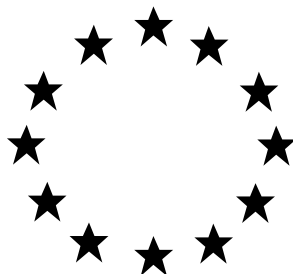


# EUROPEAN COMMISSION



## Pyriproxyfen

**LIST OF INFORMATION, TESTS AND  
STUDIES WHICH ARE CONSIDERED  
AS RELIED UPON BY THE RMS FOR  
THE EVALUATION WITH A VIEW TO  
THE RENEWAL OF THE ACTIVE  
SUBSTANCE**

**Rapporteur Member State:** The Netherlands



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
1. <b>IDENTITY</b> <b><u>ACTIVE SUBSTANCE</u></b>											
-	-	-	-	-	-	-	-	-	-	-	-
1. <b>PHYSICAL AND CHEMICAL PROPERTIES</b> <b><u>ACTIVE SUBSTANCE</u></b>											
C.A. 2.2/05	Nishiyama, M.	2007	Henry's Law Constant for pyriproxyfen Company Report No. NNP-0113 Not GLP. Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 2.4/04	Hawgawa, M.	2018	Ultraviolet-Visible (UV/VIS) Absorption Spectra of Pyriproxyfen Standard Sumika Chemical Analysis Service Ltd. Company report no. NNP-0131 Study number GP18051 GLP. unpublished	N	5.1.2 e Woo	2020	UV/VIS Absorption Spectrum of Pyriproxyfen Eurofins agrosience services Study number S20-00647 GLP. unpublished	Artikel 5.1.1.c Woo  Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 2.7/03	Walker, J.A.	2015a	4'-OH-pyr: Determination of Partition Coefficient (HPLC Method) Company Report No. NNP-0121 Harlan Laboratories Ltd., UK GLP, Unpublished	N	5.1.2 e Woo	2020	Partition Coefficient of Pyriproxyfen Metabolite 4-OH-pyr (HPLC Method) Eurofins agrosience services Study number S20-00648 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 2.7/04	Walker, J.A.	2015b	DPH-pyr: Determination of Partition Coefficient (HPLC Method) Company Report No. NNP-0122 Harlan Laboratories Ltd., UK GLP, Unpublished	N	5.1.2 e Woo	2020	Partition Coefficient of Pyriproxyfen Metabolite DPH-pyr at pH 4, 7 and 9 (HPLC Method) Eurofins agroscience services Study number S20-00649 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 2.7/05	Walker, J.A.	2015c	PYPAC: Determination of Partition Coefficient (HPLC Method) Company Report No. NNP-0123 Harlan Laboratories Ltd., UK GLP, Unpublished	N	5.1.2 e Woo	2020	Partition Coefficient of Pyriproxyfen Metabolite PYPAC (HPLC Method) Eurofins agroscience services Study number S20-00650 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 2.7/06	Walker, J.A.	2015d	PYPA: Determination of Partition Coefficient (HPLC Method) Company Report No. NNP-0124 Harlan Laboratories Ltd., UK GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
<b>5. METHODS OF ANALYSIS</b>											
<b>ACTIVE SUBSTANCE</b>											
C.A. 4.1.1/05	Reitz, G.A.	2009a	Analytical method validation for the quantitation of pyriproxyfen in pyriproxyfen technical grade Company Report No. NNA-0105 Valent Technical Center, USA GLP, Unpublished	N	5.1.2.e Woo	2020	Validation of the Method of Determination of the Active Ingredient and specified impurities in Pyriproxyfen David Norris Analytical Laboratories Ltd Study number DNA5690 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
C.A. 4.1.1/08	Reitz, G.A.	2009b	Analytical method validation for the quantitation of production process impurities in pyriproxyfen technical grade Company Report No. NNA-0106 Valent Technical Center, USA GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.1/09	Yanagisawa, Y.	2016b	Confirmation of analyte identification in pyriproxyfen technical grade (Impurity #1) Company Report No.: NNP-125 Not GLP, Unpublished	N				Artikel 5.1.1.c Woo			
C.A. 4.1.2/01	Herberth, M.T.	2010	An oral (gavage) dose range-finding acute neurotoxicity study of pyriproxyfen T.G. in rats Company Report No. NNT-0181	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			WIL Research Laboratories, LLC, USA  GLP, Unpublished					Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
C.A. 4.1.2/02	Tobimatsu, M.	2010	Validation of an analytical method for pyriproxyfen T.G. in corn oil suspension Company Report No. NNA-0124 GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/04	Kakuta, Y. hnishi, J. amada, H.	1989	Residue analytical method for pyriproxyfen in tomato Company Report No. NNA-90-0016 Not GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/06	Weber, H., Pelz, S.	2000b	Validation of DFG method S19 (extended revision) for the determination of residues of pyriproxyfen in samples of fruits with high acid content (citrus) Company Report No. NNA-0078 European Agriculture Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/08	Daneva, E., Zetzsch, A.	2010	Validation of an analytical method for determination of residues of pyriproxyfen in apples, a representative of high water crops Company Report No. NNA-0113 Eurofins Dr Specht GLP GmbH, Germany GLP,	N	-	-	-	Artikel 5.1.1.c Woo			

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Unpublished								
C.A. 4.1.2/09	Lindner, M.	2010	Validation of analytical methods for the determination of residues of pyriproxyfen in citrus (dry pomace from juice pressing) and citrus Company Report No. NNA-0112 Eurofins Dr Specht GLP GmbH, Germany GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/10	Lee, M.R.	2012	Pyriproxyfen – Amphibian Metamorphosis Assay with African Clawed Frog ( <i>Xenopus laevis</i> ) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline 231 Company Report No.: NNW-0211 Smithers Viscient, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/11	York, D.O.	2012	Pyriproxyfen – Short-Term Reproduction Assay with Fathead Minnow ( <i>Pimephales promelas</i> ) Following OPPTS Guideline 890.1350 and OECD Guideline 229 Company Report No. NNW-0212 Smithers Viscient, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/12	Hamitou, M.	2009a	DPH-Pyr (Metabolite of Pyriproxyfen): Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) under static acute conditions Company Report No.: NNW-0190 Springborn Smithers Laboratories (Europe), Switzerland GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/13	Hamitou,	2009b	DPH-Pyr (metabolite of	N	-	-	-	Ar ikel 5.1.1.c Woo			

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed			Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year		Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Y/N	
	M.		pyriproxyfen): Acute toxicity to water fleas ( <i>Daphnia magna</i> ) under static acute conditions Company Report No. NNW-0191 Springborn Smithers Laboratories (Europe), Switzerland GLP, Unpublished							
C.A. 4.1.2/14	Hara, T.	2015a	Acute toxicity study of PYPA with Rainbow trout Company Report No.: NNW-0220 Sumika Technoservice Corporation, Japan GLP, Unpublished	Y	-	-				
C.A. 4.1.2/15	Hara, T.	2015b	Acute immobilization study of PYPA with <i>Daphnia magna</i> Company Report No. NNW-0221 GLP, Unpublished	N	-	-				
C.A. 4.1.2/16	Hara, T.	2015c	Acute toxicity study of PYPA with freshwater green alga, <i>Pseudokirchneriella subcapitata</i> Company Report No. NNW-0224 GLP, Unpublished	N	-	-				
C.A. 4.1.2/17	Dionne, E.	1998	Sumilarv T.G. – Acute toxicity to eastern oyster ( <i>Crassostrea virginica</i> ) under flow-through conditions Company Report No. NNW-0138 Springborn Laboratories Inc., USA GLP, Unpublished	N	-	-				
C.A. 4.1.2/18	Sousa, J.V.	1999	Sumilarv T.G. – Acute toxicity to mysids ( <i>Mysidopsis bahia</i> ) under flow-through conditions	N	-	-				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed			Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year		Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Y/N	
			Company Report No. NNW-0139 Springborn Laboratories Inc., USA GLP, Unpublished							
C.A. 4.1.2/19	Shaw, A.C.	2015a	4'-OH-Pyr –Full Life- Cycle toxicity test with water fleas, <i>Daphnia magna</i> , under flow-through conditions following OECD Guideline #211 Company Report No. NNW-0238 Smithers Viscient, USA GLP, Unpublished	N	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/20	Shaw, A.C.	2015b	DPH-Pyr –Full Life- Cycle toxicity test with water fleas, <i>Daphnia magna</i> , under flow-through conditions following OECD Guideline #211 Company Report No. NNW-0239 Smithers Viscient, USA GLP, Unpublished	N	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/21	Picard, C.	2015	42-Day Toxicity test exposing freshwater amphipods ( <i>Hyaella azteca</i> ) to pyriproxyfen applied to sediment under static-renewal conditions following EPA test methods Company Report No. NNW-0243 Smithers Viscient, USA GLP, Unpublished	N	-	-	Artikel 5.1.1.c Woo			
C.A. 4.1.2/22	Patnaude, M.R.	2015	Pyriproxyfen T.G.: 22- Day survival of honey bee larvae, <i>Apis mellifera</i> L., during an In Vitro exposure Company Report No. NNW-0242 Smithers Viscient, USA GLP, Unpublished	N	-	-	Artikel 5.1.1.c Woo			
C.A. 4.2/03	Lindner, M.	2014	Validation of the multi- residue method QuEChERS for the determination of pyriproxyfen in different matrices of plant origin	N	5.1.2.e Woo	2020	Validation of the analytical methods for the determination of pyriproxyfen residues in the plant matrices.	Artikel 5.1.1.c Woo		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Company Report No. NNA-0117 Eurofins Agrosiences Services, Germany GLP, Unpublished				ASCENZA Laboratorio de Residuos Study number VAL11/20 GLP. unpublished	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 4.2/04	Lindner, M., Grewe, D.	2015	Validation of the multi-residue method QuEChERS for the determination of pyriproxyfen in different matrices of animal origin Company Report No. NNA-0118 Eurofins Agrosiences Services, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Validation of an Analytical Method for the Determination of Pyriproxyfen in Food of Animal Origin. ASCENZA Laboratorio de Residuos Study number VAL10/20 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 4.2/05	Maas, X.	2015	Independent Laboratory Validation of the multi-residue method QuEChERS for the determination of pyriproxyfen in different matrices of animal origin Company Report No. NNA-0122 PRTL Europe, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Independent Laboratory Validation of an Analytical Method for the Determination of pyriproxyfen in Food of Animal Origin Eurofins agroscience services Study number S20-01043 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo  finalized study is required. Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 4.2/09	Lindner, M., Leischow, J.	2015a	Validation of an analytical method for the determination of pyriproxyfen in surface water Company Report No. NNA-0120 Eurofins Agrosiences Services, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Validation of an Analytical Method for the Determination of Pyriproxyfen in Surface and Drinking Water. ASCENZA Laboratorio de Residuos Study number VAL08/20 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
C.A. 4.2/10	Merdian, H.	2009	Pyriproxyfen: Independent Laboratory Validation of method NNA-0092 for the determination of pyriproxyfen in water Company Report No. NNA-107 PRTL Europe, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Independent Laboratory Validation of Analytical Method for the Determination of Pyriproxifen in Drinking Water Eurofins agroscience services Study number S20-02866 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
C.A. 4.2/11	Lindner, M., Leischow, J.	2015b	Independent Laboratory Validation of an analytical method for the determination of pyriproxyfen in drinking water Company Report No. NNA-0121 Eurofins Agrosciences Services, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Independent Laboratory Validation of Analytical Method for the Determination of Pyriproxifen in Drinking Water Eurofins agroscience services Study number S20-02866 GLP. unpublished	Artikel 5.1.1.c Woo			

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Art kel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2.e Woo	2020	Art kel 5.1.1.c Woo	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
<b>6. TOXICOLOGY AND METABOLISM DATA</b>											
<b><u>ACTIVE SUBSTANCE</u></b>											
CA 5.1.1/06	Peris, O.	2018	Pharmacokinetic assessment of [14-C]- pyriproxyfen in rat blood samples Test faciit study: 179378 Not GLP, unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.2.7/01	Nakagawa, M.	2013	In vitro 3T3 NRU phototoxicity study of pyriproxyfen T.G. in cultured mammalian cells Company report No. NNT-0214 Mitsubishi Chemical Medicine corporation, Japan GLP, Unpublished	N	5.1.2.e Woo	2020	In vitro 3T3 NRU phototoxicity test with Pyriproxyfen Eurofins BioPharma Product Testing Study number STUGC20AA0634-2 GLP, unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.3.2/02	Koyama, Y.	1988b	Six-month chronic oral toxicity study with S-31183 in rats  Company Report No. NNT-80-0039  Biochemistry and Toxicology Laboratory, Japan  GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.7.1/01	Herberth, M.T.	2010	An oral (gavage) dose range-finding acute neurotoxicity study of pyriproxyfen T.G. in rats Company Report No. NNT-0181 WIL Research Laboratories, LLC, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
								Artikel 5.1.1.c Woo [Redacted]			
CA 5.7.1/02	Herberth, M.T.	2011a	An oral (gavage) dose acute neurotoxicity study of	Y	-	-	-	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			pynproxifen T.G. in rats Company Report No. NNT-0194 WIL Research Laboratories, LLC, USA GLP, Unpublished				Artikel 5.1.1.c Woo [Redacted] Artikel 5.1.1.c Woo [Redacted] Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]	

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			
CA 5.7.1/03	Herberth, M.T.	2011b	An 90-day oral dietary neurotoxicity study of pyriproxyfen T.G. in rats Company Report No. NNT-0202 WIL Research Laboratories, LLC, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
								Artikel 5.1.1.c Woo			

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
								Artikel 5.1.1.c Woo [Redacted]			
CA 5.8.1/01	Deguchi, Y.	2011	Acute oral toxicity study of PYPAC in rats	Y	[Redacted]	2011	Acute oral toxicity study of PYPAC in rats	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Company Report No. NNT-0224 Environmental Health Science Laboratory, Japan GLP, Unpublished				Company Report No. NNT-0224 Environmental Health Science Laboratory, Japan GLP, Unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.1/02	Kitamoto, S	2010a	Reverse mutation test of PYPAC in bacterial systems Company Report No. NNT-0190 Environmental Health Science Laboratory, Japan GLP, Unpublished	N		2020	Bacterial Reverse Mutation Test of Metabolite PYPAC ASCENZA Laboratorio de Microbiologia e Biologia Celular Study number AMES/006/20 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.1/03	Wollny, H.	2010	Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) with PYPAC	N		2020	In vitro mammalian cell gene mutation test (HPRT-Locus) in Chinese Hamster V79 cells with	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Company Report No. NNT-0191 Harlan Cytotest Cell Research GmbH, Germany GLP, Unpublished				PYPAC Eurofins BioPharma Product Testing Study number STUGC20AA0634-3 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.1/04	Kitamoto, S.	2010b	In vitro chromosomal aberration test on PYPAC in Chinese hamster lung cells (CHL/IU) Company Report No. NNT-0189 Environmental Health Science Laboratory, Japan GLP, Unpublished	N	5.1.2.e Woo	2020	In vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with PYPAC Eurofins BioPharma Product Testing Study number STUGC20AA0634-4 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.1/05	Bowen	2018	Expert review of QSAR analysis undertaken on pyriproxyfen and its related metabolites. Report No. 0387879-TOX2. Non-GLP, unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.1/06	Hara	1993	Reverse mutation test of metabolites of pyriproxyfen, 4'-OH-Pyr, 5"-OH-Pyr, DPH-Pyr, POPA and PYPAC, in bacterial systems (translation of	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Japanese original). Unpublished report no. NNT-30-0104 Non-GLP, unpublished								Artikel 5.1.1.c Woo
CA 5.8.2/01	Saunders, M.D.	2011	Pyriproxyfen: 4 week dietary immunotoxicity study in the female CD-1 mouse Company Report No. NNT-0204 Huntingdon Life Sciences, UK GLP, Unpublished	Y		2011	Pyriproxyfen: 4 week dietary immunotoxicity study in the female CD-1 mouse Company Report No. NNT-0204 Huntingdon Life Sciences, UK GLP, Unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/01	Mikata, K.	2011a	In vitro estrogen receptor binding assay of pyriproxyfen T.G. with rat uterine cytosol No. NNT-0209	N		2020	Endocrine Disruptor Test: In vitro Estrogen Receptor Binding Assay using Human Recombinant Estrogen Receptor- $\alpha$ with Pyriproxyfen	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Environmental Health Science				Eurofins BioPharma Product Testing Study number STUGC20AA0634-5 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/02	Mikata, K.	2011b	In vitro androgen receptor assay of pyriproxyfen T.G. with rat prostate cytosol Company Report No. NNT-0207 Environmental Health Science Laboratory, Japan GLP, Unpublished	N	5.1.2.e Woo	2020	Androgen Receptor Binding Assay (Rat Prostate Cytosol) with Pyriproxyfen Eurofins BioPharma Product Testing Study number STUGC20AA0634-6 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/03	Mikata, K.	2011c	In vitro inhibition assay of pyriproxyfen T.G. with human recombinant aromatase Company Report No. NNT-0206 Environmental Health Science	N	5.1.2.e Woo	2020	Endocrine Disruptor Test: Aromatase Assay (Human Recombinant) with Pyriproxyfen Eurofins BioPharma Product Testing	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Laboratory, Japan GLP, Unpublished				Study number STUGC20AA0634-7 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/04	Mikata, K.	2011d	In vitro steroidogenesis assay of pyriproxyfen T.G. with H295R cell line Company Report No. NNT-0208 Environmental Health Science Laboratory, Japan GLP, Unpublished	N	5.1.2.e Woo	2020	Endocrine Disruptor Test: In vitro Steroidogenesis Assay using Human Cell Line H295R with Pyriproxyfen Eurofins BioPharma Product Testing Study number STUGC20AA0634-8 GLP. unpublished	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/05	Ose, K.	2005	Uterotropic assay of pyriproxyfen by oral route using juvenile rat: investigation on estrogenic effect Company Report No. NNT-0180 Environmental Health Science Laboratory, Japan Non-GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
CA 5.8.3/06	Yamaguchi, T.	2011	Hershberger assay of pyriproxyfen T.G. administered orally in male rats Company Report No. NNT-0205  Environmental Health Science Laboratory, Japan GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo [Redacted]  Artikel 5.1.1.c Woo [Redacted]  Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 5.8.3/07	Herberth, M.T.	2012a	A pubertal development and thyroid function assay of pyriproxyfen T.G. administered orally in intact juvenile/peripubertal male rats Company Report No. NNT-0210 WIL Research Laboratories LLC, USA GLP, Unpublished	Y	-	-		Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
CA 5.8.3/08	Yamaguchi, T.	2012	Effects of pyriproxyfen on testosterone level and thyroid gland in intact juvenile/peripubertal male rats  Company report No. NNT-0212 Environmental Health Science Laboratory, Japan Not-GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]
CA 5.8.3/09	Herberth, M.T.	2012b	A pubertal development and thyroid function assay of pyriproxyfen T.G. administered orally in intact juvenile/peripubertal female rats Company Report No. NNT-0211 WIL Research Laboratories LLC, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [REDACTED]			
CA 5.8.3/10	Anon	2012	A Weight of evidence of the EDSP Tier 1 studies of pyriproxyfen T.G. Company Report No. NNT-0213 Environmental Health Science Laboratory, Japan Not GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo [REDACTED]			Artikel 5.1.1.c Woo [REDACTED]
<b>7. RESIDUE DATA</b> <b><u>ACTIVE SUBSTANCE / FORMULATION DATA</u></b>											
CA 6.1/03	Green, C.A.	1998	Magnitude of the residue of pyriproxyfen in/on oranges and	N	5.1.2.e Woo	2020	Determination of residues of Pyriproxyfen after one application of Pyriproxyfen 100 g/L in the RAC and	Artikel 5.1.1.c Woo [REDACTED]	n.a.	n.a.	Artikel 5.1.1.c Woo [REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			orange processing fractions Company Report No. NNR-0058 Valent USA Corporation, USA GLP, Unpublished				processed fractions of Oranges (outdoor), at 2 sites in Southern Europe, 2020 Eurofins agrosience services Study number S20-01110 GLP. unpublished  <u>Applicant, December 2020:</u> Pyriproxyfen Frozen Storage Stability in Citrus PTRL Europe GmbH Study number P2396G GLP. unpublished	Artikel 5.1.1.c Woo [Redacted]			Artikel 5.1.1.c Woo [Redacted]
CA 6.2.1/04	Herczog, K.J.S.	2004	The Metabolism of [14C] Pyriproxyfen in citrus Company Report No. NNM-0082 Ricerca Biosciences LLC, USA GLP, Unpublished Study submitted to satisfy data requirements	N	5.1.2 e Woo [Redacted]	1996	A plant metabolism study with 14C-S-71639 (pyriproxyfen) in apple trees Report No. NNM-0050 Ricerca Inc., USA GLP, Unpublished	Artikel 5.1.1.c Woo [Redacted]	n.a.	n.a.	Artikel 5.1.1.c Woo [Redacted]
					5.1.2 e Woo [Redacted]	1997	Plant metabolism study with 14C-S-71639 (pyriproxyfen)				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
					5.1.2.e Woo		in tomato plants Company Report No. NNM-0051 Ricerca Inc., USA GLP, Unpublished				
CA 6.2.1/05	Kouno, A., Nambu, K., Yamada, H.	1990	Metabolism of 14C-Pyriproxyfen in cucumber plants Company Report No. NNM-0018 Not GLP. Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/01	Grollau, G.	2000a	Magnitude of the residue of pyriproxyfen in orange Raw Agricultural Commodity, Greece and Italy – 1999 Report No. NNR- 0070 European Agricultural Services, France GLP, Unpublished	N	5.1.2.e Woo	2010	Ascenza-Afrasa-Lainco: Magnitude of Pyriproxyfen Residues in Citrus Following One Application with Pyriproxifen 100 g/L EC. Trialcamp Investigación Agrícola Study number TRC09-110 GLP	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
					5.1.2.e Woo	2011	ProPlan PPC: Magnitude of pyriproxyfen residues in citrus following one application with Pyriproxyfen 10% EC Trialcamp Investigación Agrícola Study number TRC09-139 GLP				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed			Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?	
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year		Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Y/N		Submission deadline
							Galenika Fitofarmacija: <i>To be evaluated on a Member State level, since either the crop is not included in the GAP or the study is not protected at the Member States where Galenika is seeking re-authorizations</i>	Art kel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/03	Groll eau, G.	2001b	Magnitude of the residue of pyriproxyfen in orange Raw Agricultural Commodity, Spain – 2000 Company Report No. NNR-0081 European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/04	Groll eau, G.	2000b	Magnitude of the residue of pyriproxyfen in mandarin Raw Agricultural Commodity, Greece and Italy – 1999 Report No. NNR- 0071 European Agricultural Services, France GLP, Unpublished	N	5.1.2.e Woo	2010	Ascenza-Afrasa-Lainco: Magnitude of Pyriproxyfen Residues in Citrus Following One Application with Pyriproxifen 100 g/L EC. Trialcamp Investigación Agrícola Study number TRC09-110 GLP	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
					5.1.2.e Woo	2007	Proplan PPC: Magnitude of residues in Mandarins following one application with Pyriproxyfen 10% Trialcamp Investigación Agrícola Study number TRC05-28 GLP				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
					-	-	<b>Galenika Fitofarmacija:</b> <i>To be evaluated on a Member State level, since either the crop is not included in the GAP or the study is not protected at the Member States where Galenika is seeking re-authorizations</i>	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/05	Groll eau, G.	2001c	Magnitude of the residue of pyriproxyfen in mandarin Raw Agricultural Commodity, Greece – 2000 Report No. NNR- 0082 European Agricultural Services, France GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/06	Groll eau, G.	2001d	Magnitude of the residue of pyriproxyfen in mandarin Raw Agricultural Commodity, Greece – 2000 Report No. NNR- 0079 European Agricultural Services, France GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.1/07	Groll eau, G.	2001e	Magnitude of the residue of pyriproxyfen in mandarin Raw Agricultural Commodity, Spain – 2000 Company Report No. NNR- 0083	N	-	-		Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			European Agricultural Services, France GLP, Unpublished								
CA 6.3.2/01	Grollau, G.	2011	Magnitude of the residue of pyriproxyfen in apple Raw Agricultural Commodity, Northern and Southern Europe – 2010  Report No. NNR- 0227 Staphyt, France GLP, Unpublished  Study submitted to satisfy data	N	5.1.2.e Woo	2010	Ascenza-Lainco-Afrasa: Magnitude of Pyriproxifen Residues in Apple Following One Application with Pyriproxifen 100 g/L EC  Trialcamp Investigación Agrícola Study number TRC09-54 GLP	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
					5.1.2.e Woo	2010	ProPlan PPC: Magnitude of Pyriproxifen Residues in Apple Following One Application with Pyriproxifen 100 g/L EC  Trialcamp Investigación Agrícola Study number TRC10-029 GLP				
					5.1.2.e Woo	2012E	ProPlan PPC: Magnitude of Pyriproxifen Residues in Apple Following One Application with Pyriproxifen 100 g/L EC  Trialcamp Investigación Agrícola Study TRC12-021 GLP				
					5.1.2.e Woo	2014	Galenika Fitofarmacija: Determination of residues of pyriproxyfen after two applications of HARPUN in apple (outdoor) at 4 sites in Northern				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed			Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?	
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year		Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Y/N		Submission deadline
							and Southern Europe 2013 Eurofins agrosience services Report No. S13-00231 GLP, Unpublished				
					5.1.2 e Woo	2015	Galenika Fitofarmacija: Determination of residues of pyriproxyfen after two applications of Harpun in apple (outdoor) at 12 sites in Northern and Southern Europe 2014 including Analytical Phase Report and Report Amendment No. 1 Eurofins agrosience services Report No. S14-00001 GLP, Unpublished				
CA 6.3.2/02	Bousquet, C.	2015	Magnitude of the residue of pyriproxyfen in apple (Raw Agricultural Commodity) in Southern Europe – 2014 Report No. NNR- 0265 SGS AGRIMIN, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.3/01	Grollau, G.	2001f	Magnitude of the residue of pyriproxyfen in field tomato Raw Agricultural Commodity, Greece – 2001 Report No. NNR- 0108 European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA	Groll	2001g	Magnitude of the residue of	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
6.3.3/02	eau, G.		pyriproxyfen in field tomato Raw Agricultural Commodity, Italy – 2001 Company Report No. NNR- 0109 European Agricultural Services, France GLP, Unpublished					Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 6.3.3/03	Groll eau, G.	2001h	Magnitude of the residue of pyriproxyfen in field tomato Raw Agricultural Commodity, Spain – 2001 Company Report No. NNR- 0110 European Agricultural Services, France GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.3/04	Bousquet, C.	2014	Magnitude of the residue of pyriproxyfen in field tomato Raw Agricultural Commodity, Southern Europe – 2013 Company Report No. NNR- 0258 SGS AGRIMIN, France GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.4/01	Groll eau, G.	2000c	Magnitude of the residue of pyriproxyfen in greenhouse tomato Raw Agricultural Commodity, Greece and Italy 1999 Company Report No. NNR-0067 European Agricultural Services, France GLP, Unpublished	N					n.a.	n.a.	Artikel 5.1.1.c Woo



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 6.3.4/02	Groll eau, G.	2001i	Magnitude of the residue of pyriproxyfen in greenhouse tomato Raw Agricultural Commodity, Spain 1999 Company Report No. NNR-0085  European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.4/03	Groll eau, G.	2001j	Magnitude of the residue of pyriproxyfen in greenhouse tomato Raw Agricultural Commodity and processed fractions Greece - 2000 Company Report No. NNR-0086  European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.4/04	Groll eau, G.	2001k	Magnitude of the residue of pyriproxyfen in greenhouse tomato Raw Agricultural Commodity and processed fractions Spain - 2000 Company Report No. NNR-0087  European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo
CA 6.3.4/05	Groll eau, G.	2001l	Magnitude of the residue of pyriproxyfen in greenhouse cherry tomato Raw Agricultural Commodity Italy - 2000 Company Report No. NNR-0075  European Agricultural Services, France GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 6.5.3/03	Groll eau, G.	2010	Magnitude of the residue of pyriproxyfen in citrus Raw Agricultural Commodity and processed fractions.  Southern Europe - 2010 Company Report No. NNR-0226  Staphyt, France GLP, Unpublished	N	5.1.2.c Woo	2020	Please refer to point CA 6.1/03 above  Determination of residues of Pyriproxyfen after one application of Pyriproxyfen 100 g/L in the RAC and processed fractions of Oranges (outdoor), at 2 sites in Southern Europe, 2020  Eurofins agrosience services Study number S20-01110 GLP. Unpublished.	Artikel 5.1.1.c Woo  Artikel 5.1.1.c Woo  Artikel 5.1.1.c Woo	n.a.	n.a.	Artikel 5.1.1.c Woo  Artikel 5.1.1.c Woo
<b>8. ENVIRONMENTAL FATE AND BEHAVIOR</b> <u>ACTIVE SUBSTANCE</u>											

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 7.1.1.1 /05  CA 7.1.2.1.1/12	Freedlander, S.	2016a	[14C]Pyriproxyfen - aerobic soil metabolism in two soils Sumitomo Chemical Co., Ltd, report No.: NNM-0088 Smithers Viscient GLP, Unpublished	N	5.1.2.e Woo	2020	Pyriproxyfen Aerobic Degradation and Metabolism in two Soils at 20 °C in the Dark  Eurofins agrosience services Study number S20-00614 GLP. Unpublished.	Artikel 5.1.1.c Woo	Y	Oct 2020	Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 7.1.1.1 /05a	Freedlander, S.	2018a	[14C] Pyriproxyfen Aerobic soil metabolism in two soils Company Report No. 13048.6865 Smithers Viscient, Massachusetts, USA NOT GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Wool			Artikel 5.1.1.c Wool
CA 7.1.1.1 /05b	Freedlander, S.	2018b	[14C] Pyriproxyfen Aerobic soil metabolism in two soils  Company Report No. NNM-0088-Supp Smithers Viscient, Massachusetts, USA  Not GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Wool			Artikel 5.1.1.c Wool
CA 7.1.2.1.1/10a	Fletcher, T.	2018	Pyriproxyfen: Kinetic persistence assessment of laboratory soil degradation studies Company Report No. SCC/09/14-KIN8 Not GLP.	N	-	-	-	Artikel 5.1.1.c Wool			Artikel 5.1.1.c Wool

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Unpublished								
CA 7.1.2.1.1/12	Freedlander, S.	2016a	[14C]Pyriproxyfen - aerobic soil metabolism in two soils Sumitomo Chemical Co., Ltd, report No.: NNM-0088 Smithers Visient GLP, Unpublished	N	5.1.2.e Woo	2020	Please refer to point CA 7.1.1.1/05 above  Pyriproxyfen Aerobic Degradation and Metabolism in two Soils at 20 °C in the Dark  Eurofins agrosience services Study number S20-00614 GLP. Unpublished.	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 7.1.2.1.2/01	Freedlander, S.	2016b	[14C]4'-OH-Pyr - aerobic degradation in three soils Sumitomo Chemical Co., Ltd, report No.: NNM-0089 Smithers Visient GLP Unpublished	N	5.1.2.e Woo	1990b	Aerobic soil metabolism of 14Cpyriproxyfen in sandy clay loam soil Sumitomo Chemical Co., Ltd. Report No. NNM-00-0017 Not GLP Unpublish	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2.e Woo	1994	Aerobic soil metabolism of 14Cpyriproxyfen Sumitomo Chemical Co., Ltd. Report No. NNM-41-0030 Hazleton Laboratories America, Inc. GLP Unpublished				
					5.1.2.e Woo	2001	( 14C)-Pyriproxyfen: soil metabolism and degradation Sumitomo Chemical Co , Ltd Report No. NNM-0077 Covance Laboratories Ltd GLP Unpublished				

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 7.1.2.1.2/01a	Freedlander, S.	2017a	[14C]4'-OH-Pyr-Aerobic degradation in three soils Company Report No. NNM-0089-Supp Smithers Viscient, Massachusetts, USA Not GLP Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 7.1.2.1.2/02	Freedlander, S.	2016c	[14C]PYPAC - aerobic degradation in three soils Sumitomo Chemical Co., Ltd, report No.: NNM-0090 Smithers Viscient GLP Unpublished	N	5.1.2.e Woo	1990a	Aerobic soil metabolism of 14C-pyriproxyfen in sandy clay loam soil Sumitomo Chemical Co., Ltd. Report No. NNM-00-0016 GLP Unpublish	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
					5.1.2.e Woo	1994	Aerobic soil metabolism of 14Cpyriproxyfen Sumitomo Chemical Co., Ltd. Report No. NNM-41-0030 Hazleton Laboratories America, Inc. GLP Unpublished				
					5.1.2.e Woo	2001	( 14C)-Pyriproxyfen: soil metabolism and degradation Sumitomo Chemical Co , Ltd Report No. NNM-0077 Covance Laboratories Ltd GLP Unpublished				
CA 7.1.2.1.2/02a	Freedlander, S.	2017b	[14C] PYPAC – Aerobic degradation in three soils Company Report No. NNM-0090-Supp Smithers Viscient, Massachusetts, USA Not GLP Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 7.1.2.1.2/04	Cooke, J.	2018	Pyriproxyfen: Assessment of pH dependency of soil degradation	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			and adsorption Company Report No. SCC/09/14-KIN9 Not GLP Unpublished					Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 7.1.2.2.1/08	Cooke, J.	2018	Pyriproxyfen: Assessment of US field soil dissipation studies for relevance to the EU Company Report No. SCC/09/14-KIN7 Not GLP Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 7.1.3.1.2/04	Lewis, C. J., Wallage, T.	2016	[14C]DPH-Pyr: adsorption/desorption in three soils Sumitomo Chemical Co., Ltd, report No.: NNM-0091 Smithers Visient (ESG) Ltd GLP Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 7.1.3.1.2/05	Cooke, J.	2018	Pyriproxyfen: Assessment of pH dependency of soil degradation and	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			adsorption Company Report No. SCC/09/14-KIN9  Not GLP					Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 7.2.1.2 /03	Ponte, M.	2015	Determination of the quantum yield of [14C]pyriproxyfen in pH 7 buffer solution under artificial sunlight Sumitomo Chemical Co., Ltd, report No.: NNM-0087 PTRL West GLP, Unpublished	N	5.1.2.e Woo	2020	Phototransformation and quantum yield of [14C] Pyriproxyfen in buffered pure water at pH7 Eurofins agroscience services Study number S20-00613 GLP. Unpublished.	Artikel 5.1.1.c Woo	Y	Oct 2020	Artikel 5.1.1.c Woo
CA 7.2.2.2 /01	Adam, D.	2015	[14C] Pyriproxyfen – aerobic mineralisation in surface water – simulation biodegradation test Sumitomo Chemical Co., Ltd, report No.: NNM-0086 Innovative Environmental Services (IES) Ltd GLP, Unpublished	N	5.1.2.e Woo	2020	[14C]Pyriproxyfen Aerobic Mineralisation in Surface Water Eurofins agroscience services Study number S20-00615 GLP. Unpublished.	Artikel 5.1.1.c Woo	Y	Oct 2020	Artikel 5.1.1.c Woo



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 7.2.2.2/01a	Adam, D.	2017	Statement on procedural recoveries of [14C] pyriproxyfen in aerobic mineralisation in surface water simulation biodegradation test Company report No. 20150070 Innovative Environmental Services (IES) Ltd, Switzerland Not GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
<b>9. ECOTOXICOLOGY DATA</b>											
CA. 8.1.4/01	Lee, M.R.	2012	Pyriproxyfen – Amphibian Metamorphosis Assay with African Clawed Frog ( <i>Xenopus laevis</i> ) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline 231  Company Report No.: NNW-0211 Smithers Viscient, USA GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.1.5	Anon	2012	A Weight of evidence of the EDSP Tier 1 studies of pyriproxyfen T.G. Company Report No. NNT-0213  Environmental Health Science Laboratory, Japan  Not GLP. Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.2.1/06	Hamito u, M.	2009a	DPH-Pyr (Metabolite of Pyriproxyfen): Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) under static acute conditions  Company Report No.: NNW-0190 Springborn Smithers Laboratories	Y				Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			(Europe), Switzerland GLP, Unpublished								
CA 8.2.1/07	Hara, T.	2015a	Acute toxicity study of PYPA with Rainbow trout Company Report No.: NNW-0220 Sumika Technoservice Corporation, Japan GLP, Unpublished	Y	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]
CA 8.2.2/03	Lewis, G	2016	Derivation of endpoints (EC10 and EC20 values) for fish early life- stage toxicity study with pyriproxyfen. Sumitomo Chemical Co., Ltd. Unpublished report	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			No.: NNW-0248					Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 8.2.2.1 /01	Gries, T.	2007	Pyriproxyfen: Full Life Cycle Toxicity Test with Medaka ( <i>Oryzias latipes</i> ) under Flow-Through Conditions Company Report No.: NNW-0181 Springborn Smithers Laboratories (Europe), Switzerland GLP, Unpublished	Y	-	-		Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.2.2.1 /02	York, D.O.	2012	Pyriproxyfen – Short-Term Reproduction Assay with Fathead Minnow ( <i>Pimephales promelas</i> ) Following OPPTS Guideline 890.1350 and OECD Guideline 229 Company Report No.: NNW-0212 Smithers Visient, USA GLP, Unpublished	Y	-	-		Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
CA 8.2.3/04	Hamitou, M.	2009b	DPH-Pyr (Metabolite of Pyriproxyfen): Acute toxicity to water fleas (Daphnia magna) under static acute conditions Company Report No.: NNW-0191 Springborn Smithers Laboratories (Europe), Switzerland GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.2.3/05	Hara, T.	2015	Acute immobilization study of PYPA with Daphnia magna Company Report No.: NNW-0221 Sumika Technoservice Corporation, Japan GLP, Unpublished	N	-	-		Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
CA 8.2.4/01b	Lewis, G.	2016	Derivation of endpoints (EC10 and EC20 values) for <i>Daphnia magna</i> chronic toxicity study with pyriproxyfen. Sumitomo Chemical Co., Ltd. Unpublished report No.: NNW-0247	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]
CA 8.2.4/03	Shaw, A.C.	2015a	4'-OH-Pyr – Full Life-Cycle Toxicity Test with Water Fleas, <i>Daphnia magna</i> , Under Flow-Through Conditions Following OECD Guideline #211 Company Report No.: NNW-0238 Smithers Viscient, USA GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo [Redacted]			
CA 8.2.4/04	Shaw, A.C.	2015b	DPH-Pyr – Full Life-Cycle Toxicity Test with Water Fleas, Daphnia magna, Under Static renewal Conditions Following OECD Guideline #211 Company Report No.: NNW-0239 Smithers Viscient, USA GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo [Redacted] Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]
CA 8.2.4/05	Shaw, A.C.	2015c	PYPA – Full Life- Cycle Toxicity Test with Water Fleas, Daphnia magna, Under Static renewal Conditions Following OECD Guideline #211 Company Report No.: NNW-0241	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Smithers Viscient, USA GLP, Unpublished					Artikel 5.1.1.c Woo [Redacted]			
CA 8.2.4 /11b	Lewis, G.	2016	Derivation of endpoints (EC10 and EC20 values) for Mysidopsis bahia chronic toxicity study with pyriproxyfen. Sumitomo Chemical Co., Ltd. Unpublished report No.: NNW-0249	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]
CA 8.2.4/12	Biester, M.A.	2011	Pyriproxyfen: Chronic Toxicity Test with Mayfly Nymphs (Cloeon dipterum) Under Semi-Static	N	-	-	-	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]

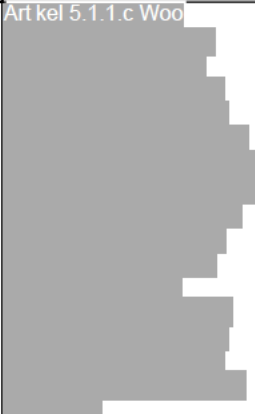

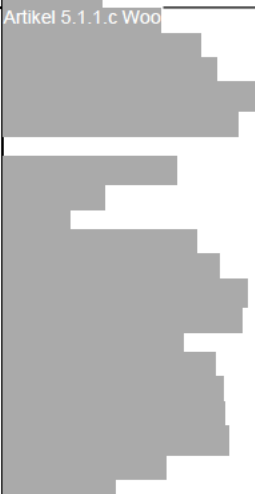


Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Conditions Company Report No.: NNW-0209 Smithers Viscient AG, Switzerland GLP, Unpublished					Artikel 5.1.1.c Woo			
CA 8.2.4/14	Picard, C.	2015	42-Day Toxicity Test Exposing Freshwater Amphipods ( <i>Hyalella azteca</i> ) to Pyriproxyfen Applied to Sediment Under Static-Renewal Conditions Following EPA Test Methods Company Report No.: NNW-0243 Smithers Viscient, USA GLP, Unpublished	N	5.1.2.e Woo	2003	Pyriproxyfen – The full life cycle to the midge ( <i>Chironomus riparius</i> ) under static conditions Report 13048.6330 GLP Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.2.5/04	Jüstrich, L.	2009	DPH-Pyr (Metabolite of Pyriproxyfen): Growth inhibition test with <i>Pseudokirchneriella subcapitata</i> (syn. <i>Selenastrum capricornutum</i> ) under static conditions Company Report No.: NNW-0192 Springborn Smithers Laboratories (Europe), Switzerland GLP, Unpublished					Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.2.5/05	Hara, T.	2015c	Growth inhibition study of PYPA with freshwater green alga <i>Pseudokirchneriella subcapitata</i> Company Report No.: NNW-0224 Sumika Technoservice Corporation, Japan GLP,	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Unpublished					Artikel 5.1.1.c Woo [Redacted]			
CA 8.2.5.2 /08	Roessink, I.	2018	Chronic effects of the insecticide pyriproxyfen to three aquatic macroinvertebrates Company Report No. NNW-0259 Alterra, The Netherlands GLP, Unpublished	N	-	-	<u>New info Dec2020:</u> Weight-of-evidence (WoE) assessment on key taxonomic group(s) for aquatic risk assessment Eurofins Agrosience Services Regulatory Spain S.L. Study number S20-09783-06/002 Unpublished	Artikel 5.1.1.c Woo [Redacted]	N		Artikel 5.1.1.c Woo [Redacted]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
CA 8.3.1.1.1 /02	Vergé, E.	2015	Pyriproxyfen TG - Acute Oral and Contact Toxicity to the Bumble Bee, <i>Bombus terrestris</i> L. under Laboratory Conditions Company Report No.: NNW-0240 Eurofins Agrosience Services EcoChem GmbH, Germany GLP, Unpublished	N	5.1.2 e Woo	2020	Pyriproxyfen technical: Acute oral and contact Toxicity to bumblebee <i>Bombus terrestris</i> L., under laboratory conditions. Eurofins agrosience services Study number S20-01358 GLP. Unpublished.	Equivalent study owned by Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
CA 8.3.1.2 /01	Roig, J.	2014	Pyriproxyfen TG - Assessment of Chronic Effects to the Honeybee ( <i>Apis mellifera</i> L.) in a 10 Days Continuous Laboratory Feeding Test Company Report No.: NNW-0219 MITOX Consultants, The Netherlands GLP, Unpublished	N	5.1.2.e Woo	2020	Ascenza-Lainco-Afrasa: Chronic oral toxicity of the test item Pyriproxyfen 10%EC to honey bees <i>Apis mellifera</i> L. (Hymenoptera: Apidae) in a 10-day test under laboratory conditions Agrotex Study number E20-0111 GLP. Unpublished.	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
					5.1.2.e Woo	2020	ProPlan PPC: Pyriproxyfen 10 % EC (MULIGAN): Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee ( <i>Apis mellifera</i> L.) under laboratory conditions Eurofins agrosience services Study number S20-02708 GLP. Unpublished.				N

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Art kel 5.1.1.c Woo 
					5.1.2.e Woo 	2020	<b>Galenika Fitofarmacija:</b> Harpun: Chronic Oral Toxicity Test on the Honey Bee ( <i>Apis mellifera</i> L.) in the laboratory. Ibacon Study number 151481136 GLP. Unpublished.		N		Artikel 5.1.1.c Woo 

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 8.3.1.3 /03	Nienst ed, K.M.	2006	Brood study exposing Apis mellifera (Hymenoptera: Apidae) to Pyriproxyfen 10 EC Company Report No.: NNW-0179 Springborn Smithers Laboratories (Europe) AG, Switzerland GLP, Unpublished	N	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.3.1.3 /04	Patnaude, M.R.	2015	Pyriproxyfen T.G.: 22-Day Survival of Honey Bee Larvae, Apis mellifera L., during an In Vitro Exposure Company Report No.: NNW-0242 Smithers Viscient, USA GLP, Unpublished	N	5.1.2 e Woo	2020	Ascenza-Lainco-Afrasa: Pyriproxyfen10%EC: Honey Bee (Apis mellifera L.) Larval toxicity test following repeated exposure under laboratory conditions Eurofins Trialcamp Study number S20-02053 GLP. Unpublished.	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2 e Woo	2020	ProPlan PPC: Pyriproxyfen 10 % EC: Honey Bee			Artikel 5.1.1.c Woo	

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
							(Apis mellifera L.) Larval toxicity test following repeated exposure under laboratory conditions Eurofins Trialcamp Study number S20-02709 GLP. Unpublished.	Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2.e Woo	2020	Galenika Fitofarmacija: Effects of Harpun of honeybees (Apis mellifera L.) 22-Day Larval toxicity test with repeated exposure Biotecnologie BT Study number BT077/20 GLP. Unpublished.				Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
CA 8.4.1/02	Straube, D.	2015a	Pyriproxyfen T.G.: Effects on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% Peat Company Report No.: NNW-0235 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Woo	2010	<b>Ascenza-Lainco- Afrasa</b> A laboratory test to determine the chronic (sub-lethal) effects of Pyriproxyfen 10 EC (Pyriproxyfen 100g/L) to the earthworm <i>Eisenia fetida</i> (Oligochaeta: Lumbricidae) Trialcamp S.L.L, Spain Report No. TRC10-063BA GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
					5.1.2.e Woo	2008	<b>Proplan PPC</b> A laboratory test to determine the chronic (sub-lethal) effects of PYRIPROXYFEN 100 g/L EC to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae). TrialCamp, Polígono Industrial les Valletes, C/Artes Gráficas 44, Nave 1A, 46192 Monserrat (Valencia) Spain. Unpublished report, No. TRC10-042BA GLP				
					5.1.2.e Woo	2016	<b>Galenika fitofarmacija Harpun</b> (Pyriproxyfen 100 g/L): Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil Ibacon Study number 113191022 Unpublished report				



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
							GLP				
CA 8.4.1/03	Straube, D.	2015b	PYPAC: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat Company Report No.: NNW-0233 IBACON GmbH, Germany GLP, Unpublished	Y	(21st) ja. 396c	2020	Metabolite PYPAC: Sublethal Toxicity to the Earthworm Eisenia fetida (oligochaeta, Lumbricidae) in artificial soil with 10% peat Eurofins Trialcamp Study number S20-01099 GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Wool
CA 8.4.1/04	Witte, B.	2015a	4'-OH-Pyr: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat Company Report No.: NNW-0230 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Wool	2020	Metabolite 4'-OH-Pyr: Sublethal Toxicity to the Earthworm Eisenia fetida (oligochaeta, Lumbricidae) in artificial soil with 5% peat Eurofins Trialcamp Study number S20-1100 GLP, Unpublished	Artikel 5.1.1.c Wool	N		Artikel 5.1.1.c Wool
CA 8.4.2.1/01	Straube, D.	2015c	Pyriproxyfen T.G.: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Company Report No.: NNW-0234 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Wool	2020	Ascenza-Lainco- Afrasa Side-effects of the test item Pyriproxyfen 10%EC on the springtail Folsomia candida Willem (Collembola, Isotomidae) under laboratory conditions Agrotox Report No. E20-0112 GLP, Unpublished	Artikel 5.1.1.c Wool	N		Artikel 5.1.1.c Wool

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2.e Woo	2020	Proplan PPC Pyriproxyfen10%EC: effects on the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomidae) in artificial soil Eurofins Trialcamp Study number S20-02706 GLP, Unpublished		N		Artikel 5.1.1.c Woo
					5.1.2.e Woo	2016	Galenika Fitofarmacija Harpun (Pyriproxyfen 100 g/L): Effects on reproduction of the collembola Folsomia candida in artificial soil with 5% peat Report No.: 113191016 ibacon GmbH, Rossdorf, Germany GLP, Unpublished		N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c
CA 8.4.2.1 /02	Witte, B.	2015b	PYPAC: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Company Report No.: NNW-0232 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Metabolite PYPAC: Effects on the Reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomidae) in artificial soil Eurofins Trialcamp Study number S20-1101 GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
CA 8.4.2.1 /03	Witte, B.	2015c	4'-OH-Pyr: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Company Report No.: NNW-0229 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Metabolite 4'-OH-Pyr: Effects on the Reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomidae) in artificial soil Eurofins Trialcamp Study number S20-1102 GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
CA 8.4.2.1 /04	Straube, D.	2015d	Pyriproxyfen T.G.: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Company Report No.: NNW-0236 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Ascenza-Lainco- Afrasa Side-effects of the test item Pyriproxyfen 10%EC on the predatory mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) under laboratory conditions Agrotox Report No. E20-0113 GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								Artikel 5.1.1.c Woo			Artikel 5.1.1.c Woo
					5.1.2.e Woo	2020	Proplan PPC Pyrproxyfen10%EC: effects on the reproductive output of the predatory mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil Eurofins Trialcamp Study number S20-02707 GLP, Unpublished		N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
					5.1.2.e Woo	2016	Galenika fitofarmacija Harpun (Pyriproxyfen 100 g/L): Effects on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat Report No.: 113191089 ibacon GmbH, Rossdorf, Germany GLP Unpublished		N		Artikel 5.1.1.c Woo
CA 8.4.2.1 /05	Witte, B.	2015d	PYPAC: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Company Report No.: NNW-0228 IBACON GmbH, Germany	N	5.1.2.e Woo	2020	Metabolite PYPAC: Effects on the Reproductive output of the predatory soil mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil Eurofins Trialcamp Study number S20-1103	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			GLP, Unpublished				GLP, Unpublished				Artikel 5.1.1.c Woo
CA 8.4.2.1 /06	Witte, B.	2015e	4'-OH-Pyr: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Company Report No.: NNW-0231 IBACON GmbH, Germany GLP, Unpublished	N	5.1.2.e Woo	2020	Metabolite 4'-OH-Pyr: Effects on the Reproductive output of the predatory soil mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil Eurofins Trialcamp Study number S20-1104 GLP, Unpublished	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author (s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Artikel 5.1.1.c Woo
-	Shimoka watoko, Y.	2018	Evaluation of insecticidal activity of PYPAC and pyriproxyfen Company Report No. NNG-0089 Not GLP, Unpublished	-	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo
-	Shimoka watoko, Y.	2018	Evaluation of insecticidal activity of PYPAC and pyriproxyfen on white peach scale, Pseudaulacapis pentagona (Targioni) Company Report No. NG-0090 Not GLP, Unpublished	-	-	-	-	Artikel 5.1.1.c Woo	N		Artikel 5.1.1.c Woo