

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Hygienix Disinfecting Gel Wash DGWG-L-11191_07

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0018737-0000 1-4

R4BP asset number: EU-0018737-0052

1. ADMINISTRATIVE INFORMATION	3
1.1. Trade name(s) of the product	3
1.2. Authorisation holder	3
1.3. Manufacturer(s) of the product	3
1.4. Manufacturer(s) of the active substance(s)	6
2. PRODUCT COMPOSITION AND FORMULATION	8
2.1. Qualitative and quantitative information on the composition of the product	8
2.2. Type(s) of formulation	8
3. HAZARD AND PRECAUTIONARY STATEMENTS	9
4. AUTHORISED USE(S)	10
4.1. Use description	10
4.2. Use description	11
4.3. Use description	12
5. GENERAL DIRECTIONS FOR USE	14
5.1. Instructions for use	14
5.2. Risk mitigation measures	14
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	14
5.4. Instructions for safe disposal of the product and its packaging	14
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	14
6. OTHER INFORMATION	15

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Hygienix Disinfecting Gel Wash DGWG-L-11191_07
---------------	--

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Hygienix B.V.
	Address	Boslaan 4 1217 CV Hilversum Netherlands (the)
Authorisation number		EU-0018737-0000 1-4
<i>R4BP asset number</i>		EU-0018737-0052
Date of the authorisation		13/07/2023
Expiry date of the authorisation		31/05/2029

1.3. Manufacturer(s) of the product

Name of manufacturer	Hygienix B.V.
Address of manufacturer	Boslaan 4 1217 CV Hilversum Netherlands (the)
Location of manufacturing sites	Boslaan 4 1217 CV Hilversum Netherlands (the)

Name of manufacturer	Multifill B.V.
Address of manufacturer	Constructieweg 25a 3641 SB Mijdrecht Netherlands (the)
Location of manufacturing sites	Constructieweg 25a 3641 SB Mijdrecht Netherlands (the) Communicatieweg 24 3641 SE Mijdrecht Netherlands (the)

Name of manufacturer	CODI International B.V.
Address of manufacturer	Accustraart 10 3903 LX Veenendaal Netherlands (the)
Location of manufacturing sites	Accustraart 10 3903 LX Veenendaal Netherlands (the) Turbinestraat 19 3903 LV Veenendaal Netherlands (the)

Name of manufacturer	Incare Wet wipes
Address of manufacturer	Keizersveld 99 5803 AP Venray Netherlands (the)
Location of manufacturing sites	Keizersveld 99 5803 AP Venray Netherlands (the)

Name of manufacturer	Innovate Wet Wipes
Address of manufacturer	Am Hohen Stein 11 06618 Naumburg Germany
Location of manufacturing sites	Am Hohen Stein 11 06618 Naumburg Germany

Name of manufacturer	Van Dam Bodegraven B.V.
Address of manufacturer	Beneluxweg 8 2411 NG Bodegraven Netherlands (the)
Location of manufacturing sites	Beneluxweg 8 2411 NG Bodegraven Netherlands (the)

Name of manufacturer	Special Fills B.V.
Address of manufacturer	De Veken 129 1716 KG Opmeer Netherlands (the)
Location of manufacturing sites	De Veken 129 1716 KG Opmeer Netherlands (the)

Name of manufacturer	Girasol Natural Products B.V.
Address of manufacturer	Minervum 7357 4817 ZH Breda Netherlands (the)
Location of manufacturing sites	Minervum 7357 4817 ZH Breda Netherlands (the)

Name of manufacturer	LABORATOIRES ANIOS
Address of manufacturer	Pavé du moulin 59260 Lille-Hellemmes France
Location of manufacturing sites	Pavé du moulin 59260 Lille-Hellemmes France 3330 Rue de Lille 59262 Sainghin-en-Mélantois France

Name of manufacturer	Nuova Farmec Srl
Address of 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 manufacturer	KiiltoClean A/S
Address of manufacturer	Plums Vej 2 DK-5610 Assens Denmark
Location of manufacturing sites	Plums Vej 2 DK-5610 Assens Denmark

Name of manufacturer	Linköpings Tekniska Fabrik AB
Address of manufacturer	Barhällsgatan 14 582 39 Linköping Sweden
Location of manufacturing sites	Barhällsgatan 14 582 39 Linköping Sweden

Name of manufacturer	CID LINES
Address of manufacturer	Waterpoortstraat 2 8900 IEPER Belgium
Location of manufacturing sites	Waterpoortstraat 2 8900 IEPER Belgium

Name of manufacturer	FAMAR
Address of 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 manufacturer	Jagopro
Address of manufacturer	Szczakowska Street 35 43-600 Jaworzno Poland
Location of manufacturing sites	Szczakowska Street 35 43-600 Jaworzno Poland

Name of manufacturer	SARAYA
Address of 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 manufacturer	Unilever Italy Manufacturing S.r.l.
Address of manufacturer	Via Lever Gibbs 3 - 26841 Casalpusterlengo (LO) Italy
Location of manufacturing sites	Via Lever Gibbs 3 - 26841 Casalpusterlengo (LO) Italy

Name of manufacturer	Unilever Magyarország KFT
Address of 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 manufacturer	Unilever UK Ltd
Address of manufacturer	Wood St. CH62 4UY Birkenhead, Wirral United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Wood St. CH62 4UY Birkenhead, Wirral United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	DRAMERS S.A.
Address of manufacturer	RABOWICE, UL. OLSZYNOWA 38 62-020 SWARZEDZ Poland
Location of manufacturing sites	RABOWICE, UL. OLSZYNOWA 38 62-020 SWARZEDZ Poland

Name of manufacturer	Farmol SPA
Address of manufacturer	VIA VERDELLA 3 24040 COMUN NUOVO Italy
Location of manufacturing sites	via Mazzini 5 25030 Berlingo BS Italy

Name of manufacturer	Nice-Pak International Ltd
Address of manufacturer	Aber Park CH6 5EX Flint United Kingdom of Great Britain and Northern Ireland (the)

Location of manufacturing sites	Aber Park CH6 5EX Flint United Kingdom of Great Britain and Northern Ireland (the)
---------------------------------	--

Name of manufacturer	Nice-Pak Deutschland GmbH
Address of manufacturer	Bahnhofstraße 47 D-39171 Osterweddingen Germany
Location of manufacturing sites	Bahnhofstraße 47 D-39171 Osterweddingen Germany

Name of manufacturer	CIP 4 SRL
Address of manufacturer	Via Idiomi 6 20090 Assago (MI) Italy
Location of manufacturing sites	Via Idiomi 6 20090 Assago (MI) Italy

Name of manufacturer	Kompak Nederland BV
Address of manufacturer	Munnikenheiweg 63 4879 NE Etten-Leur Netherlands (the)
Location of manufacturing sites	Munnikenheiweg 63 4879 NE Etten-Leur Netherlands (the)

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

Active substance	(+)-Tartaric acid
Name of manufacturer	Distillerie Bonollo S.p.A.
Address of manufacturer	Via Mosca 5 41043 Formigine Italy
Location of manufacturing sites	Localita' Paduni 03012 Anagni Italy

Active substance	(+)-Tartaric acid
Name of manufacturer	Tártaros Gonzalo Castello, SL
Address of manufacturer	Concepción Arenal 32 03660 Novelda (Alicante) Spain
Location of manufacturing sites	Concepción Arenal 32 03660 Novelda (Alicante) Spain

Active substance	(+)-Tartaric acid
Name of manufacturer	ALVINESA NATURAL INGREDIENTS S.A.
Address of 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	(+)-Tartaric acid
Name of manufacturer	Groupe Grap'sud
Address of 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	(+)-Tartaric acid
Name of manufacturer	Pahí S.L.
Address of manufacturer	Av. de Madrid 64 08028 Barcelona Spain
Location of manufacturing sites	Av. de Madrid 64 08028 Barcelona Spain

Active substance	(+)-Tartaric acid
Name of manufacturer	TARTÁRICO SARASA SL
Address of manufacturer	C/ Costa Roja sn 17481 Sant Juliá de Ramis (Girona) Spain
Location of manufacturing sites	C/ Costa Roja sn 17481 Sant Juliá de Ramis (Girona) Spain

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

Active substance	Sodium benzoate
Name of manufacturer	Eastman Chemical Company
Address of manufacturer	200 South Wilcox Drive TN 37660-5280 Kingsport United States (the)
Location of manufacturing sites	200 South Wilcox Drive TN 37660-5280 Kingsport United States (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 (%)
(+)-Tartaric acid		active substance		201-766-0	0,6
Sodium benzoate		active substance		208-534-8	0,8

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use #4.1 Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Not applicable
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use Hand wash disinfection in domestic areas (non-professional use). Hand wash 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 frequency	Application Rate: RTU Product. Dosage approximately 3 ml per use. 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 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap. - 3000 - 30000 ml (PET, PE or HDPE) jerry can to refill bottles, or to be directly connected to an industrial (PP/PE) pump system to dose soap. With (PP, PVC or PE) dosing valve, or with (PP, PVC or PE) screw-cap. - 100 - 2500 ml collapsible (PET, PE or HDPE) (laminated) bag, pouch or collapsible bottle to refill bottles or for use in soap dispensers. With (PP/PVC/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

4.1.1. Use-specific instructions for use

Hygienic Hand Wash: Wet hands. 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.

4.2. Use description

Table 2. Use #4.2 Body Wash Disinfection, PT01, pumping or squeezing, professional and non-professional

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Not applicable
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: Enveloped viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Skin disinfection in domestic areas (non-professional use). Skin disinfection in industrial areas and in other areas for professional activities, hospitals and other healthcare facilities (professional use).</p>
Application method(s)	<p>Method: Pumping or squeezing.</p> <p>Detailed description: Pumping, or squeezing bottle to dose soap onto the skin and washing.</p>
Application rate(s) and frequency	<p>Application Rate: RTU Product. Dosage approximately 60 ml per use.</p> <p>Number and timing of application: Use when necessary, as frequently as necessary.</p>
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	<p>- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.</p> <p>- 3000 - 30000 ml (PET, PE or HDPE) jerry can to refill bottles, or to be directly connected to an industrial (PP/PE) pump system to dose soap. With (PP, PVC or PE) dosing valve, or with (PP, PVC or PE) screw-cap.</p>

- 100 - 2500 ml collapsible (PET, PE or HDPE) (laminated) bag, pouch or collapsible bottle to refill bottles or for use in soap dispensers. With (PP/PVC/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

4.2.1. Use-specific instructions for use

Hygienic body wash: Use only on skin that is not damaged and skin that will not be opened after disinfection. Treat body parts separately. Apply appr. 60 ml of product (divided in portions of appr. 10 ml) onto wetted skin, rub for 60 seconds and rinse off with clean tap water. Ensure complete wetting.

4.2.2. Use-specific risk mitigation measures

None

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

None

4.2.4. 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.

4.2.5. 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.

4.3. Use description

Table 3. Use #4.3 Scalp Disinfection with Body Wash application, PT01, pumping or squeezing, professional and non-professional

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Not applicable
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: Enveloped viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Scalp disinfection in domestic areas (non-professional use). Scalp disinfection in industrial areas and in other areas for professional activities, hospitals and other healthcare facilities (professional use).</p>
Application method(s)	<p>Method: Pumping or squeezing.</p> <p>Detailed description: Pumping, or squeezing bottle to dose soap onto the scalp and washing.</p>
Application rate(s) and frequency	Application Rate: RTU Product. Dosage approximately 6 -10 ml per use.

	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 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap. - 3000 - 30000 ml (PET, PE or HDPE) jerry can to refill bottles, or to be directly connected to an industrial (PP/PE) pump system to dose soap. With (PP, PVC or PE) dosing valve, or with (PP, PVC or PE) screw-cap. - 100 - 2500 ml collapsible (PET, PE or HDPE) (laminated) bag, pouch or collapsible bottle to refill bottles or for use in soap dispensers. With (PP/PVC/PE) liquid pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

4.3.1. Use-specific instructions for use

Hygienic scalp wash: Use only on skin that is not damaged and skin that will not be opened after disinfection. Wet the hair and scalp. Spread the hair to access the scalp and apply 6 - 10 ml of product onto the scalp. Rub for 60 seconds and rinse off with clean tap water.

4.3.2. Use-specific risk mitigation measures

None

4.3.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

4.3.4. 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.

4.3.5. 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 USE¹

5.1. Instructions for use

See use-specific instructions.

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

None

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

None, the product and packaging can be discarded with general (household) waste.

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

Shelf life: 3 years. Store at room temperature. Protect from frost.

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

6. OTHER INFORMATION