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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR [NATIONAL/SIMPLIFIED/UNION] AUTHORISATION APPLICATION

Sandermix EUSG201

Product type(s) 1,2,3,4

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

Case Number in R4BP: BC-CC075733-52

Competent Authority: MSCA-Spain

Date: October/2023

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	*Spain*	BC-CC075733-52		*First authorisation*	

1 Conclusion

Sanidermix EUSG201 is an oil emulsion in water RTU biocidal product containing Lactic acid (CAS 50-21-5) as active substance. The product is used as a PT1, 2, 3 and 4 by non-professional, professional and trained professional users for the control of bacteria, yeasts, fungi and viruses.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses of hand disinfectant by rubbing (PT1) and hard surface disinfectant by spraying (PT2/3/4) 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 use(s) of the biocidal product 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 biocidal product 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 biocidal product 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 (CAS 50-21-5) is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction that *Concentration to be limited so that each biocidalproduct does not require classification according to Regulation (EC) No 1272/2008*;
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

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

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains Lactic acid (CAS 50-21-5) which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as (a) candidate(s) for substitution. Therefore, a comparative assessment of the biocidal product is not required.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal product [is / are] listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the biocidal product [are / are not] met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer(s) of the active substance(s) [is / 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 assessment carried out allows us to affirm that the results obtained are satisfactory.

The biocidal product is stable for a long-term storage (two years).

Physical hazards and respective characteristics

The product is not classified for physical hazards.

The biocidal product is not corrosive to metals.

Methods for detection and identification

Analytical method 97460/23 for the determination of Lactic acid in the biocidal product is available.

Specificity, linearity, accuracy and precision were checked and found acceptable.

Efficacy against target organisms

PT01: The biocidal product Sanidermix EUSG201 has been shown to be efficacious against proved against bacteria, yeasts, fungi and virus as hand disinfectant by rubing.

PT02/04: The biocidal product has been shown to be sufficiently efficacious against bacteria, yeasts, fungi and virus as disinfectant for non-porous surfaces including health care premises without mechanical action.

PT03: The biocidal product has been shown to be efficacious against bacteria, fungi, yeast and virus for all intended uses.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

There are no substances of concern present and the product is not classified, therefore the ES CA considers that a detailed exposure assessment is not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

Dietary risk assessment

The product was submitted by simplified authorisation and no dietary risk assessment was carried out.

Risk assessment for animal health

Lactic acid is an active substance includes in Anex I, as substance that do not have some risk. Therefore, no risk for animal health is expected.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on the active substance lactic acid which is included in the Annex I of the BPR (528/2012/EU).

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type(s)	PT1, PT2, PT3 and PT4
Type(s) of formulation	Oil emulsion in water-Ready to use

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the 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 biocidal product

Use number	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	Hygienic handrub	1	Bacteria, yeasts, fungi, virus	Rubbing liquid,wiping	3-5 mL per application	Non-professional Professional, Trained professional	A	Based on efficacy assessment the use is acceptable.
2	Hard surface – industry, institutions, households, health care	2		Spraying Manual nebulization	Spray: 40 - 50 mL/m^2 Manual nebulization: 30 – 40 ml/m^2		A	Based on efficacy assessment the use is acceptable.
3	Hard surfaces – veterinary hygiene	3	Bacteria, yeasts, virus				A	Based on efficacy assessment the use is acceptable.
4	Hard surface	4	Bacteria, yeasts, fungi, virus				A	Based on efficacy assessment the use is acceptable.

Codes for indicating the acceptability for each use

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

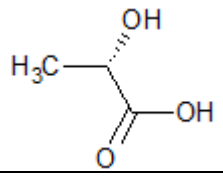
2.3 Identity and composition

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

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Lactic acid
Chemical name	2-Hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	Substance is not in Annex VI of CLP
Minimum purity / content	-
Structural formula	

2.5 Information on the source(s) of the active substance(s)

The information on the source of the active substance is not applicable.

2.6 Candidate(s) for substitution

This section does not apply.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

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

See confidential Annex.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code	None	None

Hazard Pictograms	None	None
Signal word(s)	None	None
Hazard statements	None	None
Precautionary statements*	None	None
Supplemental hazard statements	None	
Notes	None	

***P-statements that are excluded based on the risk assessment or the intended use of the product[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.

2.9 Letter of access

No Letter of Access has been submitted in this application. There are not any data on the active substance of concern since the submitted active substance is not categorised as substance of concern.

Lactic acid is an active substance includes in Annex I of BPR as it is not categorised as substance of concern.

2.10 Data submitted in relation to product authorisation

Only efficacy data were submitted in order to authorise the product according to the intended uses.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[3]	Size/volume of the packaging[4]	Material of the packaging[5]	Type and material of closure(s)	Intended user[6]	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	0.25L 0.5L	PET ALUMINUM		general public, non-	Yes

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

[3] Type of packaging e.g. bottle, rolls, can, barrel, tank.

[4] 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.

[5] 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.

[6] Intended user, e.g. professional, non-professional

	1L 5L 10L	PET HDPE	Screwcap Material: HDPE-HDPE	professional, professional*	
Stackable Jerricane	1L 5L 10L 25L	PET HDPE		Professional, Industrial*	Yes
IBC tank	200L 1000L	HDPE	Bottom Outlet - 50mm (2 inch) integrated butterfly valve - S60x6 male thread Material: PEAD-PEHD	Professional, Industrial*	Yes

* Note: In Spain, article 37 will be applied to limit the size of containers to 5L for professional and non-professional users.

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 at 20 °C and 101.3 kPa	Visual	Sanidermix EUSG201/PASG2020 Batch number: 87422/21 (0.1% w/w a.s.)	Transparent liquid	INNOAGRAL 87422/21
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual	Sanidermix EUSG201/PASG2020 Batch number: 87422/21 (0.1% w/w a.s.)	Liquid	INNOAGRAL 87422/21
3.1.2.	Colour at 20 °C and 101.3 kPa	Colorimetry	Sanidermix EUSG201/PASG2020 Batch number: 87422/21 (0.1% w/w a.s.)	Colorless	INNOAGRAL 87422/21
3.1.3.	Odour at 20 °C and 101.3 kPa	Sensory	Sanidermix EUSG201/PASG2020 Batch number: 87422/21 (0.1% w/w a.s.)	Various essential oils	INNOAGRAL 87422/21
3.2.	Acidity, alkalinity and pH value	Potentiometry	Sanidermix EUSG201/PASG2020 Batch number: 87422/21 (0.1% w/w a.s.)	3.1 - 6	INNOAGRAL 87422/21

3.3.	Relative density / bulk density	Method A.3 Relative density (Annex of Regulation (EC) No 440/2008). CIPAC method MT 186: Bulk density Pycnometer		Sanidermix EUSG201/PASG202 0 Batch nº: 97458/23	1,09 g/cm³	INNOAGRAL Report: 97458/23 2023
3.4.1.1.	Storage stability test – **accelerated storage**	Parameter Appearance Colour at 20 °C Odour Packaging Material Density 20/4 Refraction index pH Viscosity	Method Visual Colorimetry Sensory Visual Gravimetry Refractometer Potentiometry Capillary	Sanidermix EUSG201/PASG202 0 Batch nº: 87422/21 (0.1% w/w a.s.)	After 14 days at 54°C *Packing material* high density polypropylene, do not present alteration or deterioration. Time/Temperature (14 day 54±2ºC). Lactic acid content Initial: 0.1% w/w 2W: 0.1% w/w Δ = 0%	INNOAGRAL 87422/21 2021
3.4.1.2	Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3		Batch number: 87422/21 (0.1% w/w a.s.)	**2 years at 20±2ºC** Appearance, colour, odour, packaging material: without alteration. Density (trial 1): 0.999 g/cm^3 Density (trial 2): 0.999 g/cm^3 Density (trial 3): 0.999 g/cm^3 Density (trial 4): 1.004 g/cm^3 Refraction index (trial 1): 1.491	INNOAGRAL 87422/21 2023

				Refraction index (trial 2): 1.493 Refraction index (trial 3): 1.481 Refraction index (trial 4): 1.489 pH (trial 1): 5.99 pH (trial 2): 6,01 pH (trial 1): 5,94 pH (trial 1): 6,01 Viscosity (trial 1): 12 mPa·s Viscosity (trial 2): 12.1 mPa·s Viscosity (trial 1): 11.9 mPa·s Viscosity (trial 1): 12.1 mPa·s Lactic acid (trial 1): 0.103% Lactic acid (trial 2): 0.102% Lactic acid (trial 3): 0.1% Lactic acid (trial 4): 0.101%	

3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	-	*The label gives clear instructions that the product must not be stored under conditions of ≤ 0°C*
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Lactic acid UPLC	Sanidermix EUSG201/PASG202 0 Batch number: 87422/21 (0.1% w/w a.s.)	Without alteration	INNOAGRAL, 87422/21 2021
3.4.2.2	Effects on content of the active substance and technical characteristics of the biocidal product **– temperature and humidity**	CIPAC MT 46.3	Sanidermix EUSG201/PASG202 0 Batch number: 87422/21 (0.1% w/w a.s.)	Without alteration	INNOAGRAL 87422/21 2023

3.4.2.3	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Not applicable, all components are stable	-
3.5	Suspensibility, spontaneity and dispersion stability	CIPAC MT 184 CIPAC MT 160 CIPAC MT 174	Sanidermix EUSG201	72% 92% 87%	INNOAGRAL Report I-97458/23
3.5	Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3 CIPAC MT 36.3	Sanidermix EUSG201 Batch nº: 97458/23	2ml cream after 30 minutes, trace of oil. If any separation is observed re-emulsification should be complete after 24 hours. The emulsion generated under the conditions of MT 180 may be at maximum 2ml cream after 30 minutes, trace of oil. If any separation is observed, re-emulsification should be complete after 24 hours. The absorbance measured for the formulation under the	Report I-97458/23

				conditions of MT 173 must between 95-105% after four hours. Where a preparation is outside these limits then evidence must be submitted showing the preparation remains homogeneous when applied. No oil or creamseparation after 2 hours	
3.5	Persistent foaming	CIPAC MT 47.2	Sanidermix EUSG201 Batch nº: 97458/23	15 ml after 1 min	INNOAGRAL Report: 97458/23 2023
3.6	Physical and chemical compatibility with other products	-	-	Waiving. Not applicable because they are all liquids and an emulsifier is used for solubilization in water.	-
3.7	Degree of dissolution and dilution stability	-	-	Waiving. All the components are stable	-
3.8	Surface tension	Test according to EC method A.5 (Surface Tension) and OECD Test Guideline 115 (Surface Tension of Aqueous Solutions). ADSA	Sanidermix EUSG201 Batch nº: 97458/23	46 Dyn/cm	INNOAGRAL Report I-97458/23
3.9	Viscosity	The viscosity should be determined at 20 ºC and 40 ºC.	Sanidermix EUSG201 Batch nº: 97458/23	12 mPa.s	INNOAGRAL Report I-

		There is no relevant EC method. Test according to OECD Test Guideline 114 (Viscosity of Liquids) Capillary viscometer			97458/23

Conclusion on physical, chemical, and technical properties
Sanidermix EUSG201 is a oil in water emulsion (O/W). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. **Implications for labelling:** Sanidermix EUSG201 is a ready-to-use formulation. It must not be stored under conditions of ≤ 0°C.

3.3 Physical hazards and respective characteristics

Property	Guideline and Method	Test product (a.s. content)	Results	Reference
Explosives	-	-	Waiving. The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.	-
Flammable gases	-	-	Waiving. The product is a liquid.	-
Flammable aerosols	-	-	Waiving. The product is a liquid.	-
Oxidising gases	-	-	Waiving. The product is a liquid.	-
Gases under pressure	-	-	Waiving. The product is a liquid.	-
Flammable liquids	-	-	Waiving The study does not need to be conducted because the substance only contains volatile organic components with flash-points above 100°C for aqueous solutions	-

Property	Guideline and Method	Test product (a.s. content)	Results	Reference
Flammable solids	-	-	Waiving. The product is a liquid.	-
Self-reactive substances and mixtures	-	-	Waiving The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	-
Pyrophoric liquids	-	-	Waiving. No study is needed because the formulations are known to be stable in air at room temperature for prolonged periods of time. The classification procedure does not need to be applied.	-
Pyrophoric solids	-	-	Waiving. The product is a liquid.	-
Self-heating substances and mixtures	-	-	Waiving. Not self-heating mixtures.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Waiving. The mixture does Not emit flammable gases in contact with water.	-
Oxidising liquids	-	-	Waiving The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.	-
Oxidising solids	-	-	Waiving. The product is a liquid.	-
Organic peroxides	-	-	Waiving The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	-
Corrosive to metals	UN Test C.1 (UN-MTC, Part III, Section 37)	Sanidermix EUSG01 Sample data	The following materials will be used: Uncoated aluminum 7075-T6 and Steel type S235JR+CR. Three sets of test tubes of each material are used for the test. For each test, one metal cylinder is immersed in the liquid,	INNOAGRAL, Report I-97453/23

Property	Guideline and Method	Test product (a.s. content)	Results	Reference
		97453/23	another is lowered halfway, and the third is hung in the gas phase. The distance between the upper edge of the submerged test piece and the surface of the liquid is 10 mm. The test temperature is 55 ºC±1, kept constant throughout the test. The specimens are exposed to these stable conditions for a period of eight days. In view of the results obtained with a weight loss in the most extreme case of 7.41%, it can be concluded that the Sanidermix EUSG201 product is not corrosive	2023

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method [97460/23]: 200 mL of Sanidermix EUSG201 were tested in a Aluminium bottle using an UPLC (Ultra Performance Liquid Chromatography).											
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	r^2=*0.99998*		2	2	15%		3,15%	0.5%	2	1 ppm	97460/23

Table 3.7 Analytical methods for soil

As the active substance is readily degradable in soil, no analytical method is required in this matrix.

Table 3.8 Analytical methods for air

As the active substance is readily degradable in water, no analytical method is required in this matrix.

Table 3.9 Analytical methods for water

As the active substance is readily degradable in air, no analytical method is required in this matrix.

Table 3.10 Analytical methods for animal and human body fluids and tissues

This method is not required.

Table 3.11 Analytical methods for monitoring of active substances and residues in food and feeding stuff This method is not required.

Table 3.12 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical method 97460/23 for the determination of Lactic acid in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. - As no MRL were fixed, no analytical method for the determination of active substance in in food/feed of plant and animal origin is required. - As the active substance is readily degradable in soil/water/air, no analytical method is required in this matrices.

3.5 Assessment of efficacy against target organisms

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

Sandermix EUSG201 is an oil based, ready to use disinfectant (bactericide, levuricide, fungicide and virucide). It is intended to be used as PT1 for handrub disinfection, as PT2 on hard surfaces in domestic/institutional/health care premises, as PT3 on surfaces in veterinary area and as PT4 on hard surfaces in food and feed areas. It can be used by professional and non-professional users.

The typical field of use of the biocidal product is indoors, as its function is to control microorganisms from non- porous surfaces such as tables, desks and furniture in houses or offices, from porous and non-porous surfaces in veterinary areas and from hard surfaces in contact with food.

The product eliminates bacteria, yeasts and fungi in dirty conditions, and virus in clean conditions of soiling, according to the tests established in UNE EN 14885, that were performed.

The aim of the product Sandermix EUSG201 is to protect human health by preventing the spread of potentially harmful microorganisms.

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

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

3.5.3 Efficacy data

Efficacy tests were conducted with the product Sanidermix EUSG201 according to the Guidance on the BPR (Volume II Efficacy – Assssment and Evaluation, Version 5.0, November 2022) and EN 14885:2015 standard.

Table 3.2 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
PT 1,2,4 Use # 1:PT1 Hygienic handrub Use#2: PT2 Hard surface disinfection (including health care). Use #4:PT4 Hard surface disinfection.	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Bactericidal activity** *Pseudomonas aeruginosa* ATCC 15 442, *Escherichia coli* ATCC 10 536, *Staphylococcus aureus* ATCC 6 538, *Enterococcus hirae* ATCC 10 541	**UNE-EN 1276:2020** phase 2, step 1 test. • Concentrations tested: 50%, 95%, 100% (v/v) • I.S.: 3 g/l BSA (Dirty conditions) • Contact time: 1 minutes ± 5 seconds • Temperature: 20±1ºC	Concentration 100% (v/v) passed Pass criteria: >5 log reduction for all tested organisms	Analytical report: 97448/23 **R.I. 1** **Key Study**	1) bactericidal suspension EN 1276:2010
PT 1,2,4 Use # 1:PT1 Hygienic handrub Use#2 –PT2 Hard surface disinfection. Use # 4 – PT4 Hard surface disinfection	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231, *Aspergillus niger* ATCC 16 404	**UNE-EN 1650:2008 + A1** phase 2, step 1 test • Concentrations tested: 100%, 95%, 50% • I.S.: 3 g/l BSA (Dirty conditions) • Contact time: 15 min ± 10 seconds • Temperature: 20 ± 1ºC	Concentration 100% (v/v) passed Pass criteria: >4 log reduction for all tested organisms	Analytical report: 24685/20 **R.I. 1** **Key Study**	2) fungicidal yeasticidal suspension EN 1650:2008+A1
PT 2,4	Sanidermix	**Bactericidal**	**UNE-EN 13697:2015**	Concentrations	Analytical	3) bactericidal non

Use#2: PT2 Hard surface disinfection (including health care). Use # 4: PT4 Hard surface disinfection	EUSG201 0,1% (w/w) lactic acid	**activity** *Pseudomonas aeruginosa* ATCC 15 442, *Escherichia coli* ATCC 10 536, *Staphylococcus aureus* ATCC 6 538, *Enterococcus hirae* ATCC 10 541	phase 2, step 2 test • Concentrations tested: 100%, 95%, 50% • I.S.: 3 g/l BSA (Dirty conditions) • Contact time: 5 minutes ± 10 sec • Temperature: 18-25ºC	100% and 95% (v/v) passed Pass criteria: >4 log reduction for all tested organisms	report: 1755-2/20 **R.I. 1** **Key Study**	porous surfaces EN 13697
PT 2,4 Use#2: PT2 Hard surface disinfection (includindghealth care). Use # 4: PT4 Hard surface disinfection	Sanidermix EUSG201 0,1% (w/w) lactic acd	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231, *Aspergillus brasiliensis* ATCC 16404	**UNE-EN 13697 :2015** Phase 2, step 2 test • Concentrations tested: 100%, 95%, 50% • I.S.: 3 g/l BSA (Dirty conditions) • Contact time: 5 minutes ± 10 sec • Temperature: 18-25ºC	Concentrations 100% and 95% (v/v) passed Pass criteria: >4 log reduction for all tested organisms	Analytical report: 1755/20 **R.I. 1** **Key Study**	4) fungicidal yeasticidal non porous surfaces EN13697
PT 1,2,4 Use # 1:PT1 Hygienic handrub Use#2: PT2 Hard surface disinfection (includindghealth care). Use # 4 – PT4 Hard surface disinfection	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Virucidal** Poliovirus type 1, Adenovirus type 5, murine Norovirus	**UNE-EN 14476 :2014+A1** Phase 2, step 1 test • Concentrations tested: 50%, 95%, 100% • I.S.: 0,3 g/l BSA (Clean conditions) • Contact time: 60 seconds • Temperature: 20ºC ± 1ºC	Concentrations 100% and 95% (v/v) passed Pass criteria: >4 log reduction for all tested organisms	Analytical report: 23715/20 **R.I. 1** **Key Study**	4) virucidal EN 14476

PT1 Use # 1:PT1 Hygienic handrub	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Bactericidal /** *E. coli K12*	**EN 1500:2013** Phase 2, step 2 test • Concentrations tested: 50%, 95%, 100% • Contact time: 45 ± 5 seconds • Temperature 20°C ± 1°C	The tests were carried out on 20 volunteers. Passed concentration: 100 % (v/v) Acceptance criteria for test results, as given in chapter 5.7.1 of EN 1500, fulfilled.	Analytical report: 24685/20 **R.I. 1 Key Study**	6) hygienic handrub EN 1500
PT 2 (Health care) Use#2: PT2 Hard surface disinfection (includindg health care).	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Fungicidal /yeasticidal** *Candida albicans* CECT 1394, *Aspergillus brasiliensis* ATCC 16404	**UNE-EN 13624 :2014** Phase 2, step 1 test • Concentrations tested: 100%; 95%; 50% • I.S: 3 g/l BSA and 3ml/l of erythrocytes (Dirty conditions) • Contact time: 30 ± 1 seconds • Temperature: 20±1ºC	Concentration 100% and 95% (v/v) passed Pass criteria: >4 log reduction for all tested organisms	Analytical report: 97449/23	7) yeasticidal fungicidal suspension medicine EN 13624
PT 2 Use#2: PT2 Hard surface disinfection (includindghealth care).	Sanidermix EUSG201 0,1% (w/w) lactic acid	**Bactericidal/** *Pseudomonas aeruginosa* ATCC 15 442 *Escherichia coli* K12 *Staphylococcus aureus* ATCC 6 538 *Enterococcus hirae* ATCC 10 541	**UNE-EN 13727+A2 :2015** Phase 2, step 1 test • Concentrations tested: 100%; 95%; 50% • I.S: 3 g/l BSA and 3ml/l of erythrocytes (Dirty conditions) • Contact time: 30 ± 1 seconds • Temperature: 20±1ºC	Concentration 100% (v/v) passed Pass criteria: >5 log reduction for all tested organisms	Analytical report: 35189/21 **R.I 1 Key Study**	8) bactericidal suspension medicine EN 13727
PT 2, 4	Sanidermix EUSG201	**Virucidal**	**UNE-EN 16777** Phase 2, step 2 test	Concentrations 100%, 95% (v/v)	Analytical report:	10) non porous surf non mechanic

Use#2: PT2 Hard surface disinfection (includindghealth care). Use # 4 – PT4 Hard surface disinfection	0,1% (w/w) lactic acid	Polio virus type 1, LSc-2ab (Picornavirus), Adenovirus, type 5, strain Adenoid 75, ATCC VR-5 and Murine norovirus, strain S99 Berlin.	• Concentrations tested: 50%, 95%, 100% • I.S.: 0,3 g/l BSA (Clean conditions) • Contact time: 60 seconds • Temperature: 10ºC ± 1ºC	passed Pass criteria: >4 log reduction for all tested viruses	15801-1/22 , 15801-2/22 **R.I. 1 Key Study**	virucidal medic EN 16777
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Bactericidal/** *Pseudomonas aeruginosa* ATCC 15 442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6 538 *Enterococcus hirae* ATCC 10 541	**EN 1656:2010** / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 35184/21 **R.I. 1 Key Study**	11) Quantitative suspension test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in the veterinary areaUNE-EN 1656:2010
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231 *Aspergillus niger* ATCC 16 404	**EN 1657:2016** / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 30 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log	Fungicidal and yeasticidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization,	Nº 35187/21 **R.I. 1 Key Study**	12) Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity of antiseptics and chemical disinfectants used in the veterinary area UNE-EN 1657:2016

			reduction	control)		
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Virucidal** Bovine enterovirus type 1	**EN 14675:2015** / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 30 min • Temperature: 10±1ºC • I.S.: 0.3 g/l BVA Criteria: at least a 4 log reduction	Virucidal activity demonstrated at 95%. This test cannot be considered as valid to prove the efficacy of Sanidermix EUSG201 in the veterinary area because the interfering substance used does not correspond to this area. For PT3 general hard surfaces disinfectants, the soiling conditions should be: Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin	Nº 35188/21 **Additional information**	13) Ensayo cuantitativo de suspensión para la evaluación de la actividad viricida de los antisépticos y desinfectantes químicos utilizados en el área veterinaria UNE-EN 14675:2015
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Virucidal** Bovine enterovirus type 1	**EN 14675**:2015 / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 30 min • Temperature: 20±1ºC • I.S.: 10 g/l BVA and 10 g/l yeast extract Criteria: at least a 4 log reduction	Virucidal activity demonstrated at 95%. This test cannot be considered as valid to prove the efficacy of Sanidermix EUSG201 in the veterinary area because normally PT3 products are tested at 10ºC or	Nº 35188/21 **Additional information**	13) Quantitative suspension test for the evaluation of the viricidal activity of antiseptics and chemical disinfectants used in the veterinary area UNE-EN 14675:2015

				below since the temperature in animal housings can be low. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.		
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Bactericidal/** *Pseudomonas aeruginosa* ATCC 15 442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6 538 *Enterococcus hirae* ATCC 10 541	**EN 14349:2013** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 35185/21 **R.I. 1** **Key Study**	14) Quantitative surface test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in the veterinary area on non-porous surfaces without mechanical action UNE-EN 14349:2013
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Bactericidal/** *Pseudomonas aeruginosa* ATCC 15 442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6 538	**EN 14349:2013** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 30 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 35185-2/21 **R.I. 1** **Key Study**	14) Quantitative surface test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in the veterinary area on non-porous surfaces without mechanical action

		Enterococcus hirae ATCC 10 541				UNE-EN 14349:2013
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Bactericidal/** *Pseudomonas aeruginosa* ATCC 15 442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6 538 *Enterococcus hirae* ATCC 10 541	**EN 16437:2014+A1:2020** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 35186/21 **R.I. 1** **Key Study**	15) Quantitative surface test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in the veterinary area on porous surfaces without mechanical action UNE-EN 16437:2014+A1:2022.
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231 *Aspergillus niger* ATCC 16 404	**EN 16438:2014** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 30 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 3 log reduction	Fungicidal and yeasticidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 15802/22 **R.I. 1** **Key Study**	16) Valoración de la actividad fungicida y levarucida según metodo interno basado en norma UNE-EN 16438:2014
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231 *Aspergillus niger* ATCC 16 404	**EN 16438:2014** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 60 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA	Fungicidal and yeasticidal activity demonstrated at 95%. This test cannot be considered as valid to prove the efficacy in the veterinary	Nº 15800/22 **Additional information**	16) Assessment of the fungicidal and yeasticidal activity according to the internal method based on the UNE-EN 16438:2014 standard

			Criteria: at least a 3 log reduction	area because for surface disinfection in veterinary areas the normal contact time is 5 minutes. The maximum contact time is 30 minutes. Additional contact times can be considered if appropriate and justified by the application.		
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231 *Aspergillus niger* ATCC 16 404	**EN 16438:2014** / Phase 2 step 2 test (surface test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 3 log reduction	Fungicidal and yeasticidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 99714/23 **R.I. 1** **Key Study**	19) Assessment of the fungicidal and yeasticidal activity according to the internal method based on the UNE-EN 16438:2014 standard
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Fungicidal /yeasticidal** *Candida albicans* ATCC 10 231 *Aspergillus niger* ATCC 16 404	**EN 1657:2016** / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log reduction	Fungicidal and yeasticidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, dilution-neutralization, control)	Nº 99713/23 **R.I. 1** **Key Study**	20) Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity of antiseptics and chemical disinfectants used in the veterinary area UNE-EN 1657:2016
PT3	Sanidermix	**Virucidal**	**EN 14675:2015** / Phase 2	Virucidal activity	Nº	21) Quantitative

Use # 3: PT Hard surface disinfection veterinary	EUSG201 (0.1% lactic acid)	Bovine enterovirus type 1	step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 20±1ºC • I.S.: 10 g/l BVA and 10 g/l yeast extract Criteria: at least a 4 log reduction	demonstrated at 95%. This test cannot be considered as valid to prove the efficacy of Sanidermix EUSG201 in the veterinary area because normally PT3 products are tested at 10ºC or below since the temperature in animal housings can be low. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.	97450/23 **Additional information**	suspension test for the evaluation of the viricidal activity of antiseptics and chemical disinfectants used in the veterinary area UNE-EN 14675:2015
PT3 Use # 3: PT Hard surface disinfection veterinary	Sanidermix EUSG201 (0.1% lactic acid)	**Virucidal** Bovine enterovirus type 1	**EN 14675:2015** / Phase 2 step 1 test (suspension test) • Concentrations tested: 100%, 95%, 50% • Contact time: 5 min • Temperature: 10±1ºC • I.S.: 3 g/l BVA Criteria: at least a 4 log reduction	Virucidal activity demonstrated at 95%. The validity criteria of the test method are fulfilled (test suspension, filtration, control)	Nº 97944/23 **Key study**	Quantitative suspension test for the evaluation of the viricidal activity of antiseptics and chemical disinfectants used in the veterinary area UNE-EN 14675:2015

4.1.1 Efficacy assessment

For efficacy testing of the Sanidermix EUSG201 biocidal product a tiered approach has been provided according to the Guidance on the Biocidal Products Regulation Volume II Efficacy – Assessment and Evaluation (Parts B+C), to the Technical Agreements for Biocides Efficacy (EFF) and to the Minutes of Efficacy Working Group. All efficacy tests provided were performed with the product SANIDERMIX EUSG201 (0,1% (w/w) lactic acid) and were chosen according to the UNE-EN 14885 standard (Application of European Standards for chemical disinfectants and antiseptics).

Hygienic handrub PT1

The product Sanidermix EUSG201 is effective as PT1 against bacteria, fungi and virus. The product is intended to be used for handrub disinfection, with a contact time of 45 seconds and application rate of 3ml. As test EN14476 test has been done with a contact time of 60 seconds, for a virucidal effect 60 seconds of handrub are needed.

Hard surface disinfection PT2 and PT4 by spraying

Both quantitative suspension (P2/S1) and surface (P2/S1) tests were carried out to demonstrate the product efficacy against bacteria, yeasts, fungi and virus by spraying.
According to the efficacy results obtained from the studies submitted, bactericidal, yeasticidal (basic requirements), fungicidal and virucidal activity is shown with the undiluted product when used at +18-25°C with a contact time of 5 min on hard/non-porous dirty surfaces for Bacteria and fungi, and on clean surfaces for virus.
Virucidal activity is shown at 95% concentration at 10ºC (EN16777). We consider this deviation of the temperature for this standard acceptable since the action of the disinfectants normally improves at increased temperatures. As we consider this test a worse case regarding temperature compared to the use conditions, the efficacy test with the standard EN16777 against virus is deemed valid to claim viricidal action at 20ºC.

For PT2 and 4, intended for surface disinfection by spraying without mechanical action, P2S1 and all P2S2 tests are mandatory and both must be taken into account for setting up the contact time and concentration needed for each use.

According to the efficacy table, the product has demonstrated efficacy for:

Bacteria:	**Fungi**:	**Virus:**
T=20ºC	T=20ºC	T=10ºC
Contact time: 5 minutes.	Contact time: 5 minutes.	Contact time: 60 seconds.
Concentration: 100%	Concentration: 100%	Concentration: 95%
Dirty conditions	Dirty conditions	Clean conditions

According to the TAB (may 2022) it is possible to differenciate between target organisms by use conditions in case of non mandatory target organisms, for professional and non professional users.
For PT2 and PT4 is not mandatory to prove efficacy against virus, being this an optional target group. Therefore, for PT2 and PT4, a different soiling condition (clean) can be set up as part of the use if action against virus is sought.

Hard surface disinfection in the veterinary area PT3 by spraying

According to the Guidance on the Biocidal Products Regulation – Volume II Efficacy – Assessment and Evaluation (Parts B+C), veterinary biocidal products to disinfect hard

surfaces should be at least sufficiently effective against bacteria, yeasts and virus. Since room diffusion is used to disinfect hard (and soft) surfaces, the same organisms should be tested as for hard surface disinfection. Efficacy tests with these organisms should always be provided.

To substantiate the claims for bactericidal and yeasticidal and virucidal activity of the product, efficacy studies have been performed according to European Standards (EN). As the product is intended to be applied for hard surfaces, the formulation was tested in a tiered approach with a phase 2, step 1 test (quantitative suspension test) followed by a phase 2, step 2 test (quantitative carrier test).

Conclusion on efficacy for biocidal product Sanidermix EUSG201 (0.1% lactic acid)				
Activity	**European Standard (EN)**	**Contact time**	**Concentration**	**Soiling**
Bactericide	EN 1656	5 min	95%	Clean
	EN 14349	5 min	95%	Clean
	EN 16437	5 min	95%	Clean
Fungicide/Yeasticide	EN 1657	5 min	95%	Clean
	EN 16438	5 min	95%	Clean
Virucide	EN 14675	5 min	95%	Clean
The product Sanidermix EUSG201 is bactericide, fungicide and yeasticide and virucide from a 95% dilution (0.1% lactic acid) on porous and non-porous surfaces with a contact time of 5 minutes at clean conditions. Nevertheless, the product will be used at RTU.				

Sanidermix EUSG201 has been shown to be effective at 95% against bacteria *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Staphylococcus aureus* and *Enterococcus hirae* in the assay conditions stablished in the **UNE-EN 1656:2010** (phase 2 step 1) for hard surfaces disinfectants (10ºC, 5 minutes of contact time and 3 g/L of bovine albumin as interfering substance) and when is carried out the carrier tests according to **UNE EN 14349: 2013** and **UNE EN 16437:2014+A1:2020** (phase 2 step 2) in the same conditions.

In addition, this biocidal product has been shown to be effective at 95% against yeast *Candida albicans* and fungi *Aspergillus niger* in the assay conditions stablished in the **UNE-EN 1657:2016** (phase 2 step 1) for hard surfaces disinfectants (10ºC, 5 minutes of contact time and 3 g/l of bovine albumin as interfering substance) and when is carried out the carrier test according to **UNE-EN 16438:2014** (phase 2 step 2) in the same conditions.

A valid test according to UNE-EN 14675:2015 (phase 2 step 1) was provided showing that Sanidermix EUSG201 is also effective against virus Bovine Enterovirus type I from a 95% dilution in the following conditions: 10ºC, 5 minutes of contact time and 3 g/l of BVA as interfering substance.

As the efficacy has been demonstrated at clean conditions, the label instructions should state that cleaning prior disinfection is necessary.
The recommended modes of application are by spraying and by manual nebulization.

Whereas the following matters:

Other tests according to **UNE EN 14675:2015** were submitted. However, neither of them can consider as valid to prove the efficacy against virus in veterinary area because they do not fullfill the stablished criteria of the Guidance on the BPR for PT3 Veterinary hygiene biocidal products. The reasons why they would not be considered valid were set out in detail

in the Table 3.13 Efficacy data.

4.1.2 Conclusion on efficacy

Conclusion on the efficacy of the product Sanidermix *EUSG201*(0.1% LA) & validated label claims
According to the test reports listed in table 3.2 the product Sanidermix EUSG201 has shown sufficient efficacy and meets the requirements to claim the use as PTs 1,2,3 and 4 with a bactericidal, fungicidal and virucidal activity (PT1,2,4). The following uses can be granted: **PT1 Human hygiene. Handrub** With the undiluted product Application rate: 3ml At room temperature - Bacteria, yeasts and fungi: 45 seconds contact time - Virus: 60 seconds contact time. **PT2 Hard surface disinfection (includind health care). Spraying.** With the undiluted product Application rate: 30-50ml/m^2 - Bacteria, yeasts and fungi without prior cleaning - Viruses with prior cleaning 5 min contact time **PT3 Hard surface disinfection veterinary. Spraying.** With the undiluted product. Porous and non porous surfaces Application rate: 30-50ml/m^2 - Bacteria, yeasts, fungi and virus with prior cleaning 5 min contact time **PT4 Hard surface disinfection. Spraying.** With the undiluted product Application rate: 30-50ml/m^2 - Bacteria, yeasts and fungi without prior cleaning - Viruses with prior cleaning 5 min contact time The product is intended to be used without mechanical action. In conclusion, the product Sanidermix EUSG201 is effective undiluted as PT1 for hygienic handrub disinfection against bacteria, yeasts, fungi and virus; as PT2 (including healthcare) and PT4 for hard surface disinfection against bacteria, yeasts and fungi in dirty conditions and against viruses in clean conditions; and as PT3 for hard surfaces disinfectant (porous and non-porous surfaces) in veterinary area at clean conditions. The contact time required for the product to have effect against the claimed target organisms must be at least 5 minutes.

4.1.3 Occurrence of resistance and resistance management

Resistance is not known to occur.

No resistance to lactic acid has been observed in the course of the efficacy studies. Furthermore, development of resistance is considered unlikely due to the non-specific mode of action (Doc III B5.11). (Assessment Report Lactic Acid, Germany, 2017).

4.1.4 Known limitations

There are no known limitations on efficacy, including observations on undesirable or unintended side effects.

4.1.5 Relevant information if the product is intended to be authorised for use with other biocidal products

The product Sandermix EUSG201 not intended to be used in combination with other biocidal products.

4.2 Risk assessment for human health

The product Sandermix EUSG201 has been considered apt for the simplified authorisation procedure (under Regulation (EU) 528/2012, article 25). The co-formulants are either not classified as dangerous for human health according to CLP regulation. They are not present at sufficient concentrations to trigger hazard classification. For this reason, and according to data requirements under the simplified authorisation procedure, a risk assessment for human health is not necessary.

4.2.1 Assessment of effects on human health

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

There are no human health data available for the product Sandermix EUSG201. The classification and labelling are based on the available information for both the active substance the non-active substances in CL inventory, data sheets and based on CLP criteria.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritant
Justification for the value/conclusion	No human data and studies on skin corrosion/irritation are available
Classification of the product according to CLP	The product is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). The active substance and co-formulants are not present at sufficient concentrations to trigger hazard classification.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Non-irritant
Justification for the value/conclusion	No human data and studies on eye irritation are available

Classification of the product according to CLP	The product is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). The active substance and co-formulants are not present at sufficient concentrations to trigger hazard classification.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Non-irritant
Classification of the product according to CLP	There are no components in the composition that are irritating to the respiratory tract.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitiser
Justification for the value/conclusion	No human data and studies on skin sensitization are available
Classification of the product according to CLP	The product is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). Some co-formulants are sensitisers but they are not present at sufficient concentrations to trigger hazard classification. In addition, according to the criteria stablished in CLP regulation the product label will also not include the phrase EUH208

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	No animal or human data have been provided to assess the potential for respiratory sensitization. The active substance and the coformulants of the product are not classified as respiratory sensitisers and are not known to be respiratory sensitisers. Therefore, it can be concluded that the product is not classified with regards to respiratory sensitizer properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).
Classification of the product according to CLP	No classification

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	No human data or acute oral toxicity in animals is available
Justification for	Some co-formulants are classified in Annex VI of CLP regulation or in

the selected value	the C&L Inventory as Acute Tox. 4 but these co-formulants are in very low concentration in the product (less than 0.1%). For these reason, according to the criteria of CLP regulation, the product is not classified by acute oral toxicity.
Classification of the product according to CLP	No classification.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No human data or acute inhalation toxicity in animals is available
Justification for the selected value	The active substance and the coformulants of the product are not classified in this category. For this reason, according to the criteria of CLP regulation, the product is not classified by acute inhalation toxicity.
Classification of the product according to CLP	No classification.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No human data or acute dermal toxicity in animals is available
Justification for the selected value	The active substance and the coformulants of the product are not classified in this category. For this reason, according to the criteria of CLP regulation, the product is not classified by acute demal toxicity.
Classification of the product according to CLP	No classification.

Information on dermal absorption

No data of dermal absorption is available. The active substance is included in the Annex I of BPR. According to data requirements under the simplified authorisation procedure, a risk assessment for human health is not necessary.

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

The product does not contain substances of concern

4.2.3 Other

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

4.2.4 Available toxicological data relating to endocrine disruption

The biocidal product should be considered not to have endocrine-disrupting properties. The biocidal product does not contain any active substance having endocrine-disrupting properties.

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

More information is available in section 2.7 of the PAR and in the confidential annex.

4.2.5 Exposure assessment and risk characterisation for human health

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

4.2.6 Monitoring data

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

4.2.7 Dietary risk assessment

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

4.2.8 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

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

4.2.9 Overall conclusion on risk assessment for human health

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

4.3 Risk assessment for animal health

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

4.3.1 Risk for companion animals

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

4.3.2 Risk for livestock animals

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

4.4 Risk assessment for the environment

Risk assessment for the environment is a requirement for products not eligible for a simplified authorization as per Article 19, point 1. This biocidal product has been considered apt for the simplified authorisation procedure in accordance with Art. 25 of Regulation

528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012. An assessment of potential SOC's (Substances of Concern) has been made. The co-formulants are either not classified as hazardous to the environment under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification of the product. On this basis, and according to data requirements under the simplified authorisation procedure (Reg. (EU) 528/2012, chapter V, article 25), a risk assessment for the environment is not necessary and approval of SANIDERMIX EUSG201 can be authorised from an environmental perspective.

4.5 Assessment of a combination of biocidal products

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

4.6 Comparative assessment

Not relevant.

5 Appendices

5.1 Calculations for exposure assessment

No applicable.

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

No new information on the active substance(s) is available.

5.3 List of studies for the biocidal product

No studies were carried out apart from the ones required in order to demonstrate the effectiveness against target organisms, mentioned in Table 3.13 (Efficacy data).

5.4 References

5.4.1 References other than list of studies for the biocidal product

Not relevant.

5.4.2 Guidance documents

UNE EN 14885 Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics (2019)

5.4.3 Legal texts

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Regulation (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22

May 2012 concerning the making available on the market and use of biocidal products.

5.5 Confidential information

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