

Fludioxonil

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

**DOCUMENT L-CA, Section 7
Supplement Reference List**

**FATE AND BEHAVIOUR IN THE
ENVIRONMENT**

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
12/1/17	References for the metabolite SYN545245 included. All amendments are highlighted in yellow.	CGA173506_11824 11 April 2016 updated 12/1/17

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 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**KCA Section 7, Fate and behaviour in the environment**

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 7.1.1.1 / 01	Piskorski R.	2015	CGA173506 - Aerobic Soil Metabolism of 14C-CGA173506 Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20130103 GLP not published Syngenta File No CGA173506_11767	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.1.1.1 / 02	Adam D., Wijntjes C.	2015	CGA265378 - Aerobic Rate of Degradation of 14C-CGA265378 Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20140089 GLP not published Syngenta File No CGA265378_10009	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.1.1.1 / 03	Caviezel A.	2016	SYN545245 - Rate of Degradation of SYN545245 in Three Soils under Aerobic Laboratory Conditions Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20150138 GLP not published Syngenta File No SYN545245_10003	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 7.1.1.3 / 01	Miner P.	2009	Photo-transformation of [Phenyl-U-14C]CGA173506 in or on Soil Under Artificial Sunlight Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 023917-1 GLP not published Syngenta File No CGA173506_11661	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.1.1.3 / 02	Adam D.	2015	Fludioxonil - Soil Photolysis of 14C-Fludioxonil Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20130117 GLP not published Syngenta File No CGA173506_11806	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.1.2.1.1 / 01	Sachers S.	2015	Fludioxonil - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-1 Not GLP not published Syngenta File No CGA173506_11900 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

Reference List, by Data Point**KCA Section 7, Fate and behaviour in the environment**

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KCA 7.1.2.1.2 / 01	Sachers S.	2015a	CGA265378 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-2 Not GLP not published Syngenta File No CGA265378_10016 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 7.1.2.1.2 / 02	Sachers S.	2015b	CGA339833 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-3 Not GLP not published Syngenta File No CGA339833_10013 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 7.1.2.1.2 / 03	Sachers S.	2015c	CGA192155 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-4 Not GLP not published Syngenta File No CGA192155_11298 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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KCA 7.1.2.1.2 / 04	Pietsch K.	2016	SYN545245 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 105355-1 Not GLP not published Syngenta File No SYN545245_10017 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 7.1.2.1.2 / 0405	Hayes S.	2016	Fludioxonil - Kinetic Description of the Formation of Photo-degradates (CGA265378, CGA339833, CGA192155 and SYN545245) Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1132B Not GLP not published Syngenta File No CGA173506_11894 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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KCA 7.1.2.2.1 / 01	Emburey S.	2004	Fludioxonil : Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3547B GLP not published Syngenta File No CGA173506/5993	N	Y	New data as not previously relied on; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.1.2.2.1 / 02	Ford S.	2016	Fludioxonil - Kinetic Assessment of Field Dissipation Data for Trigger Endpoints Syngenta JSC International Ltd., Harrogate, United Kingdom, SYN/12/09-Kin03 Not GLP not published Syngenta File No CGA173506_11903 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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KCA 7.1.2.2.1 / 03	Ford S.	2016a	Fludioxonil - Kinetic Assessment of Temperature Normalised Field Dissipation Data for Modelling Endpoints Syngenta JSC International Ltd., Harrogate, United Kingdom, SYN/12/09-Kin02 Not GLP not published Syngenta File No CGA173506_11902 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 7.1.2.2.1 / 04	Ford S.	2016b	Fludioxonil - Kinetic Assessment of Field Dissipation Data for Modelling Endpoints Syngenta JSC International Ltd., Harrogate, United Kingdom, SYN/12/09-Kin01 Not GLP not published Syngenta File No CGA173506_11901 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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KCA 7.1.2.2.1 / 05	Patterson D.	2016	Fludioxonil - Soil Degradation Half-Life Selection for use in Environmental Fate modelling Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1136B Not GLP not published Syngenta File No CGA173506_11895 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 7.1.3.1.2 / 01	Caviezel A.	2016a	SYN545245 - Adsorption/Desorption of SYN545245 in Three Soils Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20150137 GLP not published Syngenta File No SYN545245_10015	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.2.1.2 / 01	Miner P.	2013	Photo-transformation of [Phenyl-U-14C]- CGA173506 in Sterile Buffered Aqueous Solution Under Artificial Sunlight Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 023916-1-1 GLP not published Syngenta File No CGA173506_50057	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 7.2.2.2 / 01	Matthews M., Schaefer E.	2016	Fludioxonil - Aerobic Mineralization of 14C- Labelled Fludioxonil in Surface Water Syngenta Wildlife International Ltd., Easton, Maryland 21601, USA, 528E-107 GLP not published Syngenta File No CGA173506_11940	N	N	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 7.2.2.2 / 02	Thomas K., Hand L.	2011	Assessing the potential for algae and macrophytes to degrade crop protection products in aquatic ecosystems Environmental Toxicology and Chemistry. (2011), Vol 30, No. 3, 622 - 631. Not GLP published Syngenta File No CGA173506_11944	N	N	-	-
KCA 7.2.2.4 / 01	Pietsch K.	2015	Fludioxonil - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints (including water/sediment metabolite CGA 192155) Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-5 Not GLP not published Syngenta File No CGA173506_11899 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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*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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Adam D.	KCA 7.1.1.3 / 02	2015	Fludioxonil - Soil Photolysis of 14C-Fludioxonil Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20130117 GLP not published Syngenta File No CGA173506_11806	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Adam D., Wijntjes C.	KCA 7.1.1.1 / 02	2015	CGA265378 - Aerobic Rate of Degradation of 14C-CGA265378 Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20140089 GLP not published Syngenta File No CGA265378_10009	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Caviezel A.	KCA 7.1.1.1 / 03	2016	SYN545245 - Rate of Degradation of SYN545245 in Three Soils under Aerobic Laboratory Conditions Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20150138 GLP not published Syngenta File No SYN545245_10003	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Caviezel A.	KCA 7.1.3.1.2 / 01	2016a	SYN545245 - Adsorption/Desorption of SYN545245 in Three Soils Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20150137 GLP not published Syngenta File No SYN545245_10015	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Emburey S.	KCA 7.1.2.2.1 / 01	2004	Fludioxonil : Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3547B GLP not published Syngenta File No CGA173506/5993	N	Y	New data as not previously relied on; eligible for data protection according to SANCO/12576/2012	SYN
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Hayes S.	KCA 7.1.2.1.2 / 0405	2016	Fludioxonil - Kinetic Description of the Formation of Photo-degradates (CGA265378, CGA339833, CGA192155 and SYN545245) Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1132B Not GLP not published Syngenta File No CGA173506_11894 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
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Matthews M., Schaefer E.	KCA 7.2.2.2 / 01	2016	Fludioxonil - Aerobic Mineralization of 14C-Labelled Fludioxonil in Surface Water Syngenta Wildlife International Ltd., Easton, Maryland 21601, USA, 528E-107 GLP not published Syngenta File No CGA173506_11940	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Patterson D.	KCA 7.1.2.2.1 / 05	2016	Fludioxonil - Soil Degradation Half-Life Selection for use in Environmental Fate modelling Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1136B Not GLP not published Syngenta File No CGA173506_11895 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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Pietsch K.	KCA 7.1.2.1.2 / 04	2016	SYN545245 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 105355-1 Not GLP not published Syngenta File No SYN545245_10017 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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Piskorski R.	KCA 7.1.1.1 / 01	2015	CGA173506 - Aerobic Soil Metabolism of 14C-CGA173506 Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20130103 GLP not published Syngenta File No CGA173506_11767	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Sachers S.	KCA 7.1.2.1.1 / 01	2015	Fludioxonil - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-1 Not GLP not published Syngenta File No CGA173506_11900 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
Sachers S.	KCA 7.1.2.1.2 / 01	2015a	CGA265378 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-2 Not GLP not published Syngenta File No CGA265378_10016 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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Sachers S.	KCA 7.1.2.1.2 / 02	2015b	CGA339833 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-3 Not GLP not published Syngenta File No CGA339833_10013 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
Sachers S.	KCA 7.1.2.1.2 / 03	2015c	CGA192155 - Laboratory Degradation Kinetics for Persistence and Modelling Endpoints Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-4 Not GLP not published Syngenta File No CGA192155_11298 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
Thomas K., Hand L.	KCA 7.2.2.2 / 02	2011	Assessing the potential for algae and macrophytes to degrade crop protection products in aquatic ecosystems Environmental Toxicology and Chemistry. (2011), Vol 30, No. 3, 622 - 631. Not GLP published Syngenta File No CGA173506_11944	N	N	-	-

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Listing of Test and Study Reports and published Papers not submitted, by Author**KCA Section 7, Fate and behaviour in the environment**

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None