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 AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



CITROX PRODUCT FAMILY

Product types 1,2 and 4

Lactic acid

BC-VE066169-27

FR CA

Date: [01/2024]

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | FR CA | BC-VE066169-27 | 02.09.2022 | Initial assessment |  |
| SA-AAT | FR CA | BC-YG091429-17 | 01.2024 | Modifications in confidential PAR following SN-NOT of an nMS:  -change of one component CAS number  -change of one component function’s notation |  |

# CONCLUSION

**Intended** **uses**

The products of the biocidal product family CITROX PRODUCT FAMILY are products type 1, 2 and 4 containing lactic acid used against bacteria, yeast and viruses. This is a ready-to-use product used indoor and outdoor by professional and non-professional users.

***Conclusion of the assessment***

The active substance lactic acid contained in the biocidal product CITROX PRODUCT FAMILY is listed in Annex I of EU Regulation 528/2012 and complies with the restriction reported in this Annex.

There is no substances of concern included in the product CITROX PRODUCT FAMILY.

The biocidal product CITROX PRODUCT FAMILY does not contain any nanomaterials.

The handling of the product for its intended uses does not require personal protective equipment.

Efficacy:

CITROX PRODUCT FAMILY with two META SPCs has shown a sufficient efficacy in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C):

* For the META SPC 1: Hygienic handrub application against bacteria and yeast, with 6 mL of product on visibly clean hands, with a contact time of 60 seconds.

The product volume claimed to be applied on the hand is ranged from 3 to 5 mL, but as the volume tested in the efficacy trial is 6 mL, the volume which should be applied on the hand is increased to 6 mL.

Regarding the virucidal efficacy claimed against enveloped virus, no test was provided to support this activity. Therefore this activity is not validated.

* For META SPC 2: Surface disinfection for PT2 uses by spraying on hard non-porous surfaces against bacteria, in clean conditions at room temperature, with a contact time of 5 minutes by non-professional-user.

For surface disinfection in PT2 for professional users and in PT4 for all the users, yeast is a mandatory target according to the Appendix 1 of the Echa efficacy guidance vol II, parts B&C. In absence of phase 2 step 2 on yeast, the efficacy against this target is not demonstrated and these uses are not validated.

Regarding the virucidal efficacy claimed, no test with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT was provided. After comparison of the presentative products presented to support the efficacy of the META SPC 2, differences are noticed on coformulants that can have a negative impact on the efficacy. Therefore the read across between the products is not possible. As all the products within a META SPC should have the same level of efficacy, the limited virucidal efficacy is not validated for this meta SPC.

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

Following the evaluation, FR-CA considers that the biocidal product CITROX PRODUCT FAMILY does meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012 for part of the intented uses, as described in the following tablea

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META-SPC** | **Product type** | **Target organisms** | **Application rate** | **Use conditions** | **Conclusion** |
| 1 | PT1 | Bacteria, yeasts and enveloped viruses | 3-5 mL of product on hands per application | Hygienic handrub  Professionnals and non-professionals | **Not acceptable :**   * Efficacy not demonstrated with the claimed volume and against enveloped viruses. |
| 2 | PT 2 and 4 | RTU product | Disinfection of surfaces by spraying  Professionnals and non-professionals | **Not acceptable :**   * Efficacy not demonstrated for PT4 use (professional and non-professional) * Efficacy not demonstrated for PT2 use for professionals |
| 1 | PT1 | Bacteria, yeasts | 6 mL of product on hands per application | Hygienic handrub  Professionnals and non-professionals | Acceptable |
| 2 | PT 2 | Bacteria | RTU product | Disinfection of surfaces by spraying  Non-professionals  Contact time : 5 minutes | Acceptable |

**Post-authorisation conditions**

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

Table 1.1 Post-authorisation conditions

|  |  |
| --- | --- |
| **Description** | **Due date** |
| *2 years ambient storage study of each product (or one that cover the others)or efficacy data on aged product should be provided in post-authorisation in order to support the two years shelf life in the commercial packaging (HDPE)* | *2 years* |

# 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)** |
| --- | --- |
| Citrox product family | France  Ireland |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Auranta |
| **Address** | Alexandra House  The Sweepstakes  Ballsbridge  Dublin  D04 C7H2  Ireland |
| **Authorisation number** | FR-2022-0069 | |
| **Date of the authorisation** | 02/09/2022 | |
| **Expiry date of the authorisation** | 01/09/2032 | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Bioscience Nutrition Ireland |
| **Address of manufacturer** | Grange Business Park,  Skule Hill,  Fedamore,  Co. Limerick  V35 RH74  Ireland |
| **Location of manufacturing sites** | Grange Business Park,  Skule Hill,  Fedamore,  Co. Limerick  V35 RH74  Ireland |

|  |  |
| --- | --- |
| **Name of manufacturer** | Nano 4 You GmbH |
| **Address of manufacturer** | In der Kolling 15  D-66450 Bexbach  Germany |
| **Location of manufacturing sites** | In der Kolling 15  D-66450 Bexbach  Germany |

|  |  |
| --- | --- |
| **Name of manufacturer** | ZIDAC Laboratories |
| **Address of manufacturer** | Unit 5  Merlin Park  Airport Service Rd  Portsmouth  PO3 5FU  United Kingdom |
| **Location of manufacturing sites** | Unit 5  Merlin Park  Airport Service Rd  Portsmouth  PO3 5FU  United Kingdom |

|  |  |
| --- | --- |
| **Name of manufacturer** | Citrox Biosciences Limited |
| **Address of manufacturer** | 6 Nene Road  Bicton Ind. Park  Kimbolton  Cambridgeshire  PE28 0LF  United Kingdom |
| **Location of manufacturing sites** | 6 Nene Road  Bicton Ind. Park  Kimbolton  Cambridgeshire  PE28 0LF  United Kingdom |

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

|  |  |
| --- | --- |
| **Active substance** | Lactic acid |
| **Name of manufacturer** | Purac Biochem bv |
| **Address of manufacturer** | Arkelsedijk 46  NL-4206 AC Gorinchem  The Netherlands |
| **Location of manufacturing sites** | Arkelsedijk 46  NL-4206 AC Gorinchem  The Netherlands |

### Product family composition and formulation

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

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Lactic acid |
| **IUPAC or EC name** | 2-Hydroxypropanoic acid |
| **EC number** | 200-018-0 |
| **CAS number** | 50-21-5 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | 100% (racemic) |
| **Structural formula** |  |

#### 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** |
| DL-Lactic acid (min purity of 100%) | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 | 0.2 |

#### Information on technical equivalence

Not relevant.

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

No substance of concern has been identified for human health and environment.

Please see the confidential annex for further details.

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

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.

For further details, please see the Confidential Annex.

#### 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

|  | META\_SPC\_SUFFIX\_1 |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 1 |
| --- | --- |

### 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** |
| DL-Lactic acid | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 | 0.2 |

#### 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 | - |
| Hazard statement | - |
|  | |
| **Labelling** | |
| Signal words | - |
| Hazard statements | - |
| Precautionary statements | - |
|  | |
| Note |  |

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

#### Use description

Table 1. Use # 1 – Hand disinfection

|  |  |
| --- | --- |
| **Product Type** | PT01 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  yeast |
| **Field of use** | Hand disinfection |
| **Application method(s)** | Direct application to both hands, rubbing  Apply the product to one hand and complete surface of both hands. |
| **Application rate(s) and frequency** | 6mL of product per application.  Contact time : 60 seconds |
| **Category(ies) of users** | Professional and non-professional users. |
| **Pack sizes and packaging material** | 50 mL, 500 mL and 5 L in HDPE bottles. |

##### 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. * Inform the registration holder if the treatment is ineffective. * Apply only on visibly clean hands. * Due to the contact time higher than 30s, do not use in hospitals |

#### Risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| * 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: not applicable. * 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: 2 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)** | **Citrox Protect Alcohol Free Hand Gel** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| DL-Lactic acid | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 |

**Part II - Second information level - meta SPC 2**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 2 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

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

### Meta SPC 2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| DL-Lactic acid (min purity of 100%) | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 | 0.2 |

#### Type(s) of formulation of the meta SPC 2

|  |
| --- |
| AL - Any other liquid |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | - |
| Hazard statement | - |
|  | |
| **Labelling** | |
| Signal words | - |
| Hazard statements | - |
| Precautionary statements | - |
|  | |
| Note |  |

### . Authorised use(s) of the META SPC 2

#### Use description

Table 1. Use # 1 – Surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Indoor  Household (other than kitchen) and workplace area |
| **Application method(s)** | By spraying the surface |
| **Application rate(s) and frequency** | Ready to use product  Contact time: 5 minutes  Room temperature |
| **Category(ies) of users** | Non-professional user |
| **Pack sizes and packaging material** | 750 ml trigger spray HDPE bottle. |

##### 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 2

#### Instructions for use

|  |
| --- |
| * Comply with the instructions for use. * Inform the registration holder if the treatment is ineffective. * Clean carefully the surfaces before application of the product. * Ensure complete wetting on the surfaces, leave for at least 5 minutes. * Apply on non-porous surface only. |

#### 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: not applicable. * 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: 2 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 2**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Citrox BCL 1%** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| DL-Lactic acid | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Citrox Protect Surface Cleaner and Disinfectant** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| DL-Lactic acid | 2-Hydroxy-propanoic acid | Active substance | 50-21-5 | 200-018-0 | 0.2 |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 50ml | HDPE | HDPE | Non-professional, Professional | Y |
| Bottle | 500ml | HDPE | HDPE | Non-professional, Professional | Y |
| Bottle | 5 L | HDPE | HDPE | Non-professional, Professional | Y |
| Trigger spray bottle | 750ml | HDPE | HDPE | Non-professional, Professional | Y |

### Documentation

#### Data submitted in relation to product application

Please refer to annex 3.1.

#### Access to documentation

Not relevant.

## Assessment of the biocidal product family

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

Table 1. Use # 1 – Hand Sanitiser

|  |  |
| --- | --- |
| **Product Type** | PT 01 – Human hygiene |
| **Where relevant, an exact description of the authorised use** | Hygienic handrub. |
| **Target organism (including development stage)** | Bacteria, yeasts, enveloped viruses. |
| **Field of use** | Indoor and outdoor |
| **Application method(s)** | Dispensed into palm of hand and rubbed into skin. |
| **Application rate(s) and frequency** | Approximately 3-5 ml per application. Frequency of application: use as needed. |
| **Category(ies) of users** | Non-professional, professional. |
| **Pack sizes and packaging material** | 50 mL, 500 mL and 5 L bottles. |

#### Table 2. Use # 2 – Surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectants and algaecides not intended for direct application to humans or animals  PT04 – Food and feed area |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces in the home and in workplaces. |
| **Target organism (including development stage)** | Bacteria, yeasts, enveloped viruses. |
| **Field of use** | Indoor. |
| **Application method(s)** | Sprayed onto surface. |
| **Application rate(s) and frequency** | Applied as needed. |
| **Category(ies) of users** | Non-professional, professional. |
| **Pack sizes and packaging material** | 750 ml trigger spray bottle. |

### Physical, chemical and technical properties

**Citrox BCL 1%**

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | | Undiluted | Liquid | Ercakmak (2021a) |
| Colour at 20 °C and 101.3 kPa | Visual inspection | | Undiluted | Light yellow | Ercakmak (2021a) |
| Odour at 20 °C and 101.3 kPa | Olfactory inspection | | Undiluted | Light machine oil odour | Ercakmak (2021a) |
| pH | CIPAC MT 75.3 | | Undiluted | 2.74 | Ercakmak (2021a) |
| Relative density / bulk density | OECD 109 | | Undiluted | 1.0156 | Ercakmak (2021a) |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | | Undiluted | Storage for 14 days at 54 °C  Packaging: glass bottle   |  |  |  | | --- | --- | --- | |  | Initial | 14 days | | Active ingredient content | 220.21mg/L | 220.020mg/L  Decrease: 0.089% | | Appearance | Light yellow liquid, light machine oil odour | Light yellow liquid, light machine oil odour | | pH (neat) | 2.74 | 2.58 | | Relative density | 1.0156 (Rep 1)  1.0156 (Rep 2) | 1.0153 (Rep 1)  1.0146 (Rep 2) | | Viscosity at 20 °C | 1.282 cSt | 1.310 cSt | | Viscosity at 40 °C | 0.724 cSt | 0.764 cSt | | Ercakmak (2021a) |
| Storage stability test – **long term storage at ambient temperature** | No ambient shelf life study has been provided. Regarding the accelerated storage study, the product is stable during 2 years. **However, ambient 2 years storage study is required in post-authorisation.** | | | | |
| Storage stability test – **low temperature stability test for liquids** | Test waived. The product is labelled with the sentence “Protect from frost.” | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Test waived. The product is packaged in HDPE containers that protect it from exposure to light. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Temperature: Refer to storage stability testing. Humidity is not relevant as the product is a water-based formulation. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | In-house method for analysis of trigger spray | Undiluted | | Product is compatible with container material. See result for Citrox Protect Surface Cleaner and Disinfectant. | Nichetti (2021) |
| Wettability | Not applicable for this formulation type. | | | | |
| Suspensibility, spontaneity and dispersion stability | Not applicable for this formulation type. | | | | |
| Wet sieve analysis and dry sieve test | Not applicable for this formulation type. | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Not applicable for this formulation type. | | | | |
| Disintegration time | Not applicable for this formulation type. | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not applicable for this formulation type. | | | | |
| Persistent foaming | Not applicable for this formulation type. | | | | |
| Flowability/Pourability/Dustability | Not applicable for this formulation type. | | | | |
| Burning rate — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Burning completeness — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Composition of smoke — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Spraying pattern — aerosols | Not applicable: product is not an aerosol. | | | | |
| Physical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Chemical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Degree of dissolution and dilution stability | Not applicable for this formulation type. | | | | |
| Surface tension | Not applicable for this formulation type. | | | | |
| Viscosity | OECD 114 | | Undiluted | At 20 °C: 1.282 cSt  At 40 °C: 0.724 cSt | Ercakmak (2021a) |

**Citrox Protect Surface Cleaner and Disinfectant**

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | | Undiluted | Liquid | Ercakmak (2021b) |
| Colour at 20 °C and 101.3 kPa | Visual inspection | | Undiluted | Light yellow | Ercakmak (2021b) |
| Odour at 20 °C and 101.3 kPa | Olfactory inspection | | Undiluted | Light machine oil odour | Ercakmak (2021b) |
| pH | CIPAC MT 75.3 | | Undiluted | 2.88 | Ercakmak (2021b) |
| Relative density / bulk density | OECD 109 | | Undiluted | 1.0136 (average of 2 replicates) | Ercakmak (2021b) |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | | Undiluted | Storage for 14 days at 54 °C  Packaging: glass bottle   |  |  |  | | --- | --- | --- | |  | Initial | 14 days | | Active ingredient content | 223.762 mg/l | 218.949 mg/l  Decrease: 2.151% | | Appearance | Light yellow liquid, light machine oil odour | Light yellow liquid, light machine oil odour | | pH (neat) | 2.88 | 2.77 | | Relative density | 1.0145 (Rep 1)  1.0126 (Rep 2) | 1.0144 (Rep 1)  1.0140 (Rep 2) | | Viscosity at 20 °C | 1.222 cSt | 1.318 cSt | | Viscosity at 40 °C | 0.736 cSt | 0.764 cSt | | Ercakmak (2021b) |
| Storage stability test – **long term storage at ambient temperature** | No ambient shelf life study has been provided. Regarding the accelerated storage study, the product is stable during 2 years. **However, ambient 2 years storage study is required in post-authorisation.** | | | | |
| Storage stability test – **low temperature stability test for liquids** | Test waived. The product is labelled with the sentence “Protect from frost.” | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Test waived. The product is packaged in HDPE containers that protect it from exposure to light. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Temperature: Refer to storage stability testing. Humidity is not relevant as the product is a water-based formulation. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | In-house method for analysis of trigger spray | Undiluted   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T=0 | | T=2w 54°C | | | Weight variation (%) | No significant weight variation for the test item stored in the trigger spray bottles indicating no reactivity with container. | | | | | Spray diameter from varying spray distances | Distance  cm | Diameter cm | Distance cm | Diameter cm | | 15 | 9.0 | 15 | 9.2 | | 20 | 9.5 | 20 | 12 | | 25 | 9.5 | 25 | 10.5 | | 30 | 9.2 | 30 | 10.0 | | Trigger spray head performance | The amount of test item delivered from all four trigger spray bottles was found to be constant  over the 20 spray tests. | | The amount of test item delivered from all four trigger spray bottles was found to be constant  over the 20 spray tests | | | Observation on the trigger head | - | | No build-up of crystallised material was found in the nozzle. Slight leak of test item from the  trigger head and the nozzle. The nozzle did not present clogging behaviour and blocking | | | | | Nichetti (2021) |
| Wettability | Not applicable for this formulation type. | | | | |
| Suspensibility, spontaneity and dispersion stability | Not applicable for this formulation type. | | | | |
| Wet sieve analysis and dry sieve test | Not applicable for this formulation type. | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Not applicable for this formulation type. | | | | |
| Disintegration time | Not applicable for this formulation type. | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not applicable for this formulation type. | | | | |
| Persistent foaming | Not applicable for this formulation type. | | | | |
| Flowability/Pourability/Dustability | Not applicable for this formulation type. | | | | |
| Burning rate — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Burning completeness — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Composition of smoke — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Spraying pattern — aerosols | Not applicable: product is not an aerosol. | | | | |
| Physical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Chemical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Degree of dissolution and dilution stability | Not applicable for this formulation type. | | | | |
| Surface tension | Not applicable for this formulation type. | | | | |
| Viscosity | OECD 114 | | Undiluted | At 20 °C: 1.222 cSt  At 40 °C: 0.736 cSt | Ercakmak (2021b) |

**Citrox Protect Alcohol Free Hand Gel**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | Undiluted | | Thick liquid | Ercakmak (2021c) |
| Colour at 20 °C and 101.3 kPa | Visual inspection | Undiluted | | Brownish-dark yellow | Ercakmak (2021c) |
| Odour at 20 °C and 101.3 kPa | Olfactory inspection | Undiluted | | Citrus | Ercakmak (2021c) |
| pH | CIPAC MT 75.3 | Undiluted | | 3.17 | Ercakmak (2021c) |
| Relative density / bulk density | OECD 109 | Undiluted | | 1.0118 (average of 2 replicates) | Ercakmak (2021c) |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Undiluted | | Storage for 14 days at 54 °C  Packaging glass bottle   |  |  |  | | --- | --- | --- | |  | Initial | 14 days | | Active ingredient content | 197.177 mg/l | 196.254 mg/l  Decrease: 0.468% | | Appearance | Thick liquid, brownish to dark yellow colour, citrus odour | Thick liquid, brownish to dark yellow colour, citrus odour | | pH (neat) | 3.17 | 3.04 | | Relative density | 1.0129 (Rep 1)  1.0107 (Rep 2) | 1.0174 (Rep 1)  1.0123 (Rep 2) | | Viscosity at 20 °C | 5552 cSt | 2760 cSt | | Viscosity at 40 °C | 4548 cSt | 1310 cSt | | Ercakmak (2021c) |
| Storage stability test – **long term storage at ambient temperature** | No ambient shelf life study has been provided. Regarding the accelerated storage study, the product is stable during 2 years. **However, ambient 2 years storage study is required in post-authorisation.** | | | | |
| Storage stability test – **low temperature stability test for liquids** | Test waived. The product is labelled with the sentence “Protect from frost.” | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Test waived. The product is packaged in HDPE containers that protect it from exposure to light. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Temperature: Refer to storage stability testing. Humidity is not relevant as the product is a liquid. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | In-house method for analysis of trigger spray | | Undiluted | Product is compatible with container material. See result for Citrox Protect Surface Cleaner and Disinfectant. | Nichetti (2021) |
| Wettability | Not applicable for this formulation type. | | | | |
| Suspensibility, spontaneity and dispersion stability | Not applicable for this formulation type. | | | | |
| Wet sieve analysis and dry sieve test | Not applicable for this formulation type. | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Not applicable for this formulation type. | | | | |
| Disintegration time | Not applicable for this formulation type. | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not applicable for this formulation type. | | | | |
| Persistent foaming | Not applicable for this formulation type. | | | | |
| Flowability/Pourability/Dustability | Not applicable for this formulation type. | | | | |
| Burning rate — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Burning completeness — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Composition of smoke — smoke generators | Not applicable: product is not a smoke generator. | | | | |
| Spraying pattern — aerosols | Not applicable: product is not an aerosol. | | | | |
| Physical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Chemical compatibility | Not applicable: the product is not intended for use in conjunction with other products. | | | | |
| Degree of dissolution and dilution stability | Not applicable for this formulation type. | | | | |
| Surface tension | Not applicable for this formulation type. | | | | |
| Viscosity | OECD 114 | Undiluted | | At 20 °C: 5552 cSt  At 40 °C: 4548 cSt | Ercakmak (2021c) |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Physical-chemical properties and accelerated storage stability were investigated for the following products: Citrox BCL, Citrox Protect Surface Cleaner and Disinfectant, and Citrox Protect Alcohol Free Hand Gel.  All products were shown to be stable in the accelerated storage stability studies. The active substance content decreased by between 0.089% and 2.151% in each product, which is an acceptable decline and indicates that the products will retain efficacy. The physical appearance, pH, density and kinematic viscosity did not change for any products after storage, with the exception of the kinematic viscosity of Citrox Protect Alcohol Free Hand Gel, which decreased somewhat during storage at 54 °C.  The effect of storage on the operation of trigger spray bottles was also investigated under accelerated storage conditions. The tested product was Citrox Protect Surface Cleaner and Disinfectant. Given the similarity of product compositions, read-across to other products that use trigger sprays is possible. The analysis showed that the operation of the trigger spray was unaffected by accelerated storage conditions. In addition, the sample bottles showed only slight variations in overall weight during storage, indicating that the products are compatible with the commercial packaging (given the similar compositions and physical-chemical properties of all products, read-across is possible).  **Shelf life of products:** The shelf life of all products is 2 years based on the accelerated storage study. However, 2 years ambient storage study of each product (or one that cover the others) should be provided in post-authorisation in order to support the two years shelf life in the commercial packaging.  **Implications for labelling**: Protect from frost |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | The products are not considered explosive as they do not contain substances with chemical groups associated with explosive properties. | | | |
| Flammable gases | Not applicable: the products are liquids. | | | |
| Flammable aerosols | Not applicable: the products are liquids. | | | |
| Oxidising gases | Not applicable: the products are liquids. | | | |
| Gases under pressure | Not applicable: the products are liquids. | | | |
| Flammable liquids | The products are not considered flammable as they do not contain any flammable components. | | | |
| Flammable solids | Not applicable: the products are liquids. | | | |
| Self-reactive substances and mixtures | A study does not need to be conducted because the products do not contain any components possessing chemical groups associated with explosive or self-reactive properties, with reference to Appendix 6 of the UN Manual of Tests and Criteria. | | | |
| Pyrophoric liquids | The products contain no pyrophoric substances, have a high water content, and no experience of spontaneous ignition with air has been noticed. | | | |
| Pyrophoric solids | Not applicable: the products are liquids. | | | |
| Self-heating substances and mixtures | The products are liquids and therefore have an interface area too low to bring self-heating properties. | | | |
| Substances and mixtures which in contact with water emit flammable gases | The products are stable aqueous solutions and do not emit flammable gases when diluted in water. | | | |
| Oxidising liquids | The products contain no substances with oxidizing properties, therefore they are not classified as oxidising liquids. | | | |
| Oxidising solids | Not applicable: the products are liquids. | | | |
| Organic peroxides | The products contain no substances with the bivalent O-O structure, and are therefore not classified as organic peroxides. | | | |
| Corrosive to metals | UN Manual of Tests and Criteria, Part III, 37.4  Undiluted product (Citrox Mist). This test item has identical composition to Citrox BCL 1%] | Corrosion rate, mass loss and pitting results for the 28-day exposure    *Mild Steel UNS G10200 (C1020)*  *Aluminium, non clad types 7075-T6*  **Uniform corrosion**  Based on the highest observed weight loss of 6.73wt%, the test is considered negative with respect to uniform corrosion on the steel specimen (<51.5 wt%)  Based on the highest observed weight loss of 3.72wt%, the test is considered negative with respect to uniform corrosion on the aluminium specimen (<51.5 wt%)  **Localized corrosion**  Based on the highest observed intrusion depth 128 µm, the test is considered negative with respect to localized corrosion of the steel specimen (<480 µm)  Based on the highest observed intrusion depth 393 µm, the test is considered negative with respect to localized corrosion of the aluminium specimen (<480 µm). | | Cross (2022) |
| All members of the product family have identical compositions with regard to organic acids, and the storage stability studies show that they have very similar pH values. Read-across from the result for the product “Citrox Mist” (Citrox BCL) is possible given the similar composition, and the fact that Citrox BCL 1% had a slightly lower pH than the other products and therefore may be considered the worst case in terms of pH and potential corrosivity to metals. | | | |
| Auto-ignition temperatures of products (liquids and gases) | The products are known to be stable at room temperature and do not ignite spontaneously. The products do not contain any flammable components, and the known flash points and auto-ignition temperatures of the formulants in the products are at minimum >100°C. Furthermore, the products contain >95% water and therefore auto-ignition is not expected. | | | |
| Relative self-ignition temperature for solids | Not applicable: the products are liquids. | | | |
| Dust explosion hazard | Not applicable: the products are liquids. | | | |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Products of the Citrox biocidal product family do not present a significant hazard for explosive properties, flammability, self-reactivity, self-heating properties, oxidising properties, corrosivity to metals and auto-inflammability.  Therefore, no classification and labelling for physical hazards is required for product of the Citrox biocidal product family |

### Methods for detection and identification

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%) (n=5)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Lactic acid | HPLC-UV | 5 standard solutions at concentration of 100-700 mg/l | R2 = 0.9969 | Chromatograms of blank, of sample, and standard solution have been provided. No interference is observed at the retention time of the active substance. | Conc.: 198.940 mg/l | | | - | Ercakmak (2021b) |
| 107.21-108.30 | 107.76 | 0.403 |
| Conc.: 596.820 mg/L | | | - |
| 101.09-103.59 | 102.51 | 0.917 |
| Lactic acid | HPLC-UV | 5 standard solutions at concentration of 100-700 mg/l | R2 = 0.9969 | - | Conc.: 195.804 m/g | | | - | Ercakmak (2021c) |
| 98.10-100.94 | 100.0 | 1.128 |
| Conc.: 587.412 m/g | | | - |
| 99.20-101.42 | 100.54 | 0.890 |

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| **Conclusion on the methods for detection and identification of the product** |
| The method for detecting and identifying the active substance in the product was validated on two separate occasions. In both cases the linearity, accuracy and precision were considered acceptable. |

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| **Conclusion on the methods for detection and identification of the product** |
| No residues are expected in soil, air, drinking and surface water, as well as in food and feeding stuffs and in animal and human body fluids and tissues. |

### Efficacy against target organisms

#### Function and field of use

Main group 01: Disinfectants.

Product Type 01: Human hygiene.

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

Product Type 04: Food and Feed area

The products of the “CITROX PRODUCT FAMILY” are ready-to-use disinfectant used for hand and general surface disinfection by professional and non-professional users.

The family has 2 META-SPC:

* META SPC 1: Hygienic handrub.
* META SPC 2: hard surface disinfection for general household and workplace surfaces (non-healthcare).

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

The organisms to be controlled are bacteria, yeasts and enveloped viruses.

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

The product is able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of the yeast cells (yeasticidal activity) and of infectious virus particles (virucidal activity) of the relevant test organisms under defined conditions

#### Mode of action, including time delay

As described in L(+) lactic acid Assessment Report “In solution, L(+) lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L(+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates results in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

#### Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Bactericidal* | Use 1 Hygienic handrub TP1 | *Citrox Protect Alcohol Free Hand Gel*  (0.2% lactic acid) | *E. coli,*  *S. aureus,*  *E. hirae,*  *P. aeruginosa* | EN1276: 2019  Phase 2 step 1  (suspension test) | Test concentration: neat (0.2% lactic acid)  Temperature: 20°C  Contact time: 60 seconds  Clean conditions (0.3g/L BSA)  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 80 % v/v | Watson (2021a)  CIB.21B038.IB-HR  IC2: only one concentration tested |
| *Yeasticidal* | *Use 1: Hygienic handrub* TP1 | *Citrox Protect Alcohol Free Hand Gel*  (0.2% lactic acid) | *C. albicans* | *EN1650:2019 Phase 2 step 1*  *(suspension test)* | Test concentration: neat (0.2% lactic acid)  Temperature: 20 °C  Contact time: 60 seconds  Clean conditions (0.3g/L BSA)  Criteria ≥4 log reduction | Yeasticidal activity demonstrated at 80 % v/v | *Watson (2021b)*  CIB.21.B038.IY-HR  IC2: only one concentration tested |
| *Bactericidal* | *Use 1: Hygienic handrub – medical area* TP1 | *Citrox Protect Alcohol Free Hand Gel*  (0.2% lactic acid) | *E. coli K12,*  *S. aureus,*  *E. hirae,*  *P. aeruginosa* | *EN13727:2012 + A2:2015 Phase 2, step 1*  *(suspension test)* | Test concentration: neat (0.2% lactic acid)  Temperature: 20 °C  Contact time: 60 seconds  Clean conditions (0.3g/L BSA)  Criteria ≥5 log reduction | Bactericidal activity demonstrated at 80 % v/v | *Watson (2021c)*  CIB.21B038.MB-HR  IC2: only one concentration tested |
| *Yeasticidal* | Use 1: Hygienic handrub – medical area TP1 | Citrox Protect Alcohol Free Hand Gel  (0.2% lactic acid) | *C. albicans* | EN13624:2013Phase 2, step 1  (suspension test) | Test concentration: neat (0.2% lactic acid)  Temperature: 20 °C  Contact time: 60 seconds  Clean conditions (0.3 g/L BSA)  Criteria ≥4 log reduction | Yeasticidal activity demonstrated at 80 % v/v | Watson (2021d)  CIB.21B038.MY-HR  IC2: only one concentration tested |
| *Bactericidal* | Use 1: Hygienic handrub TP1 | Citrox Protect Alcohol Free Hand Gel  (0.2% lactic acid) | *E. coli* | EN1500 (phase 2 step 2) | Test concentration: neat (0.2% lactic acid)  Temperature: 20 °C  Contact time: 60 seconds | Not validated. | Watson (2021u)  IC3 no raw data provided |
| *Bactericidal* | Use 1: Hygienic handrub TP1 | Citrox Protect Antibacterial Hand Gel Alcohol Free  (0.2% lactic acid) | *E. coli K12* | EN1500 (phase 2 step 2) | Test concentration: neat (0.2% lactic acid)  Temperature: 20 °C  Contact time: 60 seconds  Volume tested: 2 x 3 mL | Bactericidal activity demonstrated at 100% v/v | Watson (2021v)  CIB.21M065.RR  IC1 |
| META SPC 2 | | | | | | | |
| *Bactericidal* | Use 2: Surface disinfectant PT2, 4 | Citrox BCL 1% (0,2% lactic acid)  Batch  R&D 243 | *E. coli,*  *S. aureus,*  *E. hirae,*  *P. aeruginosa* | EN1276:2019  Phase 2 step 1  (suspension test) | Test concentration: 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA)  Criteria ≥5 log reduction | Bactericidal activity demonstrated at 1 % v/v | Watson (2021e)  CIB.20L045.IB4  IC2: only one concentration tested |
| *Yeasticidal* | Use 2: Surface disinfectant PT2, 4 | Citrox BCL 1%  (0.2% lactic acid)  Batch  R&D 243 | *C. albicans* | EN1650:2019  phase 2 step 1  (suspension test) | Test concentration: 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA)  Criteria ≥4 log reduction | Yeasticidal activity demonstrated at 1 % v/v | Watson (2021f)  CIB.20L045.IY4  IC2: only one concentration tested |
| *Bactericidal* | Use 2: Surface disinfectant  PT2, 4 | Citrox BCL 1%  (0.2% lactic acid)  Batch  R&D 243 | *S. aureus,*  *E. hirae,*  *P. aeruginosa* | EN13727:2012 + A2:2015 Phase 2, step 1  (suspension test) | Test concentration: 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA)  Criteria ≥5 log reduction | Bactericidal activity demonstrated at 1 % v/v | Watson (2021g)  CIB.20L045.MB4  IC2: only one concentration tested |
| *Yeasticidal* | Use 2: Surface disinfectant  PT2, 4 | Citrox BCL 1%  (0.2% lactic acid)  Batch  R&D 243 | *C. albicans* | EN13624:2013  Phase 2 step 1  (suspension test) | Test concentration: 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA)  Criteria ≥4 log reduction | Yeasticidal activity demonstrated at 1 % v/v | Watson (2021h)  CIB.20L045.MY4  IC2: only one concentration tested |
| *Bactericidal* | Use 2: Surface disinfectant  PT2, 4 | Citrox BCL 1%  (0.2% lactic acid)  Batch  R&D RD0276 | *P. aeruginosa, E. coli,*  *S. aureus,*  *E. hirae* | EN13697:2015 phase 2 step 2 | Test concentrations: 5%, 2%, 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA)  Criteria ≥4 log reduction | Bactericidal activity demonstrated at 2 % v/v | Watson (2021i)  CIB.21K074.SB  IC1 |
| *Virucidal* | Use 2: Surface disinfectant  PT2, 4 | Citrox BCL 1%  (0.2% lactic acid)  Batch  R&D RD0232 | *Modified vaccinia virus Ankara* | EN14476:2013 (phase 2 step 1) | Test concentration: 5% v/v, 2% v/v, 1% v/v  Temperature: 20 °C  Contact time: 5 minutes  Clean conditions (0.3 g/L BSA),  Criteria ≥4 log reduction | Virucidal efficacy demonstrated against enveloped virus at 1 % v/v | Barrett (2020)  J002058-1  IC1 |
| Bactericidal | Use 2: Surface disinfectant  PT2, 4 | Citrox Protect Surface Cleaner and Disinfectant  (0,2% lactic acid)  Batch RD0251 | *E. coli,*  *S. aureus,*  *E. hirae,*  *P. aeruginosa* | EN1276:2019  Phase 2 step 1  (suspension test) | Test concentration: neat  Temperature: 20°C  Contact time: 5 minutes  Dirty conditions (3 g/L BSA)  Criteria ≥5 log reduction | Bactericidal activity demonstrated at 80 % v/v | Watson (2021j)  CIB.20M0077.IB  IC2 only one concentration tested |
| Yeasticidal | Use 2: Surface disinfectant  PT2, 4 | Citrox Protect Surface Cleaner and Disinfectant  (0,2% lactic acid)  Batch RD0285 | *C. albicans* | EN1650:2019  Phase 2 step 1  (suspension test) | Test concentration: neat  Temperature 20 °C  Contact time: 5 minutes  Clean conditions (0.3g/L BSA)  Criteria ≥4 log reduction | yeasticidal activity demonstrated at 80 % v/v | Watson (2021k)  CIB.21M004.IY  IC2 only one concentration tested |
| Bactericidal | Use 2: Surface disinfectant  PT2, 4 | Citrox Protect Surface Cleaner and Disinfectant  (0,2% lactic acid)  Batch  RD0255 | *E. coli,*  *S. aureus,*  *E. hirae*  *P. aeruginosa*, | EN13697:2015+A1:2019  Phase 2 step 2 | Test concentration: neat  Temperature 20 °C  Contact time: 5 minutes  Dirty conditions (3g/L BSA)  Criteria ≥4 log reduction | Bactericidal activity demonstrated at 100 % v/v | Watson (2021l)  CIB.21C039.SB  IC2 only one concentration tested |

**Efficacy data of the CITROX PRODUCT FAMILY**

Laboratory studies were conducted with the CITROX PRODUCT FAMILY according to the Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The main points are summarized in the table above.

* **META SPC 1:**

META SPC 1 contains a ready to use product (Citrox Protect Alcohol Free Hand Gel) with lactic acid concentration of 0.2 % w/w. Laboratory studies were conducted with this product.

* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), with the product Citrox Protect Alcohol Free Hand Gel, at 20 °C, with a contact time of 60 seconds, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 80 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 13727), with the product Citrox Protect Alcohol Free Hand Gel, at 20 °C, with a contact time of 60 seconds, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 80 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 2 test (EN 1500), with the product Citrox Protect Alcohol Free Hand Gel, at 20 °C, with a contact time of 60 seconds. In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), with the product Citrox Protect Alcohol Free Hand Gel, at 20 °C, with a contact time of 60 seconds, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 80 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), with the product Citrox Protect Alcohol Free Hand Gel, at 20 °C, with a contact time of 60 seconds, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 80 % v/v.

For the efficacy claimed against virus, no test with the product Citrox Protect Alcohol Free Hand Gel was provided.

Therefore, based on the efficacy data, it can be concluded that the bactericidal and the yeasticidal efficacy are demonstrated for the ready-to-use product Citrox Protect Alcohol Free Hand Gel, for a contact time of 60 seconds, including medical area (but excluding hospital as the contact time is higher than 30 s), on visibly clean hands, at the temperature of 20 °C for handrub application.

* **META SPC 2:**

META SPC 2 contains products at 0.2% w/w lactic acid as a spray, with a range of variations for wetting agent and surfactant. Laboratory studies were performed with the representative product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT and the product CITROX BCL 1%.

Taking into account the variations of the co-formulants presented in the META-SPC2, it can be assumed that the efficacy is supported by the data set generated from the representative products.

Product CITROX BCL 1 %:

* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 13727), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 2 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 13727), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.

Based on the efficacy data, it can be concluded that the bactericidal efficacy is demonstrated for the product CITROX BCL 1%, with a contact time of 5 minutes, at the application rate of 2% v/v, in clean condition (0.3 g/L BSA), at the temperature of 20°C.

The use on porous surface is not demonstrated.

* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 13624), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v.

For the efficacy against yeast, no phase 2 step 2 test was provided. Therefore, based on the data provided, for surface disinfection, the yeasticidal efficacy of the product CITROX BCL 1% is not demonstrated.

* Virucidal activity (enveloped virus) is demonstrated in phase 2, step 1 test (EN 14476), with the product CITROX BCL 1%, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 1 % v/v.

Based on the efficacy data, it can be concluded that the virucidal (enveloped virus) efficacy is demonstrated for the product CITROX BCL 1%, with a contact time of 5 minutes, at the application rate of 1 % v/v, in clean condition (0.3 g/L BSA), at the temperature of 20°C.

Product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT

* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT, at 20 °C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 80 % v/v
* Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT, at 20 °C, with a contact time of 5 minutes, in dirty conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.

Based on the efficacy data, it can be concluded that the bactericidal efficacy is demonstrated for the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT neat, with a contact time of 5 minutes, in dirty condition (3 g/L BSA), at the temperature of 20°C. The use on porous surface is not demonstrated.

* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT, at 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 80 % v/v.

For the efficacy against yeast, no phase 2 step 2 test was provided. Therefore, based on the data provided, for surface disinfection, the yeasticidal efficacy of the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT is not demonstrated.

Regarding the virucidal efficacy, no test with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT was provided. After comparison of the presentative products presented to support the efficacy of the META SPC 2, differences are noticed on coformulants that can have a negative impact on the efficacy. Therefore the read across between the products is not possible. As all the products within a META SPC should have the same level of efficacy, the limited virucidal efficacy is not validated for this META SPC.

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that CITROX PRODUCT FAMILY with two META SPCs has shown a sufficient efficacy in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C):   * For the META SPC 1: Hygienic handrub application against bacteria and yeast, with 6 mL of product on visibly clean hands, with a contact time of 60 seconds.   The product volume claimed to be applied on the hand is ranged from 3 to 5 mL, but as the volume tested in the efficacy trial is 6 mL, the volume that should be applied on the hand is increased to 6 mL.  Regarding the virucidal efficacy claimed against enveloped virus, no test was provided to support this activity. Therefore this activity is not validated   * For META SPC 2: Surface disinfection for PT2 uses by spraying on hard non-porous surfaces against bacteria, in clean conditions at room temperature, with a contact time of 5 minutes by non-professional-user.   However, for surface disinfection in PT2 for professional users and in PT4 for all the users, according to the Appendix 1 of the Echa efficacy guidance vol II, parts B&C, an efficacy demonstration against yeast should be shown. In absence of phase 2 step 2 on yeast, the efficacy against this target is not demonstrated and these uses are not validated.  Regarding the virucidal efficacy claimed, no test was provided with the product CITROX PROTECT SURFACE CLEANER AND DISINFECTANT. Considering that all the products within a META SPC should have the same level of efficacy. The virucidal efficacy is not validated for this meta SPC. |

#### Occurrence of resistance and resistance management

No resistance phenomenon has been reported up to now with lactic acid in the scientific literature.

No incidence of resistance to Lactic acid has been recorded until now. (Source: Assessment Report. L (+) Lactic Product types 2, 3 and 4. June 2017. RMS, Germany).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

None.

#### Evaluation of the label claims

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

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

### 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 biocidal product family fulfills all conditions for a simplified authorisation procedure.

#### Assessment of effects on Human Health

There are no human health data available for the biocidal product family. The assessment, and classification and labelling are based on the agreed endpoints for the active substance and available information for the non-active substances.

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

The Citrox product family is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization and acute toxicity.

See Confidential annex for further information.

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not classified as skin corrosive or irritant. |
| Justification for the value/conclusion | The active substance and two co-formulants are present in the products at a concentration below the general concentration limit of 1%. |
| Classification of the product according to CLP | No classification is required. |

***Eye irritation***

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not classified as eye irritant. |
| Justification for the value/conclusion | The active substance and several co-formulants are present in the products at a concentration below the general concentration limit of 1%. |
| Classification of the product according to CLP | No classification required. |

***Respiratory tract irritation***

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not classified for respiratory tract irritation |
| Justification for the conclusion | One co-formulant is classified STOT SE 3 - H335 but its concentration is below the general concentration limit of 20%. |
| Classification of the product according to CLP | No classification required. |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route |
| Justification for the selected value | One of the co-formulant is classified Acute Tox. 4 – H302, but is present in the products at a concentration below the general concentration limit of 1%. |
| Classification of the product according to CLP | No classification is required. |

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

No substances of concern were identified in the products of the biocidal product family CITROX PRODUCT FAMILY according to the criteria laid out in Annex A of the guidance on the BPR, Vol III, 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.

### Risk assessment for animal health

Not relevant.

### 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.

#### **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.

#### **Substance(s) of concern**

The biocidal product family CITROX PRODUCT FAMILY 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).

#### **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.

### Assessment of a combination of biocidal products

Not relevant.

## Comparative assessment

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

# Annexes[[2]](#footnote-3)

## 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 (PUB / ORG)** |
| Barrett, M. | | 2020 | Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1)  Microbiological Solutions Limited  Report no. J002058-1  GLP: No  Unpublished | N | Y |
| Watson, T. | 2021a | | EN 1276:2019 [Non Alcohol Hand Gel]  Abbott Analytical Ltd  Report no. CIB.21B038.IB-HR  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021b | | EN 1650:2019 [Non Alcohol Hand Gel]  Abbott Analytical Ltd  Report no. CIB.21B038.IY-HR  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021c | | EN 13727:2012+A2:2015 [Non Alcohol Hand Gel]  Abbott Analytical Ltd  Report no. CIB.21B038.MB-HR  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021d | | EN 13624:2013 [Non Alcohol Hand Gel]  Abbot Analytical Ltd  Report no. CIB.21B038-MY-HR  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021e | | EN 1276:2019 [Citrox BCL]  Abbott Analytical Ltd  Report no. CIB.20L045.IB4  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021f | | EN 1650:2019 [Citrox BCL]  Abbot Analytical Ltd  Report no. CIB.20L045.IY4  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021g | | EN 13727 [Citrox BCL]  Abbot Analytical Ltd  Report no. CIB.20L045.MB4  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021h | | EN 13624:2019 [Citrox BCL]  Abbott Analytical Ltd  Report no. CIB.20L045.MY4  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021i | | EN 13697:2105+A1:2019 [Citrox BCL]  Abbott Analytical Ltd  Report no. CIB.21K074.SB  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021j | | EN 1276:2019 [Citrox Protect Surface Cleaner]  Abbott Analytical Ltd  Report no. CIB.20M077.IB  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021k | | EN 1650:2019 [Citrox Protect Surface Cleaner]  Abbot Analytical Ltd  Report no. CIB.21M004.IY  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021l | | EN 13697:2105+A1:2019 [Citrox Protect Surface Cleaner]  Abbott Analytical Ltd  Report no. CIB.21C039.SB  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021m | | EN 1276 [Caprylic acid]  Abbott Analytical  Report no. CIB.21K043.IB-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021n | | EN 1650 [Caprylic acid]  Abbott Analytical  Report no. CIB.21K043-IY-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021o | | EN 1276 [Citric acid]  Abbott Analytical  Report no. CIB.21K042.IB-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021p | | EN 1650 [Citric acid]  Abbott Analytical  Report no. CIB.21K042.IY-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021q | | EN 1276 [Malic acid]  Abbott Analytical  Report no. CIB.21K041.IB-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021r | | EN 1650 [Malic acid]  Abbott Analytical  Report no. CIB.21K041.IY-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021s | | EN 1276 [Bioflavonoids]  Abbott Analytical  Report no. CIB.21F097.IB-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021t | | EN 1650 [Bioflavonoids]  Abbott Analytical  Report no. CIB.21F097.IY-CF  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2021u | | EN 1500:2013 [Citrox Protect Antibacterial Hand Gel Alcohol Free]  Abbott Analytical  Report no. CIB.21M065.RR  GLP: No  Unpublished | N | Y | |
| Watson, T. | 2009 | | EN 1500 [Citrox non Alcohol hand gel]  Abbott Analytical  GLP: No  Unpublished | N | Y | |

## Confidential annex

See the confidential PAR

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-3)