

Summary of product characteristics for a biocidal product

Product name: Sanidermix EUSG201

Product type(s): PT01 - Human hygiene (Disinfectants)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: ES/APP(SA)-2023-01/02/03/04-00909

R4BP 3 asset reference number: EU-0029286-0000

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Administrative information

1.1. Trade names of the product

Sanidermix EUSG201

1.2. Authorisation holder

Name and address of the authorisation holder	Name	4MEDIKS S.L.U.
	Address	Calle Pau Casals, 6 5-2 AD500 Andorra La Vella Andorra
Authorisation number	ES/APP(SA)-2023-01/02/03/04-00909	
R4BP 3 asset reference number	EU-0029286-0000	
Date of the authorisation	26/12/2023	
Expiry date of the authorisation	21/12/2033	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	PROCESOS A TERCEROS
Address of the manufacturer	Avda. Principal, 37 Pol. Ind. Can Clapers 08181 Sentmenat, Barcelona Spain
Location of manufacturing sites	Avda. Principal, 37 Pol. Ind. Can Clapers 08181 Sentmenat, Barcelona Spain

1.4. Manufacturer(s) of the active substance(s)

Active substance	1421 - Lactic acid
Name of the manufacturer	PURAC bioquímica
Address of the manufacturer	Gran Vial 19-25 08160 Montmeló, Barcelona Spain
Location of manufacturing sites	Gran Vial 19-25 08160 Montmeló, Barcelona Spain

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,1

2.2. Type of formulation

EW - Emulsion, oil in water

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 – PT1 Human hygiene. Handrub.

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic handrub.
Target organism(s) (including development stage)	Scientific name: virus Common name: Virus Development stage: Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: Fungi Common name: Fungi Development stage:
Field(s) of use	Indoor Outdoor
Application method(s)	Method: Rubbing Detailed description: For human hygiene: apply a small amount to the palm of the hand and spread over the entire surface of the hands. Wait until complete absorption. Use whenever hand disinfection is required.
Application rate(s) and frequencies	Application Rate: 3 ml. Dilution (%): No dilution is required (Ready to use) Number and timing of application: Number and timing of application: 45 seconds of rubbing. For virucidal efficacy 60 seconds of rubbing.
Category(ies) of users	Trained professional Professional General public (non-professional)

Pack sizes and packaging material

Material: plastic (PET), aluminium, steel, etc.

Min. capacity: 0.05L

Max. capacity: 1000L

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

4.1.1 Use-specific instructions for use

Ready to use product, no dilution is required.

Use as a disinfectant for healthy skin: Apply a small amount on the palm of the hand and spread over the entire surface of the hands. Wait until completely absorbed.

4.1.2 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.2 Use description

Use 2 - Use # 2 – PT2 Hard surface disinfection (including health care). Spraying.

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	.
Target organism(s) (including development stage)	Scientific name: Virus Common name: Virus Development stage: Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: Fungi Common name: Fungi Development stage:
Field(s) of use	Indoor Indoor. Disinfectant suitable for non-porous surfaces in industrial, institutional (including health care premises) and households.
Application method(s)	Method: Spraying Detailed description: <ul style="list-style-type: none">- For bactericidal, yeasticidal and fungicidal effect, no pre-clean is needed. - For virucidal effect, pre-clean the surface to be disinfected before the application.

Detailed description:

Method: Spraying

Apply the product on the surface by spraying with a trigger sprayer, making sure that it impregnates the entire surface. Wait for 5 minutes before wiping.

Method: Manual nebulisation
Detailed description:

- For bactericidal, yeasticidal and fungicidal effect, no pre-clean is needed.
- For virucidal effect, pre-clean the surface to be disinfected before the application.

Method: Manual nebulisation

Fill a Nebulisation System (manual application) with the product and distribute it on the surface to be disinfected, making sure that it impregnates the surface in its totality. Wait for 5 minutes.

Application rate(s) and frequencies

Application Rate: Trigger spray application: 40-50 ml/m²
Dilution (%): .
Number and timing of application:

Trigger spray application: 40-50 ml/m²

Manual nebulization: 30-40 ml/m²

Contact time: 5 minutes

Use whenever a disinfection is required.

Application Rate: Manual nebulization: 30-40 ml/m²

Dilution (%): .

Number and timing of application:

Manual nebulization: 30-40 ml/m²

Contact time: 5 minutes

Use whenever a disinfection is required.

Category(ies) of users

Trained professional

Professional

General public (non-professional)

Pack sizes and packaging material

Material: plastic (PET), aluminium, steel, etc.

Min. capacity: 0.05L

Max. capacity: 1000L

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



4.2.1 Use-specific instructions for use

Disinfection of hard non-porous surfaces: Precleaning prior to the application is needed for use against viruses. Apply the product by spraying or nebulizing over the surface, impregnating the entire surface. Wait for 5 minutes. Make sure that the surface keeps wet during the contact time.

4.2.2 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.3 Use description

Use 3 - Use # 3 – PT3 Hard surface disinfection veterinary hygiene. Spraying

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Hard surfaces (non-porous and porous) – veterinary hygiene (1- veterinary clinics, veterinary testing laboratories and associated equipment, and 2- animal housing such as kennels, hutches and cages and associated equipment)

Target organism(s) (including development stage)

Scientific name: Virus
Common name: Virus
Development stage:

Scientific name: bacteria
Common name: Bacteria
Development stage:

Scientific name: Fungi
Common name: Fungi
Development stage:

Scientific name: yeasts
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Indoor.

Application method(s)

Method: Spraying and manual nebulization
Detailed description:

Method: Spraying

Apply the product on the surface by spraying with a trigger sprayer, making sure that it impregnates the entire surface. Wait for 5 minutes before wiping.

Method: Manual nebulisation

Fill a Nebulisation System (manual application) with the product and distribute it on the surface to be disinfected, making sure that it impregnates the surface in its totality. Wait for 5 minutes.

Application rate(s) and frequencies

Application Rate: Trigger spray application: 40-50 ml/m² Manual nebulization: 30-40 ml/m²
Dilution (%): .
Number and timing of application:

Application rate:

Trigger spray application: 40-50 ml/m²

Manual nebulization: 30-40 ml/m²

Contact time: 5 minutes

Use whenever a disinfection is required.

Category(ies) of users

Trained professional
Professional
General public (non-professional)

Pack sizes and packaging material

Material: plastic (PET), aluminium, steel, etc.

Min. capacity: 0.05L

Max. capacity: 1000L

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

4.3.1 Use-specific instructions for use

Disinfection of hard non-porous surfaces: Precleaning prior to the application is needed for use against viruses. Apply the product by spraying or nebulizing over the surface, impregnating the entire surface. Wait for 5 minutes. Make sure that the surface keeps wet during the contact time.

4.3.2 Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

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

See general instructions for use

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

See general instructions for use

4.4 Use description

Use 4 - Use # 4 – PT4 Hard surface disinfection. Spraying.

Product type

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Not relevant

Target organism(s) (including development stage)

Scientific name: Virus
Common name: Virus
Development stage:

Scientific name: bacteria
Common name: Bacteria
Development stage:

Scientific name: Fungi
Common name: Fungi
Development stage:

Field(s) of use

Indoor

Indoor. Disinfectant suitable for non-porous surfaces in Food/Feed industries.

Application method(s)

Method: Spraying y nebulización manual
Detailed description:

- For bactericidal, yeasticidal and fungicidal effect, no pre-clean is needed.

- For virucidal effect, pre-clean the surface to be disinfected before the application.

Detailed description:

Method: Spraying

Apply the product on the surface by spraying with a trigger sprayer, making sure that it impregnates the entire surface. Wait for 5 minutes before wiping.

Method: Manual nebulisation

Fill a Nebulisation System (manual application) with the product and distribute it on the surface to be disinfected, making sure that it impregnates the surface in its totality. Wait for 5 minutes.

Application rate(s) and frequencies

Application Rate: Trigger spray application: 40-50 ml/m² Manual nebulization: 30-40 ml/m²
Dilution (%): .
Number and timing of application:

Application rate:

Trigger spray application: 40-50 ml/m²

Manual nebulization: 30-40 ml/m²

Contact time: 5 minutes

Use whenever a disinfection is required.

Category(ies) of users	<p>Trained professional</p> <p>Professional</p> <p>General public (non-professional)</p>
Pack sizes and packaging material	<p>Material: plastic (PET), aluminium, steel, etc.</p> <p>Min. capacity: 0.05L</p> <p>Max. capacity: 1000L</p> <p>*Note: In Spain, article 37 will be applied to limit the size of containers to 5L for professional and non-professional users.</p>

4.4.1 Use-specific instructions for use

Disinfection of hard non-porous surfaces: Precleaning prior to the application is needed for use against viruses. Apply the product by spraying or nebulizing over the surface, impregnating the entire surface. Wait for 5 minutes. Make sure that the surface keeps wet during the contact time.

4.4.2 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

5. General directions for use

5.1. Instructions for use

Ready to use product, no dilution is required.

Enter or fill with the product on a Spray System or Nebulization System (manual machine) and distribute it on the space where is the surface and equipment to be disinfected, making sure that it impregnates the surface and equipment in its totality. Wait for 5 minutes. Use every time disinfection is required.

Disinfection of human skin

Apply a small amount (3ml) on the palm of the hand and spread over the entire surface of the hands. Wait until it is completely absorbed.

Use whenever hand disinfection is required.

Surface disinfection

Precleaning prior to the application is needed for use against viruses. Apply the product by spraying or nebulizing over the surface, impregnating the entire surface. Wait for 5 minutes. Make sure that the surface keeps wet during the contact time.

5.2. Risk mitigation measures

Keep out of the reach of children.

Do not ingest.

In case of accidental ingestion seek medical advice with the label or container at hand.

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

In case of contact with eyes, rinse thoroughly with clean, fresh water for at least 10 minutes, pulling up the eyelids.

If eye irritation occurs seek medical attention.

In cases of doubt, or when symptoms of discomfort persist, seek medical attention

5.4. Instructions for safe disposal of the product and its packaging

Discharge into sewers or watercourses is not permitted. Waste and empty containers must be handled and disposed of in accordance with local/national legislation.

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

Keep out of direct sunlight. Store in a cool, dry and well-ventilated place.

Shelf-life: 2 years

6. Other information

Definitions:

Non-professional user: Users who are not professionals and who apply the product in the context of their private life.

Professional: User applying biocidal products in their workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

Trained professional: pest control operators, having received specific training according to the national legislation in force.

