

A14111B

**Chlorothalonil 400 g/L +
Azoxystrobin 80 g/L SC**

**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
14/12/15	CP 7.2.3: Inclusion of new DFR data (all changes are highlighted in green).	A14111B_11190, 15 February 2015 updated 14/12/15
07/08/16	Minor amendment included to reflect changes in M-CA Section 8; all amendments highlighted in yellow	A14111B_11190, 15 February 2015 updated 24/8/15, 7/8/16

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.

Where the report has been previously submitted, but an OECD summary has been provided for clarity reasons only, the original report has not been submitted again and is not included in this reference list.

Reference List, by Data Point**15 February 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	Kuhn J.	2004	Amended Final Report: Acute Oral Toxicity in Rats Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8065-04 8321-03 GLP not published Syngenta File No ICI5504/2243	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.2 / 01	Kuhn J.	2004a	Amended Final Report: Acute Dermal Toxicity Study in Rats Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8066-04 8322-03 GLP not published Syngenta File No ICI5504/2244	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.3 / 01	Rattray N.J.	2004	A14111B: 4-Hour Acute Inhalation Toxicity Study in Rats Syngenta Limited, Cheshire, United Kingdom Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, HR2464 GLP not published Syngenta File No ICI5504/2229	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	Kuhn J.	2004b	Amended Final Report: Acute Dermal Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8068-04 8319-03 GLP not published Syngenta File No ICI5504/2245	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.5 / 01	Kuhn J.	2004c	Amended Final Report: Acute Eye Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8067-04 0000-03 GLP not published Syngenta File No ICI5504/2242	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.2.1.2 / 01	Wilson A.	2012	Diquat - Determination of Operator Exposure (Passive Dosimetry) during Typical Activities Associated with Mixing/Loading and Application of Reglone® (Soluble Concentrate Containing 200 g/L Diquat cation) as a Desiccant to Ware Potatoes in The Netherlands, 2011 Syngenta Agrochemex, Lawford, United Kingdom, ACI11-003 GLP not published Syngenta File No A1412A_10300	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.2.1.2 / 02	Tack T.J.	1995	To assess the potential exposure of Gesatop 500 SC to farm operators when applied through a knapsack sprayer Novartis Crop Protection AG, Basel, Switzerland Ciba Agriculture, Whittleford, United Kingdom, CSTR 39:3 GLP not published Syngenta File No G27692/1897	N	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.2.3.1 / 01	Amato SL	1998	Determination of the Effects of Freezing Tomato Leaf Discs for conducting Dislodgeable Foliar Residue Studies of Chlorothalonil Syngenta Crop Protection AG, Basel, Switzerland , 7254-97-0116-CR-001 GLP not published Syngenta File No R44686/1245	N	N	-	SYN
KCP 7.2.3.1 / 02	Roussel C.	2015	Chlorothalonil and Azoxystrobin - Determination of Dislodgeable Foliar Residues of Chlorothalonil and Azoxystrobin on wheat leaves after one application of A14111B in Northern Europe (UK and Northern France), 2014 Syngenta Staphyt, Inchy en Artois, France, ChR-14-19410 GLP not published Syngenta File No A14111B_11228	N	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

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KCP 7.3 / 01	Noakes J.	2013	Chlorothalonil/Azoxystrobin SC (A14111B) - In Vitro Absorption through Dermatomed Human Skin Using [14C]-Chlorothalonil Syngenta Dermal Technology Laboratory Ltd., Staffordshire, UK, JV2271-REG GLP not published Syngenta File No A14111B_10828	N	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
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Kuhn J.	KCP 7.1.1 / 01	2004	Amended Final Report: Acute Oral Toxicity in Rats Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8065-04 8321-03 GLP not published Syngenta File No ICI5504/2243	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**15 February 2015****KCP Section 7, Toxicological studies on the plant protection product**

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