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 150 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-NJ072024-43

Competent Authority: Latvia

Date: 10/10/2023

Table of Contents

[1 Conclusion 5](#_Toc147838377)

[2 Information on the biocidal product family 8](#_Toc147838378)

[2.1 Product type(s) and type(s) of formulation 8](#_Toc147838379)

[2.2 Uses 8](#_Toc147838380)

[2.3 Similarity of the group of products for which the authorisation as a biocidal product family is sought 10](#_Toc147838381)

[2.4 Identity and composition 10](#_Toc147838382)

[2.5 Identity of the active substance(s) 11](#_Toc147838383)

[2.6 Information on the source(s) of the active substance(s) 11](#_Toc147838384)

[2.7 Candidate(s) for substitution 11](#_Toc147838385)

[2.8 Assessment of the endocrine-disrupting properties of the biocidal product family 11](#_Toc147838386)

[2.9 Classification and labelling 12](#_Toc147838387)

[2.10 Letter of access 13](#_Toc147838388)

[2.11 Data submitted in relation to product authorisation 13](#_Toc147838389)

[2.12 Similar conditions of use across the Union 13](#_Toc147838390)

[3 Assessment of the biocidal product family 14](#_Toc147838391)

[3.1 Packaging 14](#_Toc147838392)

[3.2 Physical, chemical, and technical properties 15](#_Toc147838393)

[3.3 Physical hazards and respective characteristics 26](#_Toc147838394)

[3.4 Methods for detection and identification 29](#_Toc147838395)

[3.5 Assessment of efficacy against target organisms 31](#_Toc147838396)

[3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected) 31](#_Toc147838397)

[3.5.2 Mode of action and effects on target organisms, including unacceptable suffering 31](#_Toc147838398)

[3.5.3 Efficacy data 32](#_Toc147838399)

[3.5.4 Efficacy assessment 39](#_Toc147838400)

[3.5.5 Conclusion on efficacy 39](#_Toc147838401)

[3.5.6 Occurrence of resistance and resistance management 40](#_Toc147838402)

[3.5.7 Known limitations 40](#_Toc147838403)

[3.5.8 Relevant information if the BPF is intended to be authorised for use with other biocidal products 40](#_Toc147838404)

[3.6 Risk assessment for human health 41](#_Toc147838405)

[3.6.1 Assessment of effects on human health 41](#_Toc147838406)

[Skin corrosion and irritation 41](#_Toc147838407)

[Eye irritation 42](#_Toc147838408)

[Respiratory tract irritation 43](#_Toc147838409)

[Skin sensitization 44](#_Toc147838410)

[Respiratory sensitization 44](#_Toc147838411)

[Acute oral toxicity 45](#_Toc147838412)

[Acute inhalation toxicity 45](#_Toc147838413)

[Acute dermal toxicity 46](#_Toc147838414)

[3.6.2 Information on dermal absorption 47](#_Toc147838415)

[3.6.3 Available toxicological data relating to substance(s) of concern 47](#_Toc147838416)

[3.6.4 Other 47](#_Toc147838417)

[3.6.4.1 Food and feeding stuffs studies 47](#_Toc147838418)

[3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal products 47](#_Toc147838419)

[3.6.4.3 Other test(s) related to the exposure to humans 47](#_Toc147838420)

[3.6.5 Available toxicological data relating to endocrine disruption 47](#_Toc147838421)

[3.6.6 Exposure assessment and risk characterisation for human health 47](#_Toc147838422)

[3.6.6.1 Introductory remarks 47](#_Toc147838423)

[3.6.7 Monitoring data 47](#_Toc147838424)

[3.6.8 Dietary risk assessment 48](#_Toc147838425)

[3.6.8.1 Information of non-biocidal use of the active substance and residue definitions 48](#_Toc147838426)

[3.6.8.2 Maximum residue limits or equivalent: Not relevant. 48](#_Toc147838427)

[3.7 Risk assessment for animal health 48](#_Toc147838428)

[3.7.1 Risk for companion animals 48](#_Toc147838429)

[3.7.2 Risk for livestock animals 48](#_Toc147838430)

[3.8 Risk assessment for the environment 49](#_Toc147838431)

[3.8.1 Available studies and endpoints applied in the environmental risk assessment 49](#_Toc147838432)

[Substance(s) of concern 49](#_Toc147838433)

[Screening for endocrine disruption relating to non-target organisms 50](#_Toc147838434)

[3.9 Assessment of a combination of biocidal products 50](#_Toc147838435)

[3.10 Comparative assessment 50](#_Toc147838436)

[4 Appendices 51](#_Toc147838437)

[4.1 Calculations for exposure assessment 51](#_Toc147838438)

[4.2 New information on the active substance(s) and substance(s) of concern 51](#_Toc147838439)

[4.3 List of studies for the biocidal product family 51](#_Toc147838440)

[4.4 References 57](#_Toc147838441)

[References other than list of studies for the BPF 57](#_Toc147838442)

[4.5 Confidential information 57](#_Toc147838443)

**Changes history table**

This is the initial authorisation, so no changes were made.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | LV | BC-NJ072024-43 | 02.08.2022. | First authorisation | - |
| SA-MAC | LV | BC-QJ085908-11 | 19.06.2023. | Merge of 2 uses of Meta-SPC 2 into the following one use: “Use 2.1. Multi surfaces disinfection (professional and non-professional users); PT2, PT4; Target organisms: bacteria, yeasts and enveloped viruses.” | Section 2.2. |
| SA-AAT | LV | BC-UH089303-29 | 10.10.2023. | Post-authorisation condition (long-term storage stability test at ambient temperature – 2 years) is fulfilled. | Section 3.2. |

# Conclusion

The BPF LACTIVO 150 BPF consists of products containing the active substance Lactic acid. The products are ready-to-use water based liquids. The BPF products are used as disinfectants for human hygiene (PT1), disinfectants not intended for direct application to humans or animals (PT2) and as disinfectants in food and feed area (PT4) by professional and non-professional users (general public) for the control of bacteria, yeast and enveloped virus.

The BPF consists of 2 meta-SPCs. The structure of the BPF into meta-SPCs was based on the different product types: the products belonging to the meta-SPC 1 are hygienic handrubs, and meta-SPC 2 consists of surface disinfectants. All the products of the BPF contains the same active substance and are similar in composition; 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 uses as disinfectant for human hygiene (PT1) by professional and non-professional users, disinfectant not intended for direct application to humans or animals (PT2) by professional and non-professional users and as disinfectant in food and feed area (PT4) by professional and non-professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended uses of the 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 and 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 manufacturer of the biocidal products is 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 method for the active substance is available in section 3.4 of the PAR.

Efficacy against target organisms

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

Risk assessment for human health

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, 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 150 BPF is eligible for the Simplified authorisation procedure.

Dietary risk assessment

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

Risk assessment for animal health

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

Risk assessment for the environment

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 2023* |

The long-term storage stability test at ambient temperature was submitted and evaluated. The shelf-life of 2 years is supported by the submitted data, so the post-authorisation condition is fulfilled.

# 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 |

## 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 | Hygienic handrub (professional and non-professional users) | PT1 | Bacteria, yeasts and enveloped viruses | Manual application: spreading, spraying and foam application. | Place 3mL on clean hands and wrists. Rub for at least 30 seconds. When the product is totally absorbed on the hands, repeat the application (double application: 3 mL 30 sec+3 mL 30 sec). | 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. | Apply the product by fully wetting all surface (about 20 mL/m2) for 5 minutes. Rub or brush if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. | 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 categories, 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 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 | Product  type | Reference1 | Use pattern2 |
| 1.1 | PT1 | #1 | Human hygiene |
| 2.1 | PT2 and PT4 | #4  #30 | Hard surfaces/ instrument/ Equipment disinfection  Hard 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(s) provided by the applicant are considered acceptable.

All the intended uses as applied 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., 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(s)

Table 2.4 Identity of the active substance(s)

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **Common name** | Lactic acid |
| **IUPAC 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(s) of the active substance(s)

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

## Candidate(s) for substitution

Lactic acid is listed in annex I of Regulation EU n.528/2012 Category I and is not 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. For Lactic acid no ED assessment is required because 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: LACTIVO 150 Hands** | **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)[[1]](#footnote-2), 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: LACTIVO 150 Surfaces** | **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)[[2]](#footnote-3), are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

## Letter of access

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 | Cap, HDPE/PE | 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 | Cap, HDPE/PE | Industrial,  Professional and Non professional | Yes |
| Jerry can | 5, 10,11,15 and 20 L | HDPE, LDPE | Cap or tap, HDPE/PE | Industrial and  Professional | Yes |
| Drum | 10, 20, 25, 100, 220 L | HDPE | Cap or tap, HDPE/PE | 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 | Cap or tap, HDPE/PE | 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

Information on the choice of the worst case composition for physical, chemical, and technical properties (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 product, 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 check | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid) | Limpid colourless liquid.  Note: Inside the BPF some products are perfumed but other not (e.g. LACTIVO 150 FEE has strong aromatic odour) | Gazzotti L. (2021a+2021a-amend1+2021a-amend3) |
| 3.2. | Acidity, alkalinity, and pH value | CIPAC MT 75.3 and  CIPAC MT 191 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid) | pH=2.32 T=24°C  Acidity= 0.48% w/w as H2SO4. | Gazzotti L. (2021a) |
| 3.3. | Relative density / bulk density | OECD TG 109 /  EU Method A.3 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid) | 1.002 T= 20°C  0.999 T= 40°C | Gazzotti L. (2021a+2021a-amend2) |
| 3.4.1.1. | Storage stability test – **accelerated storage** | CIPAC MT 46.3 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid) | Test time and temperature: 14 Days at 54±2 °C;  Packaging: 50 mL transparent PET bottle/ Trigger Spray. | Gazzotti L. (2021a) |
| HPLC | Lactic acid content:  Before: 0.78 % w/w  After: 0.78 % w/w |
| Visual check | Appearance:  Before: limpid colourless liquid;  After: limpid colourless liquid. |
| Visual check | Packaging appearance and weight change:  Before: not damaged or collapsed bottle (6/32= 66.58 g)  After: not damaged or collapsed bottle (6/32= 66.15 g). |
| CIPAC MT 75.3 | pH:  Before: 2.32;  After: 2.32. |
| CIPAC MT 191 | Acidity:  Before: 0.48 % w/w (as H2SO4);  After: 0.51 % w/w (as H2SO4). |
| OECD TG 109/ EU Method  A.3 | Relative density:  Before: 1.002 (T=20°C) and 0.999 (T=40 °C);  After: 1.002 (T=20°C) and  0.992 (T=40 °C). |
| OECD TG 115/ EU Method  A.5 | Surface tension:  Before: 30.5 mN/m (T=20°C);  After: 30.9 mN/m (T=20°C). |
| OECD TG 114 | Viscosity:  Before:  - Kinematic (mm2/s): 1.07 (T=20 °C); 1.04 (T=40 °C);  - Dinamic (mPa\*s): 1.07 (T=20 °C); 1.05 (T=40 °C).  After:  - Kinematic (mm2/s): 0.75 (T=20 °C); 0.81 (T=40 °C);  - Dinamic (mPa\*s): 0.75 (T=20 °C); 0.81 (T=40 °C). |
| FEA method 644 | Spray pattern and diameter:  Before: 9x12 cm;  After: 9x12 cm. |
| Visual check | Nozzle blockage:  Before: No blockage;  After: No blockage. |
| Visual check | Valve clogging:  Before: No blockage;  After: No blockage. |
| Weighing | Discharge amount:  Before: 0.16 g/puff;  After: 0.15 g/puff. |
| CIPAC MT 187 | Particle size of the droplets:  Before: d50= 69.71 μm;  After: d50= 70.89 μm. | Before: Mazzei A. (2021a)  After: Mazzei A. (2021b) |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | Storage for 2 years at 25±3 °C. | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid). | Storage term: 2 years.  Packaging: 50 mL transparent PET bottle with Trigger Spray. | Digrandi S. (2023) |
| HPLC | Lactic acid content  Before storage: 0.78% w/w  After 2 years: 0.83% w/w (acceptable variation <10%). |
| Internal method  CC/001/ccq | Appearance  Before storage: limpid colourless liquid.  After 2 years: unchanged. |
| Internal method  CC/002/ccq | Packaging appearance and weight change  Before storage: not damaged or collapsed 50 mL transparent PET trigger bottle, weight 68.50 g.  After 2 years: unchanged, weight 66.20 g. |
| CIPAC MT 75.3 | pH  Before storage: 2.32;  After 2 years: 2.33. |
| CIPAC MT 191 | Acidity  Before storage: 0.48% w/w (as H2SO4);  After 2 years: 0.50% w/w (as H2SO4). |
| OECD TG 109/ EU Method  A.3 | Relative density  Before storage:  1.002 (T=20°C),  0.999 (T=40 °C).  After 2 years:  1.001 (T=20°C),  0.998 (T=40 °C). |
| FEA method 644 | Spray pattern and diameter  Before storage: Oval spray 9x12 cm;  After 2 years: Oval spray 9x12 cm. |
| Visual check | Nozzle blockage  Before storage: No blockage;  After 2 years: No blockage. |
| Visual check | Valve clogging  Before storage: No blockage;  After 2 years: No blockage. |
| Weighing | Discharge amount  Before storage: 0.16 g/puff;  After 2 years: 0.18 g/puff. |
| CIPAC MT 187 | Particle size of the droplets  Before storage:  d50 = 69.71 μm;  After 2 years:  d50 = 90.31 μm. |
| 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 2.0 2018”, 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 150 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. The stability is also supported by the completed long-term storage stability test showing no effects of light. | | | |
| 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. LACTIVO 150 FEE (representative product for physical-chemical properties) is stable at T=54 °C for 2 weeks. Moreover, all the products belonging to the LACTIVO 150 BPF are high diluted aqueous solutions (water above 98 % w/w) 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 check and weight change | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid). | Based on the results obtained in the accelerated stability test and long-term storage stability test, 50 mL transparent PET bottle with the trigger spray is a suitable material for packaging of LACTIVO 150 FEE and no reactivity towards container material is expected. | Gazzotti L. (2021a)  Digrandi S. (2023) |
| 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 2.0 May 2018", wettability data are required for solid preparations which are dispersed in water. All the products belonging to LACTIVO 150 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 2.0 May 2018", suspensibility, spontaneity and dispersion stability properties are required for suspensions. All the products belonging to LACTIVO 150 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 2.0 May 2018", wet sieve analysis and dry sieve test wettable 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 150 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 2.0 May 2018", emulsifiability, re-emulsifiability and emulsion stability data are required for preparations that form emulsions. All the products belonging to LACTIVO 150 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 2.0 May 2018", disintegration time is applicable to all products that are tablets. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquids, therefore the definition of disintegration time is not applicable. | | | |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 187 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid).  Packaging: 50mL transparent PET bottle with trigger spray | d50 droplets= 69.71 μm. | Mazzei A. (2021a) |
| 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 2.0 May 2018", persistent foaming data are required when the product is applied in water for use and dilution is necessary. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquids, therefore the definition of persistent foaming 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 2.0 May 2018", flowability, pourability and dustability data are required for granular materials, suspension concentrates, capsule suspensions and suspoemulsions. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquids totally dissolved in water, therefore the definitions of flowability, pourability and dustability 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 2.0 May 2018”, burning rate-smoke generators is applicable to smoke generators. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquid, therefore the definition of “Burning rate — smoke generators” 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 2.0 May 2018”, “Burning completeness - smoke generators” is applicable to smoke generators. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquids, therefore the definition of “Burning completeness - smoke generators” 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 2.0 May 2018”, “Composition of smoke - smoke generators” is applicable to smoke generators. All the products belonging to LACTIVO 150 BPF are ready-to-use water based liquids, therefore the definition of “Composition of smoke - smoke generators” is not applicable. | | | |
| 3.5.12. | Spraying pattern — aerosols / spray | FEA method 644 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid). | The test was performed with the test product in the 50 mL transparent PET bottle with trigger spray. The spray at 30 cm distance forms an oval “cloud of drops” with a diameter of 9x12 cm. | Gazzotti L. (2021a) |
| 3.6.1. | Physical compatibility | Not applicable.  According to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.0 May 2018”, 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 150 BPF are ready-to-use water based liquids and they are not intended 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 2.0 May 2018”, 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 150 BPF are ready-to-use water based liquids and they are not intended 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 2.0 May 2018”, 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 150 BPF are ready-to-use water based liquids, therefore definitions “degree of dissolution” and “dilution stability” are not applicable. | | | |
| 3.8. | Surface tension | OECD TG 115 /  EU Method A.5 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid); tested as RTU product. | 30.5 mN/m at T= 20°C. | Gazzotti L. (2021a) |
| 3.9. | Viscosity at 20°C and 40°C | OECD TG 114 | LACTIVO 150 FEE/ batch 210803LAB008 (0.75% w/w of lactic acid) | * at 20 °C: dynamic viscosity = 1.07 mPa·s; kinematic viscosity = 1.07 mm²/s; * at 40 °C: dynamic viscosity = 1.05 mPa·s; kinematic viscosity = 1.04 mm²/s. | Gazzotti L. (2021a+2021a-amend2) |

Table 3.3 Conclusion on physical, chemical and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties (meta-SPC 1)** |
| The data provided by the Applicant was acceptable.  The core composition and concentrations are equal for all the products of the meta-SPC 1 and the only difference is the presence of a perfume and its concentration. The worst case product for the physical, chemical and technical properties has been chosen considering the highest content of active substance (0.75% w/w, the same for this BPF) and the highest quantity of additional co-formulants - perfumes (i.e. 0.05 % w/w). Among the perfumes, Fresh Eucalyptus Ecolabel has been chosen based on the applicant's experience in the formulation of this kind of product (i.e. the highest level of turbidity). For this reason, the physical, chemical and technical properties have been tested on representative product LACTIVO 150 FEE (equivalent to LACTIVO 150 FEE Hands) as it contains the above mentioned perfume Fresh Eucalyptus Ecolabel.  The representative product is ready to use water-based limpid colorless liquid. The pH and the acidity of LACTIVO 150 FEE are accordingly 2.32 pH at T =24°C and 0.48 % w/w as H2SO4.  According to the accelerated storage stability test, the variation of the active ingredient content after accelerated storage was within 10%, physical-chemical properties investigated before and after the test were comparable and the type of packaging was suitable for the formulation. Based on the results of this study, the representative product is stable at T=54 °C for 2 weeks.  A long-term storage stability test at ambient temperature was a post-authorisation condition of the authorisation. The submitted test report shows that the representative product is stable at 25±3 °C for 2 years, as the variation of the active substance content after 2 years of storage is within 10%, as well physical and chemical properties investigated before and after storage are comparable and the type of packaging is suitable for the formulation. Therefore, the shelf-life of 2 years is supported by the submitted data and the post-authorisation condition is fulfilled.  No effects of light were determined during the accelerated storage stability test and long-term storage stability test, both performed with the worst case packaging, i.e. 50 mL PET transparent bottle with trigger spray.  The particle size of the droplets before and after the accelerated stability are accordingly d50 = 69.71 μm and d50 = 70.89 μm, and after 2 years of storage d50 = 90.31 μm. The spray forms at 30 cm distance an oval “cloud of drops” with a diameter of 9x12 cm. As particle size distribution has no impact on efficacy of this product as well as no impact on human exposure assessment (not applicable for simplified authorisation), the variation is considered acceptable.  **Implications for labelling for meta-SPC 1:**  Labels of biocidal products belonging to the meta-SPC 1 should contain the following condition: “Protect from the frost”. |

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties (meta-SPC 2)** |
| The data provided by the Applicant was acceptable.  The core composition and concentrations are equal for all the products of the meta-SPC 2 and the only difference is the presence of a perfume and its concentration. The worst case product for the physical, chemical and technical properties has been chosen considering the highest content of active substance (0.75% w/w, the same for this BPF) and the highest quantity of additional co-formulants - perfumes (i.e. 0.05 % w/w). Among the perfumes, Fresh Eucalyptus Ecolabel has been chosen based on the applicant's experience in the formulation of this kind of product (i.e. the highest level of turbidity). For this reason, the physical, chemical and technical properties have been tested on representative product LACTIVO 150 FEE (equivalent to LACTIVO 150 FEE Surfaces) as it contains the above mentioned perfume Fresh Eucalyptus Ecolabel.  The representative product is ready to use water-based limpid colorless liquid. The pH and the acidity of LACTIVO 150 FEE are accordingly 2.32 pH at T =24°C and 0.48 % w/w as H2SO4.  According to the accelerated storage stability test, the variation of the active ingredient content after accelerated storage was within 10%, physical-chemical properties investigated before and after the test were comparable and the type of packaging was suitable for the formulation. Based on the results of this study, the representative product is stable at T=54 °C for 2 weeks.  A long-term storage stability test at ambient temperature was a post-authorisation condition of the authorisation. The submitted test report shows that the representative product is stable at 25±3 °C for 2 years, as the variation of the active substance content after 2 years of storage is within 10%, as well physical and chemical properties investigated before and after storage are comparable and the type of packaging is suitable for the formulation. Therefore, the shelf-life of 2 years is supported by the submitted data and the post-authorisation condition is fulfilled.  No effects of light were determined during the accelerated storage stability test and long-term storage stability test, both performed with the worst case packaging, i.e. 50 mL PET transparent bottle with trigger spray.  The particle size of the droplets before and after the accelerated stability are accordingly d50= 69.71 μm and d50= 70.89 μm, and after 2 years of storage d50 = 90.31 μm. The spray forms at 30 cm distance an oval “cloud of drops” with a diameter of 9x12 cm. As particle size distribution has no impact on efficacy of this product as well as no impact on human exposure assessment (not applicable for simplified authorisation), the variation is considered acceptable.  **Implications for labelling for meta-SPC 2:**  Labels of biocidal products belonging to the meta-SPC 2 should contain the following condition: “Protect from the frost”. |

## 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 flash point has been tested on LACTIVO 150 CI and the corrosive to metals properties have been tested on LACTIVO 150 FEE.

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 150 FEE/ batch 220216LAB002  (0.75% w/w of lactic acid) | | The DSC of the sample has been recorded between 30°C and 500°C both in nitrogen and air atmosphere. In both experiments no decomposition or chemical transformation is found below 150°C and no exothermic effects is found below 500°C. | Mazzei A. (2022) |
| 4.2. | Flammable gases | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.3. | Flammable aerosols | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.4. | Oxidising gases | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.5. | Gases under pressure | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.6. | Flammable liquids | EU method A.9 and UNI EN ISO 3679 | LACTIVO 150 CI/ batch 211115LAB011 (0.75% w/w of lactic acid) | | No Flash point up to 200 °C. The product is not flammable according to CLP criteria. | Madeddu S. (2021a+2021a-amend1) |
| 4.7. | Flammable solids | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.8. | Self-reactive substances and mixtures | OECD 113 | LACTIVO 150 FEE/ batch 220216LAB002  (0.75% w/w of lactic acid) | | The DSC of the sample has been recorded between 30°C and 500°C both in nitrogen and air atmosphere. In both experiments no decomposition or chemical transformation is found below 150°C and no exothermic effects is found below 500°C. | Mazzei A. (2022) |
| 4.9. | Pyrophoric liquids | Not applicable.  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 (water above 98 %w/w) and the long experience of the applicant in handling the products confirms no concern related to pyrophoric properties of all the products belonging to LACTIVO 150 BPF. | | | | |
| 4.10. | Pyrophoric solids | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based 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. All the products belonging to biocidal product family LACTIVO 150 BPF are ready-to-use water based liquids and therefore the endpoint “self-reactive mixture” has been waived. | | | | |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | Not applicable, all the products belonging to biocidal family LACTIVO 150 BPF are stable aqueous solutions (water above 98 % w/w). | | | | |
| 4.13. | Oxidising liquids | Not applicable.  None of the co-formulants of LACTIVO 150 BPF contains oxygen, fluorine or chlorine (if O,F or Cl are present they are bonded only to carbon or hydrogen). Regarding the perfumes the SDS classification has been evaluated considering the whole mixture and none of them is classified for oxidising properties. For this reason, all the products belonging to biocidal product family LACTIVO 150 BPF are expected to be non-oxidising according to the CLP. | | | | |
| 4.14. | Oxidising solids | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water based liquids. | | | | |
| 4.15. | Organic peroxides | Not applicable.  None of the co-formulants of LACTIVO 150 BPF contain O-O bounds. Regarding the perfumes, the SDS classification has been evaluated considering the whole mixture and none of them is classified as organic peroxide. In conclusion none of the products belonging to the LACTIVO 150 BPF falls under the definition of organic peroxides according to the CLP. | | | | |
| 4.16. | Corrosive to metals | MT 37.4, Manual of test and Criteria of the Transport of Dangerous Goods of United nations. | | LACTIVO 150 FEE/ batch 211115LAB010  (0.75% 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 (13.50%). The appearance of each metal specimen after the test, shown no visible uniform layer of corrosion or localised corrosion point. | Madeddu S. (2021b+2021b-amend1) |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | Not applicable.  To support no physical hazard associated with LACTIVO 150 BPF, an evaluation of “auto-ignition” properties of the products belonging to the family has been performed. A test according to EN Method A.9 (Flash point) and according to UNI EN ISO 3679 has been performed on representative product (LACTIVO 150 CI), the conclusion was that it has no flash point up to 200°C and therefore is a liquid non-flammable in air. The study does not need to be conducted for liquids non-flammable in air, e.g. no flash point up to 200 °C. The representative product is liquid non-flammable in air, so the auto-ignition properties of the biocidal product family LACTIVO 150 BPF are of no concern. | | | | |
| 4.17.2. | Relative self-ignition temperature for solids | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based liquids. | | | | |
| 4.17.3. | Dust explosion hazard | Not applicable, all the products belonging to LACTIVO 150 BPF are ready to use water-based 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 for the active substance** | | | | | | | | | | | |
| Principle of the method: Aliquots of test item were accurately weighed into a volumetric flask, and diluted to volume with ultrapure water to a concentration of 24.5 mg/mL. The resulting solutions were transferred into vials to undergone ionic chromatography with conductimetric detection analysis. Analysis is done with HPLC (ionic chromatography with conductimetric detection) using a isocratic elution (Hydroxide generate by hydroxide generator - 30 mM) | | | | | | | | | | | |
| **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 | Single determination at 5 concentrations;  r= 0.9970 (acceptance > 0.99);  Linearity range: 0.1086 - 0.4342 mg/mL (referred to the test item solution concentration 24.5 mg/mL. 0.44 - 1.77 % w/w) | Interference from other substances < 3% of total peak area | 1 level, 2 determinations | | Range: 80 - 120%  Mean Recovery: 104.2%  Note: According to SANCO 3030/99 rev. 5 only 2 independent recovery determinations were performed, then no standard deviation can be calculated. | | | 5 independently weighed samples determination at the same conc.: mean value: 0.78% w/w.  Horrat value=0.83. | | Not applicable | Gazzotti L. (2021b+  2021b-amend1) |

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 3.7 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification** |
| An analytical method (Gazzotti L. (2021b+2021b-amend1) 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

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

All the products belonging to LACTIVO 150 BPF are ready-to-use water based disinfectant with 0.75 % w/w lactic acid. The specific function for each PT and for each user category is reported below:

* PT1 Hygienic handrub (professional and non-professional): all the products belonging to LACTIVO 150 BPF and used for PT1 are ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal efficacy against only 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 EN1500 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 150 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 only against enveloped virus for hard surfaces in domestic, industrial and institutional 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 EN 16777 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 150 BPF contain 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 0.75% w/w so 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.

### 3.5.2 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.

### 3.5.3 Efficacy data

Table 3.8 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** |
| PT1  Use 1.1. Hygienic handrub (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Bactericidal activity/  Enterococcus hirae ATCC 10541, Escherichia Coli ATCC 10536, Staphylococcus aureus ATCC 6538,  Pseudomonas aeruginosa ATCC 15442 and Escherichia coli K12 NCTC 10538. | UNI EN 1276 (2019): phase 2, step 1 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), equivalent to 0.75 % - 0.50 % - 0.0125 % w/w lactic acid in LACTIVO 150.  Interfering substance: clean condition (0.3 g/L Bovine albumin).  Test method: Dilution-neutralisation (for N) and membrane filtration (for Na, Nvo, A, B, C).  Diluent: distilled water.  Contact time: 1 min.  Temperature: 20 °C. | Concentration of 60% w/w LACTIVO 250 (1.25% w/w lactic acid) passed (> 5 log reduction) - equivalent to RTU LACTIVO 150 (0.75% w/w lactic acid).  Clean condition.  1 min contact time.  Temperature: 20 °C.  Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M.(2021a-Rev.2) +  Calassanzio M. (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.  ***plus*** Quantitative suspension test for the evaluation of E.coli k12 activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019. |
| PT1  Use 1.1.  Hygienic handrub (professional and non-professional) | LACTIVO 150  0.75% w/w lactic acid | Bactericidal activity/ E. coli K12 CECT 433 equivalent to NCTC 10538 | UNI EN 1500 (2013): phase 2, step 2 test.  Concentrations tested: 100% (w/w) of the product, 2 applications of 3 mL.  Contact time: 30 seconds X2 applications (total. 1 min).  20 volunteers.  Reference substance: Propanol-2 60% (v/v).  Test method: dilution-neutralisation.  Temperature: 20 °C. | Passed concentration: 100% (w/w) of the product, 2 applications of 3 mL.  Acceptance criteria for test results, as given in chapter 5.7.1. of EN 1500, are fulfilled.  1) 20 volunteers,  2) mean of lg prevalues for RP = 6.98 and for PP = 7.07 (both > 5),  3) No individual lg reductions of < 3.00,  4) The absolute difference between mean differences RP-PP and PP-RP was 0.04 (Abs = [0.24–0.28] < 2,).  5) Criteria of EN1500 5.7.2. and 5.7.3. fulfilled.  100% (w/w) of the product, at 2 applications of 3 mL confirms not to be inferior to reference product. | Calassanzio M. (2021b-Rev.2) | 6.7.2  HYGIENIC TREATMENT OF HANDS BY FRICTION ACCORDING TO STANDARD: UNI EN 1500: 2013 |
| PT1  Use 1.1.  Hygienic handrub (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Yeasticidal activity/  Candida albicans ATCC 10231 | UNI EN 1650 (2019): phase 2, step 1 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w lactic acid in LACTIVO 150.  Interfering substance: clean condition (0.3 g/L Bovine albumin).  Test method: dilution-neutralisation.  Diluent: distilled water.  Contact time: 1 min.  Temperature: 20 °C. | Concentration of 40% w/w and 60% w/w LACTIVO 250 (1.25% w/w lactic acid) passed (> 4 log reduction) - equivalent to 0.50% and 0.75% w/w lactic acid of RTU LACTIVO 150 (0.75% w/w lactic acid).  Clean condition.  1 min contact time.  Temperature: 20 °C.  Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M. (2021c-Rev.2) | 6.7.3  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. |
| PT1  Use 1.1.  Hygienic handrub (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Activity against enveloped virus/  Vaccinia virus Ankara (MVA), ATCC VR-1508 | UNI EN 14476 (2019): phase 2, step 1 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w lactic acid in LACTIVO 150.  Interfering substance: clean condition (0.3 g/L Bovine albumin).  Diluent: distilled water.  Contact time: 1 min.  Temperature: 20 °C. | Concentration of 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 4 log reduction)- equivalent to RTU LACTIVO 150 (0.75 % w/w lactic acid).  Clean condition.  1 min 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 3.13 after 5 min and 4.19 after 15 min;  2. Comparative virus titration resulted in 0.44 log difference (< 1 log);  3. Control for suppression of product`s activity was valid (≤0.5; 8.63 vs 8.56). | Calassanzio M.(2021d-Rev.2) | 6.7.4  Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019. |
| PT2- PT4  Use 2.1 Multi surfaces disinfection (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Bactericidal activity/  Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538 and Pseudomonas aeruginosa ATCC 15442. | UNI EN 1276 (2019): phase 2, step 1 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w lactic acid in LACTIVO 150.  Interfering substance: dirty condition (3 g/L Bovine albumin).  Test method: Dilution-neutralisation (for N) and membrane filtration (for Na, Nvo, A, B, C).  Diluent: distilled water.  Contact time: 5 min.  Temperature: 20 °C. | Concentration of 40 % and 60 w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 5 log reduction) - equivalent to 0.50 and 0.75 % w/w lactic acid of RTU LACTIVO 150 (0.75 % w/w lactic acid).  Dirty condition.  5 min contact time.  Temperature: 20 °C.  Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M.(2021e-Rev.2) | 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. |
| PT2- PT4  Use 2.1 Multi surfaces disinfection (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Yeasticidal activity/  Candida albicans ATCC 10231 | UNI EN 1650 (2019): phase 2, step 1 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w as lactic acid in LACTIVO 150.  Interfering substance: dirty condition (3 g/L Bovine albumin).  Test method: Dilution-neutralisation.  Diluent: distilled water.  Contact time: 5 min.  Temperature: 20 °C. | Concentration of 40% and 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 4 log reduction)- equivalent to 0.50% or 0.75% w/w lactic acid in RTU LACTIVO 150 (0.75 % w/w lactic acid).  Dirty condition.  5 min contact time.  Temperature: 20 °C.  Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M.(2021f-Rev.2) | 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. |
| PT2- PT4  Use 2.1 Multi surfaces disinfection (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Bactericidal and Yeasticidal activity/  Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538 and Pseudomonas aeruginosa ATCC 15442.  Candida albicans ATCC 10231 | UNI EN 13697 (2019): phase 2, step 2 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w as lactic acid in LACTIVO 150.  Interfering substance: dirty condition (3 g/L Bovine albumin).  Test method: Dilution-neutralisation.  Diluent: distilled water.  Contact time: 5 min (bacteria); 5 and 15 min (yeasts).  Temperature: 20 °C. | **For bacteria:** Concentration of 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 4 log reduction) - equivalent to RTU LACTIVO 150 (0.75 % w/w lactic acid)  **For yeast:** Concentration of 40 % and 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 3 log reduction) - equivalent to 0.50 % or 0.75 % w/w lactic acid; this test covers RTU LACTIVO 150 (0.75 % w/w lactic acid).  Dirty condition.  5 min contact time.  Temperature: 20 °C.  Validity criteria of the test (list of criteria used) fulfilled. | Calassanzio M.(2021g-Rev.2) | 6.7.7  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 |
| PT2 – PT4  Use 2.1 Multi surfaces disinfection (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Activity against enveloped virus/  Vaccinia virus Ankara (MVA), ATCC VR-1508 | UNI EN 14476 (2019): phase 2, step 1 test  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w as lactic acid in LACTIVO 150.  Interfering substance: dirty condition (3 g/L Bovine albumin+ 3 mL/L erythrocytes).  Diluent: distilled water.  Contact time: 5 min.  Temperature: 20 °C. | Concentration of 40 % and 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 4 log reduction) - equivalent to 0.50 % or 0.75% w/w lactic acid in RTU LACTIVO 150 (0.75 % w/w lactic acid).  Dirty condition.  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 3.06 after 5 min and 4.56 after 15 min  2. Comparative virus titration resulted in 0.50 log difference (< 1 log)  3. Control for suppression of product`s activity was valid (≤0.5; 8.75 vs 8.38). | Calassanzio M.(2021h-Rev.2) | 6.7.8  Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019 |
| PT2 – PT4  Use 2.1 Multi surfaces disinfection (professional and non-professional) | LACTIVO 250  1.25% w/w lactic acid | Activity against enveloped virus/  Vaccinia virus Ankara (MVA), ATCC VR-1508 | UNI EN 16777 (2019): phase 2, step 2 test.  Concentrations tested: 60 - 40 - 1 % w/w of the product (1.25 % w/w lactic acid), i.e. 0.75 % - 0.50 % - 0.0125 % w/w as lactic acid in LACTIVO 150.  Interfering substance: dirty condition (3 g/L Bovine albumin+ 3 mL/L erythrocytes).  Diluent: distilled water.  Contact time: 5 min.  Temperature: 20 °C. | Concentration of 40 % and 60 % w/w LACTIVO 250 (1.25 % w/w lactic acid) passed (> 4 log reduction) - equivalent to 0.50 % or 0.75 % w/w lactic acid in RTU LACTIVO 150 (0.75 % w/w lactic acid).  Dirty condition.  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 2.50 after 5 min;  2. No cytotoxic effect observed;  3. Comparative virus titration resulted in 0.50 log difference (< 1 log);  3. Control for suppression of product`s activity was valid (≤0.5; 8.75 vs 8.38). | Calassanzio M.(2021i-Rev.2) | 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. |

### 3.5.4 Efficacy assessment

Information on the choice of the worst case composition for efficacy (e.g. representative test product and bridging studies) 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. All the efficacy tests have been performed on LACTIVO 150 or on diluted LACTIVO 250.

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.

### 3.5.5 Conclusion on efficacy

**LACTIVO 150 BPF PT1 (Hygienic handrub):**

- **EN1276 (Bacteria, phase 2/step 1):** minimum efficacy at 60% w/w of LACTIVO 250, i.e. 0.75% w/w of lactic acid (equivalent to RTU LACTIVO 150) after 1 minute of contact time at T=20 °C in clean conditions (0.3 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 at 40% w/w of LACTIVO 250, i.e. 0.50% w/w of lactic acid after 1 minute of contact time at T=20 °C in clean conditions (0.3 g/L Bovine albumin) (EN 1650: 2019 Candida albicans ATCC 10231);

- **EN 14476 (Enveloped viruses, phase 2/step 1):** minimum efficacy at 60% w/w of LACTIVO 250, i.e. 0.75% w/w of lactic acid (equivalent to RTU LACTIVO 150) after 1 minute of contact time at T=20 °C in clean conditions (0.3 g/L Bovine albumin) (EN 14476:2019 Vaccinia virus Ankara (MVA), ATCC VR-1508).

- **EN 1500 (Bacteria, phase 2/step 2):** LACTIVO 150 (0.75% w/w of lactic acid), used twice with a 3 ml hand rub for 30 seconds, meets the basic requirements to pass the EN 1500 (EN 1500:2013 Escherichia coli K12 NCTC 10538 equivalent to CECT 433).

**Conclusion for PT1:**

**MetaSPC1, Use 1: Hygienic handrub (professional and non-professional):** Based on the results of laboratory tests reported above, all the products belonging to LACTIVO 150 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 EN1500 (Phase 2, step 2): Place 3mL on clean hands and wrists. Rub for at least 30 seconds. When the product is totally absorbed on the hands, repeat the application (Total contact time: 1 minute).

**LACTIVO 150 BPF PT2-4 (Surface disinfection):**

**- EN1276 (Bacteria, phase 2/step 1):** minimum efficacy at 40% w/w of LACTIVO 250, i.e. 0.50 % w/w of lactic acid in LACTIVO 150 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 at 40% w/w of LACTIVO 250, i.e. 0.50% w/w of lactic acid in LACTIVO 150 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 at60 % w/w of LACTIVO 250, i.e. 0.75 % w/w of lactic acid (equivalent to RTU LACTIVO 150) (against bacteria) and at 40 % w/w of LACTIVO 250, i.e. 0.50 % 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 at 40% w/w of LACTIVO 250, i.e. 0.50% w/w of lactic acid in LACTIVO 150 after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin) (EN 14476:2019 Vaccinia virus Ankara (MVA), ATCC VR-1508).

- **EN16777** (**Enveloped viruses, phase 2/step 2):** minimum efficacy at 40% w/w of LACTIVO 250, i.e. 0.50% w/w of lactic acid after 5 minutes of contact time at T=20 °C in dirty conditions (3 g/L Bovine albumin) (EN 16777:2019 Vaccinia virus Ankara (MVA), ATCC VR-1508).

**Conclusion for PT2-4:**

* **metaSPC2, Use 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 150 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 only against enveloped virus 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 and EN 16777 (Phase 2, step 2) considering for the minimum effective concentration for bacteria as worst case (0.75 % w/w lactic acid): Apply the product by fully wetting all surface (about 20 mL/m2) 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.

### 3.5.6 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 MM., 2010) concludes that no clear scientific evidence exists that target organisms have developed resistance against the organics acid, such as Lactic acid.

### 3.5.7 Known limitations

Not relevant.

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

None of the products belonging to LACTIVO 150 BPF is intended to be authorised for use with other biocidal products.

## Risk assessment for human health

According to the Article 25 of Regulation (EU) No 528/2012, a simplified authorisation 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).

The biocidal product family LACTIVO 150 BPF does not contain any substance of concern for human health and does not require any personal protective equipment.

Table 3.9 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** | 0.75 % w/w | 0.75 % w/w |

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 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.

### 3.6.1 Assessment of effects on human health

#### Skin corrosion and irritation

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to skin irritation/ skin corrosion of all co-formulants of LACTIVO 150 BPF has been performed by applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | All the products belonging to LACTIVO 150 BPF are not skin irritating/corrosive. |
| Justification for the value/conclusion | The evaluation of skin irritation/skin corrosion properties of LACTIVO 150 BPF has been performed on the worst case formulation regarding the classification of components. Please refer to Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components.  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 150 BPF at the concentration of 0.75 % 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 150 BPF is classified for skin corrosion/irritation according to the CLP Regulation EC n.1272/2008. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified for skin corrosion/irritation according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to skin irritation/ skin corrosion of all co-formulants of LACTIVO 150 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 150 BPF is classified for skin corrosion/irritation according to the CLP. |

#### 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** |
| OECD 437 BCOP | LACTIVO 150 CI, 750 µL of test item | Duration of treatment: 10 minutes at 32 ± 1 °C.  Duration of post-treatment: 2 hours at 32 ± 1 °C | IVIS: 12.25 | No stand-alone prediction can be made | Himmelsbach A.  (2022) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 zeland  White,  females  total 3 animals | LACTIVO 150 CI,  0.1 mL,  Ocular examinations were performed 24, 48 and 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. | - | Salvador M. (2022) |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | All the products belonging to LACTIVO 150 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 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components. Considering that the co-formulants classified as Eye Dam. 1 (H318) are acids or surfactants the sum of their concentrations exceeds the concentration limit 1%. To exclude the classification for eye irritation/eye damage, BCOP test according to OECD TG 437 has been performed at the end of January 2022 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 150 CI:12.25), no standalone prediction can be made for the test item. Therefore, performing the test OECD 405 is the only chance to have a clear result related to the eye irritation/damage effect of LACTIVO 150 CI. In vivo test (OECD 405) on LACTIVO 150 CI has been performed in March 2022 with clearly negative results. Based on the result of OECD 405, none of products belonging to LACTIVO 150 BPF is classified for eye damage/ eye irritation according to the CLP Regulation EC n.1272/2008. |
| Classification of the product(s) according to CLP | Based on the result of OECD405, none of products belonging to LACTIVO 150 BPF is classified for eye damage/ eye irritation according to the CLP Regulation EC n.1272/2008. |

#### Respiratory tract irritation

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to the respiratory tract irritation of all co-formulants of LACTIVO 150 BPF has been performed by applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **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 150 BPF is classified as STOT SE 3 (H335, “May cause respiratory irritation”) according to the CLP (for the perfumes the SDS classification has been evaluated considering the whole mixture), therefore all the products belonging to LACTIVO 150 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 150 BPF are not classified for respiratory tract irritation according to the CLP Regulation EC n.1272/2008 |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to respiratory tract irritation of all co-formulants of LACTIVO 150 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. All the products belonging to LACTIVO 150 BPF are not classified for respiratory tract irritation according to the CLP. |

#### Skin sensitization

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to skin sensitisation of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | All the products belonging to LACTIVO 150 BPF are not skin sensitizers. |
| Justification for the value/conclusion | The evaluation of skin sensitisation properties of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components. 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 150 BPF. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified as skin sensitiser according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to skin sensitisation of all co-formulants of LACTIVO 150 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 150 BPF are not classified for skin sensitization according to the CLP. |

#### Respiratory sensitization

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to respiratory sensitisation of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | All the biocidal products belonging to LACTIVO 150 BPF are not respiratory sensitizers. |
| Justification for the value/conclusion | The evaluation of respiratory sensitisation properties of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components. No component has 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 150 BPF. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified as respiratory sensitiser according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to respiratory sensitisation of all co-formulants of LACTIVO 150 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 150 BPF. |

#### Acute oral toxicity

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to acute oral toxicity of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value/conclusion | All the biocidal products belonging to LACTIVO 150 BPF are not harmful/toxic by oral route. |
| Justification for the selected value | According to section 3.1.3.6.1 of the CLP Regulation n.1272/2008, the additivity formula (calculation method) can be used to classify a mixture for acute toxicity when data are available for all components.  The evaluation of acute oral toxicity of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components.  To reach a conclusion regarding acute oral toxicity of the biocidal product family LACTIVO 150 BPF, the application of additivity formula is not required because there are no ‘relevant ingredients’ in the BPF to include in the additivity formula.  Therefore, no classification for acute oral toxicity according to the CLP Regulation EC n.1272/2008 is required for none of the products belonging to LACTIVO 150 BPF. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified for acute oral toxicity according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to acute oral toxicity of all co-formulants of LACTIVO 150 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 150 BPF. |

#### Acute inhalation toxicity

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to acute inhalation toxicity of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | All the biocidal products belonging to LACTIVO 150 BPF are not harmful/toxic by inhalation route. |
| Justification for the selected value | The evaluation of acute inhalation toxicity of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components.  To reach a conclusion regarding acute inhalation toxicity of the biocidal product family LACTIVO 150 BPF, the application of additivity formula is not required because there are no ‘relevant ingredients’ to include in the additivity formula.  Therefore, no classification for acute inhalation toxicity according to the CLP Regulation EC n.1272/2008 is required for none of the products belonging to LACTIVO 150 BPF. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified for acute inhalation toxicity according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to acute inhalation toxicity of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008). The classification for acute inhalation toxicity according to the CLP is not required for all of the products belonging to LACTIVO 150 BPF. |

#### Acute dermal toxicity

To support no human hazard associated with LACTIVO 150 BPF, an evaluation related to acute dermal toxicity of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | All the biocidal products belonging to LACTIVO 150 BPF are not harmful/toxic by dermal route. |
| Justification for the selected value | The evaluation of acute dermal toxicity of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 4 of the Confidential Annex for detailed BPF composition and classification of individual components.  To reach a conclusion regarding acute dermal toxicity of the biocidal product family LACTIVO 150 BPF, the application of additivity formula is not required because there are no ‘relevant ingredients’ to include in the additivity formula.  Therefore, no classification for acute dermal toxicity according to the CLP Regulation EC n.1272/2008 is required for none of the products belonging to LACTIVO 150 BPF. |
| Classification of the product(s) according to CLP | All the products belonging to LACTIVO 150 BPF are not classified for acute dermal toxicity according to the CLP Regulation EC n.1272/2008. |

|  |  |
| --- | --- |
| **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 150 BPF, an evaluation related to acute dermal toxicity of all co-formulants of LACTIVO 150 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 150 BPF. |

### 3.6.2 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.

### 3.6.3 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)).

### 3.6.4 Other

#### 3.6.4.1 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.

#### 3.6.4.2 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.

#### 3.6.4.3 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.

### 3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of non-active substances, refer to the Section 3 of the confidential annex.

### 3.6.6 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.

#### 3.6.6.1 Introductory remarks

Not relevant.

Strategy for human health risk assessment: Not relevant.

Strategy for the assessment of substance(s) of concern: Not relevant

Strategy for disinfectant by-products assessment: Not relevant.

### 3.6.7 Monitoring data

Not relevant.

### 3.6.8 Dietary risk assessment

#### 3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Not relevant.

#### 3.6.8.2 Maximum residue limits or equivalent: Not relevant.

## 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.

### 3.7.1 Risk for companion animals

Not relevant.

### 3.7.2 Risk for livestock animals

Not relevant.

## 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 with LACTIVO 150 BPF, an evaluation related to acute and chronic aquatic toxicity of all co-formulants of LACTIVO 150 BPF has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC n.1272/2008).

Information on the choice of the worst case composition for environmental risk assessment and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations in the BPF are provided in the confidential annex.

**ACUTE AQUATIC TOXICITY**

The evaluation of acute aquatic toxicity of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 5 of the Confidential Annex for detailed BPF composition and classification of individual components.

To reach a conclusion regarding acute aquatic toxicity of the biocidal product family LACTIVO 150 BPF, the application of additivity formula is not required because there are no ‘relevant ingredients’ to include in the additivity formula. 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 150 BPF are not classified for acute aquatic toxicity according to the CLP Regulation EC n.1272/2008.

**CHRONIC AQUATIC TOXICITY**

The evaluation of chronic aquatic toxicity of LACTIVO 150 BPF has been performed on worst case formulation, please refer to the Section 5 of the Confidential Annex for detailed BPF composition and classification of individual components.

To reach a conclusion regarding chronic aquatic toxicity of the biocidal product family LACTIVO 150 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 150 BPF are not classified for chronic aquatic toxicity according to the CLP Regulation EC n.1272/2008.

### 3.8.1 Available studies and endpoints applied in the environmental risk assessment

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

The evaluation related to acute and chronic aquatic toxicity of all the products belonging to LACTIVO 150 BPF has been performed based on the classifications in the suppliers’ SDSs for each co-formulant applying the principles related to the mixture as indicated in the CLP Regulation (EC n.1272/2008) (see excel file “Hazard evaluation of LACTIVO 150 BPF” attached in section 13 of the IUCLID dossier).

#### Substance(s) of concern

No substances of concern regarding environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)).

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

For the assessment of endocrine-disrupting properties of non-active substances, refer to the Section 3 of the confidential annex.

## Assessment of a combination of biocidal products

Not relevant. All the products belonging to LACTIVO 150 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

Table 4.1 List of studies for the biocidal product family

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Author (s)** | **Year/**  **Report date** | **Reference No. *(Annex III requirement)*/**  **IUCLID Section No.** | **Title.**  **Report No.** | **Type of publication** | **Source (where different from company)**  **Study sponsor** | **GLP**  **(Yes/No)** | **Data Protection Claimed**  **(Yes/No)** |
| Gazzotti L.  (2021a) | 2021a  Report date:  2021-09-20 | 3.1  3.2  3.3  3.4.1  3.5 | Title: Determination of the Physical-Chemical properties of the Product Lactivo 150 FEE, Before and After Accelerated Storage for 14 Days at 54±2 °C.  Report number: 21256-02C | 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 |
| Gazzotti L.  (2021a-amend1) | 2021a-amend1  2021-09-24 | 3.1 | Title: Amendment No.1: Determination of the Physical-Chemical properties of the Product Lactivo 150 FEE, Before and After Accelerated Storage for 14 Days at 54±2 °C.  Report number:  Amendment 1- 21256-02C | 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 |
| Gazzotti L.  (2021a-amend2) | 2021a-amend2  2021-10-05 | 3.3  3.9 | Title: Amendment No.2: Determination of the Physical-Chemical properties of the Product Lactivo 150 FEE, Before and After Accelerated Storage for 14 Days at 54±2 °C.  Report number:  Amendment 2- 21256-02C | 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 |
| Gazzotti L.  (2021a-amend3) | 2021a-amend3  2022-02-24 | 3.1 | Title: Amendment No.3: Determination of the Physical-Chemical properties of the Product Lactivo 150 FEE, Before and After Accelerated Storage for 14 Days at 54±2 °C.  Report number:  Amendment 3-21256-02C | 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 |
| Mazzei A. (2021a) | 2021a  2021-10-29 | 3.5.6 | Title: Determination Particle Size distribution on the Sample Lactivo 150 FEE (Not undergone at accelerated storage)  Report number: 2102757 (Study N. 678) | Study report | Laboratory: Innovhub – Stazioni Sperimentali per l’Industria S.r.l. Area Combustibili, Via G. Galilei, 1 20097 San Donato Milanese – Milano – ITALY  Sponsor: Specialities S.r.l. | Yes | Yes |
| Mazzei A. (2021b) | 2021b  2021-10-29 | 3.4.1 | Title: Determination Particle Size distribution on the Sample Lactivo 150 FEE (after storage at 54°C/14 days)  Report number: 2102759  (Study N.679) | Study report | Laboratory: Innovhub – Stazioni Sperimentali per l’Industria S.r.l. Area Combustibili, Via G. Galilei, 1 20097 San Donato Milanese – Milano – ITALY  Sponsor: Specialities S.r.l. | Yes | Yes |
| Digrandi S. (2023) | 2023  2023-09-29 | 3.4.1 | Title: Determination of the Four Year Storage Stability and Shelf-Life Data of the Product Lactivo 150 FEE.  Report number: 21256-03C | 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 |
| Mazzei A. (2022) | 2022  2022-06-04 | 4.1 and 4.8 | Title: Determination of Thermal Stability on the Sample Lactivo 150 FEE  Report number: 2200439  (Study N. 736) | Study report | Laboratory: Innovhub – Stazioni Sperimentali per l’Industria S.r.l. Area Combustibili, Via G. Galilei, 1 20097 San Donato Milanese – Milano – ITALY  Sponsor: Specialities S.r.l. | Yes | Yes |
| Madeddu S. (2021a) | 2021a  Report date:  2021-12-02 | 4.6 | Title: Determination of the Flash point of Lactivo 150 CI.  Report number: 21375-01C | 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 |
| Madeddu S. (2021a-amend1) | 2021a-amend1  Report date:  2022-02-24 | 4.6 | Title: Amendment No.1: Determination of the Flash point of Lactivo 150 CI.  Report number: Amendment 1- 21375-01C | 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 |
| Madeddu S. (2021b) | 2021a  Report date:  2021-12-02 | 4.16 | Title: Determination of the Corrosion to Metal of Lactivo 150 FEE.  Report number: 21374-01C | 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 |
| Madeddu S. (2021b-amend1) | 2021b-amend1  Report date:  2022-02-24 | 4.16 | Title: Amendment No.1: Determination of the Corrosion to Metal of Lactivo 150 FEE.  Report number: Amendment 1- 21374-01C | 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 |
| Gazzotti L. (2021b) | 2021b  Report date:  2021-09-20 | 5.1 | Title: Determination of the Active Ingredient Content of the Product Lactivo 150 FEE, Including Validation of the Analytical Method and Emission of Certificate of Analysis.  Report number: 21256-01C | 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 |
| Gazzotti L. (2021b-amend1) | 2021b-amend1  Report date:  2022-02-24 | 5.1 | Title: Amendment No.1: Determination of the Active Ingredient Content of the Product Lactivo 150 FEE, Including Validation of the Analytical Method and Emission of Certificate of Analysis.  Report number:  Amendment 1- 21256-01C | 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. (2021a-Rev.2) | 2021a  Report date:  2022-03-01 | 6.7.1 | Title: 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.  Report number:  2021-207NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2022) | 2022  Report date:  2022-03-01 | 6.7.1 | Title: Quantitative suspension test for the evaluation of activity against E.coli K12 of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas according to UNI EN 1276:2019.  Report number:  2021-207NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021b-Rev.2) | 2021b  Report date:  2022-03-01 | 6.7.2 | Title: HYGIENIC TREATMENT OF HANDS BY FRICTION ACCORDING TO STANDARD: UNI EN 1500: 2013.  Report number:  2021-190NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021c-Rev.2) | 2021c  Report date:  2022-03-01 | 6.7.3 | Title: 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.  Report number:  2021-207NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021d-Rev.2) | 2021d  Report date:  2022-03-01 | 6.7.4 | Title: Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019.  Report number:  2021-207NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021e-Rev.2) | 2021e  Report date:  2022-03-01 | 6.7.5 | Title: 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.  Report number:  2021-208NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021f-Rev.2) | 2021f  Report date:  2022-03-01 | 6.7.6 | Title: 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.  Report number:  2021-208NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021g-Rev.2) | 2021g  Report date:  2022-05-09 | 6.7.7 | Title: 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.  Report number:  2021-208NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021h-Rev.2) | 2021h  Report date:  2022-03-01 | 6.7.8 | Title: Quantitative suspension test for the evaluation of virucidal activity in the medical area according to UNI EN 14476:2019.  Report number: 2021-208NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Calassanzio M. (2021i-Rev.2) | 2021i  Report date:  2022-03-01 | 6.7.9 | Title: 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.  Report number:  2021-208NM | Study report | Laboratory: Renolab S.r.l., Via XXV Aprile 19, 40016 S. Giorgio di Piano, Bologna (Italy)  Sponsor: Specialities S.r.l. | No | Yes |
| Himmelsbach A. (2022) | 2022  Report date:2022-03-16 | 8.2 (Cf 8.1.2) | Title: Evaluation of LACTIVO 150 CI in the Bovine Corneal Opacity and Permeability (BCOP) Test Method following OECD Guideline 437 and EU Method B.47  Report number: 21121008G850 | Study report | Laboratory: LAUS GmbH, Auf der Schafweide 20, 67489 Kirrweiler, Germany  Sponsor: Specialities S.r.l. | Yes | Yes |
| Salvador M. (2022) | 2022  Report date:2022-04-08 | 8.2 (Cf 8.1.2) | Title: LACTIVO 150 CI ACUTE EYE IRRITATION STUDY IN RABBITS.  Report number: A4596 | Study report | Laboratory: European Research Biology Center S.r.l., Via Tito Speri 12/14, 00071 Pomezia, Italy  Sponsor: Specialities S.r.l. | Yes | Yes |

## References

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

* Theron M.M., Rykers Lues J.F. Organic Acid and Food preservation, *CRC*

*Press, 2010*

## Confidential information

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

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