

# **Fludioxonil**

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

### **DOCUMENT L-CA, Section 1 Supplement Reference List**

#### **IDENTITY OF THE ACTIVE SUBSTANCE**

## Version history<sup>1</sup>

Date	Data points containing amendments or additions and brief description	Document identifier and version number
17/1/17	CA 1.8 & CA 1.11 Additional confidential references included in response to questions from the RMS.  All amendments are highlighted in yellow.	CGA173506_11819 5 March 2016 updated 17/1/17

<sup>1</sup> 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.

Art. Justifications of steps  
33 taken to avoid animal  
(3) c 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. Reasons for necessity for  
33 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****5 March 2016****KCA Section 1, Identity of 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)
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KCA 1.8 / 01	Kendall A.	2017	Fludioxonil - EU - Data Sheets for Starting Materials Syngenta Not GLP not published Syngenta File No CGA173506_12047 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 1.8 / 02	Kendall A.	2016	Fludioxonil - Starting Materials - Confidential Statement Syngenta Not GLP not published Syngenta File No CGA173506_12043 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 1.11 / 01	Kettner R.	2016	Fludioxonil Technical - Analysis of Five Representative Batches Produced at Syngenta Crop Protection, Monthey, Switzerland Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, CHMU150973 GLP not published Syngenta File No CGA173506_11890 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 1.11 / 02	Dull B.	2016	Fludioxonil Technical Material: Statement on the Accountability/Analytical Closure for Batch Analysis (Study CHMU150973) Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300052719 Not GLP not published Syngenta File No CGA173506_11904 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 1.11 / 03	Mink C.	2016	Fludioxonil Technical - Analysis of Five Representative Batches Produced at Fine Organics Limited, Middlesbrough, United Kingdom Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, CHMU150972 GLP not published Syngenta File No CGA173506_11892 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 1.11 / 04	Simonin C.	2017	Fludioxonil Technical Material: Statement on the Accountability/Analytical Closure for Batch Analysis (Study CHMU150972) Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300073294 Not GLP not published Syngenta File No CGA173506_12021 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 1.11 / 0405	Culler M.	2011	Fludioxonil - Analysis of nitrosamines in five representative production batches produced by Fine Organics Limited, Seal Sands, Middlesbrough TS2 1UB, UK Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, TK0061748 GLP not published Syngenta File No CGA173506_11520 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 1.11 / 0506	Oggenfuss P.	1999	Validation of analytical method AG-1229 (nitrosamines) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 75686 GLP not published Syngenta File No N/0363 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 1.11 / 0607	Tomann A.	1993	Report on chemical composition (tox reserve) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland, 8873 GLP not published Syngenta File No CGA173506/0790 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 1.11 / 0708	Tomann A.	1993a	Report on chemical composition (analyses of five typical batches) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland, 8717 GLP not published Syngenta File No CGA173506/0238 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 1.11 / 0809	Ebi E.	2016	Fludioxonil - Analysis of a Tox Reserve Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, CHMU150979 GLP not published Syngenta File No CGA173506_11891 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
KCA 1.11 / 0910	Das R.	2014	Fludioxonil - Analysis of a Tox-Reserve Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 126607 GLP not published Syngenta File No CGA173506_11905 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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KCA 1.11 / 1011	Duell B.	2016	Fludioxonil Technical (CGA173506 Technical) Statement on the Analysis of Toxicology Reserve Batches Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300053068 Not GLP not published Syngenta File No CGA173506_11924 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
KCA 1.11 / 1112	Das R.	2016	Fludioxonil Technical (CGA173506 Technical) Statement on the Analyses of Batch SMOOG106 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300052965 Not GLP not published Syngenta File No CGA173506_11923 This is CONFIDENTIAL INFORMATION*	N	N	-	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.

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Culler M.	KCA 1.11 / 0405	2011	Fludioxonil - Analysis of nitrosamines in five representative production batches produced by Fine Organics Limited, Seal Sands, Middlesbrough TS2 1UB, UK Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, TK0061748 GLP not published Syngenta File No CGA173506_11520 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Das R.	KCA 1.11 / 0910	2014	Fludioxonil - Analysis of a Tox-Reserve Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 126607 GLP not published Syngenta File No CGA173506_11905 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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Dull B.	KCA 1.11 / 02	2016	Fludioxonil Technical Material: Statement on the Accountability/Analytical Closure for Batch Analysis (Study CHMU150973) Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300052719 Not GLP not published Syngenta File No CGA173506_11904 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN
Ebi E.	KCA 1.11 / 0809	2016	Fludioxonil - Analysis of a Tox Reserve Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, CHMU150979 GLP not published Syngenta File No CGA173506_11891 This is CONFIDENTIAL INFORMATION*	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN
Kendall A.	KCA 1.8 / 01	2017	Fludioxonil - EU - Data Sheets for Starting Materials Syngenta Not GLP not published Syngenta File No CGA173506_12047 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

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**Listing of Test and Study Reports and published Papers not submitted, by Author****5 March 2016****KCA Section 1, Identity of the active substance**

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None