

Appendix: List of renewal data in the Renewal Assessment Report of propiconazole/PT 8, including information on which data is considered 'relevant data' by the evaluating Competent Authority (eCA) [Article 95(7) of Regulation (EU) No 528/2012 (BPR)]¹

When the approval of an active substance/product type combination is renewed, all concerned Article 95 suppliers, who are not the applicants behind the renewal of the approval, will need to submit a letter of access (LoA) to all the relevant renewal data, as identified by the eCA, within 12 months of the renewal in order to comply with Article 95(7) BPR. A failure to do so means removal from the Article 95 list. For further details, please refer to the CA document².

To facilitate data sharing negotiations, information pertaining to the data submitted in support of the active substance/product type renewal with an indication on whether or not the data is considered 'relevant data' by the eCA is published around the same time as the Biocidal Products Committee's opinion. Any confidential or personal information are redacted by the eCA before this information is disseminated on ECHA's website. The identities of the data submitters can be obtained via the inquiry process under Article 62(2) BPR, if not disclosed.

Disclaimer: Please note that the establishment and publication of this list does not mean that the approval of the concerned active substance/product type combination will be renewed in accordance with Article 14(4) BPR. Renewal is contingent on the Commission adopting an implementing act to that effect.

Author(s)	Year	Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Data Identified as 'relevant' by the eCA ¹ (Yes/No)
[REDACTED]	2012	3.3 3.8/02 3.15	A6097 - Physical Properties of batch SMO1I367 – Final Report [REDACTED] unpublished	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2013	3.8/01	Propiconazole – Determination of Surface Tension – Final Report [REDACTED] GLP, unpublished	Yes	Syngenta Crop Protection AG	No

¹ Status: 24 January 2023

² For further information, and criteria of "relevant", please see [CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95_FINAL](#)

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[REDACTED]	2021	3.9	Determination of physico-chemical properties. Water solubility (EC A.6. and OECD 105). [REDACTED], GLP, unpublished	Yes	Lanxess Deutschland GmbH	No
[REDACTED]	2021	4.1 4.8	Determination of physico-chemical properties. Thermal Stability (OECD 113). Explosive Substances (UN Class 1). Screening Self-Reactive Substances (UN Class 4, Division 4.1) [REDACTED], GLP, unpublished	Yes	Lanxess Deutschland GmbH	No
[REDACTED]	2021	4.8	Expert statement regarding the appraisal of the Self-Accelerating-Decomposition.Temperature (SADT) for transport classification of self-reactive substances based on DSC measurements, [REDACTED]	Yes	Lanxess Deutschland GmbH	No
[REDACTED]	2020	4.16	Determination of the Metal Corrosive Properties for [REDACTED] [REDACTED] GLP, unpublished	Yes	LANXESS Deutschland GmbH	No
[REDACTED]	2010	5.1/01	Propiconazole - Validation of Analytical Method SA-47/1 - Final report,	Yes	Syngenta Crop Protection AG	No

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			[REDACTED] GLP, unpublished			
[REDACTED]	2013	5.1/02	Statement of Validation of Method SA-47/2 Determination of Propiconazole in technical Propiconazole, [REDACTED], unpublished	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2013b	5.1/03	Propiconazole tech., Propiconazole – Validation of Analytical Method SB-73/1, Final Report, GLP [REDACTED]	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2013c	5.1/04	Analytical Method SB-73/1, Propiconazole, content of by-products, [REDACTED]	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2014	5.1/05	Propiconazole – Analysis of Five representative Batches Produced at Syngenta in Monthey, Switzerland, Final Report, GLP [REDACTED]	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2020	5.1/06	Determination of content of by-products in Propiconazole Technical Grade Active Ingredient, [REDACTED]	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2021	5.1/07	Statement on Validity and Equivalence of Methods SB-73/1 and SB-73/2. Propiconazole. Determination of byproducts in Propiconazole, [REDACTED]	Yes	Syngenta Crop Protection AG	No

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[REDACTED]	2014	5.2/01	Propiconazole - Validation of an Analytical Method for Determination of Propiconazole and its Metabolites in Soil - Final Report, [REDACTED] GLP, unpublished	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2007	5.2/02	Cyproconazole - Analytical Method GRM033.01A for the Determination of Cyproconazole, 1,2,4-Triazole and Triazole Acetic Acid in Soil Using Liquid Chromatography-Electrospray Ionization Tandem Mass Spectrometry (Including Validation Data) – Method, [REDACTED] GLP, unpublished	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2014	5.2/03	Propiconazole – Validation of Analytical Method GRM050.05A for the Determination of Propiconazole in Air by LC-MS/MS, [REDACTED] GLP, unpublished	Yes	Syngenta Crop Protection AG	No
[REDACTED]	2006	5.2/04	Propiconazole (CGA64250) – Validation of a Residue Analytical Method for the Determination of Residues of Propiconazole in Water, [REDACTED] GLP, unpublished	Yes	PPZ TF (Propiconazole Taskforce)	No
[REDACTED]	2015	5.2/05	Propiconazole (CGA64250): Validation of a Residue Analytical Method for the Determination of	Yes	PPZ TF (Propiconazole Taskforce)	No

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			Residues of Propiconazole in Water, ██████ unpublished			
██████	2016	5.2/06	Propiconazole (CGA64250): Validation of QuEChERS Analytical Method for the Determination of Residues of Propiconazole in Body Fluids by LC-MS/MS	Yes	Syngenta Crop Protection AG	No
██████	2004	5.2/07	Analytical method for the determination of triazole in soil and sediment. Report No ██████ CLP, unpublished	Yes	Bayer CropScience	No
██████	2015	6.6 / 01	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997). GLP: No, but complies to guideline / Unpublished	Yes	LANXESS Deutschland GmbH, Leverkusen, Germany	No
██████	2013 2014	6.6 / 02	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (1988). GLP: No, but complies to guideline / Unpublished	Yes	LANXESS Deutschland GmbH, Leverkusen, Germany	No
██████	2013	6.6 / 03	Laboratory method for determining the protective	Yes	LANXESS Deutschland	No

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			effectiveness of a preservative treatment against blue stain according to EN 152 (2011) after 4 weeks of artificial weathering. GLP: No, but complies to guideline / Unpublished		GmbH, Leverkusen, Germany	
██████████	2010	8.1.1 / 01	Propiconazole tech.: Primary skin irritation study in rabbits. ██████████ GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2010	8.1.2 / 01	Propiconazole tech.: Acute eye irritation study in rabbits.	Yes	Syngenta Crop Protection AG	Yes
██████████	2014	8.5.4 / 01	Propiconazole tech.: Salmonella typhimurium and Escherichia coli reverse mutation assay. ██████████ GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2014	8.5.4 / 02	Propiconazole tech.: Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells. ██████████ GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2017	8.5.4 / 03 ³	Propiconazole: In Vitro Micronucleus Test in Human	Yes	Syngenta Crop Protection AG	Yes

³ Note! The study was unintentionally missed out in the reference list of the final RAR.

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			Lymphocytes [REDACTED] GLP / Unpublished			
[REDACTED]	2010	8.7.1 / 01	Propiconazole tech.: Acute oral toxicity study in the rat (up and down procedure). [REDACTED] GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2012	8.7.3 / 01	Propiconazole tech.: Acute dermal toxicity study in rats. [REDACTED] GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2012	8.9.5.1 / 01.2	13 Week dietary toxicity study in male mice. Supplemental statistical analysis [REDACTED] GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
Costa, N.O., Vieira, M. L., Sgarioni, V., Pereira, M.R. F., Montagnini, B.G., Mesquita, S.D.F.P. and Gerardin, D.C.C.	2015	8.10.2 / 02	Evaluation of the reproductive toxicity of fungicide propiconazole in male rats. Toxicology, 335; 55-61 Non-GLP / Published	No	Published	No
Vieira, M. L., Costa, N. O., Pereira, M. R.	2017	8.10.2 / 03	Chronic exposure to the fungicide propiconazole:	No	Published	No

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F., Mesquita, S. D. F. P., Moreira, E. G. and Gerardin, D. C. C.			Behavioral and reproductive evaluation of F1 and F2 generations of male rats. Toxicology, 389; 85-93 Non-GLP / Published			
██████████	2012	8.11 / 02.4	CGA64250: Long-term feeding study in mice. Supplemental statistical analysis. ██████████ GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2012	8.11 / 03.3	CGA64250: 18 months oncogenicity study in mice. Supplemental statistical analysis ██████████ GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
Anonymous	2013	8.12.2 / 02	Review of the exposure incidences of Propiconazole formulations reported between 2004 and 2012. ██████████ Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2014	8.13.3 / 01.1	Propiconazole - Review for potential for endocrine disruption. ██████████ Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2016	8.13.3 / 01.2	Propiconazole - Review for potential for endocrine disruption - Amendment 1. ██████████ Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
██████████	2012	8.13.3 / 20	Propiconazole: Estrogen receptor binding (rat uterine cytosol).	Yes	Syngenta Crop Protection AG	Yes

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			[REDACTED] GLP / Unpublished			
[REDACTED]	2012	8.13.3 / 21	Propiconazole: Uterotrophic assay in ovariectomized rats. [REDACTED] GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2011	8.13.6 / 01.1	Propiconazole: Toxicogenomics re-analysis to investigate the MOA of carcinogenesis by propiconazole and phenobarbital. Company Review of published data [REDACTED] Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2012	8.13.6 / 02	Propiconazole: Cytochrome P450 2b, 3a and DNA- synthesis induction in cultured male mouse hepatocytes. [REDACTED] Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2011	8.13.6 / 03	Propiconazole: Cytochrome P450 2B, 3A and DNA- synthesis induction in cultured male human hepatocytes. [REDACTED] Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes

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[REDACTED]	2012	8.13.6 / 08	Propiconazole: CAR3 Direct Activation Assay with Mouse, Rat and Human CAR. [REDACTED] Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2012	8.13.6 / 32	Propiconazole - Human relevance framework assessment of liver tumour induction in mice. [REDACTED] Non-GLP / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2001a	9.1.1/03	R116857: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>). [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2001b	9.1.2/03	R116857: Acute toxicity to <i>Daphnia magna</i> . [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Crop Protection AG, Basle, Switzerland)	Yes
[REDACTED]	2001	9.1.3/04	R116857: Toxicity to the green alga <i>Selenastrum capricornutum</i> . [REDACTED]	Yes	Propiconazole Task Force (Study sponsor: Syngenta Crop Protection AG,	Yes

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			[REDACTED] GLP: Yes / Unpublished		Basle, Switzerland)	
[REDACTED]	2014	9.1.6.1 9.10.1/01	Propiconazole - A Fish Life-Cycle Toxicity Test with the Fathead Minnow (<i>Pimephales promelas</i>). [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd., Berkshire, United Kingdom)	Yes
[REDACTED]	2014	9.1.6.1/01 9.10.1/02	CGA-64250 - Statistical Re-analysis: The chronic toxicity of CGA-64250 Technical (Propiconazole) to sheepshead minnow (<i>Cyprinodon variegatus</i>). [REDACTED] GLP: No / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2014	9.1.6.2/01 9.10.1/06	Propiconazole: Full life-cycle toxicity test with water fleas, <i>Daphnia magna</i> , under static renewal conditions. [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Crop Protection AG)	Yes
[REDACTED]	2014e	9.2.1/03	SYN547889 - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests).	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd., Berkshire,	Yes

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			[REDACTED] GLP: Yes / Unpublished		UK)	
[REDACTED]	2014f	9.2.1/04	NOA436613 - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests). [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd., Berkshire, UK)	Yes
[REDACTED]	2002	9.2.1/05	The Effects of R116857 (Metabolite of Hexaconazole) on Soil Respiration and Nitrification. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG	Yes
[REDACTED]	2013b	9.2.2/02	Propiconazole EC (A6097AF) - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % Peat. [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd, Berkshire, UK)	Yes
[REDACTED]	2004	9.2.2/05	1,2,4-Triazole: Reproduction toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil. [REDACTED] GLP: Yes / Unpublished	Yes	Bayer CropScience AG, Monheim, Germany	Yes
[REDACTED]	2014c	9.2.2/07	SYN547889 - Sublethal Toxicity	Yes	Propiconazole Task	Yes

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			to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % Peat. [REDACTED] GLP: Yes / Unpublished		Force (Study sponsor: Syngenta Ltd, Berkshire, UK)	
[REDACTED]	2014d	9.2.2/08	NOA436613 - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % Peat. [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd, Berkshire, UK)	Yes
[REDACTED]	2013c	9.2.2/09	CGA91305 - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % Peat. [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Ltd, Berkshire, United Kingdom)	Yes
[REDACTED]	2002	9.5	1,2,4-Triazole: Acute and reproduction toxicity to the collembolan species <i>Folsomia candida</i> . [REDACTED] GLP: Yes / Unpublished	Yes	TDMG (triazole derivative metabolites group)	Yes
[REDACTED]	2014/2016	9.10.1/10	Propiconazole – Review for Potential for Endocrine Disruptors (incl. Amendment 1). [REDACTED] GLP: No / Unpublished	Yes	Syngenta Ltd., UK	Yes

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[REDACTED]	2012	9.10.1/11	Propiconazole – Fish Short-Term Reproduction Assay with Fathead Minnow (<i>Pimephales promelas</i>). [REDACTED] GLP: Yes / Unpublished	Yes	Propiconazole Task Force (Study sponsor: Syngenta Crop Protection USA)	Yes
[REDACTED]	2012	9.10.1/13	Propiconazole - Amphibian Metamorphosis Assay with African Clawed Frog (<i>Xenopus laevis</i>). [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection USA	Yes
[REDACTED]	2014	10.1.2/07	Propiconazole - Adsorption and Desorption of [14C]- SYN547889 in One Soil. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes
[REDACTED]	2014	10.1.2/08	Propiconazole. Adsorption and Desorption Study of [14C]-NOA436613 in Four Soils. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes
[REDACTED]	2012a	10.1.2/09	Propiconazole – Adsorption and Desorption of [14C]-CGA91305 in Multiple Soils. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes

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[REDACTED]	2012b	10.1.2/10	Propiconazole - Adsorption and Desorption of [14C]-CGA217495 in Multiple Soils. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes
[REDACTED]	2013	10.1.3.2(a)	Propiconazole - Aerobic mineralisation of 14C-labelled propiconazole in surface water. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes
[REDACTED]	2010	10.1.5/09	Determination of the Residues of 1,2,4-Triazole in/on soil after spraying of 1,2,4-Triazole (1000 XX) in the field in Germany, Italy, Great Britain, and Spain. [REDACTED] GLP: Yes / Unpublished	Yes	TDMG (triazole derivative metabolites group)	Yes
[REDACTED]	2007	10.2.1/02	Rate of Degradation of 14C-triazole labelled propiconazole in three soils under laboratory conditions. [REDACTED] GLP: Yes / Unpublished	Yes	Syngenta Crop Protection AG, Basle/Switzerland	Yes
[REDACTED]	2013	10.2.1/03	CGA64250: Aerobic Soil	Yes	Syngenta Crop	Yes

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			Metabolism of [14C-triazole]-CGA64250 in One Soil. [REDACTED] GLP: Yes / Unpublished		Protection AG, Basle/Switzerland	
[REDACTED]	2014	10.2.1/11	Propiconazole: Degradation rate in soil for parent and its metabolites from laboratory study data according to FOCUS kinetics guidelines. [REDACTED] GLP: No / Unpublished	Yes	Syngenta Crop Protection Ltd., UK	Yes
Anonymous	2013	10.2.1/12 and 10.1.5	Commission Regulation 1107/2009 - Triazole Derived Metabolite: 1,2,4-Triazole Proposed revision to DT50 Summary, Scientific Evaluation and Assessment. GLP: No / Unpublished	No	Bayer CropScience AG	No
[REDACTED]	2015	B10.3/01	NT BUILD 509 "Leaching of active ingredients from preservative-treated timber-Semi-field testing". [REDACTED] Report No.: [REDACTED] (first year) / [REDACTED] (second year)	Yes	LANXESS Deutschland GmbH	No

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			GLP: No / Unpublished			