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

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

(submitted by the evaluating Competent Authority)



BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR

PT2

VINEGAR

Case Number in R4BP: BC-DW065233-23

Case Number SA-MAC in R4BP: BC-AY078940-08

FR CA

Date: 29/11/2021

Updated Date: 20/01/2023

Table of Contents

[Table of Contents 2](#_Toc124935313)

[0 Dossier’s history 4](#_Toc124935314)

[*1* CONCLUSION 5](#_Toc124935315)

[*2* ASSESSMENT REPORT 7](#_Toc124935316)

[2.1 Summary of the product assessment 7](#_Toc124935317)

[2.1.1 Administrative information 7](#_Toc124935318)

[**2.1.1.1** Identifier of the product family 7](#_Toc124935319)

[**2.1.1.2** Authorisation holder 7](#_Toc124935320)

[**2.1.1.3** Manufacturer(s) of the products of the family 7](#_Toc124935321)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 8](#_Toc124935322)

[2.1.2 Product family composition and formulation 9](#_Toc124935323)

[**2.1.2.1** Identity of the active substance 9](#_Toc124935324)

[**2.1.2.2** Candidate(s) for substitution 9](#_Toc124935325)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product family2 9](#_Toc124935326)

[**2.1.2.4** Information on technical equivalence 9](#_Toc124935327)

[**2.1.2.5** Information on the substance(s) of concern 9](#_Toc124935328)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product family 10](#_Toc124935329)

[**2.1.2.7** Type of formulation 10](#_Toc124935330)

[2.1.3 Meta SPC 1 administrative information 10](#_Toc124935331)

[**2.1.3.1** Meta SPC identifier 10](#_Toc124935332)

[**2.1.3.2** Suffix to the authorisation number 10](#_Toc124935333)

[**2.1.3.3** Product type(s) 10](#_Toc124935334)

[2.1.4 Meta SPC 1 composition 10](#_Toc124935335)

[**2.1.4.1** Qualitative and quantitative information on the composition of the meta SPC 1 10](#_Toc124935336)

[**2.1.4.2** Type(s) of formulation of the meta SPC 1 10](#_Toc124935337)

[2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1 11](#_Toc124935338)

[2.1.6 Authorised use(s) of the META SPC 1 11](#_Toc124935339)

[**2.1.6.1** Use description 11](#_Toc124935340)

[2.1.7 General directions for use of the meta SPC 1 12](#_Toc124935341)

[**2.1.7.1** Instructions for use 12](#_Toc124935342)

[**2.1.7.2** Risk mitigation measures 12](#_Toc124935343)

[**2.1.7.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 13](#_Toc124935344)

[**2.1.7.4** Instructions for safe disposal of the product and its packaging 13](#_Toc124935345)

[**2.1.7.5** Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc124935346)

[2.1.8 Other information 13](#_Toc124935347)

[2.1.9 Trade name(s), authorisation number and specific composition of each individual product 13](#_Toc124935348)

[2.1.10 Packaging of the biocidal product 14](#_Toc124935349)

[2.1.11 Documentation 15](#_Toc124935350)

[**2.1.11.1** Data submitted in relation to product application 15](#_Toc124935351)

[**2.1.11.2** Access to documentation 15](#_Toc124935352)

[2.2 Assessment of the biocidal product family 16](#_Toc124935353)

[2.2.1 Intended use(s) as applied for by the applicant 16](#_Toc124935354)

[2.2.2 Physical, chemical and technical properties 17](#_Toc124935355)

[2.2.3 Physical hazards and respective characteristics 29](#_Toc124935356)

[2.2.4 Methods for detection and identification 40](#_Toc124935357)

[2.2.5 Efficacy against target organisms 41](#_Toc124935358)

[**2.2.5.1** Function and field of use 41](#_Toc124935359)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 41](#_Toc124935360)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 41](#_Toc124935361)

[**2.2.5.4** Mode of action, including time delay 41](#_Toc124935362)

[**2.2.5.5** Efficacy data 42](#_Toc124935363)

[**2.2.5.6** Occurrence of resistance and resistance management 44](#_Toc124935364)

[**2.2.5.7** Known limitations 44](#_Toc124935365)

[**2.2.5.8** Evaluation of the label claims 44](#_Toc124935366)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 44](#_Toc124935367)

[2.2.6 Human health 45](#_Toc124935368)

[2.2.7 Animal health 48](#_Toc124935369)

[2.2.8 Environment 49](#_Toc124935370)

[2.2.9 Measures to protect man, animals and the environment 49](#_Toc124935371)

[2.2.10 Assessment of a combination of biocidal products 49](#_Toc124935372)

[*3* Annexes 49](#_Toc124935373)

[3.1 List of studies for the biocidal product family 49](#_Toc124935374)

# Dossier’s history

**Note to the reader**

This consolidated PAR for the **major** change application of the product authorisation is based on the PAR of the first authorisation, in which all necessary addenda have been included.

In part 2.2 of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post authorisation data...) the assessments related to the major / minor change of the product are at the end of each section and are highlighted in grey.

In part 2.1 of the consolidated PAR: the summary of product characteristics is pointed out and corresponds to the decision for the major/minor change application.

**History of the dossier**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | MSCA-France | BC-DW065233-23 | 13.08.2021 | Initial assessment simplified procedure |  |
| SA-AAT | MSCA-France | BC-AN071803-37 | 29.11.2021 | Amendment of simplified authorisation |  |
| SA-MAC | MSCA-France | BC-AV080011-39 |  | * Addition of the professional user category * Addition of two new packages for professional users |  |

# CONCLUSION

**Intended** **uses**

The products of the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR are products type 2 containing vinegar used against green algae (*Chlorophyta spp.)*. This is a ready-to-use product used outdoor on hard porous surfaces by non-professional users and by wetting (spraying or pouring).

***Conclusion of the assessment***

The active substance vinegar contained in the biocidal product BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR is listed in Annex I of EU Regulation 528/2012.

The product BURG BIOCIDAL PRODUCT is classified H290.

There is no substances of concern included in the product BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR.

Efficacy studies submitted demonstrate that the product BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR is efficient, in the conditions of use presented in the SPC.

The biocidal product BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR does not contain any nanomaterials.

No PPE are required during the manipulation of the product.

**GENERAL CONCLUSION: Eligibility for the simplified authorisation procedure**

Following the evaluation, FR-CA considers that the biocidal product BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR does meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012.

**Therefore, the biocidal product shall be authorised for the following use:**

|  |  |  |
| --- | --- | --- |
| **Target organisms** | **Application rate** | **Use conditions** |
| Green algae (*Chlorophyta spp.)* | Ready to use  3L per 10m² | Outdoor  Non-professionnals  Spraying or pouring on hard porous surfaces. |

SA-MAC major change application 2022

Major change description:

* Add the professional user category
* Addition of two new packages for professional users

**Conclusion**

* **Intended uses**

The products of the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR are products type 2 containing vinegar used against green algae (*Chlorophyta spp.)*. This is a ready-to-use product used outdoor on hard porous surfaces by professional and non-professional users and by wetting (spraying or pouring).

* **Conclusion of the assessment**

The data submitted regarding the new package sizes of the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR have been evaluated and found to be in compliance.

No PPE are required for the new user category and for the two new packages.

**General conclusion: Eligibility for the simplified authorisation procedure**

**Therefore, the biocidal product shall be authorised for the following use:**

|  |  |  |
| --- | --- | --- |
| **Target organisms** | **Application rate** | **Use conditions** |
| Green algae (*Chlorophyta spp.)* | Ready to use  3L per 10m² | Outdoor  Non-professionnals and professionnals  Spraying or pouring on hard porous surfaces. |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| Burg Biocidal Product Family “Natural Vinegar” | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Burg Groep B.V. |
| **Address** | Marconistraat 26  1704 RG Heerhugowaard  Netherlands |
| **Authorisation number** | FR-2021-0033 | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Burg Groep B.V. |
| **Address of manufacturer** | Marconistraat 26  1704 RG Heerhugowaard  Netherlands |
| **Location of manufacturing sites** | Burg Azijn B.V.  Marconistraat 26  1704 RG Heerhugowaard  Netherlands |
| Burg Essig GmbH  Preβburger Strasse 8  D-94315 Straubing-Sand  Deutschland |
| Burg Vinegar Belgium NV/SA  Ramerstraat 26  B1760 Roosdaal  België |
| Burg Vinaigres SAS  1-3 Zac Des Bregaudieres  17390 La Tremblade  France |
| Burg Ocet s.r.o.  Octarna Bzenec  U Bzinku 409  696 81 Bzenec  Czech Republic |

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

|  |  |
| --- | --- |
| **Active substance** | Vinegar |
| **Name of manufacturer** | Burg Groep B.V. |
| **Address of manufacturer** | Marconistraat 26  1704 RG Heerhugowaard  Netherlands |
| **Location of manufacturing sites** | Burg Azijn B.V.  Marconistraat 26  1704 RG Heerhugowaard  Netherlands |
| Burg Essig GmbH  Preβburger Strasse 8  D-94315 Straubing-Sand  Deutschland |
| Burg Vinegar Belgium NV/SA  Ramerstraat 26  B1760 Roosdaal  België |
| Burg Vinaigres SAS  1-3 Zac Des Bregaudieres  17390 La Tremblade  France |
| Burg Ocet s.r.o.  Octarna Bzenec  U Bzinku 409  696 81 Bzenec  Czech Republic |

### Product family composition and formulation

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Vinegar |
| **IUPAC or EC name** | Not applicable |
| **EC number** | Not applicable |
| **CAS number** | 8028-52-2 |
| **Index number in Annex VI of CLP** | Not applicable |
| **Minimum purity / content** | 100% Natural vinegar active substance, containing up to 10% acetic acid |
| **Structural formula** | Not applicable |

#### Candidate(s) for substitution

Not relevant

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Vinegar | n.a. | Active substance | 8028-52-2 | n.a. | 100 | 100 |

#### Information on technical equivalence

The active substance contained in the biocidal product family is listed in category 4 of BPR Annex I. Therefore, technical equivalence is not relevant for the active substance.

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

The biocidal product family does not contain any substance of concern.

Please see the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal product family

No co-formulant contained in the BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR is regulatory identified as endocrine disruptors or have significant ED properties.

#### Type of formulation

|  |
| --- |
| AL –Any other liquid |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

| Number 1 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Vinegar | n.a. | Active substance | 8028-52-2 | n.a. | 100 | 100 |

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| AL –Any other liquid |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

| **Classification** | |
| --- | --- |
| Hazard category | Warning |
| Hazard statement | H290 May be corrosive to metals cat 1 |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H290 May be corrosive to metals cat 1 |
| Precautionary statements | P234: Keep only in original container.  P390: Absorb spillage to prevent material damage.  P406: Store in corrosive resistant/... container with a resistant inner liner. |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 1

#### Use description

Table 1. Use # 1 – Green algae removal - surface wetting

|  |  |
| --- | --- |
| **Product Type** | Product Type 2 - Disinfectants and algaecides not intended for direct application to humans or animals |
| **Where relevant, an exact description of the authorised use** | Algaecide  Removal of green surface contamination from hard porous surfaces (such as pavements, patios or concrete), by surface wetting. |
| **Target organism (including development stage)** | Green algae (*Chlorophyta spp.)* |
| **Field of use** | Outdoor |
| **Application method(s)** | Full wetting of the treatment area by pouring or spraying. |
| **Application rate(s) and frequency** | Ready to use product.  Application rate: 3 L for 10 m² |
| **Category(ies) of users** | Non professional  Professional |
| **Pack sizes and packaging material** | Packaging material:  (r)\*PET or (r)\*HDPE bottle with (r)HDPE or (r)LDPE press or screw cap  Pack sizes:  500 ml - 750 ml - 1 litre - 1.5 litre - 3 litre - 4 litre - 5 litre –  Only for professionals users :  5L in (r)\*PET or (r)\*HDPE bottle with (r)HDPE or (r)LDPE press or screw cap  Jerrycan 25 litre in (r)\*HDPE  IBC container 1000L in (r)\*HDPE  (r)\* : recycled or not |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use of the meta SPC 1

#### Instructions for use

|  |
| --- |
| * Comply with the instructions for use. * Apply the product to a visibly dry surface. * Do not treat in rainy weather or on frozen surfaces. * Do not clean the surface after treatment. * Allow the product to take effect for at least several days. * The efficacy is observed up to four months. In case of re-infestation, renew the application. * The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

#### Risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| * IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. * IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. * IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * If medical advice is needed, have product container or label at hand |

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

|  |
| --- |
|  |

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

|  |
| --- |
| * Protect from frost. * Shelf life: 3 years. * Keep out of reach of children and non-target animals/pets |

### Other information

|  |
| --- |
| - |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Vintastic Destructeur d’algues vertes**  **Rio Destructeur d’algues vertes**  **AH Destructeur d’algues vertes**  **Jumbo Destructeur d’algues vertes**  **COOP Destructeur d’algues vertes**  **PLUS Destructeur d’algues vertes**  **Gwoon Destructeur d’algues vertes**  **1 de beste Destructeur d’algues vertes**  **Groenland Destructeur d’algues vertes**  **Felicia Destructeur d’algues vertes**  **Delhaize Destructeur d’algues vertes**  **Loda Destructeur d’algues vertes**  **Kruidvat Destructeur d’algues vertes**  **Trekpleister Destructeur d’algues vertes**  **Una Destructeur d’algues vertes**  **W5 Destructeur d’algues vertes**  **Effekt Destructeur d’algues vertes**  **Superschoon Destructeur d’algues vertes**  **OKE Destructeur d’algues vertes**  **Kristal Destructeur d’algues vertes** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Vinegar | - | Active substance | 8028-52-2 | - | 100 |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Sizes/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 500 ml  750 ml  1 litre  1.5 litre  3 litre  4 litre  5 litre | PET or rPET or rPET/PET-mix | (r)HDPE or (r)LDPE press cap or screw cap | General public (non-professional) | Yes |
| Bottle | 500 ml  750 ml  1 litre  1.5 litre  3 litre  4 litre  5 litre | HDPE or rHDPE\* or rHDPE/HDPE-mix | (r)HDPE or (r)LDPE press cap or screw cap | General public (non-professional) | Yes |

\* recycled PET/HDPE

* SA-MAC major change application (2022)

Additional packagings

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Sizes/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 5 litre | (r)\*PET or (r)\*HDPE | (r)HDPE or (r)LDPE press or screw cap | Professionals | Yes |
| Jerry can | 25 litre | (r)\*HDPE | (r)HDPE or (r)LDPE press cap or screw cap | Professionals | Yes |
| IBC container | 1000 litre | (r)\*HDPE | (r)HDPE or (r)LDPE press cap or screw cap | Professionals | Yes |

### Documentation

#### Data submitted in relation to product application

Please refer to annex 3.1

#### Access to documentation

No letter of access has been submitted.

## Assessment of the biocidal product family

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

Table 1. Meta-SPC 1 - Use 1 – Surface wetting

|  |  |
| --- | --- |
| Product Type | Product Type 2 (Disinfectants and algaecides not intended for direct application to humans or animals). |
| Where relevant, an exact description of the authorised use | Algaecide. |
| Target organism (including development stage) | Green algae. |
| Field of use | Outdoor.  Removal of green surface contamination from hard and semi-permeable substrates (such as pavements, patios or concrete), by surface wetting. |
| Application method(s) | Full wetting of the treatment area by pooring or spraying. |
| Application rate(s) and frequency | The product is ready to use.  Application rate:  Coverage rates may depend on the surface type. General guideline: 3 liter per 10 m2.  Frequency: Treat as needed. |
| Category(ies) of users | General public (non-professional) & Professionals |
| Pack sizes and packaging material | *Packaging material:*  (r)\*PET or (r)\*HDPE bottle or IBC container or Jerry can with (r)HDPE or (r)LDPE press or screw cap  *Pack sizes:*  500 ml - 750 ml - 1 litre - 1.5 litre - 3 litre - 4 litre - 5 litre -25 litre – 1000 litre |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **eCA conclusion** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | *Method:*  Visual inspection | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | Liquid. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Colour at 20 °C and 101.3 kPa | *Method:*  Visual inspection | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | Clear, colourless. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Odour at 20 °C and 101.3 kPa | *Method:*  Olfactory inspection | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | Vinegar. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Acidity / alkalinity | *Method:*  OECD TG 122, Determination of pH, Acidity and Alkalinity, 2013. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | *Acidity:*  7.76% m/m (calculated as H2SO4),  corresponding to  9.50 % m/m calculated as acetic acid (CH3COOH). | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| pH | *Method:*  OECD TG 122, Determination of pH, Acidity and Alkalinity, 2013.  Determination of the acidity of the formulated test item by titration with standard alkali using electrometric end point determination. | *Undiluted test item:*  Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020")  *Diluted test item:*  1% w/v solution of natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | *pH undiluted test item:*  2.3  *pH diluted test item (1% w/v):*  3.3 | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Relative density / bulk density | *Method:*  EC Method A.3, Relative density, March 4, 2016.  OECD TG 109, Density of Liquids and Solids, October 2, 2012.  Determination of the density and relative density of the test substance using a 10 mL. pycnometer | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | *Density (ρ) @ 20 oC.:*  1.01 g/cm3  Relative density:  ( ):  1.01 | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Storage stability test – **accelerated storage** | / | / | Data on compatibility of biocidal product with packaging was submitted at elevated temperature. See below  Temperature conditions vinegar does not oxidise or degrade and retains its specific properties. | No data on stability of vinegar is available on these studies.  However, due the reason described before no limitation of temperature is set. | Burg Groep B.V. QHE Mgt, Memorandum "Summary on the stability and shelf life of vinegar 4-10%", E. Zaal, January 22, 2021 |
| Storage stability test – **long term storage at ambient temperature** | Not applicable, no long term storage study at elevated temperatures was performed. | Natural vinegar > 4% - < 10% acetic acid | Natural vinegar stable > 3 years according to EU regulation No 1169/2011  (an indication of the date of minimum durability shall not be required for vinegar) | No data submitted.  However, according to EU regulation No 1169/2011, no data is require for stability of vinegar.  Shelf life of Biocidal product is stable 3 year | Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers |
|  | Statement proposed by the applicant |  | All Burg Group sites have been certified according to IFS food safety management system with requirements to assure the stability of the products.  Reference bottles for each batch are stored for 3 years after production. According to a predefined schedule, random batches are retested to verify if the product and packaging still meets the product specifications on parameters like acid contents, packaging integrity and appearance.  Burg has never found any significant deviation regarding shelf life and confirms that the natural vinegar products have almost indefinite shelf life. | No analysis submitted, only a statement that QC data are performed in the company.  Due to the compound, this is acceptable.  The Biocidal product is stable during 3 years | Burg Groep B.V. QHE Mgt, Memorandum "Summary on the stability and shelf life of vinegar 4-10%", E. Zaal, January 22, 2021 |
| Storage stability test – **low temperature stability test for liquids** | Not applicable, no storage study at low temperatures was performed. |  | Not relevant. The statement “Protect from frost” is included on the product label. | The statement “Protect from frost” is added to SPC |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not relevant, no storage study to evaluate the effects of light was performed.  Transparent bottles are commonly used to store food grade vinegar. Vinegar does not require special storage conditions such as protection from light.  *Light:*  Not relevant. Product is stable under ambient light. | Acetic Acid is not sensible to light  Acceptable | Burg Groep B.V. QHE Mgt, Memorandum "Summary on the stability and shelf life of vinegar 4-10%", E. Zaal, January 22, 2021 |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not relevant, no storage study to evaluate the effects of humidity was performed.  Vinegar does not require special storage conditions such as protection from humidity. The vinegar product already contains > 90% water and mixes with water in all proportions. The packaging is appropriately sealed, the content is protected from humidity entering from the outside. | Acceptable | Burg Groep B.V. QHE Mgt, Memorandum "Summary on the stability and shelf life of vinegar 4-10%", E. Zaal, January 22, 2021  Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**  **- PET** | *Methods*  Composition check of sample material  Overall migration  CEN method EN 1186-9:2002 (17 April 2002)  Specific migration  CEN method EN 13130-1:2004 (26 May 2004)  10 days of contact at 60oC. | 3% acetic acid solution (simulant) in rPET (Sample 1) and PET (Sample 2) | No detectable overall or specific migration from packaging in contact with simulant. Samples 1 and 2 are considered suitable for single use contact with acetic foodstuff for long-term storage at room temperature | Acceptable, biocidal product is compatible with claimed packagings | Triskelion, Analytical report "Food contact compliance investigation according to EU legislation", Study Ref. No. P20171-20223, G. Haagh, October 2020 and related compliance statements |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**  **- HDPE** | *Methods*  Composition check of sample material  Overall migration testing  Specific migration testing  10 days of contact at 40oC. | 3% acetic acid solution (simulant) in HDPE sample | Samples are in compliance with referenced food contact regulations and considered suitable for long term contact with acidic foodstuff at room temperature or below. | Acceptable  Biocidal product is stable in contact wit HPDE | HDPE Supplier 1, "Certificate of Conformity", F. Brucker, November 2020.  HDPE Supplier 2, "Declaration of Conformity for materials in contact with food", H. Sturm, February 2014. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**  **- PET** |  |  | PET exhibits good chemical resistance against 1-10% acetic acid | *Acceptable*  *Biocidal product is stable in contact with PET* | *Additional information:*  Chemical resistance information on packaging material - example information PET from Supplier 3, as included in Reference List. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**  **- HDPE** |  |  | HDPE is shown to have satisfactory chemical resistance against 1-10% acetic acid, at 21 and 60 oC. | *Acceptable* | *Additional information:*  Chemical resistance information on packaging material - example information HDPE from Supplier 4, February 2012, as included in Reference List. |
| Wettability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not to be dispersed or suspended in water. | / |  |
| Suspensibility, spontaneity and dispersion stability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not to be dispersed or suspended in water. | / |  |
| Wet sieve analysis and dry sieve test | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not to be dispersed or suspended in water. | / |  |
| Emulsifiability, re-emulsifiability and emulsion stability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not to be emulsified. | / |  |
| Disintegration time | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not a dispersible or soluble tablet. | / |  |
| Particle size distribution, content of dust/fines, attrition, friability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not a solid in the form of a powder or granules. | / |  |
| Persistent foaming | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not intended to be applied in water for use. | / |  |
| Flowability/Pourability/Dustability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not granular materials, suspension concentrates, capsule suspensions or suspoemulsions, or applied as a dust. | / |  |
| Burning rate — smoke generators | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not intended to be applied as a smoke. | / |  |
| Burning completeness — smoke generators | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not intended to be applied as a smoke. | / |  |
| Composition of smoke — smoke generators | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not intended to be applied as a smoke. | / |  |
| Spraying pattern — aerosols | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not supplied as an aerosol. | / |  |
| Physical compatibility | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid. No standard label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes). | / |  |
| Chemical compatibility | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid. No standard label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes). | / |  |
| Degree of dissolution and dilution stability | Not applicable. |  | Not applicable because the products in the BPF are a ready to use liquid and not a tablet or to be used in a water-soluble bag. | / |  |
| Surface tension | *Method:*  EC Method A.5, Surface Tension, March 04, 2016.  OECD TG 115, Surface Tension of Aqueous Solutions, July 27, 1995.  Determination of surface tension using harmonised ring method and tensiometer | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") (1 g/L in water) | *Surface tension of 1g/L of test substance in water:*  70.75 mN/m  Because surface tension ≥ 60 mN/m, test item is considered not to be surface active. | Acceptable  Biocidal product is not surface active. | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Viscosity | *Method:*  OECD TG 114, Viscosity of liquids, October 2, 2012.  ISO Guide 3104, Petroleum Products - Transparent and Opaque Liquids - Determination of Kinematic Viscosity and Calculation of Dynamic Viscosity, 1994.  Determination of kinematic viscosity by using a glass capillary viscometer. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020") | Kinematic viscosity  At 20°C: 1.21 mm2/s  At 40°C: 0.790 mm2/s | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The biocidal products of the family BURG BPF NATURAL VINEGAR are aqueous AL formulations (Any Other Liquid) and ready-to-use. The appearance of the natural vinegar product is that of a clear, colourless liquid, with a vinegar odour. The product is acidic with a pH of 2.3 and has a density and viscosity comparable to that of water.  For storage, natural vinegar is considered stable under ambient conditions and the packaging is suitable for its contents.  *Product label:*  Low-temperature storage study was not performed, the sentence *"Protect from* *frost"* is required on the label.   * SA-MAC major change application (2022)   The new packaging (bottle 5L, jerry can 25L and IBC 1000L in HDPE or LDPE) are covered by the first authorisation. New packagings are acceptable.  Rest of the dossier was not revised. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **eCA comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Not applicable. | Vinegar -Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food). | Vinegar (<10%) is not explosive. It does not fulfil criterion (a) of art. 28(2), as confirmed by the BPC Opinion adopted 14 december 2017 and the subsequent listing of the active substance on BPR Annex I, Category 4. | Acceptable,  Not classified | Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Eligibility of certain food and feed active substances for inclusion into Annex I to the BPR  ECHA/BPC/186/2017  Commission Delegated Regulation (EU) 2019/1819 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include vinegar as an active substance in Annex I thereto |
| Flammable gases | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a gas. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Flammable aerosols | Not applicable. |  | Not applicable because the product is not supplied as an aerosol dispenser. | Acceptable |  |
| Oxidising gases | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a gas. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Gases under pressure | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a gas. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Flammable liquids | *Guideline:*  ECHA Guidance on the Application of the CLP Criteria, Section 2.7 Flammable liquids.    *Method:*  EC Method A.9, Flash-point, March 04, 2016.  ASTM Method D7094, Standard Test Method for Flash Point by Modified Continuously Closed Cup (MCCCFP) Tester, 2012.  Determination of flash point by using closed cup method | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | The test item has no flash point, as no flammable vapour/air mixture was produced at temperatures below boiling, which was observed visually at 100°C.  The product is not a flammable liquid. | Acceptable,  Not classified | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Flammable solids | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a solid. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Self-reactive substances and mixtures | *Guideline:*  Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Sixth revised edition, UN Procedures, 2015.  *Method:*  Appendix 6 screening method.  Determination of the exothermic decomposition energy by Differential Scanning Calorimetry. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not self-reactive, as no onset of decomposition  < 200 °C and heat of decomposition  < 300 J/g | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Pyrophoric liquids | *Guideline:*  ECHA Guidance on the Application of the CLP Criteria, Chapter 2.9.4 Classification of substances and mixtures as pyrophoric liquids.  *Method:*  Observation during production or handling.  The classification procedure for pyrophoric liquids need not be applied when experience, in production or handling, shows that the substance does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)). |  | Vinegar is not a pyrophoric liquid, because it is known to be stable at room temperature for prolonged periods of time (days)). | acceptable |  |
| Pyrophoric solids | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a solid. | acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Self-heating substances and mixtures | *Guideline:*  ECHA Guidance on the Application of the CLP Criteria, Section 2.11.4., Classification of self-heating substances and mixtures.  *Method:*  Screening. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is drastically reduced. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not self-heating, because the product is a liquid, not a solid. The products is also not adsorbed on a large surface (e.g. on powder particles). | acceptable |  |
| Substances and mixtures which in contact with water emit flammable gases | Screening.  The classification procedure for this class need not be applied if:  (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or  (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or  (c) the substance or mixture is known to be soluble in water to form a stable mixture. |  | The product does not emit flammable gases in contact with water, because  (a) the chemical structure of the product does not contain metals or metalloids; or  (b) experience in production or handling shows that the product does not react with water, e.g. the product is manufactured with water or washed with water; or  (c) the substance or mixture is known to be soluble in water to form a stable mixture. | acceptable | The natural vinegar product is produced in accordance with NEN-EN 13188, Vinegar - Product made from liquids of agricultural origin - Definition, requirements, marking, July 2000. |
| Oxidising liquids | Screening procedure by evaluation based on chemical groups. For organic compounds, the classification procedure for oxidizing substances need not be applied if:  (a) The compound does not contain oxygen, fluorine or chlorine; or  (b) The compound contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not oxidising, because none of the components of the test item does contain groups that act as an oxidizing agent. The oxygen atoms that are present in the molecular structure of the test item are chemically bonded to carbon or hydrogen. | Acceptable,  Not classified | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Oxidising solids | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a solid. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Organic peroxides | Not applicable. | Vinegar -Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food). | Vinegar (<10%) does not contain organic peroxides. It does not fulfil criterion (a) of art. 28(2), as confirmed by the BPC Opinion adopted 14 december 2017 and the subsequent listing of the active substance on BPR Annex I, Category 4. | Acceptable,  Not classified | Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Eligibility of certain food and feed active substances for inclusion into Annex I to the BPR  ECHA/BPC/186/2017  Commission Delegated Regulation (EU) 2019/1819 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include vinegar as an active substance in Annex I thereto |
| Corrosive to metals | Guideline:  Manual of tests and criteria for TGD - 6th revised edition, 2015.  Method:  UN Method C.1 Test for Determination the Corrosive Properties of Liquids and Solids that may become Liquid during Transport as Dangerous Goods of Class 8, Packing Group III. 2015.  Determination of corrosivity to metals by measuring of weight loss and measurement of hole depth on localised corrosion, using aluminium and steel plates exposed to the product at 55°C. over a 7-day test period. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | *Uniform corrosion*  All weight losses of aluminium and steel <13.5%, equivalent to a corrosion rate of  < 6.25 mm/year  *Localised corrosion*  Not observed with aluminium. **For steel: depth of deepest hole 269 μm (>= 120μm.)**  Corrosive based on the criterion for localized corrosion but not corrosive based on the weight loss criterion.  Product is not classified as "Corrosive to metals" category 1. | No photography is available in the report. However, other parameters are clearly reported. no more information on tests are required.  Disagree with industry conclusion that the product is not classified.  Due to the high pitting observed, **product is classified as "Corrosive to metals" category 1.** | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Auto-ignition temperatures of products (liquids and gases) | *Method:*  EC Method A.15. Auto-Ignition Temperature (Liquids and Gases). March 04, 2016.  Deutsches Institut für Normung (DIN) Guide 51794: Determining the Ignition Temperature of Petroleum Products. May 2003. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | The product is not auto-ignitable since no auto-ignition temperature was observed ≤ 650°C.  at an atmospheric pressure of 1013 hPa. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Relative self-ignition temperature for solids | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a solid. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |
| Dust explosion hazard | Not applicable. | Natural vinegar 9.56 g/100 ml. acetic acid (Lot No. "Test Product 22-07-2020" | Not applicable, because the product is a liquid, not a dust. | Acceptable | Charles River Laboratories Den Bosch, "Determination of Physico-Chemical Properties of  Natural vinegar 9.5%", Test facility Study No. 20263819, Z. Jovic Madzarevic, 2020 |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Biocidal products of the family BURG BPF NATURAL VINEGAR do not possess explosive or oxidising properties, and are not flammable.  Due to pitting observed on steel, the biocidal product is classified H290 cat 1.   * SA-MAC major change application (2022)   This part of the dossier was not revised for this major change application. |

### Methods for detection and identification

***I - Methods of analysis for the product***

No analytical methods for determination of active substance in products of the biocidal product family have been submitted:

For this simplified authorisation, an analytical method would only be required to validate the method used during shelf life evaluation studies.

However, for vinegar, by legal exemption, in accordance with Annex X item 1(d), of Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers, an indication of the date of minimum durability shall not be required. This, as well as routine quality control reflects that under ambient conditions vinegar does not oxidise or degrade and retains its specific properties. Vinegar furthermore does not require special storage conditions. From this it is concluded that there is no need for a shelf-life study to confirm the stability of (the active substance in) the product. No shelf-life study is proposed, thus no method is considered to be functional or required.

In addition, the products in the Natural Vinegar Biocidal Products Family do not contain any substances of concern.

***II - Methods of analysis for other media***

No analytical methods for the determination of the active substance and residues in a) environmental media (soil, air and water), b) animal and human body fluids and tissues, and c) food or feeding stuffs have been submitted since these are not considered relevant for the Natural Vinegar Biocidal Product Family in the framework of a simplified authorisation.

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| **Conclusion on the methods for detection and identification of the product** |
| Detection and identification of the biocidal products of the family BURG BPF Natural Vinegar including the vinegar as active substance, impurities and residues are not relevant for the product as such, nor for other media.  For the simplified authorisation of the products of the BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR, analytical methods are not required.   * SA-MAC major change application (2022)   This part of the dossier was not revised for this major change application. |

### Efficacy against target organisms

#### Function and field of use

Main Group 01: Disinfectants

Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals

The biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR are ready-to-use products intended to be used by pouring or spraying directly on hard surfaces to kill green algae by non-professional users.

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

The products are intended for the removal of green surface contamination caused by green algae (*Chlorophyta spp*.) from hard porous surfaces (such as pavements, patios or concrete).

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

The biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR are used as algaecide on hard surfaces.

When applied in sufficient quantities to growing plants such as algae, acetic acid causes the algal cell structure to break down.

#### Mode of action, including time delay

Natural vinegar is a contact algaecide, it only affects plant tissue it touches.

The effects on the cell structure take place from the moment the algal cell is in contact with the liquid product containing the acetic acid, but the effects are visible later. Algae growth is not only pH dependent - low pH slows down photosynthesis -, but in addition, the small acetic acid molecule penetrates cell membranes and causes electrolyte leakage, resulting in the algae cells to dry out and die.

Depending on environmental conditions such as air temperature, humidity, and direct sunlight levels, this may take from a few hours to several days. Organic growth will typically visibly decline after 24 hours and this will continue for a number of weeks

#### Efficacy data

There is no standard test method for algaecide efficacy testing that is currently recommended in the draft guidance on efficacy assessment for PT 2 biocides.

Field studies were conducted with the formulation claimed for the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR according to an in-house methodology. The results are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Algaecide | Hard and semi-permeable substrates (such as pavements, patios or concrete) | *Test substance*  Green algae remover (Natural vinegar 9.5 % w/v acetic acid, Lot No. 19071801)  tested at four use rates  *Untreated control*  Water | Green algae (*Chlorophyta spp.*)  Initial surface coverage: between 50-100% | *Guidelines:*  1) EPPO PP1/117(3) Weeds on hard and semi-permeable surfaces  2) EPPO PP1/152(4) Design and analysis of efficacy trials  3) EPPO PP1/181(4) Conduct and reporting of efficacy  *Method:*  Application of the test substances by wetting the surface with watering can through a rose attachment. | *Application rate*  300 ml/m2 of test substance applied at four concentrations:  1) N (9.5%, undiluted)  2) 075 N (7.13%)  3) 0.5 N (4.75%)  4) 0.25N (2.38%)  *Treatment*  5 Treatments (4 application rates with test product and negative controls), 4 replicates (shaded patio slab walkway, concrete, 1 m2 plot) per treatment on Day 0  Exposure times  (observations):  Days 0, 1, 3, 7, 14, 30, 60, 90, 120, 150 and 180.  Information recorded at each assessment:  • % total coverage of algae in each plot  • % control (comparison to the untreated plots)  • Photographs of all treatments  • Any changes in colour / stains to the test surface following application | Mean percentage control (Henderson-Tilton (n=4): Corrected % control = 1 – (Ta/Ca) x (Cb/Tb) x 100  Where:  Ta = Mean % algal coverage in treated plots after application  Ca = Mean % algal coverage in control plots after application  Cb = Mean % algal coverage in control plots before application  Tb = Mean % algal coverage in treated plots before application   |  |  |  |  | | --- | --- | --- | --- | | **Treatment** | **Day**  **7** | **Day 14** | **Day 180** | | *Natural vinegar N* | 71.3 | 93.6 | 98.1 | | *Natural vinegar 0.75 N* | 51.9 | 80.6 | 87.6 | | *Natural vinegar*  *0.5 N* | 37.1 | 75.0 | 78.3 | | *Natural vinegar 0.25 N* | 28.5 | 29.7 | 63.1 |   These trials showed that the product Green algae remover (N 9.5%, undiluted) is an effective algaecide (efficacy >90%) against green algae (*Chlorophyta spp.)* when applied on porous hard surfaces (concrete). | Dylan Gibson, 2020I2L Reseach Ltd. Cardiff, "Efficacy evaluation of an algae-removal product under field conditions"  Study Code 19/268  R.I.: 1 |

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| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the submitted tests, for the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR, ready to use products, are efficient against green algae (*Chlorophyta spp.*) up to 4 months, at the application rate of 3 liters of product per 10 m2 by spraying and pouring on hard porous surfaces.   * SA-MAC major change application (2022)   This part of the dossier was not revised for this major change application. |

#### Occurrence of resistance and resistance management

The mode of action is specific in the sense that the active substance affects the cell membrane and controls the process of photosynthesis, but the underlying mechanisms are universal; the occurrence of resistance is therefore not expected.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR, ready-to-use, has shown a sufficient efficacy, for the use in curative treatment against green algae (*Choloryphyta spp.*) up to 4 months at the application rate of 3 liters of product per 10 m2 by spraying and pouring on hard porous surfaces.

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

Not applicable, the products in this biocidal product family are not intended to be used in combination with other biocidal products.

### Human health

No toxicological studies have been submitted for the biocidal product family BURG BIOCIDAL PRODUCT FAMILY NATURAL VINEGAR. The classification of the product has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not classified as skin irritant. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification is required. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not classified as eye irritant |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification is required |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Conclusion | Not irritation for the respiratory tract |
| Justification for the conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not classified as a skin sensitiser |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not classified as a respiratory sensitiser |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value/conclusion | Not classified for oral acute toxicity |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value/conclusion | Not classified for acute inhalation toxicity |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value/conclusion | Not classified for acute dermal toxicity |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product |
| Classification of the product according to CLP | No classification required |

***Dietary exposure***

No relevant food and feedstuff exposure is to be expected since the product is not intended to be applied where food and feedstuff is stored. Therefore, dietary exposure is considered as not relevant.

**Conclusion**

The biocidal product of the family BURG BPG NATURAL VINEGAR does not meet any classification criteria for human health.

No substance of concern has been identified.

No PPE are required during the manipulation of the product.

* SA-MAC major change application (2022)

The major change application for the new user category and new packaging has no impact on the Human health conclusions.

### 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.

* SA-MAC major change application (2022)

This part of the dossier was not revised for this major change application.

### Environment

The active substance is not classified as hazardous to the environment under Reg. (EC) 1272/2008. The product is not classified for the environment as it does not contain any substance of concern.

* SA-MAC major change application (2022)

This part of the dossier was not revised for this major change application.

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

Please refer to the SPC.

### Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

# Annexes

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner** | **Attached in IUCLID section** |
| Z. Jovic Madzarevic | 2020 | "Determination of Physico-Chemical Properties of Natural vinegar 9.5%", Charles River Laboratories Den Bosch Test facility Study No. 20263819, GLP  / Unpublished. | Yes | Burg Groep B.V. | 3.1 |
| G.Haagh | 2020 | Analytical report "Food contact compliance investigation according to EU legislation", Triskelion, Study Ref. No. P20171-20223, G. Haagh, October 2020 and related compliance statements  / Unpublished. | Yes | Burg Groep B.V. | 3.4.1.a, b, c and d |
| F. Brucker, Supplier 1 | 2020 | "Certificate of Conformity" - HDPE Supplier 1 | n.a. |  | 3.4.1.e |
| H. Sturm,  Supplier 2 | 2014 | "Declaration of Conformity for materials in contact with food" - HDPE supplier 2 | n.a. |  | 3.4.1.f |
| E. Zaal | 2021 | Memorandum "Summary on the stability and shelf life of vinegar 4-10%", Burg Groep B.V. QHE Mgt, January 22, 2021  / Unpublished | Yes | Burg Groep B.V. | 3.4.1.g |
| Supplier 3 |  | Chemical resistance information on packaging material - example information PET from Supplier 3. | n.a. |  | 3.4.1.h |
| Supplier 4 | 2012 | Chemical resistance information on packaging material - example information HDPE from Supplier 4, February 2012 | n.a. |  | 3.4.1.i |
| D. Gibson | 2020 | "Efficacy evaluation of an algae-removal product under field conditions", I2L Reseach Ltd. Cardiff, Study Code 19/268, GEP, Unpublished. | Yes | Burg Groep B.V. | 6.a and b |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)