

Product name: Revus Pro
Product code: GLOB2106cF
Active Substances: Propamocarb-HCl 450 g/L
Mandipropamid 75 g/L

REGISTRATION REPORT – POLAND

Part B, Sec. 1 to 9

Reference List

Application for authorisation (Article 33)

Applicant: Globachem NV

MS Finalisation date: 06/03/2024

Section 1, 2, 4

List of data submitted by the applicant and relied on

Annex 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	Sowle J.	2022	Determination of storage stability and shelf life specification data for a formulation GLOB2106cF containing Propamocarb HCl and Mandipropamid stored at 54°C±2°C for two weeks, in compliance with good laboratory practice DNA6686 David Norris Analytical Laboratories Ltd. GLP Unpublished	Y	Y	Globachem NV
KCP2.2.1-2.2.2	Norris D.	2023	Theoretical certificate of explosive and oxidising properties for a formulation containing propamocarb HCl and mandipropamid	N	Y	Globachem NV

Section 3

List of data submitted by the applicant and relied on

Annex 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 6.2-01	Spurova R.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPCMB-CZ01 ZS Trutnov GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-02	Mareckova J.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPCMB-CZ02 ZS Krasne Udoli (Ing. Jitka Mareckova) GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-03	Dana P.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPCMB-CZ03 ZS Kujavy GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-04	de Vries H.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPCMB-NL05 Verify / Proeftuin Zwaagdijk GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-05	Olejniak H.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPCMB-PL06 Field Research Support (FRS) PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-06	Piotrowski G.	2019	Efficacy and selectivity of Propamocarb 722 SL against PHYTIN in potato. FE-19-A-PPMCPB-PL07 Syntech PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-11	Šafář J.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCPB-CZ01 Agritec GEP, not published	Y	Y	Globachem N.V.

Annex 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 6.2-12	Dana P.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-CZ02 ZS Kujavy GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-13	Zöllner H.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-DE03 Field Research Support (FRS) DE GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-14	Magyaróvári V.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-DE04 Agrartest GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-15	Vasatkova-Štanclova L.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-CZ05 ZS Nechanice GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-16	Rivet J.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-FR06 Essais+ GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-17	Kohrman E.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-NL07 Cultus GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-18	Umiński P.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-PL08 Field Research Support (FRS) PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-19	Piotrowski G.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-PL09 Syntech PL GEP, not published	Y	Y	Globachem N.V.
KCP 6.2-20	Kolditz M.	2020	Efficacy of propamocarb against PHYTIN in potato. FE-20-A-PPMCB-DE10 BioChem agrar GEP, not published	Y	Y	Globachem N.V.

Annex 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 6.2-21	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 6.2-22	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 6.2-23	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 6.2-24	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 6.2-25	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 6.2-27	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 6.2-28	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.

Annex 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 6.2-30	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 6.2-32	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 6.2-33	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 6.2-35	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 6.2-36	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 6.2-37	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 6.2-39	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 6.2-40	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.

Annex 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 6.2-41	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 6.2-42	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 6.2-43	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 6.2-44	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 6.2-45	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 6.2-46	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 6.2-47	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.

Annex 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 6.2-48	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 6.2-49	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 6.2-50	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 6.2-51	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 6.2-52	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 6.2-53	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 6.2-54	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 6.2-56	de Vries H.	2022	Efficacy of fungicides based products against PHYTIN. FE-22-B-GLOB2013F-2106F-2007F-NL07 Verify / Proeftuin Zwaagdijk GEP, not published	Y	Y	Globachem N.V.

Annex 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 6.2-57	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 6.2-59	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 6.2-61	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 6.2-62	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 6.2-63	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 6.5-01	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.

Annex 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 6.5-02	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 6.5-03	Stead A.	2022	GLOB2106cF: Seedling Emergence and Seedling Growth Test: Terrestrial Non-Target Plant Species following incorporation into soil. STC/22/E1577 GLP, not published	Y	Y	Globachem N.V.

Section 5

List of data submitted by the applicant and relied on

Annex 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	Sowle J.	2022	Validation of the methods of determination of propamocarb HCl and Mandipropamid and a specified impurity in a formulation GLOB2106cF, in compliance with good laboratory practice DNA6689 David Norris Analytical Laboratories Ltd GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 Submitted as KCP 10.2.1	Lührs U.	2023	GLOB2106cF: acute toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour static test 169461230 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 Submitted as KCP 10.2.1	Ganßmann M.	2023a	GLOB2106cF: Acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilisation test 169461220 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 Submitted as KCP 10.2.1	Ganßmann M.	2023b	GLOB2106cF: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 169461210 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 Submitted as KCP 10.3.1.1	Chwiesko D.	2023	GLOB2106cF: acute contact and oral toxicity to bumblebees (<i>Bombus terrestris</i> L.) in the laboratory 169461105 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 Submitted as KCP 10.3.1.2	Venturi S.	2023	Chronic oral effects of GLOB2106cF to adult worker honeybees (<i>Apis mellifera</i> L.) in a 10-day feeding laboratory test BT262/22 BioTecnologie BT S.r.l. GLP Unpublished	Y	Y	Globachem NV

Annex 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 5.2.1 5.1.2 <i>Submitted as KCP 10.3.1.3</i>	Colli M.	2023	Effects of GLOB2106cF on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. BT126/22 BioTecnologie BT S.r.l. GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 <i>Submitted as KCP 10.6</i>	Stead, A.	2023a	GLOB2106cF: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test STC/22/E1576 Stockbridge Technology Centre Ltd GLP Unpublished	Y	Y	Globachem NV
KCP 5.2.1 5.1.2 <i>Submitted as KCP 10.6</i>	Stead, A.	2023b	GLOB2106cF: OECD Terrestrial Plant Test - Vegetative Vigour Test STC/22/E1575 Stockbridge Technology Centre Ltd GLP Unpublished	Y	Y	Globachem NV

Section 6

List of data submitted by the applicant and relied on

Annex 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.	2023	Propamocarb-HCl – In vitro percutaneous penetration of [¹⁴ C]Propamocarb-HCl formulated as GLOB2106cF through human skin membranes 20220226 Innovative Environmental Services GLP Unpublished	Y	Y	Globachem NV

Section 7

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

Annex 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 6.6.2 /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, 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	N	Y	TF-BCS-Arysta LifeScience
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

Annex 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 6.6.2 /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 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	N	Y	TF-BCS-Arysta LifeScience
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 6.1	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

Annex 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	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 Schering AgrEvo GmbH; Ecochemistry Frankfurt Germany Document No: A85149 GLP / GEP Yes un-published	N	Y	Bayer CropScience
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

Annex 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	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 with Proplant (in mixture with mancozeb); Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20284; GLP, unpublished (season 2001); final report.	N	Y	Chimac Agriphar
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 unpublished	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 unpublished	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

Annex 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	KCA 6.3
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	KCA 6.3

Section 8

List of data submitted by the applicant and relied on

Annex 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 9.2.4	Keunen E.	2023	Estimation of the PECgw of Propamocarb-HCl, Mandipropamid and relevant metabolites GLOB2106cFGWC Globachem NV non GLP Unpublished	N	Y	Globachem NV
KCP 9.2.5	Keunen E.	2023	Estimation of the PECsw and PECsed of Propamocarb-HCl, Mandipropamid and relevant metabolites GLOB2106cFSWC Globachem NV non GLP Unpublished	N	Y	Globachem NV

Section 9

List of data submitted by the applicant and relied on

Annex 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
KCA1 8.2.5.3	Kimmel, S.	2011	Mandipropamid – Effects on the development of sediment-dwelling larvae of Chironomus riparius in water-sediment systems with spiked sediment Report No. D13764 Document No. VV-397081 , NOA446510_10741 Test Facility Harlan Laboratories Ltd. GLP Unpublished	Y	Y	Syngenta (LoA Globachem NV)
KCP 10.1.2.2	Cairns, S.	2013	Mandipropamid – Foliage Decline Study with A12946B on Cereals in Northern France, Germany and the United Kingdom in 2013 Report No. 34472 Document No. VV-405547 , A12946B_11634 Test Facility Charles River Laboratories GLP Unpublished	Y	Y	Syngenta (LoA Globachem NV)
KCP 10.2.1	xxxxxxxxxx	2023	GLOB2106cF: acute toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour static test 169461230 xxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Y	Globachem NV
KCP 10.2.1	Ganßmann M.	2023a	GLOB2106cF: Acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilisation test 169461220 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.2.1	Ganßmann M.	2023b	GLOB2106cF: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 169461210 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.1.1	Schabio S.	2023	GLOB2106cF: Effects (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory 169461035 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV

Annex 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 10.3.1.1	Chwiesko D.	2023	GLOB2106cF: acute contact and oral toxicity to bumblebees (<i>Bombus terrestris</i> L.) in the laboratory 169461105 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.1.2	Venturi S.	2023	Chronic oral effects of GLOB2106cF to adult worker honeybees (<i>Apis mellifera</i> L.) in a 10-day feeding laboratory test BT262/22 BioTecnologie BT S.r.l. GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.1.3	Colli M.	2023	Effects of GLOB2106cF on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure BT126/22 BioTecnologie BT S.r.l. GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.2.2	Leopold, J.	2023a	GLOB2106cF: Effects on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended laboratory study – Dose response test 169461062 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.2.2	Leopold, J.	2022	GLOB2106cF: Effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae), Extended laboratory study – Dose response test 169461002 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.2.2	Leopold, J.	2023b	GLOB2106cF: Effects on the lacewing <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae), Extended laboratory study – Dose response test 169461047 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.3.2.2	Leopold, J.	2023c	GLOB2106cF: Effects on the ladybird beetle <i>Coccinella septempunctata</i> (Coleoptera, Coccinellidae), Extended laboratory study – Dose response test 169461012	Y	Y	Globachem NV

Annex 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
			Ibacon GmbH GLP Unpublished			
KCP 10.4.1.1	Straube, D.	2022a	GLOB2106cF: Effects on reproduction and growth of earthworms <i>Eisenia andrei</i> in artificial soil 169461022 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022b	GLOB2106cF: Effects on reproduction of the Collembola (<i>Folsomia candida</i>) in artificial soil 169461016 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.4.2.1	Straube, D.	2022c	GLOB2106cF: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil 169461089 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.5	Hammesfahr, U.	2022	GLOB2106cF: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) 169461080 Ibacon GmbH GLP Unpublished	Y	Y	Globachem NV
KCP 10.6	Stead, A.	2023a	GLOB2106cF: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test STC/22/E1576 Stockbridge Technology Centre Ltd GLP Unpublished	Y	Y	Globachem NV
KCP 10.6	Stead, A.	2023b	GLOB2106cF: OECD Terrestrial Plant Test - Vegetative Vigour Test STC/22/E1575 Stockbridge Technology Centre Ltd GLP Unpublished	Y	Y	Globachem NV