

Summary of product characteristics for a biocidal product family

Family name: Citrox product family

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

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

Authorisation number: FR-2022-0069

R4BP 3 asset reference number: EU-0026473-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Citrox product family

1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

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

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Auranta
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Address	The Sweepstakes Ballsbridge D04 C7H2 Dublin Ireland
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Authorisation number

FR-2022-0069

R4BP 3 asset reference number

EU-0026473-0000

Date of the authorisation

02/09/2022

Expiry date of the authorisation

01/09/2032

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Bioscience Nutrition Ireland

Address of the manufacturer

Skule Hill, Fedamore V35 RH74 Co. Limerick Ireland

Location of manufacturing sites

Skule Hill, Fedamore V35 RH74 Co. Limerick Ireland

Name of the manufacturer	Nano 4 You GmbH
Address of the manufacturer	In der Kolling 15 D-66450 Bexbach Germany
Location of manufacturing sites	In der Kolling 15 D-66450 Bexbach Germany

Name of the manufacturer	ZIDAC Laboratories
Address of the manufacturer	Unit 5, Merlin Park, Airport Service Rd PO3 5FU Portsmouth United Kingdom
Location of manufacturing sites	Unit 5, Merlin Park, Airport Service Rd PO3 5FU Portsmouth United Kingdom

Name of the manufacturer	Citrox Biosciences Limited
Address of the manufacturer	6 Nene Road, Bicotn Ind. Park, Cambridgeshire PE28 0LF Kimbolton United Kingdom
Location of manufacturing sites	6 Nene Road, Bicotn Ind. Park, Cambridgeshire PE28 0LF Kimbolton United Kingdom

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

Active substance	1421 - Lactic acid
Name of the manufacturer	Purac Biochem bv
Address of the manufacturer	Arkelsedijk 46 NL-4206 AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46 NL-4206 AC Gorinchem Netherlands

2. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2 - 0,2

2.2. Type(s) of formulation

AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

META SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2 - 0,2

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Hand disinfection

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Field(s) of use

Other

Hand disinfection

Application method(s)

Method: Manual application
Detailed description:
Direct application to both hands, rubbing

Apply the product to one hand and complete surface of both hands.

Application rate(s) and frequencies

Application Rate: 6mL
Dilution (%): 0
Number and timing of application:
6mL of product per application.

Contact time : 60 seconds

Category(ies) of users

Professional
General public (non-professional)

Pack sizes and packaging material

50 mL, 500 mL and 5 L in HDPE bottles

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

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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

-

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

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Inform the registration holder if the treatment is ineffective.
- Apply only on visibly clean hands.
- Due to the contact time higher than 30s, do not use in hospitals

5.2. Risk mitigation measures

-

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

- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: not applicable.
- If medical advice is needed, have product container or label at hand

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

-

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

- Protect from frost.
- Shelf life: 2 years.
- Keep out of reach of children and non-target animals/pets.

6. Other information

-

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Citrox Protect Alcohol Free Hand Gel

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0026473-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2

1. Meta SPC administrative information

1.1. Meta SPC identifier

META SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2 - 0,2

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection

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: Common name: Bacteria Development stage:
Field(s) of use	Indoor Household (other than kitchen) and workplace area
Application method(s)	Method: Spraying Detailed description: By spraying the surface
Application rate(s) and frequencies	Application Rate: - Dilution (%): 0 Number and timing of application: Ready to use product Contact time: 5 minutes Room temperature
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	750 ml trigger spray HDPE bottle.

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

-

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

-

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

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Inform the registration holder if the treatment is ineffective.
- Clean carefully the surfaces before application of the product.
- Ensure complete wetting on the surfaces, leave for at least 5 minutes.
- Apply on non-porous surface only.

5.2. Risk mitigation measures

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

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: not applicable.
- If medical advice is needed, have product container or label at hand.

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

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

- Protect from frost.
- Shelf life: 2 years.
- Keep out of reach of children and non-target animals/pets.

6. Other information

-

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Citrox BCL 1%

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0026473-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2

Trade name(s)

Citrox Protect Surface Cleaner and Disinfectant

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0026473-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,2

