#### **ANNEX**

### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

#### SANYTOL LACTIC SA-APP

### **Product type(s)**

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

PT04: Food and feed area

**Authorisation number** FR-2024-0018

**R4BP asset number** EU-0030696-0000

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### Part I. FIRST INFORMATION LEVEL

#### 1. ADMINISTRATIVE INFORMATION

### 1.1. Family name

Name	SANYTOL LACTIC SA-APP

### **1.2.** Product type(s)

Product type(s)	PT02: Disinfectants and algaecides not intended for	
	direct application to humans or animals	
	DTO4. Food and food area	
	PT04: Food and feed area	

#### 1.3. Authorisation holder

	Name	GRUPO AC MARCA S.L.
Name and address of the authorisation holder	Address	Avda. Carrilet, 293-297 08907 L'Hospitalet de Llobregat Spain
Authorisation number		FR-2024-0018
R4BP asset number		EU-0030696-0000
Date of the authorisation		27/03/2024
Expiry date of the authorisation		26/03/2034

### **1.4.** Manufacturer(s) of the product

Name of manufacturer	Grupo AC Marca, S.L.
Address of manufacturer	AVDA Carrilet n°293-297 08907 L'Hospitalet de Llobregat Spain
Location of manufacturing sites	Grupo AC Marca, S.L. site 1
	Polígono Industrial Can Serra III, Parcela I 08791 Sant Llorenç d'Hortons Spain
	Grupo AC Marca, S.L. site 2
	Polígono Industrial Can Barri. C/ Esqueis S/N 08415 Bigues i Riells - Barcelona Spain
	Grupo AC Marca, S.L. site 3
	Jana Čermáka 124 28201 Přišimasy République Tchèque
	Grupo AC Marca, S.L. site 4
	65, rue Alexandre DUMAS CS10314 69518 VAULX EN VELIN, Cedex France

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

Active substance	Lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. Portuaire BP 32 67390 Marckolsheim France

Location of manufacturing sites	Jungbunzlauer S.A. site 1
	Jungbunzlauer S.A. Z.I. Portuaire BP 32 67390 Marckolsheim France

### 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	50-21-5	200-018-0	0,86 - 0,86 % (w/
					w)

### 2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid
	Impregnated wipes

# $\label{eq:partII.} \textbf{Part II.} \\ \textbf{SECOND INFORMATION LEVEL - META SPC}(S)$

#### 1. META SPC 1 ADMINISTRATIVE INFORMATION

### 1.1. Meta SPC 1 identifier

Identifier	Meta SPC: META SPC 1: MU/LH/DEO TEXTILE	
1.2. Suffix to the authorisation number		
Number 1-1		
1.3. Product type(s)		
Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals	

PT04: Food and feed area

#### 2. META SPC 1 COMPOSITION

### 2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86 - 0,86 % (w/
					w)

### 2.2. Type(s) of formulation of the meta SPC 1

	AT A ST. 11
Formulation type(s)	AL Any other liquid
Tornialation type(s)	The Thirty other riquid

### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H290: May be corrosive to metals.
Precautionary statements	P234: Keep only in original packaging.
	P390: Absorb spillage to prevent material damage.
	P406: Store in a a corrosion-resistant container with a resistant inner liner.

#### 4. AUTHORISED USE(S) OF THE META SPC

### 4.1. Use description 1

Table 1. Soft surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: not applicable Scientific name: Common name: Yeasts Development stage: not applicable Scientific name: Common name: Enveloped viruses Development stage: not applicable
Field(s) of use	indoor use  Indoor, non-washable textiles or textiles difficult to wash (non-medical areas)
Application method(s)	Method: spraying  Detailed description: Spraying
Application rate(s) and frequency	Dilution (%): 0  Number and timing of application: RTU  Contact time:15 minutes Dirty conditions Room temperature
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	BHDPE trigger spray (trigger: TS5 spray med screw 28410 (PP) or TS3 Dexter sanytol spray Verde' 19 (PP) or bottle from 50 mL up to 5000 mL PET Sampling sachet from 45 mL up to 1000 mL PET-PE Doypack (refill packaging) from 45 mL up to 2000 mL

#### 4.1.1. Use-specific instructions for use

• Spray the product uniformly 20 cm away from the textile to be treated.

Wet the surfaces completely with the product, leave to act for the recommended contact time.

• Let the surfaces dry.

### 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

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# 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

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### 4.2. Use description 2

Table 2. Hard surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: not applicable
	Scientific name: - Common name: Yeasts Development stage: not applicable
	Scientific name: - Common name: Fungi Development stage: not applicable
	Scientific name: - Common name: Enveloped viruses Development stage: not applicable
Field(s) of use	indoor use Indoor use, Disinfectant without rinsing for hard non porous surfaces (non-medical areas)
Application method(s)	Method: spraying
	Detailed description: Spraying (and wiping) Method: pouring  Detailed description: Pouring (and wiping)
Application rate(s) and frequency	Dilution (%): 0
	Number and timing of application:
	• RTU
	• Contact time: Bacteria, yeasts, enveloped viruses: 5 minutes Fungi: 15 minutes (mechanical action) or 60 minutes (non mechanical action)
	Dirty conditions
	• Room temperature

	Application Rate: use enough amount of liquid to ensure that surfaces remain wet during contact time  Dilution (%): 0  Number and timing of application: Application rate: use enough amount of liquid to ensure that surfaces remain wet during contact time Contact time: Bacteria, yeasts, enveloped viruses: 5 minutes Fungi: 15 minutes (mechanical action) or 60 minutes (non mechanical action) Dirty conditions Room temperature
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	HDPE bottle equipped or not with a spray device (type device TS5 spray med screw 28410 (PP) or TS3 Dexter sanytol spray Verde' 19 (PP)) from 50 mL up to 5000 mL PET Sampling sachet from 45 mL up to 1000 mL PET-PE Doypack (refill packaging) from 45 mL up to 2000 mL

#### **4.2.1.** Use-specific instructions for use

- Apply only on non-porous surfaces.
- Manual spray (and wiping) on hard surface: Hold the trigger upright 20 cm from the surface. Spray and spread the product with a clean, damp cloth onto the surface with enough amount to ensure that the surface remains wet at least 5 min for bactericidal, yeasticidal and virucidal efficacy against enveloped viruses, and 15 min (mechanical action) or 60 minutes (non mechanical action) for fungicidal activity.
- Manual pouring (and wiping) on hard surface: Spray and spread the product with a clean, damp cloth onto the surface with enough amount to ensure that the surface remains wet at least 5 min for bactericidal and yeasticidal and virucidal efficacy against enveloped viruses, and 15 min (mechanical action) or 60 minutes (non mechanical action) for fungicidal activity.
- Let the surface dry.
- Activity against additional bactericidal strains (*Salmonella enterica* and *Listeria monocytogenes*) with 5 min contact time, additional fungicidal strains *Microsporum canis* and *Trichosporon cutaneum* with 15 min contact time (mechanical action) or 60 minutes (non mechanical action), and additional virucidal strains (H1N1, human coronavirus) with 5 min contact time have been also tested.

#### 4.2.2. Use-specific risk mitigation measures

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# 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

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

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# 4.2.5. 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 1

#### **5.1.** Instructions for use

Comply with the instructions of use.

#### 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

- Keep out of reach of children and non-target animals/pets.
- Shelf life: 3 years

#### 6. OTHER INFORMATION

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#### 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

	Sanytol Désinfectant Nettoyant Multi-usages care	Market area: FR
Authorisation number		EU-0030696-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

## 7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Nettoyant	
	Désinfectant	
	Sols et	
	Surfaces	
	Care	
Authorisation number		EU-0030696-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# 7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Désinfectant	
	Nettoyant	
	Multi-usages	
	Eucalyptus	
	Care	
Authorisation number		EU-0030696-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# 7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Nettoyant	
	Désinfectant	
	Sols et	
	Surfaces	
	Eucalyptus	
	Care	

Authorisation number		EU-0030696-0004 1-1			
Common name   IUPAC name   Function   CAS num				EC number	Content (%)
Lactic acid active substance			50-21-5	200-018-0	0,86

# 7.5. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Désodorisant	
	Désinfectant	
	Spécial	
	Textil Grand	
	Air	
Authorisation number		EU-0030696-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# 7.6. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Désodorisant	
	Désinfectant	
	Spécial	
	Textil	
	Brume d'été	
Authorisation number		EU-0030696-0006 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# 7.7. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Désodorisant	
	Textile	
	Désinfectant	
	Odeurs	
	Animaux	
	Care	
Authorisation number		EU-0030696-0007 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# 7.8. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Sanytol	Market area: FR
	Désodorisant	

2	Désinfectant Spécial Textil Care
Authorisation number	EU-0030696-0008 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

#### 1. META SPC 2 ADMINISTRATIVE INFORMATION

### 1.1. Meta SPC 2 identifier

Identifier	Meta SPC: META SPC 2: STD WIPES				
1.2. Suffix to the authorisation number					
Number 1-2					
1.3. Product type(s)					
Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals				

PT04: Food and feed area

#### 2. META SPC 2 COMPOSITION

### 2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86 - 0,86 % (w/
					w)

### 2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	Impregnated wipes
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### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H290: May be corrosive to metals.
Precautionary statements	P234: Keep only in original packaging.
	P390: Absorb spillage to prevent material damage.
	P406: Store in a a corrosion-resistant container with a resistant inner liner.

#### 4. AUTHORISED USE(S) OF THE META SPC

#### 4.1. Use description 1

Table 1. Hard surface disinfection – Impregnated wipes

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Scientific name: -
stage)	Common name: Bacteria
	Development stage: not applicable
	Scientific name: -
	Common name: Yeasts
	Development stage: Not applicable
	Scientific name: -
	Common name: Fungi
	Development stage: not applicable
	Scientific name: -
	Common name: Enveloped viruses
	Development stage: not applicable
Field(s) of use	indoor use
	Indoor, hard non porous surface disinfection (non-medical areas)
Application method(s)	Method:
	Detailed description: Wiping
Application rate(s) and frequency	Dilution (%): 0
	Number and timing of application:
	• RTU
	• Contact time:
	Bacteria, yeasts, enveloped virus : 5 minutes
	Fungi: 15 minutes
	Dirty conditions
	Room temperature
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	multilayer (PET + PE/EVOH/PE or PET/PE) Flowpack containing from 3 up to 300 cellulose wipes

### 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
- 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 2

#### **5.1.** Instructions for use

- Comply with the instructions of use.
- Apply only on non-porous surfaces.
- Ensure that the surface remains wet at least 5 min for bactericidal, yeasticidal and virucidal efficacy against enveloped viruses, and 15 min for fungicidal activity. Let the surface dry.
- Activity against additional bactericidal strains (*Salmonella* and *Listeria*) with 5 min contact time, additional fungicidal strains *Microsporum canis* and *Trichosporon cutaneum* with 15 min contact time and additional virucidal strains (H1N1, human Coronavirus) with 5 min contact time have been also tested.
- Close the package carefully after opening.

#### **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

- Keep out of reach of children and non-target animal/pets.
- Shelf life: 2 years

#### 6. OTHER INFORMATION

#### 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

# $\textbf{7.1.} \quad \textbf{Trade name}(s), \textbf{ authorisation number and specific composition of each individual product}$

Trade name(s)	Sanytol Lingettes Care	Market area: FR
Authorisation number		EU-0030696-0009 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance	50-21-5	200-018-0	0,86

# $\textbf{7.2.} \quad \textbf{Trade name}(s), \textbf{ authorisation number and specific composition of each individual product}$

Trade name(s)	Sanytol Lingettes Eucalyptus Care	Market area: FR
Authorisation number		EU-0030696-0010 1-2

(	Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
I	Lactic acid		active substance	50-21-5	200-018-0	0,86	