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)



PIEGE VOLANTS

Product type 19

*Saccharomyces cerevisiae* as included in the Annex I of Regulation (EU) No 582/2012

Case Number SA–BBP in R4BP: BC-XE066688-15

Case number SA-MIC : BC-TD084873-26

Competent Authority: FR CA

Date: 11/07/2023

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**Note to the reader**

The product PIEGE VOLANTS is a Same of the reference product, ATTRACTIF MGF. The authorization of the product ATTRACTIF MGF was granted by French competent authorities on April 2022 (authorization number FR-2022-0036) and the product PIEGE VOLANTS was granted by French competent authorities on 29th of April 2022.

In R4BP:

- the asset number for PIEGE VOLANTS is EU-0026957-0000,

- the asset number for ATTRACTIF MGF, the reference product is EU-0026845-0000 .

This consolidated PAR for the SA-MIC of the product PIEGE VOLANTS is based on the consolidated PAR the product ATTRACTIF MGF granted by FR on March 2023 for the SA-MIC application in which all necessary addenda have been included.

In this consolidated PAR:

* each section contains the initial assessment and the subsequent successive assessments (minor change, post authorisation data...) in a chronological order. These assessments are pointed out with specific titles corresponding to the type of application and the year at which it was delivered.
* the assessments related to the minor change of the product are at the end of each section and are highlighted in grey.

**Changes history table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** |
| SA-APP | *FR CA* | BC-LQ066682-15 | 08/04/2022 | *Initial assessment: ATTRACTIF MGF* |
| SA-BBP | *FR CA* | BC-XE066688-15 | 29/04/2022 | *authorisation of the same biocidal product: PIEGE VOLANTS* |
| SA-MIC | *FR CA* | BC-ET079250-26 | 01/03/2023 | Minor change of the reference product ATTRACTIF MF: Extension of shelf life from 2 years (24 months) to 69 months |
| SA-MIC | *FR CA* | BC-TD084873-26 | 11/07/2023 | Minor change of the same product PIEGE VOLANTS: Extension of shelf life from 2 years (24 months) to 69 months |

# Conclusion

PIEGE VOLANTS is a PT19 biocidal product containing *Saccharomyces cerevisiae* (yeast) as active substance. The product is a wettable powder (WP) used outdoor by *non professional users* for the control of *wasps and flies*.

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 to attract wasps and flies 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 uses 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 *Saccharomyces cerevisiae* is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction that *Saccharomyces cerevisiae* is 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 product PIEGE VOLANTS according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is not necessary.

The biocidal product does not contain any non-active substance which is considered as a 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.

More information is available in the confidential annex.

**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 1.4 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 1.5 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.

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

Validated analytical methods for the determination of the concentration of the active substance and microbial contaminants are not available. Nevertheless, as the product is a food grade product, no more data is required. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

Validated analytical method for monitoring of residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff are not necessary. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The efficacy of the biocidal product PIEGE VOLANTS as an attractant has been shown against house fly (*Musca domestica,* adult*)* and wasp (*Vespula* *vulgaris,* adult*)* at the application rate of 20 g of powder diluted in 500 mL of water per trap, each 5 m apart, during 14 days.

More information is available in section 3.5 of the PAR.

Human health

No substances of concern regarding human health were identified.

The handling of the product and its intended use do not require personal protective equipment.

Environment

No substances of concern regarding environment were identified.

**Post-authorisation conditions**

None

* **Minor change for PIEGE VOLANTS - 2023**

The minor change consists of the extension of shelf life from 2 years (24 months) to 69 months.

**Physico-chemical properties:**

New data on the reference product PIEGE VOLANTS were provided to demonstrate that the level of microbial contamination remains in acceptable limits after 69 months. **According to those data, a shelf life up to 69 months can be granted**.

**The following precautionary measure should be added: “Wash hands after handling the product”.**

# 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** | WP |

## 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] | Wasp Attractant – Non professionals - Outdoor | PT19 | Vespinae  Wasps – Adults | Product needs to be re-hydrated with water.  The diluted product is placed in an appropriate trap and the trap is placed outdoor | 20 g of product diluted in 500 mL of water | Non professionals | A | Product is efficient until 14 days |
| [2] | Fly Attractant – Non professionals - Outdoor | *Musca domestica* – Adults | A | Product is efficient until 14 days |

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 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.

According to the information provided :

* The product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.
* All the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex.

## Identity of the active substance(s)

Table 2.3 Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **Common name** | *Saccharomyces cerevisiae* |
| **Chemical name** | - |
| **EC number** | 614-750-7 |
| **CAS number** | 68876-77-7 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | 100 %  (10x109 - 30x109 CFU/g) |
| **Structural formula** | Not relevant |

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

The information on the source of the active substance 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 substance 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** | *-* | - |
| **Hazard Pictograms** | *-* | - |
| **Signal word(s)** | - | *-* |
| **Hazard statements** | - | *-* |
| **Precautionary statements\*** | - | - |
| **Supplemental hazard statements** | - | |
| **Notes** | - | |

**\***P-statements that are excluded based on the risk assessment or the intended use of the product[[2]](#footnote-3), are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

## 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

*Please refer to section 4.3.*

# 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)** |
| Vacuum sachet | 7 to 20 g | PET/Alu/PE | Sealed bag | Non professionals | Yes |
| Vacuum sachet | 500 g | PET/Alu/PE | Sealed bag | Non professionals | Yes |

## Physical, chemical, and technical properties

Use concentrations: 4 % (w/v) (20g in 500 mL of water)

Type of declared packaging: Bag PET/Alu/PE

Type of the product: WP

According to the Applicant the product is the same as a foodgrade product and already commercialised as food product (MAURIPAN RES 10kg). The technical sheet of this product is available in the dossier. The product is marketed in the exact same packaging as the one supplied by the product manufacturer, which provide the product in its final 7-20 g and 500 g packs.

Physical and chemical properties of the product have not been provided by the applicant.

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** | **Conclusion** |
| --- | --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa | Waived | Not required in the context of simplified authorisations. | / | / |  |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.1.2. | Colour at 20 °C and 101.3 kPa | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.1.3. | Odour at 20 °C and 101.3 kPa | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.2. | Acidity, alkalinity and pH value | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.3. | Relative density / bulk density | Waived | No study performed. | / | / | Acceptable |
| 3.4.1.1. | Storage stability test – **accelerated storage** | Waived | No study performed. | / | / | Acceptable  As the product is a foodgrade product and already commercialised as food product (MAURIPAN RES 10kg) no more data required.  The product can be considered stable 24months at ambient temperature (<25°C) like indicated in the technical sheet of MAURIPAN RES 10 kg See section 3.4.1.2. for more details. |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | Waived | No study performed.  Efficacy data show that the product is still efficacious after 8 years at ambient temperature.  The food product MAURIPAN RES 10kg technical data sheet indicates a shelf life of 2 years at temperature lower than 25 °C.  Data on microbial contaminants indicated in technical data sheet of MAURIPAN RES 10kg (at T0) are the following: | / | / | The content of the active substance in biocidal product before and after storage (2 years and 8 years) and the content of microbial contaminants after storage are not available.  The content of microbial contaminants at T0 is in the acceptable limits according to OECD 65.  Physical and chemical properties were not provided before and after storage.  As the product is identical to marketed foodgrade product (MAURIPAN RES 10kg), data from MAURIPAN RES 10kg can be used .  Based on MAURIPAN RES 10kg information, the shelf life is set at 24 months at temperature < 25°C. |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | Waived | No relevant considering the formulation type. | / | / | Acceptable  Neverheless, as the active substance is a microbial active substance the effect of low temperature can affect the efficacy. The mitigation measure “Protect from frost” should be indicated. |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** | Waived | No study performed. Yeast is inert and does not react with the packaging material, which is the one that is supplied by the active substance/product manufacturer. | / | / | Acceptable  Nevertheless, the effect of light was not indicated. The mitigation measure “Protect from light” should be indicated. |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.5.1. | Wettability *[indicate the concentration tested]* | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]* | Waived | Not relevant considering the formulation type. | / | / | Acceptable |
| 3.5.3. | Wet sieve analysis and dry sieve test *[indicate the concentration tested]* | Waived | Not relevant considering the formulation type. | / | / | Acceptable |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability *[indicate the concentration tested]* | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.5.5. | Disintegration time | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability | Waived | Not required in the context of simplified authorisations. | / | / | Acceptable |
| 3.5.7. | Persistent foaming | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.8. | Flowability/pourability/dustability | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.9. | Burning rate — smoke generators | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.10. | Burning completeness — smoke generators | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.11. | Composition of smoke — smoke generators | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.5.12. | Spraying pattern — aerosols / spray | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.6.1. | Physical compatibility | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.6.2. | Chemical compatibility | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.7. | Degree of dissolution and dilution stability | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.8. | Surface tension *[indicate the conditions of the test and the concentration tested]* | Waived | Not required considering the formulation type. | / | / | Acceptable |
| 3.9. | Viscosity *[indicate the shear rate and the temperature tested]* | Waived | Not required considering the formulation type. | / | / | Acceptable |

Table 3.3 Conclusion on physical, chemical, and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| No storage stability study is available, content of microbial contaminants and physical and chemical properties after storage are not available. Acceptable characteristics and analysis of microbial contaminants in the product were not provided after 8 years of storage.  The shelf-life of 24 months at temperature lower than 25°C can be set based on the technical data sheet of the product MAURIPAN RES 10kg as no re-packing is performed by applicant.  **Implications for labelling:**  Shelf-life: 24 months  Store at temperature lower than 25°C.  Protect from frost.  Protect from light.  Protect from humidity.   * **Minor change - 2022**   The applicant has claimed a maximum storage duration of 69 months.  New data are presented in the context of this minor change to support:   * The increase of the shelf-life from 2 years to 69 months.   + Additionnal data on microbial contaminants are available at 69 months of shelf life for the representative product/sample.   Data are reported below. |

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** | **Conclusion** |
| --- | --- | --- | --- | --- | --- | --- |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | Waived | Product Levure de panification sèche Active (*Saccharomyces cerevisiae*)  V0020AT | Data on microbial contaminants for the food product with an aged sample (V0020AT) was performed after 69 months of storage and is presented in the certificate of analysis:    Sample production : 09/2016  Sample testing : 24/06/2022 | CoA, 2022, AB MAURI | A CoA was provided on batch manufactured on 09/2016 and analysed on 24/06/2022 (approx.69 months). Data provided for *Salmonella*, aerobic plate count, *Staphylococcus aureus,* *E. Coli*, and Coliforms are sufficient to demonstrate that no significant microbial contamination will occur after 69 months.  For *Staphylococcus aureus (*coagulase positive), *E. Coli* and coliforms, the detection limit is higher than the limit in OECD 65.  However, considering that these threshold limits are not applicable to biocidal product and considering the intented uses (not for feeding), the level of contamination can be considered acceptable after 69 months by adding as a precautionary measure:  “Wash hands after handling the product”. |

Table 3.3 Conclusion on physical, chemical, and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties – Minor change Application 2022** |
| No storage stability study is available, physical and chemical properties after storage are not available. Acceptable characteristics and analysis of microbial contaminants in the product are provided at T0 and after 69 months of storage.  The shelf-life of 69 months at temperature lower than 25°C can be set based on the technical data sheet of the product MAURIPAN RES 10kg and the microbial contaminant after storage as no re-packing is performed by applicant and by adding the precautionnary measure “Wash hands after handling the product”.  **Implications for labelling:**  Shelf-life: 69 months  Store at temperature lower than 25°C.  Protect from frost.  Protect from light.  Protect from humidity. |

## 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** | **Conclusion** |
| --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | 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 explosiveness, this property is considered not applicable. | Acceptable |
| 4.2. | Flammable gases | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.3. | Flammable aerosols | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.4. | Oxidising gases | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.5. | Gases under pressure | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.6. | Flammable liquids | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.7. | Flammable 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 flammability, this property is considered not applicable. | Acceptable |
| 4.8. | Self-reactive substances and mixtures | 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-reactivity, this property is considered not applicable. | Acceptable |
| 4.9. | Pyrophoric liquids | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.10. | Pyrophoric solids | Waived | / | The product is known to be stable in contact with air. | Acceptable |
| 4.11. | Self-heating substances and mixtures | 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-heating, this property is considered not applicable. | Acceptable |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | Waived | / | The product is known to be stable in contact with water. | Acceptable |
| 4.13. | Oxidising liquids | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.14. | Oxidising 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 oxidising properties, this property is considered not applicable. | Acceptable |
| 4.15. | Organic peroxides | Waived | / | Not relevant because the product does not fall under the definition of organic peroxides. | Acceptable |
| 4.16. | Corrosive to metals | Waived | / | Not relevant because the product is a solid. | Acceptable |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | Waived | / | Not relevant because the product 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. | Acceptable |
| 4.17.3. | Dust explosion hazard | 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 dust explosion, this property is considered not applicable. | Acceptable |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on 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. |

## Methods for detection and identification

**Identification:**

Methods for the identification of the active substances are not available. Considering the type of the active substances and the type of the dossier for simplified authorisation application, the identification methods are not required in the framework of this dossier.

**Methods for detection of the active substance *Saccharomyces cerevisieae***

According to the Applicant considering that the product corresponds to the active substance, *Saccharomyces cerevisiae*, for which no specifications have been set except being food grade, which it is, and that no follow-up of the content of active substance in the biocidal product during storage is required to prove its stability, no analytical methods have been developed and/or validated for the analysis of *Saccharomyces cerevisiae* in the ATTRACTIF MGF.

As the product is a food grade product no more data is required.

**Methods for detection of microbial contaminants**

The validated methods or international standard methods used for the storage stability for the determination of microbial contaminants in the product ATTRACTIF MGF were not provided. Nevertheless, as acceptable content of microbial contaminants was indicated in the technical sheet of a marketed food grade product MAURIPAN RES 10kg (identical to Attractif MGF) no more data required.

**Methods for detection of the active substance *Saccharomyces cerevisieae in*** ***human body fluids and tisues soil water and air***

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 3.12 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification** |
| Methods for the determination of the active substance *Saccharomyces cerevisiae* and of microbial contaminants in the biocidal product ATTRACTIF MG are not available. Nevertheless, as the product is identical to a marketed food grade product MAURIPAN RES 10kg, no more data required.  Methods for the detection of *Saccharomyces cerevisiae* in soil, air, water, and animal and human body fluids and tissues were not provided and not necessary as MRL were fixed and no residue definifinition set. |

## Assessment of efficacy against target organisms

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

The product ATTRACTIF MGF is a wettable powder attractant used in traps against fly (*Musca domestica*), wasp (*Vespula vulgaris*), for outdoor use. The product is used to attract these insects in traps which are source of nuisance through their stings and their presence near food.

The product is used to protect human health and food.

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

The product ATTRACTIF MGF is used in combination with a trap. Once activated with water the attractive powder produces a characteristic odour attracting the insects 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** | **Reference** | **Number in IUCLID section 6.7/Test report title** |
| PT19  Attractantfor flies and wasps - outdoor | ATTRACTIF MGF  Sample lot 1253: Saccharomcyces Fermentation Yeast – CAS No: 68876-77-7  (fresh product) | Attractant:  Wasp (*Vespula vulgaris*) 10 waps released into room  House flies (*Musca domestica*) 50 flies released into room | Laboratory test  Indoor  Test system and exposure time  The product is put into trap bottle. Two adjacent rooms sperated with a glass partition are chosen for the study. The partition ends two feet below the ceiling of the rooms. The trap is placed in the center of the room 1 and control attractant in the center of room 2 (competition source of food). The insects are released into the room 1.  Every 24 hours, the number of insects captured in the trap is recorded.  Control: attractant trap without attractant in the room 1.  Temperature: 28°C Humidity: 50% RH  1 replicate  Concentration applied  20 g of powder in the trap with 500 mL of water. | **Against *Vespula vulgaris***   |  |  |  | | --- | --- | --- | | S.No. | Time period of study | % Efficacy | | 1 | 24 hrs ( 1 day) | 50% | | 2 | 2 days | 100% |   **Against *Musca domestica***   |  |  |  | | --- | --- | --- | | S.No. | Time period of study | % Efficacy | | 1 | 24 hrs ( 1 day) | 70% | | 2 | 2 days | 100% |   **Conclusion:**  After 2 days, all the flies and wasps were caught in the trap with the product in room 1. An efficacy level of 100% is thus achieved in 2 days. | Kiran Kumar B.B. 2021  RI=3  (Indoor test, only 1 replicat)  Supportive data | STUDY REPORT: Attractant test Report for Liquid device (PT-19 3E)  C0031/1920/01/AM/0002 |
| PT19  Attractant for flies and wasps - outdoor | ATTRACTIF MGF:  -Fresh product - (batch XJUN082210)  -Aged product (2013 - 8 years old) - (batch XJUL19201502) | Wasp (*Vespula vulgaris*)  House flies (*Musca domestica*) | Field test  Test system and exposure time :  The product is put in a trap bottle.  9 sites (reprensentative of the claimed uses) have been tested with three different position for each site (called serie). Three different products are tested during each test : fresh product, 8 years old product and control (water). The position of the trap is changed between each serie so it can be tested in each position of the site.  The distance between each trap are 5 m and each trap is suspended at a heigh around 2 m of the ground.  Measures were taken every day for 7 to 21 days. A final count of organisms was performed at the end of the trial to count the exact number of captured insects.  The percentage of efficacy is calculated by comparing the number of insects trapped in the untreated and in the treated traps:  % of efficacy = [ (population trapped with attractant - population trapped without attractant) / population trapped with attractant ] x 100  Concentration applied :  20g / 500 mL of product in a trap.  The first check is performed 24 hours after placing the product in the water. | Catched insects :   |  |  |  |  | | --- | --- | --- | --- | | Product | Flies | Wasps | Other | | Fresh | 17609 | 62 | 6127 | | 8 years old | 18207 | 48 | 6355 | | Control | 5 | 0 | 2 |   Flies = *Musca domestica*  Wasps = *Vespula vulgaris*  Others = Moths, spiders and other flies (non *Musca domestica*)  It can be noted that a lot of flies (*Musca domestica*) were captured during the trials in both fresh and aged product traps and no fly was captured in the control.  Rq: 12462 of the other captured insects in the fresh and aged product traps are other species of flies that are also considered as a nuisance (such as *Calliphora Vomitoria*, *Fannia canicularis*).  More than 100 wasps were captured during the trials. It has to be noted that in the tested region, in the summer 2021, the weather was not optimal for the wasp activity that coud explain the low number of wasp catched in the treated traps over the test period. But by comparison with the control trap the attractive efficacy has been sufficiently shown.  Conclusion :  Therefore, it can be concluded that the product ATTRACTIF MGF is efficient to attract flies (*Musca domestica*) and wasp *Vespula vulgaris*) up to 14 days.  The producted has also demonstrated that the product remains efficient after 8 years of storage. | F. Lacombe & E. Villard 2021  RI=1 | Etude d’efficacité d’un produit attractif « Mouches, Guêpes »  « ATTRACTIF MGF »  Rapport 060621-AMGF-V1 |

### Efficacy assessment

The available simulated use study shows that the product is effective for attracting and catching flies and wasps. Nevertheless, in the test, the product is applied indoor, which is not representative of the use of the product. For that reason, this test is considerate as laboratory test. It has been noted that no replicate was performed in this trail.

The field test study shows that the product is efficient against *Musca domestica* and *Vespula vulagris* during 14 days.

It has also been demonstrated that the product remains efficient after 8 years of storage.

### Conclusion on efficacy

The efficacy of the biocidal product ATTRACTIF MGF as an attractant has been shown against house fly (*Musca domestica,* adult*)* and wasp (*Vespula* *vulgaris,* adult*)* at the application rate of 20 g of powder diluted in 500 mL of water per trap, each 5 m apart, during 14 days. After 8 years of storage, the product remains efficient.

### Occurrence of resistance and resistance management

Not expected to be relevant for the product ATTRACTIF MGF since it is based on olfaction.

### Known limitations

There are no known limitations to the product ATTRACTIF MGF.

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

Not applicable, as the product ATTRACTIF MGF is not intended to be used with other biocidal products. However, the product ATTRACTIF MGF should be used in combination with an appropriate trap to catch the insects that it attracts. The trap to be used is not specific to the product and is therefore not included in the product authorization.

## 

## Risk assessment for human health

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

### 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 endpoints for the active substances and available information for the non-active substances.

The classification of the product ATTRACTIF MGF has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

The biocidal product ATTRACTIF MGF does not contain any classified ingredient and therefore is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization and acute toxicity.

### 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)).

### Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

### 3.7.4. Dietary exposure

Active substances are listed in Annex I of Regulation (EU) No 528/2012. Moreover, considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible.

## Animal health

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

## 3.9. Environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

### 3.9.1 Classification

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.

### 3.9.2 Substance(s) of concern

The product ATTRACTIF MGF 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).

### 3.9.3 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

## 3.10. Assessment of a combination of biocidal products

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

## 3.11. Comparative assessment

As active substances are listed in Annex I of Regulation (EU) No 528/2012, a comparative assessment is not relevant.

## 3.12. Assessment of a combination of biocidal products

Not applicable

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

# Appendices

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

No new information on the active substances is available

No new information on the substances of concern is available

## 4.2 List of studies for the biocidal product

Table 4.3 List of studies for the biocidal product

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author (s)** | **Year**  **Report date** | **Reference No. *(Annex III requirement)***  **/**  **IUCLID Section No.** | **IUCLID Document name** | **Title.**  **Report No.** | **Type of publication** | **Source (where different from company)**  **Study sponsor** | **GLP**  **(Yes/No)** | **Data Protection Claimed**  **(Yes/No)** |
| F. Lacombe & E. Villard | 2021  2021-09-30 | 6 | Efficacy against flies and wasps (Field Test) | Etude d’efficacité d’un produit attractif “Mouches, Guêpes ” “ATTRACTIF MGF”  Rapport 060621-AMGF-V1 | Unpublished | VNM / Terrium | No | Yes |
| Kiran Kumar B.B. | 2021  2021-05-06 | 6 | Efficacy against flies and wasps | Attractant test Report for Liquid device (PT-19 3E)  C0031/1920/01/AM/0002 | Unpublished | Terrium SAS 728, avenue de la Gare, 42210 Montrond les Bains, France | No | Yes |

## 4.3 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)
2. Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at <https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b>. [↑](#footnote-ref-3)