|  |
| --- |
| REGISTRATION REPORT  Part A  Risk Management |
| 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 |
| NATIONAL 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 based on first draft and supplemented data provided in **November** by the applicant |
| March 2024 | Finalised after applicant comments. |
| July 2024 | Evaluation of a two-year storage stability study in Poland |
|  |  |

Table of Contents

[1 Details of the application 5](#_Toc176860213)

[1.1 Application background 5](#_Toc176860214)

[1.2 Letter of Access 5](#_Toc176860215)

[1.3 Justification for submission of tests and studies 5](#_Toc176860216)

[1.4 Data protection claims 6](#_Toc176860217)

[2 Details of the authorization decision 6](#_Toc176860218)

[2.1 Product identity 6](#_Toc176860219)

[2.2 Conclusion 7](#_Toc176860220)

[2.3 Substances of concern for national monitoring 7](#_Toc176860221)

[2.4 Classification and labelling 7](#_Toc176860222)

[2.4.1 Classification and labelling under Regulation (EC) No 1272/2008 7](#_Toc176860223)

[2.4.2 Standard phrases under Regulation (EU) No 547/2011 8](#_Toc176860224)

[2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) 8](#_Toc176860225)

[2.5 Risk management 8](#_Toc176860226)

[2.5.1 Restrictions linked to the PPP 8](#_Toc176860227)

[2.5.2 Specific restrictions linked to the intended uses 8](#_Toc176860228)

[2.6 Intended uses (only NATIONAL GAP) 9](#_Toc176860229)

[3 Background of authorization decision and risk management 12](#_Toc176860230)

[3.1 Physical and chemical properties (Part B, Section 2) 12](#_Toc176860231)

[3.2 Efficacy (Part B, Section 3) 12](#_Toc176860232)

[3.3 Efficacy data 12](#_Toc176860233)

[3.3.1 Information on the occurrence or possible occurrence of the development of resistance 13](#_Toc176860234)

[3.3.2 Adverse effects on treated crops 13](#_Toc176860235)

[3.3.3 Observations on other undesirable or unintended side-effects 13](#_Toc176860236)

[3.4 Methods of analysis (Part B, Section 5) 14](#_Toc176860237)

[3.4.1 Analytical method for the formulation 14](#_Toc176860238)

[3.4.2 Analytical methods for residues 14](#_Toc176860239)

[3.5 Mammalian toxicology (Part B, Section 6) 15](#_Toc176860240)

[3.5.1 Acute toxicity 15](#_Toc176860241)

[3.5.2 Operator exposure 15](#_Toc176860242)

[3.5.3 Worker exposure 17](#_Toc176860243)

[3.5.4 Bystander and resident exposure 18](#_Toc176860244)

[3.6 Residues and consumer exposure (Part B, Section 7) 18](#_Toc176860245)

[3.6.1 Residues 19](#_Toc176860246)

[3.6.2 Consumer exposure 19](#_Toc176860247)

[3.7 Environmental fate and behaviour (Part B, Section 8) 19](#_Toc176860248)

[3.7.1 Predicted environmental concentrations in soil (PECsoil) 19](#_Toc176860249)

[3.7.2 Predicted environmental concentrations in groundwater (PECgw) 19](#_Toc176860250)

[3.7.3 Predicted environmental concentrations in surface water (PECsw) 20](#_Toc176860251)

[3.7.4 Predicted environmental concentrations in air (PECair) 20](#_Toc176860252)

[3.8 Ecotoxicology (Part B, Section 9) 20](#_Toc176860253)

[3.8.1 Effects on terrestrial vertebrates 20](#_Toc176860254)

[3.8.2 Effects on aquatic species 20](#_Toc176860255)

[3.8.3 Effects on bees 20](#_Toc176860256)

[3.8.4 Effects on other arthropod species other than bees 21](#_Toc176860257)

[3.8.5 Effects on soil organisms 21](#_Toc176860258)

[3.8.6 Effects on non-target terrestrial plants 21](#_Toc176860259)

[3.8.7 Effects on other terrestrial organisms (Flora and Fauna) 21](#_Toc176860260)

[3.9 Relevance of metabolites (Part B, Section 10) 21](#_Toc176860261)

[4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) 21](#_Toc176860262)

[5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization 22](#_Toc176860263)

[Appendix 1 Copy of the product authorization 23](#_Toc176860264)

[Appendix 2 Copy of the product label 24](#_Toc176860265)

[Appendix 3 Letter of Access 25](#_Toc176860266)

[Appendix 4 Lists of data considered for national authorization 26](#_Toc176860267)

PART A

RISK MANAGEMENT

# Details of the application

**Applicant:**

Name: XXXX

Address: XXXX

Tel.: XXXX

Fax: XXXX

**represented by:**

Tel.: XXXX

Fax: XXXX

Contact person: XXXX

**Producer of the preparation:**

Name: XXXX

Address: XXXX

Tel.: XXXX

Fax: XXXX

All the requested data/studies/information necessary for national authorization have been submitted. No risk mitigation measures are required based on performed risk assessment.

## Application background

The dossier has been submitted for the purpose of the national authorisation for plant protection product FUNABEN® 018 PA. The product containing 18g/kg (1,8 %) of the active substance Thiabendazole is a fungicide against *Pezicula malicorticis*, *Pezicula alba* and *Nectria galligena* on apple, as well as against *Leucostoma sp.* on peach.

Poland is zRMS, for which competent authority for the evaluation is Ministry of Agriculture and Rural Development. Poland is also “concerned” Member State, for whom is this Part A being written and for which use are being applied.

## Letter of Access

The data for the active substance Thiabendazole are provided by Syngenta Crop Protection AG, based on Letter of Access.

## Justification for submission of tests and studies

The following studies are necessary for the first authorisation of plant protection product

FUNABEN® 018 PA:

* One preliminary efficacy study against *Neofabraea alba* and *Neonectria galligena* on apple
* One preliminary efficacy study against *Leucostoma cinctum* on peach
* Four efficacy studies (from 2 seasons) against *Leucostoma sp.* on peach
* Eight efficacy studies (from 2 seasons) against *Nectria galligena* on apple
* Eight efficacy studies (from 2 seasons) against *Pezicula malicorticis* and *Pezicula alba* on apple

Above studies were provided to fill the requirements described in section 6 from Part A of Regulation (EC) 284/2013.

* Four studies on residues on apple from 2 seasons (2 studies from field phase + 2 studies from laboratory phase)
* Four studies on residues on peach from 2 seasons (2 studies from field phase + 2 studies from laboratory phase)
* Validation study on residues

Above studies were provided to fill the requirements described in section 8 from Part A of Regulation (EC) 284/2013 as well as in section 6 from part A of Regulation (EC) 283/2013.

* Validation study for determination of the active substance content in the preparation
* Study for determination of physicochemical properties of the initial preparation and after accelerated storage

Above studies were provided to fill the requirements described in section 5 from Part A of Regulation (EC) 284/2013 and in order to specify expiry date as 2 years from the date of production. Another study for determination of physicochemical properties after 1 year of storage at ambient temperature was also provided at the moment of submitting the application.

* Studies for acute toxicity (oral and dermal) as well as for irritation of skin and eyes, performed on vertebrates for reference product FUNABEN® PLUS 03 PA

These studies were provided to perform assessment of toxicological properties of FUNABEN® 018 PA, using bridging approach as well as for avoiding unnecessary suffering of vertebrates. For the confidential details please refer to Part C.

## Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4. For the details please refer to Part C.

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | FRE 001/08/2020 |
| Product name in MS | FUNABEN® 018 PA |
| Authorization number | not relevant – first authorisation |
| Function | fungicide |
| Applicant | XXXX |
| Active substance(s)  (incl. content) | Thiabendazole, 18 g/kg (1,8 %) |
| Formulation type | PA |
| Packaging | 0.4 liter PP can (350 g of product) with PP cap, for professional and non-professional users |
| Coformulants of concern for national authorizations | NR |
| Restrictions related to identiy | NR |
| Mandatory tank mixtures | NR |
| Recommended tank mixtures | NR |

## Conclusion

The evaluation of the application for FUNABEN® 018 PA resulted in the decision to grant the authorization.

All uses applied for were authorised (see paragraph 2.6).

## Substances of concern for national monitoring

Not relevant – product does not contain substances of concern, requiring monitoring.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class, categories | Skin Sens. 1A; H317  Aquatic Chronic 3 |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

|  |  |
| --- | --- |
| Hazard pictograms or Code for hazard pictogram | GHS07 |
| Signal word | Warning |
| Hazard statement | H317, H412 |
| Precautionary statement(s) | P272  P280  P302 + P352  P333 + P313  P362 + P364  P501  SP1 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
|  | 1,2-benzisothiazol-3-one.  ~~Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction. [EUH208]~~ |
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | **To avoid risks to human health and the environment, comply with the instructions for use.** |
| 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).** |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| ~~EUH 208~~ | **~~Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction.~~** |

See Part C for justifications of the classification and labelling proposals.

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | 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). |

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not relevant.

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
| NR | PPE not required for professional users |
| Worker protection: |  |
| NR | PPE not required |
| Integrated pest management (IPM)/sustainable use: | |
| NR | Max number of uses: 1/each wound per use and 1/each wound per crop/season  PHI not required |
| Environmental protection | |
| NR | Do not use, when the rain falls. |
| Other specific restrictions | |
| NR | Do not dilute the product. |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
| NR | NR |

### Specific restrictions linked to the intended uses

Not relevant.

## Intended uses (only NATIONAL GAP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | |  | | | | | |  | | | GAP rev.      , date: year-month-day | | | | |
| PPP (product name/code): | | | | FUNABEN® 018 PA / FRE 001/08/2020 | | | | | | Formulation type: | | | PA (a, b) | | | | |
| Active substance 1: | | | | Thiabendazole | | | | | | Conc. of as 1: | | | 18 g/kg (c) | | | | |
| Active substance 2: | | | | - | | | | | | Conc. of as 2: | | | - (c) | | | | |
| Active substance.…: | | | | - | | | | | | Conc. of as -: | | | - (c) | | | | |
| Safener: | | | | - | | | | | | Conc. of safener: | | | - (c) | | | | |
| Synergist: | | | | - | | | | | | Conc. of synergist: | | | - (c) | | | | |
| Applicant: | | | | XXXX | | | | | | Professional use: | | |  | | | | |
| Zone(s): | | | | Central (d) | | | | | | Non professional use: | | |  | | | | |
| Verified by MS: | | | | - | | | | | |  | | |  | | | | |
|  | | | |  | | | | | |  | | |  | | | | |
| Field of use: | | | | fungicide | | | | | |  | | |  | | | | |
| 1 | 2 | 3 | | 4 | 5 | 6 | 7 | 8 | | 9 | 10 | | 11 | 12 | 13 | 14 | |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | | **Application rate** | | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | Min. interval between applications (days) | g product / m2  a) max. rate per appl.  b) max. total rate per crop/season | | g as/m2  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | |
| 1 | PL | Peach | | Fpn | Leucostoma sp. | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 2 | PL | Apple | | Fpn | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| **Minor uses according to Article 51 (zonal uses)** | | | | | | | | | | | | | | | | | |
| 3 | PL | Pear, Asian pear, European crab apple | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 4 | PL | Apricot, Plum, Cherry, Sweet cherry, Nectarine | | F | Leucostoma sp.  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 5 | PL | Ornamental plants (deciduous and coniferous trees and bushes),  Nursery ornamental plants | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 6 | PL | Forest nurseries plants, restockings, afforestations and forest trees’ seed orchards;  Christmas trees grown on plantations | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 7 | PL | Peach, Chaenomeles | | F | Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 8 | PL | Bird cherry, Mahaleb cherry | | F | Leucostoma sp.  Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |
| 9 | PL | Chokeberry, Blackberry, Raspberry | | F | Pezicula malicorticis  Pezicula alba | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | | NR | a) 555,6\*  b) 555,6\* | | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Remarks**  **table heading:** | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| **Remarks**  **columns:** | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the  use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

# Background of authorization decision and risk management

## Physical and chemical properties (Part B, Section 2)

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 gray 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 %.

## Efficacy (Part B, Section 3)

Preliminary studies against *Neonectria galligena, Neofabraea* alba *Leucostoma cinctum* were performed.

Efficacy studies of FUNABEN® 018 PA at the proposed rate of 555,6 g/m2 of wound area (equivalent to 100 g/18 dm2 of wound area) against *Nectria galligena*, *Pezicula malicorticis* and *Pezicula alba* on apple were performed.

Efficacy studies of FUNABEN® 018 PA at the proposed rate of 555,6 g/m2 of wound area (equivalent to 100 g/18 dm2 of wound area) against *Leucostoma sp*. on peach were performed.

## Efficacy data

Preliminary studies against *Neonectria galligena*, *Neofabraea alba* and *Leucostoma cinctum* were performed to demonstrate, under laboratory conditions (tests *in vitro*), effect of different concentrations of thiabendazole in the paste on the growth of colonies. All samples with thiabendazole (concentrations 0,25 %, 1,0 % and 2,0 %) strongly inhibited growth of the colony of *Neofabraea alba* and *Leucostoma cinctum*. On the other hand, the strongest effect of inhibition of growth of colony of *Neonectria galligena* were observed in case of paste containing 2,0 % of thiabendazole.

Based on these results, efficacy trials were performed under field conditions: four efficacy studies (from 2 seasons) against *Leucostoma sp.* on peach; eight efficacy studies (from 2 seasons) against *Nectria galligena* on apple; and eight efficacy studies (from 2 seasons) against *Pezicula malicorticis* and *Pezicula alba* on apple.

As preliminary studies demonstrated, that strongest effect of inhibition of colony growth of *Neonectria galligena* was achieved for paste containing 2,0 % of thiabendazole – minimum effective dose has been assessed for apple crops against *Nectria galligena*. Paste containing 0,4 %, 0,7 %, 1,1 % and 1,8 % of thiabendazole were used for field trials (first season only). As dose of product was the same in all trials and taking into account results of these trials, it has been assessed, that the concentration 1,8 % of thiabendazole and dose 555,6 g of product / m2 (of wound area) can be considered as minimum effective dose against all claimed pests.

Results of field trials against *Nectria galligena*, *Pezicula malicorticis* and *Pezicula alba* (concentration 1,8 % of thiabendazole) on apple demonstrated high efficacy - caused significant faster wound healing statistically comparable with reference product FUNABEN® PLUS 03 PA.

Results of field trials against *Leucostoma sp.* (concentration 1,8 % of thiabendazole) on peach demonstrated high efficacy - had significant impact on limitating number of infected shoots - statistically comparable with reference product FUNABEN® PLUS 03 PA.

### Information on the occurrence or possible occurrence of the development of resistance

No resistance effects were observed in presented preliminary and field trials. Based on proposed uses and doses – locally on trees wounds, the risk of occurrence of resistance is expected minimal and acceptable. Product should be used according to proposed GAP table and good agricultural practice.

### Adverse effects on treated crops

16 trials were carried out on Apple in Poland from 2020-2022 on a wide range of commercially grown varieties. No phytotoxicity symptoms caused by FUNABEN® 018 PA at the proposed dose rate of 555,6 g/m2 of wounds was recorded in all trials.

4 trials were carried out on Peach in Poland from 2021-2022 on a wide range of commercially grown varieties. No phytotoxicity symptoms caused by FUNABEN® 018 PA at the proposed dose rate of 555,6 g/m2 of wounds was recorded in all trials.

In relation to high efficacy of FUNABEN® 018 PA against all pests, this product has positive effect on the yield of apple and peach.

Because of conditions of use (locally on wounds of trees), no effects on:

* the quality of plants or plant product;
* on transformation processes;
* on treated plants or plant products to be used for propagation

are expected.

### Observations on other undesirable or unintended side-effects

Taking into account the form of product and mode of application (paste for brushing locally on wounds of trees; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants) no effect on adjacent crops via drift is expected.

Due to proposed uses in orchards and gardens and mode of application, no impact on succeeding crops is expected (apple and peach are multiyear trees).

When using according to destination, there is no possibility to contact of beneficial organisms (ex. bees, earthworms) with the product.

The present dossier has been drafted for the registration of the new product FUNABEN® 018 PA. The product containing 18g/kg (1,8 %) of the active substance Thiabendazole is a fungicide against *Pezicula malicorticis*, *Pezicula alba* and *Nectria galligena* on apple, as well as against *Leucostoma sp.* on peach.

In order to support the proposed use of FUNABEN® 018 PA, data is presented from:

* Four efficacy trials (from 2 seasons) against *Leucostoma sp.* on peach
* Eight efficacy trials (from 2 seasons) against *Nectria galligena* on apple
* Eight efficacy trials (from 2 seasons) against *Pezicula malicorticis* and *Pezicula alba* on apple

**Preliminary range-finding tests**

All samples containing thiabendazole (at concentrations of 0.25%, 1.0%, and 2.0%) strongly inhibited fungal colony growth. FUNABEN® 018 PA, containing 2.0% thiabendazole, showed the most potent inhibitory effect on *Neonectria galligena*. This concentration of thiabendazole is deemed clearly justified.

**Minimum effective dose tests**

Based on the efficacy trials submitted, the concentration of 1.8% thiabendazole and a dose of 555.6 g of product/m2 (wound area) can be deemed as the minimum effective dose against all claimed pests.

**Efficacy tests**

The data collected showed that the use of FUNABEN® 018 PA at the recommended concentration was effective against *Leucostoma sp.* on peaches*, Nectria galligena, Pezicula malicorticis* and *Pezicula alba* on apples with similar efficacy to the reference product.

**Information on the occurrence or possible occurrence of the development of resistance**

Under the proposed GAP, the risk of resistance development from the use of FUNABEN® 018 PA is considered acceptable.

The applicant has not provided data on the risk to succeeding crops, adjacent crops, beneficial organisms and non-target arthropods. Considering the specific method of application, which involves painting wounds on trees with a brush (local), and the formulation of the product, FUNABEN® 018 PA is not expected to have any adverse effect on succeeding crops, adjacent crops, beneficial organisms or non-target arthropods, when applied according to current label claims.

The applicant supports the use of the product on several crops under Article 51 of Regulation (EC) 1107/2009 (extension of authorisations for minor uses). It is noted that these specific uses have not been evaluated as part of this application. In Poland, separate applications for authorization under Article 51 are required.

## Methods of analysis (Part B, Section 5)

The method for determination of Thiabendazole content in FRE 01/08/2020 – 1,8% preparation was developed and validated in Analytical Research Laboratory of the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Ł-IPO) in Warsaw according to EU requirements described in SANCO/3030/99 rev.5, 22 March 2019 guideline. The study was performed in accordance with the study plan and procedures. The aim of the study indicated in the study plan has been reached.

The method for determination of Thiabendazole residues on apple and peach was developed and validated in FERTICO Sp. z o.o. The aim of studies has been reached.

### Analytical method for the formulation

The standard solution was prepared by weighing 80.78 mg of thiabendazole (accuracy to 0.01 mg) into a 10 ml volumetric flask and filled with methanol to the nominal volume. The flask was placed in an ultrasonic bath (25°C) for 5 minutes, and after cooling the solution was diluted and analysed.

The test sample solution was prepared by weighing approximately 60 mg of the test sample (with an accuracy of 0.01 mg) into a 10 ml flask and adding 2 ml of water and methanol. The flask was placed in an ultrasonic bath for 5 minutes (25°C). After cooling, methanol was added to nominal volume, filtered through a syringe filter and analysed.

Analyses were performed using high-performance liquid chromatography (HPLC) with UV-VIS detection. Chromatography conditions: oven temperature 30°C, eluent flow (acetonitrile + 0.02 M NaH2PO4 30 + 70 v/v), wavelength λ = 290 nm, sample volume: 20 μl. Under these conditions, the thiabendazole retention time was 6.1 min ± 0.1 min. The total analysis time is 15 minutes.

### Analytical methods for residues

The study in the analytical phase consists of a quantitative analysis of thiabendazole. The test was carried out using liquid chromatography (LC-MSMS). Analysis was performed on apple matrix. The lower limit of quantification (LOQ) of thiabendazole is 0,01 mg/kg. After approval of validation, analytical studies were performed on 2 matrices: apple and peach (both of them containing high amount of water).

Analytical results of residues of thiabendazole in apple and peach fruits demonstrated “zero residue” situation – all the obtained results are below limit od detection (<0,003 mg/kg).

**zRMS**:

The relevant methods are available. The multi-residue QuEChERS method in combination with LC-MS/MS, as described by CEN (2008), is reported for the analysis of parent thiabendazole with an LOQ of 0.01 mg/kg in high water content, high oil content and acidic commodities (EFSA Journal 2014; 12(7):3750).

## Mammalian toxicology (Part B, Section 6)

Classification and labelling of the product was performed.

Toxicological properties of the product were assessed using bridging approach. For this purpose, studies for reference product FUNABEN® PLUS 03 PA were used for avoiding unnecessary suffering of vertebrates. For confidential details please refer to Part C.

No unacceptable risk for operators (professional and non-professional), workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

### Acute toxicity

Taking into account, that bridging approach was performed and comparing of the composition between evaluated product FRE 001/08/2020 / FUNABEN® 018 PA and reference product: “Pasta do smarowania ran drzew 3 % Tiofanat metylu” // FUNABEN® PLUS 03 PA – no classification for acute toxicity (oral and dermal route), as well as for skin and eye irritation, and skin sensitization is required for evaluated product.

The composition of both products is very similar. The content of Thiabendazole in FUNABEN® 018 PA is lower than content of Methyl thiophanate in FUNABEN® PLUS 03 PA. On the opposite to Methyl thiophanate, Thiabendazole shows no health hazards, e.g. has a low acute toxicity via oral and dermal route, is not a skin or eye irritant nor a skin sensitizer. So there is no indications to expect that FUNABEN® 018 PA shows these properties. Besides, unnecessary suffering of vertebrates was avoided. For the confidential details please refer to Part C. Studies for reference product FUNABEN® PLUS 03 PA are acceptable for the purpose of evaluation of product FUNABEN® 018 PA.

### Operator exposure

Taking into account, that Thiabendazole shows low acute toxicity via oral, dermal and inhalatory routes; it is not a skin or eye irritant nor a skin sensitizer and no AAEOL value is available, only longer term exposure has been estimated.

Due to form of product (thick paste) and specific mode of application (locally on wound of trees, using brush; small areas of plants); and lack of appropriate standardised first-tier methods, calculation of the exposure for non-professional users was performed using *ConsExpo web* tool (adapted model for Painting with brush). For professional users *German model for operator, 90th percentile* (properly adapted for specific mode of application) was used. For the details please refer to Part B6.

Input parameters considered for the estimation of operator exposure (professional)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Formulation type | PA | | Crop type | apple |
| Application rate (AR)\*\* | 0,1 | kg a.s./ha | Application method | painting |
| Area treated per day (A)\* | 0,15 | ha | Application equipment | brush |
| Dermal absorption (DA) | N/A | % (concentr.) | Indoor/outdoor | Outdoor |
| 50 % | % (dilution) | Closed cabin | N/A |
| Inhalation absorption (IA) | 100 | % | Drift reduction | N/A |
| Body weight (BW) | 60 | kg/person | Cultivation | Normal |
| AOEL | 0,07 | mg/kg bw/d | Water soluble bag | N/A |
| AAOEL | N/A | mg/kg bw/d |  |  |

**Additional justifications:**

\*Area treated per day (0,15 ha) – estimated based on average planting rate for apples (2000 plants/ha – data from efficacy studies), average amount and area of wounds on each tree (2 wounds, 25 cm2 each – data obtained from the performer of the efficacy studies) and real perceptual abilities of operator. In result, the operator is able to use the product on 300 trees (located on 0,15 ha) / day (worst-case scenario).

\*\*Application rate (0,1 kga.s./ha) – based on average amount and area of wounds on each tree (2 wounds x 25 cm2→50 cm2 area of wounds on each tree), dose of product per m2 of wound area (555,6 g / m2) and estimated average planting rate (2000 plants/ha). In result: 2000 plants x 50 cm2 of wounds = 100 000 cm2 of wounds. Operator will then use 5,556 kg of FUNABEN® 018 PA, containing 0,1 kg of Thiabendazole. Using of PPE – gloves only

**Input parameters considered for the estimation of operator exposure (non-professional)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Formulation type | PA | | Exposed area (hands) | 820 cm2 |
| Frequency | 3 | Per year | Weight fraction substance | 1,8 % |
| Exposure model (dermal) | Direct contact-instant application | | Product amount | 4 g |
| Absorption fraction | 50 | % (dilution) | Retention factor | 0,1 |
|  |  |
| Inhalation absorption (IA) | N/A | % |  |  |
| Body weight (BW) - adult | 60 | kg/person |  |  |
| AOEL | 0,07 | mg/kg bw/d |  |  |
| AAOEL | N/A | mg/kg bw/d |  |  |

Additional justifications:

Model for painting with brush was chosen. In this model non-professional user will use the product 3 times per year and have direct contact (hands) with 4 g of product (worst-case scenario). 10 % of the product will remain on skin (the rest will be removed, e.g by washing the hands). Due to form of product (thick-paste), using outdoor, only dermal exposure is expected.

Estimation of longer term operator exposure towards Thiabendazole according to EFSA guidance (professional user)

|  |  |  |
| --- | --- | --- |
| **Internal dose on day of exposure [mg/kg bw/ day]** | **AOEL [mg/kg bw/day]** | **% AOEL** |
| 0,0698275 (without PPE) | 0,07 | 99,75 |
| 0,0623575 (with PPE) | 89,08 |

Conclusion: exposure for the operator (professional) is acceptable, even without using PPE.

Estimation of longer term operator exposure towards Thiabendazole according to EFSA guidance (non-professional user)

|  |  |  |
| --- | --- | --- |
| **Internal dose on day of exposure [mg/kg bw/ day]** | **AOEL [mg/kg bw/day]** | **% AOEL** |
| 0,06 | 0,07 | 86 |

Conclusion: exposure for the operator (non-professional) is acceptable.

**zRMS**:

There is no EU harmonised, recommended model for estimation of exposure of operator applying a pesticide using paintbrush application (Guidance on the assessment of exposure of operators, workers, residents and bystanders. EFSA Journal 2022;20(1):7032). In the opinion of zRMS the model, assumptions and input data used by the applicant for estimation exposure for professional users (*German model for operator, 90th percentile* properly adapted for specific mode of application) and for non-professional users (*ConsExpo web* adapted model for Painting with brush) are considered as acceptable .

The exposure of professional operator applying on wounds of tree using brush a product FRE 001/08/2020/FUNABEN® 018 PA in line with GAP at a dose of 555,6 g of product/m2 of wound area (10 g of active substance/m2) and not wearing PPE amounts 99.75% of AOEL, and when wearing PPE ( gloves , protective cloths) 89% of AOEL. Since the exposure is below AOEL it does not pose an unacceptable health risk, but since a product is classified as skin sensitiser an operator should wear protective clothing and protective gloves during mixing/loading and application of the product.

The exposure of non-professional operator applying on wounds of tree using brush a product FRE 001/08/2020/FUNABEN® 018 PA in line with GAP at a dose of 555,6 g of product/m2 of wound area (10 g of active substance/m2) and not wearing PPE amounts 86% of AOEL. Since the exposure is below AOEL it does not pose an unacceptable health risk, but since a product is classified as skin sensitiser a non-professional operator should wear a workwear covering body, legs and arms and protective gloves during mixing/loading and application of the product.

### Worker exposure

Input parameters considered for the estimation of worker exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended uses | Painting with brush, apple (covering of all uses) | | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s./tree |
| Dose (R)\* | 0,00005 | kg a.s./tree | Dermal absorption (DA) | 50 | % (worst case) |
| Number of applications (NA) | 1 |  | Inhalation absorption (IA) | 100 | % |
| Interval between applications | N/A | days | Task duration (T) | 8 | h/d |
| Half-life of active substance | N/A | days | TC dermal (potential) | 14000 | cm2/h |
| Multiple application factor (MAF) | N/A |  | TC dermal (work wear) | 5000 | cm2/h |
| Body weight (BW) | 60 | kg/person | TC dermal (work wear, gloves) | 1400 | cm2/h |
| AOEL | 0,07 | mg/kg bw/d | Task specific factor inhalation | N/A | ha/h x 10-3 |
| AAOEL | N/A | mg/kg bw/d |  |  |  |

**Additional justifications:**

\*Dose (0,00005 kga.s / tree) – taking into account specific mode of application (locally on wounds of trees, small area of wounds and small area of crop), dose of product per m2 of wounds (555,6 g / m2), average amount and area of wounds on each tree (2 wounds, 25 cm2 of area, each → 50 cm2 of wounds; data obtained from the performer of efficacy studies) **The following equation [based on german model BBA from 1998: “*Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen*** *(worker re-entry*) **and** *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products; EFSA Journal 2022; Volume 20, Issue 1*) was used forthe calculation of dermal exposure:

DE = DFR x TC x T x R, where:

DFR (dislogeable foliar residue): 3 [μga.s.x tree / cm2 x kga.s]

TC (transfer coefficient): 22500 [cm2/h/person – potential exposure (orchards, worst-case scenario)

TC (transfer coefficient): 5000 [cm2/h/person] – work wear, no gloves (ornamentals, worst-case scenario)

TC (transfer coefficient): 1400 [cm2/h/person] – work wear with gloves (ornamentals, worst-case scenario)

T (task duration): 8 h/d

R (dose): 0,00005 [kg a.s./ tree]

DE – dermal exposure [mga.s./person x d]

Dermal absorption factor = 0,5 (50 %)

Dermal exposure has been estimated for: worker wearing protective clothing, with gloves (TC = 1400

cm2/h/person) and without (TC = 5000 cm2/h/person) gloves; a well as for case of total potential exposure

(TC = 22500 cm2/h/person).

TAD (total adsorbed dose, mga.s./kgbw x d] = Dermal exposure \* Dermal absorption factor / body weight (60 kg, adult)

For details please refer to Part B6.

Estimation of acute worker exposure towards Thiabendazole according to EFSA guidance

Taking into account, that Thiabendazole shows low acute toxicity via oral, dermal and inhalatory routes; it is not a skin or eye irritant nor a skin sensitizer; and no AAEOL value is available, only longer term exposure has been estimated.

Estimation of longer term worker exposure towards Thiabendazole according to EFSA guidance

|  |  |  |  |
| --- | --- | --- | --- |
|  | **TAD [mga.s./kgbw x d]** | **AOEL [mg/kg bw/day]** | **% AOEL** |
| Potential | 0,000225 | 0,07 | 0,32 |
| Work wear, no gloves | 0,00005 | 0,07 |
| Work wear + gloves | 0,000014 | 0,02 |

Conclusion: exposure (long-term) for the worker is acceptable, even without using any PPE.

**zRMS**:

The potential exposure of worker performing such tasks as cutting, sorting, bundling, carrying and fruit picking – within 8 hours/day after entry into an area previously treated with FRE 001/08/2020/FUNABEN® 018 PA according to GAP calculated with German model BBA from 1998 amounted to 0.32% of AOEL, when wearing work wear covering arms, body and legs to 0.07 % AOEL, and work ear and protective gloves 0.02% of AOEL.

Since the exposure is below AOEL it does not pose an unacceptable health risk for worker, but since a product is classified as skin sensitiser a worker should wear a workwear covering body, legs and arms and protective gloves while performing his task in treated area.

### Bystander and resident exposure

It has been assessed, that due to form of product (thick paste) and specific mode of application (locally on wounds of trees, small area of wounds, small area of crops), no exposure of residents/bystanders is expected. In result, no exposure calculation is necessary.

**zRMS** is of the opinion that during application of a product FRE 001/08/2020/FUNABEN® 018 PA according to GAP by painting with brush there will be no exposure for residents or bystanders since no aerosol will be created, so health risk for bystanders and resident will be negligible. .

## Residues and consumer exposure (Part B, Section 7)

**zRMS**:

The authorisation request has been accepted. No residues in the proposed crops were determined.

Thiabendazole residues are unlikely to present a public health concern.

### Residues

According to the available data (4 trials on Apple and 4 trials on Peach – all results below limit of detection), the intended uses on Apple and Peach are considered acceptable.

Taking into account, that Regulation (EU) No 544/2011 foresees reduction in the number of trials required for “zero residues” (< limit of detection) situations, extrapolation to all minor uses (please refer to GAP table) is possible without performing additional trials. The data submitted show, that no exceedance of the MRL will occur. All the intended uses described in the GAP table are considered acceptable.

### Consumer exposure

Not relevant – taking into account specific mode of application and obtained results of residues (“zero residues” situation) – no consumer exposure is expected.

## Environmental fate and behaviour (Part B, Section 8)

No studies related to fate and behaviour in the environment have been performed. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when the rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants into environment compartments – they are “trapped”), there is no possibility to expect for Thiabendazole and/or its metabolites for getting through to soil, groundwater, surfacewater and air, when plant protection product is used in accordance with the label. Such approach is compliant with EPPO Standards:

- Environmental risk assessment scheme for plant protection products (introduction) (Bulletin OEPP/EPPO Bulletin, Volume: 33, No: 2, pages: 147-149, year: 2003)

- Environmental risk assessment scheme for plant protection products - PP 3/2(2) Chapter 4: Soil (Bulletin OEPP/EPPO Bulletin, Volume: 33, No: 2, pages: 151-162, year:2003)

- Environmental risk assessment scheme for plant protection products - PP 3/4(2) Chapter 5: Groundwater (Bulletin OEPP/EPPO Bulletin, Volume: 33, No: 2, pages: 163-168, year: 2003)

- Environmental risk assessment scheme for plant protection products - PP 3/5(2) Chapter 6: Surface water and sediment (Bulletin OEPP/EPPO Bulletin, Volume: 33, No: 2, pages: 169-181,year:2003).

### Predicted environmental concentrations in soil (PECsoil)

No studies have been performed. There is no possibility to expect for FUNABEN® 018 PA for getting through the soil, when used in accordance with the label. Please also refer to section 3.7 for further explanations.

### Predicted environmental concentrations in groundwater (PECgw)

No studies have been performed. There is no possibility to expect for FUNABEN® 018 PA for getting through the groundwater, when used in accordance with the label. Please also refer to section 3.7 for further explanations.

### Predicted environmental concentrations in surface water (PECsw)

No studies have been performed. There is no possibility to expect for FUNABEN® 018 PA for getting through the surfacewater, when used in accordance with the label. Please also refer to section 3.7 for further explanations.

### Predicted environmental concentrations in air (PECair)

No studies have been performed. There is no possibility to expect for FUNABEN® 018 PA for getting through the air, when used in accordance with the label. Please also refer to section 3.7 for further explanations.

## Ecotoxicology (Part B, Section 9)

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect the exposure for FUNABEN® 018 PA in case of: birds (KCP 10.1.1), terrestrial vertebrates other than birds (KCP 10.1.2), other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3), aquatic organisms (KCP 10.2), bees (KCP 10.3.1), anthropods other than bees (KCP 10.3.2), non-target soil meso- and macrofauna (KCP 10.4), soil microbial activity (KCP 10.5), non-target terrestrial plants (KCP 10.6) and other terrestrial organisms (KCP 10.7).

### Effects on terrestrial vertebrates

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect the exposure for FUNABEN® 018 PA in case of birds, terrestrial vertebrates other than birds and other terrestrial vertebrate wildlife (reptiles and amphibians).

### Effects on aquatic species

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect the exposure for FUNABEN® 018 PA in case of aquatic organisms.

### Effects on bees

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect that plant protection product FUNABEN® 018 PA has any impact on bees.

### Effects on other arthropod species other than bees

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect that plant protection product FUNABEN® 018 PA has any impact on anthropods (other than bees).

### Effects on soil organisms

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which pre-vents from getting through active substance and other co-formulants into the soil), there is no possibility to expect that plant protection product FUNABEN® 018 PA has any impact on non-target soil meso- and macrofauna as well as on soil microbial activity.

### Effects on non-target terrestrial plants

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which pre-vents from getting through of active substance and other co-formulants), there is no possibility to expect that plant protection product FUNABEN® 018 PA has any impact on non-target terrestrial plants.

### Effects on other terrestrial organisms (Flora and Fauna)

No studies have been provided. Taking into account specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used when rain falls; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no possibility to expect that plant protection product FUNABEN® 018 PA has any impact on other terrestrial organisms (flora and fauna).

## Relevance of metabolites (Part B, Section 10)

No metabolites of thiabendazole are predicted to occur in groundwater. Taking into account the form of product (thick paste) and mode of application (painting with brush locally on wounds of trees), it has been assessed, that there is no possibility to expect the pollution of groundwater.

Especially taking into account EPPO guidelines: *Environmental risk assessment scheme for plant protection products, Chapter 6: Surface water and sediment* (EPPO bulettin 2003, 33, pages 169-181).

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant – plant protection product FUNABEN® 018 PA contains only one active substance (Thiabendazole) which is not considered as candidate for substitution.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

~~Physicochemical properties:~~

~~The signed “expert judgment” is requested to cover justification for physicochemical CLP classification. Furthermore, The two year storage stability is ongoing, the study can be assessed in the post-registration when available.~~ ~~Moreover, there is a missing description of commercial packaging used in accelerated and ambient storage stability. Please provide. Please add some data on the PPP density (please refer to the point KCP 2.6.1).~~

1. Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

1. Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

1. Letter of Access

XXXX

1. Lists of data considered for national authorization

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XXX | XXX | XXX | 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | Owner |
|  |  |  |  |  |  |  |  |