

A14325E

Cyprodinil 300 g/L EC

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

**DOCUMENT L-CP, Section 7 Reference
List**

**TOXICOLOGICAL STUDIES ON THE PLANT
PROTECTION PRODUCT**

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number

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**9 October 2015****KCP Section 7, Toxicological studies on the plant protection product**

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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KCP 7.1.1 / 01	Straube E.	2005	CGA219417 300g/l EC Formulation (A14325E) :Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, 859442 GLP not published Syngenta File No CGA219417/1325	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.2 / 01	Straube E.	2005a	CGA219417 300g/l EC Formulation (A14325E): Acute Dermal Toxicity Study in Rats Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, 859443 GLP not published Syngenta File No CGA219417/1326	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.1.4 / 01	Straube E.	2005b	CGA219417 300g/l EC Formulation (A14325E): Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application) Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, 859444 GLP not published Syngenta File No CGA219417/1328	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.5 / 01	Straube E.	2005c	CGA219417 300g/l EC Formulation (A14325E): Primary Eye Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, 859446 GLP not published Syngenta File No CGA219417/1327	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.1.6 / 01	Straube E.	2005d	CGA 219417 300g/l EC Formulation (A14325E): Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test (9 induction) Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, RCC 859447 GLP not published Syngenta File No CGA219417/1379	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.3 / 01	Smith A.	2005	CGA 219417 300g/l EC Formulation (A14325E): In Vivo Dermal Penetration Study in The Rat Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, UR0863 GLP not published Syngenta File No CGA219417/1380	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.3 / 02	Johnson I.	2005	CGA219417 300g/l EC Formulation (A14325E): In Vitro Absorption of Cyprodinil Through Human Epidermis Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, JV1862 GLP not published Syngenta File No CGA219417/1377	N	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

KCP 7.3 / 03	Johnson I.	2005a	CGA219417 300G/l EC (A-14325E): In Vitro Absorption of Cyprodinil Through Rat Epidermis Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, JV1863 GLP not published Syngenta File No CGA219417/1376	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
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Smith A.	KCP 7.3 / 01	2005	CGA 219417 300g/l EC Formulation (A14325E): In Vivo Dermal Penetration Study in The Rat Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, UR0863 GLP not published Syngenta File No CGA219417/1380	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
Straube E.	KCP 7.1.1 / 01	2005	CGA219417 300g/l EC Formulation (A14325E) :Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, 859442 GLP not published Syngenta File No CGA219417/1325	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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Listing of Test and Study Reports and published Papers not submitted, by Author**9 October 2015****KCP Section 7, Toxicological studies on the plant protection product**

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None