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 competent authority)



SILENCE PIEGE A MOUCHE

Product type 19

Saccharomyces cerevisiae and powdered egg

Case Number in R4BP: BC-YR071756-96

Competent Authority: France

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | France | BC-YR071756-96 | dd.mm.yyyy | Initial assessment |  |

# Conclusion

SILENCE PIEGE A MOUCHE is a Bait Concentrate in Soluble Bags (BC/SB) biocidal product containing 30% of Saccharomyces cerevisiae and 20% powdered egg as active substances. The product is used as an attractant by non-professional users for the control of house fly.

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 as traps against fly (*Musca domestica*) for outdoor use by non-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 substances *Saccharomyces cerevisiae* and whole egg powder included in the product are listed in Annex I of Regulation (EU) 528/2012 and respect the restrictions reported in the Annex I;
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 according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is not necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

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

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.

The biocidal product contains *Saccharomyces cerevisiae* and whole egg powder which do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered as candidates 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 are listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

**Conclusions of the assessments for each area**

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

Physical, chemical and technical properties

Determination of physical, chemical and technical properties is not a data requirement for an application in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

Indeed, the shelf-life of the product will be supported solely by efficacy results on aged samples (see section 3.2).

The properties of the SILENCE PIEGE A MOUCHE have therefore not been assessed. No physicochemical stability study has been carried out.

More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Considering the composition of the product and the fact that the active substance is included in Annex I of the BPR, it can be concluded that the product presents no physical hazards.

More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring 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

The efficacy of the biocidal product SILENCE PIEGE A MOUCHE as an attractant has been shown against house fly (*Musca domestica)* at the application rate of 20 g of powder diluted in 600 mL of water per trap, each 5 m apart, until 8 weeks.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

There is no substances of concern included in the product SILENCE PIEGE A MOUCHE.

No Personal Protective Equipment are required during the manipulation of the product.

No risk assessment is required, according to Article 25 of Regulation (EU) 528/2012.

Dietary risk assessment

As *saccharomyces cerivisiae* and powdered egg are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin, a dietary risk assessment is not relevant.

Risk assessment for animal health

Considering the use, exposure to animals is not expected. Therefore, no risk assessment or animal health has been performed.

Risk assessment for the environment

The biocidal product SILENCE PIEGE A MOUCHE is eligible for the simplified authorization procedure regarding the environment in accordance with Article 25 of the BPR. Detailed exposure and risk assessments are not required in accordance with Article 20(1)(b) of the BPR. Therefore, the biocidal product doesn’t pose a risk for the environment. See more details in the section 3.8 of this PAR.

# 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)** | PT19 |
| **Type(s) of formulation** | BC/SB: Bait Concentrate in Soluble Bag |

## 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 number** | **Use description** | **PT** | **Target organisms** | **Application method5** | **Application rate6**  **(min-max)** | **User category7** | **Conclusion**  **(eCA/ refMS)8** | **Comment (eCA/refMS)9** |
| 1 | Silence Fly trap | PT18 | House fly (*Musca domestica*) | Bait application | 20 g of product with 600mL of water per trap | Non-professional | R | - |

*Codes for indicating the acceptability for each use*

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

## 

## Identity and 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 of the PAR.

## Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

|  |  |
| --- | --- |
| **Main constituent** | |
| **Common name** | Yeast (Brewers), dry, powder TECHNICAL |
| **Chemical name** | *Saccharomyces cerevisiae* |
| **EC number** | */* |
| **CAS number** | 68876-77-7 |
| **Index number in Annex VI of CLP** | / |
| **Minimum purity / content** | / |
| **Structural formula** | / |

|  |  |
| --- | --- |
| **Main constituent** | |
| **Common name** | Whole egg powder |
| **Chemical name** | / |
| **EC number** | */* |
| **CAS number** | */* |
| **Index number in Annex VI of CLP** | / |
| **Minimum purity / content** | 100 % |
| **Structural formula** | / |

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

The information on the sources of the active substances is not applicable.

## Candidate(s) for substitution

Not relevant

## 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.

See Confidential annex for further information.

## Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

|  | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | *-* | - |
| **Hazard Pictograms** | *-* | - |
| **Signal word(s)** | *-* | *-* |
| **Hazard statements** | *-* | *-* |
| **Precautionary statements\*** | *-* | The authorisation holder is responsible to choose the relevant P-statements to be included on the label. |
| **Supplemental hazard statements** | - | |
| **Notes** | *[Where necessary, add a justification for excluding certain P-statements.]* | |

## 

## Letter of access

Not relevant

## Data submitted in relation to product authorisation

Not applicable

## 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)** |
| Trap bottle containing 1 PVOH (polyvinyl alcohol) water-soluble sachet (20g). | 20 g | PET | PP | Non-professional | Yes |

## Physical, chemical, and technical properties

*Use concentrations: 3.3 % (w/v) (20 g in 600 mL of water)*

*Type of declared packaging: PET trap bottle contained 1 PVOH water soluble sachet*

Type of the product: BC/SB

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** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa |  |  |  |  |  |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa | OPPTS 830.6303 | House Fly Trap (SCHO-101HFT) (*Saccharomyces cerevisiae* 30% + Powdered egg 20%)  Water soluble bag (20g) | homogenous powder | Acceptable | SCHOPF Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.1.2. | Colour at 20 °C and 101.3 kPa | OPPTS 830.6302 | House Fly Trap (SCHO-101HFT) (*Saccharomyces cerevisiae* 30% + Powdered egg 20%)  Water soluble bag (20g) | brownish | Acceptable | SCHOPF Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.1.3. | Odour at 20 °C and 101.3 kPa | OPPTS 830.6304 | House Fly Trap (SCHO-101HFT) (*Saccharomyces cerevisiae* 30% + Powdered egg 20%)  Water soluble bag (20g) | yeast | Acceptable | SCHOPF Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.2. | Acidity, alkalinity and pH value | CIPAC MT 75.3 | House Fly Trap (SCHO-101HFT) (*Saccharomyces cerevisiae* 30% + Powdered egg 20%)  Water soluble bag (20g) | 7.4 at 20°C | Acceptable | SCHOPF Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.3. | Relative density / bulk density | - | - | - | - | - |
| 3.4.1.1. | Storage stability test – **accelerated storage** | *OPPTS 830.6302;*  *OPPTS 830.6303;*  *OPPTS 830.6304;*  *OECD 114;*  *CIPAC MT 75.3;* | House Fly Trap (SCHO-101HFT) (Saccharomyces cerevisiae 30% + Powdered egg 20%)  Water soluble bag (20g) | |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 8 weeks of storage at 40°C** | | Packaging | Bag sealed and without clumping or leakages | Sample sound, sealed and without clumping or leakages | | Weight variation (g) | 20 g | 20 g | | Appearance  (Colour, odour and  physical state) | homogenous powder, brownish, yeast | homogenous powder, brownish, yeast | | Viscosity (diluted according to the instructions for use) | 3:23 | 3:19 | | pH value (1% aqueous  dilution) (1) | 7.40 | 7.39 |  |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 8 weeks of storage at 20°C** | | Packaging | Bag sealed and without clumping or leakages | Sample sound, sealed and without clumping or leakages | | Weight variation (g) | 20 g | 20.1 g | | Appearance  (Colour, odour and  physical state) | homogenous powder, brownish, yeast | homogenous powder, brownish, yeast | | Viscosity | 3:23 | 3:23 | | pH value (1% aqueous  dilution) (1) | 7.40 | 7.42 | | Acceptable  No modification of physical and chemical properties and of commercial packaging (PVOH sachet in PET bottle) have been observed after accelerated storage for 8 weeks at 40°C nor after 8 weeks at 20°C. The determination of the content of the active substances and microbial contaminants before and after storage was not performed, nevertheless the shelf life is based on efficacy study (see 3.4.1.2) | Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | *Waived* | - | *The shelf life of 36 months is supported by efficacy data, showing the attractant effect remains unchanged after 36 months of storage.*  *Please refer to section 2.2.5.5.*  Microbial contaminants are not considered as a relevant information in support of the conclusion that the biocidal product fully “meets the conditions laid down in the article 25” Moreover, the product specification sheet testifies that at manufacturing stage there is <10000 CFU/g of Enterobacteriaceae which remain in satisfactory ranges for a microbiological active substance-based product. For the given dry bait, if stored and used according to the “instructions for use”, there is no risk of contamination during the 3 years claimed storage.  Then, the risk of contamination in the non-opened stored product will not lead to any risk as the fly trap bait is neither aimed to be eaten, drunk (oral uptake) nor applied on human or animal skin.  According to the document “Consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure. CA-May14-Doc.5.5 – Final”, “Silence piège à mouche” is a Bait Concentrate (CB) formulation so the option (b) of the below proof applies, it appears that the best option is that stability data are waived as soon as the applicant demonstrates the efficacy of the aged product, which was done in the efficacy study (3 years stored product + 8 weeks opened; “double-aged”) presented in the simplified authorisation submission dossier. | Acceptable  Applicant justification and product specification sheet on microbial contaminants can be considered acceptable.  Content of microbial active substances was not determined.  The shelf life of the product can be set for 3 years at ambient temperature “23°C”) based on  the acceptable results of efficacy study |  |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | *OPPTS 830.6302;*  *OPPTS 830.6303;*  *OPPTS 830.6304;*  *OECD 114;*  *CIPAC MT 75.3;* | House Fly Trap (SCHO-101HFT) (Saccharomyces cerevisiae 30% + Powdered egg 20%)  Water soluble bag (20g) | |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 8 weeks of storage at 0°C** | | Packaging | Bag sealed and without clumping or leakages | Sample sound, sealed and without clumping or leakages | | Weight variation (g) | 20 g | 20.1 g | | Appearance  (Colour, odour and  physical state) | homogenous powder, brownish, yeast | homogenous powder, brownish, yeast | | Viscosity | 3:23 | 3:24 | | pH value (1% aqueous  dilution) (1) | 7.40 | 7.39 | | Acceptable  No modification of physical and chemical properties and of commercial packaging (PVOH sachet in PET bottle) have been observed after accelerated storage for 8 weeks at 0°C.  The determination of the content of the active substance and microbial contaminants before and after storage was not performed, nevertheless the shelf life is based on efficacy study (see 3.4.1.2) | Stephan., Arthur Schopf Hygiene GmbH & Co. KG, Germany,  2021. Study No.: 2021/06-003 |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** | Waived |  | According to the label, the product must not be exposed to sunlight during transport and storage. | Acceptable |  |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived |  | According to the label, the product must be protected from humidity and stored in cool places. | Acceptable |  |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | Refer to 3.4.1.2 |  |  |
| 3.5.1. | Wettability *[indicate the concentration tested]* | Waived |  | This test is not relevant for the type of application (dilution in the trap, not used for spraying) | Acceptable  Nevertheless, considering the type of the product BC-WP, the the product should be mixed well before application. |  |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]* | Waived |  | House Fly Trap is not intended to be used by spraying. | Acceptable |  |
| 3.5.3. | Wet sieve analysis and dry sieve test *[indicate the concentration tested]* | Waived |  | House Fly Trap is not intended to be used by spraying. | Acceptable |  |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability *[indicate the concentration tested]* | Waived |  | Not applicable since biocidal product does not need to be emulsified. | Acceptable |  |
| 3.5.5. | Disintegration time | Waived |  | Not applicable since biocidal product is not a tablet. | Acceptable |  |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability *[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed. ]* | Waived |  | Not required for BC or BC/SB. | Acceptable |  |
| 3.5.7. | Persistent foaming *[indicate the concentration tested]* | Waived |  | Not applicable | Acceptable  Considering the product composition, the application mode and the intended uses, the persistent foaming is not expected |  |
| 3.5.8. | Flowability/pourability/dustability | Waived |  | Not applicable since biocidal product is not granular/a suspension. | Acceptable |  |
| 3.5.9. | Burning rate — smoke generators | Waived |  | Not applicable since the biocidal product is no smoke generator. | Acceptable |  |
| 3.5.10. | Burning completeness — smoke generators | Waived |  | Not applicable since the biocidal product is no smoke generator. | Acceptable |  |
| 3.5.11. | Composition of smoke — smoke generators | Waived |  | Not applicable since the biocidal product is no smoke generator. | Acceptable |  |
| 3.5.12. | Spraying pattern — aerosols / spray | Waived |  | Not applicable since the biocidal product is not an aerosol. | Acceptable |  |
| 3.6.1. | Physical compatibility | Waived |  | The biocidal product is not intended to be added or mixed with any other products. | Acceptable |  |
| 3.6.2. | Chemical compatibility | Waived |  | The biocidal product is not intended to be added or mixed with any other products. | Acceptable |  |
| 3.7. | Degree of dissolution and dilution stability *(indicate the concentration tested)* |  |  |  |  |  |
| 3.8. | Surface tension *[indicate the conditions of the test and the concentration tested]* | Waived |  | Not applicable since biocidal product is a solid. | Acceptable |  |
| 3.9. | Viscosity *[indicate the shear rate and the temperature tested]* | Waived |  | Not applicable since biocidal product is a solid. | Acceptable |  |

Table 3.3 Conclusion on physical, chemical, and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| The product SILENCE PIEGE A MOUCHE is a Bait Concentrate (associated with a soluble bag BC/SB).  The appearance of the product is a brownish homogeneous powder with a characteristic odour of yeast. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. Furthermore, there is no effect of ambient temperature and low temperature on the stability of the formulation, since after 8 weeks at 20°C and 0°C when stored in commercial packaging “PVOH sachets in PE bottle”.  According to the acceptable results of efficacy study and according to the content product specification sheet and to the justification on content of microbial contaminants (Enterobacteriaceae) in the product the shelf life can be set for 3 years at 23°C.  Its technical characteristics are acceptable for a BC/SB formulation.  Labelling implication:  Protect from light.  Protect from the humidity and from frost  The diluted product should be stirred before application  Shelf life: 3 years. |

## 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** | **FR**  **Evaluation** |
| --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | Waiving | / | None of the ingredients in the product possesses explosive properties and, on the basis of the information available (such as experience with the formulation, the intrinsic properties of the ingredients, their chemical structures and functional groups and the information retrieved from their SDSs), the product is unlikely to present such hazard. Therefore, according to article 14 of CLP Regulation, the product is not classified as explosive. | Acceptable |
| 4.2. | Flammable gases | / | / | The study does not need to be conducted because the substance is a solid | Not relevant |
| 4.3. | Flammable aerosols | / | / | The study does not need to be conducted because the substance is a solid | Not relevant |
| 4.4. | Oxidising gases | Waiving |  | The study does not need to be conducted because the substance is not able of reacting exothermically with combustible materials  Furthermore, considering the composition of the product and the fact that the active substance is included in Annex I of the BPR – category 4, and as such doesn’t give rise to concern for oxidizing behaviour, this property is considered not applicable. | Not relevant |
| 4.5. | Gases under pressure |  |  | The study does not need to be conducted because the substance is a solid | Not relevant |
| 4.6. | Flammable liquids |  |  | The study does not need to be conducted because the substance is a solid | Not relevant |
| 4.7. | Flammable solids |  |  | The study does not need to be conducted | Acceptable  considering, the type of the dossier (simplified authorisation for application) and the composition of the product it is not expected that the product is flammable product. |
| 4.8. | Self-reactive substances and mixtures | Waiving |  | The product does not have explosive, oxidising or pyrophoric properties and is not an organic peroxide. Moreover, taking this into account and considering experience with the formulation, the classification of the individual components, their intrinsic properties, their molecular structure and the information retrieved from their SDSs, the product is not expected to be self-reactive. Self-heating test performed evidenced that from the obtained experimental data according to the Test N. 4, it can be concluded that the test item sample is not classified as a self-heating mixture. | Acceptable  considering, the type of the dossier (simplified authorisation for application) and the composition of the product it is not expected that the product has self reactive properties. |
| 4.9. | Pyrophoric liquids |  |  | The study does not need to be conducted because the substance is a solid. | Not relevant |
| 4.10. | Pyrophoric solids |  |  | See point 4.8. | Acceptable |
| 4.11. | Self-heating substances and mixtures |  |  | See point 4.8. | Acceptable |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases |  |  | See point 4.8. | Acceptable |
| 4.13. | Oxidising liquids |  |  | The study does not need to be conducted because the substance is a solid. | Acceptable |
| 4.14. | Oxidising solids |  |  | See point 4.8. | Acceptable |
| 4.15. | Organic peroxides |  |  | Based on the chemical structure of the components and their CLP classification, the product is not classified as organic peroxide. | Acceptable |
| 4.16. | Corrosive to metals |  |  | The product is a solid, therefore it is not considered as corrosive to metals. Moreover, none of the components of the product is classified as corrosive to metals or contains any functional group related to this hazard. Moreover, none of the commercial packagings are made of metal nor the product is intended to be applied on any metal surfaces. | Acceptable |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) |  |  | The study does not need to be conducted because the substance is a solid. | Acceptable |
| 4.17.2. | Relative self-ignition temperature for solids | Waived | / | / | Considering the composition of the product and the fact that the active substance is included in Annex I of the BPR – category 4, and as such does not give rise to concern for self-ignition, this property is considered not applicable |
| 4.17.3. | Dust explosion hazard |  |  | See point 4.8. | Acceptable |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| The product is not classified for physical hazards  Implication concerning labelling: None |

## Methods for detection and identification

*No data provided.*

Table 3.12 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification** |
| Methods for the determination of the active substances *Saccharomyces cerevisiae* and whole egg powder in the biocidal product SILENCE PIEGE A MOUCHE are not available. Nevertheless, no additional data are required considering the type of the active substances (food grade) and the type of the dossier for simplified authorisation application.  Methods for the determination of microbial contaminants in the product were not provided. Nevertheless, data of product specification are considered sufficient in the framework of this dossier.  Methods for the detection of *Saccharomyces cerevisiae* and whole egg powder in soil, air, water, and animal and human body fluids and tissues were not provided and not necessary as no MRL were fixed and no residue definition set. |

## 

## Assessment of efficacy against target organisms

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

The product SILENCE PIEGE A MOUCHE is a bait concentrate, as a powder to be diluted in water, used in traps against fly (*Musca domestica*) for outdoor use. The product is used to attract this insect in traps and keep the terrace area, garden and playgrounds free from annoying flies.

The product is used to protect human health and food.

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

The product SILENCE PIEGE A MOUCHE is used in combination with a trap. The attracting effect is activated by UV-rays within 2 - 3 days. Once activated the attractive powder produces a characteristic odour attracting the flies into the trap out of which they cannot go and eventually drown into it.

It is an olfactory attractant.

## 

### Efficacy data

Table 3.13 Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects**  *[address here results related to efficacy of the test product and validity of the test]* | **Reference** | **Number in IUCLID section 6.7/Test report title** |
| PT19  Attractant | Test item SCHO-101HFT  Dry yeast (*Saccharomyces cerevisia*) and powdered egg  3 year old formulation | Attractant:  House flies (*Musca domestica*)  Green bottle/Blow fly (*Lucilia sericata*) | Field test outdoor (table on a terrace of a home backyard)  The three years old product was tested fresh opened and 8 weeks opened (double-aged i.e 3 years old product activated 8 weeks before testing).  Two test designs were developed :   1. Classical test design for baited trap systems   Per replication (3 replicates) 3 traps of the treatment group (test item) will be compared with 3 traps of the untreated, negative control group (traps with water, no bait / no active substance).  The traps with test item were placed 5 m away from the negative control group traps.  Test capture period: 60 minutes.     1. Tent test design for baited trap systems   Per replication (3 replicates) numbers of fly captures of 3 traps of the treatment group (test item) will be compared with the number of captures of a tent covering food attractive (bread, sausage, cheese and butter) for flies.  The shown food tent test design is designed to mimic the situation on a terrace in which a light meal will be taken and where house and blowflies are present. The food source will be covered with a meshed insect tent modified to the purpose given; flies are allowed to approach the food source from all 4 sides (360°), through a gap of about 2 cm at the base of the tent; captures will be counted, numbers will be recorded (release of the flies after the test). This display acts as untreated, negative control.  Test capture period: 60 minutes    **Concentration applied in each test designs:**  20g sachet (dry powder in a water-soluble bag) is activated by adding 600 mL of warm tap water. | 1. Classical test design for baited trap systems   Total catched insects **(treated):**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | SCHO-101HFT 60 min capture period | | | | | | | |  | **fresh opened** | | | **8 weeks opened** | | | | Site 1 | Site 2 | Site 3 | Site 1 | Site 2 | Site 3 | | *M. domestica* | 43 | 52 | 88 | 66 | 60 | 60 | | *L. sericata* | 77 | 82 | 78 | 68 | 107 | 82 |   Total catched insects **(control):**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | SCHO-101HFT 60 min capture period | | | | | | | |  | **Control for fresh opened** | | | **Controls for 8 weeks opened** | | | | Site 1 | Site 2 | Site 3 | Site 1 | Site 2 | Site 3 | | *M. domestica* | 3 | 3 | 8 | 6 | 4 | 6 | | *L. sericata* | 4 | 2 | 5 | 5 | 6 | 8 |  1. Tent test design for baited trap systems   Total catched insects **(treated):**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | SCHO-101HFT 60 min capture period | | | | | | | |  | **fresh opened** | | | **8 weeks opened** | | | | Site 1 | Site 2 | Site 3 | Site 1 | Site 2 | Site 3 | | *M. domestica* | 67 | 58 | 59 | 60 | 63 | 70 | | *L. sericata* | 47 | 126 | 102 | 71 | 100 | 57 |   Total catched insects **(control):**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | SCHO-101HFT 60 min capture period | | | | | | | |  | **Control for fresh opened** | | | **Controls for 8 weeks opened** | | | | Site 1 | Site 2 | Site 3 | Site 1 | Site 2 | Site 3 | | *M. domestica* | 2 | 3 | 2 | 5 | 4 | 6 | | *L. sericata* | 2 | 5 | 2 | 7 | 3 | 6 |   **Conclusion:**  Therefore, it can be concluded that the product SILENCE PIEGE A MOUCHE is efficient to attract housefly (*Musca domestica*) and blow fly (*Lucilia sericata*) up to 8 weeks.  Both test set-ups a) the classical trap test design and b) the food (capture) tent test design delivered very similar results for fresh and for 8 weeks aged fly bait.  The results demonstrated that the product remains efficient after 3 years of storage. | Stephan Schopf 2021  RI=2  Test realised during 60 minutes | KC\_SH\_016\_02 |

### Efficacy assessment

A field trial has been performed with the product SILENCE PIEGE A MOUCHE (SCHO-101HFT (30% *Saccharomyces cerevisiae* + 20% powdered egg)) on 3 different sites in Israel, in 2021 with a fresh formulation and a formulation aged of 8 weeks.

The products were tested during 60 minutes.

Two test designs were developed, a classical test design for baited trap systems and a tent test design for baited trap systems.

From the results, it appeared that both test set-ups delivered very similar results for fresh and the aged fly bait. Indeed, no significant different between the two test systems “classical trap test” and “tent captures” was noted. Moreover, a statistical difference was noted between treated and untreated product.

This study showed the attractant efficacy of the product SILENCE PIEGE A MOUCHE fresh and aged formulation against housefly (*Musca domestica*) and blow fly (*Lucilia sericata*).

### Conclusion on efficacy

The efficacy of the biocidal product SILENCE PIEGE A MOUCHE as an attractant has been shown against house fly (*Musca domestica*) at the application rate of 20 g of powder diluted in 600 mL of water per trap, each 5 m apart, until 8 weeks.

After 3 years of storage, the product remains efficient.

### Occurrence of resistance and resistance management

Not expected to be relevant for the product SILENCE PIEGE A MOUCHE since it is based on olfaction.

### Known limitations

There are no known limitations to the product SILENCE PIEGE A MOUCHE.

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

Not applicable, as the product SILENCE PIEGE A MOUCHE is not intended to be used with other biocidal products.

## Risk assessment for human health

### Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoint(s) for the active substances and available information for the non-active substances.

The classification of the product SILENCE PIEGE A MOUCHE has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

The product SILENCE PIEGE A MOUCHE does not contain any classified ingredient and therefore is not classified.

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

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

#### Food and feeding stuffs studies

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

#### Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

#### Other test(s) related to the exposure to humans

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of (the) non-active substance(s), refer to the respective section of the confidential annex.

### Exposure assessment and risk characterisation for human health

**Conclusion**

The biocidal product SILENCE PIEGE A MOUCHE does not meet any classification criteria for human health.

No substance of concern has been identified.

No Personal Protective Equipment (PPE) are required during the manipulation of the product.

### Dietary risk assessment

As *saccharomyces cerivisiae* and powdered egg are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin, a dietary risk assessment is not relevant.

## Risk assessment for animal health

There is no substance of concern and the biocidal product is not classified. Therefore, it is considered that there is no concern for animal health.

## Risk assessment for the environment

The active substances *Saccharomyces cerevisiae* and powdered egg are active substances included into Annex I of Regulation (EU) No 528/2012, Category 4.

The product SILENCE PIEGE A MOUCHE does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017) nor endocrine disruptors or nano materials. Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified. Moreover there is no need for risk mitigation measure to protect the environment.

Based on the above information, SILENCE PIEGE A MOUCHE is eligible for the simplified authorization procedure regarding the environment in accordance with Article 25 of the BPR. Detailed exposure and risk assessments are therefore not required in accordance with Article 20(1)(b) of the BPR.

### Available studies and endpoints applied in the environmental risk assessment

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Emission estimation

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Exposure calculation and risk characterisation

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Primary and secondary poiso**n**ing

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Mixture toxicity

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Aggregated exposure (combined for relevant emission sources)

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

## Assessment of a combination of biocidal products

*Not relevant*

## Comparative assessment

*Not relevant*

# 

# 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 substances are available.

## List of studies for the biocidal product

Not relevant

## 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)