



Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Retained Regulation (EC) 1107/2009**
as it applies in Great Britain

Prosulfuron

Volume 2

GB Article 7 Amendment

Great Britain

September 2023

Version History

When	What
September 2023	HSE Initial Assessment

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A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED

A.1. IDENTITY

No new studies have been submitted for identity as part of this Article 7 amendment application.

A.2. PHYSICAL AND CHEMICAL PROPERTIES

No new studies have been submitted for physical and chemical properties as part of this Article 7 amendment application.

A.3. DATA ON APPLICATION AND EFFICACY

No new studies have been submitted for data on application and efficacy as part of this Article 7 amendment application.

A.4. FURTHER INFORMATION

No new studies have been submitted for further information as part of this Article 7 amendment application.

A.5. METHODS OF ANALYSIS

No new studies have been submitted for method of analysis as part of this Article 7 amendment application.

A.6. TOXICOLOGY AND METABOLISM DATA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 7.1.7/13	██████████	2020	Title: IN-A4098: In vitro mammalian cell micronucleus test in human peripheral lymphocytes Sub Company : Owner Company : FMC AGRO LIMITED Report No : 8441503 Date : 25/09/2020 GLP Status : yes	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	FMC Agro Limited	-
KCP 9.2.4/01	██████████ █	2021	Title: CGA325025 - Micronucleus test in human lymphocytes in vitro Final Report Sub Company : Owner Company : SYNGENTA UK LIMITED Report No : 2147800 Date : 07/06/2021 GLP Status : yes	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-

A.7. RESIDUE DATA

No new studies have been submitted for residues as part of this Article 7 amendment application.

A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KIIA 7.2.1 / 06	[REDACTED]	2016 a	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Breitenwisch, Germany in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05212 GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.1 / 07	[REDACTED]	2016 b	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Castelsarrasin, France in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05218 GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.1 /	[REDACTED]	2016 c	Prosulfuron – Soil Dissipation Study with	N	Y	New data; eligible for	Syngenta	-

08	████████		Bare Soil Application in Bogense - Nørreby, Denmark in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05216 GLP, not published			data protection according to SANCO/1257 6/2012		
KIIA 7.2.1 / 09	████████ ████████ ████████	2016 d	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Wilson, UK in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05214 GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.1 / 10	████████ ████████ ████████	2016 e	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Saint-Cyprien, France in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05219 GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.1 / 11	████████ ████████ ████████	2016f	Prosulfuron – Soil Dissipation Study with Bare Soil Application in	N	Y	New data; eligible for data	Syngenta	-

			Canals, Spain in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05220 GLP, not published			protection according to SANCO/1257 6/2012		
KIIA 7.2.1 / 12	██████████ ██████████ ██████████	2016 a	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C (Q ₁₀ 2.58). Final report. Syngenta Battelle UK Ltd., NC/15/041A Not GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.1 / 14	██████████	2018	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C and pF2. Final Report. Syngenta Battelle UK Ltd., NC/18/031A Not GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.2.3 / 10	██████████	2014	Prosulfuron – Rate of Degradation of [¹⁴ C]-SYN547308. Final Report. Syngenta	N	Y	New data; eligible for data protection according to	Syngenta	-

			Smithers Viscient (ESG) Ltd., Harrogate, United Kingdom, 3200460 GLP, not published			SANCO/1257 6/2012		
KIIA 7.2.3 /11	██████	2014	Prosulfuron – Laboratory Degradation Kinetics for Modelling Endpoints for the soil metabolite SYN547308. Final Report. Syngenta, RAJ1065B Not GLP, not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIA 7.4.2 / 09	██████ ██████	2014	SYN547308 – Adsorption and Desorption Properties of ¹⁴ C-SYN547308, a Metabolite of Prosulfuron Syngenta Smithers Viscient (ESG) Ltd. Harrogate, UK, 3200461 GLP, Not published	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-
KIIIA 9.6.1/ 02	██████	2018	Final Prosulfuron Technical letter. RE: A leaching Assessment for Prosulfuron and its Soil Metabolites CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and	N	Y	New data; eligible for data protection according to SANCO/1257 6/2012	Syngenta	-

			SYN547308 Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU – Plant uptake of 0.15. Syngenta Not GLP, not published					
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A.9. ECOTOXICOLOGY DATA

No new studies have been submitted for ecotoxicology as part of this Article 7 amendment application.