

Product name: Observer
Product code: GLOB2013F
Active Substances: Zoxamide 450 g/L

REGISTRATION REPORT – POLAND

Part B, Sec. 1 to 9

Reference List

Application for authorisation (Article 33)

Applicant: Globachem NV

MS Finalisation date: 12/2025

Section 1, 2, 4

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 2.1-2.8	Pomeroy, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for a Suspension Concentrate Formulation containing Zoxamide stored at 54°C±2°C for Two Weeks, in Compliance With Good Laboratory Practice, Report No.: DNA6205, David Norris Analytical Laboratories Ltd., GLP, Unpublished	Y	Y	Globachem NV
KCP 2.2 (filed in part C)	Sowle, J.	2023	Theoretical certificate of explosive and oxidising properties for a suspension concentrate for formulation containing zoxamide, Report No.: DNA6414, David Norris Analytical Laboratories Ltd., Unpublished	N	Y	Globachem NV
KCP 2.7	Pomeroy, D.	2023	Determination of Storage Stability and Shelf Life Specification Data for a Suspension Concentrate Formulation containing Zoxamide stored at ambient temperature for 2 years, in Compliance With Good Laboratory Practice, David Norris Analytical Laboratories Ltd., Report No.: DNA6206, GLP, Unpublished	Y	Y	Globachem NV
KCP 2.7	Pomeroy, D.	2024	Determination of Storage Stability and Shelf Life Specification Data for a Suspension Concentrate Formulation containing Zoxamide stored at ambient temperature for 3 years, in Compliance With Good Laboratory Practice, Company Report No.: DNA6207, David Norris Analytical Laboratories Ltd., GLP, Unpublished	Y	Y	Globachem NV
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A24 (HPLC method) for Zoxamide metabolite RH-150721, Centre Wallon De Recherches Agronomiques, Report No.: 25488, GLP, Unpublished	Y	Y	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 1.11	Pomeroy, D.	2021	Analysis of Five batches of Zoxamide Technical Material to determine the content of the Active Ingredient and specified impurities, with associated validation, in compliance with Good Laboratory Practice, David Norris Analytical Laboratories Ltd., Report No.:	Y	Y	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			DNA6314, GLP, Unpublished			
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A24 (HPLC method) for Zoxamide metabolite RH-24549, Centre Wallon De Recherches Agronomiques, Report No.: 25489, GLP, Unpublished	Y	Y	Globachem NV
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A8 (shake-flask method) for Zoxamide metabolite RH-141452, Centre Wallon De Recherches Agronomiques, Report No.: 25675, GLP, Unpublished	Y	Y	Globachem NV

Section 3

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.4	Dana P.	2020	Efficacy of zoxamide mixtures against PHYTIN in potato. FE-20-A-ZOXxPPMCB-CZ01 ZS Kujavy GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Zöllner H.	2020	Efficacy of zoxamide mixtures against PHYTIN in potato. FE-20-A-ZOXxPPMCB-DE02 Field Research Support (FRS) DE GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Ewaldz T.	2020	Efficacy of zoxamide mixtures against PHYTIN in potato. FE-20-A-ZOXxPPMCB-SE03 HUSEC GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Szrama K.	2020	Efficacy of zoxamide mixtures against PHYTIN in potato. FE-20-A-ZOXxPPMCB-PL04 Staphyt PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Gulbis K.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-A-GLOB2013F-2106F-2007F-LV02 Latvian Plant Protection Research Centre (LAAPC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Umiński P.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-A-GLOB2013F-2106F-2007F-PL03 Field Research Support (FRS) PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Piotrowski G.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-A-GLOB2013F-2106F-2007F-PL04 Syntech PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Sipos P.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-HU01 Eurofins Agroscience Services Kft. GEP, not published	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.2 KCP 6.4	Mareckova J.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-CZ02 ZS Krasne Udoli (Ing. Jitka Mareckova) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Junglee S.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-FR04 Promo-Vert FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Junglee S.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-ES05 Promo-Vert ES GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Russo A.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-IT07 Agri 2000 (Net) GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Dorotea Nagy C.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-B-GLOB2013F-2106F-2007F-RO09 Biotek RO GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Trnka M.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-C-GLOB2013F-2106F-2007F-CZ01 Zemservis GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Barasits T.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-C-GLOB2013F-2106F-2007F-HU03 CPR Europe Kft. GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Calari A.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-C-GLOB2013F-2106F-2007F-IT04 Sagea GEP, not published	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.4	Gulbis K.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-C-GLOB2013F-2106F-2007F-LV05 Latvian Plant Protection Research Centre (LAAPC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Rezmerska-Pietka J.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-C-GLOB2013F-2106F-2007F-PL07 PerfectBAD GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Lang B.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-HU01 Plant-Art. GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Tvarůžek L.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-CZ02 Zvu Kromeriz GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Russo A.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-IT03 Agri 2000 (Net) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Gulbis K.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-LV04 Latvian Plant Protection Research Centre (LAAPC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Beyreiss S.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-UK05 Oxford Agricultural Trials (OAT) GEP, not published	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.2 KCP 6.4	Gajek D.	2021	Efficacy of fungicides based products against PHYTIN. FE-21-D-GLOB2013F-2106F-2007F-PL06 Agro Research Consulting (ARC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Ewaldz T.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-A-GLOB2013F-2106F-2007F-SE01 HUSEC GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Sipos P.	2022	Efficacy of fungicides based products against PHYTIN FE-22-A-GLOB2013F-2106F-2007F-HU02 Eurogins HU GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Barasits T.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-A-GLOB2013F-2106F-2007F-HU03 CPR Europe Kft. GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Gulbis K.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-A-GLOB2013F-2106F-2007F-LV04 Latvian Plant Protection Research Centre (LAAPC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Ewaldz T.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-A-GLOB2013F-2106F-2007F-SE05 HUSEC GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Dana P.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-CZ01 ZS Kujavy GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Bernardová M.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-CZ02 ZZS Kluky GEP, not published	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.4	Burger P.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-DE04 Quintus GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Crepin D.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-FR05 Essais+ GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	de Vries H.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-NL07 Vertify / Proeftuin Zwaagdijk GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Umiński P.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLBO2013F-2106F-2007F-PL08 Field Research Support (FRS) PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-58	Huszcza-Podgórska A.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLBO2013F-2106F-2007F-PL09 Green & Property Consulting GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Gulbis K.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-C-GLOB2013F-2106F-2007F-LV01 Latvian Plant Protection Research Centre (LAAPC) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Ramos J.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-D-GLOB2013F-2106F-2007F-ES03 BioChem AGROLOGIA SLU GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Zappalà P.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-D-GLOB2013F-2106F-2007F-IT05 Agrigeos GEP, not published	Y	Y	Globachem N.V.

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KCP 6.4	de Vries H.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-D-GLOB2013F-2106F-2007F-NL04 Verify / Proeftuin Zwaagdijk GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Richter T.	2021	Efficacy of zoxamide mixtures against PLASVI in grapes. FE-21-A-GLOB2105F-2013F-CZ01 Ekovin GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Marenco M.	2021	Efficacy of zoxamide mixtures against PLASVI in grapes. FE-21-A-GLOB2105F-2013F-IT04 Sagea IT GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Szrama K.	2021	Efficacy of zoxamide mixtures against PLASVI in grapes. FE-21-A-GLOB2105F-2013F-BL05 Staphyt BG GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Barasits T.	2021	Efficacy of zoxamide mixtures against PLASVI in grapes. FE-21-B-GLOB2105F-2013F-HU03 CPR Europe Kft. GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Doerr S.	2021	650F+ZOX / GLOB 2105F / GRAPES / PLASVI / EFFICACY FE-21-C-GLOB2105F-2013F-DE01 BASF SE GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Garcia A.	2021	650+ZOX, GLOB 2105F / VIGNE / PLASVI FE-21-C-GLOB2105F-2013F-FR02 BASF FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Richter T.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-CZ01 Ekovin GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Richter T.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-CZ02 Ekovin GEP, not published	Y	Y	Globachem N.V.

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KCP 6.4	Richter T.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-CZ03 Ekovin GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Camuñez S.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-DE05 Staphyt DE GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Lunzenfichter D.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-FR06 Qualiphyt GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Lunzenfichter D.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-A-GLOB2105F-GLOB2013F-FR07 Qualiphyt GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Camuñez S.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-B-GLOB2105F-GLOB2013F-BL01 Staphyt BG GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Barasits T.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-B-GLOB2105F-GLOB2013F-HU02 CPR Europe Kft. GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Marenco M.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-B-GLOB2105F-GLOB2013F-BL03 Sagea BG GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Tetuan B.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-ES01 GMW Biosciences GEP, not published	Y	Y	Globachem N.V.

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KCP 6.4	Camuñez S.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-ES02 Staphyt ES GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Marenco M.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-IT04 Sagea IT GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Russo A.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-IT05 Agri 2000 (Net) GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Muscarà A.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-IT06 Agricola 2000 GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Camuñez S.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-FR08 Staphyt FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Barnabè D.	2022	Efficacy of zoxamide against PLASVI in grapes. FE-22-C-GLOB2105F-GLOB2013F-FR09 Agri 2000 FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Raffaello Z.	2022	BAS 9671SAF / GLOB 2105 F / VITVI / PLASVI / EFFICACY FE-22-D-GLOB2105F-GLOB2013F-HU01 BASF HU GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Raffaello Z.	2022	BAS 9671SAF / GLOB 2105 F / VITVI / PLASVI / EFFICACY FE-22-D-GLOB2105F-GLOB2013F-IT02 BASF IT GEP, not published	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.4	Raffaello Z.	2022	BAS 9671SAF / GLOB 2105 F / VITVI / PLASVI / EFFICACY FE-22-D-GLOB2105F-GLOB2013F- FR03 BASF FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Raffaello Z.	2022	BAS 9671SAF / GLOB 2105 F / VITVI / PLASVI / EFFICACY FE-22-D-GLOB2105F-GLOB2013F BASF FR GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Raffaello Z.	2022	BAS 9671SAF / GLOB 2105 F / VITVI / PLASVI / EFFICACY FE-22-D-GLOB2105F-GLOB2013F- DE06 BASF DE GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Wegiel P.	2023	Efficacy of fungicides based products against PHYTIN. FE-23-A-GLOB2013F-2106F-2007F- MA01 Staphyt MA GEP, not published	Y	Y	Globachem N.V.
KCP 6.2 KCP 6.4	Wegiel P.	2023	Efficacy of fungicides based products against PHYTIN. FE-23-A-GLOB2013F-2106F-2007F- MA02 Staphyt MA GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Savvidis M.	2023	Impact of zoxamide on the quality of grapes. FS-23-A-GLOB2013F-2105F-GR01 Agri 2000 GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Savvidis M.	2023	Impact of zoxamide on the quality of grapes. FS-23-A-GLOB2013F-2105F-GR02 Agri 2000 GEP, not published	Y	Y	Globachem N.V.
KCP 6.5	Mieszozka M.	2022	Comparative of sensory analysis of 6 potato samples from the Czech Republic. 098/2022 InHort Polish National Institute of Hortocultural Research, not published.	Y	Y	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.5	Mieszozka M.	2022	Comparative of sensory analysis of 6 potato samples from Germany. 099/2022 InHort Polish National Institute of Horticultural Research, not published.	Y	Y	Globachem N.V.
KCP 6.4	Richter T.	2023	Efficacy of zoxamide against PLASVI in grapes. Czech 2023 FE-23-A-GLOB2105F-GLOB2013F- CZ01 EKOVIN GEP, not published	Y	Y	Globachem N.V.
KCP 6.4	Richter T.	2023	Efficacy of zoxamide against PLASVI in grapes. Czech 2023 FE-23-A-GLOB2105F-GLOB2013F- CZ02 EKOVIN GEP, not published	Y	Y	Globachem N.V.

Section 5

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 5.1.1	Pomeroy, D.	2021	Validation of the Methods of Determination of Zoxamide in an SC Formulation containing 450g/L zoxamide, in Compliance with Good Laboratory Practice, David Norris Analytical Laboratories Ltd, UK, Report No.: DNA6208, GLP, Unpublished	Y	Y	Globachem NV
KCP 5.1.1	Świstak, M.	2021	Validation of analytical method for the determination of active substance – zoxamide of the test item Zoxamide 450 SC in 50% sucrose solution, Sorbolab Research Laboratory Llc, Report No.: 0064/0014/FA, GLP, Unpublished	Y	Y	Globachem NV
KCP 5.1.1	Świstak, M.	2021	Validation of analytical method for the determination of active substance – zoxamide of the test item Zoxamide 450 SC in aqueous solutions, Sorbolab Research Laboratory Llc, Report No.: 0064/0011/FA, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Gustloff, C.	2022	Validation of Analytical Methods to Determine Residues of Zoxamide in Plant Matrices, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07039, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Gustloff, C.	2022	Validation of an Analytical Method to Determine Residues of Zoxamide Metabolites (RH-1452 and RH-1455) in Grape and Potato Matrices, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07040, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Gustloff, C.	2022	Validation of an Analytical Method for Determination of Zoxamide Metabolite RH-150721 in Wine, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07042, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Maric, A.	2023	Determination of Extraction Efficiency by Comparison of Methods for [14C]Zoxamide in Grape Plants, Eurofins Agroscience Services Ecochem Gmbh, Report No.: S23-100483, GLP, Unpublished	Y	Y	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 4.1.2	DeVellis, S.	2023	Zoxamide Metabolite (RH-163353) - Analytical Method Validation for the Determination of a Test Substance in Aqueous Solutions, Smithers Ers Ltd, Report No.: 14365.6100, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-139432 in Salt Water Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26104-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-139432 in Algae Media Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26103-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-127450 in Salt Water Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26101-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-127450 in Algae Media Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26102-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-141455 in Salt Water Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26105-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Liu, Y.	2023	RH-24549 in Salt Water Enforcement Analytical Method, Stillmeadow Inc, Report No.: 26107-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Gustloff, C.	2023	Validation of Analytical Methods for Determination of Propamocarb-HCl, Zoxamide and its metabolites RH-1452, RH-1455 and RH-150721 in Honey, Eurofins Agroscience Services Chem Gmbh, Report No.: S23-100692, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.1.2	Gustloff, C.	2024	Validation of Analytical Methods for Determination of Propamocarb-HCl, Zoxamide and its metabolites RH-1452, RH-1455 and RH-150721 in Honey, Amendment 1 to Final Report, Eurofins Agroscience Services Chem Gmbh, Report No.: S23-100692, GLP, Unpublished	Y	Y	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 4.1.2	Asekunowo, J.	2023	Independent Laboratory Validation of Analytical Methods for Determination of Propamocarb-HCl, Zoxamide and its Metabolites in Honey, Eurofins Agroscience Services Eag Laboratories Gmbh, Report No.: S23-100694, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.2	Gustloff, C.	2023	Validation of an Analytical Method for Determination of Zoxamide in Body Fluids and Animal Tissues, Eurofins Agroscience Services Chem Gmbh, Report No.: S23-100691, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1 (filed in Part B Section 9)	Wilkins, S.	2023	GLOB2013F: <i>Daphnia magna</i> Acute Immobilisation Test, Fera Science Ltd, Report No.: FR/002721, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1 (filed in Part B Section 9)	Wright, E.	2023	GLOB2013F: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002720, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1 (filed in Part B Section 9)	Jarratt, N.	2023	Zoxamide Technical: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002786, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.3.1.3 (filed in Part B Section 9)	Aguilar-Alberola, J.	2023	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Eurofins Trialcamp S.L.U., Report No.: S23-106642, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2 (Submitted in Part B Section 9)	Dewson, S.	2023	GLOB2013F: OECD Terrestrial Plant Test - Vegetative Vigour Test, Report No.: STC/22/E1557, Laboratory: Stockbridge Technology Centre Ltd., GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2 (Submitted in Part B Section 9)	Stead, A.	2023	GLOB2013F: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Report No.: STC/22/E1558, Laboratory: Stockbridge Technology Centre Ltd., GLP, Unpublished	Y	Y	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 4.2	Homazava, N.	2022	Validation of LC-MS/MS Analytical Method for Zoxamide in Soil, Innovative Environmental Services, Report No.: 20210506, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.2	Homazava, N.	2022	Validation of LC-MS/MS Analytical Method for Zoxamide in Water Matrices, Innovative Environmental Services, Report No.: 20210507, GLP, Unpublished	Y	Y	Globachem NV
KCA 4.2	Homazava, N.	2022	Validation of LC-MS/MS Analytical Method for Zoxamide in Air, Innovative Environmental Services, Report No.: 20210508, GLP, Unpublished	Y	Y	Globachem NV
KCP 4.2	Ducat, N.	2022	Determination of zoxamide residues in drinking water. Independent Laboratory Validation (ILV) of the analytical method described in the final report IES study 20210507 of Innovative Environmental Services (IES) Ltd, Switzerland for Globachem., Centre Wallon De Recherches Agronomiques, Report No.: 25674, GLP, Unpublished	Y	Y	Globachem NV

Section 6

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 7.3	Hassler, S.	2022	Zoxamide – In vitro percutaneous penetration of [¹⁴ C]Zoxamide formulated as GLOB2013F through Human Skin Membranes, Innovative Environmental Services, Report No.: 20220116, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.4.1	Burns, K.	2023	Reverse Mutation Assay using Bacteria (Salmonella typhimurium and Escherichia coli) with Zoxamide metabolite RH-150721, Eurofins Biopharma Product Testing Munich GmbH, Report No.: STUGC22AA1264-2, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.4.1	Smith, K.	2023	RH-150721: Bacterial Reverse Mutation Assay, Labcorp Early Development Laboratories Ltd., Report No.: 8512200, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.4.1	Gilby, B.	2023	RH-150721: In Vitro Human Lymphocyte Micronucleus Assay, Labcorp Early Development Laboratories Ltd., Report No.: 8512201, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.4.2	xxxxxxx	2024	In vivo Mammalian Alkaline Comet Assay of Liver and Glandular Stomach Cells in Rats with RH-150721 [CAS No.: 209809-78-9] xxx Report No.: STUGC23AA0970-2, GLP, Unpublished	Y	Y	Globachem NV

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 5.2.7	Brinkmann, C.	2022	In Vitro 3T3 NRU Phototoxicity Test with Zoxamide Tech, Eurofins Biopharma Product Testing Munich GmbH, Report No.: STUGC22AA0666-2, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.8.1	Schmidt, E.	2022	In vitro Mammalian Cell Gene Mutation Assay (Thymidine Kinase Locus/tk+/-) in L5178Y Mouse Lymphoma Cells with Zoxamide metabolite RH-141455, Eurofins Biopharma Product Testing Munich GmbH, Report No.: STUGC22AA1264-3, GLP, Unpublished	Y	Y	Globachem NV
KCA 5.8.1	Graf, J.	2022	In vitro Mammalian Micronucleus Assay in Human Lymphocytes with Zoxamide metabolite RH-141455, Eurofins Biopharma Product Testing Munich GmbH, Report No.: STUGC22AA1264-4, GLP, Unpublished	Y	Y	Globachem NV

Section 7

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.1	Gustloff, C.	2023	Storage stability of Zoxamide and its metabolites RH-1452 and RH-1455 in Plant Matrices under Deep Frozen Conditions, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07041, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.1	Gustloff, C.	2023	Storage Stability of Zoxamide and its metabolites RH-1452 and RH-150721 in Wine under Deep Frozen Conditions, S21-07043, Eurofins Agroscience Services Chem GmbH, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.1	Gustloff, C.	2023	Storage Stability of Propamocarb-HCl, Zoxamide and its metabolites RH-1452, RH-1455 and RH-150721 in Honey under Deep Frozen Conditions, Eurofins Agroscience Services Chem Gmbh, Report No.: S23-100693, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.2.1	Maric, A.	2023	Metabolism of [¹⁴ C]Zoxamide in Grape Plants, S22-01899, Eurofins Agroscience Services EcoChem GmbH, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.3	Kroniewicz, L.	2022	Determination of residues of zoxamide after two applications of GLOB2013F in grape (outdoor) at 4 sites in Northern Europe 2021, on RAC samples and processed commodities, S21-07247, Eurofins Agroscience Services France SAS, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.3	Kroniewicz, L.	2023	Determination of residues of zoxamide after two applications of GLOB2013F in grape (outdoor) at 4 sites in Southern Europe 2022, S22-01848, Eurofins Agroscience Service France SAS, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.5.1	Maric, A.	2022	[¹⁴ C]Zoxamide Hydrolysis under Typical Conditions (pH, Temperature and Time) of Processing, S21-07903, Eurofins Agroscience Services EcoChem GmbH, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.5.3	Gustloff, C.	2022	Determination of residues of RH-150721 after two applications of GLOB2013F in grape (outdoor) at 4 sites in Northern Europe 2021, on pasteurized juice samples, S22-08244, Eurofins Agroscience Services Chem GmbH, GLP, Unpublished	Y	Y	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.10.1	Poráčski, K.	2023	Magnitude of residues of Zoxamide in Spring Oilseed Rape (<i>Brassica napus</i> L.) honey after two applications of GLOB2013F under semi-field conditions in Central and Southern Europe, Biochem Agrar Gmbh, Report No.: 23 48 BTR 0003, GLP, Unpublished	Y	Y	Globachem NV
KCA 6.10.1	Knoll, M.	2024	Determination of Residues of Zoxamide and Propamocarb-HCl in Honey after Five Applications in Total of GLOB2008F and GLOB2013F in <i>Phacelia tanacetifolia</i> at Four Sites in Central and Southern Europe in 2023, Eurofins Mitox Fopse Sarl, Report No.: S23-100687, GLP, Unpublished	Y	Y	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.2.1/01	Reibach, PH, Spencer, WO	1998a	¹⁴ C-RH-117,281: Nature of the residue in Fruiting grape plants, Rohm and Haas Technical Report No. 34-98-49, October1, 1998 GLP, Unpublished	N	Y	Gowan
KCA 6.2.1/05	Staffa, C. and Mondel, M.	2014	¹⁴ C-phenyl UL zoxamide: Plant metabolism in grape. RLP AgroScience GmbH, Breitenweg 71, 67435 Neustadt, Germany Report Number: S12-03952 Interim Report GLP, Not published	N	Y	Gowan
KCA 6.3.1/05	Wais, A.	1999d	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1997 Report no. 652252, March 18, 1999 GLP, unpublished ER ref. no. R 64.4/R 64.5	N	Y	Gowan
KCA 6.3.1/07	Wais, A.	1999f	Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1997 Report no. EA970131, April 6, 1999 GLP, unpublished ER ref. no. R 64.1	N	Y	Gowan

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3.1/08	Wais, A.	1999g	Determination of residues of RH-117281 and mancozeb in /on potatoes (RAC tubers) following treatment with RG-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy; 1997 Report no. 652285, March 25, 1999 GLP, unpublished ER ref. no. R65.3/R 65.4	N	Y	Gowan
KCA 6.3.1/09	Wais, A.	1999h	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117, 281 75 DG Blenc from field trials in Greece; 1997 Report no. 652307, March 17,1999 GLP, unpublished ER ref. no. R 64.2/64.3	N	Y	Gowan
KCA 6.3.1/10	Wais, A.	1999i	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in Germany; 1998 Report no. 688904, April 13, 1999 GLP, unpublished,ER ref. no. R 68.1/R 68.2	N	Y	Gowan
KCA 6.3.1/14	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH141,455 in/on potatoes (RAC tubers) following treatment with RH7281/mancozeb 75WG from a field trial (semi residue decline study) in the Netherlands; 1999 Report no. 734567, January 2000 GLP, unpublished ER ref. no. R 72.5	N	Y	Gowan
KCA 6.3.1/17	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 Report no. 734545, March 2000 GLP, unpublished ER ref. no. R 73.2	N	Y	Gowan

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3.2/01	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Germany; 1996 Report no. 553001/649765, April 16,1999 GLP, unpublished ER ref. no. R 69.4/R 69.5	N	Y	Gowan
KCA 6.3.2/02	Grolleau, G.	1999b	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine and Processed Fractions – Northern and Southern France – 1996 Report no. EA960110, March 15,1999 GLP, unpublished ER ref. no. R 60.1	N	Y	Gowan
KCA 6.3.2/03	Wais, A.	1999m	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1996 Report no. 553101/649787, April 16,1999 GLP, unpublished ER ref. no. R 70.1/ R 70.2	N	Y	Gowan
KCA 6.3.2/04	Wais, A.	1999n	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1996 Report no. 553102/649798, April 16,1999 GLP, unpublished ER ref. no. R 71.3/ R 71.4	N	Y	Gowan
KCA 6.3.2/05	Wais, A.	1999o	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Spain, 1996 Report no. 553200/620875, April 16,1999 GLP, unpublished ER ref. no. R 70.5/ R 70.6	N	Y	Gowan
KCA 6.3.2/06	Wais, A.	1999p	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Germany, 1997 Report no. 652241, April 16,1999 GLP, unpublished ER ref. no. R 71.1/ R 71.2	N	Y	Gowan

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3.2/07	Grolleau, G.	1999c	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine – Northern and Southern France – 1997 Report no. EA 970130, March 15,1999 GLP, unpublished ER ref. no. R 62.3	N	Y	Gowan
KCA 6.3.2/08	Wais, A.	1999q	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1997 Report no. 652274, April 14,1999 GLP, unpublished ER ref. no. R 68.5/ R 68.6	N	Y	Gowan
KCA 6.3.2/09	Wais, A.	1999r	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Greece, 1997 Report no. 652296, April 14,1999 GLP, unpublished ER ref. no. R 69.2/ R 69.3	N	Y	Gowan
KCA 6.3.2/10	Wais, A.	1999s	Determination of residues of RH-117281 and mancozeb in/on table grapes(RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1997 Report no. 660688, March 19,1999 GLP, unpublished ER ref. no. R 65.1/ R 65.2	N	Y	Gowan
KCA 6.3.2/11	Wais, A.	1999t	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), Dithane/RH-117,281 75 WP Blend (8:1) and RH-7281 2F Experimental fungicide from four field trials in Germany, 1998 Report no. 688893, April 13,1999 GLP, unpublished ER ref. no. R 67.2/ R 67.3	N	Y	Gowan
KCA 6.3.2/12	Grolleau, G.	1999d	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine – Northern and Southern France – 1998 Report no. EA 980117, March 15,1999 GLP, unpublished ER ref. no. R 63.1	N	Y	Gowan

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3.2/13	Wais, A.	1999u	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in Italy, 1998 Report no. 688961, April 12,1999 GLP, unpublished ER ref. no. R 66.2/ R 66.3	N	Y	Gowan
KCA 6.3.2/14	Wais, A.	1999v	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), from two field trials in Spain, 1998 Report no. 688915, April 14,1999 GLP, unpublished ER ref. no. R 67.4	N	Y	Gowan
KCA 6.3.2/15	Wais, A.	1999w	Determination of residues of RH-117,281 and mancozeb in/on table grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), from two field trials in Spain, 1998 Report no. 693674, April 12,1999 GLP, unpublished ER ref. no. R 66.1	N	Y	Gowan
KCA 6.3.2/16	Wais, A.	1999x	Determination of residues of RH-117,281 and mancozeb in/on table grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), from two field trials in Portugal, 1998 Report no. 688948, April 14,1999 GLP, unpublished ER ref. no. R 69.1	N	Y	Gowan
KCA 6.3.2/19	Grolleau, G.	2000	Magnitude of the Residue of RH-7281/mancozeb 76.25WG in grapes raw agricultural commodity – Northern France – 1999 Report no. EA 990175, March 2000 GLP, unpublished ER ref. no. R 73.3	N	Y	Gowan
KCA 6.3.2/20	Grolleau, G.	2000	Magnitude of the Residue of RH-7281/mancozeb 76.25WG in grapes raw agricultural commodity – Southern France – 1999 Report no. EA 990176, March 2000 GLP, unpublished ER ref. no. R 73.4	N	Y	Gowan

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.5.1/01	Mamouni, A.	1998	Mamouni, A, 14C-RH-117281: Vinification Study, RCC Ltd., Rohm and Haas Technical Report No. 34-98-151 December 3, 1998 GLP, unpublished	N	Y	Gowan

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List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 7.1.2.1.2	Jensch, S.	2022	RH-141455 Determination of Adsorption/Desorption in 3 Soils, Eurofins Agroscience Services Ecochem Gmbh, Report No.: S21-09180, GLP, Unpublished	Y	Y	Globachem NV
KCA 7.1.3.1.2	Jensch, S.	2022	RH-141455 Degradation in three Soils at 20 °C in the Dark, Eurofins Agroscience Services Ecochem Gmbh, Report No.: S21-09181, GLP, Unpublished	Y	Y	Globachem NV
KCA 7.2.2.2	Maric, A.	2022	[14C]Zoxamide Aerobic Mineralisation in Surface Water – OECD309, Eurofins Agroscience Services Ecochem Gmbh, Report No.: S21-09182, GLP, Unpublished	Y	Y	Globachem NV
KCA 7.2.2.2	Maric, A.	2023	Identification of Unknown Metabolites of Zoxamide after Aerobic Mineralisation in Surface Water, Eurofins Agroscience Services Ecochem Gmbh, Report No.: S23-102105, GLP, Unpublished	Y	Y	Globachem NV

Section 9

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 10.2.1	Wilkins, S.	2023	GLOB2013F: <i>Daphnia magna</i> Acute Immobilisation Test, Fera Science Ltd, Report No.: FR/002721, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1	Wright, E.	2023	GLOB2013F: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002720, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Przychodzka, A.	2021	Honeybees, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 213, Sorbolab Research Laboratory Llc, Report No.: 0064/0009/E, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Konieczna, A.	2021	Bumblebee, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD 247 Guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0016/E, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Przychodzka, A.	2021	Honeybees, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 214, Sorbolab Research Laboratory Llc, Report No.: 0064/0010/E, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Konieczna, A.	2021	Bumblebee, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD 246 guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0013/E, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.2	Konieczna, A.	2021	Honey Bee, chronic oral toxicity test of the test item Zoxamide 450 SC according to OECD 245 Guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0015/E, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.3	Konieczna, A.	2021	Honey Bee Larval Toxicity Test following Repeated Exposure to the test item Zoxamide 450 SC according to OECD GD 239 ENV/JM/MONO(2016)34, Sorbolab Research Laboratory Llc, Report No.: 0064/0012/E, GLP, Unpublished	Y	Y	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 10.3.2.1	Leopold, J.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates, Ibacon Gmbh, Report No.: 169571063, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.2.1	Leopold, J.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates, Ibacon Gmbh, Report No.: 169571001, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.1.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169571022, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169571089, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil, Ibacon Gmbh, Report No.: 169571016, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.5	Hammesfahr, U.	2022	GLOB2013F: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Ibacon Gmbh, Report No.: 169571080, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2	Dewson, S.	2023	GLOB2013F: OECD Terrestrial Plant Test - Vegetative Vigour Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1557, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2	Stead, A.	2023	GLOB2013F: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1558, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.1	xxxxxxxxx	2020	RH-163353: Fish, acute toxicity test - Amended final report 1, xxxxxx, Report No.: 3202385, GLP, Unpublished	YN	Y	Gowan*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 8.2.1	xxxxxxx	2020	RH-141455: Fish, acute toxicity test, xxxxxxxx, Report No.: 3202716, GLP, Unpublished	Y N	Y	Gowan*
KCA 8.2.1	xxxxxxx	2020	RH-127450: Fish, acute toxicity test, xxxxxxxx, Report No.: 3202373, GLP, Unpublished	Y N	Y	Gowan*
KCA 8.2.4.2	Mikulas, J.	2023	RH-139432 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25769-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.4.2	Doig, A.	2023	RH-24549 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25772-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.4.2	Mikulas, J.	2023	RH-127450 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25833-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.4.2	Mikulas, J.	2023	RH-141455 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25771-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.4.2	Shaw, A.	2023	RH-163353 - Acute Toxicity to Mysids (<i>Americamysis bahia</i>) Under Static Conditions, Smithers Ers Ltd, Report No.: 14365.6102, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Jarratt, N.	2023	Zoxamide Technical: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002786, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Softcheck, K.	2023	RH-163353 - 72-Hour Toxicity Test with the Freshwater Green Alga, <i>Raphidocelis subcapitata</i> , Smithers Ers Ltd, Report No.: 14365.6101, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Mikulas, J.	2023	RH-139432 72-Hour Algal Inhibition Test with <i>Pseudokirchneriella subcapitata</i> , Stillmeadow Inc, Report No.: 25770-22, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Mikulas, J.	2023	RH-127450 72-Hour Algal Inhibition Test with <i>Pseudokirchneriella subcapitata</i> , Stillmeadow Inc, Report No.: 25834-22, GLP, Unpublished	Y	Y	Globachem NV

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KCA 8.3.1.3	Aguilar-Alberola, J.	2023	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Eurofins Trialcamp S.L.U., Report No.: S23-106642, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-24549: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 166191022, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-127450: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 175161022, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-163353: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 175171022, GLP, Unpublished	Y	Y	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 8.2.4.1	Siche, O.	2022	RH-24549: Acute Toxicity to <i>Daphnia magna</i> in a Static 48-hour Immobilisation Test, Ibacon Gmbh, Report No.: 166191220, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Siche, O.	2023	(R)-Zoxamide: Toxicity to <i>Desmodesmus subspicatus</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 168331210, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Siche, O.	2023	(S)-Zoxamide: Toxicity to <i>Desmodesmus subspicatus</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 168321210, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Siche, O.	2022	Algae Growth Inhibition Study Green Algae (<i>Desmodesmus subspicatus</i>), Ibacon Gmbh, Report No.: 166191210, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.6.1	Siche, O.	2022	RH-141455: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 166221210, GLP, Unpublished	Y	Y	Globachem NV

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KCA 8.4.1	Straube, D.	2022	RH-141455: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon GmbH, Report No.: 166221022, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.5	Bauer, J.	2022	RH-141455: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Ibacon GmbH, Report No.: 166221080, GLP, Unpublished	Y	Y	Globachem NV

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 8.3.1.3	Aguilar-Alberola, J.	2023	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Eurofins Trialcamp S.L.U., Report No.: S23-106642, GLP, Unpublished	Y	N	Globachem NV