

Mesotrione

**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

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.

Reference List, by Data Point

06 December 2013

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 / 01	Fish L.	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10160	N	N	-	SYN*
KCA 7.1.1.2 / 01	Hand L.	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10185	N	N	-	SYN*
KCA 7.1.1.3 / 01	Graham R., Gilbert J.	2013	Mesotrione - Soil Photolysis of [14C]- Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8252086 GLP, not published Syngenta File No ZA1296_10106	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN
KCA 7.1.2.1.1 / 01	Hardy I.	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10135	N	N	-	SYN*
KCA 7.1.3.1.1 / 01	Hand L., Davison K.	2005	Mesotrione: Adsorption/Desorption Properties in a Volcanic Ash Soil Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3635B GLP, not published Syngenta File No ZA1296/1916	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN

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KCA 7.1.3.1.1 / 02	Bramley YM, Pinheiro S I, Verity A A	2002	Mesotrione Comparison of Adsorption Properties of Mesotrione and Its copper Salt in Four Soils Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, RJ3289B GLP, not published Syngenta File No ZA1296/0831	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN
KCA 7.1.3.1.2 / 01	Hurst L.	2013	SYN546974 - Adsorption and Desorption Properties of Phenyl-U-14C-SYN546974, a Metabolite of Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252095 GLP, not published Syngenta File No SYN546974_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN
KCA 7.2.1.3 / 01	Oliver R., Edwards P.	2005	Mesotrione (ZA1296): [U-14C]-Phenyl Labelled Sterile Natural Water Photolysis Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3634B 04JH012 GLP, not published Syngenta File No ZA1296/1990	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN

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KCA 7.2.2.2 / 01	Graham R., Yeomans P.	2013	Mesotrione - Aerobic Mineralisation of 14C- Phenyl Labelled ZA1296 in Surface Water Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252099 GLP, not published Syngenta File No ZA1296_10118	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN
KCA 7.2.2.3 / 01	Graham R., Gilbert J.	2013a	Mesotrione - Aerobic and Anaerobic Aquatic Sediment Metabolism of [Phenyl-14C]- Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8236956 GLP, not published Syngenta File No ZA1296_10105	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN
KCA 7.2.2.3 / 02	Hardy I.	2013a	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10136	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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Fish L.	KCA 7.1 / 01	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10160	N	N	-	SYN*
Graham R., Gilbert J.	KCA 7.1.1.3 / 01	2013	Mesotrione - Soil Photolysis of [14C]- Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8252086 GLP, not published Syngenta File No ZA1296_10106	N	Y	New data; eligible for data protection according to SANCO/12576/2 012	SYN

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Hand L.	KCA 7.1.1.2 / 01	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10185	N	N	-	SYN*

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Hardy I.	KCA 7.1.2.1.1 / 01	2013	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10135	N	N	-	SYN*
Hardy I.	KCA 7.2.2.3 / 02	2013a	This is CONFIDENTIAL INFORMATION – please refer to Document J Syngenta File No ZA1296_10136	N	N	-	SYN*
Hurst L.	KCA 7.1.3.1.2 / 01	2013	SYN546974 - Adsorption and Desorption Properties of Phenyl-U-14C-SYN546974, a Metabolite of Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252095 GLP, not published Syngenta File No SYN546974_10000	N	Y	New data; eligible for data protection according to SANCO/12576/2012	SYN

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