Summary of product characteristics for a biocidal product

Product name: Hygienix Disinfecting Gel Wash DGWG-L-11191_06

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

Authorisation number: NL-0018737-0000

R4BP 3 asset reference number: EU-0018737-0021

Table Of Contents

1.1. Trade names of the product 1.2. Authorisation holder 1.3. Manufacturer(s) of the biocidal products 1.4. Manufacturer(s) of the active substance(s) 2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 5.4. Instructions for safe disposal of the product and its packaging	Administrative information	
1.2. Authorisation holder 1.3. Manufacturer(s) of the biocidal products 1.4. Manufacturer(s) of the active substance(s) 2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 5.4. Instructions for safe disposal of the product and its packaging	Administrative information	1
1.3. Manufacturer(s) of the biocidal products 1.4. Manufacturer(s) of the active substance(s) 2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	1.1. Trade names of the product	1
1.4. Manufacturer(s) of the active substance(s) 2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	1.2. Authorisation holder	1
1.4. Manufacturer(s) of the active substance(s) 2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	1.3. Manufacturer(s) of the biocidal products	1
2. Product composition and formulation 2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	1.4. Manufacturer(s) of the active substance(s)	7
2.1. Qualitative and quantitative information on the composition of the biocidal product 2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	2. Product composition and formulation	9
2.2. Type of formulation 3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	2.1. Qualitative and quantitative information on the composition of the biocidal product	9
3. Hazard and precautionary statements 4. Authorised use(s) 5. General directions for use 5.1. Instructions for use 1 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	2.2. Type of formulation	9
4. Authorised use(s) 5. General directions for use 1 5.1. Instructions for use 1 5.2. Risk mitigation measures 1: 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	3. Hazard and precautionary statements	9
5. General directions for use 5.1. Instructions for use 1.5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	4. Authorised use(s)	10
5.1. Instructions for use 5.2. Risk mitigation measures 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	5. General directions for use	11
5.2. Risk mitigation measures 1.5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	5.1. Instructions for use	
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 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	E 2. Dick mitigation managers	11
protect the environment 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	5.2. Risk miligation measures	12
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage		12
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	5.4. Instructions for safe disposal of the product and its packaging	12
	5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	12
6. Other information	6. Other information	12

Administrative information

1.1. Trade names of the product

Hygienix Disinfecting Gel Wash DGWG-L-11191_06	

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Hygienix B.V.
Address	Rijksstraatweg 104B 3632 AD Loenen aan de Vecht Netherlands

Authorisation number

NL-0018737-0000 1-4

R4BP 3 asset reference number

EU-0018737-0021

Date of the authorisation

31/05/2019

Expiry date of the authorisation

31/05/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Hygienix B.V.

Address of the manufacturer

Rijksstraatweg 104b 3632 AD Loenen aan de Vecht Netherlands

Location of manufacturing sites

Rijksstraatweg 104b 3632 AD Loenen aan de Vecht Netherlands

Multifill B.V.		
Constructieweg 25a 3641 SB Mijdrecht Netherlands		
Constructieweg 25a 3641 SB Mijdrecht Netherlands		
Communicatieweg 24 3641 SE Mijdrecht Netherlands		
CODI International B.V.		
Accustraat 10 3903 LX Veenendaal Netherlands		
Accustraat 10 3903 LX Veenendaal Netherlands		
Turbinestraat 19 3903 LV Veenendaal Netherlands		
Incare Wet wipes		
Keizersveld 99 5803 AP Venray Netherlands		
Keizersveld 99 5803 AP Venray Netherlands		
Innovate Wet Wipes		
Am Hohen Stein 11 06618 Naumburg Germany		
Am Hohen Stein 11 06618 Naumburg Germany		
Van Dam Bodegraven B.V.		
Beneluxweg 8 2411 NG Bodegraven Netherlands		

Beneluxweg 8 2411 NG Bodegraven Netherlands

Name of the manufacturer	Special Fills B.V.		
Address of the manufacturer	De Veken 129 1716 KG Opmeer Netherlands		
Location of manufacturing sites	De Veken 129 1716 KG Opmeer Netherlands		
Name of the manufacturer	Girasol Natural Products B.V.		
Address of the manufacturer	Minervum 7357 4817 ZH Breda Netherlands		
Location of manufacturing sites	Minervum 7357 4817 ZH Breda Netherlands		
Name of the manufacturer	ECL Châlons		
Address of the manufacturer	94 Avenue de General Patton 51000 CHALONS EN CHAMPAGNE France		
Location of manufacturing sites	94 Avenue de General Patton 51000 CHALONS EN CHAMPAGNE France		
Name of the manufacturer	ECL Leeds		
Address of the manufacturer	Lotherton Way LS25 2JY Garforth, Leeds United Kingdom		
Location of manufacturing sites	Lotherton Way LS25 2JY Garforth, Leeds United Kingdom		
Name of the manufacturer	ECL Maribor		
Address of the manufacturer	Vajngerlova Ulica 4 2000 Maribor Slovenia		
Location of manufacturing sites	Vajngerlova Ulica 4 2000 Maribor Slovenia		
Name of the manufacturer	ECL Nieuwegein		
Address of the manufacturer	Brugwal 11 A 3432 NZ NIEUWEGEIN Netherlands		

Brugwal 11 A 3432 NZ NIEUWEGEIN Netherlands

Name of the manufacturer ECL Rozzano Address of the manufacturer Via A. Grandi 20089 Rozzano MI Italy **Location of manufacturing sites** Via A. Grandi 20089 Rozzano MI Italy Name of the manufacturer ECL Tessenderlo Address of the manufacturer Havenlaan 4, Ravenshout 4 210 B-3980 Tessenderlo Belgium Location of manufacturing sites Havenlaan 4, Ravenshout 4 210 B-3980 Tessenderlo Belgium Name of the manufacturer **ECL** Weavergate Address of the manufacturer PO Box 11, Winnington Avenue CW8 4DX Northwich, Cheshire United Kingdom Nalco Manufacturing Limited, Winnington Avenue CW8 3AA Northwich, Cheshire United Location of manufacturing sites Kingdom Name of the manufacturer Ecolab Ltd Baglan Address of the manufacturer Plot 7a Baglan Energy Park, Brunel way SA11 2GA Baglan, Port Talbot United Kingdom Location of manufacturing sites Plot 7a Baglan Energy Park, Brunel way SA11 2GA Baglan, Port Talbot United Kingdom Name of the manufacturer LABORATOIRES ANIOS Address of the manufacturer Pavé du moulin 59260 Lille-Hellemmes France

Pavé du moulin 59260 Lille-Hellemmes France

3330 Rue de Lille 59262 Sainghin-en-Mélantois France

Name of the manufacturer	Nuova Farmec Srl		
Address of the manufacturer	Via Flemming 7 37026 Settimo di Pescantina (VR) Italy		
Location of manufacturing sites	Via Flemming 7 37026 Settimo di Pescantina (VR) Italy		
Name of the manufacturer	KiiltoClean A/S		
Address of the manufacturer	Plums Vej 2 DK-5610 Assens Denmark		
Location of manufacturing sites	Plums Vej 2 DK-5610 Assens Denmark		
Name of the manufacturer	Linköpings Tekniska Fabrik AB		
Address of the manufacturer	Barhällsgatan 14 582 39 Linköping Sweden		
Location of manufacturing sites	Barhällsgatan 14 582 39 Linköping Sweden		
Name of the manufacturer	CID LINES		
Address of the manufacturer	Waterpoortstraat 2 8900 IEPER Belgium		
Location of manufacturing sites	Waterpoortstraat 2 8900 IEPER Belgium		
Name of the manufacturer	FAMAR		
Address of the manufacturer	29 Avenue Charles de Gaulle 69230 Saint-Genis-Laval France		
Location of manufacturing sites	29 Avenue Charles de Gaulle 69230 Saint-Genis-Laval France		
Name of the manufacturer	Jagopro		
Address of the manufacturer	Szczakowska Street 35 43-600 Jaworzno Poland		

Szczakowska Street 35 43-600 Jaworzno Poland

Name of the manufacturer	SARAYA		
Address of the manufacturer	Allée Alfred Nobel, ZI de la Praye 55500 Velaines France		
Location of manufacturing sites	Allée Alfred Nobel, ZI de la Praye 55500 Velaines France		
Name of the manufacturer	Unilever Italy Manufacturing S.r.l.		
Address of the manufacturer	Via Lever Gibbs 3 - 26841 Casalpusterlengo (LO) Italy		
Location of manufacturing sites	Via Lever Gibbs 3 - 26841 Casalpusterlengo (LO) Italy		
Name of the manufacturer	Unilever Magyarorszag KFT		
Address of the manufacturer	Nyirbatori Gyar, Tancsics utca 2-4 4300 Nyirbator Hungary		
Location of manufacturing sites	Nyirbatori Gyar, Tancsics utca 2-4 4300 Nyirbator Hungary		
Name of the manufacturer	Unilever UK Ltd		
Address of the manufacturer	Wood St. CH62 4UY Birkenhead, Wirral United Kingdom		
Location of manufacturing sites	Wood St. CH62 4UY Birkenhead, Wirral United Kingdom		
Name of the manufacturer	DRAMERS S.A.		
Address of the manufacturer	RABOWICE, UL. OLSZYNOWA 38 62-020 SWARZEDZ Poland		
Location of manufacturing sites	RABOWICE, UL. OLSZYNOWA 38 62-020 SWARZEDZ Poland		
Name of the manufacturer	Farmol SPA		
Address of the manufacturer	VIA VERDELLA 3 24040 COMUN NUOVO Italy		

via Mazzini 5 25030 Berlingo BS Italy

Name of the manufacturer	Nice-Pak International Ltd		
Address of the manufacturer	Aber Park CH6 5EX Flint United Kingdom		
Location of manufacturing sites	Aber Park CH6 5EX Flint United Kingdom		
Name of the manufacturer	Nice-Pak Deutschland GmbH		
Address of the manufacturer	Bahnhofstraße 47 D-39171 Osterweddingen Germany		
Location of manufacturing sites	Bahnhofstraße 47 D-39171 Osterweddingen Germany		
Name of the manufacturer	CIP 4 SRL		
Address of the manufacturer	Via Idiomi 6 20090 Assago (MI) Italy		
Location of manufacturing sites	Via Idiomi 6 20090 Assago (MI) Italy		
Name of the manufacturer	Kompak Nederland BV		
Address of the manufacturer	Munnikenheiweg 63 4879 NE Etten-Leur Netherlands		

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

Location of manufacturing sites

Active substance	1423 - Sodium benzoate
Name of the manufacturer	Emerald Kalama Chemical B.V.
Address of the manufacturer	Mijnweg 1 6167 AP Geleen Netherlands
Location of manufacturing sites	Montrealweg 15 3197 KH Rotterdam Netherlands

Munnikenheiweg 63 4879 NE Etten-Leur Netherlands

Active substance	1423 - Sodium benzoate
Name of the manufacturer	Eastman Chemical Company
Address of the manufacturer	200 South Wilcox Drive TN 37660-5280 Kingsport United States
Location of manufacturing sites	200 South Wilcox Drive TN 37660-5280 Kingsport United States
Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Distillerie Bonollo S.p.A.
Address of the manufacturer	Via Mosca 5 41043 Formigine Italy
Location of manufacturing sites	Localita' Paduni 03012 Anagni Italy
Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Tártaros Gonzalo Castello, SL
Address of the manufacturer	Concepción Arenal 32 03660 Novelda (Alicante) Spain
Location of manufacturing sites	Concepción Arenal 32 03660 Novelda (Alicante) Spain
Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	ALVINESA NATURAL INGREDIENTS S.A.
Address of the manufacturer	Cra. Daimiel – Valdepeñas, Km 4,8 13250 Daimiel (Ciudad Real) Spain
Location of manufacturing sites	Cra. Daimiel – Valdepeñas, Km 4,8 13250 Daimiel (Ciudad Real) Spain
Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Groupe Grap'sud
Address of the manufacturer	120 chemin de la regor 30360 Cruviers-Lascours France
Location of manufacturing sites	120 chemin de la regor 30360 Cruviers-Lascours France

Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Pahí S.L.
Address of the manufacturer	Av. de Madrid 64 08028 Barcelona Spain
Location of manufacturing sites	Av. de Madrid 64 08028 Barcelona Spain
Active substance	4404 (i) Tartaria said
7.0t. Fo Guideland	1424 - (+)-Tartaric acid
Name of the manufacturer	TARTÁRICO SARASA SL
Name of the manufacturer	TARTÁRICO SARASA SL

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 (%)
(+)-Tartaric acid		Active Substance		201-766-0	0,6
Sodium benzoate		Active Substance		208-534-8	0,8

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	

Precautionary statements				
4. Authorised use(s)				
4.1 Use description				
Use 1 - Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional				
Product type	PT01 - Human hygiene (Disinfectants)			
Where relevant, an exact description of the authorised use	Not applicable			
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:			
	Scientific name: Common name: Yeasts Development stage:			
	Scientific name: Common name: Enveloped viruses (limited virucidal) Development stage:			
Field(s) of use	Indoor			
	Hand disinfection in domestic areas (non-professional use). Hand disinfection in industrial areas and in other areas for professional activities, hospitals and other healthcare facilities (professional use).			
Application method(s)	Method: Pumping or squeezing. Detailed description: Pumping, or squeezing bottle to dose soap onto the hands and washing.			
Application rate(s) and frequencies	Application Rate: RTU Product. Use when necessary, as frequently as necessary. Dosage approximately 3 ml per use. Dilution (%): Number and timing of application: Use when necessary, as frequently as necessary.			

Category(ies) of users

Professional

General public (non-professional)

Pack sizes and packaging material

- 100, 125, 150, 200, 250, 300, 350, 400, 450, 500, 600, 650, 700, 750, 1000, 1100, 1200, 1300, 1500 or 2000 ml PET, PE or HDPE bottle with PP/PE liquid pump, PP, PVC or PE flip-top cap, pull-cap, push-cap or press-top cap.

- 4000, 5000, 6000, 7000, 10000, 15000, 20000, 25000 or 30000 ml PE or HDPE jerry can with PP, PVC or PE screw cap or dosing valve to refill bottles, or to be directly

connected to an industrial PP/PE pump system to dose soap.

- 100, 125, 150, 200, 250, 300, 350, 400, 450, 500, 600, 650, 700, 750, 1000, 1100, 1200, 1300, 1500 or 2000 ml collapsible PET, PE or HDPE bag or collapsible PET, PE or HDPE bottle with PP/PE liquid pump for use in soap dispensers.

4.1.1 Use-specific instructions for use

Hygienic Hand Wash: Wet hands. Pump at least 2 times to dose 3 ml of liquid on the hands. Rub hands in a washing motion. Continue washing motion for at least 60 seconds, rinse off with tap water and dry hands with a clean towel or paper cloth.
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
None
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
None, the product and packaging can be discarded with general (household) waste.
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.
5. General directions for use
5.1. Instructions for use
See use-specific instructions.