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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 (wipes)

Product type(s)

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

PT04: Food and feed area

Authorisation number: EU-0018737-0001

R4BP asset number: IE-0024601-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Hygienix Cleaner Disinfectant Hygienix Cleaning and Disinfection Wipes EcoSan Germshield Wipes Hygienix Cleaner Disinfectant Wipes BactoGuard Wipes Hygienix Disinfecting Wipes Dreumex Disinfectant & Cleaning Wipes
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Hygienix B.V.
	Address	Boslaan 4 1217 CV Hilversum Netherlands
Authorisation number		EU-0018737-0001
<i>R4BP asset number</i>		IE-0024601-0000
Date of the authorisation		31/05/2019
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	Hygienix B.V. site 1 Boslaan 4 1217 CV Hilversum Netherlands (the)

Name of manufacturer	CODI International B.V.
Address of manufacturer	Accustraat 10 3903 LX Veenendaal Netherlands (the)
Location of manufacturing sites	CODI International B.V. site 1 Accustraat 10 3903 LX Veenendaal Netherlands (the) CODI International B.V. site 2 Turbinestraat 19 3903 LV Veenendaal Netherlands (the)

Name of manufacturer	Multifill B.V.
Address of manufacturer	Constructieweg 25a 3641 SB Mijdrecht Netherlands (the)
Location of manufacturing sites	Multifill B.V. site 1 Constructieweg 25a 3641 SB Mijdrecht Netherlands (the) Multifill B.V. site 2 Communicatieweg 24 3641 SE Mijdrecht Netherlands (the)

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

Location of manufacturing sites	Incare Wet wipes site 1 Keizersveld 99 5803 AP Venray Netherlands (the)
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Name of manufacturer	Innovate Wet Wipes
Address of manufacturer	Am Hohen Stein 11 06618 Naumburg Germany
Location of manufacturing sites	Innovate Wet Wipes site 1 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	Van Dam Bodegraven B.V. site 1 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	Special Fills B.V. site 1 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	Girasol Natural Products B.V. site 1 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	LABORATOIRES ANIOS site 1 Pavé du moulin 59260 Lille-Hellemmes France LABORATOIRES ANIOS site 2 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	Nuova Farmec Srl site 1 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	KiiltoClean A/S site 1 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	Linköpings Tekniska Fabrik AB site 1 Barhällsgatan 14 582 39 Linköping Sweden
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Name of manufacturer	CID LINES
Address of manufacturer	Waterpoortstraat 2 8900 IEPER Belgium
Location of manufacturing sites	CID LINES site 1 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	FAMAR site 1 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	Jagopro site 1 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	SARAYA site 1 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	Unilever Italy Manufacturing S.r.l. site 1 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	Unilever Magyarország KFT site 1 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	Unilever UK Ltd site 1 Wood St. CH62 4UY Birkenhead, Wirral United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	DRAMERS S.A.
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Address of manufacturer	RABOWICE, UL. OLSZYNOWA 38 62-020 SWARZEDZ Poland
Location of manufacturing sites	DRAMERS S.A. site 1 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	Farmol SPA site 1 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	Nice-Pak International Ltd site 1 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	Nice-Pak Deutschland GmbH site 1 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	CIP 4 SRL site 1 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	Kompak Nederland BV site 1 Munnikenheiweg 63 4879 NE Etten-Leur Netherlands (the)

Name of manufacturer	Dreumex B.V.
Address of manufacturer	Dommelstraat 1 5347 JK Oss Netherlands (the)
Location of manufacturing sites	Dreumex B.V. site 1 Dommelstraat 1 5347 JK Oss 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	Distillerie Bonollo S.p.A. site 1 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	Tártaros Gonzalo Castello, SL site 1 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	ALVINESA NATURAL INGREDIENTS S.A. site 1 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	Groupe Grap'sud site 1 120 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	Pahí S.L. site 1 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	TARTÁRICO SARASA SL site 1 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	Emerald Kalama Chemical B.V. site 1 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	Eastman Chemical Company site 1 200 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	0,4
Sodium benzoate		active substance		208-534-8	0,4

2.2. Type(s) of formulation

AL and XX, ready to use liquids and wipes

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses and mycobacteria, surface application followed by wiping, professional and non-professional

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
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 Scientific name: no data Common name: Mycobacteria Development stage: no data
Field(s) of use	indoor use Disinfection of hard surfaces in and around the house and work spaces. Disinfection of hard surfaces in the industrial sector, public sector, in hospitals and in other institutes for healthcare..
Application method(s)	Method: Spraying, foaming or pouring, followed by wiping. Detailed description: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	Application rate: RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m ²). 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	- 50 - 3000 ml (PET, PE or HDPE) bottle with (PP/PVC/PE) spray pump, foam sprayer, trigger sprayer or pressurized sprayer, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

	- 3000 - 30000 ml (PET, PE or HDPE) jerry can with (PP/PVC/PE) dosing pump or pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.
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4.1.1. Use-specific instructions

Apply product to the surface by spraying, foaming or pouring. Spread the liquid with a wipe onto the surface to ensure the whole surface is well wetted. Allow the surface to remain wet for at least the applicable contact time and let air dry. For use against mycobacteria: use only on surfaces that can be excluded from patients and staff for the duration of the contact time.

Contact times (min):

Bacteria, yeasts and enveloped viruses - 2

Mycobacteria - 30

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

For non-professional use: Keep away from children. Do not use on acid sensitive stone, such as marble, or on soft metals.

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

None

4.1.5. 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.

4.1.6. 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. Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses and mycobacteria, surface application followed by wiping, professional and non-professional

Product type	PT04: Food and feed area
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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> <p>Scientific name: no data Common name: Mycobacteria Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of hard surfaces that can be in contact with food and feed and food ingredients, including kitchens in hospitals and kitchens in other institutes for healthcare.</p>
Application method(s)	<p>Method: Spraying, foaming or pouring, followed by wiping.</p> <p>Detailed description: Application to the surface followed by wiping with unspecified wipe.</p>
Application rate(s) and frequency	<p>Application rate: RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m²).</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>- 50 - 3000 ml (PET, PE or HDPE) bottle with (PP/PVC/PE) spray pump, foam sprayer, trigger sprayer or pressurized sprayer, 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 with (PP/PVC/PE) dosing pump or pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.</p>

4.2.1. Use-specific instructions

Apply product to the surface by spraying, foaming or pouring. Spread the liquid with a wipe onto the surface to ensure the whole surface is well wetted. Allow the surface to remain wet for at least the applicable contact time and let air dry.

Contact times (min):
Bacteria, yeasts and enveloped viruses - 2
Mycobacteria - 30

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

For non-professional use: Keep away from children. Do not use on acid sensitive stone, such as marble, or on soft metals.

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

None

4.2.5. 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.

4.2.6. 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. Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
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

	<p>Scientific name: no data Common name: Enveloped viruses Development stage: no data</p> <p>Scientific name: no data Common name: Mycobacteria Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of hard surfaces in and around the house and work spaces. Disinfection of hard surfaces in the industrial sector, public sector, in hospitals and in other institutes for healthcare.</p>
Application method(s)	<p>Method: Wiping with an impregnated wet wipe.</p> <p>Detailed description: Wiping the surface with an impregnated wet wipe.</p>
Application rate(s) and frequency	<p>Application rate: RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m²).</p> <p>Number and timing of application: Use when necessary, as frequently as necessary.</p>
Category(ies) of users	<p>professional ; general public (non-professional)</p>
Pack sizes and packaging material	<p>Single (1) wipe sachet, made of laminated or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package.</p> <p>- The size of the wipe ranges from 5 cm x 5 cm to 40 cm x 40 cm, whereby each wipe is impregnated with 250% to 450% of liquid weight to the wipe weight.</p> <p>- Wipe substrate weight ranges from 35 – 70 gr/m².</p> <p>- Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester, Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.</p>

4.3.1. Use-specific instructions

Take a wipe from the pack. Use only wipes that are moist. Wipe the surface until the whole surface is wet. Allow the surface to remain wet for at least the applicable contact time and let air dry, or wipe dry with a (paper) towel or (micro-)fibre cloth. Where applicable: close the lid or label to seal the pack after use. For use against mycobacteria: use only on surfaces that can be excluded from patients and staff for the duration of the contact time.

Contact times (min):
Bacteria, yeasts and enveloped viruses - 2
Mycobacteria - 30

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

For non-professional use: Keep away from children. Do not use on acid sensitive stone, such as marble, and on soft metals.

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

None

4.3.5. 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.

4.3.6. 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.

4.4. Use description

Table 4. Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional

Product type	PT04: Food and feed area
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

	<p>Common name: Enveloped viruses Development stage: no data</p> <p>Scientific name: no data Common name: Mycobacteria Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of hard surfaces that can be in contact with food and feed and food ingredients, including kitchens in hospitals and kitchens in other institutes for healthcare.</p>
Application method(s)	<p>Method: Wiping with an impregnated wet wipe.</p> <p>Detailed description: Wiping the surface with an impregnated wet wipe.</p>
Application rate(s) and frequency	<p>Application rate: RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m2).</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>Single (1) wipe sachet, made of laminated or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package.</p> <p>- The size of the wipe ranges from 5 cm x 5 cm to 40 cm x 40 cm, whereby each wipe is impregnated with 250% to 450% of liquid weight to the wipe weight.</p> <p>- Wipe substrate weight ranges from 35 – 70 gr/m2.</p> <p>- Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester, Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.</p>

4.4.1. Use-specific instructions

Take a wipe from the pack. Use only wipes that are moist. Wipe the surface until the whole surface is wet. Allow the surface to remain wet for at least the applicable contact time and let air dry, or wipe dry with a (paper) towel or (micro-)fibre cloth. Where applicable: close the lid or label to seal the pack after use.

Contact times (min):

Bacteria, yeasts and enveloped viruses - 2

Mycobacteria - 30

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

For non-professional use: Keep away from children. Do not use on acid sensitive stone, such as marble, and on soft metals.

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

None

4.4.5. 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.

4.4.6. 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

See use-specific risk mitigation measures.

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