regulatory Toxicology and Pharmacology</i> 55 (2009) 188–199 Not GLP published Syngenta File No NA_13830	N	N	-	-

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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)
Lehmeier D.	KCA 5.2.7 / 01	2014	Cyprodinil technical - In Vitro 3T3 NRU Phototoxicity Test Syngenta BSL Bioservice Scientific, Planegg, Germany, 142177 GLP not published Syngenta File No CGA219417_11555	N	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN
Li Y., Chen L., Chen Z., Coehlo J., Cui L., Liu Y., Lopez T., Sankaran G., Vega H., Krieger R.	KCA 5.9.2 / 02	2011	Glove accumulation of pesticide residues for strawberry harvester exposure assessment Bull Environ Contam Toxicol. 86:615-620 Not GLP published Syngenta File No NA_13851	N	N	-	-
Manton J. Booth E.	KCA 5.8.1 / 01	2016	MULTI-(Q)SAR Genotoxicity Assessment of Cyprodinil and Dietary Metabolites Syngenta Not GLP not published Syngenta File No CGA219417_11750	N	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)
Medjakovic S. et al	KCA 5.8.3 / 07	2013	Effect of Nonpersistent Pesticides on Estrogen Receptor, Androgen Receptor, and Aryl Hydrocarbon Receptor Wiley Online Library (wileyonlinelibrary.com).DOI 10.1002/tox.21852 Not GLP published Syngenta File No NA_13826	N	N	-	-
Naumann S.	KCA 5.4.1 / 04	2017	Cyprodinil - Micronucleus Test in Human Lymphocytes <i>In Vitro</i> . Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1791000 GLP not published Syngenta File No CGA219417_11780	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Naumann S.	K-CA 5.8.1/03	2017a	The following study is ongoing: NOA422054 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. NOA422054_10000	N	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

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Naumann S.	K-CA 5.8.1/05	2017b	The following study is ongoing: CGA321915 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP Unpublished. Syngenta File No. CGA321915_10021	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Naumann S.	K-CA 5.8.1/1314	20162017	The following study is ongoing: CGA304075 - Micronucleus test in human lymphocytes <i>in vitro</i> . Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany 1781700 GLP Unpublished. Syngenta File No CGA304075_10003	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Orton F. et al	KCA 5.8.3 / 06	2012	Competitive Androgen Receptor Antagonism as a Factor Determining the Predictability of Cumulative Antiandrogenic Effects of Widely Used Pesticides <i>Environ Health Perspect</i> 120 :1578–1584 Not GLP published Syngenta File No NA_13820	N	N	-	-

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

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)
Orton F., Rosivatz E., Scholze M., Kortenkamp A.	KCA 5.8.3 / 05	2011	Widely Used Pesticides with Previously Unknown Endocrine Activity Revealed as in Vitro Antiandrogens <i>Environ Health Perspect</i> 119 :(6)794–800 Not GLP published Syngenta File No NA_13741	N	N	-	-
Prutner W. et al	KCA 5.8.3 / 09	2013	Effects of single pesticides and binary pesticide mixtures on estrone production in H295R cells <i>Arch Toxicol.</i> 87 :2201–2214 Not GLP published Syngenta File No NA_13824	N	N	-	-
Rapagnani M., Rossi R., Caffarelli V., Mazzini F.	KCA 5.9.2 / 05	2007	Evaluation of potential health risk for operators in Emilia Romagna region (Italy) using exposure models XIII Symposium Pesticide Chemistry - Environmental Fate & Ecological Effects Not GLP published Syngenta File No NA_13848	N	N	-	-

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

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Reif D., et al.	KCA 5.8.3 / 02	2010	Endocrine Profiling and Prioritization of Environmental Chemicals Using ToxCast Data <i>Environ. Health Perspec.</i> 118(12) : 1714-1720 Not GLP published Syngenta File No NA_13716	N	N	-	-
Retroff D.	KCA 5.8.2 / 10	2010a	Xenobiotic-metabolizing enzyme and transporter gene expression in primary cultures of human hepatocytes modulated by toxcast chemicals <i>Journal of Toxicology and Environmental Health, Part B: Critical Reviews</i> , 13:2-4, 329- 346, DOI: 10.1080/10937404.2010.483949 Not GLP published Syngenta File No NA_13823	N	N	-	-
Retroff D. et al	KCA 5.8.2 / 09	2010	Incorporating Human Dosimetry and Exposure into High-Throughput In Vitro Toxicity Screening <i>Toxicological Sciences</i> 117(2), 348-358 Not GLP published Syngenta File No NA_13825	N	N	-	-

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Retroff D., et al	KCA 5.8.3 / 04	2014	Predictive Endocrine Testing in the 21st Century Using in Vitro Assays of Estrogen Receptor Signaling Responses <i>Environ. Sci. Technol.</i> 48 : 8706-8716, Not GLP published Syngenta File No NA_13715	N	N	-	-
Retroff D., et al.	KCA 5.8.3 / 03	2013	Using in Vitro High Throughput Screening Assays to Identify Potential Endocrine- Disrupting Chemicals <i>Environ. Health Perspec.</i> 121(1) : 7-14 Not GLP published Syngenta File No NA_13717	N	N	-	-
Schoch M.	KCA 5.8.1 / 1920	1994	Acute oral toxicity in the rat. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 943053 GLP not published Syngenta File No CGA304075/0001	Y	Y	New data; eligible for data protection according to SANCO/12576/ 2012	SYN

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Schummer C., Salquebre G., Briand O., Millet M., Appenzeller B.	KCA 5.9.2 / 01	2012	Determination of farm workers' exposure to pesticides by hair analysis Toxicology Letters 210;203-210 Not GLP published Syngenta File No NA_13850	N	N	-	-
Shah I. et al	KCA 5.8.2 / 03	2011	Using Nuclear Receptor Activity to Stratify Hepatocarcinogens PLoS ONE. Vol 6, Issue 2, e14584 Not GLP published Syngenta File No NA_13828	N	N	-	-
Sipes N. et al	KCA 5.6.2 / 01	2011	Predictive Models of Prenatal Developmental Toxicity from ToxCast High-Throughput Screening Data Toxicological Sciences. 124(1), 109-127 Not GLP published Syngenta File No NA_13834	N	N	-	-
Sipes N. et al	KCA 5.8.3 / 08	2013	Profiling 976 ToxCast Chemicals across 331 Enzymatic and Receptor Signaling Assays Chem. Res. Toxicol. 26, 878-895 Not GLP published Syngenta File No NA_13822	N	N	-	-

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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 5.4.1 / 01	2009	Cyprodinil tech. - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta - Jealott's Hill, Bracknell, United Kingdom RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 1247000, T009018-08 GLP not published Syngenta File No CGA219417_11373	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Sommer E	KCA 5.3.3 / 01	2008	CGA219417 Tech - 28 day dermal toxicity (semi occlusive) study in the Wistar rat Syngenta - Jealott's Hill, Bracknell, United Kingdom RCC Ltd., Itingen, Switzerland, B65485, T004770-07 GLP not published Syngenta File No CGA219417_10986	Y	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Thibaut R.	KCA 5.1.1 / 01	2017	Cyprodinil - In Vitro Comparative Metabolism of 14C-Cyprodinil in Human and Rat Liver Microsomes Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20160331 GLP not published Syngenta File No CGA219417_11769	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Wetmore B. et al	KCA 5.8.2 / 05	2012	Integration of Dosimetry, Exposure, and High-Throughput Screening Data in Chemical Toxicity Assessment Toxicological Sciences 125(1), 157-174 Not GLP published Syngenta File No NA_13821	N	N	-	-
Wollny H.	KCA 5.4.1 / 03	2017	Cyprodinil - Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT) Syngenta Envigo CRS GmbH, Rossdorf, Germany, 1791000 GLP not published Syngenta File No CGA219417_11767	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

*Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta's commercial interests by providing access to Syngenta specific know-how used to develop unique positions and approaches to risk assessment.

Listing of Test and Study Reports and published Papers not submitted, by Author**8 October 2015****KCA Section 5, Toxicological and metabolism studies on the active substance**

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)
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None