Registration Report, ZRMS: Poland

Product name: Heksal 100 WG/Jamur 100 WG

Product code: CHR/RW/PROH 100 WG

Active Substance: Prohexadione calcium 100 g/kg

**REGISTRATION REPORT – POLAND**

**Part B, Sec. 1 to 9**

**Reference List**

**Application for authorisation (Article 33)**

Applicant: Innvigo Sp. z o.o.

Date: 22/04/2022

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 |
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| KCP 2.1/02 | Patrzałek, M. | 2020 | *Determination of physicochemical properties after shelf-life test.*  ICB/92/2019- Part 1  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
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| KCP 2.3.3 | Flasińska, P. | 2019 | *Determination of flammability, relative self-ignition temperature and oxidizing properties*  BC-18/19  Insytut Przemysłu Organicznego, Warsaw, Poland  GLP  Unpublished | Y | Y | Chemirol |
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| KCP 2.8.3.1/04 | Łebek, B. | 2021 | *Determination of physicochemical properties after shelf-life test.*  ICB/92/2019- Part 2  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
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| KCP 2.8.5.1.1/01 | Patrzałek, M. | 2019 | *Determination of physicochemical properties*  ICB/91/2019  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
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| KCP 2.8.5.1.2/03 | Łebek, B. | 2021 | *Determination of physicochemical properties after shelf-life test.*  ICB/92/2019- Part 2  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 2.8.5.1.3/01 | Patrzałek, M. | 2019 | *Determination of physicochemical properties*  ICB/91/2019  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
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| KCP 2.8.5.2.1/03 | Arévalo, E. | 2020 | *Determination of dustiness after one year of storage.*  BF-36/20  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 2.8.5.2.1/04 | Zieliński, J. | 2021 | *Determination of dustiness after two years of storage.*  BF-43/21  ICB Pharma, Jaworzno, Poland  GLP  Unpublished | Y | Y | Chemirol |
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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** |
| --- | --- | --- | --- | --- | --- | --- |
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| KCP 6  KCP 6.2  KCP 6.4.1  KCP 6.4.2  KCP 6.4.3 | M. Budziński  J. Guzińska | 2020 | Assessment of the effect of CHR/RW/PROH 100 WG on reduction of hight and preventing lodging of winter wheat, Poland 2020.  A.T Sp. z o.o.  ul. Przemysłowa 3  88-300 Mogilno  Poland  Report no.: A.T/2020/002/PO  GEP - yes  Unpublished | Y | Y | Chemirol |
| KCP 6  KCP 6.2  KCP 6.4.1  KCP 6.4.2  KCP 6.4.3 | M. Budziński  K. Wołowicz  J. Guzińska | 2020 | Assessment of the effect of CHR/RW/PROH 100 WG on reduction of hight and preventing lodging of winter wheat, Poland 2020.  A.T Sp. z o.o.  ul. Przemysłowa 3  88-300 Mogilno  Poland  Report no.: A.T/2020/003/PO  GEP - yes  Unpublished | Y | Y | Chemirol |
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| KCP 6  KCP 6.2  KCP 6.4.1  KCP 6.4.2  KCP 6.4.3 | P. Hojka | 2020 | Plant growth regulator PGR: CHR/RW/PROH 100 WG prohexadione calcium 100 g/kg. Poland 2019  STAPHYT Sp. z o.o.  ul. Ziębicka 2  60-164 Poznań  POLAND  Report no.: CHR/RW/PROH / MPI-19-39959-PL05 | Y | Y | Chemirol |

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 |
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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 |
| --- | --- | --- | --- | --- | --- | --- |
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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 7.1.1 | Adamczak, A. | 2020 | *Toxicological classification of product CHR/RW/PROH 100 WG based on calculation method taking into consideration health hazards of constituent substances.*  PUH Chemirol Sp. z o.o.  non GLP  Unpublished | N | Y | Chemirol |
| KCP 7.1.4 | Adamczak, A. | 2020 | *Toxicological classification of product CHR/RW/PROH 100 WG based on calculation method taking into consideration health hazards of constituent substances.*  PUH Chemirol Sp. z o.o.  non GLP  Unpublished | N | Y | Chemirol |
| KCP 7.1.5 | Adamczak, A. | 2020 | *Toxicological classification of product CHR/RW/PROH 100 WG based on calculation method taking into consideration health hazards of constituent substances.*  PUH Chemirol Sp. z o.o.  non GLP  Unpublished | N | Y | Chemirol |

Section 7

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 6.1/01 | Stewart, J. M. | 2002 | *Storage stability of BAS 125 W and metabolite BW 125 31 F in apples*  2001/5002487  GLP  Unpublished | N | Y | BASF |
| KCA 6.1/02 | Mackenrot, H. C. | 1995 | *Investigation of the storage stability of prohexadione-Ca in wheat: Test of storage stability in green matter, grain and straw*  95/10624  GLP  Unpublished | N | Y | BASF |
| KCA 6.2.1/01 | Patel, J. R., et. Al. | 1998 | *Metabolism of 14C-BAS 125 W in apples*,  1997/5005  GLP  Unpublished | N | Y | BASF |
| KCA 6.2.1/02 | Steginsky, C. A., et al. | 1997 | *Metabolism of 14 C BAS 125 W (Prohexadione Calcium) in peanut*  1997/5341  GLP  Unpublished | N | Y | BASF |
| KCA 6.6.1 | Steginsky, C. A., et al. | 1996 | *Confined rotational crop study with 14C-BAS 9054 W (Prohexadione-Calcium*  1996/5005  GLP  Unpublished | N | Y | BASF |

Section 8

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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 |
| --- | --- | --- | --- | --- | --- | --- |
| KCP 9.1.3, KCP 9.2.4, KCP 9.2.5 | - | 2020 | CHR/RW/PROH Efate Calculations  Innvigo Sp. z o.o.  Non GLP  Unpublished | N | Y | Innvigo |

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| --- | --- | --- | --- | --- | --- | --- |
| KCP 9.1.1.1/01 | Class, T. | 2008 | *Final report. 14C-Prohexadione-Calcium: Study on Aerobic Soil Degradation Using Four Different Soils at 20°C.*  2008/1032660  GLP-Yes  Unpublished | N | Y | BASF |
| KCP 9.1.1.1/02 | Vankatesh, K. | 1995 | *Photolysis of 14C-BAS 125 W on Soil*  1995/5187  GLP-No  Unpublished | N | Y | BASF |
| KCP 9.1.1.1/03 | Callow, B, Jarvis, T. | 2008d | *Determination of rates of decline for Prohexadione calcium from the soil metabolism study (BASF Doc ID 1993/10256) according to the guidance within the FOCUS Kinetics Guidance Document.*  2008/1042834  GLP-Yes  Unpublished | N | Y | BASF |
| KCP 9.2 | Callow, B., Jarvis, T. | 2008b | *Determination of rates of decline for Prohexadione-calcium from the Sediment-Water study (BASF Doc ID 1994/10949) according to the guidance within the FOCUS Kinetics Guidance Document.*  2008/1042832  Not subject to GLP regulations  Unpublished | N | Y | BASF |

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 10.2/01 | Polińska, A. | 2019 | *CHR/RW/PROH 100 WG Daphnia magna, Acute immobilisation test*  W/37/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.2/02 | Polińska, A. | 2019 | *CHR/RW/PROH 100 WG Raphidocelis subcapitata SAG 61.81 (formely Pseudokirchneriella subcapitata) Growth inhibition test*  W/38/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.2/03 | Polińska, A. | 2019 | *CHR/RW/PROH 100 WG Lemna gibba CPCC 310, Growth inhibition test*  W/39/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.2/04 | Polińska, A. | 2019 | *CHR/RW/PROH 100 WG Anabaena flos-aquae UTEX B 1444 Growth inhibition test*  W/40/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.3.1/01 | Stalmach, M. | 2019 | *Prohexadion calcium 100 WG [CHR/RW/PROH 100 WG] Honeybees (Apis mellifera L.), Acute Oral Toxicity Test*  B/38/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.3.1/02 | Stalmach, M. | 2019 | *Prohexadion calcium 100 WG [CHR/RW/PROH 100 WG] Honeybees (Apis mellifera L.), Acute Contact Toxicity Test*  B/39/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.3.2/01 | Stalmach, M. | 2019 | *A laboratory test for evaluating the effects of Prohexadione calcium 100 WG on the predatory mite, Tyohlodromus pyri*  B/36/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.3.2/02 | Stalmach, M. | 2019 | *A laboratory test for evaluating the effects of Prohexadion calcium 100 WG on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez.)*  B/37/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.4/01 | Wróbel, A. | 2019 | *Prohexadione calcium 100 WG Earthworm Reproduction Test (Eisenia andrei)*  G/40/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.4/02 | Wołany, M. | 2019 | *Prohexadione calcium 100 WG Collembolan (Folsomia candida) Reproduction test*  G/41/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.4/03 | Wołany, M. | 2019 | *Prohexadione calcium 100 WG Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil*  G/42/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.5 | Wołany, M. | 2019 | *Prohexadione calcium 100 WG Soil Microorganisms: Nitrogen Tranformation Test*  G/43/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.6/01 | Wołany, M. | 2019 | *Prohexadione calcium 100 WG Terretial Plant Test: Vegetative Vigour Test*  G/44/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |
| KCP 10.6/02 | Wołany, M. | 2019 | *Prohexadione calcium 100 WG, Terrestial Plant Test: Seedling Emergence and Seedling Growth Test* G/45/19  IPO Pszczyna, Poland  GLP  Unpublished | Y | Y | Chemirol |

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| --- | --- | --- | --- | --- | --- | --- |
| KCP 10.1.1/01 | xxxxxxxxxxxxxxx | 1990b | *The acute oral toxicity (LD50) of BX-112 to the bobwhite quail*  1990/10238  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/02 | xxxxxxxxxxxxxxx | 1990a | *The acute oral toxicity (LD50) of BX-112 to the mallard duck*  1990/10237  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/03 | xxxxxxxxxxxxxx | 1990c | *The dietary toxicity (LC50) of BX-112 to the mallard duck*  1990/10239  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/04 | xxxxxxxxxxx. | 1990d | *The dietary toxicity (LC50) of BX-112 to the bobwhite quail*  1990/10240  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/05 | xxxxxxxxxxxxx | 1993 | *Subchronic toxicity/reproduction study on the Japanese quail with Prohexadione-calcium, techn. by dietary admixture for a period of 6 weeks.*  1993/10317  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/06 | xxxxxxxxxxxxx. | 1997 | *Amendment No, 1: Subchronic toxicity/ reproduction study on the Japanese quail with Prohexadione-calcium, techn. By dietary admixture for a period of 6 weeks*  1993/10301  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/07 | xxxxxxxxxxxxx | 1996 | *Prohexadione-calcium-1-generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet.*  1996/10868  GLP  Unpublished | N | Y | BASF |
| KCP 10.1.1/08 | xxxxxxxxxxx | 1996 | *Prohexadione-calcium tech: A reproduction study with the mallard*  1996/10095  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/01 | xxxxxxxxxx | 1990b | *The acute toxicity of BX-112 to rainbow trout (Salmo gairdneri)*  1990/10242  xxxxxxxxxxxx  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/02 | xxxxxxxxxxxx | 1990a | *The acute toxicity of BX-112 to bluegill sunfish (Lepomis macrochirus)*  1990/10241  xxxxxxxxxxxxxxx  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/03 | xxxxxxx | 1992 | *Sublethal toxic effects on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of Prohexadione-calcium, tech. Wirkstoff in a flow-through system (28 days)*  1992/11646  xxxxxxxxxxxxxx  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/04 | Douglas, M. T., et al. | 1990c | *The acute toxicity of BX-112 to Daphnia Magna*  1990/10243  Huntingdon Research Centre Ltd, United Kingdom  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/05 | Elendt-Schneider, B. | 1992 | *Determination of the chronic toxicity of Prohexadione-Calcium to the water flea Daphnia magna STRAUS*  1993/10072  BASF AG, Germany  GLP  Unpublished | N | Y |  |
| KCP 10.2/06 | Douglas, M. T., et al. | 1990d | *The alistatic activity of BX-112*  1990/10244  Huntingdon Research Centre Ltd, United Kingdom  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/07 | Haughey, D. W. et al. | 1997 | *A 5-day toxicity test with the fresshwater alga (Anabaena flos-aquae)*  1997/5013  Wildlife International Ltd., USA  GLP  Unpublished | N | Y | BASF |
| KCP 10.2/08 | Thompson | 1997 | *BAS 125 W: A 14-Day toxicity test with duckweed (Lemma gibba G3)*  1997/5016  Wildlife International Ltd., USA  GLP  Unpublished | N | Y | BASF |
| KCP 10.3.1/01 | Cole, J. H. | 1989 | *The acute contact and oral toxicity to honey bees of technical BX-112*  1989/10161  Huntingdon Research Centre Ltd, United Kingdom  GLP  Unpublished | N | Y | BASF |
| KCP 10.4 | Hakin, B.,  Johnson, A. J. | 1990 | *The acute toxicity (LC50) of BX-112 to the earthworm (Eisenia foetida)*  1990/10246  Huntingdon Research Centre Ltd, United Kingdom  GLP  Unpublished | N | Y | BASF |
| KCP 10.5 | Hossack, D. J. N. | 1991 | *The effects of BX-112 on soil carbon and nitrogen cycle micro-organisms*  1991/11433  Huntingdon Research Centre Ltd, United Kingdom  GLP  Unpublished | N | Y | BASF |