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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: **FRE 001/08/2020**  Product name: **FUNABEN® 018 PA**  Chemical active substance:  **Thiabendazole, 18 g/kg (1,8 %)** |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT/ Poland  (authorization) |
| Applicant: XXXX  Submission date: 07/07/2023 / 24/05/2024\*  \*additions  Evaluation date: 12/2023 / 07/2024  MS Finalisation date: 03/2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| December 2023 | Version evaluated by zRMS PL |
| March 2024 | Corrected due to applicant clarification |
| July 2024 | Evaluation of a two year storage stability study in Poland |
|  |  |

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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: none

* The signed “expert judgment” is requested to cover justification for physicochemical CLP classification,
* The two year storage stability is ongoing, the study can be assessed in the post-registration when available,
* Description of commercial packaging used in accelerated and ambient storage stability study is missing. Please provide
* Please provide some data on the PPP density. For full details please refer to the point KCP 2.6.1.

# Section 1: Identity of the plant protection product

## Applicant (KCP 1.1)

Name: XXXX

Address: XXXX

Tel.: XXXX

Fax: XXXX

**represented by:**

Tel.: XXXX

Fax: XXXX

Contact person: XXXX

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

### Producer of the preparation

Name: XXXX

Address: XXXX

Tel.: XXXX

Fax: XXXX

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

### Producer of the active substance

Name: XXXX

Address: XXXX

Tel.: XXXX

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

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

#### Thiabendazole

|  |  |
| --- | --- |
| Thiabendazole | ≥ 985 g/kg |

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

|  |  |
| --- | --- |
| Trade name: | FUNABEN® 018 PA |
| Company code number: | FRE 001/08/2020 |

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

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

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

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

| Active substance / variant | Declared content of the pure active substance (g/kg) | FAO Limits  (min – max) | Technical content\*  (g/kg) | Technical content  (%w/w) |
| --- | --- | --- | --- | --- |
| Thiabendazole | ≥ 985 | none | 18,3 | 1,83 |

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

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

Table 1.4‑2: Information on Thiabendazole

| Type | Name |
| --- | --- |
| ISO common name | Thiabendazole |
| CAS No. | 148-79-8 |
| EC No. | 205-725-8 |
| CIPAC No. | 323 |

### 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: Paste | Code: PA |

## Function (KCP 1.6)

Fungicide.

# 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 homogenous light grey paste, with a slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In 5 % w/w of aqueous dispersion, it has a pH value around 8 at 20 °C. 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 *PP cans*. Its technical characteristics are acceptable for a *Paste* formulation.

The intended concentration of use is 1,8 %.

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

H412 Harmful to aquatic life with long lasting effects.

EUH208 Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction.

EUH041 To avoid risks to human health and the environment, comply with the instructions for use.

Signal word: none

Pictograms: none

Notifier Proposals for Risk and Safety Phrases (KCP 12)

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

Compliance with FAO specifications:

The product FUNABEN® 018 PA complies with FAO specifications.

Formulation used for tests

The product used for testing has the same composition as indicated in Part C of the Registration Report.

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) | Pharmacopea Poland, Edition VI (2002) and EPA Product Properties Test Guidelines OPPTS 830.6301-04. | | FRE 01/08/2020 – 1,8 % | Starting material is homogenous, light gray paste  with slight characteristic odour. | | Yes | KCP 2.1 (REPORT  FRE 01/08/2020 – 1,8 %  Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2022)  Study code: **BF-04/22** | | Accepted |
| Explosive properties  (KCP 2.2.1) | ~~Study not required. The assessment based on the analysis of the chemical structure of the active substance and the composition of the agent indicates that its ingredients do not have explosive properties and do not cause exothermic reactions.~~ | | | | | | | | ~~Not accepted~~  ~~Technically, so called “expert judgment” containg the author signature should be provided to recognise the physicochemical CLP classification. The applicant is requested to provide this information~~ |
| Expert judgment | |  | Not flammable | N | | | Nowakowski K  2024 | Accepted |
| Oxidizing properties  (KCP 2.2.2) | ~~Study not required. In the assessment, based on the analysis of thermodynamic data of the active substance and the structure of other components, it was established that the product does not cause exothermic reactions with combustible materials.~~ | | | | | | | | ~~Not accepted~~  ~~Technically, so called “expert judgment” containg the author signature should be provided to recognise the physicochemical CLP classification. The applicant is requested to provide this information~~ |
| Expert judgment | |  | Not oxidizing | N | | | Nowakowski K  2024 | Accepted |
| Flash point  (KCP 2.3.1) | ~~Study not required. The product does not contain flammable solvents, and its form (paste) and physicochemical properties resulting from the composition make it impossible to test the flash point.~~ | | | | | | | | ~~Not accepted~~  ~~Technically, so called “expert judgment” containg the author signature should be provided to recognise the physicochemical CLPclassification. The applicant is requested to provide this information~~ |
| Expert judgment | |  | Not flammable | N | | | Nowakowski K | Accepted |
| Flammability  (KCP 2.3.2) | ~~Study not required. The product does not contain flammable solvents in amounts that could cause classifying in terms of flammability. Other components also do not have flammable properties.~~ | | | | | | | | ~~Not accepted~~  ~~Technically, so called “expert judgment” containg the author signature should be provided to recognise the physicochemical CLP classification. The applicant is requested to provide this information~~ |
| Expert judgment | |  | Not flammable | N | | | Nowakowski K | Accepted |
| Self-heating  (KCP 2.3.3) | ~~Study not required. Assessing the composition of the product, it can be concluded, that there is no possibility that FUNABEN~~~~®~~~~018 PA is thermally unstable.~~ | | | | | | | | ~~Not accepted~~  ~~Technically, so called “expert judgment” containg the author signature should be provided to recognise the physicochemical CLP classification. The applicant is requested to provide this information~~ |
| Expert judgment |  | | Not flammable | N | | | Nowakowski K | Accepted |
| Acidity or alkalinity and pH  (KCP 2.4.1) | pH of 1 % water dispersion is 4÷10 | | | | | | | |  |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | Pocedure SPO/BF/02/b (edition 5) in accordance with CIPAC MT 75.3 | | FRE 01/08/2020 -1,8 % | pH 1 % (aqueous dispersion) = 9,03 | | yes | KCP 2.4.2  (REPORT  FRE 01/08/2020 – 1,8 %  Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2022)  Study code: **BF-04/22** | | Accepted |
| Viscosity  (KCP 2.5.1) | Study not required – product is in a form of paste. | | | | | | | | Not applicable |
| Surface tension  (KCP 2.5.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Relative density  (KCP 2.6.1) | Study not required – product is in a form of paste. | | | | | | | | ~~Not accepted~~  Accepted  ~~This parameter is formally required by some national inspections. For many pastes, the density, e.g. g/cm~~~~3~~~~, is indicated. Please carry out the test or provide sufficient justification that this test cannot be done for this PA formulation, which is a non-Newtonian fluid, or so-called “Bingham plastic”.~~ |
| Bulk density  (KCP 2.6.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Storage Stability after 14 days at 54º C  (KCP 2.7.1) | - Procedure SPO/BF/08/b (edycja 4) and method CIPAC 46.4  -HPLC/UV-Vis – validated method in accordance with SANCO/3030/99, rev. 5 | | FRE 01/08/2020 – 1,8 % | The following parameters were measured and determined:  - Physical state, color and odour: homogeneous, light grey paste with a slight, characteristic odor; after accelerated storage ~ 10% by volume solution of surfactants on surface, and after intensive mixing a homogeneous, light grey paste with a slight characteristic odor  - pH of 1% water dispersion: before storage 9.03, and after - 8.80  - pH of 5% water dispersion: before storage 8.28, and after - 7.96  - measured content of the active substance (thiabendazole): 1.83% before storage, 1.81% after accelerated storage | | Yes | KCP 2.7.1  - REPORT  FRE 01/08/2020 – 1,8 %  Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2022  Study code: **BF-04/22**  - REPORT  FRE 01/08/2020 – 1,8 %  Method validation for determination of the active substance content in the preparation;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2022  Study code: **BA-11/22**  Jeschke (2024) | | Accepted  ~~Applicant is requested to provide some details on the commercial packaging- there is missing information in the accelerated study”~~  One commercial packaging was used: PP can containing 350 g of product, with PP cap (87 mm inner diameter of the closure). No visible changes of appearance of packaging were observed after accelerated study (Part I) and storage at ambient temperature after 1 year |
| Stability after storage for other periods and/or temperatures  (KCP 2.7.2) | Accelerated storage was performed (14 days at 54°C) – product is stable.  Stability study after 1 year of storage at ambient temperature was provided – product is stable.  Stability study after 2 years of storage at ambient temperature was provided – product is stable.  Stability study after 3 years of storage at ambient temperature is planned. | | | | | | | |  |
| Minimum content after heat stability testing  (KCP 2.7.3) | The results were verified in the accelerated storage test at 54ºC for 14 days, the minimum content of the active substance was 1.81%, which means a decrease of 1.1% compared to the value before storage. | | | | | | | |  |
| Effect of low temperatures on stability  (KCP 2.7.4) | Study not required – product should be stored in a temperature 5 ÷ 30°C. | | | | | | | |  |
| Ambient temperature shelf life  (KCP 2.7.5) | GIFAP no 17 | | FRE 01/08/2020 – 1,8%  Batch: 20220208/1.8% | Study performed after 1 year of storage – for details please refer to REPORT FRE 01/08/2020 – 1,8 %  Part II: Determination of physicochemical properties of the preparation after one year of storage  Study code: BF-04/22    Study performed after 2 years of storage – for details please refer to REPORT FRE 01/08/2020 – 1,8 %  Part III: Determination of physicochemical properties of the preparation after two years of storage  Study code: BF-04/22  Study after 3 years of storage is planned. | | Y | REPORT  FRE 01/08/2020 – 1,8 %  Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2022  Study code: BF-04/22  (2022)  REPORT  FRE 01/08/2020 – 1,8% - Part II: Determination of physicochemical properties of the preparation after one year of storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2023  Study code: BF-04/22  (2023)  REPORT FRE 01/08/2020 – 1,8 % - Part III: Determination of physichochemical properties of the preparation after two years of storage;  Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego, May 2024  Study code: BF-04/22  (2024) | | Accepted  ~~On-going~~  ~~A year of the storage stability is covered at now. Applicant is requested to provide the two-year study when available.~~  ~~Furthermore, applicant is requested to provide some details on the commercial packaging- there is missing information in the ambient storage stability study~~  One commercial packaging was used: PP can containing 350 g of product, with PP cap (87 mm inner diameter of the closure). No visible changes of appearance of packaging were observed after accelerated study (Part I) and storage at ambient temperature after 1 year  Given data allow to accept the two-year shelf life for the PPP. All tested phisicochemical parameters before and after storage are accepted. Packaging (a contaner made of PP) remained intact after storage. |
| Shelf life in months (if less than 2 years)  (KCP 2.7.6) | Study not required – product remains stable in accelerated storage (14 days at 54°C). | | | | | | | |  |
| Wettability  (KCP 2.8.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Persistence of foaming  (KCP 2.8.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Suspensibility  (KCP 2.8.3.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Spontaneity of dispersion  (KCP 2.8.3.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Dispersion stability  (KCP 2.8.3.3) | Study not required – product is in a form of paste. | | | | | | | |  |
| Degree of dissolution and dilution stability  (KCP 2.8.4) | Study not required – product is in a form of paste. | | | | | | | |  |
| Particle size distribution / nominal size range of granules  (KCP 2.8.5.1.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Wet sieve test  (KCP 2.8.5.1.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Dust content  (KCP 2.8.5.2.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Particle size of dust  (KCP 2.8.5.2.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Attrition  (KCP 2.8.5.3) | Study not required – product is in a form of paste. | | | | | | | |  |
| Hardness and integrity  (KCP 2.8.5.4) | Study not required – product is in a form of paste. | | | | | | | |  |
| Emulsifiability  (KCP 2.8.6.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Emulsion stability  (KCP 2.8.6.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Re-emulsifiability  (KCP 2.8.6.3) | Study not required – product is in a form of paste. | | | | | | | |  |
| Flowability  (KCP 2.8.7.1) | Study not required – product is in a form of paste. | | | | | | | |  |
| Pourability  (KCP 2.8.7.2) | Study not required – product is in a form of paste. | | | | | | | |  |
| Dustability following accelerated storage  (KCP 2.8.7.3) | Study not required – product is in a form of paste. | | | | | | | |  |
| Physical compatibility of tank mixes  (KCP 2.9.1) | Study not performed. FUNABEN® 018 PA will not be used simultaneously with other products. | | | | | | | |  |
| Chemical compatibility of tank mixes  (KCP 2.9.2) | Study not performed. FUNABEN® 018 PA will not be used simultaneously with other products. | | | | | | | |  |
| Adhesion to seeds  (KCP 2.10.1) | Study not required. The product is not intended to use as seed treatment. | | | | | | | |  |
| Distribution to seed  (KCP 2.10.2) | Study not required. The product is not intended to use as seed treatment. | | | | | | | |  |
| Other/special studies  (KCP 2.11) | No additional studies are required. | | | | | | | |  |

# 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 0.4 liter can (350 g of product)

| Type | Description |
| --- | --- |
| Material: | PP |
| Shape/size: | cylindrical / diameter at the base 78 mm, height without covering 79 mm |
| Opening: | 87 mm inner diameter |
| Closure: | PP cap |
| Seal: | none |
| Manner of construction | extruded |
| UN/ADR | N/A |

2. Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 2.1  KCP 2.4.2  KCP 2.7.1 | K. Bajdor  J. Kupiec  A. Gralak  S. Kowalska | 2022 | REPORT  FRE 01/08/2020 – 1,8 %  Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage  Study code: BF-04/22  Source: Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego  GLP: Yes  Unpublished | N | XXXX |
| KCP 2.7.5 | K. Bajdor  J. Kupiec  A. Gralak  S. Kowalska | 2023 | REPORT  FRE 01/08/2020 – 1,8 %  Part II: Determination of physicochemical properties of the preparation after one year of storage  Study code: BF-04/22  Source: Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego  GLP: Yes  Unpublished | N | XXXX |
| KCP 2.7.1 | K. Bajdor  S. Kowalska | 2022 | REPORT  FRE 01/08/2020 – 1,8 %  Method validation for determination of the active substance content in the preparation  Study code: BA-11/22  Source: Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego  GLP: Yes  Unpublished | N | XXXX |
| KCP 2.2.1  KCP 2.2.2  KCP 2.3.1  KXP 2.6.1 | Nowakowski K. | 2024 | Technical evaluation of physicochemical properties and CLP classification  for FUNABEN" 018 PA  non GLP, unpublished | N | XXXX |
| KCP 2.7.1  KCP 2.7.5 | Jeschke P. | 2024 | Declaration regarding to commercial packaging used for storage stability test (studies of accelerated storage and at ambient temperature) for FUNABEN® 018 PA | N | XXXX |
| KCP 2.7.5 | Gadek J.  Rymarzak O.  Gralak A.  Biegniewski G.  Kowalska S. | 2024 | REPORT  FRE 01/08/2020 – 1,8 %  Part III: Determination of physicochemical properties of the preparation after two years of storage  Study code: BF-04/22  Source: Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego  GLP: Yes  Unpublished | N | XXXX |

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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | 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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non 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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

1. Additional data on the physical, chemical and technical properties of the active substance
   1. Thiabendazole

No additional information.