

Cyprodinil

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 history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
20 May 2016	CA 1.8: Additional reference included in response to questions from the RMS (changes highlighted in yellow)	CGA219417_11578 7 October 2015 updated 20/5/16

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.

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**7 October 2015****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)
KCA 1.8 / 01	Gardinal P.	2016	Cyprodinil - Starting Materials - Confidential Statement Syngenta Not GLP not published Syngenta File No CGA219417_11682 This is CONFIDENTIAL INFORMATION	N	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN*

KCA 1.11 / 01	Mink C.	2014	Cyprodinil - Analysis of Five Representative Batches Produced at Syngenta Monthey Switzerland Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, CHMU140561 GLP not published Syngenta File No CGA219417_11561 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	Oggenfuss P.	1999	<p>Nitrosamines in CGA 219417 tech. Novartis Crop Protection AG, Basel, Switzerland</p> <p>Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 77589</p> <p>GLP not published Syngenta File No CGA219417/0944</p> <p>This is CONFIDENTIAL INFORMATION</p>	N	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN*
KCA 1.11 / 03	Birk R.	1994	<p>Report on chemical composition (tox-reserves) Novartis Crop Protection AG, Basel, Switzerland</p> <p>Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland, 24652</p> <p>GLP not published Syngenta File No CGA219417/0349</p> <p>This is CONFIDENTIAL INFORMATION</p>	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN*

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KCA 1.11 / 04	Voellmin S.	2009	Chemical characterization (batch SMU9AP001) Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 119539 GLP not published Syngenta File No CGA219417_11366 This is CONFIDENTIAL INFORMATION	N	Y	New data; eligible for data protection according to SANCO/12576/2012	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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Cardinal P.	KCA 1.8 / 01	2016	Cyprodinil - Starting Materials - Confidential Statement Syngenta Not GLP not published Syngenta File No CGA219417_11682 This is CONFIDENTIAL INFORMATION	N	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN*

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Oggenfuss P.	KCA 1.11 / 02	1999	Nitrosamines in CGA 219417 tech. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 77589 GLP not published Syngenta File No CGA219417/0944 This is CONFIDENTIAL INFORMATION	N	N	Existing data; no longer eligible for data protection according to SANCO/12576/2012	SYN*

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Listing of Test and Study Reports and published Papers not submitted, by Author**7 October 2015****KCA Section 1, Identity of the active substance**

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None