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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Kenosan Hand Rub

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0027740-0000 1-14

R4BP asset number: IS-0029946-0017

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Kenosan Hand Rub
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	CID LINES NV
	Address	Waterpoortstraat 2 8900 Ieper Belgium
Authorisation number	EU-0027740-0000 1-14	
<i>R4BP asset number</i>	IS-0029946-0017	
Date of the authorisation	01/09/2022	
Expiry date of the authorisation	31/08/2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	CID LINES NV
Address of manufacturer	Waterpoortstraat 2 8900 Ieper Belgium
Location of manufacturing sites	CID LINES NV site 1
	Waterpoortstraat 2 8900 Ieper Belgium

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46 4206 Gorinchem Netherlands (the)
Location of manufacturing sites	Purac Biochem bv site 1
	Arkelsedijk 46 4206 Gorinchem Netherlands (the)

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. et Portuaire, B.P. 32 67390 Marckolsheim France
Location of manufacturing sites	Jungbunzlauer S.A. site 1
	Z.I. et Portuaire, B.P. 32 67390 Marckolsheim France

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	3,6
Natríumlárylsúlfat	Brennisteinssýra, mónó-C12-14-alkýl esterar, natrífumsölt	Non-active substance	85586-07-8	287-809-4	2
Ísóprópanól	Própan-2-ól	Non-active substance	67-63-0	200-661-7	4
Bútýldiglykól	2-(2-butoxyethoxy)etanol	Non-active substance	112-34-5	203-961-6	10

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H318: Causes serious eye damage.
Precautionary statements	P280: Wear verndar auga/andlit. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a doctor.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Hreinlætishandrúbbur, fyrir faglega notkun (PT1)

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Á ekki við
Target organism(s) (including development stage)	Scientific name: önnur: bakteríur Common name: Bacteria Development stage: no data Scientific name: önnur: gær Common name: Yeasts Development stage: no data
Field(s) of use	indoor use í matvæla-/dýrafæðisidnaðinum; í almennings rýmum; Kitchens Hygienic handáburður, á sýnilega hreinar hendur
Application method(s)	Method: Með því að nudda hendurnar Detailed description: /
Application rate(s) and frequency	Application Rate: 6 ml af lyfi Dilution (%): - Number and timing of application: Virkt gegn bakteríum og gersveppum: RTU (með 3,6 % Mjólkursýru) 6 ml (það er ýta þrisvar sinnum fyrir báðar hendur saman) 1 mín. snertitími
Category(ies) of users	professional
Pack sizes and packaging material	50 ml, 75 ml, 100 ml, 150 ml, 500 ml, 1L, 5L, 10L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000L, 1100 L HDPE (háþéttni pólýetýlen)

4.1.1. Use-specific instructions for use

sjá almennar notkunarleiðbeiningar fyrir Meta SPC 14

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

sjá almennar notkunarleiðbeiningar fyrir Meta SPC 14

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

sjá almennar notkunarleiðbeiningar fyrir Meta SPC 14

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

sjá almennar notkunarleiðbeiningar fyrir Meta SPC 14

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Notið 6 ml af vörunni óþynnt. Fjarlægið eftir 1 mínútu. Þurrkið vandlega eftir sóttþreinsun. Eingöngu til faglegrar notkunar

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

EF Á HÚÐ: Þvoið húðina strax með miklu vatni. Fjarlægðu síðan allt mengað fót og þvoðu það áður en það er notað aftur. Haltu áfram að þvo húðina með vatni í 15 mínútur. Hringdu í Eitrunarmiðstöð, s. 543-2222 eða í 112 eða lækni.

EF INNÖNDUNIN ER: Ef einkenni koma fram skal hringja í Eitrunarmiðstöð, s. 543-2222 eða í 112 eða lækni.

EF Í AUGUM: Skolaðu tafarlaust með vatni í nokkrar mínútur. Fjarlægið augnlinsur ef til staðar og auðvelt er. Haltu áfram að skola í að minnsta kosti 15 mínútur. Hringdu strax í 112/sjúkrabíl til að fá lækniástoð.

EF GLEYPT ER: Hreinsaðu munninn strax. Gefið eitthvað að drekka ef einstaklingur sem hefur verið útsett getur gleypt. EKKI valda uppköstum. Hringdu í 112/sjúkrabíl til læknishjálpar

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

Farga skal umbúðum og innihaldi sem hættulegu úrgangsefni og er förgun á fullri ábyrgð eiganda úrgangsefnisins. Ekki má farga úrgangi í holræsi og vatnssvæði. Fargið á öruggan hátt í samræmi við gildandi reglur á hverjum stað.

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

Geymið aðeins í upprunalegu ílátinu á kældu, vel loftuðum stað. Geymið ílátið lokað þegar það er ekki í notkun. Geymsluþol efnisins er 2 ár.

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

6. OTHER INFORMATION

The hazard and precautionary statements shall be in Icelandic on the product label.

The Hazard Statements

H318: Veldur alvarlegum augnskaða.

The Precautionary statements

P280: Notið augnhlífur/andlitshlífur.

P305+P351+P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægið snertilinsur ef það er auðvelt. Skolið áfram.

P310: Hringið umsvifalaust í lækni