

Product name: Observer Pro

Product code: GLOB2007bF

Active Substances: Zoxamide 67.5 g/L, Propamocarb-HCl 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: 13/11/2024

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	De Ryckel, B.	2022	Physico-chemical properties and storage stability of a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, first interim report, Centre Wallon De Recherches Agronomiques, Report No.: 25509, GLP, Unpublished	Y	Y	Globachem NV
KCP 2.1-2.8	Kamran, A.	2022	Physico / Chemical Testing on a Sample of GLOB2007bF, Dekra Uk Ltd., Report No.: GLP3016012288R1/2022, GLP, Unpublished	Y	Y	Globachem NV
KCP 2.1-2.8	De Ryckel, B.	2022	Accelerated storage stability or 8 weeks at 40°C of GLOB2007bF, a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, Centre Wallon De Recherches Agronomiques, Report No.: 25644, GLP, Unpublished	Y	Y	Globachem NV
KCP 2.1-2.8	Fourmanoir, S.	2023	Accelerated storage stability for 8 weeks at 40°C and shelf-life storage for 2 and 3 years at 20°C of GLOB2007bF (batch: KS080523-1), a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, second interim report, Centre Wallon De Recherches Agronomiques, Report No.: 25755, GLP, Unpublished	Y	Y	Globachem NV
KCP 2.2.1-2.2.2 (filed in Part C)	Norris, D.	2022	THEORETICAL CERTIFICATE OF EXPLOSIVE AND OXIDISING PROPERTIES FOR A FORMULATION CONTAINING ZOXAMIDE AND PROPAMOCARB HCl, David Norris Analytical Laboratories Ltd., Report No.: DNA7098, Unpublished	N	Y	Globachem NV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.: DNA6314, 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-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 6.2	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 6.2	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 6.2	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 6.2	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 6.4	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.

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	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.
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.

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	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 CPRP 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.
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.

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-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.
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 CPRP 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.

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	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.
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 6.4	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.

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.	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.
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 6.5	Mieszozka M.	2022	Comparative of sensory analysis of 6 potato samples from the Czech Republic. 098/2022 InHort Polish National Institute of Horticultural Research, not published.	Y	Y	Globachem N.V.
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.

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	De Ryckel, B.	2022	Validation of HPLC methods for the determination of zoxamide content (both stereoisomers content and total zoxamide content) and of propamocarb-HCl content in a formulation suspension concentrate (SC) containing 67.5g/L zoxamide and 450g/L propamocarb-HCl, Centre Wallon De Recherches Agronomiques, Report No.: 25508, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1 (filed in Part B Section 9)	xxxxxxx	2023	GLOB2007bF: Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour Semi-Static Test,xxxxxxx, Report No.: 169561230, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1 (filed in Part B Section 9)	Thorpe, K.	2023	GLOB2007bF: <i>Daphnia magna</i> Acute Immobilisation Test, Fera Science Ltd, Report No.: FR/002723, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1 (filed in Part B Section 9)	Wright, E.	2023	GLOB2007bF: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002722, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1 (filed in Part B Section 9)	Chwiesko, D.	2023	GLOB2007bF: Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory, Ibacon GmbH, Report No.: 169561105, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.2 (filed in Part B Section 9)	Schabio, S.	2023	GLOB2007bF: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory, Ibacon GmbH, Report No.: 169561136, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.3 (filed in Part B Section 9)	Colli, M.	2022	Honey Bee Larvae Toxicity Test (<i>Apis mellifera</i>), Biotechnologie Bt S.R.L., Report No.: BT127/22, 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 10.6.2 (filed in Part B Section 9)	Davies, C.	2023	GLOB2007bF: OECD Terrestrial Plant Test - Vegetative Vigour Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1555, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2 (filed in Part B Section 9)	Stead, A.	2023	GLOB2007bF: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1556, GLP, Unpublished	Y	Y	Globachem NV
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 4.2	Gustloff, C.	2023	Validation of an Analytical Method for Determination of Zoxamide in Body Fluids and Animal Tissues, Eurofins Agrosience Services Chem Gmbh, Report No.: S23-100691, 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

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 (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

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 4.1.2	Gustloff, C.	2022	Validation of Analytical Methods to Determine Residues of Zoxamide in Plant Matrices, Eurofins Agrosience 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 Agrosience Services Chem Gmbh, Report No.: S21-07040, GLP, Unpublished	Y	Y	Globachem NV
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
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
KCP 10.2.1	Wright, E.	2023	GLOB2013F: Pseudokirchneriella subcapitata Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002720, GLP, Unpublished	Y	Y	Globachem NV

Section 6

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 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 Residues of Zoxamide and its Metabolites in/on Grape and Potato Matrices, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07041, 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
CA, 6.1/01	Ross, JR	1998a	Ross, J.R., Storage Stability of RH-117281 Residues in Grapes, Grape Juice, Raisins and Potatoes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-161, December 15, 1998, GLP, unpublished. ER ref. no. R 61.1	N	Y	Gowan
CA, 6.1/02	Ross, JR	1998b	Ross, J.R., Stability of RH-141455 and RH-141452 Residues in Potatoes, Potato Chips, and Potato Flakes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-162, December 15, 1998, GLP, unpublished. ER ref. no. R 61.2	N	Y	Gowan
CA, 6.1/03	Reibach, P.H.	2000	Storage Stability of RH-117,281 Residue in Potato Samples under Conditions of Frozen Storage: Supplement to TR34-98-161 (ER 61.1) Rohm and Haas unpublished Technical Report No. 34-00-80 September 2, 2000 ER ref. no. R 77.11 (submitted with 44.7)	N	Y	Gowan
CA, 6.2.1/02	Reibach, PH, Spencer, WO	1998b	Reibach, PH and Spencer, WO, 14C-RH-117,281: Nature of the Residue in Potato, Rohm and Haas Technical Report No. 34- 98-50, September 17, 1998, GLP, unpublished. ER ref. no. 14.3	N	Y	Gowan
CA, 6.2.3/01	-	1998	xxxxxxxxxx, Metabolism of 14C-RH-117,281 in lactating goats, Technical Report No. 34-97-166, September 10, 1998, GLP, unpublished. ER ref. no. 16.1	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
CA, 6.3.1/01	Wais, A.	1999a	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; 1996 Report no. 553002/649776, April 12, 1999 GLP, unpublished ER ref. no. R 66.4/R 66.5	N	Y	Gowan
CA, 6.3.1/02	Wais, A.	1999b	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 the United Kingdom; 1996 Report no. 553300/649811, April 16, 1999 GLP, unpublished ER ref. no. R 70.3/R 70.4	N	Y	Gowan
CA, 6.3.1/03	Grolleau, G.	1999a	Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1996 Report no. EA960112, April 6, 1999 GLP, unpublished ER ref. no. R 63.3	N	Y	Gowan
CA, 6.3.1/04	Wais, A.	1999c	Determination of residues of RH-117281 and mancozeb in/on potato (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Italy; 1996 Report no. 553103/649800, April 13, 1999 GLP, unpublished ER ref. no. R 67.5/R 67.6	N	Y	Gowan
CA, 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
CA, 6.3.1/06	Wais, A.	1999e	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 UK; 1997 Report no. 652263, March 23, 1999 GLP, unpublished ER ref. no. R 65.5/R 65.6	N	Y	Gowan
CA, 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	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
			Commodity. Northern and Southern France, 1997 Report no. EA970131, April 6, 1999 GLP, unpublished ER ref. no. R 64.1			
CA, 6.3.1/08	Wais, A.	1999g	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 Italy; 1997 Report no. 652285, March 25, 1999 GLP, unpublished ER ref. no. R 65.3/R 65.4	N	Y	Gowan
CA, 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 Blend from field trials in Greece; 1997 Report no. 652307, March 17, 1999 GLP, unpublished ER ref. no. R 64.2/R 64.3	N	Y	Gowan
CA, 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/RH-117,281 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
CA, 6.3.1/11	Wais, A.	1999j	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in UK; 1998 Report no. 688937, April 13, 1999 GLP, unpublished,ER ref. no. R 68.3/R 68.4	N	Y	Gowan
CA, 6.3.1/12	Wais, A.	1999k	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from four field trials in Spain; 1998 Report no. 688926, April 13, 1999 GLP, unpublished ER ref. no. R 66.6/R 66.7	N	Y	Gowan
CA, 6.3.1/14	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with	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
			RH-7281/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			
CA, 6.3.1/15	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Northern France; 1999 Report no. 734556, February 2000 GLP, unpublished ER ref. no. R 72.9	N	Y	Gowan
CA, 6.3.1/16	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with RH-7281/mancozeb 75WP from a field trial (semi residue decline study) in Northern France; 1999 Report no. 739001, March 2000 GLP, unpublished ER ref. no. R 72.4	N	Y	Gowan
CA, 6.3.1/17	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/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
IIA, 6.6.1/01	Kim-Kang, H	1998	Kim-Kang, H., 14C-RH-117,281: Confined Rotational Crop Study, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-98-144, December 4, 1998, GLP, unpublished. ER ref. no. R 60.2	N	Y	Gowan
KCA 6.2.2-6.2.5	xxxxxx	2010	Metabolism of [14c]-propamocarb hydrochloride in the laying hen xxxxxxxxxxxxx, Report No.: MEPRX029, Edition Number: M-366633-01-1 Date: 2010-04-08 GLP, unpublished	N	Y	Bayer CropScience
KCA 6.6.2 /02	Klein, E. H. J.	2004	Decline of residues in white cabbage, lamb's lettuce and wheat Field Rotation Crop Study European Union (Northern zone) 2002 Propamocarb hydrochloride,	N	Y	TF-BCS-Arysta LifeScience

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
			AE B066752 Water soluble concentrate (SL); 66.5 percent w/w (= 722 g/L) Bayer CropScience GmbH, Frankfurt am Main, Germany TF-BCS-Arysta LifeScience, Report No.: C039190, Edition Number: M-226597-01-1 Date: 2004-03-04 GLP/GEP: yes, unpublished			
KCA 6.6.2 /03	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands - Rotational crop study Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2504, Report includes Trial Nos.: 08-2504-01 08-2504-02 08-2504-03 Edition Number: M-349882-02-1 Date: 2009-06-22 ...Amended: 2010-01-13 GLP/GEP: yes, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.6.2 /04	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) - Rotational crop study Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2505, Report includes Trial Nos.: 08-2505-01 08-2505-02 08-2505-03 Edition Number: M-349137-02-1 Date: 2009-06-12 ...Amended: 2010-01-12 GLP/GEP: yes, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.6.2 /05	Melrose, I.; Portet, M.	2010	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain Bayer S.A.S., Bayer CropScience, Lyon, France	N	Y	TF-BCS-Arysta LifeScience

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
			TF-BCS-Arysta LifeScience, Report No.: 08-2506, Report includes Trial Nos.: 08-2506-01 08-2506-02 08-2506-03 Edition Number: M-361470-01-1 Date: 2010-01-14 GLP/GEP: yes, unpublished			
KCA 6.6.2 /06	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2507, Report includes Trial Nos.: 08-2507-01 08-2507-02 08-2507-03 Edition Number: M-349147-02-1 Date: 2009-06-12 Amended: 2010-01-15 GLP/GEP: yes, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.6.2	Gateaud, L.	2010	Statement concerning the reduction of the plant back interval for products containing propamocarb Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: M-359448-02-1, Edition Number: M-359448-02-1 Date: 2010-01-18 GLP/GEP: n.a., unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.1	Everitt, S. L.; Charter, G. E	1998	Potatoes tubers: Stability during deep freeze storage up to 26 months propamocarb hydrochloride active substance, Code: AE B066752 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C003683, Report includes Trial Nos.: 067/02/004 Edition Number: M-167991-02-1 EPA MRID No.: 45090807 Date: 1998-07-15 ...Amended: 1999-04-29 GLP/GEP: yes, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.1	Everitt, S. L.; Charter, G. E	2000	Cabbage: Stability during deep freeze storage up to 39 months active substance Propamocarb hydrochloride	N	Y	TF-BCS-Arysta LifeScience

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
			Code: AE B066752 Aventis CropScience UK Limited, Residues & Human Exposure, Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C009293, Report includes Trial Nos.: 067/02/005 Edition Number: M-198306-01-1 Date: 2000-11-06 GLP/GEP: yes, unpublished			
KCA 6.1	Moede J.	1990	Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published	N	Y	Bayer CropScience
KCA 6.1	Sutton A.L., Charter G.E.	1999	Tomatoes: Stability during deep freeze storage up to 26 months Propamocarb hydrochloride Active substance Generated by: AgrEvo UK Limited; Chesterford Park, England Document No: C003740 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.1	Wrede-Rücker A.	1990	Stability of propamocarb x HCl in lettuce during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85303 GLP / GEP No un-published	N	Y	Bayer CropScience
KCA 6.2.1	Rupprecht K. J., Daniel L. E.	2000	Metabolism of [14C]-Propamocarb Hydrochloride in Spinach (Amended Report Replacing Report AV97E519, Document A89868) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002936 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.2.1	Foertsch A.	1991	The fate of Propamocarb x HCl in potato tubers Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85140 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.2.1	Foertsch A.	1994	The fate of Propamocarb hydrochloride in potato tubers addendum to report UPSR 14/91 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85141 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.2.1	Rupprecht K.J., Feyerabend M.	1998	Metabolism of propamocarb HCL in cucumber grown in soil and hydroculture propamocarb hydrochloride Generated by: Hoechst	N	Y	Bayer CropScience

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
			Schering AgrEvo GmbH; Ecochemistry Frankfurt Germany Document No: A85149 GLP / GEP Yes un-published			
KCA 6.2.1	Goodyear, A.	2001	(14C)-Propamocarb: Metabolism in tomatoes; Covance Labs. study # 1669/3-D2149, GLP, unpublished	N	Y	Chimac Agriphar
KCA 6.2.1	Goodyear, A.	2002	(14C)-Propamocarb: Metabolism in lettuce; Covance Labs. study # 1669/6- D2149, GLP, unpublished	N	Y	Chimac Agriphar
KCA 6.2.1	Goodyear, A.	2002	(14C)-Propamocarb: Metabolism in potatoes; Covance Labs. study # 1669/5- D2149, GLP, unpublished	N	Y	Chimac Agriphar
KCA 6.2.1	Cooke J.	2002	(14C)-Propamocarb: Identification of metabolites in Tomato, Potato and lettuce plant extracts; Covance Labs. study # 1669/10-D2149, GLP, unpublished	N	Y	Chimac Agriphar
KCA 6.2.2- 6.2.5	Rupprecht K. J., Daniel L.E.	2000	Propamocarb: Ruminant (Cow) - Metabolism, Distribution and Nature of the Residues in Milk and Edible Tissues (Amended Report Replacing Report AV97E521, Document A91204) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002935 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.1	Moede J.	1990	Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published	N	Y	Bayer CropScience
KCA 6.3	Pigeon, O.	2000	Determination of residues of propamocarb in potatoes after treatment with Proplant. Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 11992; GLP, unpublished (season 1999); final report.	N	Y	Chimac Agriphar
KCA 6.3	Pigeon, O.	2002	Determination of residues of propamocarb in potatoes after treatments with Proplant (in mixture with DITHANE M 45 WP); Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20237; GLP, unpublished (season 2001); final report.	N	Y	Chimac Agriphar
KCA 6.3	Pigeon, O.	2002	Determination of residues of propamocarb in potatoes after treatment	N	Y	Chimac Agriphar

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
			with Proplant (in mixture with mancozeb); Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20284; GLP, unpublished (season 2001); final report.			
KCA 6.6.1	Meyer B.N.	2000	Uptake of [14C]-Propamocarb Hydrochloride Residues in Soil by Rotational Crops Under Confined Conditions (Amended Report Replacing Report AV96E518, Document A91264) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002934 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.6.2	Singer S.S.	1999	AT HARVEST PROPAMOCARB HYDROCHLORIDE DERIVED RESIDUES IN ROTATIONAL CROPS FOLLOWING SEQUENTIAL APPLICATIONS OF BANOL® TO BARE SOIL AT THE MAXIMUM PROPOSED RATE AND THE SHORTEST ROTATIONAL INTERVAL, USA, 1997 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: C003451 GLP / GEP Yes un-published	N	Y	Bayer CropScience
KCA 6.3	Sonder K.H.	2003	Residue behaviour in potatoes European Union (Northern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU;Residues and Human Exposure, Frankfurt Bayer CropScience AG, Report No.: 02R286 (C032828), Edition Number: M-232144-01-1 Pages: 1-90 Date: 02.09.2003 GLP, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.3	Sonder K.-H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	Y	TF-BCS-Arysta LifeScience

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	Sonder K.- H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	Y	TF-BCS-Arysta LifeScience
KCA 6.3	Sonder K.- H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	Y	TF-BCS-Arysta LifeScience

Section 8

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	[¹⁴ C]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	xxxxxxx	2023	GLOB2007bF: Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour Semi-Static Test, xxxxxx, Report No.: 169561230, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1	Thorpe, K.	2023	GLOB2007bF: <i>Daphnia magna</i> Acute Immobilisation Test, Fera Science Ltd, Report No.: FR/002723, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.2.1	Wright, E.	2023	GLOB2007bF: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002722, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Knautz, T.	2022	GLOB2007bF: Effects (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory, Ibacon Gmbh, Report No.: 169561035, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Chwiesko, D.	2023	GLOB2007bF: Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory, Ibacon Gmbh, Report No.: 169561105, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.2	Schabio, S.	2023	GLOB2007bF: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory, Ibacon Gmbh, Report No.: 169561136, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.1.3	Colli, M.	2022	Effects of GLOB2007bF on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure, Biotechnologie Bt S.R.L., Report No.: BT127/22, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.2.1	Leopold, J.	2022	GLOB2007bF: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates, Ibacon Gmbh, Report No.: 169561001, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.3.2.1	Leopold, J.	2022	GLOB2007bF: 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.: 169561063, 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 10.4.1.1	Straube, D.	2022	GLOB2007bF (Zoxamide 67.5 g/L + propamocarb HCL 450 g/L SC): Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169561022, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.1.1	Straube, D.	2023	GLOB2007bF (Zoxamide 67.5 g/L + propamocarb HCL 450 g/L SC): Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169562022, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.1.1	Straube, D.	2023	GLOB2007bF: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Natural Soil, Ibacon Gmbh, Report No.: 169563022, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	GLOB2007bF (Zoxamide 67.5 g/L + propamocarb HCL 450 g/L SC): Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil, Ibacon Gmbh, Report No.: 169561016, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169561089, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.5	Hammesfahr, U.	2022	GLOB2007bF: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Ibacon Gmbh, Report No.: 169561080, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2	Davies, C.	2023	GLOB2007bF: OECD Terrestrial Plant Test - Vegetative Vigour Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1555, GLP, Unpublished	Y	Y	Globachem NV
KCP 10.6.2	Stead, A.	2023	GLOB2007bF: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1556, GLP, Unpublished	Y	Y	Globachem NV
KCA 8.2.1	xxxxxxx	2020	RH-163353: Fish, acute toxicity test - Amended final report 1, xxxxxxxx, Report No.: 3202385, GLP, Unpublished	Y	Y	Gowan*
KCA 8.2.1	xxxxxxx	2020	RH-141455: Fish, acute toxicity test, xxxxxxxx, Report No.: 3202716, GLP, Unpublished	Y	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	xxxxxxxxxxxx	2020	RH-127450: Fish, acute toxicity test, xxxxxxxxxxxx d, Report No.: 3202373, GLP, Unpublished	Y	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
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

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 8.4.1	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
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

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	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 10.3.1.2	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 10.3.1.2	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