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

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

(submitted by the evaluating Competent Authority)



SPRAY Twice a Day by PanzerGlass™

Product type(s) PT2

Case Number in R4BP: SA-APP - BC-HB058275-52

Evaluating Competent Authority: MSCA - Denmark

Date: 08/12/2020

Amendment to PAR because of major change

Date: 19/10/2021

# Overview of applications

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **Ref MS** | **Case number in the ref MS** | **Decision date** | **Assessment carried out (i.e. first authorisation/**  **amendment/renewal)** |
| SA-APP | DK | BC-HB058275-52 | 08.12.2020 | First authorisation |
| SA-AAT | DK | BC-HB058275-52 | 19.10.2021 | Amendment of simplified authorisation |
| SA-MAC | DK | BC-HU063584-12 | 19.10.2021 | Amendment, major change |

Revised 19. October 2021:

The PAR has been revised with the following changes:

|  |  |
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| Section | Changes |
| 1 Conclusion | The date to submit the long term stability study has been changed from 1st January 2023 to 1st September 2023, as a new study has been started due to a new analytical method. |
| 4.1.2. Storage stability test – **accelerated storage** | A new validated analytical method has been submitted and to confirm the stability og the product, new accelerated storage stability test has been performed, |
| 4.1.2 Storage stability test – **long term storage at ambient**  **temperature** | A new validated analytical method has been submitted. Therefor has the longterm storage stability study been restarted were the AS has been tested with the new analytical method at t0. The study is ongoing and shall be submitted by 1st of September 2023, as a post authorisation request. |
| 4.1.3 | A new validated analytical methods for the analysis of the active substance in the product has been submitted as a result of a referral from CZ |
| 3.1 List of studies for the biocidal product | The study reports L20/0903MV.1 and L20/0903R.1 have been added. |
| 4.2 SA-MAC 19.10.2021 | SA-MAC to include a claim against enveloped viruses has been added.  Please note the label claim now includes efficacy against bacteria and enveloped viruses with a 5 minute contact time.  Application rate and timing of application have been divided to make the application method more readable:  “Application rate: Use enough to ensure the surface is wet for five minutes.  Number and timing of application: As many times as needed”. |
| SPC | The SPC has been updated to include use against enveloped viruses with a 5 minute contact time.  Application rate and timing of application have been specified to make the application method more readable:  “Application rate: Use enough to ensure the surface is wet for five minutes.  Number and timing of application: As many times as needed”. |

Revised 9. April 2021:

The PAR has been revised with the following changes:

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| Section | Changes |
| 2.2.4 Methods for detection and identification | The wording in the introduction has been revised to: Method for detection is done using LC-MS with a total ion current chromatogram. |

Revised 10. Marts 2021:

The PAR has been revised with the following changes:

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| Section | Changes |
| 2.2.5.5 Efficacy data | The column “Test substance” has been clarified with the following note: (a) SPRAY Twice a Day was tested under the name “Screen Cleaner” in test reports no. 922903 Rev. 2 and 935530 rev. 1.” |
| 2.2.6.1 Assessment of effects on human health | Added an explanation of why the co-formulant does not contribute to a classification even though it is a surfactant:  “One co-formulant is self-classified as eye damaging at ECHA inventory ([C&L Inventory - ECHA (europa.eu)](https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/)) by a majority of notifiers.  The co-formulant is a surfactant and according to the CLP guidance, section 3.3.3.3.4.1. *„Particular care must be taken when classifying certain types of mixtures containing substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in Sections 3.3.3.3.1 and 3.3.3.3.2 might not work given that many such substances are seriously damaging to the eye/eye irritant at concentrations < 1 %“*  A.S and co-formulant are in the product at a concentration below 1%.  The co-formulant is a surfactants, but there are no indications that the surfactant is seriously damaging to the eye/eye irritant at concentrations <1%.  The a.s and the co-formulant are present in the product in concentrations significantly below the classification limits therefore the GHS criteria are not met. There are no indications that the surfactants are seriously damaging to the eye/eye irritant at concentrations <1%.  The surfactant is able to form micelles depending on the concentration in the liquid (the critical micelle concentration CMC is 8mmol/l (0.23 % w/w)). The concentration of the surfactant in the liquid is above 0.23 % w/w. The concentration indicate that there are micelles in the liquid. The micelles are envenly distributed in the liquid, and the concentration in the interphase (between liquid and gasphase) are 0.23% w/w. there are no risk of accumulation of the surfactant in the interphase.  The product is not classified.” |

Revised 26. February 2021:

The PAR has been revised with the following changes:

|  |  |
| --- | --- |
| Section | Changes |
| 1 Conclusion | The sentence “No co-formulants were identified having endocrine disputing properties” has been added. |
| 2.1.2.3 Qualitative and quantitative information | The content of water has been removed from the table |
| 2.1.5.1 Instruction for use | The wording of the following sentence is revised (throughout PAR and SPC): Apply the product after pre-cleaning of the screen. Keep the surface wet for 5 minutes and wipe off with a clean cloth  Wash hands after the use. |
| 2.2.3 Physical hazards and respective characteristics | Corrosive to metals:  The product contains more than 98% water, contains no halogens and pH is about 4. The product is considered not corrosive to metal. |
| 2.2.5.5 Efficacy data | The efficient dose has been added to the test results for the EN 13697 test.  The following clarification has been added to note (a): In the EN 1276 test, efficacy is achieved at the dilution 40% v/v, i.e. 0.4% lactic acid. |
| 2.2.6.1 Assessment of effects on human health | The sentence has been added: Considering the available information for the co-formulant, the substance cannot be identified as having endocrine disrupting properties, and the available information does not indicate a need for further investigation (see confidential PAR). |

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# CONCLUSION

The Danish eCA proposes the authorisation of the biocidal product ‘SPRAY Twice a Day’ as a surface disinfectant (PT 2) for non-professional use against bacteria for the disinfection electronic screens. The biocidal product contains the active substance lactic acid (CAS no. 50-21-5) at a concentration of 0.4% (w/w).

SPRAY Twice a Day is eligible for a simplified authorisation according to Article 25 of Regulation No. 528/2012 (BPR) as:

1. the product contains only active substances listed on Annex I of Regulation No. 528/2012 and satisfies the restriction specified in that Annex (i.e. that the product does not require classification for hazards to human health or safety, or to the environment, according to Regulation No. 1272/2008 (CLP)),
2. the product does not contain any substances of concern,
3. the product does not contain any nanomaterials,
4. the product is sufficiently effective, and
5. handling of the product and its intended use do not require protective equipment.

The pH is stable at pH 4.08 and there is no degradation of the active substance based on the accelerated stability study. The shelf-life of the product is limited to 2 years at ambient temperature. The long-term storage stability study is requested by the applicant in a post-authorisation condition to be submitted by 1st September 2023.

Efficacy has been demonstrated against bacteria with a contact time of five minutes under clean conditions.

The biocidal product does not pose a risk to human health when following the described intended use and does not require the use of personal protection equipment. No co-formulants were identified having endocrine disrupting properties.

The biocidal product does not pose a risk to the environment when following the described intended use.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| SPRAY Twice a Day |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Panzerglass |
| **Address** | Delta 8, DK-8382 Hinnerup, Denmark |
| **Authorisation number** | EU-0024114-0000 | |
| **Date of the authorisation** | 08/12/2020 | |
| **Expiry date of the authorisation** | 08/12/2030 | |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Panzerglass |
| **Address of manufacturer** | Delta 8, DK-8382 Hinnerup |
| **Location of manufacturing sites** | Delta 8, DK-8382 Hinnerup |

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

|  |  |
| --- | --- |
| **Active substance** | Lactic acid |
| **Name of manufacturer** | Corbion Purac Biomaterials |
| **Address of manufacturer** | Arkelsedijk 46, 4206 AC Gorinchem, The Netherlands |
| **Location of manufacturing sites** | Arkelsedijk 46, 4206 AC Gorinchem, The Netherlands |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No  The substance is included in Annex I under Regulation No. 528/2012

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Lactic Acid |
| **IUPAC or EC name** | Propanoic acid, 2-hydroxy- |
| **EC number** | 200-018-0 |
| **CAS number** | 50-21-5 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | 100 |
| **Structural formula** | C3H6O3 |

#### Candidate(s) for substitution

Not applicable. Lactic acid is listed in Annex I under Regulation No. 528/2012 (CLP) under Category 1 – Substances authorised as food additives according to Regulation (EC) No. 1333/2008.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (w/w %)** |
| --- | --- | --- | --- | --- | --- |
| Lactic acid |  | Active substance | 50-21-5 | 200-018-0 | 0,4 |

The full composition can be found in the confidential annex.

#### Information on technical equivalence

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

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| AL Any other Liquid |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Not classified |
| Hazard statement | No hazard statement required |
|  | |
| **Labelling** | |
| Signal words | No signal word required |
| Hazard statements | No hazard statement required |
| Precautionary statements | No precautionary statements required |
|  | |
| Note | No notes required |

### Authorised use(s)

#### Use description

Table 2.1. Use # 1 – name of the use

|  |  |
| --- | --- |
| **Product Type** | Product type 2 |
| **Where relevant, an exact description of the authorised use** | Disinfectant for screens on electronic equipment. Apply product by spraying – wipe off with a cloth. |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | As often as needed. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 8 ml (PETG), 30 ml (PETG), 100 ml (PETG), 80 ml (PET). |

#### Use-specific instructions for use

|  |
| --- |
| Apply the product after pre-cleaning of the screen. Keep the surface wet for 5 minutes and wipe off with a clean cloth.  Wash hands after the use. |

#### Use-specific risk mitigation measures

|  |
| --- |
| No special considerations. |

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

|  |
| --- |
| If swallowed: immediately call a POISON CENTER or doctor/physician.  In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water. |

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

|  |
| --- |
| No special considerations. Dispose of content/container according to national regulation. |

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

|  |
| --- |
| Store above freezing point and below 30 degrees in closed pump container.  Products can be stored at room temperature up to 24 months. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Apply the product after pre-cleaning of the screen. Keep the surface wet for 5 minutes and wipe off with a clean cloth  Wash hands after the use. |

#### Risk mitigation measures

|  |
| --- |
| Not needed |

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

|  |
| --- |
| If swallowed: immediately call a POISON CENTER or doctor/physician.  In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water. |

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

|  |
| --- |
| Dispose of content/container according to national regulation. |

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

|  |
| --- |
| Store above freezing point and below 30 degrees in closed pump container.  Products can be stored at room temperature up to 24 months. |

### Other information

|  |
| --- |
| - |

### 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)** |
| AL Any other liquid | 80 ml | PET | N/A | non-professional | Yes |
| AL Any other liquid | 100 ml | PETG | N/A | non-professional | Yes |
| AL Any other liquid | 30 ml | PETG | N/A | non-professional | Yes |
| AL Any other liquid | 8 ml | PETG | N/A | non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

Data generated for SPRAY Twice a Day:

* efficacy studies
* stability studies accelerated
* Studies on density and pH
* Studies on stability of pH

The studies are listed in Annex 3.1 List of Studies for the biocidal product and attached in relevant sections in the IUCLID file.

#### Access to documentation

According to Article 20(1)b of Regulation No. 528/2012 (BPR), a Letter of Access is not required for application for authorisation under the simplified authorisation procedure. In addition, as the active substance is not included on the Union List of approved active substances, no dossier exists.

#### Similar conditions of use

N/A

## Assessment of the biocidal product

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

Table 1.2. Intended use # 1 – name of the use

|  |  |
| --- | --- |
| Product Type(s) | EU BPR Product type 2 |
| Where relevant, an exact description of the authorised use | Disinfection of screens on electronic equipment |
| Target organism (including development stage) | Bacteria |
| Field of use | Indoor use |
| Application method(s) | Spraying |
| Application rate(s) and frequency | As often as needed. Product name suggests using two times a day. |
| Category(ies) of user(s) | non-professional |
| Pack sizes and packaging material | 80 ml PET  100 ml PETG  30 ml PETG  8 ml PETG |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  |  | Liquid |  |
| Colour at 20 °C and 101.3 kPa |  |  | Colourless |  |
| Odour at 20 °C and 101.3 kPa |  |  | Sour |  |
| Acidity / alkalinity |  |  | pH: 4.04 ±0.04 | Schjøth-Eskesen(2020) |
| Relative density / bulk density |  |  | 1.001±0.002 | Schjøth-Eskesen(2020) |
| Storage stability test – **accelerated storage** | Cipac MT 46.3: 14 days at 54°C tested for AS-conc.  Stability of pH  pH tested at 60°C for 4 weeks | 0.4% | Cipac MT 46.3 study:  Initial active substance content 0.31 w/w % and after 2 weeks at 54°C 0.38 w/w %, the change is 22.5%.  This is considered acceptable as the concentration of AS is within the tolerance of the declared content.  Stability of pH-study:  Initial pH 4.10 and after 4 weeks at 60°C the pH is 3.81  Stable under recommended storage and handling conditions. | Wang and Yuan (2020)  Lou (2020) |
| Storage stability test – **long term storage at ambient temperature** |  |  | The longterm storage stability study is ongoing. The study will be submitted as a post-authorisation request condition. The product is considered stable for 2 years. |  |
| Storage stability test – **low temperature stability test for liquids** |  |  | The product is recommended not to be stored at temperature ≤ 0°C. Therefore, no testing is necessary. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Stable under recommended storage and handling conditions. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The product contains 98 % water. No testing necessary. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The product contains 98% water. The he product and the bottle have no negative effect on each other. |  |
| Wettability |  |  | Not relevant for AL formulations. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant for AL formulations. |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant for AL formulations. |  |
| Emulsifiability, re-emulsifiability and emulsion stability | Not relevant for AL formulations. | | | |
| Disintegration time | Not relevant for AL formulations. | | | |
| Particle size distribution, content of dust/fines, attrition, friability | Not relevant for AL formulations. | | | |
| Persistent foaming | Not relevant for AL formulations. | | | |
| Flowability/Pourability/Dustability | Not relevant for AL formulations. | | | |
| Burning rate — smoke generators | N/A | | | |
| Burning completeness — smoke generators | N/A | | | |
| Composition of smoke — smoke generators | N/A | | | |
| Spraying pattern — aerosols | Not relevant – the product is an aerosol. | | | |
| Physical compatibility | Not relevant as the product should not be mixed with other products. | | | |
| Chemical compatibility | Not relevant as the product should not be mixed with other products. | | | |
| Degree of dissolution and dilution stability | Not relevant for water-based products. | | | |
| Surface tension | The surface tension of 1g/l solution of lactic acid in water is 70.7 mN/m. The product is not considered surface active. | | | |
| Viscosity | Not relevant for water-based products. The product does not contain >=10% hydrocarbons. | | | |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product SPRAY Twice a Day is a clear liquid with a sour odor. The pH of the product is 4.08.  There is no decrease of AS during the accelerated stability study for 14 at 54 C.  The long-term storage test is ongoing and is to be submitted as a post authorisation condition. The product is considered stable for 24 months in PET and PETG container.  Stable under recommended storage and handling conditions. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives |  |  | None of the components in the product are classified as explosive, and considering the high water content, the product is not considered explosive. |  |
| Flammable gases |  |  | Not relevant, the product is not a gas |  |
| Flammable aerosols |  |  | Not relevant as the product is not an aerosol |  |
| Oxidising gases |  |  | Not relevant, the product is not a gas. |  |
| Gases under pressure |  |  | Not a gas under pressure. |  |
| Flammable liquids |  |  | Not combustible, the product contains 99% water. |  |
| Flammable solids |  |  | Not relevant, the product is not solid. |  |
| Self-reactive substances and mixtures |  |  | Not a self-reactive mixture. |  |
| Pyrophoric liquids |  |  | Not pyrophoric, the product contains 99 % water. |  |
| Pyrophoric solids |  |  | Not relevant, the product is not solid. |  |
| Self-heating substances and mixtures |  |  | Not relevant as the product does not contain any self –heating substances. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | No, the product contains 99% water. |  |
| Oxidising liquids |  |  | None of the components in the product are classified as oxidizing, and considering the high water content, the product is not considered oxidizing. |  |
| Oxidising solids |  |  | Not relevant, the product is a liquid. |  |
| Organic peroxides |  |  | Not an organic peroxide. |  |
| Corrosive to metals |  |  | The product contains more than 98% water, contains no halogens and pH is about 4. The product is considered not corrosive to metal. |  |
| Auto-ignition temperatures of products (liquids and gases) |  |  | The product contains >98% water and is not flammable. |  |
| Relative self-ignition temperature for solids |  |  | N/A |  |
| Dust explosion hazard |  |  | N/A |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product SPRAY Twice a Day is a ready to use water based liquid. No physical hazards. |

### Methods for detection and identification

Method for detection is done using LC-MS with a total ion current chromatogram.

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Accuracy** | | | **Limit of quantification (LOQ)** | **Reference** |
| Range | Mean | RSD |
| Lactic acid | LC-MS with total ion current chromatogram | 1.0-100.0 mg/L  Numbers of measurement: 5 | Correlation coefficient (r) 0.996 | No interference | 1.0 – 100.0 mg/l  0.4%  Recovery  80-120% | 95% | RSD 2.40%  Horwitz ratio 1.56 | 1.0mg/L | TÜV SÜD (2020) |

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| **Conclusion on the methods for detection and identification of the product** |
| The LC-MS analytical method used for the quantification of the active substance Lactic Acid in the product Spray Twice a Day is sufficiently validated. The method shows linearity, accuracy and specifity. |

### Efficacy against target organisms

#### Function and field of use

SPRAY Twice a Day is a spray-on and wipe-off bactericidal disinfectant intended to be used as a general surface disinfectant on screens of electronic equipment (PT2). The active substance is lactic acid at a concentration of 0.4% (w/w).

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

The product is intended to control bacteria on screens of electronic equipment (touch screens).

The applicant only wishes to claim bactericidal activity.

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

The product is applied by spray application, enough to ensure the surface remains wet for the five-minute contact time; the product is then wiped off.

No unacceptable suffering is foreseen as a result of using SPRAY Twice a Day.

#### Mode of action, including time delay

In a solution, lactic acid exists in a pH-dependent equilibrium between the un-dissociated and dissociated form. The acid is only able to pass the cell membrane in the un-dissociated form. At a relatively low pH, the uncharged acid enters the cell; inside the cell, 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.

Decrease of membrane permeability for amino acids, organic acids and phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system and inhibition of glycolysis have been reported.

#### Efficacy data

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance(a)** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results:** | **Reference** |
| PT 2 – Surface disinfectant | Antibacterial Screen disinfectant for electronic screens. Indoor.  Non-professional users. | Screen Cleaner  1.0% Lactic acid(b) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | DS/EN 1276:2019  Phase 2, step 1  Quantitative suspension test | Clean conditions (0,3 g/L bovine serum albumin) / 10, 100, 200% / 20-25°C / 5 min. ± 10 sec. | *P. aeruginosa* RF 5.2 at 100%, ≥ 5.3 at 200% after 5 min.  *E. coli* RF ≥ 5.4 at 100, 200% after 5 min.  *E. hirae* RF ≥ 5.3 at 100, 200%.  *S. aureus* RF ≥ 5.4 at 100, 200%.(c) | Danish Technological Institute  Test report no. 922903 Rev. 2  Date: 08.09. 2020 |
| PT 2 – Surface disinfectant | Antibacterial Screen disinfectant for electronic screens. Indoor.  Non-professional user. | Screen Cleaner  0,4% Lactic acid | *Enterococcus hirae*  *Staphylococcus aureus*  *Pseudomonas aeruginosa*  *Escherichia coli* | EN 13697:2015 +A1:2019  Phase 2, step 2  Quantitative non-porous surface test without mechanical action.  Stainless steal surface. | Clean conditions (0.3 g/L bovine serum albumin) / 10, 50, 100% / 20-25°C / 5 min. ± 10 sec. | *P. aeruginosa* RF 4.3 at 100% after 5 min.  *E. coli* RF ≥ 4.2 at 50, 100% after 5 min.  *S. aureus* RF≥ 6.9 at 50, 100% after 5 min.  *E. hirae* RF≥ 6.6 at 50, 100% after 5 min. | Danish Technological Institute  Test report no. 935530 rev. 1  Date: 08.09.2020 |

(a) SPRAY Twice a Day was tested under the name “Screen Cleaner” in test reports no. 922903 Rev.2 and 935530 rev. 1.

(b) The sPray Twice a Day formulation used for the EN 1276 test was produced specifically for the EN 1276 test. The active ingredient was 250% of the applied for ready-to-use formulation (increased from 0.4% to 1.0%). In the EN 1276 test, efficacy is achieved at the dilution 40% v/v, i.e. 0.4% lactic acid.

(c) N, N0, Na, lg N, lg N0, lg Na and lg R have been recalculated by the eCA for *P. aeruginosa, E. coli, S. aureus* and *E. hirae.*

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| **Conclusion on the efficacy of the product** |
| According to Guidance on the BPR, Efficacy, Vol. II, Parts B+C, 2018, Appendix 4; for a PT2 product, not intended to be used in health care, the basic requirements are EN 1276 and EN 13697 tests against bacteria.  The applicant has submitted one EN 1276 (phase 2, step 1) test against bacteria demonstrating sufficient bactericidal activity under clean conditions at a contact time of five minutes. This was confirmed by the submitted EN 13697 (phase 2, step 2) test against bacteria. |

#### Occurrence of resistance and resistance management

No known occurrence of resistance. Due to the unspecific mode of action of lactic acid, development of resistance is not expected.

No management strategies have been developed since resistance is not observed. In the Biocidal Products Committee (BPC) Opinion on approval of lactic acid in PT1, 2, 3 and 4 it is stated: “Development of resistance is considered unlikely due to the non-specific mode of action”.

The DK eCA accepts that there is no significant risk of development of resistance for the active substance and the product, however, if the applicant becomes aware of any reports of resistance of the active substance lactic acid, and/or the product these should be reported to appropriate bodies (e.g. the efficacy working group and/or concerned member states) so that it can be determined if further action is needed.

#### Known limitations

None known. No undesired or unintended side effects have been observed during the studies on efficacy against target organisms of the biocidal product SPRAY Twice a Day.

Due to lack of residual activity, repeated applications are required to maintain the disinfection effect; the product is most suitable when persistent activity is not required.

Ensure the surface is visibly clean before disinfecting.

#### Evaluation of the label claims

The biocidal product, SPRAY Twice a Day, fulfils the basic requirements for phase 2, step 1 and phase 2, step 2 tests in accordance with the EN standards to support the label claim against bacteria.

The following label claim is supported by the data based on efficacy:

Product type: PT2 – hard surface disinfection

Use area: electronic screens (touch screens).

Efficacy and (contact time): bacteria (5 minutes).

Application method: Apply the product after pre-cleaning of the screen. Keep the surface wet for 5 minutes and wipe off with a clean cloth.

Application rate: As many times as needed. Use enough to ensure the surface is wet for five minutes.

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

Not relevant.

### Risk assessment for human health

#### Assessment of effects on Human Health

The active substance Lactic acid is included in Annex 1 (Category 1) and Regulation No. 528/2012 (BPR). According to the SDS for SPRAY Twice a Day and CL inventory, Lactic acid is classified Skin Irrit 2; H315 and Eye Dam. 1; H318. The concentration of lactic acid in the biocidal product is 0.4%, which is below the concentration limit triggering classification for Skin Irritation and Eye Damage.

One co-formulat is self classified as eye damaging at ECHA inventory ([C&L Inventory - ECHA (europa.eu)](https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/)) by a majority of notifiers.

The co-formulant is a surfactant and according to the CLP guidance, section 3.3.3.3.4.1. „Particular care must be taken when classifying certain types of mixtures containing substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in Sections 3.3.3.3.1 and 3.3.3.3.2 might not work given that many such substances are seriously damaging to the eye/eye irritant at concentrations < 1 %“

A.S and co-formulant are in the product at a concentration below 1%.

The co-formulant is a surfactants, but there are no indications that the surfactant is seriously damaging to the eye/eye irritant at concentrations <1%.

The a.s and the co-formulant are present in the product in concentrations significantly below the classification limits therefore the GHS criteria are not met. There are no indications that the surfactants are seriously damaging to the eye/eye irritant at concentrations <1%.

The surfactant is able to form micelles depending on the concentration in the liquid (the critical micelle concentration CMC is 8mmol/l (0.23 % w/w)). The concentration of the surfactant in the liquid is above 0.23 % w/w. The concentration indicate that there are micelles in the liquid. The micelles are envenly distributed in the liquid, and the concentration in the interphase (between liquid and gasphase) are 0.23% w/w. there are no risk of accumulation of the surfactant in the interphase.

The product is not classified.

The biocidal product does not pose a risk to human health when following the described intended use and does not require the use of personal protection equipment.

Considering the available information for the co-formulant, the substance cannot be identified as having endocrine disrupting properties, and the available information does not indicate a need for further investigation (see confidential PAR).

The eCA concludes that the qualitative risk assessment for human health does not preclude approval of the biocidal product according to the simplified procedure.

### Risk assessment for the environment

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| **Overall conclusion on the risk assessment for the environment of the product** |
| A risk assessment for the environment is not required by the conditions of article 25:   1. Lactic acid is authorised as a food additive according to Regulation (EC) No 1333/2008 and is listed in Annex I under Regulation (EC) No 528/2012 (BPR). 2. The concentration of lactic acid (0.4%) does not trigger a classification of the biocidal product SPRAY Twice a Day according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008. 3. Based on the SDS for lactic acid (provided by the applicant), neither lactic acid nor the biocidal product SPRAY Twice a Day should be classified as hazardous to the environment.   The eCA DK therefore concludes that the biocidal product SPRAY Twice a Day does not pose a risk to the environment. |

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

No special measures are necessary, if the use instruction is followed.

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes

## List of studies for the biocidal product

DS/EN 1276:2019

EN 13697:2015+A1:2019

EN 14476:2013+A2:2019 (Test report L20/0903MV.1)

EN 14476:2013+A2:2019 (Test report L20/0903R.1)

Stability test – CIPAC method MT 46.3

Stability of pH

Determination of density and pH.

## Output tables from exposure assessment tools

Not applicable to a simplified authorisation.

## New information on the active substance

Not applicable to a simplified authorisation.

## Residue behaviour

Not applicable to a simplified authorisation.

## Summaries of the efficacy studies (B.5.10.1-xx)

No Annex is included.

The summaries is available in section 2.2.5 and in relevant sections in the IUCLID-file.

## Confidential annex

Please see separate confidential document.

## Other

Not relevant.

# Amendment

## SA-AAT 19.10.2021

## Addendum to PAR

Amendment of simplified authorisation.

R4BP case no.: BC-FD069183-52

Authorisation no.: BPR-reg no. 983-1

Date: 19.10.2021

### Background

As a result of a referral from CZ, May 2021, a new analysis of the active substance in the product has been submitted. Due to the new analytical method for the analysis of the active substance, Lactic Acid, in the product, Spray Twice a Day, a new accelerated storage stability study has been performed and a long term storage study has been started.

## 

### Physical, chemical and technical properties

There is a new validated analytical method. To confirm the stability of the product, there is performed a new accelerated storage stability test and a long term storage at ambient temperature is ongoing.

A new accelerated storage study has been submitted. The new material has been assessed and summary of the new study is shown in table Physical, chemical and technical properties

**Physical, chemical and technical properties**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Storage stability test – **accelerated storage** | Cipac MT 46.3: 14 days at 54°C | 0.4%  (Batch No. 221PO0124) | Initial active substance content 0.422 w/w % and after 2 weeks at 54°C 0.411 w/w %, the change is 2.6%.  Appearance of product: Transparent, colourless liquid, after 2 weeks at 54°C unchanged. | Johannesen (2021)  Reportnr: 979628 |
| Storage stability test – **long term storage at ambient**  **temperature** |  | 0.4%  (Batch No. 221PO0124) | The longterm  storage stability  study is  ongoing. The  study will be  submitted as a  post-authorisation  request  condition. The  product is  considered  stable for 2  years. |  |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| There has been performed a new accelerated storage stability study as a result of a new validated analytical method, to confirm stability of the product regarding the content of AS.  The decrease of AS during the accelerated stability study for 14 at 54 C is 2.6% w/w and this is within the limit.  The long-term storage test is ongoing and is to be submitted by 1st September 2023as a post authorisation condition. The product is considered stable for 24 months in PET and PETG container. Stable under recommended storage and handling conditions. |

### Methods for detection and identification

There has been submitted a new analytical method for the analysis of the active substance Lactic Acid in the Spray Twice a Day as a result of a referral from CZ.

The new material has been assessed and summary of the new study is shown in the table

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Accuracy** | | | **Limit of quantification (LOQ)** | **Reference** |
| Range | Mean | RSD |
| Lactic acid | HPLC-DAD  (Method: CSA 217) | 0.43%-0.48%, n=2  Repeatability:  n=5  mean: 0.422%  %RSD: 0.17 | 1.0-100.0 µg/mL  Numbers of measurement: 8 (duplicates)  y = 3.863 ∙ x + 1.275  Correlation coefficient (r) 0.99997 | No interference, blank chromatogram | 98.6-100.2% | 99,4% | RSD 0% | 1.0 µg/mL | Johannesen (2021)  Reportnr: 979628 CSA-217 |

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| **Conclusion on the methods for detection and identification of the product** |
| The HPLC-DAD analytical method used for the quantification of the active substance Lactic Acid in the product Spray Twice a Day is sufficiently validated. The method shows linearity, accuracy, specificity and repeatability. |

### Conclusion

The new analytical methods for the analysis of the active substance Lactic Acid in the Spray Twice a Day has been sufficiently validated.

The decrease of AS during the accelerated stability study for 14 at 54 C is 2.6% w/w, this is within the limit. The long-term storage test is ongoing and is to be submitted by 1st September 2023 as a post authorisation condition.

## SA-MAC 19.10.2021

## Addendum to PAR

Major change of the product approval.

R4BP case no.: BC-HU063584-12

Authorisation no.: BPR-reg no. 983-1

Date: 19.10.2021

### Background

The applicant has applied for a major change of the authorisation of the product SPRAY Twice a Day.

The change applied for is:

1) Efficacy claim for additional target organisms: enveloped viruses. The applicant has submitted tests against *vaccinia virus* and *Human rotavirus*.

## 

### Efficacy against target organisms

New studies have been submitted concerning the efficacy against enveloped viruses. The new material has been assessed and summaries of the new studies are shown in table 4.2.2.1 Efficacy data below.

#### 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:** | **Reference** |
| PT 2 – Surface disinfectant | Antiviral Screen disinfectant for electronic screens. Indoor.  Non-professional users. | Spray Twice A Day  0.4% Lactic acid | Modified *vaccinia virus* Ankara (MVA) | EN 14476:2013 +A2:2019  Phase 2, step 1  Quantitative suspension test | Clean conditions (0,3 g/L bovine serum albumin) / 0.1, 10, 50, 80% / 20°C ± 1.0°C / 5 min. | RF ≥4.00 ± 0.00 at 80.0%, 50.0%, 10.0% after 5 minutes. | Dr. Brill + Partner GmbH,  Test report L20/0903MV.1  Date 20.11.2020 |
| PT 2 – Surface disinfectant | Antiviral Screen disinfectant for electronic screens. Indoor.  Non-professional user. | Spray Twice A Day  0,4% Lactic acid | Human *rotavirus strain* (Wa) | EN 14476:2013 +A2:2019  Phase 2, step 1  Quantitative suspension test | Clean conditions (0,3 g/L bovine serum albumin) / 0.1, 10, 50, 80% / 20°C ± 1.0°C / 5 min. | RF ≥4.00 ± 0.35 at 80.0%, 50.0%, 10.0% after 5 minutes. | Dr. Brill + Partner GmbH,  Test report L20/0903R.1  Date 07.11.2020 |

The EN 14476:2013+A2:2019 against modified *vaccinia virus* Ankara (MVA) (L20/0903MV.1) failed to fulfil the control of efficiency for suppression of the product’s activity (the difference to the test suspension was ≥ 0.5 lg).

The testing laboratory has provided a justification for the discrepancy. A 10% solution of the product was active against *vaccinia virus* with no residual virus and RF ≥4.00 ± 0.00 after five minutes. A reduction was detected in the after-effect control with a small amount of residual virus, meaning the test concentration of 10% (corresponding to 8% after addition of cell culture and interfering substance) in the after-effect control was sufficient for reaching a significant RF despite immediate dilution. This is acceptable because there was no residual virus in the 10 % solution and because of the long incubation time in the after-effect control (30 minutes). R*otavirus* is more stable than *vaccinia virus*, here the product was also effective in the 10% solution, but there was no reduction in the control of efficacy, despite the long incubation time.

The eCA accepts the testing laboratory’s justification, moreover the activity against enveloped viruses is supported by the supplementary data submitted for biocidal activity against *rotavirus*.

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| **Conclusion on the efficacy of the product** |
| According to Guidance on the BPR, Efficacy, Vol. II, Parts B+C, 2018, Appendix 4; for a PT2 product, not intended to be used in health care, the basic requirements are EN 1276 and EN 13697 tests against bacteria.  The applicant has submitted one EN 1276 (phase 2, step 1) test against bacteria demonstrating sufficient bactericidal activity under clean conditions at a contact time of five minutes. This was confirmed by the submitted EN 13697 (phase 2, step 2) test against bacteria.  The applicant applied for a major change 21.12.2020 in order to include a claim against enveloped viruses. The submitted EN 14476 (phase 2, step 1) test against enveloped viruses demonstrate sufficient virucidal activity against enveloped viruses with a contact time of five minutes. |

#### Evaluation of the label claims

The biocidal product, SPRAY Twice a Day, fulfils the basic requirements for phase 2, step 1 and phase 2, step 2 tests in accordance with the EN standards to support the label claim against bacteria and enveloped viruses.

The following label claim is supported by the data based on efficacy:

Product type: PT2 – hard surface disinfection

Use area: electronic screens (touch screens).

Efficacy and (contact time): bacteria and enveloped viruses (5 minutes).

Application method: Apply the product after pre-cleaning of the screen. Keep the surface wet for 5 minutes and wipe off with a clean cloth.

Application rate: Use enough to ensure the surface is wet for five minutes.

Number and timing of application: As many times as needed.

#### Conclusion

The new studies support a claim against enveloped viruses.

The major change does not result in changes of the instructions for use or risk mitigation measures.