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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION**

(Submitted by the evaluating Competent Authority)



MAGNET GEL SILVERFISH

Product type(s) 19

D-Fructose as included in the Annex I

of Regulation (EU) No 582/2012

Case Number in R4BP: BC-AA082142-72

evaluating Competent Authority: Greece

Date: September 2023

Table of Contents

[1 Conclusion 5](#_Toc140661498)

[2 Information on the biocidal product 9](#_Toc140661499)

[2.1 Product type(s) and type(s) of formulation 9](#_Toc140661500)

[2.2 Uses 9](#_Toc140661501)

[2.3 Identity and composition 11](#_Toc140661502)

[2.4 Identity of the active substance(s) 11](#_Toc140661503)

[2.5 Information on the source(s) of the active substance(s) 11](#_Toc140661504)

[2.6 Candidate(s) for substitution 11](#_Toc140661505)

[2.7 Assessment of the endocrine-disrupting properties of the biocidal product 11](#_Toc140661506)

[2.8 Classification and labelling 12](#_Toc140661507)

[2.9 Letter of access 12](#_Toc140661508)

[2.10 Data submitted in relation to product authorisation 12](#_Toc140661509)

[2.11 Similar conditions of use across the Union 12](#_Toc140661510)

[3 Assessment of the biocidal product 13](#_Toc140661511)

[3.1 Packaging 13](#_Toc140661512)

[3.2 Physical, chemical, and technical properties 15](#_Toc140661513)

[3.3 Physical hazards and respective characteristics 22](#_Toc140661514)

[3.4 Methods for detection and identification 24](#_Toc140661515)

[3.5 Assessment of efficacy against target organisms 27](#_Toc140661516)

[3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected) 27](#_Toc140661517)

[3.5.2 Mode of action and effects on target organisms, including unacceptable suffering. 27](#_Toc140661518)

[3.5.3 Efficacy data 28](#_Toc140661519)

[3.5.4 Efficacy assessment 30](#_Toc140661520)

[3.5.5 Conclusion on efficacy 30](#_Toc140661521)

[3.5.6 Occurrence of resistance and resistance management 31](#_Toc140661522)

[3.5.7 Known limitations 31](#_Toc140661523)

[3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products 31](#_Toc140661524)

[3.6 Risk assessment for human health 31](#_Toc140661525)

[3.6.1 Assessment of effects on human health 31](#_Toc140661526)

[3.6.1.1 Skin corrosion and irritation 32](#_Toc140661527)

[3.6.1.2 Eye irritation 32](#_Toc140661528)

[3.6.1.3 Respiratory tract irritation 33](#_Toc140661529)

[3.6.1.4 Skin sensitization 33](#_Toc140661530)

[3.6.1.5 Respiratory sensitization 34](#_Toc140661531)

[3.6.1.6 Acute oral toxicity 34](#_Toc140661532)

[3.6.1.7 Acute inhalation toxicity 35](#_Toc140661533)

[3.6.1.8 Acute dermal toxicity 35](#_Toc140661534)

[3.6.2 Information on dermal absorption 36](#_Toc140661535)

[3.6.3 Available toxicological data relating to substance(s) of concern 36](#_Toc140661536)

[3.6.4 Other 36](#_Toc140661537)

[3.6.5 Available toxicological data relating to endocrine disruption 36](#_Toc140661538)

[3.6.6 Exposure assessment and risk characterisation for human health 36](#_Toc140661539)

[3.6.7 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product 37](#_Toc140661540)

[3.6.8 Overall conclusion on risk assessment for human health 37](#_Toc140661541)

[3.7 Risk assessment for animal health 37](#_Toc140661542)

[3.8 Risk assessment for the environment 37](#_Toc140661543)

[3.9 Assessment of a combination of biocidal products 37](#_Toc140661544)

[3.10 Comparative assessment 37](#_Toc140661545)

[4 Appendices 38](#_Toc140661546)

[4.1 Calculations for exposure assessment 38](#_Toc140661547)

[4.2 New information on the active substance(s) and substance(s) of concern 38](#_Toc140661548)

[4.3 List of studies for the biocidal product 38](#_Toc140661549)

[4.4 References 38](#_Toc140661550)

[4.4.1 References other than list of studies for the biocidal product 38](#_Toc140661551)

[4.4.2 Guidance documents 38](#_Toc140661552)

[4.4.3 Legal texts 38](#_Toc140661553)

[4.5 Confidential information 38](#_Toc140661554)

**Changes history table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | EL | BC-AA082142-72 | 06.10.2023 | Initial assessment |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

# Conclusion

MAGNET GEL SILVERFISH is an attractant - (ready for use)biocidal product containing D-Fructose as active substance. The product is used as a PT 19 by non-professional, professional and trained professional users for the control of silverfish.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses #1 and #2 by non-professional, professional and trained professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance(s) D-Fructose is listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that exclude D-Fructose that is not food or feed;
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification of the biocidal product MAGNET GEL SILVERFISH according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is not necessary.

The biocidal product does not contain any non-active substances (so called “co-formulants”) which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.The biocidal product does not contain any active substances having endocrine-disrupting properties. In addition, based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product. More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains D-Fructose which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

**Conclusions of the assessments for each area**

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR. The long-term storage stability study is ongoing and requested as a post-authorization condition when completed (see table 1 below).

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance D-Fructose in the product Magnet Gel Silverfish is available. More information on the analytical method for the active substance is available in section 3.4 of the PAR.

Validated analytical methods are not required for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

Based on the results of the submitted efficacy data, the product was effective when applied by professional, trained professional and non-professional users as:

Gel in syringes/ cartridges with sticky traps indoors at 0.2g/ sticky trap/ 1.5m2. (Intended Use #1)

- The product increases the efficacy of the sticky trap.

- The product controls the infestation in approximately 2 weeks after application.

- The product is effective when applied up to 2 weeks after opening.

Gel in capsules with sticky substance indoors at 0.5g/ 4.5 m2 floor surface. (Intended Use #2)

- The product increases the efficacy of the re-usable bait station.

- The product controls the infestation in approximately 2 weeks after application.

- The product is effective when applied up to 2 weeks after opening.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

The biocidal product MAGNET GEL SILVERFISH is not classified for human health hazards according to Regulation (EC) No. 1272/2008 (CLP).

Furthermore, the product does not contain any substance of concern (SoC) in accordance with the guidance CA-Nov14-Doc.5.11, which defines the criteria for the identification of SoC.

In addition, the handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

Therefore, based on the above, MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012 and hence a detailed human health exposure assessment is not required according to the information provided in Article 20.1(b) of the Regulation (EU) No. 528/2012.

Dietary risk assessment

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012. A detailed dietary risk assessment is therefore not required according to the information provided in Article 20.1(b) of the Regulation (EU) No. 528/2012.

Risk assessment for animal health

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012. A detailed exposure assessment is therefore not required according to the information provided in Article 20.1(b) of the Regulation (EU) No. 528/2012.

Risk assessment for the environment

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the BPR. Detailed exposure assessments are therefore not required in accordance with Article 20(b)(1) of the BPR.

The only component classified for environmental hazards (H411) is XXXXXXXXXXXXX but according to summation method the product in NOT classified for the environment.

**Post-authorisation conditions**

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

|  |  |
| --- | --- |
| **Description** | **Due date** |
| Staorage stability test – Long-term storage at ambient temperature for syringe and capsule packaging materials. | Expected time of finalisation of experimental phase of 48 months is September 2026, with interim reports at 12, 24 and 36 months.24 months interim report should be provided as soon as available (i.e., October 2024). |

# Information on the biocidal product

## Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

|  |  |
| --- | --- |
| **Product type(s)** | PT-19: Repellents and attractants |
| **Type(s) of formulation** | GD – Gel for direct application |

## Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use number1** | **Use description2** | **PT3** | **Target organisms4** | **Application method5** | **Application rate6** **(min-max)** | **User category7** | **Conclusion****(eCA/ refMS)8** | **Comment (eCA/refMS)9** |
| 1  | Attractant for silverfishes. | PT19 | *Lepisma saccharina -* Common silverfish – Adults and nymphs | Gel attractant with sticky cardboard traps | Apply 0.2 gr of product (4 drops) per sticky cardboard trap. Place one trap each 1.5 m2 of floor surface.Frequency of treatment: Once full, replace the trap with a new one. | General public (non-professional)ProfessionalTrained professional | A*(Acceptable)* | EfficacyThe product controls the infestation in approximately 2 weeks after application.The product is effective when applied up to 2 weeks after opening. |
| 2 | Attractant for silverfishes. | PT19 | *Lepisma saccharina -* Common silverfish – Adults and nymphs | Ready-to-use capsules in re-usable bait stations | One capsule containing 0.5 g per 4.5 m2 of floor surface.Frequency of treatment: Once full, remove the cup from the bait station and replace with a new one. | General public (non-professional)ProfessionalTrained professional | A*(Acceptable)* | EfficacyThe product controls the infestation in approximately 2 weeks after application.The product is effective when applied up to 2 weeks after opening. |

1 Use number (as applied for), as indicated in the SPC

2 Title of the specific use (as applied for), as indicated in the SPC

3 Product type(s) of the use(s)

4 Target organisms, group of organisms

5 Application method for the specific use

6 Min-max. application rate of the product for the specific use

7 User categor(y/ies), e.g. general public, non-professional, professional, industrial

8 eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

*Codes for indicating the acceptability for each use*

|  |  |
| --- | --- |
| A | Acceptable |
| R | Acceptable with further restriction or risk mitigation measures (RMM) |
| N | Not acceptable |

9 If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

## Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product evaluated in connection with the inclusion of the active substance in Annex I of Regulation (EU) No 528/2012, is not applicable.

MAGNET GEL SILVERFISH contains 6% (technical content) D-Fructose as active substance which is included into Annex I (cat. 4) of the BPR. The active substance also meets the specified restrictions in the respective Commission Delegated Regulations.

MAGNET GEL SILVERFISH does not contain any substance of concern or nanomaterials.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

## Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | Fructose |
| **Chemical name** | D-Fructose |
| **EC number** | 200-333-3 |
| **CAS number** | 57-48-7 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | ≥99.5%Excluding D-fructose that is not food or feed. |
| **Structural formula** |  |

## Information on the source(s) of the active substance(s)

The information on the source of the active substance is not applicable for simplified authorisation.

## Candidate(s) for substitution

D-Fructose does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. It is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

## Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

## Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

|  | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | None | None |
| **Hazard Pictograms** | None | None |
| **Signal word(s)**  | None | None |
| **Hazard statements** | None | None |
| **Precautionary statements\*** | None | None |
| **Supplemental hazard statements** | None |
| **Notes** | None |

##

## Letter of access

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR (category 4). The applicant is the owner of all submitted data.

## Data submitted in relation to product authorisation

No new data on the active substance has been submitted.

## Similar conditions of use across the Union

This section is not relevant.

# Assessment of the biocidal product

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic syringe | 1, 2, 3, 4, 5, 8, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 g | LDPE | cap, HDPE | General public (non-professional)ProfessionalTrained professional | Yes |
| Plastic tube  | 1, 2, 3, 4, 5, 8, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 g  | LDPE/HDPE | cap, PP | General public (non-professional)ProfessionalTrained professional | Yes |
| Plastic cartridge  | 1, 2, 3, 4, 5, 8, 10, 15, 20, 25, 30, 35, 40 50, 60, 75, 80, 100, 125, 175, 200, 250, 300, 350, 400, 450 and 500g  | PP | Cap, HDPE | Only professional and trained professional  | Yes |
| Pre-filled capsule | 0.5 g | PET-PE | Lid, Aluminium | General public (non-professional)ProfessionalTrained professional | Yes |
| * Secondary packaging for all types of packaging: Cardboard box
* Square cardboard traps or corner cardboard traps supplied with the plastic syringe, plastic tube and plastic cartridge.
* Re-usable bait station supplied with the pre-filled capsule.
 |

Below are representative pictures of the packaging proposed.

|  |  |
| --- | --- |
|  |  |
| Plastic syringe | Plastic cartridge |
|  |  |
|  |  |
| Plastic tube | Pre-filled capsule |

|  |
| --- |
| **Conclusion on the packaging of the biocidal product** |
| Syringe, cartridge and tubeAn acceptable accelerated storage stability test for 14 days at 54°C (in syringe) demonstrated compatibility with the packaging material LDPE. According to BPR Guidance Volume I Parts A+B+C, for water based formulations, extrapolation to all types of packaging is considered acceptable apart for metal. In addition, extrapolation between different packaging sizes of the same material is also acceptable. Therefore, the above-mentioned proposed packaging for syringes, cartridges and tubes are considered acceptable for commercial use.CapsuleCapsule packaging material is heat sensitive, as also confirmed by the accelerated study conducted for 14 days at 54°C. However, an acceptable accelerated storage stability test for 18 weeks at 30°C, demonstrated compatibility with the packaging material PET-PE (lid-aluminium). Therefore, the above-mentioned proposed packaging for capsule is considered acceptable for commercial use with labelling “Keep the capsules away from heat or direct sunlight and at a maximum temperature of 30°C”. |

## Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| - | Active ingredient content | SANCO 3030/99 rev5 | D-Fructose 6% GELBatch GSF-89c  | 5.95 ±0.074 % w/w | XXXXXXXXXXXXXXXXXXXXXX |
| 3.1. | Appearance at 20 °C and 101.3 kPa | Visual inspection (OPPTS 830.6303) | D-Fructose 6% GELBatch GSF-89c | Gel  | XXXXXXXXXXXXXXXXXXXXXX |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa | ASTM D 4359-90(non-GLP) | D-Fructose 6% GELBatch GSF-89c | Magnet Gel Silverfish can be considered as a liquid, since all the product came out immediately when the can was put upside down | XXXXXXXXXXXXX XXXXXXXXXXX |
| 3.1.2. | Colour at 20 °C and 101.3 kPa | Visual inspection (OPPTS 830.6302) | D-Fructose 6% GELBatch GSF-89c | Brown  | XXXXXXXXXXXXXXXXXXXXXX |
| 3.1.3. | Odour at 20 °C and 101.3 kPa | Visual inspection (OPPTS 830.6304) | D-Fructose 6% GELBatch GSF-89c | Nutty odour | XXXXXXXXXXXXXXXXXXXXXX |
| 3.2. | Acidity, alkalinity and pH value | CIPAC MT 75.3 | D-Fructose 6% GELBatch GSF-89c  | Acidity and alkalinity are not required, pH>4 and <10. pH: neat=6.29 1%=7.17 | XXXXXXXXXXXXXXXXXXXXXX |
| 3.3. | Relative density / bulk density | A.3/OECD 109 | D-Fructose 6% GELBatch GSF-89c | 20 °C = 1.3250 g/mL40 °C = 1.3247 g/mL | XXXXXXXXXXXXXXXXXXXXXX |
| 3.4.1.1 | Storage stability test – **accelerated storage (14d at 54ºC)** | CIPAC MT 46.4 | D-Fructose 6% GELBatch GSF-89c (syringe) | 14d at 54ºCThe physical-chemical properties investigated before and after accelerated storage were comparable,and are in compliance with the requirement of the appropriate clauses. The type of packaging (Syringe) is suitable for the formulation. | XXXXXXXXXXXXXXXXXXXXXX |
| Active ingredient content | HPLC-ELSD | Initially: 5.95 ± 0.074 % w/wAfter 14d at 54ºC: 6.03 ± 0.090 % w/w.  |
| Appearance | Visual inspection (OPPTS 830.6303) | AppearanceInitially: Brown gel with nutty odourAfter 14d at 54ºC: UnchangedStability of packagingInitially: Intact, no leaks, nodamages. Original packaging: Syringe 2/5: 141.50 gAfter 14d at 54ºC: Unchanged. Weight change: Syringe 2/5: -0.34 g |
| Acidity/alkalinity pH | CIPAC MT 75.3CIPAC MT 191 | Acidity/Alcalinity not required.Required only if pH <4 or >10pH neatInitially: 6.29After 14d at 54ºC: 5.84pH 1%Initially: 7.17After 14d at 54ºC: 6.89 |
| Homogeneity of application | Internal Method | Initially: Spot: 34.1 mg/spotLine: 220.4 mg/lineAfter 14d at 54ºC: Spot: 36.7 mg/spotLine: 156.9 mg/line |
| 3.4.1.2 | Storage stability test – **accelerated storage (14d at 54ºC)** | CIPAC MT 46.4 | D-Fructose 6% GELBatch GSF-89c (capsule) | 14d at 54ºCThe product is stable according to the analysis and results of the Accelerated storage performed in syringes, but the capsules did not resist the high temperatures. It is recommended to keep the capsules away from heat or direct sunlight and at a maximum temperature of 30ºC. | XXXXXXXXXXXXXXXXXXXXXX |
| Active ingredient content | HPLC-ELSD | Initially: 6.13 w/w ±0.160 After 14d at 54ºC:5.98 w/w±0.111 |
| Appearance | Visual inspection (OPPTS 830.6303) | AppearanceInitially: brown gel with nutty odour.After 14d at 54ºC: the gel was dry in all the stored capsules.Stability of packagingInitially: Intact, no leaks, no damages.Original packaging: package 2/8: 19.91 g, package 3/8: 16.95 gAfter 14d at 54ºC:the sticky substance came out of the capsule. The gel remained in the centrale compartment. Weight change: package 2/8: -1.08 gPackage 3/8: -0.88 g |
| Acidity/alkalinity pH | CIPAC MT 75.3CIPAC MT 191 | pH neatInitially: 6.29After 14d at 54ºC: 5.84pH 1%Initially: 7.17After 14d at 54ºC: 6.89Acidity/alkalinity is not required. Required only if pH <4 or >10. |
| 3.4.1.3 | Storage stability test – **accelerated storage (18 weeks at 30ºC)** | CIPAC MT 46.4 | D-Fructose 6% GELBatch GSF-89c (capsule) | 18 weeks at 30ºCThe stability study conducted at 54ºC for 14 days concluded that the capsule is heat-sensitive. A new study was conducted at 30ºC for 18 weeks. | XXXXXXXXXXXXXXXXXXXXXX |
| Active ingredient content | HPLC-ELSD | Initially: 6.13 w/w ±0.160 After 18 weeks at 30ºC:6.15 w/w±0.331 |
| Appearance | Visual inspection (OPPTS 830.6303) | AppearanceInitially: brown gel with nutty odour.After 18 weeks at 30ºC: UnchangedStability of packagingInitially: Intact, no leaks, no damages.Original packaging: package 6/8: 18.99 g, package 7/8: 19.37 gAfter 18 weeks at 30ºC:Unchanged. Weight change: package 6/8: -0.54 gPackage 7/8: -0.35 g |
| Acidity/alkalinity  | CIPAC MT 75.3CIPAC MT 191 | pH neatInitially: 6.29After 18 weeks at 30ºC: 6.22pH 1%Initially: 7.17After 18 weeks at 30ºC: 7.00Acidity/alkalinity is not required. Required only if pH <4 or >10. |
| 3.4.1.4 | Storage stability test – **long-term storage at ambient temperature** | CIPAC MT 46.4 | D-Fructose 6% GELBatch GSF-89c (Syringe) | The study is being conducted.48 months at ambient temperature | XXXXXXXXXXXXXXXXXXXXXX |
| Active ingredient content  | HPLC-ELSD | Initially: 5.95 ± 0.074 % w/wAfter 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| Appearance  | Visual inspection (OPPTS 830.6303) | Initially: brown gel with nutty odour.After 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| Acidity/alkanity | CIPAC MT 75.3CIPAC MT 191 | Initially: 6.29 (neat), 7.17 (1%)After 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| Homogeneity of application | Inthernal method | Initially: Spot: 34.1 mg/spotLine: 220.4 mg/lineAfter 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| 3.4.1.5 | Storage stability test – **long-term storage at ambient temperature** | CIPAC MT 46.4 | D-Fructose 6% GELBatch GSF-89c (capsule) | The study is being conducted.48 months at ambient temperature | XXXXXXXXXXXXXXXXXXXXXX |
| Active ingredient content  | HPLC-ELSD | Initially: 6.13 w/w ±0.160% w/wAfter 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| Appearance  | Visual inspection (OPPTS 830.6303) | Initially: brown gel with nutty odour.After 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| Acidity/alkanity | CIPAC MT 75.3CIPAC MT 191 | Initially: 6.29 (neat), 7.17 (1%)After 12m: PendingAfter 24m: PendingAfter 36m: PendingAfter 48m: Pending |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | Waived - No study performed.According to the Guidance on the BPR Vol I Parts A+B+C (May 2018), the following restriction “Protect from frost” should be added to the label if no low temperature stability test for liquids is performed. |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** | The storage stability studies were conducted in syringes and capsules at accelerated conditions (54ºC, artificial light, no humidity) and at ambient conditions (ambient temperature, light and humidity) and no effects on content of the active substance and technical characteristics of the biocidal product were observed. |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | The storage stability studies were conducted in syringes and capsules at accelerated conditions (54ºC, artificial light, no humidity) and at ambient conditions (ambient temperature, light and humidity) and no effects on content of the active substance and technical characteristics of the biocidal product were observed. |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | The storage stability studies were conducted in syringes and capsules at accelerated conditions (54ºC, artificial light, no humidity) and at ambient conditions (ambient temperature, light and humidity) and no effects on content of the active substance and technical characteristics of the biocidal product were observed. |
| 3.5.1. | Wettability  | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.3. | Wet sieve analysis and dry sieve test | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.5. | Disintegration time | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability  | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.7. | Persistent foaming | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.8. | Flowability/pourability/dustability | Waived - Not applicable. The product is a ready-to-use gel. |
| 3.5.9. | Burning rate — smoke generators | Waived - Not applicable. The product is not a smoke generator. |
| 3.5.10. | Burning completeness — smoke generators | Waived - Not applicable. The product is not a smoke generator. |
| 3.5.11. | Composition of smoke — smoke generators | Waived - Not applicable. The product is not a smoke generator. |
| 3.5.12. | Spraying pattern — aerosols / spray | Waived - Not applicable. The product is not an aerosol. |
| 3.6.1. | Physical compatibility | Waived - Not applicable. The product is not intended to be applied in combination with other chemical products. |
| 3.6.2. | Chemical compatibility | Waived - Not applicable. The product is not intended to be applied in combination with other chemical products. |
| 3.7. | Degree of dissolution and dilution stability | Waived - Not applicable. The product is not intended to be diluted. |
| 3.8. | Surface tension | EC A.5/OECD 115 | D-Fructose 6% GELBatch GSF-89c | 1 g/L dilution at 25 °C: 65.1 mN/m  | XXXXXXXXXXXXXXXXXXXXXX |
| 3.9. | Viscosity | OECD 114 | D-Fructose 6% GELBatch GSF-89c | Kinematic (mm2/s)20 °C = 74149.140 °C = 32789.4Dynamic (mPa·s)20 °C = 98250.040 °C = 43437.5 | XXXXXXXXXXXXXXXXXXXXXX |

Table 3.3 Conclusion on physical, chemical, and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| Magnet Gel Silverfish is a brown liquid with nutty odour. Its pH is 6.29 and its density is around 1.3250 g/cm3 at 20ºC. The product has a superficial tension of 65.1 mN/m (1 g/L dilution) at 25ºC and a dynamic viscosity of 98250.0 mPa·s at 20ºC. After storage at 54°C for 14 days (for syringe) and at 30ºC for 18 weeks (for capsules), the test item did not show any significant difference in terms of active ingredient content and physico-chemical properties, compared to the initial conditions. The long-term storage stability study at ambient temperature is ongoing and should be submitted when completed, to confirm the proposed shelf-life of the biocidal product **(post authorization data requirement)**. However, the results from acceptable accelerated storage stability test indicate that the biocidal product Magnet Gel Silverfish is anticipated to be stable for up to two years when stored in its initial commercial packaging.The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.**Implications for labelling:** Store in the original container tightly closed. Store in a cool and dry place. Protect from the frost.Only for the capsule: Keep the capsules away from heat or direct sunlight and at a maximum temperature of 30ºC. |

## Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product / batch (AS% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | Manual of Tests and Criteria-United Nations, 2019 ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3 | MAGNET GEL SILVERFISH6.0% d-Fructose | Total heat of decomposition = -172 J/gCritera for classification as a UN Class 1 (lower than -500 J/g) not met. | XXXXXXXXXXXXXXXXXXXXXX |
| 4.2. | Flammable gases | - | - | Waived - Not relevant because the product is a liquid.  |  |
| 4.3. | Flammable aerosols | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.4. | Oxidising gases | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.5. | Gases under pressure | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.6. | Flammable liquids | Method A.9 of Council Regulation (EC) No 440/2008 and ISO EN 3680 | MAGNET GEL SILVERFISH6.0% d-Fructose | Flash point not observed up to 190ºC (the test item boiled).Criteria for classification as flammable liquid (<60ºC) not met. | XXXXXXXXXXXXXXXXXXXXXX |
| 4.7. | Flammable solids | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.8. | Self-reactive substances and mixtures | - | - | Waived – The exothermic heat of decomposition of the product is less than 300 J/g  |  |
| 4.9. | Pyrophoric liquids | - | - | Waived - The liquid does not ignite spontaneously on coming into contact with air at normal temperatures. |  |
| 4.10. | Pyrophoric solids | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.11. | Self-heating substances and mixtures | - | - | Waived - Not relevant because the product is a liquid. The phenomenon of self-heating applies only to solids or liquids adsorbed on larges surfaces. |  |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | - | - | Waived – The product contains water in its composition and forms a stable mixture. |  |
| 4.13. | Oxidising liquids | Test O.2 (Part III, sub-section 34.4.2 of the Manual of Tests and Criteria-United Nations, 2019 | MAGNET GEL SILVERFISH6.0% d-Fructose | Mean pressure rise time:65% Nitric Acid : Cellulose (1:1) = 3829 msTest item : Cellulose (1:1) = 12581 msCriteria for classification as oxidising liquid (< mean pressure rise time of the reference substance) not met. | XXXXXXXXXXXXXXXXXXXXXX |
| 4.14. | Oxidising solids | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.15. | Organic peroxides | - | - | Waived - Not relevant because the product does not fall under the definition of organic peroxides. |  |
| 4.16. | Corrosive to metals | UN Test C.1, Section 37, Manual of Tests and Criteria-United Nations, 2019 | MAGNET GEL SILVERFISH6.0% d-Fructose | SteelFully immersed – 0.00% weight loss. No corrosion observed.50% immersion – 0.00% weight loss. No corrosion observed.Over – 0.00% weight loss. No corrosion observed.AluminiumFully immersed – 0.00% weight loss. No corrosion observed.50% immersion – 0.00% weight loss. No corrosion observed.Over – 0.00% weight loss. No corrosion observed. | XXXXXXXXXXXXXXXXXXXXXX |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | - | - | Waived - The liquid does not ignite spontaneously on coming into contact with air at normal temperatures. Furthermore, flash point was not observed up to 190ºC in which the test was stopped because the mixture violently boiled, therefore no flash point is expected below 200ºC. |  |
| 4.17.2. | Relative self-ignition temperature for solids | - | - | Waived - Not relevant because the product is a liquid. |  |
| 4.17.3. | Dust explosion hazard | - | - | Waived - Not relevant because the product is a liquid. |  |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| The product has no classification according to CLP criteria for physical hazards, in line with the criteria for simplified authorisation. |

## Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities, and residues** |
| Principle of the method[XXXXXXXXXXX]:HPLC-ELSDxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| **Analyte** (type of analyte e.g. active substance) | **Linearity** | **Specificity** | **Fortification range, level and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of Quantification LOQ** *– only for impurity* | **Reference** |
| Level | Number of measurements | Mean | RSD | Concentration tested | Number of replicates |
| D-fructose | Conc. Range0.1843-0.3482 mg/mL4,61-8,70 % w/w1Calibration functionSlope 2038,2578Intercept-216,4161R2=0.9992 | No interference | 0.2458 mg/ml | n=2 | 107.5 | 2.33 | 5.95+- 0.074 | 5 | Not relevant | XXXXXXXXXXXXXXXXXXXXXX |

Table 3.7 Analytical methods for soil, air, water, animal and human body fluid and tissues, for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring, soil, air, water, animal and human body fluids and tissues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

Table 3.8 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification**  |
| Analytical method following SANCO/3030/99for the determination of D-fructose in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable.The retention time of active ingredient in the test item solution matched the retention time in the reference item solution; the placebo showed no interference. The relative standard deviation for the active ingredient determined was within the proposed acceptability assessed by Horwitz equation. Active ingredient concentration in sample solutions was within the linear range of the detector response.The data presented in this report demonstrate that the analytical method provides a specific, reliable, accurate and precise procedure for the determination of active ingredient D-fructose in biocidal product Magnet Gel Silverfish.Analytical methods for monitoring, soil, air, water, animal and human body fluids and tissues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations. |

## Assessment of efficacy against target organisms

### Function (organisms to be controlled) and field of use (products or objects to be protected)

Magnet Gel Silverfish is an attractant for silverfish (PT-19: Repellents and attractants) to be used indoors (Private houses and commercial buildings). It is intended for *Lepisma saccharina* – Common silverfish – Adults and nymphs.

Silverfish become a nuisance during winter and humid periods. The product attracts the insects into a sticky trap. Once inside, the trapped silverfish cannot free themselves.

### Mode of action and effects on target organisms, including unacceptable suffering.

Magnet Gel Silverfish is an attractant, and it is presented in 2 formats:

* Gel attractant with sticky cardboard traps. It is used by applying the gel from a syringe/cartridge directly in the sticky cardboard traps.
* Ready-to-use cups in re-usable bait stations. The cups with gel and a sticky substance are placed in re-usable bait stations.

D-Fructose (CAS 57-48-7) is an active substance, which is known to attract insects. It is expected that the attractant effect is based on olfactory attraction. The product is effective when applied into traps. Unacceptable suffering is not expected.

### Efficacy data

Table 3.9 Efficacy data

At the time of submission, no specific efficacy protocols and guidelines were available to evaluate PT19 products against silverfish. Therefore, the tests have been done using in-house protocols. One simulated use test was conducted with MAGNET GEL SILVERFISH in order to evaluate the efficacy and the residual activity of the product.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference**  | **Number in IUCLID section 6.7/Test report title** |
| PT-19: Repellents and attractants (Pest control) | Magnet gel silverfishD-Fructose 6% GELSticky trap and Re-usable station  | Attractant Test insects: *Lepisma saccharina* – Common silverfish – Adults and nymphs | Type of test: Simulated use test in laboratory conditions (T:26±1oC, RH: 50±10oC, photoperiod: 12:12). Test arena: Rooms of 9m2 with alternative food source and a shelter to simulate real conditions of use (kitchen or bathroom).Test population: 20 male/female + 20 individuals of smaller size (considered to be nymphs) (40 in total) per replicate. The silverfish were acclimatized in the test arenas with water and alternative food consisting of paper glue (dry) for 24 hours before the beginning of the trial. Experimental design: 5 replicates for the product and 5 parallel replicates for the negative control (sticky traps or capsules without attractant), each replicate consisting of one test arena (9 m2) with alternative food source. Residual efficacy was also tested in 5 more replicates by exposing new batches of silverfish to the 15 days aged product (15 days after opening). The product was placed on the floor of the room after the silverfish’s acclimatization and left open between the persistent dates. Sticky traps or capsules without attractant were used in the negative control.Dose in the test with sticky traps: 4 drops/sticky trap/1.5 m2 (equivalent to 0.2 g/sticky trap/1.5 m2)Quantity of product applied per test arena (9 m2): 6 sticky traps with 0.2 g of product each. The quantity applied was accurately weighed to 0.2g using an electronic balance. 4 drops of approximately 0.05g each were applied.Dose in the test with re-usable station: 0.5 g/capsule/4.5 m2Quantity of product applied per test arena (9 m2): 2 capsules with 0.5 g of product each. Each capsule was manufactured containing exactly 0.5g.Assessments: Trapped insects were recorded every day until the captures were ≥80% of the initial population or higher. Criteria: The required results for demonstrating that the product possesses a sufficient level of efficacy were established as 4:1 of insects trapped compared with the control and ≥80% population reduction within a claimed period, in line with the general requirements for PT19 Repellents and attractants reported in the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 4.1 - February 2022 – ECHA. | Sticky trapAfter 12 days, 88.1% of the insects were caught in the treatment with fresh attractant, 82.5% of the insects were caught in the trap with aged attractant. In the trap without attractant (control), 15.6% and 14.4% of the individuals were caught with fresh and aged attractant respectively. CapsuleThe percentage of insects that were trapped was 81.3% with fresh product and 81.7% with aged attractant after 17 days. The percentage of individuals trapped in the re-usable bait station without attractant (control) was 13.1% and 13.0% with aged and fresh attractant respectively.The percentage or insects trapped in the negative controls was >10% because the sticky traps or capsules without attractant used in the negative controls are shelters for *Lepisma saccharina* and therefore have some attractive effect on them.Overall, Magnet Gel Silverfish increases the efficacy of the traps and it also shows that the attractant is still working 15 days after application. The criteria of ≥80% of population reduction and 4:1 insects trapped compared with the control was met. | XXXXXXX XXXX | 6.7.16.7.2 |

### Efficacy assessment

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intended to be used as gel in syringes/ cartridges with sticky traps and as gel in ready to use capsules with sticky traps indoors against silverfish *Lepisma saccharina* (Intended Use #1 and #2 respectively).

One SUT was submitted by the applicant to substantiate label claims:

The test was conducted in 2022 with the product Magnet Gel Silverfish. Five replicates containing 40 silverfish of mixed age were performed in a simulated kitchen of 9 m2 (test arena), along with five more replicates to assess the residual efficacy and the relevant parallel controls (containing the trap without attractant).

Concerning the exact number of males, females and nymphs that were introduced to the test arenas applicant stated the following: “silverfish present gender dimorphism and it is not possible to visually establish their sex. Furthermore, silverfish are ametabolous, which means that the insects that hatch from the eggs are miniature versions of the adult. Thus, it is not possible to distinguish the nymph stage except from the size.

In the study, the populations consisted of 20 male/female + 20 individuals of smaller size (considered to be nymphs) obtained from a specified laboratory culture bred in Mylva S.A. The 20 male/female resemble the same rate that would be obtained in a natural infestation.”

Two different application methods were assessed: gel in syringes/ cartridges with sticky trap and gel in ready to use capsule with sticky traps.

Gel in syringes/ cartridges with sticky trap: After 12 days, 88.1% of the insects were caught in the treatment with fresh attractant, 82.5% of the insects were caught in the trap with aged attractant. In the trap without attractant (control), 15.6% and 14.4% of the individuals were caught with fresh and aged attractant respectively.

Gel in ready to use capsule with sticky traps: The percentage of insects that were trapped was 81.3% with fresh product and 81.7% with aged attractant after 17 days. The percentage of individuals trapped in the re-usable station without attractant (control) was 13.1% and 13.0% with aged and fresh attractant respectively.

Overall, Magnet Gel Silverfish increases the efficacy of the traps, and it also shows that the attractant is still working 15 days after application. The criteria of ≥80% of population reduction and 4:1 insect trapped compared with the control was met.

Based on the results of the aforementioned efficacy data, the intended uses #1 and #2, from an efficacy point of view, are acceptable as applied for by the applicant, noting that the product is effective when applied up to 2 weeks after opening and controls silverfish (*Lepisma saccharina*) in approximately 2 weeks after the application.

### Conclusion on efficacy

One simulated use efficacy study was submitted for Magnet Gel Silverfish (ready to use) containing D-Fructose 6%. Based on the results of the submitted efficacy study, the product was effective when applied by professional, trained professional and non-professional users as:

Gel in syringes/ cartridges with sticky traps indoors at 0.2g/ sticky trap/ 1.5m2. (Intended Use #1)

* The product increases the efficacy of the sticky trap.
* The product controls the infestation in approximately 2 weeks after application.
* The product is effective when applied up to 2 weeks after opening.

Gel in capsules with sticky substance indoors at 0.5g/ 4.5 m2 floor surface. (Intended Use #2)

* The product increases the efficacy of the re-usable bait station.
* The product controls the infestation in approximately 2 weeks after application.
* The product is effective when applied up to 2 weeks after opening.

### Occurrence of resistance and resistance management

The occurrence of resistance is not considered an issue for attractants.

Not examined by the applicant.

### Known limitations

None known.

Capsules should be stored away from light and heat sources and at a maximum temperature of 30ºC.

### Relevant information if the product is intended to be authorised for use with other biocidal products

Not applicable.

## Risk assessment for human health

### Assessment of effects on human health

The biocidal product MAGNET GEL SILVERFISH is a ready-to-use gel attractant (RB) to attract silverfish (PT-19: Repellents and attractants). It is intended to be used indoors by professionals and non-professionals.

The product contains 6% D-Fructose as active substance, which is included into Annex I of the BPR and also meets the specified restrictions in the respective Commission Delegated Regulations.

The product MAGNET GEL SILVERFISH does not contain either any substance of concern according to EC Guidance on SoC (CA-Nov14-Doc.5.11) or any nanomaterials. In addition, no indications of endocrine-disrupting properties were identified for the substances contained in the biocidal product, according to Commission Delegated Regulation (EU) 2017/2100.

The classification of the product has been conducted according to the classification rules for mixtures laid down in Regulation (EC) No. 1272/2008 (CLP). MAGNET GEL SILVERFISH is not classified for human health hazards and the handling of the product as part of its intended use does not require any personal protective equipment (PPE).

Based on the above, MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure and hence a detailed exposure assessment is not required according to Article 20.1(b) of the Regulation (EU) No. 528/2012.

#### Skin corrosion and irritation

Table 3.10 Conclusion used in Risk Assessment – Skin corrosion and irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not irritating or corrosive to skin. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for skin corrosion/irritation, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.11 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Skin corrosion and irritation. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Eye irritation

Table 3.12 Conclusion used in Risk Assessment – Eye irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation** |
| Value/conclusion | Not irritating to eyes. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for eye irritation, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.13 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Eye irritation. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Respiratory tract irritation

Table 3.14 Conclusion used in the Risk Assessment – Respiratory tract irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Respiratory tract irritation** |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for respiratory tract irritation, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.15 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Respiratory tract irritation. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Skin sensitization

Table 3.16 Conclusion used in Risk Assessment – Skin sensitization

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitizing to the skin. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for skin sensitization, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.17 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Skin sensitization. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Respiratory sensitization

Table 3.18 Conclusion used in Risk Assessment – Respiratory sensitization

|  |
| --- |
| **Conclusion used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not a respiratory sensitizer. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for respiratory sensitization, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.19 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Respiratory sensitization. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Acute oral toxicity

Table 3.20 Value used in the Risk Assessment – Acute oral toxicity

|  |
| --- |
| **Conclusion used in Risk Assessment – Acute oral toxicity** |
| Value/conclusion | Non-toxic *via* the oral route. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for acute oral toxicity, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.21 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute oral toxicity. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Acute inhalation toxicity

Table 3.22 Value used in the Risk Assessment – Acute inhalation toxicity

|  |
| --- |
| **Conclusion used in Risk Assessment – Acute inhalation toxicity** |
| Value/conclusion | Non-toxic *via* the inhalation route. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for acute inhalation toxicity, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.23 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute inhalation toxicity. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

#### Acute dermal toxicity

Table 3.24 Value used in the Risk Assessment – Acute dermal toxicity

|  |
| --- |
| **Conclusion used in Risk Assessment – Acute dermal toxicity** |
| Value/conclusion | Non-toxic *via* the dermal route. |
| Justification for the value/conclusion | No study has been performed on the biocidal product MAGNET GEL SILVERFISH. Classification of the product was conducted by the calculation method according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Neither the active substance nor the co-formulants of MAGNET GEL SILVERFISH are classified for acute dermal toxicity, hence no classification is triggered for the product. |
| Classification of the product according to CLP  | Not classified. |

Table 3.25 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute dermal toxicity. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable. |

### Information on dermal absorption

Table 3.26 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Dermal absorption |
| Justification | Assessment of dermal absorption is not a data requirement for simplified authorisation procedures. |

### Available toxicological data relating to substance(s) of concern

Regarding human health, the biocidal product MAGNET GEL SILVERFISH does not contain any substances of concern (SoC), in accordance with the EC Guidance CA-Nov14-Doc.5.11, which defines the criteria for the identification of SoC.

### Other

No other information is required.

### Available toxicological data relating to endocrine disruption

The biocidal product MAGNET GEL SILVERFISH does not contain any active substances having endocrine-disrupting properties.

In addition, based on the available information, no indications of endocrine-disrupting properties according to Commission Delegated Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

### Exposure assessment and risk characterisation for human health

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012. Therefore, a detailed human health exposure assessment is not required according to the information provided in Article 20.1(b) of the same Regulation.

### Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product MAGNET GEL SILVERFISH is not classified and does not contain any classified ingredient or substance of concern. A risk characterisation is not required, and authorization is acceptable under the simplified authorisation procedure according to Regulation (EU) No. 528/2012.

### Overall conclusion on risk assessment for human health

The biocidal product MAGNET GEL SILVERFISH is not classified for human health hazards according to Regulation (EC) No. 1272/2008 (CLP) and does not contain any substance of concern (SoC) in accordance with the EC Guidance CA-Nov14-Doc.5.11, which defines the criteria for the identification of SoC. In addition to the above, the handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE). Therefore, MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012.

According to the information provided in Article 20.1(b) of the Regulation (EU) No. 528/2012, a detailed human health exposure assessment is not required for products meeting the conditions laid down in Art. 25 of the same regulation (simplified authorization procedure).

## Risk assessment for animal health

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the Regulation (EU) No. 528/2012. A detailed exposure assessment is therefore not required in accordance with Article 20.1(b) of the same regulation.

## Risk assessment for the environment

MAGNET GEL SILVERFISH is eligible for the simplified authorization procedure in accordance with Article 25 of the BPR. Detailed exposure assessments are therefore not required in accordance with Article 20(b)(1) of the BPR.

The only component classified for environmental hazards (H411) is xxxxxxxxxxxx but according to summation method the product in NOT classified for the environment.

## Assessment of a combination of biocidal products

Not applicable, the biocidal product Magnet Gel Silverfish is not intended to be used in combination with other biocidal products.

## Comparative assessment

Not relevant. The active substance is no candidate for substitution.

# Appendices

## Calculations for exposure assessment

Not applicable.

## New information on the active substance(s) and substance(s) of concern

No new information on the active substance is available.

## List of studies for the biocidal product

Please refer to confidential annex.

## References

### References other than list of studies for the biocidal product

Not relevant.

### Guidance documents

* Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0 July 2017
* Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.1, March 2022
* Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022
* Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017
* Guidance on the compilation of safety data sheets, Version 4.0 December 2020

### Legal texts

Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products.

Regulation (EC) No 1272/2002 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Commission Delegated Regulation (EU) 2019/1823 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include D-fructose as an active substance in Annex I thereto.

## Confidential information

Please refer to the separate document Confidential Annex of the PAR.

1. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [↑](#footnote-ref-2)