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| REGISTRATION REPORT  **Part B**  Section 1: Identity Section 2: Physical and chemical properties Section 4: Further information  Detailed summary of the risk assessment |
| Product code: ADM.09250.H.1.A  Product name(s): **2,4-D 95 SP**  Chemical active substance:  2,4-dichlorophenoxy acetic acid**,** 80.4% or 804 g/Kg |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: XXXX  Sponsor: XXXX  Submission date: March 2023  Evaluation date: December 2023  MS Finalisation date: March 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| March 2023 | 1st applicant version |
| December 2023 | Initial version of RR |
|  |  |
|  |  |

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

the two-year study is ongoing. It has to be provided and assessed in post registration to confirm the two-year shelf life.

~~data gap 2~~

~~data gap 3~~

# Section 1: Identity of the plant protection product

## Applicant (KCP 1.1)

Name: XXXX

Address: XXXX

## Producer of the plant protection product and of the active substances (KCP 1.2)

### Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

### Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

### Statement of purity (and detailed information on impurities) of the active substance(s)

#### 2,4-dichlorophenoxy acetic acid (2,4-D)

Purity of 2,4-D as:

|  |  |
| --- | --- |
| 2,4-D acid | min. 970 g/kg |

The minimum purity of the active substance for the approved source is 960 g/kg (EFSA Journal 2014;12(9):3812).

Confidential information or data are provided separately (Part C). The following impurities of 2,4-D technical a max level is defined, in view of their toxicological relevance.

* Free phenols (expressed as 2,4 DCP): not more than 3 g/kg
* Sum of dioxins and furans (WHO-TCDD-TEQ): not more than 0.01 mg/kg.

## Trade names and producer’s development code numbers for the preparation (KCP 1.3)

|  |  |
| --- | --- |
| Trade name: | Pielik 95 SP  Please refer to Registration Report Part A for the relevant country information |
| Company code number: | ADM.09250.H.1.A |
|  |  |

## Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

### Composition of the plant protection product (KCP 1.4.1)

2,4-D 95 SP was not the representative formulation for the EU renewal evaluation of 2,4-D. It contains nominal 950 g/kg 2, 4-D sodium salt monohydrate with the formulants making up the remainder.

Table 1.4‑1: Active substance(s) and variant(s) of the active substance(s)

| Active substance/ ~~variant~~ | Declared content of the pure active substance/variant (g/L or g/kg) | FAO Limits (min–max) | Technical content\*  (g/L or g/kg) | Technical content  (%w/w) |
| --- | --- | --- | --- | --- |
| 2,4,-D acid | 804 g/L | 804 ± 25 g/kg  (778 – 829) | 828.9 g/L | 82.9 |
| 2,4,-D acid sodium salt monohydrate | 950 | 950 ± 25 g/kg  (925 – 975) | 979.4 g/L | 97.9 |

\* Based on the minimum purity (97.0%) of the active substance declared for registration in the active substance dossiers

Table 1.4‑2: Relevant impurities

| Relevant impurity | Maximum content |
| --- | --- |
| Dioxins and furans | 0.01 mg/kg |
| Free phenol | 3.0 g/kg |

### Information on the active substance(s) (KCP 1.4.2)

Table 1.4‑3: Information on 2,4-D

| Type | 2,4-D/ ADM.09250.H.1.A | |
| --- | --- | --- |
| ISO common name | 2,4-D | 2,4-D sodium salt monohydrate |
| CAS No. | 94-75-7 | 7084-86-8 |
| EC No. | 202-361-1 | - |
| CIPAC No. | 1 | - |

### Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

## Type and code of the plant protection product (KCP 1.5)

|  |  |
| --- | --- |
| Type: Soluble powder | [Code: SP] |

## Function (KCP 1.6)

Herbicide.

# Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white powder. It is not explosive, has no oxidising properties. The product is not highly flammable and does not readily combust. It does not have a self-ignition temperature under the conditions of the test. In aqueous solution, it has a pH value around 7.2. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in 300 g laminated heat-sealed sachets. Its technical characteristics are acceptable for a SP formulation.

The intended concentration of use is 0.311% to 0.466%. w/v.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

The product 2,4-D 95 SP (ADM.09250.H.1.A) does not meet any of the criteria for classification and labelling on the basis of its physical and chemical properties.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

The product is not classified for physical and chemical properties; therefore, no risk and safety phrases are required.

Compliance with FAO specifications:

The product 2,4-D 95 SP (ADM.09250.H.1.A) complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

| Annex point | Method used/ deviations | Test material | Findings | GLP Y/N | Reference | Acceptability/ comments |
| --- | --- | --- | --- | --- | --- | --- |
| Colour and  physical state  (KCP 2.1) | Visual inspection  Nasal inhalation | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Fine white powder.  A malt-like odour was noted during handling.  The colour was also assessed by the Munsell colour system. Under normal daylight and assigned as N 9.5 as a point of reference. | Y | Comb, T. 2022a  Report No. ACE-21-385  Reference No. 000109839 | Accepted |
| Explosive properties  (KCP 2.2.1) | EC Method A.14  EPA/OCSPP 830.6316  Appendix 6 of the UN Manual of Tests and Criteria (Rev. 7). | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Not exposive, the test item was observed to exhibit no reaction during any tests. The test result is therefore considered to be negative.  The energy of decomposition was 448 J/g, which was less than the threshold level of 500 J/g stated in UN guidance, the test item would not have explosive or self-reactive properties | Y | Comb, T. 2022b  Report No. ACE-21-384  Reference No. 000109840 | Accepted |
| Oxidizing properties  (KCP 2.2.2) | UN Test O.1 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Not oxidising (not Division 5.1) | Y | Comb, T. 2022b  Report No. ACE-21-384  Reference No. 000109840 | Accepted |
| Flash point  (KCP 2.3.1) | - | - | Not required for a SP formulation. | - | - |  |
| Flammability  (KCP 2.3.2) | EC Method A.10  UN Test N.1 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Not highly flammable (not Division 4.1) | Y | Comb, T. 2022b  Report No. ACE-21-384  Reference No. 000109840 | Accepted |
| Self-heating  (KCP 2.3.3) | EC Method A.16 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Did not have a self-ignition temperature under the conditions of the test (up to 400°C) | Y | Comb, T. 2022b  Report No. ACE-21-384  Reference No. 000109840 | Accepted |
| Acidity or alkalinity and pH  (KCP 2.4.1) | - | - | The determination of the free acidity or alkalinity was not carried out as the pH value measured in diluted test item was between 4 and 10. | - | - |  |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | CIPAC MT 75.3 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Initial: pH 7.2  After storage : pH 7.1 | Y | Comb, T. 2022a  Report No. ACE-21-385  Reference No. 000109839 | Accepted |
| Viscosity  (KCP 2.5.1) | - | - | Not required for a SP formulation. | - | - |  |
| Surface tension  (KCP 2.5.2) | - | - | Not required for a SP formulation. | - | - |  |
| Relative density  (KCP 2.6.1) | - | - | Not required for a SP formulation. | - | - |  |
| Bulk density  (KCP 2.6.2) | CIPAC MT 186 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Pour density 0.55 g/mL  Tap density 0.74 g/mL | Y | Comb, T. 2022b  Report No. ACE-21-384  Reference No. 000109840 | Accepted |
| Storage Stability after 14 days at 54º C  (KCP 2.7.1) | CIPAC MT 46.3  Free phenol content: CIPAC MT 69.1 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Accelerated temperature stability for 14 days at 54°C in foil sachet PET12/MPET12/LLDPE  Metalized Polyester (MPET)  Linear Low Density Polyethylene (LLDPE)  Polyethylene Terephthalate (PET)  Appearance initial and after storage: white powder  2,4-D sodium salt: 95.1 % w/w  2,4-D sodium salt: after storage: 95.3 % w/w  No significant change to appearance or weight of container after storage.  Stable formulation: see Table 2-2 for findings | Y | Comb, T. 2022a  Report No. ACE-21-385  Reference No. 000109839 | Accepted |
| Accelerated temperature stability for 14 days at 54°C in foil sachet PET12/MPET12/LLDPE  Metalized Polyester (MPET)  Linear Low Density Polyethylene (LLDPE)  Polyethylene Terephthalate (PET)  Free phenol content: 0.85 g/kg  Free phenol content: after storage: 0.79 g/kg  Free phenols are not formed on storage  Dioxins and furans are manufacturing impurities and will not be formed on storage. Therefore the content of dioxins and furans was not assessed in the storage stability assessment | Y | Comb, T. 2023  Report No. ACE-22-293  Reference No. 000112209 | Accepted |
| Stability after storage for other periods and/or temperatures  (KCP 2.7.2) | - | - | Not required as the product was proven to be stable under accelerated storage conditions (i.e. 14 days at 54°C). | - | - |  |
| Minimum content after heat stability testing  (KCP 2.7.3) | - | - | Not required as the product was proven to be stable under accelerated storage conditions (i.e. 14 days at 54°C). | - | - |  |
| Effect of low temperatures on stability  (KCP 2.7.4) | - | - | Not required for a SP formulation. | - | - |  |
| Ambient temperature shelf life  (KCP 2.7.5) |  |  | **Study ongoing**, due for completion in 2024  Ambient temperature stability for 24 months at 25°C in foil sachet PET12/MPET12/LLDPE  Metalized Polyester (MPET)  Linear Low Density Polyethylene (LLDPE)  Polyethylene Terephthalate (PET)  Appearance initial: white powder  2,4-D sodium salt: initial: 95.1 % w/w  Free phenol content: 0.85 g/kg | Y | Report No. ACE-21-386  Reference No. 000109841  Study ongoing | On going |
| Shelf life in months (if less than 2 years)  (KCP 2.7.6) | - | - | Not required as the product was proven to be stable under exaggerated conditions (*i.e.* 14 days at 54 °C) which supports a shelf life of 2 years at ambient temperature. | - | - |  |
| Wettability  (KCP 2.8.1) | CIPAC MT 53.3 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Wettability initial : 10 seconds  Wettability after storage: 11 seconds | Y | Comb, T. 2022a  Report No. ACE-21-385  Reference No. 000109839 |  |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Performed at minimum (3.11 g test item/L) and maximum (4.66 g test item/L) application rates in standard water D.  Initial: After several inversions of the test item diluted, foam was observed initially and after 10 seconds. After 1 min of standing, no foam was present. Test performed at 20°C.  After storage: After several inversions of the test item diluted, foam was observed initially and after 10 seconds. After 1 min of standing, no foam was present. Test performed at 22°C. | Y | Comb, T. 2022a  Report No. ACE-21-385  Reference No. 000109839 | Accepted |
| Suspensibility  (KCP 2.8.3.1) | - | - | Not required for a SP formulation. | - | - |  |
| Spontaneity of dispersion  (KCP 2.8.3.2) | - | - | Not required for a SP formulation. | - | - |  |
| Dispersion stability  (KCP 2.8.3.3) | - | - | Not required for a SP formulation. | - | - |  |
| Degree of dissolution and dilution stability  (KCP 2.8.4) | CIPAC MT 179.1 | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | Performed at highest recommended concentration within the scope of the method (3 g in 250 mL).  5 minute test:  Initial 0.032% w/w residue  After storage 0.0955 % w/w resudie  24 hour test:  No residue initially or after storage | Y |  | Accepted |
| Particle size distribution/nominal size range of granules  (KCP 2.8.5.1.1) | - | - | Not required for a SP formulation. | - | - |  |
| Wet sieve test  (KCP 2.8.5.1.2) | - | - | Not required for a SP formulation. | - | - |  |
| Dust content  (KCP 2.8.5.2.1) | - | - | Not required for a SP formulation. | - | - |  |
| Particle size of dust  (KCP 2.8.5.2.2) | - | - | Not required for a SP formulation. | - | - |  |
| Attrition  (KCP 2.8.5.3) | - | - | Not required for a SP formulation. | - | - |  |
| Hardness and integrity  (KCP 2.8.5.4) | - | - | Not required for a SP formulation. | - | - |  |
| Emulsifiability  (KCP 2.8.6.1) | - | - | Not required for a SP formulation. | - | - |  |
| Emulsion stability  (KCP 2.8.6.2) | - | - | Not required for a SP formulation. | - | - |  |
| Re-emulsifiability  (KCP 2.8.6.3) | - | - | Not required for a SP formulation. | - | - |  |
| Flowability  (KCP 2.8.7.1) | - | - | Not required for a SP formulation. | - | - |  |
| Pourability  (KCP 2.8.7.2) | - | - | Not required for a SP formulation. | - | - |  |
| Dustability following accelerated storage  (KCP 2.8.7.3) | - | - | Not required for a SP formulation. | - | - |  |
| Physical compatibility of tank mixes  (KCP 2.9.1) | - | - | Not required, formulation will not be used in tank mixtures | - | - |  |
| Chemical compatibility of tank mixes  (KCP 2.9.2) | - | - | Not required, formulation will not be used in tank mixtures | - | - |  |
| Adhesion to seeds  (KCP 2.10.1) | - | - | Not required for a SP formulation. | - | - |  |
| Distribution to seed  (KCP 2.10.2) | - | - | Not required for a SP formulation. | - | - |  |
| Other/special studies  (KCP 2.11) | Determination of chlorophenols | 2,4-D 95 SP  ADM.09250.H.1.A  Batch: 2111140274 | No chlorophenol impurities were detected (≤ 0.2 g/kg per analyte, LOD) in the tested batch (exception: 2,4,6-trichlorophenol, content <0.5 g/kg LOQ). | Y | Bacher, R. 2023  Report No. S21-07464  Reference No. 000109288 | Accepted |

Table 2-2: Summary of accelerated temperature storage stability

| Test | Method | Initially | After 14 days at 54°C |
| --- | --- | --- | --- |
|  |  | Comb, T. 2022a, Report No. ACE-21-385, Reference No. 000109839 | |
| Appearance (KCP 2.1)  Product | Visual assessment | Fine white powder.  A malt-like odour was noted during handling.  The colour was also assessed by the Munsell colour system. Under normal daylight and assigned as N 9.5 as a point of reference. | Fine white powder.  A malt-like odour was noted during handling.  The colour was also assessed by the Munsell colour system. Under normal daylight and assigned as N 9.5 as a point of reference. |
| Appearance (KCP 2.1)  Packaging | Visual assessment | 300 g laminated sachets | 300 g laminated sachets with no signs of any weight change |
| Acidity/alkalinity and pH value (KCP 2.4.1) | CIPAC MT 75.3 | The pH of a 1% w/v solution of test item in distilled water was 7.2 | The pH of a 1% w/v solution of test item in distilled water was 7.1 |
| Storage Stability after 14 days at 54º C  Active and impurity content (KCP 2.7.1) | CIPAC MT 46.3 | 2,4-D content: 95.1 % w/w | 2,4-D content: 95.3 % w/w |
| Free phenol content: 0.85 g/kg | Free phenol content: 0.79 g/kg |
| Wettability  (KCP 2.8.1) | CIPAC MT 53.3 | Wettability: 10 seconds | Wettability: 11 seconds |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | Performed at minimum (3.11 g test item/L) and maximum (4.66 g test item/L) application rates in standard water D.  After several inversions of the test item diluted, foam was observed initially and after 10 seconds. After 1 min of standing, no foam was present. Test performed at 20°C. | Performed at minimum (3.11 g test item/L) and maximum (4.66 g test item/L) application rates in standard water D.  After several inversions of the test item diluted, foam was observed initially and after 10 seconds. After 1 min of standing, no foam was present. Test performed at 22°C. |
| Degree of dissolution and dilution stability  (KCP 2.8.4) | CIPAC MT 41.1 | Performed at highest recommended concentration within the scope of the method (3 g in 250 mL)  5 minute test: 0.032% w/w residue  24 hour test: No residue | Performed at highest recommended concentration within the scope of the method (3 g in 250 mL)  5 minute test:0.0955 % w/w residue  24 hour test: No residue |

Table 2-3: Summary of long-term storage stability

| Test | Method | Initially | After 2 years at 25°C |
| --- | --- | --- | --- |
|  |  | Comb, T. Report No. ACE-21-386, Reference No. 000109841, Study ongoing | |
| Appearance (KCP 2.1)  Product | Visual assessment | Fine white powder.  A malt-like odour was noted during handling.  The colour was also assessed by the Munsell colour system. Under normal daylight and assigned as N 9.5 as a point of reference. |  |
| Appearance (KCP 2.1)  Packaging | Visual assessment | 300 g laminated sachets |  |
| Acidity/alkalinity and pH value (KCP 2.4.1) | CIPAC MT 75.3 | The pH of a 1% w/v solution of test item in distilled water was 7.2 |  |
| Ambient temperature shelf life (KCP 2.7.5) |  | 2,4-D content: 95.1 % w/w |  |
| Free phenol content: 0.85 g/kg |  |
| Wettability  (KCP 2.8.1) | CIPAC MT 53.3 | Wettability: 10 seconds |  |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | Performed at minimum (3.11 g test item/L) and maximum (4.66 g test item/L) application rates in standard water D.  After several inversions of the test item diluted, foam was observed initially and after 10 seconds. After 1 min of standing, no foam was present. Test performed at 20°C. |  |
| Degree of dissolution and dilution stability  (KCP 2.8.4) | CIPAC MT 41.1 | Performed at highest recommended concentration within the scope of the method (3 g in 250 mL)  5 minute test: 0.032% w/w residue  24 hour test: No residue |  |

# Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

# Section 4: Further information on the plant protection product

## Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1‑1: Packaging information for 1 kg laminated sachet

| Type | Description |
| --- | --- |
| Material: | PET12/MPET12/LLDPE  Metalized Polyester (MPET)  Linear Low Density Polyethylene (LLDPE)  Polyethylene Terephthalate (PET) |
| Shape/size: | Rectanglar sachet appromimately 305mm x 175mm x 30 mm |
| Opening: | Heat sealed along top edge |
| Closure: | Not resealable once opened |
| Seal: | Heat sealed |
| Manner of construction | - |
| UN/ADR | UN 3077 |

**RMS comment:**

Based on the accelerated study these packages are accepted for the PPP.

2. Lists of data considered in support of the evaluation

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 | Vertebrate study Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 2.l  KCP 2.4.2  KCP 2.7.1  KCP 2.8.1  KCP 2.8.2  KCP 2.8.4 | Comb, T. | 2022a | 2,4 D 95 SP: Accelerated storage stability  Report No.: ACE-21-385  Reference No.: 000109839  AgroChemex Environmental Ltd, UK  GLP, unpublished | N | Adama |
| KCP 2.2.1  KCP 2.2.2  KCP 2.3.2  KCP 2.3.3  KCP 2.6.2 | Comb, T. | 2022b | 2,4 D 95 SP: Physicochemical properties  Report No.: ACE-21-384  Reference No.: 000109840  AgroChemex Environmental Ltd, UK  GLP, unpublished | N | Adama |
| KCP 2.7.1 | Comb, T. | 2022c | 2,4 D 95 SP: Accelerated storage stability: assessment of free phenols content  Report No.: ACE-22-293  Reference No.: 000112209  AgroChemex Environmental Ltd, UK  GLP, unpublished | N | Adama |
| KCP 2.7.5 | Comb, T. | - | 2,4 D 95 SP: Two Year Ambient Storage Stability  **Study Plan N°: ACE-21-386**  Sponsor Reference: 000109841  AgroChemex Environmental Ltd, UK  GLP, unpublished | N | Adama |
| KCP 2.11 | Bacher, R. | 2023 | Method validation and analysis of impurities of chlorophenols in a batch of Pielik 95 SP  Report No.: S21-07464  Reference No.: 000109288  Eurofins Agroscience Services EAG Laboratories GmbH, Germany  GLP, unpublished | N | Adama |

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 | Vertebrate study Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |
|  |  |  |  |  |  |

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| CP XX | Author | YYYY | Title  Company Report No  Source  GLP/Not GLP/GEP/Not GEP, Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| CP XX | Author | YYYY | Title  Company Report No  Source  GLP/Not GLP/GEP/Not GEP, Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

1. Additional data on the physical, chemical and technical properties of the active substance
   1. 2,4-D

Not required, there is no new additional data on the physical and chemical properties of the active substance.