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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

REW2441_LEM2

Product type(s)

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

PT04: Food and feed area

Authorisation number: 3568-1 1-3

R4BP asset number: BG-0026943-0007

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	SANYTOL TOALLITAS 4 ACCIONES Sanytol désinfectant Lingettes 4 actions Sanytol désinfectant Lingettes 4 actions Sanytol Desinfecierende 4-in-1-doekjes Sanytol désinfectant Lingettes 4 actions Sanytol 4-in-1 Desinfektionstücher Sanytol dezinfekční ubrousky 4 v 1 Dezinficijenski brisači sanitol 4 u 1 Sanytol 4-v-1 robčki z dezinfekcijskim sredstvom Sanytol neli-ühes desinfitseerivad puhastuslapid Sanytol 4-in-1-desinfiointipyyhkeet Sanytol 4 az 1-ben fertőtlenítő kendő Sanytol désinfectant Lingettes 4 actions Sanytol Toalhetes Desinfetantes 4-em-1 Sanytol #erve#ele dezinfecante 4-ín-1 Sanytol 4 v 1 Dezinfekčné utierky Sanytol 4-i-1 desinfektionsservietter Sanytol chusteczki dezynfekujące 4 w 1 Sanytol 4 в 1 дезинфекциращи кърпички Sanytol 4 i 1 Våtserverter Salviettine disinfectanti 4 in 1 Sanytol Απολυμαντικά μαντηλάκια 4 σε 1 Sanytol Dezinficējošās Salvetes 4-in-1 'Sanytol' „Sanytol“ dezinfekuojančios servetėlės „keturi viename“ Sanytol 4-in-1 Desinfecierende doekjes
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	GRUPO AC MARCA S.L.
	Address	Avda. Carrilet, 293-297 08907 L'Hospitalet de Llobregat Spain
Authorisation number		3568-1 1-3
R4BP asset number		BG-0026943-0007
Date of the authorisation		28/03/2024
Expiry date of the authorisation		18/10/2031

1.3. Manufacturer(s) of the product

Name of manufacturer	Grupo AC Marca, S.L.
Address of manufacturer	AVDA Carrilet nº293-297 08907 L'Hospitalet de Llobregat Spain
Location of manufacturing sites	Polígono Industrial Can Serra III, Parcela I 08791 Sant Llorenç d'Hortons Spain Polígono Industrial Can Barri. C/ Esqueis S/N 08415 Bigues i Riells Spain

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem
Address of manufacturer	Arkelsedijk 46 NL-4206 Gorinchem Netherlands (the)
Location of manufacturing sites	Arkelsedijk 46 NL-4206 Gorinchem Netherlands (the)

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	0,86
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	Non-active substance	68515-73-1	483-960-7	0,54
1-Decanamine, N,N-dimethyl-, N-oxide	1-Decanamine, N,N-dimethyl-, N-oxide	Non-active substance	2605-79-0	220-020-5	0,46
Ethanol	Ethanol	Non-active substance	64-17-5	200-578-6	9,6
1-Deoxy-1- (methyl-(C8-10- (even)alkanoyl)amino)- D-Glucitol	1-Deoxy-1- (methyl-(C8-10- (even)alkanoyl)amino)- D-Glucitol	Non-active substance	1591782-62-5		0,63
Sodium benzoate	Sodium benzoate	Non-active substance	532-32-1	208-534-8	0,1

2.2. Type(s) of formulation

impregnated wipes

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P301+P312: IF SWALLOWED: Call a POISON CENTER if you feel unwell.</p> <p>P501: Dispose of contents to hazardous or special waste collection point.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. SURFACE DISINFECTION

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	SURFACE DISINFECTION
Target organism(s) (including development stage)	Scientific name: Pseudomonas aeruginosa Common name: Bacteria Development stage: not applicable Scientific name: other: Enterococcus hirae Common name: Bacteria Development stage: not applicable Scientific name: Staphylococcus aureus Common name: Bacteria Development stage: not applicable Scientific name: Candida albicans Common name: Yeasts Development stage: not applicable Scientific name: Influenza A (H1N1) Common name: Virus Development stage: not applicable
Field(s) of use	indoor use Other Surface disinfection
Application method(s)	Method: Wiping Detailed description: Remove organic remains (if any) before using the product. Wipe the surface. For an optimal bactericidal, yeasticidal and virucidal (Influenza A virus H1N1) action ensure that the surface keeps moistened during 5 minutes. No need to rinse
Application rate(s) and frequency	Application Rate: As often as it is needed by the consumer Dilution (%): Not diluted Number and timing of application: As often as it is needed by the consumer
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Multilayer film with cellulose wipes Pack sizes (range): 3- 120 wipes

4.1.1. Use-specific instructions for use

See in Detailed description of the method

4.1.2. Use-specific risk mitigation measures

None

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

Dispose of contents and container in a public collection point for hazardous or special waste if it is not entirely consumed.

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

Dispose of contents and container in accordance with applicable local, regional, national, and/or international regulations

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

Shelf-life two years.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Remove organic remains (if any) before using the product. Wipe the surface. For an optimal bactericidal, yeasticidal and virucidal (Influenza A virus H1N1) action ensure that the surface keeps moistened during 5 minutes. No need to rinse

5.2. Risk mitigation measures

None

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

Dispose of contents and container in a public collection point for hazardous or special waste if it is not entirely consumed.

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

Dispose of contents/container in accordance with applicable local, regional, national, and/or international regulations

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

Shelf-life two years.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION

Category(ies) of users: General public (non-profesisonal) including small business users
Do not ingest