Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

*A 2850-4/2020/KBKHF számú határozat 4. számú melléklete*

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Protect fáraóhangya-irtó csalétek

(Biopren® Pharaoh’s Ant Colony Eliminator)

Product type 18

S-methoprene as included in the Union list of approved active substances

Asset Number in R4BP: HU-0013143-0000

Evaluating Competent Authority:HUNGARY

Date: 15/04/2019

Table of Contents

[1 CONCLUSION 4](#_Toc12957488)

[2 ASSESSMENT REPORT 7](#_Toc12957489)

[2.1 Summary of the product assessment 7](#_Toc12957490)

[2.1.1 Administrative information 7](#_Toc12957491)

[2.1.1.1 Identifier of the product 7](#_Toc12957492)

[2.1.1.2 Authorisation holder 7](#_Toc12957493)

[2.1.1.3 Manufacturer(s) of the product 7](#_Toc12957494)

[2.1.1.4 Manufacturer(s) of the active substance(s) 7](#_Toc12957495)

[2.1.2 Product composition and formulation 8](#_Toc12957496)

[2.1.2.1 Identity of the active substance 8](#_Toc12957497)

[2.1.2.2 Candidate(s) for substitution 8](#_Toc12957498)

[2.1.2.3 Qualitative and quantitative information on the composition\* of the biocidal product 9](#_Toc12957499)

[2.1.2.4 Information on technical equivalence 9](#_Toc12957500)

[2.1.2.5 Information on the substance(s) of concern 9](#_Toc12957501)

[2.1.2.6 Type of formulation 9](#_Toc12957502)

[2.1.3 Hazard and precautionary statements 9](#_Toc12957503)

[2.1.4 Authorised use(s) 10](#_Toc12957504)

[2.1.4.1 Use description 10](#_Toc12957505)

[2.1.4.2 Use-specific instructions for use 11](#_Toc12957506)

[2.1.4.3 Use-specific risk mitigation measures 11](#_Toc12957507)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc12957508)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 11](#_Toc12957509)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc12957510)

[2.1.5 General directions for use 12](#_Toc12957511)

[2.1.5.1 Instructions for use 12](#_Toc12957512)

[2.1.5.2 Risk mitigation measures 12](#_Toc12957513)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc12957514)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 12](#_Toc12957515)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc12957516)

[2.1.6 Other information 13](#_Toc12957517)

[2.1.7 Packaging of the biocidal product 13](#_Toc12957518)

[2.1.8 Documentation 14](#_Toc12957519)

[2.1.8.1 Data submitted in relation to product application 14](#_Toc12957520)

[2.1.8.2 Access to documentation 14](#_Toc12957521)

[2.2 Assessment of the biocidal product 15](#_Toc12957522)

[2.2.1 Intended use(s) as applied for by the applicant 15](#_Toc12957523)

[2.2.2 Physical, chemical and technical properties of the product 16](#_Toc12957524)

[2.2.3 Physical hazards and respective characteristics of the product 23](#_Toc12957525)

[2.2.4 Methods for detection and identification 24](#_Toc12957526)

[2.2.5 Efficacy against target organisms 27](#_Toc12957527)

[2.2.5.1 Function and field of use 27](#_Toc12957528)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 27](#_Toc12957529)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 27](#_Toc12957530)

[2.2.5.4 Mode of action, including time delay 27](#_Toc12957531)

[2.2.5.5 Efficacy data 28](#_Toc12957532)

[2.2.5.6 Occurrence of resistance and resistance management 32](#_Toc12957533)

[2.2.5.7 Known limitations 32](#_Toc12957534)

[2.2.5.8 Evaluation of the label claims 32](#_Toc12957535)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 33](#_Toc12957536)

[2.2.6 Risk assessment for human health 34](#_Toc12957537)

[2.2.6.1 Assessment of effects on Human Health 34](#_Toc12957538)

[2.2.6.2 Exposure assessment 41](#_Toc12957539)

[2.2.6.3 Risk characterisation for human health 46](#_Toc12957540)

[2.2.7 Risk assessment for animal health 48](#_Toc12957541)

[2.2.8 Risk assessment for the environment 48](#_Toc12957542)

[2.2.8.1 Effects assessment on the environment 48](#_Toc12957543)

[2.2.8.2 Exposure assessment 54](#_Toc12957544)

[2.2.8.3 Risk characterisation 55](#_Toc12957545)

[2.2.9 Measures to protect man, animals and the environment 57](#_Toc12957546)

[2.2.10 Assessment of a combination of biocidal products 58](#_Toc12957547)

[2.2.11 Comparative assessment 58](#_Toc12957548)

[3 Annexes 59](#_Toc12957549)

[3.1 List of studies for the biocidal product 59](#_Toc12957550)

[3.2 Output tables from exposure assessment tools 61](#_Toc12957551)

[3.3 New information on the active substance 62](#_Toc12957552)

[3.4 Residue behaviour 62](#_Toc12957553)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 62](#_Toc12957554)

[3.6 Confidential annex 62](#_Toc12957555)

# CONCLUSION

This product is an insecticidal ant bait used for the control of Pharaoh ants, containing 0.5% S-methoprene in the form of a granule in ready to use plastic bait stations.

Protect fáraóhangya-irtó csalétek was the representative biocidal product during the approval of S-methoprene named as Biopren® Pharaoh’s Ant Colony Eliminator.

Sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product according to the following conditions:

1. Target organisms: Pharaoh ant (*Monomorium pharaonis*).

2. Users: non-professional, professional and trained professional users.

3. The concentration of the active substance S-methoprene in biocidal product is 0.5%. The approved supplier of S-methoprene is the applicant, Bábolna Bio Ltd.

Minimum purity of a.s.: 95%.

4. The product is used indoors.

5. The application rate is 2 x 2.5 g / 20 m2.

6. Shelf-life of two years is supported. (Date of manufacture must be shown on the label or packaging.)

7. The authorisation holder must submit the endpoint results of the ongoing long term storage stability studies until the 31st December 2018.

8. The product is used according to the instructions of use.

9. The risk mitigation measures and conditions of storage are followed.

***Physical-chemical hazard:***

Protect fáraóhangya-irtó csalétek is a ready to use ant bait (PT18), that is formulated as granules in bait stations. The product does not pose physical-chemical hazard, no risk is expected from the product with regards to the physical-chemical properties and no classification is required.

***Human health hazard:***

Protect fáraóhangya-irtó csalétek was not found to be irritating to the skin or eyes and the product does not have skin sensitising properties.

The acute toxicity of Protect fáraóhangya-irtó csalétek has been investigated in GLP-compliant studies via the oral, dermal and inhalatory routes.

There was no mortality in the acute oral, dermal or inhalation studies.

In the acute oral toxicity study one male animal had slight diarrhoea at the very early stages of the study. Body weight gain was also somewhat affected. One male and one female lost weight between days 0 and 7, and the other four males lost weight between days 7 and 14.

In the acute dermal toxicity study diarrhoea was noted in one male on day 1, all the animals gained weight with the exception of one male. All females were normal throughout the study. Very slight erythema was noted in 3 males and 2 females on day 1. All animals recovered by day 4. Desquamation was recorded in one male on day 4 and had recovered by day 7.

In the acute inhalation study three female animals lost weight from day 0-7 however all animals gained weight from day 7-14. Animals showed activity decrease and piloerection but were asymptomatic by day 3.

Based on the above mentioned results, Protect fáraóhangya-irtó csalétek remains unclassified for acute oral, acute dermal and acute inhalation toxicity and requires no pictogram or hazard phrases.

In the available *in vitro* percutaneous absorption study the test material contained radioactively labelled S-methoprene in a concentration similar to the product. The dermal absorption rate of the active substance is 5%.

Human exposure is acceptable for professional workers and non-professional users. Protect fáraóhangya-irtó csalétek does not produce unacceptable effects when a child forces open the bait station and touches – or even puts in its mouth – the bait granules. Consuming the whole content of the bait station, however, may lead to symptoms of toxicity. Although the product contains a bittering agent against accidental or deliberate consumption, the label should contain a warning: Keep out of the reach of children.

***Environmental risk assessment:***

There are no unacceptable risks identified as a result of the indoor bait application of the biocidal product for any of the environmental compartments.

***Efficacy:***

Studies proved an acceptable efficacy against the target organism (Pharaoh ant) even in the presence of challenge diet, also under field conditions. Palatability of the aged bait was also proven, 3 years of shelf life was supported from this point of view, but final results of
3 years storage stability studies at ambient temperature are not available yet.

It was revealed that the application dose of 2 x 2 g / 20 m2 is sufficient to eliminate pharaoh ants, provided that this initial dose is replenished, supplemented, renewed and put down by the paths of ants, control can be achieved even in flats with higher level of ant infestation. Therefore a prescribed dose of 2 x 2.5 gram (2 bait boxes) / 20 m2 is considered rational with the same restrictions.

Studies have shown that the time required to reduce the ant population by ≥90% is more than 2-4 weeks, that is described in the TNsG for PT18 products (bait products against ants). This however is acceptable, and can be explained by delayed mechanism of action of the active substance. Therefore, as indicated in the instructions for use section, the product should be left at the application site for 3 months, to ensure reliable control of ants.

According to the studies, during the baiting period (3 months opened), the bait retains its potential. However, it is prone to lose effect/palatability etc. when it gets damaged by elements, especially water. Therefore, as indicated in the instructions, the bait must be protected from water (e.g. during cleaning).

Resistance for the active substance is not expected to build up when used according to the instructions.

The product is not intended to be used with other products. Other insecticides should not be used during baiting.

Update (minor change submitted 25/10/2018): The results of the 36 months storage stability study were submitted and accepted. As palatability of the 3 years aged product was proven in the earlier assessment, a shelf-life of 3 years is supported.

***General:***

HU CA considers Protect fáraóhangya-irtó csalétek acceptable for authorisation.

**Minor change (submitted 25/10/2018)**

The applicant applied for a minor change concerning the change of shelf-life from 2 years to 3 years. The submission of the results of the 36 months storage stability by 31/12/2018 at the latestwas a post-authorisation conditionthat was fulfilled by applying for the minor change 25/10/2018. HU CA considers that this change is justified and acceptable.The points of the authorisation affected by the change:

- section 2.2.2 Physical, chemical and technical properties of the product

- section 2.2.5 Efficacy against target organisms

- PAR and SPC Conditions of storage and shelf-life of the product under normal conditions of storage.

# ASSESSMENT REPORT

## Summary of the product assessment

### 2.1.1 Administrative information

#### 2.1.1.1 Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| Protect fáraóhangya-irtó csalétek (Biopren® Pharaoh’s Ant Colony Eliminator) | Hungary |

#### 2.1.1.2 Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Bábolna Bioenvironmental Centre Ltd.(Bábolna Bio Ltd.) |
| **Address** | Szállás u. 6.H-1107 BudapestHungary |
| **Authorisation number** | HU-2017-PA-18-00189-0000 |
| **Date of the authorisation** | 02.08.2017. |
| **Expiry date of the authorisation** | 01.05.2027. |

#### 2.1.1.3 Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Bábolna Bioenvironmental Centre Ltd. |
| **Address of manufacturer** | Szállás u. 6.H-1107 BudapestHungary |
| **Location of manufacturing sites** | Köves J. u. 3.H-2943 BábolnaHungary |

#### 2.1.1.4 Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | S-methoprene |
| **Name of manufacturer** | Bábolna Bioenvironmental Centre Ltd. |
| **Address of manufacturer** | Szállás u. 6.H-1107 BudapestHungary |
| **Location of manufacturing sites** | Szállás u. 6.H-1107 BudapestHungary |

### 2.1.2 Product composition and formulation

Full composition of the product is provided in the confidential annex (see Section 3.6).

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No. 528/2012.

Yes ☒

No [ ]

#### 2.1.2.1 Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | S-methoprene |
| **IUPAC or EC name** | Isopropyl-(2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate |
| **EC number** | 613-834-0 |
| **CAS number** | 65733-16-6 |
| **Index number in Annex VI of CLP** | not available |
| **Minimum purity / content** | 950 g/kg |
| **Structural formula** |  |

#### 2.1.2.2 Candidate(s) for substitution

S-methoprene is not a candidate for substitution; see Reg. (EU) 91/2014 and CAR of
S-methoprene.

####  2.1.2.3 Qualitative and quantitative information on the composition\* of the biocidal product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| S-methoprene | Isopropyl-(2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate | Active substance | 65733-16-6 | 613-834-0 | 0.5% |

\* For the full composition of the product see Section 3.6 Confidential Annex

Tolerance limits of the active substance content: 0.5% ± 25% (0.375% – 0.625%).

#### 2.1.2.4 Information on technical equivalence

Technical equivalence study is not necessary as the source of active substance is the same as the one that was reviewed for the approval of active substances under Regulation (EU) No. 528/2012.

#### 2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

According to the list of ingredients and their concentration no substance of concern is in the biocidal product.

#### 2.1.2.6 Type of formulation

|  |
| --- |
| RB – Bait (ready for use; GR – Granule)  |

### 2.1.3 Hazard and precautionary statements

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

| **Classification** |
| --- |
| Hazard class and category | Aquatic Chronic 3 |
| Hazard statement | H412 Harmful to aquatic life with long-lasting effects |
|  |
| **Labelling** |
| **GHS pictogram** | not necessary |
| Signal word | not necessary |
| Hazard statement | H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P273 Avoid release to the environmentP501 Dispose of contents/container in accordance with applicable regulations |
|  |
| Note | - |

According to the RAC opinion adopted on 3 June 2016, the harmonised classification of S-methoprene is Aquatic Acute 1 (M(acute): 1) and Aquatic Chronic 1 (M(chronic): 1).

### 2.1.4 Authorised use(s)

#### 2.1.4.1 Use description

Table 1. for all user categories

\**Authorised use section is not separated to professional, trained professional and non-professional user categories, because in case of this product only the size of the packaging differs, the manner of use, the instructions and the risk mitigation measures are the same for all categories.*

|  |  |
| --- | --- |
| **Product Type** | Product Type 18 (insecticides, acaricides and products to control other arthropods) |
| **Where relevant, an exact description of the authorised use** | The bait stations are placed along the foraging routes of ant workers |
| **Target organism (including development stage)** | Pharaoh ant (*Monomorium pharaonis*)larvae and queens |
| **Field of use** | Indoors |
| **Application method(s)** | Bait application in pre-filled bait stations |
| **Application rate(s) and frequency** | 2 bait stations / 20 m2(0.25 g/m2) |
| **Category(ies) of users** | Professional, trained professional and general public users |
| **Pack sizes and packaging material** | For general public:3 x 2.5 grams in plastic (PVC + PE) bait stationstotal 7.5 grams2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 3 blisters / package.total 7.5 gramsFor professionals and trained professionals:2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 12 blisters / package.total 30 grams2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 24 blisters / package.total 60 grams |

#### 2.1.4.2 Use-specific instructions for use

|  |
| --- |
| - |

#### 2.1.4.3 Use-specific risk mitigation measures

|  |
| --- |
| - |

#### 2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

#### 2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

#### 2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

### 2.1.5 General directions for use

#### 2.1.5.1 Instructions for use

|  |
| --- |
| Cut at the dotted line at the end of the plastic pack and remove the protective foil from the sticky pad.Fasten the bait along the foraging routes of ant workers (very close to the route, but not directly on it) with its opening on top or at side. Avoid spillage of the granules.The bait should be placed in the premises where ants appear, mainly in the kitchen and the bathroom. Use the product in other premises as well if necessary.Recommended dose: 2 bait stations / 20 m2.Following bait placement, for a short period of time more ants may be observed than before, but this is the result of the attractiveness of the bait substance.After placement the product starts to act gradually and reaches full effect within 10-14 weeks. To ensure full population control it is recommended to leave the baits in place for a period of at least 3 months even if the foraging ant workers disappear from the premises earlier.If a bait station becomes empty (or nearly empty) or damaged (e.g. drenched), it must be replaced with a new one. Protect the placed baits from water (e.g. during cleaning) as the product may lose its efficacy because of water.Attention! While you use ant baits, do not apply any other insecticides! |

#### 2.1.5.2 Risk mitigation measures

|  |
| --- |
| Keep out of the reach of children, do not allow use by children. The bait should be placed inaccessible to children or domestic animals.After handling, wash hands with plenty of water and soap.Avoid release to the environment. Prevent the product residues or its container from entering drains or watercourses. |

#### 2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| If inhaled: Keep patient calm, remove to fresh air. Seek medical advice.After contact with skin: Wash thoroughly with soap and water.After eye contact: Rinse with plenty of water for several minutes. If irritation persists, seek medical attention.If swallowed: get medical attention if feeling unwell.When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].Contain the spill, sweep spillage and transfer into waste containers for disposal. |

#### 2.1.5.4 Instructions for safe disposal of the product and its packaging

|  |
| --- |
| The bait stations should not be washed or reused.Dispose of waste products and bait stations after treatment in accordance with local requirements. If it is not contrary to official specifications, the packaging may be treated like household waste. Prevent contamination of environment by wastes. |

#### 2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Shelf-life and storage: 3 years if stored in original unopened package in a dark, dry, cool and frost-free place. Keep away from feed and foodstuffs, medicines. (Date of manufacture must be shown on the label.) |

### 2.1.6 Other information

|  |
| --- |
| The product contains a bittering agent – denatonium benzoate – which helps prevent incidental human consumption.Application codesTarget organisms to be controlledI.3.10.3 Myrmicinae ants (e.g. Pharaoh ant)Developmental stages of target organisms to be controlled.II.1.2 larvaeII.1.5 adults (queen)Function/mode of actionIII.1.1 ingestion (bait)III.2.4 growth regulating effectIII.3.3 can control entire colonies (eradication)Field of useIV.1 indoor useUser categoryV.1 non-professionalV.2 professionalV.3 specialised (trained) professionalMethod of applicationVI.6 bait application |

### 2.1.7 Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging**  | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Ready-to-use pre-filled secure bait stations | 3 x 2.5 grams | PVC + Polyethylene (PE) | - | professional and non-professional | Yes |
| Transparent plastic blisters with adhesive sticker on each blister | 2.5 grams of bait / blister 3 blisters / package.total 7.5 grams | PVC + Polyethylene (PE) |  | professional and non-professional | Yes |
| Transparent plastic blisters with adhesive sticker on each blister | 2.5 grams of bait / blister 12 blisters / package.total 30 grams | PVC + Polyethylene (PE) |  | trained professionals | Yes |
| Transparent plastic blisters with adhesive sticker on each blister | 24 blisters / package.total 60 grams | PVC + Polyethylene (PE) |  | trained professionals | Yes |

### 2.1.8 Documentation

#### 2.1.8.1 Data submitted in relation to product application

See Annex 3.1. for complete references.

#### 2.1.8.2 Access to documentation

On Article 95 list Bábolna Bio Ltd. is the only approved supplier of the active substance S-methoprene and Bábolna Bio Ltd. is the manufacturer of the product as well, therefore a letter of access is unnecessary.

Access to the dossier of S-methoprene is granted.

## Assessment of the biocidal product

### 2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use

|  |  |
| --- | --- |
| Product Type(s) | Product Type 18 (insecticides, acaricides and products to control other arthropods) |
| Where relevant, an exact description of the authorised use | The bait stations are placed along the foraging routes of ant workers |
| Target organism (including development stage) | Pharaoh ant (*Monomorium pharaonis*)larvae and queens |
| Field of use | Indoors |
| Application method(s) | Bait application in pre-filled bait stations |
| Application rate(s) and frequency | 2 bait stations / 20 m2 |
| Category(ies) of user(s) | Professional, trained professional and non-professional users |
| Pack sizes and packaging material | For non-professionals:3 x 2.5 grams in plastic (PVC + PE) bait stationstotal 7.5 grams2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 3 blisters / package.total 7.5 gramsFor professionals and trained professionals:2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 12 blisters / package.total 30 grams2.5 grams of bait in transparent plastic blisters with adhesive sticker on each blister, 24 blisters / package.total 60 grams |

### 2.2.2 Physical, chemical and technical properties of the product

| **Property** | **Guideline and method** | **Test item** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Sensory analysisOPPTS 830.6303 | Batch No.: 45506active subs.:0.47% | solid, small granules | LAB International Research Centre HungaryLtd.Study Code:06/228-357AN(GLP) |
| Colour at 20 °C and 101.3 kPa | Sensory analysisOPPTS: 830.6302 | Batch No.: 45506active subs..:0.47% | light and dark brown |
| Odour at 20± 2 °C and 101.3 kPa | Sensory analysisOPTTS 830.6304 | Batch No.: 45506active subs.:0.47% | unpleasant (as feeding stuff of laboratory animals) |
| pH at 20 ± 1°C | 1% aqueous dispersion CIPAC Method MT 75.2 | Batch No.: 45506active subs.:0.47% | 6.6 | LAB International Research Centre HungaryLtd.Study Code:06/228-338AN (GLP) |
| Acidity / alkalinity | CIPAC Method MT 31.1.2. | Batch No.: 45506active subs.:0.47% | Free acidity determined as H2SO4 content: 0.034%  | LAB International Research Centre HungaryLtd.Study Code:06/228-361AN (GLP) |
| Density / bulk density | CIPAC Method MT 159 andOPPTS 830.7300 | Batch No.: 45506active subs.:0.47% | Pour density: 0.524 g/cm3Tap density: 0.569 g/cm3 | LAB International Research Centre HungaryLtd.Study Code:06/228-325AN (GLP) |
| Self ignition temperature  | A16Relative self-ignition temperature for solids | Batch No.: 45506active subs.:0.47% | 216°C | LAB International Research Centre HungaryLtd.Study Code:06/228-355AN (GLP) |
| Flammability | Method: A10 Flammability (solids) | Batch No.: 45506active subs.:0.47% | not flammable | LAB International Research Centre HungaryLtd., Study Code:06/228-356AN (GLP) |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.354±2°C, 14 days | Batch No.: 103921active subs.:0.52% (in house GC method) | No significant changes in the active substance content and appearance of the product.HPLC/UV:start (a.s. content (%)):0.491 ± 0.006End (a.s. content (%)):0.489 ± 0.004Packing (plastic, transparent flat box) does not change.Shelf life of the product is likely at least two years. No other parameter was determined. | TOXI-COOP Zrt., HungaryStudy No.:484-160-0415(GLP) |
| Storage stability test – **long term storage at ambient temperature** | GIFAP, technical Monograph, 2009andOPPTS 830.6303OPPTS 830 6302OPPTS 830 6304 | Batch No.:103921 active subs.:0.52%(in house GC method) | HPLC/UV:(a.s. content (%)):Start: 0.491± 0.006; after 6 months: 0.476± 0.004after 12 months:0.480± 0.011Packaging (commercial plastic packaging (PVC+PE)) bait does not change.Results after 1 year storage are not available, study is ongoing.No significant change in characteristics only odour of the product became sweetish after 12 months. No other parameter was determined. | TOX-COOP Zrt., HungaryStudy No.: 484-170-0416(GLP)Interim Report availableResults only after 6, 12 months storage are available.Manufacturer’s plan is to perform 3 years ambient storage stability test  |
| submitted for the MINOR CHANGE (25/10/2018)Storage stability test – **long term storage at ambient temperature** | GIFAP, technical Monograph, 2009andOPPTS 830.6303OPPTS 830 6302OPPTS 830 6304 | Batch No.:103921 active subs. content:0.52%(in house GC method) | Product in commercial plastic packaging (PVC+PE) bait packaging was stored for 3 years at room temperature (19 - 21°C); a.s. content was determined with validated HPLC/UV method.

|  |  |  |
| --- | --- | --- |
| Time point | a.s. content(w/w%) | Deviation(%) |
| Initial | 0.483 |  |
| 6 months | 0.468 | -3.11 |
| 12 months | 0.472 | -2.28 |
| 18 months | 0.466 | -3.52 |
| 24 months | 0.477 | -1.24 |
| 30 months | 0.462 | -4.35 |
| 36 months | 0.483 | 0 |

Stability of packaging material: no adverse interaction was observed, packaging remains intact with well readable inscriptions.No significant change in appearance (solid, brown heterogeneous granules) only smell felt sweetish at time points: 12, 24, 30 and 36 months. No other parameter was determined as formulation of the product is ready to use bait. | TOX-COOP Zrt., HungaryStudy No.: 484-170-0416(GLP study)Determination of the long-term Storage Stability of Biopren Pharaoh’s Ant Colony Eliminator |
| Storage stability test – **low temperature stability test for liquids** | not required as the product is not a liquid preparation. |  | As cold temperature storage data have not been provided then protect from frost should appear on the label. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **light** |  |  | According to the manufacturer’s declaration the product has shown no reactivity to light.During storage the product is not exposed to light as the baits are in sealed plastic boxes that are placed in a paper box. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The bait is in a water-proof sealed plastic box so during storage period humidity does not affect fitness of the product. During baiting period the product must be protected from flooding and washing up rather than humidity. Influence of moisture in the air due to the tiny holes of the bait cannot be significant. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Accelerated Storage stability test  |  | No evidence of corrosion or other signs of deterioration of plastic packaging was observed. |  |
| Wettability |  |  | Data waiving is acceptable, not required for formulations which are not diluted with water. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable ready to use product |  |
| Wet sieve analysis and dry sieve test |  |  | Data waiving is acceptable. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Data waiving is acceptable, not required for granules. |  |
| Disintegration time |  |  | Data waiving is acceptable, product is not in form of tablets. |  |
| Particle size distribution | CIPAC method MT59Sieve screening | Batch No.: 45506active subs.:0.5% (nominal)0.47% (GC) | Fraction of 98.42% is greater than 250 µm size.0.62% passed 106 µm sieve screen mesh size. | Covance lab. Ltd., UKStudy Number: 2694/002(GLP) |
| Content of dust/fines, friability |  |  | Dustiness was not investigated because the granules are in a special shaped and sealed plastic box and during baiting period only two tiny holes are formed by cutting at the dotted line at each end of the plastic box. Due to this special packaging dust cannot be liberated into the air when the product is handled, applied. |  |
| Attrition Resistance  | CIPAC methodMT178Attrition resistance of granules | Batch No.: 103921active subs.:0.52% | 99.9% | TOXI-COOP Zrt. HungaryStudy Report: 484-178-0420 (GLP) |
| Persistent foaming |  |  | Not required for a ready to use product, product is not diluted with water.  |  |
| Pourability/Dustability |  |  | Data waiving is acceptable. |  |
| Flowability  | after CIPAC MT 46.1 test (54°C, 2 weeks) sieve testCIPAC method MT 170 was performed | Batch No.: 45506active subs.:0.47% | 86-99 % of the sample dropped through the 5 mm mesh sieve spontaneously, 0 -1.2% remained on the sieve after5 liftings. All the material passed the sieve after 20 liftings. | LAB International Research Centre HungaryLtd., Study Code:06/228-360AN(GLP) |
| Burning rate — smoke generators | not relevant |  |  |  |
| Burning completeness — smoke generators | not relevant |  |  |  |
| Composition of smoke — smoke generators | not relevant |  |  |  |
| Spraying pattern — aerosols | not relevant |  |  |  |
| Physical compatibility | CIPAC MT 46.354±2°C, 14 days | Batch No.: 103921active subs.:0.47% | No reactivity and incompatibility to the material of the container.  | TOXI-COOP Zrt. Hungary484-160-0415 (GLP) |
| Chemical compatibility | CIPAC MT 46.354±2°C, 14 days | Batch No.: 103921active subs.:0.47% | No reactivity and incompatibility to the material of the container. | TOXI-COOP Zrt. Hungary484-160-0415 (GLP) |
| Degree of dissolution and dilution stability | not relevant for a ready to use product |  |  |  |
| Surface tension in aqueous solution | Method: A5(30 mg/L, at 20±1°C) | Batch No.: 45506active subs.: 0.47% | 70.1 mN/m | LAB International Research Centre, HungaryLtd.Study Code:06/228-326AN |
| Viscosity | not relevant, for solid material |  |  |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Studies are acceptable, results of these studies show that the biocidal product named Protect fáraóhangya-irtó csalétek does not pose any physical-chemical hazards. The formulation is not explosive, flammable or oxidising.3 years storage stability study is ongoing, started in February 2015.Available storage stability data support a shelf life of 2 years.Results of the ongoing long term storage stability study at ambient temperature (Study No.: 484-170-0416) should be submitted by 31st December 2018, at the latest.Update (minor change:25/10/2018):At the time of first authoristation the long term stability study was still on-going, only interim results of 6 and 12 months stability were available. Post-authorisation data for storage stability of 3 years has been submitted to change the currently authorised shelf life of 2 years to 3 years. Data are acceptable and therefore a shelf life of 3 years can be granted. |

### 2.2.3 Physical hazards and respective characteristics of the product

| **Property** | **Guideline and Method** | **Results** | **Reference** |
| --- | --- | --- | --- |
| Explosives | None of the ingredients are considered explosive therefore formulation is not explosive. | no classification |  |
| Flammable gases | not relevant | no classification |  |
| Flammable aerosols | not relevant | no classification |  |
| Oxidising gases | not relevant | no classification |  |
| Gases under pressure | not relevant | no classification |  |
| Flammable liquids | not relevant | no classification |  |
| Flammable solids | A10 | no classification;no ignition and no combustion was noted  | LAB, Study Code: 06/228-356/AN |
| Self-reactive substances and mixtures | not relevant | no classification |  |
| Pyrophoric liquids | not relevant | no classification |  |
| Pyrophoric solids | Not pyrophoric. None of the components of the product contain groups that might lead to ignition in contact with air. | no classification |  |
| Self-heating substances and mixtures | None of the co-formulants are classified as being self-heating. | no classification |  |
| Substances and mixtures which in contact with water emit flammable gases | not relevant | no classification |  |
| Oxidising liquids | not relevant | no classification |  |
| Oxidising solids | None of the components contains groups that act as an oxidizing agent. | no classification |  |
| Organic peroxides | not relevant | no classification |  |
| Corrosive to metals | not relevant | no classification |  |
| Auto-ignition temperatures of products (liquids and gases) | not relevant | no classification |  |
| Relative self-ignition temperature for solids | A16 | 216°Cno classification | LAB, Study code.06/228-355-AN |
| Dust explosion hazard | not relevant | no classification |  |
|  |  |  |  |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product does not represent physical hazard, no classification is required.It is not flammable, explosive or oxidising.  |

### 2.2.4 Methods for detection and identification

Data are sufficient to demonstrate that the method used for analyses is suitable for purpose of determination of S-methoprene concentration in the biocidal product.

The method is validated in accordance with SANCO/3030/99 rev. 4. Linearity was checked in range of 80 – 120% of nominal content with five concentration levels on four different days with 3 replicate samples and 2 injections.

Recovery was performed at 0.45% and 0.55% level.

Summary of the validation data are shown in the following table:

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Analyte**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| **S-methoprene** | reverse phaseHPLC-UV | Five conc. levels in range of 0.5±20% a.s.content with 3 parallels. Each concentration level was prepared and analysed four times. Repeatability of preparation:RSD: 1.3% | 0.5%±20%r2:>0.999 | Method is specific, no inter-ference.  | 0.45–0.55 | 102–104 | 1.6–1.2 | LOQ: not known.Method is fully validated in range of0.45 – 0.55% a.s. content  | \* |
| 5 parallels of 2 concentration levels |

\*: Study Report, GLP – Toxi-Coop Zrt. Validation of the Analytical Method (HPLC) for the determination of S-methoprene in Biopren Pharaoh’s Ant Colony Eliminator (Protect fáraóhangya-irtó csalétek, Study No.: 484-100-0414, 2015).

Analytical methods for determination of S-methoprene residues were assessed by data set of the active substance during its approval, please refer to the CAR of S-methoprene.

Sufficient monitoring methods for the determination of residues in water, surface water and ground water are available as a part of active substance approval.

|  |
| --- |
| **Analytical methods for monitoring purposes in water, surface water and groundwater** |
| **S-methoprene**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| drinking water | GC-MS(m/z = 175, 191 and 219) | 0.07 µg/L– 1.2 µg/L(at 8 levels) | r >0.996 | highly specific (GC-MS with 3 ions). | 74 – 107 | 95 | 13.3 | 0.1 μg/L | Report no: CRA119111 |
| surface water | r >0.996 | 70 – 82 | 75 | 6.1 | 0.1 μg/L |
| groundwater | r >0.996 | 74 – 96 | 82 | 10.6 | 0.1 μg/L |

\* fortification level: 0.1µg/L

According to the assessment report of the active substance analytical method for determination of S-methoprene in soil was not submitted based on the specific use of the product, as only indoor usage is permitted.

|  |
| --- |
| **Analytical methods for soil** |
| **Analyte**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* |

According to the assessment report of the active substance analytical method for determination of S-methoprene in air is not required as vapour pressure is less 0.01Pa, a.s. is non-volatile.

|  |
| --- |
| **Analytical methods for air** |
| **Analyte**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* |

S-methoprene is not classified as being toxic or highly toxic. It is therefore proposed that analytical methods in animal and human body fluids and tissues are not required.

|  |
| --- |
| **Analytical methods for human body fluids and tissues** |
| **Analyte**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* |

According to the assessment report of the active substance analytical method for determination of S-methoprene in food and foodstuffs was not submitted based on the specific use of the product. It is intended to be applied out of reach of food or feed; no residues are to be left.

|  |
| --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| **Analyte**  | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* | *–* |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Based on the results a validated analytical method exists for determination of active ingredient content of the product named Protect fáraóhangya-irtó csalétek.According to the assessment report of the active substance analytical methods for determination of S-methoprene exist in relevant matrices such as water, surface water and groundwater. |

### 2.2.5 Efficacy against target organisms

#### 2.2.5.1 Function and field of use

The product is a ready-to-use (RB) bait formulation insecticide for indoor use.

#### 2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The product is intended to control colonies of Pharaoh ant(*Monomorium pharaonis*).

#### 2.2.5.3 Effects on target organisms, including unacceptable suffering

The ant bait is taken back to the nest by foraging workers where it prevents the normal development of brood stages and sterilises the queen. The eradication of the ant colonies exposed to S-methoprene is a result of the morphogenetic effects of the insect growth regulator (IGR) on the brood stages coupled with the action of the compound on the ovaries of the queen, which become atrophied, and stop producing oocytes. The resulting sterility of the queens may be due entirely to the physiological effects of the hormone on the ovaries but may be compounded by the disruption of social interactions necessary for egg-laying as a result of the absence of brood stages killed by the morphogenetic action of the IGR.

#### 2.2.5.4 Mode of action, including time delay

The active substance S-methoprene, which is effective against Pharaoh ants (*Monomorium pharaonis*) is an insect growth regulator that acts as a juvenile hormone mimic to disrupt the normal development of insects. It displays no immediate killing effect on the target organisms but inhibits the egg-laying capacity of the queen and the development of the brood. The granular bait containing the active substance is transported by the target organisms into the colony nest where it is fed to the colony resulting in complete extermination within 12-14 weeks.

#### 2.2.5.5 Efficacy data

| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| --- |
| **Function** | **Field of use envisaged** | **Test substance\*** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *insecticide**(colony eradication)* | *indoors* | *PROTECT-B ant killer bait, containing 0.5% S-Metho-prene* | *Pharaoh ants (Monomorium pharaonis)* | field trial | 2 x 2g/20 m2 or 4 x 2g/20 m2 in a three storey building containing 13 flats over a 12 week period.To assess the need for preliminary and final spraying prior to and following treatment with Protect-B, 5 flats were subjected to preliminary spraying with Protect-B household spray and a final spray, following bait treatment with Protect-B cockroach and ant killer aerosol. | A bait dose of 2 x 2g/20 m2 is effective in controlling Pharaoh ants. By week 5, five flats were no longer infested while by week 12, ants were completely eliminated. Interviews conducted 6 weeks after final spraying revealed there were no Pharaoh ants in the building.Preliminary spraying is considered unnecessary as baits placed in flats which did not undergo preliminary spraying were as effective in controlling ants as those in which preliminary spraying was undertaken. Final spraying may provide protection against re-infestation (while it remains effective) and kill the few worker Pharaoh ants that may remain in the building. | *State Public Health and Medical Officer Service Metropolitan Institute Budapest, Hungary**Ref. no.: 103/97* |
| *insecticide**(colony eradication)* | *indoors* | *Pharaoh’s ant bait matrix M containing 0.5% S-methoprene* | *Pharaoh ants (Monomorium pharaonis)* | labora-tory trial(simula-ted use)  | Isolated colonies of Pharaoh ants were given ant bait matrix T or ant bait matrix M. With both of the matrices, challenge diet (normal food) was provided in parallel with the bait. | Both methoprene formulations showed potential for control against Pharaoh ant. Matrix M (equivalent of Protect fáraóhangya-irtó csalétek) was preferred by the ants over matrix T. Degenerated queens were found during the experiment. These are not able to produce brood. Both matrices achieved >95% elimination of brood by week 12. | *School of Biological Sciences, Universiti Sains Malaysia**ref. no.: BB/001/2003* |
| *insecticide**(colony eradication)* | *indoors* | *BIOPRENE BMS ant bait, containing 0.5% S-metho-prene* | *Pharaoh ants (Monomorium pharaonis)* | labora-tory trial(simula-ted use) | Pharaoh ants were investigated in a plastic chamber furnished similarly to a breeding chamber and coated with Fluon-PTFE to prevent ants from escaping. A hollowed beech-wood ant nest was placed in the chamber with one bait box and three feeding dishes containing sugar, fresh dead cockroaches and finely ground dried dog food, placed at equal distances from the ant nest.The test took place in a 45x25x20 cm plastic chamber. 1 bait box was introduced to the chamber. | By week 12 and 13 of the experiment only one queen was observed. The number of queens in the nest ranged from 4 at study initiation to 1 at study termination.From week 8, more straggling workers were observed outside of the nest as pupae and larvae diminished. Worker numbers ranged from 250 at study initiation to just 1 by week 10.Brood numbersbegan to decrease by week 3 and were completely eliminated by week 7 (100%). | *Bábolna Bioenvironmental Centre Ltd.**code no.: 035.006.* |
| *insecticide**(colony eradication)* | *indoors* | *PROTECT-fáraóhan-gya-irtó csalétek, containing 0.5% S-metho-prene,**aged* | *Pharaoh ants (Monomorium pharaonis)* | labora-tory trial (simula-ted use) | Pharaoh ant colonies were introduced to plastic observation containers. Containers were coated with Fluon-PTFE to prevent ants from escaping. Ant colonies were living in plastic cylinders within the observation containers. One bait box (with aged bait after storage for 3.5 and 4 years) and feeding dishes containing sugar, fresh dead cockroaches and dead flies were placed as challenge diet. | By week 10, 75-100% of ant queens were eliminated. The number of ant workers decreased by 97-100%. After week 8, no more ant larvae or pupae were observed. The amount of bait taken away from the station by ants was the greatest during the first two weeks. After week 4 the ants did not take any more bait from the station. Colonies collapsed and were eliminated by week 10. | *Bábolna Bioenvironmental Centre Ltd.**code no.: 169.001-006.* |
| *insecticide**(colony eradication)* | *indoors* | *LO312 (Biopren BMS ant colony eliminator) contain-ing 0.3% S-metho-prene* | *Pharaoh ants (Monomorium pharaonis)* | field trialsupport-ing study | The product was used in 3 ant-infested premises (altogether 40 residences). The infested apartments (2 out of 4; 11 out of 22 and 5 out of 14 apartments in the three premises respectively) were treated with the dose of 4-6 bait boxes/apartment , while the surrounding apartments were treated preventively with 2-4 boxes/apartment to prevent the spread of the infestation. | After 4 months, ants were completely eliminated from all of the treated premises. It took less than 18, 19 and 13 weeks in the 3 buildings to control the infestation. | *Luxan,**Pharaoh’s Ant Control with S-Methoprene – Dutch Field Testing* |

\* The composition of Pharaoh’s ant bait matrix M, BIOPREN BMS ant bait and Protect-B ant killer bait is identical to Protect Pharaoh’s Ant Colony Eliminator and Protect fáraóhangya-irtó csalétek.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| At product authorisation level three studies have been submitted to prove the efficacy of this product.The simulated test *(study no. 035.006)* proved that the bait is capable of controlling colonies of Pharaoh ant (*Monomorium pharaonis*) even in the presence of challenge diet. The ant colony was eliminated in approximately 8 weeks. An untreated, negative control ant population was used to support the test results. Another simulated use study (*study no. BB/001/2003)* also found that the formulated product has a potential to control Pharaoh ant colonies in a long term treatment programme.The product was also proven efficacious among field conditions. A field trial was conducted in a three-story building comprising 15 flats *(study no. 103/97).* Total control of ants was achieved in 12 weeks. 6 weeks after the end of the treatment, Pharaoh ants were still not present in the premises. The bait was applied in the corresponding blister package, so it is also demonstrated that, if used correctly, the commercial package (blister baitbox) is suitable for applying the bait.For further support of the field test results, the applicant submitted a supporting field test. (*Luxan, Pharaoh’s Ant Control with S-Methoprene – Dutch Field Testing)*. In this study 3 different premises (altogether 40 apartments) were treated with the bait. After 4 months ants were eliminated in all of the premises. Composition of the investigated product in this test, referred to as “LO312 or Biopren BMS ant colony eliminator” is slightly different than the product under evaluation. The active substance content in LO312 is only 0.3% S-methoprene, whereas the current product contains 0.5% S-methoprene. Otherwise, the formulations are identical (honey content is also different, but considered negligible). As the tested product contains less active substance, but the same amount of other ingredients, the current ant bait with more IGR content is expected to be even more efficacious. Therefore, HU CA accepts this field test as a supportive study. For comparison of product compositions, the exact composition of the tested product and the applicant’s justifying statement see the confidential annex of the PAR.However, palatability of the stored bait was not supported, therefore the HU CA asked the applicant for a complementary study. For this purpose the applicant submitted a simulated use test performed with aged bait (Schmidt, 2016, study no. 169.001-169-006) This study supports 3 years of shelf life for the product, as even after storage the ant bait was found to be palatable over the challenge diet and adequately efficacious. However, results of available storage stability tests support 2 years of shelf life so far. The 3 years long-term storage stability test is ongoing.The Assessment Report on the active substance S-methoprene suggests that conclusions on the application rate can be drawn at the product authorisation stage (CAR section 2.1.2.2.). In the conducted field trial it was revealed that the application dose of 2 x 2g / 20m2 is sufficient to eliminate Pharaoh ants, provided that this initial dose is replenished, supplemented, renewed and put down by the paths of ants, control can be achieved even in flats with a higher level of ant infestation. Therefore, a prescribed dose of 2 x 2.5 gram (2 bait boxes) / 20 m2 is considered appropriate and expected to be efficacious with the same restrictions.*Note: During the MRP process, concerns were raised by Competent Authorities because the application rate suggested in the field study (study no. 103/97) does not strictly correspond to the rate actually used in the field study.**HU CA is on the opinion that the dosage of the bait given in bait station/m2 unit is a theoretical, comparative information, but in practice bait stations would not be spread evenly in an apartment. The direction for use also says “Fasten the bait along the foraging routes of ant workers very close, but not directly on the route, with its opening on top or at side. The bait should be placed in the premises where ants appear, mainly in the kitchen and the bathroom.” This explains why bait stations are likely to be placed more frequently in the bathroom than the living room (i.e.: the density of bait stations at the site of the treatment matches the recommended dose, whereas in the irrelevant parts of the apartment it is different). The important thing is that bait should be available and easily accessible to the ants and it should be replenished if necessary.*Studies have shown that the time required to reduce the ant population by ≥90% is more than the 2-4 weeks that is described in the TNsG for PT18 products (bait products against ants). This, however, is acceptable, and can be explained by delayed mechanism of action of the active substance. Therefore, as indicated in the instructions for use section, the product should be left at the application site for 3 months to ensure reliable control of ants.According to the studies, during the baiting period (3 months opened) the bait retains its potential. However, it is prone to lose effect/palatability etc. when it gets damaged by elements, especially water. Therefore, as indicated in the instructions for use section the bait must be protected from water (e.g. during cleaning).Update (minor change 25/10/2018): The results of the 36 months storage stability study were submitted and accepted. As palatability of the 3 years aged product was proven in the earlier assessment, a shelf-life of 3 years is supported. |

#### 2.2.5.6 Occurrence of resistance and resistance management

In published studies S-methoprene was proven to be capable of inducing resistance in isolated fly and mosquito populations, but in ants this phenomenon was not described so far and is unlikely. The product should be used only when there is a Pharaoh ant infestation. Normally, exposure of target species to the substance is limited to the period of the treatment.

Also, in case of ants with only one or few specimens (queens) that lay eggs for a long period and a biocide that kills the whole colony most of the time, resistance is not expected to build up. Therefore, a resistance management strategy does not need to be provided for ants for evaluation at product authorisation.

#### 2.2.5.7 Known limitations

* Bait must be protected from water (e.g. during cleaning) so that it does not get damaged and retains its potential.
* Ants that rely on the perception of trail pheromones can be repelled, deterred or confused by chemicals used in surface treatment (eg.: CIK aerosols) making them unable to access the bait. Therefore, use of such other insecticides simultaneously with baiting is not advised. This warning is prescribed in the instructions for use section.

#### 2.2.5.8 Evaluation of the label claims

The HU CA approves the following label claims, reflecting on the efficacy of the product:

* The product is to be used by general public, professional and trained professional users.
* The product is to be used indoors.
* The target organism is Pharaoh ant (*Monomorium pharaonis*), as this species was used in the efficacy trials.
* The formulation is capable of eliminating colonies of Pharaoh ant (*Monomorium pharaonis*), because in the efficacy trials complete colonies of this ant species were observed.
* Based on the results of the field trial the recommended application dose is 2 bait stations (2.5 grams each) / 20 m2. Equivalent to a dose of 0.25 grams / m2.
* Foraging ants must have access to the bait, so the bait should be placed very close to the route (but not directly on it) with its opening on top or at side. The bait box can be fixed to surfaces with the help of the sticky pad on its back. Avoid spillage of the bait.
* The bait should be placed in the premises where ants appear, usually in the kitchen and the bathroom. Use the product in other premises as well, if necessary.
* The expected time for the bait to take total control of an ant colony is 12 weeks or less. It is possible, that after a few weeks, the numbers of foraging ants are reduced. A member of general public without experience and thorough observation may think that the colony is eliminated. Nonetheless, there might be more survivors in the nest. Therefore, the bait must be left at the application site for 3 months even if the ants disappear from the premises earlier. This statement complies with the residual efficacy of 10-14 weeks.
* Following bait placement, for a short period of time more ants may be observed than before, but this is the result of the attractiveness of the bait substance.
* If necessary, bait must be replenished, supplemented or replaced, making sure that ants have access to the required amount of bait throughout the treatment period.
* Bait must be protected from water (e.g. during cleaning) so that it does not get damaged and retains its potential.
* Do not use other insecticides simultaneously with the bait. See: point 2.2.5.9.

#### 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other biocidal products. It was verified in field test that surface spraying preceding or after the baiting period is not necessary.

2.2.6 Risk assessment for human health

#### 2.2.6.1 Assessment of effects on Human Health

***Skin corrosion and irritation***

**Summary of *in vitro* studies on skin corrosion/irritation**

No *in vitro* skin corrosion/irritation studies are available.

|  |
| --- |
| **Summary table of animal studies on skin corrosion /irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results** | **Remarks** | **Reference**  |
| *US EPA Guideline 81-5 and OPPTS 870.2500,**GLP: Yes,**Reliability: 1* | Species: Rabbit,Strain: New Zealand White,Sex: male and femaleNo/group: 3 animals/ sex | *Biopren® Pharaoh’s Ant Colony Eliminator (LX 125-10)*Vehicle: deionised water,███████████████████████████████████████████████████████████████████████████████ | *█████████████████████████████████████████████████████████████████*████████████████████████████████████████████████████████████████████████████████████████████ | Deviation: Examination for local toxic effects such as defatting of the skin and any systemic adverse effects was not reported as recommended in the guideline | Kuhn, J.O. (1999c) Primary dermal irritation study in rabbits. Stillmeadow, Inc., 12852 Park one drive, Sugar Land, TX 77478, USA, unpublished report no.: 4814-98 |

**Summary of human data on skin corrosion/irritation**

No human skin corrosion/irritation data is available.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Protect fáraóhangya-irtó csalétek remains unclassified as a skin irritant and requires no pictogram or hazard statements |
| Justification for the value/conclusion | ██████████████████████████████████████████████████████████████████████████████████████████████ |
| Classification of the product according to CLP and DSD | No classification is warranted |

***Eye irritation***

**Summary of *in vitro* studieson serious eye damage and eye irritation**

No *in vitro* eye irritant studies are available.

|  |
| --- |
| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group**  | **Test substance,Dose levels, Duration of exposure** | **Results** | **Remarks**  | **Reference** |
| *US EPA Guideline 81-4 and OPPTS 870.2400,**GLP: Yes,**Reliability: 1* | Species: rabbit,Strain: New Zealand White,Sex: male and female,No/group: 3 animals/ sex | *Biopren® Pharaoh`s Ant Colony Eliminator (LX 125-10),*Dose: 0.055 g/ treated eyeDuration of exposure: 24 hours | Average scores (24, 48, 72 hours) for cornea opacity, iris lesion and chemosis were 0 and for redness 0.167 Reversibility: Yes | - | Kuhn, J.O., (1999d), Primary eye irritation study in rabbits. Stillmeadow, Inc., 12852 Park One Drive Sugar Land, TX 77478, USA, unpublished report no.: 4813-98 |

**Summary of human data on serious eye damage and eye irritation**

No human eye irritation data is available.

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Protect fáraóhangya-irtó csalétek remains unclassified as an eye irritant and requires no pictogram or hazard statements |
| Justification for the value/conclusion | It was concluded that a single installation of 0.055 g Protect fáraóhangya-irtó csalétek is non-irritant to rabbit eye |
| Classification of the product according to CLP and DSD | No classification is warranted |

***Respiratory tract irritation***

|  |
| --- |
| **Data waiving** |
| Information requirement | There is no information in the assessment report of S-methoprene. |
| Justification | Only reversible eye and skin irritation were observed, so it was concluded that Protect fáraóhangya-irtó csalétek is not expected to be irritating to the respiratory tract.One of the components is classified for respiratory irritation, but its concentration is below the general concentration limit within the product. |

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method,Guideline, GLP status, . Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure**  | **Results** | **Remarks** | **Reference** |
| *US EPA Guideline 81-6 and OPPTS 870.2600,**GLP:* Yes*,*Reliability*:*1 | Species: Guinea pig,Strain: Hartley albino,Sex: male and female,No/group: Range finding study: 2 animals/ sex,Main study: 5 animals/ sex (treated group), 5 animals/ sex (naïve control) | Biopren® Pharaoh’s Ant Colony Eliminator (LX 125-10),███████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████ | ██████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████ | ████████████████████████████████████████████████████████████████████████████████████████████████████ | Kuhn, J. O. (1999e), Dermal sensitization study in guinea pigs. Stillmeadow, Inc., 12852 Park One Drive Sugar Land, TX 77478, USA, unpublished report no.: 4815-98 |

**Summary of human data on skin sensitisation**

No human skin sensitisation data is available.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Protect fáraóhangya-irtó csalétek remains unclassified as a dermal sensitiser and requires no pictogram or hazard statements |
| Justification for the value/conclusion | ██████████████████████████████████████████████████████████████ |
| Classification of the product according to CLP and DSD | No classification is warranted |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Data waiving** |
| Information requirement | There is no information in the assessment report of S-methoprene. |
| Justification | We see above that skin sensitisation was not observed, so it was concluded that Protect fáraóhangya-irtó csalétek is not expected to be a sensitizer to the respiratory tract. Furthermore, no components are classified for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

███████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████

Based on the results Protect fáraóhangya-irtó csalétek remains unclassified for acute oral toxicity and requires no pictogram or hazard statements.

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline****GLP status, Reliabilit**y | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** | **Signs of toxicity** | **ValueLD50** | **Remarks** | **Reference** |
| US EPA Guideline 81-1 and OPPTS 870.1100GLPReliability: 1 | Rat:Albino rat; HSD:SDSex: male and female No/group:5 animals / sex | Biopren® Pharaoh’s Ant Colony Eliminator; 5050 mg/kg bwSingle dose,gavage | ████████████████████████████████████████████████████████████ | > 5050 mg/kg bw | Product does not require classification | Kuhn, J. O., (1999a) |

No human data is available.

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | > 5050 mg/kg bw |
| Justification for the selected value | No mortality occurred at 5050 mg/kg bw and no significant clinical signs were observed. |
| Classification of the product according to CLP and DSD | Product is not classified. |

*Acute toxicity by inhalation*

In the acute inhalation study three female animals lost weight from day 0-7 however all animals gained weight from day 7-14. Animals showed activity decrease and piloerection but were asymptomatic by day 3.

Based on the results Protect fáraóhangya-irtó csalétek remains unclassified for acute inhalation toxicity and requires no pictogram or hazard statements.

|  |
| --- |
| **Summary table of animal studies on acute inhalation toxicity** |
| **Method,Guideline,****GLP status , Reliability** | **Species,Strain,Sex,No/group** | **Test substance, form and particle size (MMAD)****Actual and nominal concentration, Type of administration** | **Signs of toxicity** | **LC50** | **Remarks** | **Reference** |
| US EPA Guideline 81-3 and OPPTS 870.130GLPReliability: 1 | RatHSD: Sprague-DawleySex: male and female No/group:5 animals / sex | Biopren® Pharaoh’s Ant Colony Eliminator; Dust aerosol2.78 mg/LNominal concentration: 62.4 mg/LMMAD: 3.8 μmsingle dose;nose-only | █████████████████████████████████████████████████████████████████████████████████████████ | > 2.78 mg/L single dose | Product does not require classification | Bennick, J.E., (1999) |

No human data is available.

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | > 2.78 mg/L single dose |
| Justification for the selected value | ███████████████████████████████████████ 2.78 mg/L was the maximal technically attainable dose. |
| Classification of the product according to CLP | Product is not classified. |

 *Acute toxicity by dermal route*

█████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████

Based on the results Protect fáraóhangya-irtó csalétek remains unclassified for acute dermal toxicity and requires no pictogram or hazard statements.

|  |
| --- |
| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline,****GLP status,****Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** | **LD50** | **Remarks** | **Reference** |
| US EPA guideline 81-2 and OPPTS 870.1200GLPReliability 1 | Species: rabbit,Strain: New Zealand White,Sex: male and female,No/group: 5 animals/ sex | 5050 mg/kg bwSingle dose;Not less than 10% of the total body surface area | ███████████████████████████████████████████████████████████████ | > 5050 mg/kg bw | Product does not require classification | Kuhn, J. O. (1999b) |

No human data is available.

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | > 5050 mg/kg bw |
| Justification for the selected value | No mortality occurred at limit concentration 5050 mg/kg bw/d and no significant clinical signs were observed. |
| Classification of the product according to CLP and DSD | Product is not classified. |

***Information on dermal absorption***

The product corresponds to the dummy product of the active substance’s inclusion dossier. Therefore no new study was conducted and the results of the human *in vitro* percutaneous absorption test of the dossier was used in the risk assessment.

| **Summary table of in vitro studies on dermal absorption** |
| --- |
| **Method, Guideline,****GLP status, Reliability** | **Species, Number of skin samples tested per dose** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Remarks**  | **Reference** |
| *in vitro* human study, OECD 428GLP: yesReliability: 1 | 5 human skin samples per dose group | radiolabelled S-methopreneconcentration: 0.49%  | receptor fluid: 0.04%viable skin: 1.61%tape strips 3-5: 0.58%tape strips 6-20: 1.22%final: 3.45% | mean recovery: 98.89±2.82% | Toner, F. (2009) The In Vitro Percutaneous Absorption of Radiolabelled S-Methoprene Through Human Skin (unpublished)  |

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | S-methoprene |
| Value(s) | 5%\* |
| Justification for the selected value(s) | Difference between data points was too high (more than 25% from the mean), hence the standard deviation (1.44) is added to the measured value\*\* and rounded up, resulting in a dermal absorption of 5%. |

*\** the concentration range is valid for the product

\*\*Guidance on Dermal Absorption (EFSA, 2012)

***Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)***

The preparation does not contain any non-active substances of toxicological concern.

Denatonium benzoate, butylhydroxy-toluene and sorbic acid are present in concentrations less than 1%. The other ingredients in the product are bait base and nutrient compounds that are not classified and are expected to be of no toxicological concern.

***Available toxicological data relating to a mixture***

There are no non-active substances of concern present in the mixture. The assessment of available toxicological data and effects on human health are summarized above in section 2.2.5.10.

#### 2.2.6.2 Exposure assessment

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

Protect fáraóhangya-irtó csalétek is supplied in sealed, tamper-proof, transparent plastic bait stations. During the placement of the bait boxes they should be cut open, to allow ants to access the granules inside. During this procedure the user normally will not come into contact with the bait, but accidentally dermal exposure may occur.

Bait stations themselves are quite sturdy but a child with some effort (standing on it or using tools) may be capable to open them and may handle, mouth or ingest the bait granules.

In the particle size distribution study 98.42% of particles were greater than 250 μm and 0.62% were smaller than 106 µm. Furthermore, the product’s granules predominantly remain in the bait station. A minimal amount might escape, but aerosol or airborne dust formation is not expected in any of the reasonable worst case scenarios. The active substance is not volatile (its vapour pressure is 6.23x10-4 Pa at 20°C) therefore, inhalation exposure is not a concern.

| **Summary table: relevant paths of human exposure** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | NA\* | no | no | NA | no | no | no |
| Dermal | NA | yes | yes | NA | no | yes | no |
| Oral | NA | no | no | NA | no | yes | no |

\*The product is not used in industrial settings

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| 1. | professional application | primary: placing bait stations | professionals |
| 2. | non-professional application | primary: placing bait stations | non-professionals |
| 3. | handling by a child | secondary: touching the content of an opened bait box | bystanders |
| 4. | mouthing by a child | secondary: mouthing the content of an opened bait box | bystanders |
| 5. | ingested by a child | secondary: eating the content of an opened bait box | bystanders |

***Industrial exposure***

There is no industrial use of the product

***Professional exposure***

According to the exposure assessment in the Competent Authority Report of S-methoprene professional workers are expected to place 75 bait stations per day. Usually the box placement is done without direct contact to the bait material inside, but is some cases a few granules may leak out or the ants bring them outside and the worker touches them while gathering the used stations. As there is no generally acceptable model for this scenario, it is assumed that the professional worker comes into contact with 1% of the content of the bait station. 1% is regularly used for very small quantities in risk assessment as an expert judgement.

*Scenario 1*

| **Description of Scenario 1** |
| --- |
| The worker cuts open the bait station along the dotted line with a scissor and similar tool, removes the protective foil from the sticky pad and fastens the box along the foraging routes of the ants. He or she will handle 75 stations per day and may come into contact with 1% of the content of the boxes. Exposure is medium-term (as it was accepted in the CAR of S-methoprene). |
|  | Parameters | Value |
| ██████ | ███████████████████████████ | █████ |
| ██████████████ | ██ |
| ██████████████████ | ██ |
| █████████████████████████████ | ████ |
| █████████████████████████████████ | ██ |
| ███████████ | █████  |

**Calculations for Scenario 1**

For the detailed calculations see Annex 3.2

| **Summary table: estimated exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| Scenario 1 | Tier 1no PPE | █ | ██████ | █ | ██████ |

***Non-professional exposure***

Exposure of amateur users is similar to the professional workers’; the procedure of bait station placement is identical. The main differences are in the exposure duration (it is short-term) and the number of placed boxes. As stated in the instructions of use, 2 boxes are recommended for a 20 m2 area and 3 boxes are in the package of the product, therefore, as a reasonable worst case, it is assumed that the user will place all the three.

*Scenario 2*

| **Description of Scenario 2** |
| --- |
| The non-professional user cuts open the bait station along the dotted line with a scissor and similar tool, removes the protective foil from the sticky pad and fastens the box along the foraging routes of the ants. He or she will handle 3 stations per day and may come into contact with 1% of the content of the boxes. Exposure is short-term (as it was accepted in the CAR of S-methoprene). |
|  | Parameters | Value |
| ██████ | ███████████████████████████ | █████ |
| ██████████████ | ██ |
| ██████████████████ | █ |
| █████████████████████████████ | ████ |
| █████████████████████████████████ | ██ |
| ███████████ | █████ |

**Calculations for Scenario 2**

(For the detailed calculations see Annex 3.2)

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| Scenario 2 | Tier 1no PPE | █ | ████████ | █ | ████████ |

***Exposure of the general public***

█The worst case of secondary exposure is when a toddler is exposed to the content of a damaged bait station, either dermally or orally. In the assessment it is assumed that a 10 kg child touches the granules, puts them into his mouth or even swallows some. The product contains a bittering agent, thus lengthy mouthing or eating a large quantity is unlikely.

*Scenario 3*

| **Description of Scenario 3** |
| --- |
| A toddler touches the entire content of a bait station. Exposure is acute (short-term). |
|  | Parameters | Value |
| ██████ | ██████████████ | █████ |
| █████████████████████████████ | ████ |
| █████████████████████████████████ | ██ |
| ███████████ | █████ |

**Calculations for Scenario 3**

(For the detailed calculations see Annex 3.2)

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| Scenario 3 | Tier 1no PPE | █ | ██████ | █ | ██████ |

*Scenario 4*

| **Description of Scenario 4** |
| --- |
| A toddler transiently mouthes a portion of the content of a bait station.  |
|  | Parameters | Value |
| ██████ | ███████████████████████ | ████████████ |
| █████████████████████████████ | ████ |
| ███████████████████████████████ | ███ |
| ███████████ | █████ |

**Calculations for Scenario 4**

(For the detailed calculations see Annex 3.2)

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| Scenario 4 | Tier 1no PPE | █ | █ | ███████ | ███████ |

*Scenario 5*

| **Description of Scenario 5** |
| --- |
| A toddler ingests the entire content of a bait station.  |
|  | Parameters | Value |
| ██████ | ███████████████████████ | █████ |
| █████████████████████████████ | ████ |
| ███████████████████████████████ | ███ |
| ███████████ | █████ |

**Calculations for Scenario 5**

(For the detailed calculations see Annex 3.2)

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| Scenario 5 | Tier 1no PPE | █ | █ | ██████ | ██████ |

*Combined scenarios*

| **Summary table: combined systemic exposure from non-professional uses** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake****mg/kg bw/day** |
| █████████████ | █ | ██████ | ███████ | ███████ |

***Dietary exposure***

There is no dietary exposure of the product.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** |
| --- |
| **Scenario number** | **Exposed group****(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake****mg/kg bw/day** |
| 1. | professionals | Tier 1/no PPE | ██████ |
| 2. | non-professionals | Tier 1/no PPE | ████████ |
| 3. | bystanders | Tier 1/no PPE | ██████ |
| 4. | bystanders | Tier 1/no PPE | ███████ |
| 5. | bystanders | Tier 1/no PPE | ██████ |
| 3+4 | bystanders | Tier 1/no PPE | ██████ |

#### 2.2.6.3 Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AEL short-term | teratogenicity (rabbit) | 100 | 100 | 0.35 | 0.35 |
| AEL medium-term | 90 day repeated dose (dog) | 100 | 100 | 0.35 | 0.35 |
| AEL long-term | chronic/carcinogenicity (rat) | 21.7 | 100 | 0.35 | 0.076 |

The assessment factor is a combination of the standard factor of 10 for interspecies and another 10 for intraspecies differences. Other factors (for LOAEL-NOAEL conversion, CMR properties or other special toxicity effects) are not needed in case of S-methoprene.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 1 | Tier 1no PPE | ██ | ████ | ██████ | ████ | yes |

**Conclusion**

Placement of the biocidal product by professional users is considered safe even in the absence of personal protective equipment (gloves). It should be noted that an adult person should be exposed dermally to the full content of 33 bait boxes before reaching the AEL (one box contains 12.5 mg a.s.; 0.625 mg absorbed, which corresponds to 0.0104 mg/bw kg internal dose).

***Risk for non-professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 2 | Tier 1no PPE | ██ | ████ | ████████ | █████ | yes |

**Conclusion**

Placement of the entire content of a package (3 bait stations) is considered safe for non-professional users. Wearing any PPE is not assumed.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 3 | Tier 1no PPE | ██ | ████ | ██████ | █████ | yes |
| Scenario 4 | Tier 1no PPE | ██ | ████ | ███████ | ████ | yes |
| Scenario 5 | Tier 1no PPE | ██ | ████ | ██████ | ███ | no |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 3+4 | Tier 1no PPE | ██ | ████ | ██████ | ██ | yes |

**Conclusion**

From the human health viewpoint it is considered acceptable if a toddler touches and transiently mouthes the content of a bait station. It should be noted that a toddler should be exposed dermally to the full content of 5 bait boxes before reaching the AEL.

It is unacceptable for a child to eat the bait granules. However, this is an unlikely scenario, as the bait stations are tamper-proof and hard to open. Additionally, the granules contain a bittering agent (denatonium benzoate). Nevertheless, the label of the product should contain the phrase: Keep out of the reach of children.

### 2.2.7 Risk assessment for animal health

Protect fáraóhangya-irtó csalétek is used in areas where domestic pets are around. Cats cannot reach the bait in the stations. Dogs theoretically can chew the plastic box until the granules inside become available, but the stations are attached to the surfaces which makes access hard for them.

### 2.2.8 Risk assessment for the environment

The composition and use patterns of the product *Protect fáraóhangya-irtó csalétek* are exactly the same as the product *Biopren® Pharaoh’s Ant Colony Eliminator* evaluated during the approval of S-methoprene.

No ecotoxicological data of the product are available. The environmental effect assessment has been evaluated during the approval of the active substance. Environmental exposure of the product is expected to be negligible according to the PT18 ESD guidance. Therefore, the PEC values are effectively zero and the risk quotients for the product under the proposed use conditions are all less than one.

#### 2.2.8.1 Effects assessment on the environment

According to the CAR of S-methoprene, the PNEC for the aquatic compartment is
0.19 µg/L based on the NOEC of 0.019 mg/L for *Daphnia magna* and an assessment factor of 100. The 0.38 µg/kgwwt as PNEC for sediment is calculated using the equilibrium partitioning from PNECwater with an additional factor of 10 (logKow>5). Similarly, the equilibrium partitioning method was used with the factor of 10 for the soil compartment, thus the PNECsoil is 0.3 µg/kgwwt.

Although the logKow of S-methoprene is 6.34, the potential for bioaccumulation and secondary poisoning are improbable due to the use pattern of the product.

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

No further information is available.

***Further Ecotoxicological studies***

No further studies are required.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No further studies are required.

***Supervised trials to assess risks to non-target organisms under field conditions***

No trials are available.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No further studies are required.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No new data is available.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

The environmental exposure of the product is expected to be negligible.

***Further studies on fate and behaviour in the environment (ADS)***

|  |
| --- |
| **Summary table on further studies on fate and behaviour in the environment** |
| Method, Guideline, GLP status, Reliability | Compartment | pH | Temp [°C] | Initial TS concentra-tion, C0[mol/l] | Half-life, DT50 [d] | Re-marks | Reference |
| *compatible with OECD 307* | *soil* | *5.5-7.1* | *20±2 °C* | 0.5 mg a.s/kg dry soil | mean: 0.83 d | *Test item:**[14C]S-methoprene* | *III.A, 7.2.2.1 Feldmann, S. (2015)* |
| *compatible with OECD 308* | *water and sediment* | *average: 8.26-8.33* | *20±2 °C* | 0.059 mg/kg and 0.061 mg/kg (total system) | 0.87-1.32 d (total system, river and pond) | *Test item:**[14C]S-methoprene* | *III.A, 7.1.2.2.2 Gassen, M. (2015)* |

|  |
| --- |
| **Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment** |
| Value/conclusion | Due to the intended use of the product, the environmental exposure is expected to be negligible. |
| Justification for the value/conclusion | Due to the environmental exposure of the product being negligible these studies have not been evaluated. |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

***Leaching behaviour (ADS)***

No further studies are required.

***Testing for distribution and dissipation in soil (ADS)***

**Distribution**

No further studies are required.

**Dissipation**

| **Summary table on half lives in soil** |
| --- |
| Process | DT50 measured in test | DT50 at 12°C | Rate constant at 12°C | Remarks | Reference |
| *aerobic degradation (loamy sand)* | 0.93 d | 1.76 d | 0.39 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.2.2.1 Feldmann, S. (2015)* |
| *aerobic degradation (sandy loam)* | 0.78 d | 1.48 d | 0.47 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.2.2.1 Feldmann, S. (2015)* |
| *aerobic degradation (clay)* | 0.79 d | 1.5 d | 0.46 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.2.2.1 Feldmann, S. (2015)* |
| *aerobic degradation (silt loam)* | 0.83 d | 1.57 d | 0.44 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.2.2.1 Feldmann, S. (2015)* |

|  |
| --- |
| **Conclusion used in Risk Assessment – Distribution and dissipation in soil** |
| Value/conclusion | Due to the intended use of the product, the environmental exposure is expected to be negligible. |
| Justification for the value/conclusion | The aerobic degradation of [14C]S-methoprene was investigated in 4 soils incubated under aerobic conditions, using a study plan designed to be compatible with OECD 307. The four soils were treated with 0.5 mg S-methoprene per kg dry soil. The results showed that [14C]S-methoprene degraded very rapidly, the calculated DT50 values were between 0.78-0.93 days. The degradation products were minor and transparent, not exceeding 5.9% of the applied radioactivity at any sampling interval. A significant amount of [C14]S-methoprene was mineralised to CO2 (maximum levels of 51.1%-61.5% on day 118). |

***Testing for distribution and dissipation in water and sediment (ADS)***

**Distribution**

No further studies are required.

**Dissipation**

| **Summary table on half lives in water and sediments** |
| --- |
| Compartment /process  | DT50 measured in test | DT50 at 12°C | Rate constant at 12°C | Remarks | Reference |
| *Freshwater* |  |  |  |  |  |
| *Aerobic degradation (river)* | 0.78 d | 1.48 d | 0.47 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.1.2.2.2 Gassen, M. (2015)* |
| *Aerobic degradation (pond)* | 0.54 d | 1.02 d | 0.68 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.1.2.2.2 Gassen, M. (2015)* |
| *Freshwater sediment* |  |  |  |  |  |
| *Aerobic degradation (river)* | 3.74 d | 7.09 d | 0.1 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.1.2.2.2 Gassen, M. (2015)* |
| *Aerobic degradation (pond)* | 6.72 d | 12.74 d | 0.05 d-1 | *Test item:**[14C]S-methoprene* | *III.A, 7.1.2.2.2 Gassen, M. (2015)* |

|  |
| --- |
| **Conclusion used in Risk Assessment –distribution and dissipation in water and sediment** |
| Value/conclusion | Due to the intended use of the product, the environmental exposure is expected to be negligible. |
| Justification for the value/conclusion | The degradation of [14C]S-methoprene was investigated in two aquatic systems (river and pond) under aerobic conditions. The study is compatible with the OECD 308. The CO2 evaluation was significant, 54.9% (river) and 67.5% (pond) of the applied radioactivity were mineralised after 100 days of incubation. S-methoprene and its transient metabolites dissipated rapidly from the total system. |

***Testing for distribution and dissipation in air (ADS)***

No further studies are required.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not relevant.

**Acute aquatic toxicity (S-Methoprene)**

|  |
| --- |
| **Summary table for acute aquatic toxicity** |
| Guideline/Test method/GLP status/reliability | Species | End point | Exposure | Results | Re-marks | Refe-rence |
| Design | Duration | LC/EC0 | LC/EC50 | LC/EC100 |
| *Fish* |
| *OECD 203/GLP/2* | *Brachydanio rerio* | Mortality and sublethal effects | Static | 96 h |  | 4.26 mg/L |  |  | III.A, 7.4.1.1/01 Gáty, S. (2002c) |
| *Invertebrates* |
| *OECD 202/GLP/2* | *Daphnia magna* | Immobility |  | 48 h |  | 0.38 mg/L |  |  | III.A, 7.4.1.2/01 Gáty, S. (2002d) |
| *OECD 202,Regulation No. 404/2008/EC and EPA guideline 712-C-96-114/GLP* | *Daphnia magna* | Immobility | Semi-static | 48 h |  | 0.22 mg/L | 0.66 mg/L |  | III.A, 7.4.1.2/02 Istvan, A. (2012) |
| *Algae (growth inhibition)* | NOErC/ErC10 | EbC501 | ErC502 |  |
| *OECD 201/GLP/2* | *Selenastrum capricornutum* | Growth inhibition | Static | 72 h |  |  | 2.264 mg/L |  | III.A, 7.4.1.3/01 Hernádi, D. (2002) |
| 1 calculated from the area under the growth curve2 calculated from growth rate |

**Chronic aquatic toxicity (S-Methoprene)**

|  |
| --- |
| **Summary table for chronic aquatic toxicity** |
| Guideline/Test method /GLP status/reliability | Species | End point/ Type of test | Exposure | Results | Remarks | Reference |
| Design | Dura-tion | LOEC/NOEC/EC10 |
| *Invertebrates* |
| *OECD 211, Regulation No. 440/2008/EC and EPA guideline 212-C-96-120/GLP/1* | *Daphnia magna* | Reproduction | Semi-static | 21 days | NOEC: 0.019 mg/L |  | III.A, 7.4.3.4/01Istvan, A. (2012) |

|  |
| --- |
| **Conclusion used in Risk Assessment - Chronic Aquatic toxicity** |
| Value/conclusion | The PNEC for the aquatic compartment is 0.19 µg/L based on the NOEC of 0.019 mg/L for *Daphnia magna* and an assessment factor of 100. |
| Justification for the value/conclusion | The similar assessment of the product can be found in the CAR of S-methoprene. |

**Measured aquatic bioconcentration**

No further studies are required.

**Estimated aquatic bioconcentration**

No new data is available.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

Not relevant.

#### 2.2.8.2 Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | *PT 18* |
| Assessed scenarios | *-* |
| ESD(s) used | *OECD Series on Emission Scenario Documents, Number 18 (ENV/JM/MONO(2008)14), 17-Jul-2008, Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses* |
| Approach | *-* |
| Distribution in the environment | *-* |
| Groundwater simulation | *-* |
| Confidential Annexes | *NO*  |
| Life cycle steps assessed | *Scenario n:**Production: No**Formulation No**Use: No**Service life: No* |
| Remarks | Due to the intended use of the product, the environmental exposure of the product is expected to be negligible according to the PT18 ESD guidance. The similar assessment of the product can be found in the CAR of S-methoprene. |

***Emission estimation***

The product Protectfáraóhangya-irtó csalétek is intended to control Pharaoh ants by professional, trained professional and non-professional users. The product is to be placed indoors as a ready to use granulated bait formulation, containing 0.5% S-methoprene.

According to the PT18 ESD, environmental exposure is expected to be negligible in consequence of the intended use.

***Fate and distribution in exposed environmental compartments***

The environmental exposure of the product is expected to be negligible.

***Calculated PEC values***

There are not any PEC values calculated.

***Primary and secondary poisoning***

S-methoprene has a log Kow of 6.34. However, the indicated use of the product ensures that the primary and secondary poisoning are not expected.

#### 2.2.8.3 Risk characterisation

The biocidal product Protect fáraóhangya-irtó csalétek is intended for indoor use as a ready-to-use bait formulation. According to the ESD PT18, the emissions from the indoor use to the aquatic and terrestrial compartments are expected to be negligible. Thus, risks to the environment are acceptable for all the environmental compartments in case of indoor application of the product.

***Atmosphere***

Conclusion: In the absence of environmental exposure no risk assessment is presented.

***Sewage treatment plant (STP)***

Conclusion: In the absence of environmental exposure no risk assessment is presented.

***Aquatic compartment***

Conclusion: In the absence of environmental exposure no risk assessment is presented.

***Terrestrial compartment***

Conclusion:In the absence of environmental exposure no risk assessment is presented.

***Groundwater***

In the absence of environmental exposure no risk assessment is presented.

***Primary and secondary poisoning***

Conclusion: In the absence of environmental exposure no risk assessment is presented.

***Mixture toxicity***

Conclusion: Not relevant.

***Aggregated exposure (combined for relevant emmission sources)***

Conclusion: Not relevant.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| In the absence of environmental exposure no risk assessment is presented. |

### 2.2.9 Measures to protect man, animals and the environment

**Recommended methods and precautions concerning storage of biocidal product; shelf-life of biocidal product**

|  |
| --- |
| Shelf-life and storage: 2 years if stored in original unopened package in a dark, dry, cool and frost-free place. Keep away from feed and foodstuffs, medicines. (Date of manufacture must be shown on the label.) |

**Recommended methods and precautions concerning handling and transport**

|  |
| --- |
| Precaution: Keep out of the reach of children, do not allow use by children. The bait should be placed inaccessible to children or domestic animals. After handling, wash hands with plenty of water and soap.Safe handling: Keep away from heat, sources of ignition! Do not eat, drink or smoke during work. Wash hands after work.Transport information: Non-dangerous goods.  |

**Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.**

|  |
| --- |
| Extinguishing media: powder, CO2 , waterspray, foam.Hazards: toxic fumes may form (plastic containers).Protective equipment: self-contained respiratory protective device and protective clothing.Special hazards: Toxic gases may form during combustion.Advice for fire-fighters: wear self-contained breathing apparatus and usual protective clothes.  |

**Particulars of likely direct or indirect adverse effects**

|  |
| --- |
| No adverse effects are expected. The granules are in bait stations (blisters). The product contains an extremely bitter ingredient – denatonium benzoate – which helps prevent incidental human consumption.  |

**First aid instructions, antidotes**

|  |
| --- |
| If inhaled: Keep patient calm, remove to fresh air. Seek medical advice.After contact with skin: Wash thoroughly with soap and water.After eye contact: Rinse with plenty of water for several minutes. If irritation persists, seek medical attention.If swallowed: get medical attention if feeling unwell.Most important symptoms and effects:Inhalation: not knownEye contact: slight irritation may occurIngestion: not relevant  |

**Emergency measures to protect environment in case of accident**

|  |
| --- |
| Contain the spill, sweep spillage and transfer into waste containers for disposal. |
|  |

**Control measures of repellents or poison included in the biocidal product to prevent action against non-target organisms**

|  |
| --- |
| The granules are in bait stations (blisters). The product contains an extremely bitter ingredient – denatonium benzoate – which helps prevent incidental consumption by non-target animals.  |

**Possibility of destruction or decontamination following release in or on the following:**

**Air**

|  |
| --- |
| The granules are in bait stations (blisters) and the active substance is non-volatile, therefore release into the air is not expected.  |

**Water, including drinking water**

|  |
| --- |
| Prevent spillages from reaching surface waters or other water supplies. Contain the spill, sweep spillage and transfer into waste containers for disposal. |

**Soil**

|  |
| --- |
| Prevent spillages from reaching surface waters or other water supplies. Contain the spill, sweep spillage and transfer into waste containers for disposal.  |

**Procedures for waste management of active substance/biocidal product and if appropriate, its packaging:**

|  |
| --- |
| The bait stations should not be washed or reused.Dispose of waste products and bait stations after treatment in accordance with local requirements. If it is not contrary to official specifications, the packaging may be treated like household waste. Prevent contamination of environment by wastes. Prevent the product residues or its container from entering drains or watercourses. |

### 2.2.10 Assessment of a combination of biocidal products

The product is not intended to be used with other biocidal products.

### 2.2.11 Comparative assessment

Not relevant.

# Annexes[[1]](#footnote-1)

## List of studies for the biocidal product

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section number** | **Reference number** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | **Data protection claimed** |
| Yes | No | Yes | No |
| 2.2.2. | Study Code: 06/228-357AN | V. Laky | 2006 | Determination of the physical state, colour and odour of Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-338AN | V. Laky | 2006 | Determination of the pH value of Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-361AN | V. Laky | 2006 | Determination of the free acidity of Biopren Pharaoh’s Ant Colony Eliminator  | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-325AN | V. Laky | 2006 | Determination of the bulk densityof Biopren Pharaoh’s Ant Colony Eliminator  | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-356AN | V. Laky | 2006 | Determination of the flammabilityof Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-355AN | V. Laky | 2006 | Determination of self-ignition temperature | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code: 06/228-360AN | V. Laky | 2006 | Determination of the flowability of Biopren Pharaoh’s Ant Colony Eliminator after heat test | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code:484-160-0415 | Zs. Gaál | 2015 | Determination of accelerated storage stability of Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code:06/228-360AN | V. Laky | 2006 | Determination of flowabilityof Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code:484-178-0420 | V. Laky | 2015 | Determination of attrition resistance of Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd. |  | X | X |  |
| 2.2.2. | 2694/002-D21499 | M.L. Bates, MPhil | 2007 | Biopren Pharaoh’s Ant Colony Eliminator: Evaluation of particle size Distribution | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code:06/228-326AN | V. Laky | 2006 | Determination of the surface tension of Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.2. | Study Code:484-170-0416 | Zs. Gaál | 2016 | Determination of long-term storage stability of Biopren Pharaoh’s Ant Colony Eliminator INTERIM | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.3. | Study Code:484-100-0414 | Zs. Gaál | 2015 | Validation of the Analytical Method for determination os S-methoprén in Biopren Pharaoh’s Ant Colony Eliminator | Bábolna Bio. Ltd.  |  | X | X |  |
| 2.2.5.5. | 035.006 | Schmidt, J. | 2004. | Report on biological efficacytest of BIOPREN-BMSPharaoh Ant ColonyEliminator Bait (Unpublished) | Bábolna Bio Ltd. |  |  | x |  |
| 2.2.5.5. | 103/97 | Tajti, L.andDudas, E. | 1997. | Final report on fieldexperiment onProtect-B Pharaoh antkiller bait | Bábolna Bio Ltd. |  |  | x |  |
| 2.2.5.5. | 169.001-169-006 | Schmidt, J. | 2016.  | Report on efficacy of Protect fáraóhangya-irtó csalétek after 3,5- 4 years of storage | Bábolna Bio Ltd |  |  | x |  |
| 2.2.5.5. | BB/001/2003 | Lee, C.Y. | 2003. | Evaluation of methoprene bait formulations against the Pharaoh’s ant | Bábolna Bio Ltd |  |  | x |  |
| 2.2.5.5. |  | Buijs, J. and Rawart, V. | 2004 | Pharaoh’s Ant Control with S-Methoprene – Dutch Field Testing | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no.: 4810-98, | Kuhn, J. O.  | 1999a  | Acute Oral Toxicity Study in Rats. Stillmeadow, Inc., GLP (unpublished)  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no.: 4811-98, | Kuhn, J. O.  | 1999b  | Acute Dermal Toxicity Study in Rabbits. Stillmeadow, Inc., GLP (unpublished)  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | report no.: 4812-98, | Bennick, J.E.  | 1999  | Acute Inhalation Toxicity Study in Rats. Stillmeadow, Inc., GLP (unpublished)  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no.: 4813-98, | Kuhn, J.O.  | 1999c  | Primary Eye Irritation Study in Rabbits. Stillmeadow, Inc., GLP unpublished  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no.: 4814-98, | Kuhn, J.O.  | 1999d  | Primary Dermal Irritation Study in Rabbits. Stillmeadow, Inc., GLP (unpublished)  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no.: 4815-98, | Kuhn, J. O.  | 1999e  | Dermal Sensitization Study in Guinea Pigs. Stillmeadow, Inc., USA, GLP (unpublished)  | Bábolna Bio Ltd |  |  | X |  |
| 2.2.5.10. | Report no. 30885 | Toner, F  | 2009  | The In Vitro Percutaneous Absorption of Radiolabelled S-Methoprene Through Human Skin. Charles River, (Unpublished)  | Bábolna Bio Ltd |  |  | X |  |

## Output tables from exposure assessment tools

Calculations for human exposure assessment:

|  |
| --- |
| **Scenario 1 – Professional exposure** |
| ███████████████████████████ | █████ |
| ██████████████████ | ██ |
| ██████████████ | █████████████ |
| █████████████████████████████ | ████ |
| ██████████████████████████████ | ████████ |
| █████████████████████████████████ | ██ |
| █████████████████ | ██████████ |
| ███████████ | ██████ |
| ██████████████ | ██████████████████████ |
|  |
| **Scenario 2 – Non-professional exposure** |
| ███████████████████████████ | █████ |
| ██████████████████ | █ |
| ██████████████ | ██████████ |
| █████████████████████████████ | ████ |
| ██████████████████████████████ | ████████ |
| █████████████████████████████████ | ██ |
| █████████████████ | ██████████ |
| ███████████ | ██████ |
| ██████████████ | ██████████████████████ |
|  |
| **Scenario 3 – Toddler touches the content of a bait station**  |
| ██████████████ | █████ |
| █████████████████████████████ | ████ |
| ██████████████████████████████ | ███████ |
| █████████████████████████████████ | ██ |
| █████████████████ | ████████ |
| ███████████ | █████ |
| █████████████ | ███████████████████ |
|  |  |
| **Scenario 4 – Toddler puts the content of a bait station in its mouth** |
| ███████████████████████ | ██████ |
| █████████████████████████████ | ████ |
| █████████████████████████ | ███████ |
| ███████████████████████████████ | ███ |
| █████████████████ | ████████ |
| ███████████ | █████ |
| ██████████████ | ███████████████████ |
|  |  |
| **Scenario 5 – Toddler eats the content of a bait station** |
| ███████████████████████ | █████ |
| █████████████████████████████ | ████ |
| █████████████████████████ | ███████ |
| ███████████████████████████████ | ███ |
| █████████████████ | ████████ |
| ███████████ | █████ |
| ██████████████ | ███████████████████ |

## New information on the active substance

III.A, 7.2.2.1, Feldmann, S. (2015), S-methoprene: Degradation and Metabolism in Four Soils of [14C]S-methoprene Incubated under Aerobic Conditions. Harlan Laboratories Ltd., Zelgliweg 1, 4452 Itigen / Switzerland, unpublished report no.: D93717, Owner of data: Bábolna Bio. Ltd., Letter of Access: No, Data protection claimed: Yes

III.A, 7.1.2.2.2, Gassen, M. (2015), S-Methoprene: Route and Rate of Degradation of [14C]S-Methoprene in Aerobic Aquatic Sediment Systems. Harlan Laboratories Ltd., Zelgliweg 1, 4452 Itingen / Switzerland, unpublished report no.: D93728, Owner of data: Bábolna Bio. Ltd., Letter of Access: No, Data protection claimed: Yes

## Residue behaviour

**-**

## Summaries of the efficacy studies (B.5.10.1-xx)[[2]](#footnote-2)

Summaries of the efficacy studies are listed in the respective IUCLID file.

References can be found in Annex 3.1.

## Confidential annex

Confidential annex

| **███████████** | **██████████** | **████████** | **██████████** | **█████████** | **██████████████** |
| --- | --- | --- | --- | --- | --- |
| **████████████** | **█████████████████████████████████████████████████████████████████████** | **████████████████** | **██████████** | **█████████** | **█████** |
| ███████████████████ | ███████████████████████████████████████████████████████████████████████████████████████ | ███████████████ | █████████ | █████████ | █████ |
| ████████████████ | ████████████████ | ███████ | ███████ | █████████ | █████ |
| ██████████████████████████ | ████████████████████████████████ | ███████████ | ████████ | █████████ | █████ |
| █████████████ | █ | ███████ | █████████ | █████████ | █████ |
| ███████████ | █████████████████████ | ████████████ | ████████ | █████████ | █████ |
| █████ | █ | ████████ | ████████ | █████████ | ██████ |
| ██████████████████ | █ | ████████ | ███████ | █ | ██████ |
| ██████████████ | █ | ███████ | ███████ | █ | ██████ |
| **█████** |  | ███ |

NB: This information is confidential and should not be disclosed to third parties

**Qualitative and quantitative information on the composition of Protect fáraóhangya-irtó csalétek**

1. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-1)
2. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-2)