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 SIMPLIFIED AUTHORISATION APPLICATION**

(submitted by the competent authority)



**LACTIVO 170 BPF**

Product types: 1, 2 and 4

Lactic acid as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-BQ084260-37

Competent Authority: Latvia

Date: 25 August 2023

Table of Contents

[1 Conclusion 5](#_Toc143161454)

[2 Information on the biocidal product family 8](#_Toc143161455)

[2.1 Product type(s) and type(s) of formulation 8](#_Toc143161456)

[2.2 Uses 8](#_Toc143161457)

[2.3 Similarity of the group of products for which the authorisation as a biocidal product family is sought 10](#_Toc143161458)

[2.4 Identity and composition 10](#_Toc143161459)

[2.5 Identity of the active substance 10](#_Toc143161460)

[2.6 Information on the source of the active substance 11](#_Toc143161461)

[2.7 Candidates for substitution 11](#_Toc143161462)

[2.8 Assessment of the endocrine-disrupting properties of the biocidal product family 11](#_Toc143161463)

[2.9 Classification and labelling 11](#_Toc143161464)

[2.10 Letter of access 12](#_Toc143161465)

[2.11 Data submitted in relation to product authorisation 12](#_Toc143161466)

[2.12 Similar conditions of use across the Union 12](#_Toc143161467)

[3 Assessment of the biocidal product family 13](#_Toc143161468)

[3.1 Packaging 13](#_Toc143161469)

[3.2 Physical, chemical, and technical properties 14](#_Toc143161470)

[3.3 Physical hazards and respective characteristics 22](#_Toc143161471)

[3.4 Methods for detection and identification 24](#_Toc143161472)

[3.5 Assessment of efficacy against target organisms 27](#_Toc143161473)

[3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected) 27](#_Toc143161474)

[3.5.2 Mode of action and effects on target organisms, including unacceptable suffering 27](#_Toc143161475)

[3.5.3 Efficacy data 28](#_Toc143161476)

[3.5.4 Efficacy assessment 34](#_Toc143161477)

[3.5.5 Conclusion on efficacy 34](#_Toc143161478)

[3.5.6 Occurrence of resistance and resistance management 35](#_Toc143161479)

[3.5.7 Known limitations 35](#_Toc143161480)

[3.5.8 Relevant information if the BPF is intended to be authorised for use with other biocidal products 35](#_Toc143161481)

[3.6 Risk assessment for human health 36](#_Toc143161482)

[3.6.1 Assessment of effects on human health 36](#_Toc143161483)

[3.6.1.1 Skin corrosion and irritation 36](#_Toc143161484)

[3.6.1.2 Eye irritation 37](#_Toc143161485)

[3.6.1.3 Respiratory tract irritation 39](#_Toc143161486)

[3.6.1.4 Skin sensitization 39](#_Toc143161487)

[3.6.1.5 Respiratory sensitization 40](#_Toc143161488)

[3.6.1.6 Acute oral toxicity 40](#_Toc143161489)

[3.6.1.7 Acute inhalation toxicity 41](#_Toc143161490)

[3.6.1.8 Acute dermal toxicity 42](#_Toc143161491)

[3.6.2 Information on dermal absorption 42](#_Toc143161492)

[3.6.3 Available toxicological data relating to substance(s) of concern 42](#_Toc143161493)

[3.6.4 Other 42](#_Toc143161494)

[3.6.4.1 Food and feeding stuffs studies 42](#_Toc143161495)

[3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal products 42](#_Toc143161496)

[3.6.4.3 Other test(s) related to the exposure to humans 43](#_Toc143161497)

[3.6.5 Available toxicological data relating to endocrine disruption 43](#_Toc143161498)

[3.6.6 Exposure assessment and risk characterisation for human health 43](#_Toc143161499)

[3.6.7 Monitoring data 43](#_Toc143161500)

[3.6.8 Dietary risk assessment 43](#_Toc143161501)

[3.7 Risk assessment for animal health 43](#_Toc143161502)

[3.7.1 Risk for companion animals 43](#_Toc143161503)

[3.7.2 Risk for livestock animals 43](#_Toc143161504)

[3.8 Risk assessment for the environment 44](#_Toc143161505)

[3.8.1.1 Substance(s) of concern 44](#_Toc143161506)

[3.8.1.2 Screening for endocrine disruption relating to non-target organisms 44](#_Toc143161507)

[3.9 Assessment of a combination of biocidal products 44](#_Toc143161508)

[3.10 Comparative assessment 44](#_Toc143161509)

[4 Appendices 45](#_Toc143161510)

[4.1 Calculations for exposure assessment 45](#_Toc143161511)

[4.2 New information on the active substance(s) and substance(s) of concern 45](#_Toc143161512)

[4.3 List of studies for the biocidal product family 45](#_Toc143161513)

[4.4 References 51](#_Toc143161514)

[4.4.1 References other than list of studies for the BPF 51](#_Toc143161515)

[4.4.2 Guidance documents 51](#_Toc143161516)

[4.4.3 Legal texts 51](#_Toc143161517)

[4.5 Confidential information 51](#_Toc143161518)

**Changes history table**

This is the initial authorisation.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP | Latvia | BC-BQ084260-37 | 25.08.2023 | Initial assessment |  - |

# Conclusion

The BPF LACTIVO 170 BPF consists of products containing the active substance Lactic acid. The products are ready-to-use water based liquids. The BPF is used for handwash disinfection (PT1) and hard surface disinfection (PT2, PT4) by professional, industrial and non-professional users for the control of bacteria, yeasts and enveloped viruses.

The BPF consists of 2 meta-SPCs. The structure of the BPF into meta-SPCs was based on difference in product types: the products belonging to the meta-SPC 1 are PT1 hand disinfection products for hygienic handwash, and meta-SPC 2 consists of PT2 and PT4 surface disinfectants. The intended uses are considered similar.

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the use 1.1. Handwash disinfectant (professional and non-professional) and the use 2.1. Multi surfaces disinfection (professional and non-professional), as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended uses of the BPF as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the BPF and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals, and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the BPF does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance Lactic acid is listed in Annex I of Regulation (EU) 528/2012 satisfies the restriction that concentration must be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008;
2. The BPF does not contain any substance of concern;
3. The BPF does not contain any nanomaterials;
4. The BPF is sufficiently effective;
5. The handling of the BPF as part of its intended use does not require any personal protective equipment (PPE).

**Composition**

The qualitative and quantitative information on the non-confidential composition of the BPF is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturers of the biocidal products are listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the BPF are met. More information is available in sections 2.5 and 2.6 of the PAR. The manufacturers of the active substance are listed in section 1.5 of the SPC.

**Conclusions of the assessments for each area**

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

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal products. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

Validated analytical methods for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff are not required for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Efficacy against target organisms

The BPF has been shown to be efficacious against bacteria, yeasts and enveloped viruses for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

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

To support the non-classification of all products belonging to the biocidal products family LACTIVO 170 BPF, the assessment of effects on human health has been performed for all the co-formulants. More information is available in section 3.6 of the PAR. Since no substance of concern has been identified, the conclusion can be made that the LACTIVO 170 BPF is eligible for the Simplified authorisation procedure.

Dietary risk assessment

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

Risk assessment for animal health

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

Risk assessment for the environment

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

To support the non-classification of all products belonging to the biocidal products family LACTIVO 150 BPF, an evaluation related to acute and chronic aquatic toxicity of all co-formulants has been performed. More information is available in section 3.8 of the PAR. Since no substance of concern has been identified, the conclusion can be made that the LACTIVO 150 BPF is eligible for the Simplified authorisation procedure.

**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** |
| Long-term storage stability test at ambient temperature | 1 September 2024  |

# Information on the biocidal product family

## Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

|  |  |
| --- | --- |
| **Product type(s)** | PT1 for meta-SPC 1; PT2 and PT4 for meta-SPC 2 |
| **Type(s) of formulation** | Ready-to-use water based liquids (for meta-SPC 1 and 2) |

## Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the BPF

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use number1** | **Use description2** | **PT3** | **Target organisms4** | **Application method5** | **Application rate6** **(min-max)** | **User category7** | **Conclusion****(by CA)8** | **Comment9** |
| 1.1 | Handwash Disinfectant (professional and non-professional users) | PT1 | Bacteria, yeasts and enveloped viruses | Manual application: spreading, spraying and foam application | 4.5 ml (equivalent to 3 foam pumps) | Industrial,Professional and non-professional | A | - |
| 2.1 | Multi surfaces disinfection (professional and non-professional users) | PT2, PT4 | Bacteria, yeasts and enveloped viruses | Manual application: spreading, spraying and foam application | fully wet all surface (about 20 ml/m2) | Industrial,Professional and non-professional | A | - |

1 Use number (as applied for) to be indicated together with the meta-SPC number, as in the SPC (e.g. 1.2, where “1” is the meta-SPC and “2” is the use number within the meta-SPC)

2 Title of the specific use (as applied for), as indicated in the SPC

3 Product type(s) of the use(s)

4 Target organisms, group of organisms

5 Application method for all meta-SPCs for the specific use

6 Min-max. application rate of the product(s) for the specific use

7 User categor(y/ies), e.g. general public, non-professional, professional, industrial

8 eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

*Codes for indicating the acceptability for each use*

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

9 If the use or meta-SPC is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

## Similarity of the group of products for which the authorisation as a biocidal product family is sought

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health, and the environment, and the minimum level of efficacy.

All the products applied for include the same active substance(s) and are similar in composition. Information on the similarity of composition and the identified worst and best case composition are provided in the confidential annex.

Table 2.3 Overview regarding the similarity of the intended uses

|  |  |  |  |
| --- | --- | --- | --- |
| Use number | Producttype | Reference1 | Use pattern2 |
| 1.1 | PT1 | #1 | Human hygiene |
| 2.1 | PT2 and PT4 | #4#30 | Hard surfaces/ instrument/ equipment disinfectionHard surfaces/ instrument/ equipment disinfection |

1, 2 As indicated in the Note for Guidance “Implementing the concept of biocidal product family“ (CA-July19-Doc4.2-Final).

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled “Implementing the concept of biocidal product family”.

In accordance with the agreed general criteria, all the intended uses are considered similar uses, in line with the document CG-34-2019-12 AP 15.1 Assessment of similarity in BPF.docx (“Section 2 – Similarity of uses”). The corresponding justification provided by the applicant is considered acceptable.

All the intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bear a consistent set of instructions for use, RMMs etc. (e.g. same RMMs from best to worst case composition), it was ensured that all products of the BPF have a similar level of risk and efficacy.

## Identity and composition

The determination whether the identity and composition of the biocidal products within the BPF are identical or not identical to the identity and composition of the products evaluated in connection with the inclusion of the active substance in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the meta-SPCs and of the individual products is detailed in sections 2.1 and 7 of the SPC, respectively. Information on the full composition is provided in the confidential annex.

## Identity of the active substance

Table 2.4 Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | Lactic acid |
| **Chemical name** | 2-hydroxypropanoic acid |
| **EC number** | 200-018-0 |
| **CAS number** | 50-21-5 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | - |
| **Structural formula** |  |

## Information on the source of the active substance

Lactic acid is included in the Category 1 of the Annex I of Regulation No. 528/2012, therefore the information on the source of the active substance is not applicable.

## Candidates for substitution

Biocidal product family does not contain any co-formulant identified as a candidate for substitution.

## Assessment of the endocrine-disrupting properties of the biocidal product family

The BPF does not contain any active substances having endocrine-disrupting properties. Lactic acid is not subject to ED assessment since this active substance is included in Annex I of the BPR.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) No 2017/2100 were identified for the non-active substances contained in the BPF.

## Classification and labelling

Table 2.5 Classification and labelling of the BPF

| **Meta-SPC 1** | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | Not classified | None |
| **Hazard Pictograms** | None | None |
| **Signal word(s)**  | None | None |
| **Hazard statements** | None | None |
| **Precautionary statements\*** | None | None |
| **Supplemental hazard statements** | None |
| **Notes** | *-* |

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

| **Meta-SPC 2** | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | Not classified | None |
| **Hazard Pictograms** | None | None |
| **Signal word(s)**  | None | None |
| **Hazard statements** | None | None |
| **Precautionary statements\*** | None | None |
| **Supplemental hazard statements** | None |
| **Notes** | *-* |

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

## Letter of access

Lactic acid (CAS No. 50-21-5) is included in Annex I of the BPR, Category 1, therefore no letter of access is required.

## Data submitted in relation to product authorisation

For the simplified authorisation application this section is not relevant.

## Similar conditions of use across the Union

For the simplified authorisation application this section is not relevant.

# Assessment of the biocidal product family

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging1** | **Size/volume of the packaging2**  | **Material of the packaging3** | **Type and material of closure(s)** | **Intended user4** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bag/Sack | 0.05, 0.10, 0.45, 0.50, 0.75, 1 and 5 L | HDPE, LDPE, PET, PE, PP | HDPE/PE cap | Industrial,Professional and Non professional | Yes |
| Bottle | 0.05, 0.075, 0.10, 0.42, 0.50, 0.75, 1 and 2 L | HDPE, LDPE, PET, PE, PP | HDPE/PE cap | Industrial,Professional and Non professional | Yes |
| Jerry can | 5, 10, 11, 15 and 20 L | HDPE, LDPE | HDPE/PE cap or tap | Industrial andProfessional | Yes |
| Drum | 10, 20, 25, 100, 220 L | HDPE | HDPE/PE cap or tap | Industrial and Professional | Yes |
| Bottle with spray/foam trigger | 0.05, 0.075, 0.10, 0.42, 0.50, 0.75, 1 and 2 L | HDPE, LDPE, PET, PE, PP | Spay and foam trigger | Industrial,Professional and Non professional | Yes |
| IBC | 1000L | HDPE | HDPE/PE cap or tap | Industrial and Professional | Yes |

1 Type of packaging e.g. bottle, rolls, can, barrel, tank.

2 Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage, and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.

For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height\*Length\*Width for rolls / number and weight of wipes.

3 For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.

4 Intended user, e.g. professional, non-professional

## Physical, chemical, and technical properties

The representative product for determination of physical, chemical and technical properties is LACTIVO 170 FEE. Information on the choice of the worst case composition for physical, chemical, and technical properties (e.g. representative test products and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF) are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.2 Physical, chemical, and technical properties

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance (Physical state, colour and odour) at 20 °C and 101.3 kPa | Visual assessment, internal method CC/001/ccq | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | Transparent liquid with citrus like odour.Note: Inside the BPF some products are perfumed (5 different perfumes) and other not. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.2. | Acidity, alkalinity, and pH value | CIPAC MT 75.3 and CIPAC MT 191 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | pH=2.59 T=24°CAcidity= 0.52% w/w as H2SO4. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.3. | Relative density | CIPAC MT 3.1EU Method A.3OECD TG 109 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | 1.011 at T= 20°C1.003 at T= 40°C | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.4.1.1. | Storage stability test – **accelerated storage** | CIPAC MT 46.4 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | Test time and temperature: 14 days at 54±2 °C;Packaging: 50 mL commercial transparent PET bottle with trigger spray.The product LACTIVO 170 FEE is stable for 14 days at T=54 ± 2 °C. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022)+ Amendment No.1 |
| Visual assessmentInternal method CC/001/ccq | Appearance at 20 °C and 101.3 kPaBefore: transparent liquid, citrus like odour;After: unchanged. |
| Visual assessmentInternal methodCC/002/ccq  | Stability of packagingand weight change Before: transparent trigger spray bottle.After: unchanged.Mean weight change:-0.21g |
| CIPAC MT 75.3 | pHbefore: 2.59;after: 2.66. |
| CIPAC MT 191 | AcidityBefore: 0.52 % w/w (as H2SO4);After: 0.55 % w/w (as H2SO4). |
| CIPAC MT 3.1EU Method A.3OECD TG 109 | Relative densityBefore: 1.011 at T=20°C and 1.003 at T=40 °C;After: 1.011 at T=20°C and 1.006 at T=40 °C. |
| EU Method A.5OECD 115 | Surface tension at T=20°CBefore: 28.17 mN/m;After: 27.62 mN/m; Therefore the product is surface-active. |
| OECD 114 (capillary method) | Viscosity at T=20 °C and at T=40 °C (dynamic and kinematic)Before:Dynamic viscosity 1.31 mPa·s (T=20°C); 0.97 mPa·s (T=40°C).Kinematic viscosity 1.30 mm2/s (T=20°C); 0.97 mm2/s (T=40°C).After:Dynamic viscosity 1.34 mPa·s (T=20°C); 0.89 mPa·s (T=40°C).Kinematic viscosity 1.33 mm2/s (T=20°C); 0.89 mm2/s (T=40°C). |
| FEA method 644 | Spray pattern and diameterBefore: 11x10 cm circular shape and uniform distribution;After: 12x11 cm circular shape and uniform distribution. |
| Visual assessment | Nozzle blockage and valve cloggingBefore: not found;After: not found. |
| In-house method, to check the valves do not malfunction or clog. Measured at 90%, 50% and 25% capacity of Trigger spray bottle. | Discharge rate/amountof spray deliveredBefore:90%:0.16 g/puff50%:0.16 g/puff25%:0.16 g/puffAfter: 90%:0.15 g/puff50%:0.16 g/puff25%:0.15 g/puff |
| CIPAC MT 187 | Particle size analysis by laser diffractionBefore:Dv(10) (μm) 32.67Dv(50) (μm) 74.31Dv(90) (μm) 175D[4][3] (μm) 90.69After:Dv(10) (μm) 37.52Dv(50) (μm) 88.38Dv(90) (μm) 200.4D[4][3] (μm) 105. |
| Ionic liquid chromatography |  | Active ingredient determination: Before: 0.80 % w/wAfter: 0.80 % w/w | Mengoli C.(Study code: 22313-01C, Date: 10 October 2022) |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | - | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid). | Ongoing study: started in August 2022, the expecting end date – August 2024.Packaging: 50 mL commercial transparent PET bottle with trigger spray. | Mengoli C.(Study plan code: 22313-03C, Date: 16 August 2022) |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | According to Annex IV of the BPR and according to ECHA “Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, low temperature stability test is required except if the label gives clear instructions that the product must not be stored under conditions of ≤ 0°C. The labels of all the products included in the LACTIVO 170 BPF contain the following storage condition: “Protect from the frost”. |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** | The study has been waived since the effects of the light were investigated in accelerated storage stability test which has been performed with a sample in the worst case packaging - 50 mL transparent PET bottle with trigger spray. The results of this test presented above has shown that the product is stable after 14 days storage at 54±2°C and light has no effect on technical characteristics of biocidal product. Moreover, a long-term stability test at ambient temperature for 24 months using the same worst case packaging is on-going and the results will additionally indicate on the effects of the light on LACTIVO 170 FEE during the long-term storage. |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | The study has been waived since the effects of the temperature were investigated in accelerated storage test: the representative product for physical-chemical properties (LACTIVO 170 FEE) is stable at T=54 °C for 2 weeks. Moreover, all the products belonging to the LACTIVO 170 BPF are high diluted aqueous solutions and none effect produced by humidity is expected. |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Visual assessment and weight changeInternal methodCC/002/ccq | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | Based on the results obtained in the accelerated stability test, transparent PET bottle with the trigger spray is a suitable material for packaging of representative product and no reactivity towards container material is expected. After storage at T=54°C for 2 weeks, neither change in packaging appearance/ weight nor blockage of spray nozzle has been observed and the discharge rate of the spray has been similar. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022)+ Amendment No.1 |
| 3.5.1. | Wettability  | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", wettability data are required for solid preparations which are dispersed in water. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore wettability definition is not applicable. |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability  | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", suspensibility, spontaneity and dispersion stability properties are required for suspensions. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids totally dissolved in water, therefore suspensibility, spontaneity and dispersion stability properties are not applicable. |
| 3.5.3. | Wet sieve analysis and dry sieve test  | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", wet sieve analysis and dry sieve test are applicable to powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids totally dissolved in water, therefore wet sieve analysis and dry sieve test are not applicable. |
| 3.5.4. | Emulsifiability, re-emulsifiability, and emulsion stability  | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", emulsifiability, re-emulsifiability and emulsion stability data are required for preparations that form emulsions. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids totally dissolved in water, therefore emulsifiability, re-emulsifiability and emulsion stability are not applicable. |
| 3.5.5. | Disintegration time | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", disintegration time is applicable to all products that are tablets. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore the disintegration time is not applicable. |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 187 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid). Packaging: 50mL transparent PET bottle with trigger spray | Dv(50) droplets = 74.31 μm.Below are reported the other Dv obtained:Dv(10) (μm) 32.67Dv(50) (μm) 74.31Dv(90) (μm) 175D[4][3] (μm) 90.69 | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.5.7. | Persistent foaming  | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", persistent foaming data are required when the product is applied in water for use and dilution is necessary. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore the persistent foaming property is not applicable. |
| 3.5.8. | Flowability/pourability/dustability | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022", flowability, pourability and dustability data are required for granular materials, suspension concentrates, capsule suspensions and suspoemulsions. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids totally dissolved in water, therefore flowability, pourability and dustability properties are not applicable. |
| 3.5.9. | Burning rate — smoke generators | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, burning rate-smoke generators is applicable to smoke generators. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquid, therefore the burning rate property is not applicable. |
| 3.5.10. | Burning completeness — smoke generators | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, “Burning completeness - smoke generators” is applicable to smoke generators. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore the burning completeness property is not applicable. |
| 3.5.11. | Composition of smoke — smoke generators | Not applicable.According to Annex IV of the BPR and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, “Composition of smoke - smoke generators” is applicable to smoke generators. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore the determination of the composition of smoke is not applicable. |
| 3.5.12. | Spraying pattern — aerosols / spray | FEA method 644 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid). Packaging: 50mL transparent PET bottle with trigger spray. | At 30 cm distance the spray forms a circular shaped cloud of drops with a diameter of 11x10 cm and with regular and uniform distribution. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.6.1. | Physical compatibility | Not applicable.According to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids and they are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, the determination of physical compatibility has been waived. |
| 3.6.2. | Chemical compatibility | Not applicable.According to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids and they are not marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of chemical compatibility has been waived. |
| 3.7. | Degree of dissolution and dilution stability  | Not applicable.According to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022”, data to address the degree of dissolution is required for products used in a water soluble bag and for all tablets; and the dilution stability should be determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids, therefore degree of dissolution and dilution stability properties are not applicable. |
| 3.8. | Surface tension  | EU Method A.5OECD TG 115  | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | 28.17 mN/m at T= 20°C, therefore the product is surface-active. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |
| 3.9. | Viscosity at 20°C and 40°C, dynamic and kinematic | OECD 114(capillary method) | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | Dynamic viscosity at T=20°C: 1.31mPa·s;Dynamic viscosity at T=40°C: 0.97mPa·s.Kinematic viscosity at T=20°C: 1.30 mm2/s;Kinematic viscosity at T=40°C: 0.97 mm2/s. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) |

Table 3.3 Conclusion on physical, chemical and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| Meta-SPC 1**:**The representative product of LACTIVO 170 BPF - LACTIVO 170 FEE is a ready-to-use water based liquid. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The physical-chemical properties before and after storage at T=54 °C for 2 weeks were comparable and no significant changes were observed. The type of packaging is considered to be suitable for the formulation and the variation of the active substance content after accelerated storage was within 10%.**Implications for labelling for meta-SPC 1:** the wording “protect from frost” need to be reported since no low temperature stability test have been conducted.Meta-SPC 2:The representative product of LACTIVO 170 BPF - LACTIVO 170 FEE is a ready-to-use water based liquid. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The physical-chemical properties before and after storage at T=54 °C for 2 weeks were comparable and no significant changes were observed. The type of packaging is considered to be suitable for the formulation and the variation of the active substance content after accelerated storage was within 10%.**Implications for labelling for meta-SPC 2:** the wording “protect from frost” need to be reported since no low temperature stability test have been conducted. |

## Physical hazards and respective characteristics

Information on the choice of the worst case composition for physical hazards and respective characteristics (e.g. representative test products) and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.4 Physical hazards and respective characteristics

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product / batch (AS% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | OECD 113 | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | There are no chemical groups associated with explosive properties present in the molecule (please find the screening for explosive properties in Section 6.1. of the Confidential annex). Moreover, the DSC shows that product is considered to be stable at room temperature, since no decomposition or chemical transformation is found below 500 °C.  | Lodi M.(Study code: 22313-04C, Date: 28 July 2023) |
| 4.2. | Flammable gases | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.3. | Flammable aerosols | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.4. | Oxidising gases | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.5. | Gases under pressure | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.6. | Flammable liquids | EU method A.9 and UNI EN ISO 3680 | LACTIVO 170 CI/ batch 220729LAB100 (0.85% w/w of lactic acid) | The test item has no flash point up to 100 °C. At temperature ≥70°C flame off due to vapour. Flash point not detected, measurement performed in triplicate. LACTIVO 170 CI is not a flammable liquid. | Mengoli C. (Study code: 22312-01C, Date: 10 October 2022) |
| 4.7. | Flammable solids | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.8. | Self-reactive substances and mixtures | OECD 113 | LACTIVO 170 FEE/ batch 220729LAB101 (0,85% w/w of lactic acid) | There are no chemical groups present in molecule associated with explosive or self-reactive properties (please find the screening for self-reactive properties in Section 6.1. of the Confidential annex). Moreover, the DSC test shows that no decomposition or chemical transformation is found until 500 °C. The representative product is considered to be stable at room temperature. | Lodi M.(Study code: 22313-04C, Date: 28 July 2023) |
| 4.9. | Pyrophoric liquids | According to the SDSs provided by the suppliers, none of the co-formulants of LACTIVO 150 BPF is classified as pyrophoric liquid. All the products in the family are high diluted aqueous solutions and the long experience of the applicant in handling the products confirms that the products are stable in contact with air at room temperature for prolonged periods of time (days), so there is no concern related to pyrophoric properties of all the products belonging to LACTIVO 170 BPF and the study does not need to be conducted. |
| 4.10. | Pyrophoric solids | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.11. | Self-heating substances and mixtures | Not applicable. According to the “Guidance on the application of the CLP criteria”, version 5.0, July 2017 section 2.11.4.2, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | Not applicable. All the products belonging to LACTIVO 170 BPF are stable aqueous solutions (water above 95 % w/w).  |
| 4.13. | Oxidising liquids | In accordance with CLP Annex I Section 2.13. the screening was made to assess whether co-formulants of LACTIVO 170 BPF contains oxygen, fluorine or chlorine that are chemically not bonded to carbon and hydrogen. The results of the screening shows that products does not have oxidising properties and the study can be waived. For details please refer to Section 6.1. of the Confidential annex. |
| 4.14. | Oxidising solids | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.15. | Organic peroxides | None of the co-formulants of LACTIVO 170 BPF contains O-O bounds. For details please refer to Section 6.1. of the Confidential annex. |
| 4.16. | Corrosive to metals | MT 37.4, Manual of test and Criteria of the Transport of Dangerous Goods of United nations. | LACTIVO 170 FEE/ batch 220729LAB101 (0.85% w/w of lactic acid) | The test item resulted not corrosive for both metals, aluminium and steel, since the maximum weight loss registered was below the threshold weight loss (51.50 %) and local corrosion was not observed. The appearance of each metal specimen after the test shown no visible uniform layer of corrosion or localised corrosion point. Therefore, LACTIVO 170 FEE and all the biocidal products belonging to “LACTIVO 170 BPF” are not classified as corrosive to metals according to the CLP Regulation EC n.1272/2008. | Mengoli C.(Study code: 22313-02C, Date: 10 October 2022) + Amendment No.1 |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | EU Method A.15 | LACTIVO 170 CI/ batch 221223LAB110 (0.85% w/w of lactic acid) | Auto-ignition temperature was not observed up to 600°C. | Lodi M.(Study code: 23010-01C, Date: 20 January 2023) |
| 4.17.2. | Relative self-ignition temperature for solids | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |
| 4.17.3. | Dust explosion hazard | Not applicable. The study does not need to be conducted because all the products belonging to LACTIVO 170 BPF are liquids. |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| Based on the assessment of the representative products, meta-SPC 1 and meta-SPC 2 are not classified for the physical hazards. |

## Methods for detection and identification

Information on the choice of the worst case composition for methods for detection and identification (e.g. representative test product) and the justification for why the chosen test product is considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

|  |
| --- |
| **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) | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of Quantification LOQ** *– only for impurit(y/ies)* | **Reference** |
| Level | Number of measurements | Range | Mean | RSD | Concentration tested | Number of replicates |
| Lactic acid (active substance) | Single determination at 5 concentrations. Correlation coefficient r2 =0.9991. Range of concentrations: 0.0431-0.1292 mg/mL(0.43 %-1.29 % w/w, referred to the test item solution concentration at 10.0 mg/mL). | Interferences from impurities did not contribute > 3% to the total peak area measured for the target analyte. Chromatograms provided for solvent formulation, calibration solution, test item and recovery solution. | 1 | 2 | Range: 96.3-93.7%Mean: 95.0%RSD: According to SANCO 3030/99 rev. 5 only 2 independent recovery determinations were performed, then no standard deviation can be calculated. | The repeatability test was performed by processing five independent sample solutions.Mean content of lactic acid: 0.80 ± 0.01 % w/w.Horrat value 0.29 (≤ 1) | Not applicable | Mengoli C.(Study code: 22313-01C, Date: 10 October 2022) |

For simplified authorisation, data related to residues in soil, air, water, animal/ human body fluids and tissues or in food/feed are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

It is important to note:

- Lactic acid is a naturally occurring alpha-hydroxy acid. According to SDSs provided by the suppliers it is not classified as toxic or very toxic and therefore analytical methods in body fluids and tissues are not required.

- Lactic acid has been approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. Lactic acid has been approved in the EU as a food additive without an ADI or upper limit.

- Lactic acid also occurs naturally in the soil. Furthermore, Lactic acid is ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source. According to it, residues determination in air, water, soil are not considered to be relevant.

Table 3.12 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification**  |
| An analytical method (Ionic Chromatography) for the determination of lactic acid is available. Specificity, linearity, accuracy and precision were checked and found acceptable.For simplified authorisation, data related to residues in soil, air, water, animal/ human body fluids and tissues or in food/feed are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.  |

##

## Assessment of efficacy against target organisms

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

All the products belonging to LACTIVO 170 BPF are ready-to-use water based disinfectants with 0.85 % w/w lactic acid. The specific function for each PT and for each user category is reported below:

* PT1 Hygienic handwash (professional and non-professional): all the products belonging to LACTIVO 170 BPF and used for PT1 are ready-to-use disinfectants for hands with a bactericidal, yeasticidal and virucidal efficacy only against enveloped viruses in domestic, institutional and industrial area (Note: Products are not intended for use in medical area). These claims are supported by tests EN1276, EN1650, EN14476 and EN1499 reported in the section 3.5.3 below and all efficacy tests are performed on the representative non scented product (for details see section 1.3 of the Confidential Annex). The target users for PT1 are industrial, professional and non-professional users for indoor and outdoor applications.
* PT2-4 Multi surfaces disinfection (professional and non-professional): all the products belonging to LACTIVO 170 BPF and used by industrial, professional and non-professional users for PT2-4 indoor and outdoor applications are ready-to-use disinfectants with a bactericidal, yeasticidal and virucidal efficacy against only enveloped viruses for hard surfaces in domestic, institutional and industrial area (Note: Products are not intended for use in medical area or for milk and meat industry). These claims are supported by tests EN1276, EN1650, EN13697, EN14476 and EN16777 reported in the section 3.5.3 below and all efficacy tests are performed on the representative non scented product (for details see section 1.3 of the Confidential Annex).

All the products belonging to LACTIVO 170 BPF contains lactic acid (EC No.200-018-0; CAS No. 50-21-5) included in Annex I of the BPR Regulation EU n.528/2012, all at concentration of 0.85% w/w and none of the product is classified according to the CLP Regulation EC n.1272/2008 and the simplified authorisation procedure according to article 25 of the BPR Regulation EU n.528/2012 is applicable. For this reason, there is low concern for non-target organisms.

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

The dissociation degree of Lactic acid in solution depends on pH value. In contact of undissociated form of Lactic acid with biological material, such as micro-organisms, the Lactic acid is able to pass the cells membrane. At a relatively low pH, the Lactic acid inhibits the pathogens through the penetration of the undissociated form across the membrane which interferes with the metabolic functions of the pathogen. The decrease in the intracellular pH causes dissipation of the membrane and leads to membrane disruption.

##

### Efficacy data

Table 3.13 Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference**  | **Number in IUCLID section 6.7/Test report title** |
| PT1Use 1.1. Hygienic handwash (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Bactericidal activity:*Enterococcus hirae* ATCC 10541, *Escherichia coli* K12 NCTC 10538, *Staphylococcus aureus* ATCC 6538,*Pseudomonas aeruginosa* ATCC 15442. | EN 1276 (2019): phase 2, step 1 test.Concentrations tested: 50 - 25 - 1 % w/w of the product, equivalent to 0.425 % - 0.21 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin).Test method: Dilution-neutralization method using spread plate technique.Diluent: sterile hard water (HW).Contact time: 60 sec.Temperature: 20 °C. | Concentration of 50% w/w LACTIVO 170 (0.425% w/w lactic acid) demonstrated >3 log reduction for all bacterial species tested under dirty conditions and 60 sec contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (Study code: 2020-209NM, Date: 8 November 2022) | 6.7.1Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019. |
| PT1Use 1.1.Hygienic handwash (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Bactericidal activity:*Escherichia coli* K12, NCTC 10538 | EN 1499 (2013): phase 2, step 2 test.Concentrations tested: 100% (w/w) of the product.Contact time: 60 seconds.Reference substance: unmedicated liquid soft soap 200g/l.Test method: dilution-neutralisation.Number of volunteers: 12.Temperature: 20 °C. | Passed concentration: 100% (w/w) of the product, 4.5 ml of product (equivalent to 3 foam pumps).Acceptance criteria for test results, as given in chapter 5.7.1. of EN 1499, are fulfilled.1) results from 12 volunteers are available,2) mean of log prevalues for RP = 6.50 and for PP = 6.66 (both > 5),3) The absolute difference between mean differences RP-PP and PP-RP was 0.21 (<2). 4) Criteria of EN1499 5.7.2. and 5.7.3. fulfilled.100% (w/w) of the product, 4.5 ml of product (equivalent to 3 foam pumps) confirms not to be inferior to reference product. | Calassanzio M. (Study code: 2021-246NM, Date: 3 December 2022) | 6.7.4Evaluation of Bactericidal activity by hygienic hand washing according to UNI EN 1499:2013 |
| PT1Use 1.1.Hygienic handwash (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Yeasticidal activity:*Candida albicans* ATCC 10231  | EN 1650 (2019): phase 2, step 1 test.Concentrations tested: 50 - 25 - 1 % w/w of the product, equivalent to 0.425 % - 0.21 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin).Test method: dilution-neutralisation method using spread plate technique.Diluent: sterile hard water (HW).Contact time: 60 sec.Temperature: 20 °C. | Concentration of 50% w/w LACTIVO 170 (0.425% w/w lactic acid) demonstrated > 2 log reduction under dirty conditions and 60 sec contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (Study code: 2020-209NM, Date: 8 November 2022) | 6.7.2Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1650:2019. |
| PT1Use 1.1.Hygienic handwash (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Activity against enveloped viruses:*Vaccinia virus Ankara* (MVA), ATCC VR-1508 | EN 14476 (2019): phase 2, step 1 test.Concentrations tested: 50 - 25 - 1 % w/w of the product, equivalent to 0.425 % - 0.21 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin + 3 ml/L erythrocytes).Diluent: distilled water.Contact time: 60 sec.Temperature: 20 °C. | Concentration of 50 % w/w LACTIVO 170 (0.425 % w/w lactic acid) demonstrated ≥ 4 log reduction under dirty conditions and 60 sec contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled.The results for the controls according to EN14476: 1.The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test was 3.25 after 5 min and 3.75 after 15 min;2. Comparative virus titration resulted in 0.13 log difference (< 1 log);3. Control for suppression of product`s activity was valid (≤0.5; 8.63 vs 8.38). | Calassanzio M. (Study code: 2022-209NM, Date: 8 November 2022) | 6.7.3Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019. |
| PT2- PT4Use 2.1. Multi surfaces disinfection (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Bactericidal activity:*Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442. | EN 1276 (2019): phase 2, step 1 test.Concentrations tested: 80 - 40 - 1 % w/w of the product, equivalent to 0.68 % - 0.34 % - 0.0085 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin).Test method: Dilution-neutralization method using spread plate technique.Diluent: sterile hard water (HW).Contact time: 5 min.Temperature: 20 °C. | Concentration of 80 % w/w LACTIVO 170 (0.68 % w/w lactic acid) demonstrated ≥ 5 log reduction for all tested bacterial species under dirty conditions and 5 min contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (Study code: 2020-209NM, Date: 8 November 2022) | 6.7.5Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019. |
| PT2- PT4Use 2.1. Multi surfaces disinfection (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Yeasticidal activity:*Candida albicans* ATCC 10231 | EN 1650 (2019): phase 2, step 1 test.Concentrations tested: 80 - 40 - 1 % w/w of the product, equivalent to 0.68 % - 0.34 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin).Test method: Dilution-neutralization method using spread plate technique.Diluent: sterile hard water (HW).Contact time: 5 min.Temperature: 20 °C. | Concentration of 80% w/w LACTIVO 170 (0.68 % w/w lactic acid) demonstrated ≥ 4 log reduction under dirty conditions and 5 min contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (Study code: 2020-209NM, Date: 8 November 2022) | 6.7.6Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1650:2019. |
| PT2- PT4Use 2.1. Multi surfaces disinfection (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Bactericidal and Yeasticidal activity:*Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442 and*Candida albicans* ATCC 10231 | EN 13697 (2019): phase 2, step 2 test.Concentrations tested: 100 - 40 - 1 % w/w of the product, equivalent to 0.85 % - 0.34 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin).Test method: Dilution-neutralization method using spread plate technique.Diluent: sterile hard water (HW).Contact time: 5 min.Temperature: 20 °C. | **For bacteria:** Concentration of 100 % w/w LACTIVO 170 (0.85 % w/w lactic acid) demonstrated ≥ 4 log reduction for all tested bacterial species.**For yeast:** Concentration of 100 % w/w LACTIVO 170 (0.85 % w/w lactic acid) demonstrated ≥ 3 log reduction.Dirty conditions.5 min contact time.Temperature: 20 °C.Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (Study code: 2020-209NM, Date: 8 November 2022) | 6.7.8Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas according to UNI EN 13697:2019 |
| PT2 – PT4Use 2.1. Multi surfaces disinfection (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Activity against enveloped virus:*Vaccinia virus Ankara* (MVA), ATCC VR-1508 | EN 14476 (2019): phase 2, step 1 testConcentrations tested: 80 - 40 - 1 % w/w of the product, equivalent to 0.68 % - 0.34 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin+ 3 mL/L erythrocytes).Diluent: distilled water.Contact time: 5 min.Temperature: 20 °C. | Concentration of 80 % w/w LACTIVO 170 (0.68 % w/w lactic acid) demonstrated ≥ 4 log reduction under dirty conditions and 5 min contact time.Temperature: 20 °C.The results for the controls according to EN14476: 1. The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test was 3.44 after 5 min and 3.75 after 15 min.2. Comparative virus titration resulted in 0.25 log difference (< 1 log)3. Control for suppression of product`s activity was valid (≤0.5; 8.75 vs 8.38). | Calassanzio M. (Study code: 2022-209NM, Date: 8 November 2022) | 6.7.7Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019 |
| PT2 – PT4Use 2.1. Multi surfaces disinfection (professional and non-professional) | LACTIVO 170,0.85% w/w lactic acid | Activity against enveloped virus:*Vaccinia virus Ankara* (MVA), ATCC VR-1508 | EN 16777 (2019): phase 2, step 2 test.Concentrations tested: 100 - 40 - 1 % w/w of the product, equivalent to 0.85 % - 0.34 % - 0.008 % w/w lactic acid in LACTIVO 170.Interfering substance: dirty conditions (3g/L Bovine albumin+ 3 mL/L erythrocytes).Diluent: distilled water.Contact time: 5 min.Temperature: 20 °C. | Concentration of 100 % w/w LACTIVO 170 (0.85 % w/w lactic acid) demonstrated ≥ 4 log reduction under dirty conditions and 5 min contact time.Temperature: 20 °C.The results for the controls according to EN16777: 1.The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test was 2.81 after 5 min;2. No cytotoxic effect observed;3. Comparative virus titration resulted in 0.25 log difference (< 1 log);3. Control for suppression of product`s activity was valid (≤0.5; 8.75 vs 8.38). | Calassanzio M. (Study code: 2022-209NM, Date: 8 November 2022) | 6.7.9Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area according to UNI EN 16777:2019. |

### Efficacy assessment

Information on the choice of the worst case composition for efficacy (e.g. representative test product and expert judgement/bridging studies where applicable) and the justification for why the chosen test product is considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

### Conclusion on efficacy

**LACTIVO 170 BPF Meta-SPC 1, PT1 (Hygienic handwash):**

- **EN1276 (Bacteria, phase 2/step 1):** minimum efficacy (> 3 log) at 50 % w/w of LACTIVO 170, i.e. 0.425% w/w of lactic acid (equivalent to RTU LACTIVO 170) after 1 minute of contact time at T=20 °C in dirty conditions (3,0 g/l Bovine Albumin) (EN 1276:2019 *Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* K12 NCTC 10538);

- **EN1650 (Yeasts, phase 2/step 1):** minimum efficacy (> 2 log) at 50 % w/w of LACTIVO 170, i.e. 0.425% w/w of lactic acid after 1 minute of contact time at T=20 °C in dirty conditions (3,0 g/l Bovine Albumin) (EN 1650: 2019 *Candida albicans* ATCC 10231);

- **EN 14476** **(Enveloped viruses, phase 2/step 1):** minimum efficacy (> 4 log) at 50 % w/w of LACTIVO 170, i.e. 0.425% w/w of lactic acid (equivalent to RTU LACTIVO 170) after 1 minute of contact time at T=20 °C in dirty conditions (3,0 g/l Bovine Albumin + 3 ml/l erythrocytes) (EN 14476:2019 *Vaccinia virus Ankara* (MVA), ATCC VR-1508).

- **EN 1499** **(Bacteria, phase 2/step 2):** LACTIVO 170 (0.85% w/w of lactic acid), using 4.5 ml (equivalent to 3 foam pumps) for 60 seconds (1 wash only), meets the basic requirements to pass the EN 1499 (EN 1499:2013 *Escherichia coli* K12, NCTC 10538).

**Conclusion for Meta-SPC 1:**

**Use 1.1 Hygienic handwash (professional and non-professional) PT1**:

Based on the results of laboratory tests reported above, all the products belonging to LACTIVO 170 BPF and used for PT1 are ready-to-use disinfectants for hands with a bactericidal, yeasticidal and virucidal efficacy only against enveloped viruses in domestic, institutional and industrial area (Note: Products are not intended for use in medical area). The instructions of use for PT1 applications derive from test EN1499 (Phase 2, step 2): Place 4.5 mL on wetted hands and wrists. Rub for at least 60 seconds, then rinse. Apply once, repeat if renewed hand disinfection is needed.

**LACTIVO 170 BPF Meta-SPC 2, PT2-4 (Surface disinfection):**

 **- EN1276 (Bacteria, phase 2/step 1):** minimum efficacy (>5 log) at 80 % w/w of LACTIVO 170, i.e. 0.68 % w/w of lactic acid after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin) (EN 1276:2019 *Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 10536);

 - **EN1650 (Yeasts, phase 2/step 1):** minimum efficacy (> 4 log) at 80 % w/w of LACTIVO 170, i.e. 0.68 % w/w of lactic acid after 5 minute of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin) (EN 1650: 2019 *Candida albicans* ATCC 10231);

**- EN 13697 (Bacteria and yeasts, phase 2/step 2):** minimum efficacy (> 4 log) at 100 % w/w of LACTIVO 170, i.e. 0.85 % w/w of lactic acid (equivalent to RTU LACTIVO 170) (against bacteria) and > 3 log at 100 % w/w of LACTIVO 170, i.e. 0.85 % w/w of lactic acid (against yeasts) after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin) (EN 13697: 2019 *Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 10536, *Candida albicans* ATCC 10231).

 **- EN 14476 (Enveloped viruses, phase 2/step 1):** minimum efficacy (> 4 log) at 80 % w/w of LACTIVO 170, i.e. 0.68 % w/w of lactic acid after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin + 3 ml/L erythrocytes) (EN 14476:2019 *Vaccinia virus* Ankara (MVA), ATCC VR-1508).

 - **EN16777** (**Enveloped viruses, phase 2/step 2):** minimum efficacy (> 4 log) at 100 % w/w of LACTIVO 170, i.e. 0.85 % w/w of lactic acid after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin + 3 ml/L erythrocytes) (EN 16777:2019 *Vaccinia virus* Ankara (MVA), ATCC VR-1508).

**Conclusion for Meta-SPC 2:**

**Use 1.1 Multi surfaces disinfection (professional and non-professional) PT2-4:** Based on the results of laboratory tests reported above, all the products belonging to LACTIVO 170 BPF and used by industrial, professional and non-professional users for PT2-4 indoor and outdoor applications are ready-to-use disinfectants with a bactericidal and yeasticidal efficacy and virucidal efficacy against enveloped viruses for hard surfaces in domestic, institutional and industrial area (Note: Products are not intended for use in medical area or for milk and meat industry). The instructions of use for PT2-4 applications derive from test EN13697 (Phase 2, step 2) and EN 16777 (Phase 2, step 2 for enveloped viruses) considering for the minimum effective concentration for bacteria, yeasts and enveloped viruses as worst case (0.85 % w/w lactic acid equivalent to the ready to use product): Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. Apply once. Repeat the application if necessary.

### Occurrence of resistance and resistance management

Development of resistance is considered unlikely due to the non-specific mode of action. Moreover, according to information included in the scientific literature (Theron M.M., 2010) concludes that no clear scientific evidence exists that target organisms have developed resistance against the organics acid, such as Lactic acid.

### Known limitations

Not relevant.

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

None of the products belonging to LACTIVO 170 BPF is intended to be authorised for use with other biocidal products.

## Risk assessment for human health

For simplified authorisation, data related to human health are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. According to Article 25 a simplified authorization procedure may be applied where the product does not contain any substance of concern (SoC), and the handling of the biocidal product and its intended use do not require personal protective equipment (PPE).

Regarding SoC, the biocidal product family LACTIVO 170 BPF does not contain substances that meet any of the criteria defined in the EU SoC guidance (CA-Nov14-Doc.5.11) and does not require use of any personal protective equipment.

Table 3.14 Overview table of the concentrations of the active substance(s) and substance(s) of concern contained in the BPF

|  |
| --- |
| **Concentration range of the BPF (%)** |
| **meta-SPC number** | **1** | **2** |
| **Active substance – Lactic acid** | 0.85% w/w | 0.85% w/w |
| **Substances of concern** | None | None |

Information on the choice of the worst case composition for human health risk assessment (e.g. representative test product) and the justification for why the chosen test product is considered sufficient to cover the whole range of specified variations (use/composition) in the BPF is provided in the confidential annex.

The test product chosen, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

### Assessment of effects on human health

There are no human health data available for the products.

To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to the toxicological properties of LACTIVO 170 BPF has been performed by applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

#### Skin corrosion and irritation

Table 3.18 Conclusion used in Risk Assessment – Skin corrosion and irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | All the products belonging to LACTIVO 170 BPF are not skin irritating/corrosive. |
| Justification for the value/conclusion | According to the suppliers’ SDS, for lactic acid (CAS 50-21-5) (racemic mixture) the classification for skin irritation is H315 (Skin Irrit. 2). The RAC opinion on L-(+)-lactic acid (CAS 79-33-4) (adopted 9 March 2018; corrigendum 3 December 2019) is to adopt the classification H314 1C. The biocide Coordination Group agrees to apply the RAC opinion classification for CAS 79-33-4 also to CAS 50-21-5. However, the “relevant ingredients” of a mixture are those which are present in concentrations ≥ 1 %. Considering the classification of the RAC opinion for lactic acid CAS 50-21-5 - Skin Corr.1C H314, and considering that the lactic acid is present in all biocidal products belonging to LACTIVO 170 BPF at the concentration of 0.85 % w/w, as well as that there are no other ingredients in the mixture classified H314, the conclusion was made that none of products belonging to LACTIVO 170 BPF is classified for skin corrosion/irritation according to the CLP Regulation EC n.1272/2008. LACTIVO 170 BPF contains no “relevant ingredients” classified as skin irritants, so none of products belonging to LACTIVO 170 BPF is classified for skin irritation according to the CLP Regulation EC n.1272/2008. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified for skin corrosion/irritation according to the CLP Regulation EC n.1272/2008. |

Table 3.19 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to skin irritation/corrosion are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to skin irritation/ skin corrosion of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008) - see Section 4 of the Confidential Annex. None of products belonging to LACTIVO 170 BPF is classified for skin corrosion/irritation according to the CLP. |

#### Eye irritation

Table 3.20 Summary table of in vitro studies on serious eye damage and eye irritation

| **Summary table of in vitro studies on serious eye damage and eye irritation**  |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| BCOP Test MethodOECD 437 and EU Method B.47 | LACTIVO 170 Cl, 750 μL of test item | Test item LACTIVO 170 CI was brought onto the cornea of a bovine eye which previously had been incubated with cMEM without phenol red at 32 ± 1 °C for 1 hour and whose opacity had been determined. The test item was incubated on the cornea for 10 minutes at 32 ± 1 °C. After removal of the test item and 2 hours post-incubation, opacity and permeability values were measured. | IVIS: 15.05 | A substance with an IVIS > 3 and ≤ 55 induces effects on the cornea, that cannot be classified in an UN GHS Category for eye damage with the BCOP study only. No stand-alone prediction can be made. | Himmelsbach A. (Study No:21121007G850 Date: 14 March 2022) |
| BCOP Test MethodOECD 437 | LACTIVO 150 CI, 750 μL of test item | Duration of treatment: 10 minutes at 32 ± 1 °C. Duration treatment: 2 hours at 32 ± 1 °C. | IVIS: 12.25 | No stand-alone prediction can be made. | Himmelsbach A. (Study No:21121008G850Date: 16 March 2022) |

Table 3.21 Summary table of animal studies on serious eye damage and eye irritation

|  |
| --- |
| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Dose levels, Duration of exposure** | **Results***Average score (24, 48, 72h)/**observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD 405 | Rabbit, New Zeeland White, females. Total 3 animals.  | LACTIVO 150 CI, 0.1 mL, Ocular examinations were performed after 24, 48, 72 hours | No irritation was recorded in any treated animal during the observation period. These results indicate that the test item, LACTIVO 150 CI, has no effect on the eye of the rabbit. | Read-across | Salvador M. (Study No: A4596, Date: 8 April 2022) |

Table 3.23 Conclusion used in Risk Assessment – Eye irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | All the products belonging to LACTIVO 170 BPF do not cause eye damage/are not eye irritant. |
| Justification for the value/conclusion | According to the paragraph 3.3.3.3.1 of CLP Regulation, the “relevant ingredients” of a mixture are those which are present in concentrations ≥ 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a presumption (e.g. in the case of skin corrosive ingredients) that an ingredient present at a concentration < 1 % can still be relevant for classifying the mixture for serious eye damage/eye irritation. Point 3.3.3.3.4.1. of CLP also states that 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 %.The evaluation of eye irritation/eye damage properties of LACTIVO 170 BPF has been performed on worst case formulation, please refer to the Section 1.3. of the Confidential Annex. Considering that the co-formulants classified as Eye Dam. 1 (H318) are acids, the sum of their concentrations exceeds the concentration limit 1%. To exclude the classification for eye irritation/eye damage, in vitro BCOP test according to OECD TG 437 has been performed using as the test item the worst case product within the family for eye damage/eye irritation. Based on the result of the test (IVIS for LACTIVO 170 CI: 15.05), no stand-alone prediction can be made for the test item. To support a non-classification of the products belonging to the LACTIVO 170 BPF and to avoid unnecessary animal testing, a read-across to the OECD 405 test was made. The tested product (LACTIVO 150 CI) is not a member the biocidal product family LACTIVO 170 BPF, but it has similar composition and was tested in the frame of another simplified authorisation of the same Applicant. Please see Section 4 of the Confidential Annex for the detailed information on the tested products’ composition and detailed justification for read-across. For LACTIVO 150 CI, no irritation was recorded in any treated animal during the observation period, the results of the testing was strongly negative. Taking into account, that difference in compositions of LACTIVO 170 CI and LACTIVO 150 CI is very small, difference in IVIS of both products is negligible, and the animal study showed strongly negative results, it is feasible to conclude that LACTIVO 170 CI has no eye irritation/corrosion properties. |
| Classification of the product(s) according to CLP  | Based on the result of BCOP Test, as well as read-across to the BCOP test and animal study OECD 405 of LACTIVO 150 CI, it is possible to conclude that none of products belonging to LACTIVO 170 BPF is classified for eye damage/ eye irritation according to the CLP Regulation EC n.1272/2008.  |

Table 3.24 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to serious eye damage / irritation are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, in vitro BCOP test was conducted, showing that no stand-alone prediction can be made (IVIS 15.05). Based on read-across data to OECD 405 test it is possible to conclude that none of products belonging to LACTIVO 170 BPF is classified for eye damage/ eye irritation according to the CLP Regulation EC n.1272/2008. |

#### Respiratory tract irritation

Table 3.27 Conclusion used in the Risk Assessment – Respiratory tract irritation

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | Based on the information included in the SDSs provided by the suppliers, none of the co-formulants of LACTIVO 170 BPF is classified as STOT SE 3 (H335, “May cause respiratory irritation”) according to the CLP, therefore all the products belonging to LACTIVO 170 BPF are not classified for respiratory tract irritation according to the CLP Regulation EC n.1272/2008. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified for respiratory tract irritation according to the CLP Regulation EC n.1272/2008 |

Table 3.28 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to respiratory tract irritation are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to respiratory tract irritation of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008) – please see Section 4 of the Confidential Annex. All the products belonging to LACTIVO 170 BPF are not classified for respiratory tract irritation according to the CLP. |

#### Skin sensitization

Table 3.32 Conclusion used in Risk Assessment – Skin sensitisation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | All the products belonging to LACTIVO 170 BPF are not skin sensitizers. |
| Justification for the value/conclusion | The only co-formulants that could require a skin sensitisation classification according to suppliers’ SDSs are all 5 perfumes at maximum concentration of 0.05 % w/w in all the products of BPF. According to the table 3.4.5 of the CLP regulation and considering the concentration of the perfume lower than generic concentration limit triggering classification of the mixture for skin sensitiser component category 1 (≥ 1% w/w for H317 and H317 1B components and ≥ 0.1 % for H317 1A components), no classification as skin sensitiser according to the CLP Regulation EC n.1272/2008 is required for the products belonging to LACTIVO 170 BPF. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified as skin sensitiser according to the CLP Regulation EC n.1272/2008. |

Table 3.33 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to skin sensitisation are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to skin sensitisation of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008). All the products belonging to LACTIVO 170 BPF are not classified for skin sensitization according to the CLP. |

#### Respiratory sensitization

Table 3.36 Conclusion used in Risk Assessment – Respiratory sensitisation

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | All the biocidal products belonging to LACTIVO 170 BPF are not respiratory sensitizers. |
| Justification for the value/conclusion | No components have a respiratory sensitisation classification (H334) according to the supplier SDSs. Also considering each component of the perfumes, none of them is classified H334 according to the CLP Regulation. Therefore, no classification as respiratory sensitiser according to the CLP is required for none of the products belonging to LACTIVO 170 BPF. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified as respiratory sensitiser according to the CLP Regulation EC n.1272/2008. |

Table 3.37 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to respiratory sensitisation are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to respiratory sensitisation of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation. No classification as respiratory sensitizer according to the CLP is required for the products belonging to LACTIVO 170 BPF. |

#### Acute oral toxicity

Table 3.40 Value used in the Risk Assessment – Acute oral toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | All the biocidal products belonging to LACTIVO 170 BPF are not harmful/toxic by oral route. |
| Justification for the selected value | According to cut-off values indicated in the table 1.1 of the CLP Regulation EC n. 1272/2008, the relevant ingredients to consider in the additivity formula to calculate ATE mix are those classified for acute toxicity category 1-3 at concentration of at least 0.1 % w/w and for category 4 at concentration of at least 1% w/w. To reach a conclusion regarding acute toxicity of the biocidal product family LACTIVO 170 BPF, the application of additivity formula is not required because there are no “relevant ingredients” to include in the additivity formula. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified for acute oral toxicity according to the CLP Regulation EC n.1272/2008. |

Table 3.41 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to acute oral toxicity are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to acute oral toxicity of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008). No classification for acute oral toxicity according to the CLP is required for none of the products belonging to LACTIVO 170 BPF. |

#### Acute inhalation toxicity

Table 3.44 Value used in the Risk Assessment – Acute inhalation toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | All the biocidal products belonging to LACTIVO 170 BPF are not harmful/toxic by inhalation route. |
| Justification for the selected value | According to cut-off values indicated in the table 1.1 of the CLP Regulation EC n. 1272/2008, the relevant ingredients to consider in the additivity formula to calculate ATE mix are those classified for acute toxicity category 1-3 at concentration of at least 0.1 % w/w and for category 4 at concentration of at least 1% w/w. To reach a conclusion regarding acute toxicity of the biocidal product family LACTIVO 170 BPF, the application of additivity formula is not required because there are no “relevant ingredients” to include in the additivity formula. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified for acute inhalation toxicity according to the CLP Regulation EC n.1272/2008. |

Table 3.45 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to acute inhalation toxicity are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to acute inhalation toxicity of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008). No classification for acute inhalation toxicity according to the CLP is required for none of the products belonging to LACTIVO 170 BPF. |

#### Acute dermal toxicity

Table 3.48 Value used in the Risk Assessment – Acute dermal toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | All the biocidal products belonging to LACTIVO 170 BPF are not harmful/toxic by dermal route. |
| Justification for the selected value | According to cut-off values indicated in the table 1.1 of the CLP Regulation EC n. 1272/2008, the relevant ingredients to consider in the additivity formula to calculate ATE mix are those classified for acute toxicity category 1-3 at concentration of at least 0.1 % w/w and for category 4 at concentration of at least 1% w/w. To reach a conclusion regarding acute toxicity of the biocidal product family LACTIVO 170 BPF, the application of additivity formula is not required because there are no “relevant ingredients” to include in the additivity formula. |
| Classification of the product(s) according to CLP  | All the products belonging to LACTIVO 170 BPF are not classified for acute dermal toxicity according to the CLP Regulation EC n.1272/2008. |

Table 3.49 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | For simplified authorisation, data related to acute dermal toxicity are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. |
| Justification | To support no human hazard associated with LACTIVO 170 BPF, an evaluation related to acute dermal toxicity of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008). No classification for acute dermal toxicity according to the CLP is required for none of the products belonging to LACTIVO 170 BPF. |

### Information on dermal absorption

For simplified authorisation, data related to dermal absorption are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012*.*

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

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

### Other

#### Food and feeding stuffs studies

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

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

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

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

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Available toxicological data relating to endocrine disruption

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

### Exposure assessment and risk characterisation for human health

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Monitoring data

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Dietary risk assessment

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

## Risk assessment for animal health

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Risk for companion animals

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

### Risk for livestock animals

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

## Risk assessment for the environment

Risk assessment for the environment is not required for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

However, to support no environmental hazard associated to LACTIVO 170 BPF, an evaluation related to acute and chronic aquatic toxicity of all co-formulants of LACTIVO 170 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

**ACUTE AQUATIC TOXICITY**

To reach a conclusion regarding acute aquatic toxicity of the biocidal product family LACTIVO 170 BPF, the application of additivity formula is not required because there are no “relevant ingredients” according to the CLP to include in the additivity formula. In fact, only one component requires H400 classification but it is included in the mixture in quantity below 0.1 % w/w and, therefore, all the products belonging to LACTIVO 170 BPF are not classified for acute aquatic toxicity according to the CLP Regulation EC n.1272/2008.

**CHRONIC AQUATIC TOXICITY**

To reach a conclusion regarding chronic aquatic toxicity of the biocidal product family LACTIVO 170 BPF, the application of additivity formula is not required because there are no “relevant ingredients” to include in the additivity formula. Therefore, all the products belonging to LACTIVO 170 BPF are not classified for chronic aquatic toxicity according to the CLP Regulation EC n.1272/2008.

Taking into account all before mentioned, all products belonging to the LACTIVO 170 BPF possess no environmental hazard and are eligible for the Simplified authorisation procedure.

#### Substance(s) of concern

The biocidal products family does not contain any substance of concern regarding the environment.

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

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

## Assessment of a combination of biocidal products

Not relevant. All the products belonging to LACTIVO 170 BPF are ready-to-use water based liquids not intended to be used in conjunction with other biocidal products.

## Comparative assessment

Not relevant. For simplified authorisation comparative assessment is not applicable.

# Appendices

## Calculations for exposure assessment

For simplified authorisation, calculations for exposure assessment for human health, dietary assessment and environment are not relevant.

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

No new information on the active substance is available.

## List of studies for the biocidal product family

*[List the studies by Reference No (Annex III requirement)/IUCLID Section Number and within a section alphabetically by author.]*

Table 4.3 List of studies for the biocidal product family

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author (s)** | **Year****Report date** | **Reference No. *(Annex III requirement)*****/ IUCLID Section No.** | **IUCLID Document name** | **Title.****Report No.** | **Type of publication**  | **Source (where different from company)****Study sponsor** | **GLP** **(Yes/No)** | **Data Protection Claimed****(Yes/No)** |
| Mengoli C. | 2022Report date:10.10.2022 | 3.1.3.1.1.3.1.2.3.1.3.3.2.3.3.3.4.1.1.3.4.2.3.3.5.6.3.5.123.83.94.16 | Determination of the Physical-Chemical properties of the product LACTIVO 170 FEE, Before and After Accelerated Storage for 14 days at 54 ± 2 °C. | 22313-02C | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Mengoli C. | 2022Report date:16.08.2022. | 3.4.1.2. | Determination of the Two Year Storage Stability and Shelf-Life Data of the Product Lactivo 170 FEE | 22313-03C | Study plan | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Lodi M. | 2023 Report date: 28.07.2023 | 4.14.8 | Determination of the explosive properties of the LACTIVO 170 FEE | 22313-04C | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Mengoli C. | 2022Report date: 10.10.2022 | 4.6 | Flash point temperature determination of the LACTIVO 170 CI product | 22312-01C | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Lodi M. | 2023Report date: 20.01.2023 | 4.17.1. | Auto-Ignition Temperature Determination of the LACTIVO 170 CI Product | 23010-01C | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Mengoli C. | 2022Report date: 10.10.2022 | 5.1 | Determination of the Active Ingredient Content of the Product LACTIVO 170 FEE, Including Validation of the Analytical Method | 22313-01C | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.1. | Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019 | 2020-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.2 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1650:2019. | 2020-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.3 | Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019. | 2022-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2021Report date: 03.12.2021 | 6.7.4 | Evaluation of Bactericidal activity by hygienic hand washing according to UNI EN 1499:2013 | 2021-246NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.5 | Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019. | 2020-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.6 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1650:2019. | 2020-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.7 | Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019. | 2022-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.8 | Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas according to UNI EN 13697:2019. | 2020-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Calassanzio M. | 2022Report date: 08.11.2022 | 6.7.9 | Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area according to UNI EN 16777:2019. | 2022-209NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)Sponsor: Specialities S.r.l. | Yes | Yes |
| Himmelsbach A. | 2022Report date: 14.03.2022 | 8.1.2 | Evaluation of LACTIVO 170 Cl in the Bovine Corneal Opacity and Permeability (BCOP) Test Method following OECD Guideline 437 and EU Method B.47 | 21121007G850 | Study report | Laboratory: LAUS GmbH Auf der Schafweide 20, 67489 Kirrweiler, GermanySponsor: Specialities S.r.l. | Yes | Yes |
| Himmelsbach A. | 2022Report date:16.03.2022 | 8.1.2 | Evaluation of LACTIVO 150 CI in the Bovine Corneal Opacity and Permeability (BCOP) Test Method following OECD Guideline 437 and EU Method B.47 | 21121008G850 | Read-across to the study report | Laboratory: LAUS GmbH, Auf der Schafweide 20, 67489 Kirrweiler, GermanySponsor: Specialities S.r.l. | Yes | Yes |
| Salvador M. | 2022Report date:08.04.2022 | 8.1.2 | LACTIVO 150 CI ACUTE EYE IRRITATION STUDY IN RABBITS. | A4596 | Read-across to the study report | Laboratory: European Research Biology Center S.r.l., Via Tito Speri 12/14, 00071 Pomezia, ItalySponsor: Specialities S.r.l. | Yes | Yes |

## References

### References other than list of studies for the BPF

* Theron MM, Rykers Lues J.F. Organics Acid and Food preservation, CRC Press, 2010

### Guidance documents

* Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), year 2022
* Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), year 2022
* Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C), year 2022
* Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), year 2022

### Legal texts

* Regulation (EU) No 528/2012 Regulation (Eu) No 528/2012 Of The European Parliament And Of The Council Of 22 May 2012

## Confidential information

Please refer to the separate document Confidential Annex of the PAR.