Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the eCA)

Hygienix Biocidal Product Family

Product types PT01, PT02, PT04

L-(+)-Tartaric Acid and Sodium Benzoate as included in Annex I

Asset Number: EU-0018737-0000
Evaluating Competent Authority: Ctgb, The Netherlands

Date: September 2022

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1 CONCLUSION

The Hygienix Biocidal Product Family is a family based on the active substances tartaric acid and sodium benzoate, substances which are both included in the Annex I of the BPR (528/2012/EU).

None of the products within the family require a hazard classification according to Regulation (EC) 1272/2008, which allows the family to be considered in a simplified authorization procedure.

The shelf-life of Meta SCP 1, 2, 4 and 5 is supported to be 3 years. The shelf-life of Meta SPC 3 and 6 is supported to be 2 years. Storage conditions proposed include 'protect from frost' and to store the products at room temperature.

Efficacy: The Hygienix Biocidal Product Family will be authorized for use on hard surfaces and on human skin. The target organisms for which efficacy is substantiated are bacteria, yeast, enveloped viruses, viruses and mycobacteria. In Meta SPC 1 the full virus claim is not substantiated, only enveloped viruses can be authorized as target organism. In Meta SPC2 full virucidal activity is substantiated for all uses.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Hygienix Biocidal Product Family	Netherlands

The structure of the Hygienix Biocidal Product Family, with the meta-SPC's and the products per meta-SPC is detailed in the **Confidential Annex** "*Product (family) structure and formulations*". In this **Confidential Annex** more detailed information is provided on the qualitative and quantitative information on the composition of the biocidal product family, the compositions of the meta-SPC's and qualitative and quantitative information on the composition of the biocidal products.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Hygienix B.V.
	Address	Koninginneweg 8, 1217 KX Hilversum Netherlands
Authorisation number	EU-0018737-0000	
Date of the authorisation	31 May 2019	
Expiry date of the authorisation	31 May 2029	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Hygienix B.V.
Address of manufacturer	Koninginneweg 8, 1217 KX Hilversum Netherlands
Location of manufacturing sites	Koninginneweg 8, 1217 KX Hilversum Netherlands

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

Name of manufacturer	CODI International B.V.
Address of manufacturer	Accustraat 10, 3903 LX Veenendaal Netherlands
Location of manufacturing sites	Accustraat 10, 3903 LX Veenendaal Netherlands Turbinestraat 19, 3903 LV Veenendal Netherlands

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

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
Location of manufacturing sites	Beneluxweg 8, 2411 NG Bodegraven Netherlands

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

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

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 Magyarorszag 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
Location of manufacturing sites	Wood St., CH62 4UY Birkenhead, Wirral United Kingdom

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
Location of manufacturing sites	Aber Park, CH6 5EX Flint United Kingdom

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
Location of manufacturing sites	Munnikenheiweg 63, 4879 NE Etten-Leur Netherlands

Name of manufacturer	Dreumex B.V.
Address of manufacturer	Dommelstraat 1, 5347 JK Oss Netherlands
Location of manufacturing sites	Dommelstraat 1, 5347 JK Oss Netherlands

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Sodium Benzoate
Name of manufacturer	Emerald Kalama Chemical B.V.
Address of manufacturer	Mijnweg 1, 6167 AP, Geleen, The Netherlands
Location of manufacturing sites	Montrealweg 15, 3197 KH Rotterdam, The Netherlands

Active substance	Sodium Benzoate
Name of manufacturer	Eastman Chemical Company
Address of 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	(+)-Tartaric Acid
Name of manufacturer	Distillerie Bonollo S.p.A.
Address of manufacturer	Via Mosca 5, 41043 Formigine (MO), Italy
Location of manufacturing sites	Localita' Paduni, 03012 Anagni (FR), 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

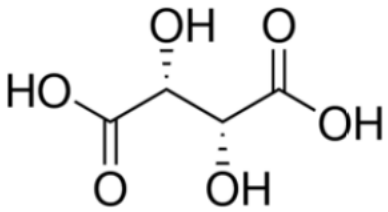
2.1.2 Product (family) composition and formulation

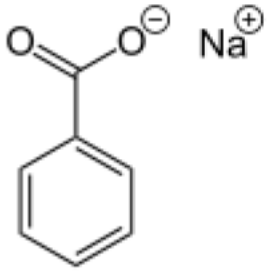
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No X (not applicable, active substances are on Annex I)

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	L-(+)-Tartaric Acid
IUPAC or EC name	(2R,3R)-(+)-2,3-Dihydroxybutanedioic acid
EC number	201-766-0
CAS number	87-69-4
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	99.7%
Structural formula	

Main constituent(s)	
ISO name	Sodium Benzoate
IUPAC or EC name	Sodium Benzoate
EC number	208-534- 8
CAS number	532-32-1
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	99.9%
Structural formula	

2.1.2.2 Candidate(s) for substitution

The biocidal product family does not contain candidates for substitution in accordance with article 10 of the BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
(+)-Tartaric acid	(2R,3R)-(+)-2,3-Dihydroxybutane dioic acid	Active substance	87-69-4	201-766-0	0.4	0.9
Sodium Benzoate	Sodium benzoate	Active substance	532-32-1	208-534-8	0.4	0.9
Other		Non-active substance			To 100	To 100

2.1.2.4 Information on technical equivalence

Not applicable. The substances are included in annex I of the BPR. No reference specifications are available.

2.1.2.5 Information on the substance(s) of concern

No substances of concern were identified.
No alerts for endocrine disruptor were identified for the co-formulants.

2.1.2.6 Type of formulation

AL-Any other liquid XX-Other: ready to use wipes

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	none
Hazard statement	none
Labelling	
Signal words	none
Hazard statements	none
Precautionary statements	none
Note	-

* According to the Note for Guidance, CA-Nov14-Doc.5.8 – Final; Implementing the new concept of biocidal product families, points (28), (30), and (31), the "worst case" assessment (i.e. lowest efficacy and highest risk) may be done on the Meta SPC level, when an overall worst case for the whole family cannot readily be established, and taking

into consideration the composition of the products and the different uses described in each meta SPC.
The minimum and maximum concentration products for the whole Hygienix Biocidal Product Family, per its composition on the highest level (level 1), do not represent actual potential biocidal products within the family, and should rather be considered theoretical concepts. In reality, at the highest level a choice of (concentrations of) substances and substance combinations will be made, rather than just applying all substances at their maximum concentrations.
The Meta SPCs therefore more accurately reflect the actual biocidal products of the Hygienix Biocidal Product Family. Consequently, the minimum efficacy and maximum risk were determined on the level of the six Meta SPCs.
The maximum risk for each Meta SPC was assessed based on the determination of the hazard classification and labelling of the formulation with the maximum concentration of all substances within each Meta SPC. From these assessments for all Meta SPCs (references 11-16), it can be concluded that the maximum concentration of active and non-active ingredients (except water) within each Meta SPC does not result in a hazard classification of the products of the biocidal product family. As such, none of the products of the biocidal product family are classified as hazardous and no personal protective equipment is necessary for the use of the products covered by the Hygienix Biocidal Product Family.

2.1.4 Authorised use(s)

Meta SPC 1: Surface disinfection
(Representative product: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008)

2.1.4.1 Use description for use #1.1

Table 1 Use #1.1 – Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, and mycobacteria, surface application followed by wiping, professional and non-professional

Product Type	PT02
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Mycobacteria
Field of use	Indoor. 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)	Spraying, foaming or pouring, followed by wiping: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)

Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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.

2.1.4.2 Use-specific instructions for use #1.1

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

2.1.4.3 Use-specific risk mitigation measures for use #1.1

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

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #1.1

None

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #1.1

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

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #1.1

See general directions for use.

2.1.4.7 Use description for use #1.2

Table 2 Use #1.2 – Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses and mycobacteria, surface application followed by wiping, professional and non-professional

Product Type	PT04

Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Mycobacteria
Field of use	Indoor. 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.
Application method(s)	Spraying, foaming or pouring, followed by wiping: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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.

2.1.4.8 Use-specific instructions for use #1.2

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

2.1.4.9 Use-specific risk mitigation measures for use #1.2

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

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #1.2

None

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #1.2

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

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #1.2

See general directions for use.

2.1.4.13 Use description for use #1.3

Table 3 Use #1.3 – 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
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Mycobacteria
Field of use	Indoor. 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)	Wiping with an impregnated wet wipe: Wiping the surface with an impregnated wet wipe.
Application rate(s) and frequency	RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m^2). Use when necessary, as frequently as necessary
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	Single (1) wipe sachet, made of laminated PET, PET/PE, PE or blends thereof, or; Flow pack made of laminated PET, PET/PE or PE with 8 - 200 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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. - Wipe substrate weight ranges from 35 – 70 gr/m2. - 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 variations thereof.

2.1.4.14 Use-specific instructions for use #1.3

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 dry (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

2.1.4.15 Use-specific risk mitigation measures for use #1.3

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

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #1.3

None

2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #1.3

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

2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #1.3

See general directions for use.

2.1.4.19 Use description for use #1.4

Table 4 Use #1.4 – 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
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Mycobacteria
Field of use	Indoor.

	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.
Application method(s)	Wiping with an impregnated wet wipe: Wiping the surface with an impregnated wet wipe.
Application rate(s) and frequency	RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	Single (1) wipe sachet, made of laminated PET, PET/PE, PE or blends thereof, or; Flow pack made of laminated PET, PET/PE or PE with 8 - 200 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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. - Wipe substrate weight ranges from 35 – 70 gr/m2. - 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 variations thereof.

2.1.4.20 Use-specific instructions for use #1.4

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 dry (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

2.1.4.21 Use-specific risk mitigation measures for use #1.4

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

2.1.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #1.4

None

2.1.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #1.4

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

2.1.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #1.4

See general directions for use.

Meta SPC 2: Surface disinfection
(Representative product: Hygienix Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022)

2.1.4.25 Use description for use #2.1

Table 5 Use #2.1 – Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, surface application followed by wiping, professional and non-professional

Product Type	PT02
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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)	Spraying, foaming or pouring, followed by wiping: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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.

2.1.4.26 Use-specific instructions for use #2.1

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 viruses and 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 Viruses - 30 Mycobacteria - 60

2.1.4.27 Use-specific risk mitigation measures for use #2.1

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

2.1.4.28 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.1

None

2.1.4.29 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.1

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

2.1.4.30 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #2.1

See general directions for use.

2.1.4.31 Use description for use #2.2

Table 6 Use #2.2 – Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, surface application followed by wiping, professional and non-professional

Product Type	PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor.

	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.
Application method(s)	Spraying, foaming or pouring, followed by wiping: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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.

2.1.4.32 Use-specific instructions for use #2.2

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
Viruses - 30
Mycobacteria - 60

2.1.4.33 Use-specific risk mitigation measures for use #2.2

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

2.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.2

None

2.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.2

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

2.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #2.2

See general directions for use.

2.1.4.37 Use description for use #2.3

Table 7 Use #2.3 – Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, spraying or foaming, professional and non-professional

Product Type	PT02
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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)	Spraying, or foaming with a foam sprayer or foam nozzle: Coarse spraying, or foaming with a foam sprayer or foam nozzle.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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) pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

2.1.4.38 Use-specific instructions for use #2.3

Spray liquid or foam onto the surface until the whole surface is wet (approximately 20 ml/m^2). Allow the surface to remain wet for at least the applicable contact time and let air dry, or wipe dry with a dry (paper) towel or (micro-)fibre cloth. For use against viruses and 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 - 5
Viruses - 30
Mycobacteria - 60

2.1.4.39 Use-specific risk mitigation measures for use #2.3

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

2.1.4.40 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.3

None

2.1.4.41 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.3

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

2.1.4.42 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #2.3

See general directions for use.

2.1.4.43 Use description for use #2.4

Table 8 Use #2.4 – Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, spraying or foaming, professional and non-professional

Product Type	PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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.
Application method(s)	Spraying, or foaming with a foam sprayer or foam nozzle: Coarse spraying, or foaming with a foam sprayer or foam nozzle.
Application rate(s) and frequency	RTU Product. Use as much liquid as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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) pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

2.1.4.44 Use-specific instructions for use #2.4

Spray liquid or foam onto the surface until the whole surface is wet (approximately 20 ml/m2). Allow the surface to remain wet for at least the applicable contact time and let air dry, or wipe dry with a dry (paper) towel or (micro-)fibre cloth. Contact times (min): Bacteria, yeasts and enveloped viruses - 5 Viruses - 30 Mycobacteria - 60

2.1.4.45 Use-specific risk mitigation measures for use #2.4

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

2.1.4.46 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.4

None

2.1.4.47 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.4

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

2.1.4.48 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #2.4

See general directions for use.

2.1.4.49 Use description for use #2.5

Table 9 Use #2.5 – Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, pouring and spreading, professional and non-professional

Product Type	PT02
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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)	Pouring and spreading: Pouring the liquid onto the surface and spreading with a cloth, towel, scrubber, mop, etc.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 3000 ml (PET, PE, or HDPE) bottle for direct use or as refill. With (PP, PVC or PE) screw-, pull-, push- or flip-top cap. - 3000 - 30000 ml (PET, PE or HDPE) jerry can with (PP, PVC or PE) dosing valve for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

2.1.4.50 Use-specific instructions for use #2.5

Pour liquid through dosing mechanism onto the surface and spread liquid with a (micro-fibre) towel or cloth, scrubber or floor mop 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 dry (paper) towel or (micro-fibre) cloth, or rinse with water. For use against viruses and/or 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 - 5
Viruses - 30
Mycobacteria - 60

2.1.4.51 Use-specific risk mitigation measures for use #2.5

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

2.1.4.52 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.5

None

2.1.4.53 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.5

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

2.1.4.54 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #2.5

See general directions for use.

2.1.4.55 Use description for use #2.6

Table 10 Use #2.6 – Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, pouring and spreading, professional and non-professional

Product Type	PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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.
Application method(s)	Pouring and spreading: Pouring the liquid onto the surface and spreading with a cloth, towel, scrubber, mop, etc.
Application rate(s) and frequency	RTU Product. Use as much liquid as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 3000 ml (PET, PE, or HDPE) bottle for direct use or as refill. With (PP, PVC or PE) screw-, pull-, push- or flip-top cap. - 3000 - 30000 ml (PET, PE or HDPE) jerry can with (PP, PVC or PE) dosing valve for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

2.1.4.56 Use-specific instructions for use #2.6

Pour liquid through dosing mechanism onto the surface and spread liquid with a (micro-fibre) towel or cloth, scrubber, or floor mop 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 dry (paper) towel or (micro-fibre) cloth, or rinse with water.

Contact times (min):
Bacteria, yeasts and enveloped viruses - 5
Viruses - 30
Mycobacteria - 60

2.1.4.57 Use-specific risk mitigation measures for use #2.6

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

2.1.4.58 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.6

None

2.1.4.59 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.6

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

2.1.4.60 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #2.6

See general directions for use.

2.1.4.61 Use description for use #2.7

Table 11 Use #2.7 – Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional

Product Type	PT02
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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)	Wiping with an impregnated wet wipe: Wiping the surface with an impregnated wet wipe.
Application rate(s) and frequency	RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m^2). Use when necessary, as frequently as necessary
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	Single (1) wipe sachet, made of laminated PET, PET/PE, PE or blends thereof, or; Flow pack made of laminated PET, PET/PE or PE with 8 - 200 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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.

	- Wipe substrate weight ranges from 35 – 70 gr/m2. - 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 variations thereof.

2.1.4.62 Use-specific instructions for use #2.7

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 dry (paper) towel or (micro-)fibre cloth. Where applicable: close the lid or label to seal the pack after use. For use against viruses and/or 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 Viruses - 30 Mycobacteria - 60

2.1.4.63 Use-specific risk mitigation measures for use #2.7

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

2.1.4.64 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.13

None

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.7

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

2.1.4.66 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #2.7

See general directions for use.

2.1.4.67 Use description for use #2.8

Table 12 Use #2.8 – Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional

Product Type	PT04

Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. 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.
Application method(s)	Wiping with an impregnated wet wipe: Wiping the surface with an impregnated wet wipe.
Application rate(s) and frequency	RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	Single (1) wipe sachet, made of laminated PET, PET/PE, PE or blends thereof, or; Flow pack made of laminated PET, PET/PE or PE with 8 - 200 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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. - Wipe substrate weight ranges from 35 – 70 gr/m2. - 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 variations thereof.

2.1.4.68 Use-specific instructions for use #2.8

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 dry (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 Viruses - 30 Mycobacteria - 60

2.1.4.69 Use-specific risk mitigation measures for use #2.8

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

2.1.4.70 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #2.8

None

2.1.4.71 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #2.8

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

2.1.4.72 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage for use #2.8

See general directions for use.

Meta SPC 3: Hand disinfection
(Representative product: Hygienix Disinfecting Foam Wash DFWG-L-06163)

2.1.4.73 Use description for use #3.1

Table 13 Use #3.1 – Hand and skin disinfection, PT01, foaming or spraying, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor. 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)	Foaming or spraying: Dosing foam or liquid onto the hands and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 3 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)

Pack sizes and packaging material	- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) foam pump, liquid pump or spray 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) foam pump, liquid pump or spray pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

2.1.4.74 Use-specific instructions for use #3.1

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 30 seconds, rinse off with tap water and dry hands with a clean towel or paper cloth.

2.1.4.75 Use-specific risk mitigation measures for use #3.1

None

2.1.4.76 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #3.1

None

2.1.4.77 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #3.1

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

2.1.4.78 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #3.1

See general directions for use.

Meta SPC 4: Hand disinfection (Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06161)

2.1.4.79 Use description for use #4.1

Table 14 Use #4.1 – Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional

Product Type	PT01

Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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)	Pumping or squeezing: Pumping, or squeezing bottle to dose soap onto the hands and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 3 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
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.

2.1.4.80 Use-specific instructions for use #4.1

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.

2.1.4.81 Use-specific risk mitigation measures for use #4.1

None

2.1.4.82 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #4.1

None

2.1.4.83 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #4.1

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

2.1.4.84 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #4.1

See general directions for use.

2.1.4.85 Use description for use #4.2

Table 15 Use #4.2 – Body Wash Disinfection, PT01, pumping or squeezing, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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).
Application method(s)	Pumping or squeezing: Pumping, or squeezing bottle to dose soap onto the skin and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 60 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
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.

2.1.4.86 Use-specific instructions for use #4.2

Hygienic body wash: Use only on skin that is not damaged and skin that will not be opened after disinfection. Treat body parts separately. For a complete body wash, 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.

2.1.4.87 Use-specific risk mitigation measures for use #4.2

None

2.1.4.88 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #4.2

None

2.1.4.89 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #4.2

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

2.1.4.90 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #4.2

See general directions for use.

2.1.4.91 Use description for use #4.3

Table 16 Use #4.3 – Scalp Disinfection with Body Wash application, PT01, pumping or squeezing, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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).
Application method(s)	Pumping or squeezing: Pumping, or squeezing bottle to dose soap onto the scalp and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 6 -10 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
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.

2.1.4.92 Use-specific instructions for use #4.3

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.

2.1.4.93 Use-specific risk mitigation measures for use #4.3

None

2.1.4.94 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #4.3

None

2.1.4.95 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #4.3

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

2.1.4.96 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #4.3

See general directions for use.

Meta SPC 5: Hand disinfection (Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06163)

2.1.4.97 Use description for use #5.1

Table 17 Use #5.1 – Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor. 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)	Pumping or squeezing: Pumping, or squeezing bottle to dose soap onto the hands and washing.

Application rate(s) and frequency	RTU Product. Dosage approximately 3 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
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.

2.1.4.98 Use-specific instructions for use #5.1

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 30 seconds, rinse off with tap water and dry hands with a clean towel or paper cloth.

2.1.4.99 Use-specific risk mitigation measures for use #5.1

None

2.1.4.100 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #5.1

None

2.1.4.101 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #5.1

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

2.1.4.102 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #5.1

See general directions for use.

Meta SPC 6: Hand disinfection (Representative product: Hygienix Disinfecting Foam Wash DFWS-L-06161)

2.1.4.103 Use description for use #6.1

Table 18 Use #6.1 – Hand and skin disinfection, PT01, foaming or spraying, professional

and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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)	Foaming or spraying: Dosing foam or liquid onto the hands and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 3 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) foam pump, liquid pump or spray 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) foam pump, liquid pump or spray pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

2.1.4.104 Use-specific instructions for use #6.1

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 30 seconds, rinse off with tap water and dry hands with a clean towel or paper cloth.

2.1.4.105 Use-specific risk mitigation measures for use #6.1

None

2.1.4.106 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #6.1

None

2.1.4.107 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #6.1

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

2.1.4.108 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #6.1

See general directions for use.

2.1.4.109 Use description for use #6.2

Table 19 Use #6.2 – Body Wash Disinfection, PT01, foaming or spraying, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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).
Application method(s)	Foaming or spraying: Dosing foam or liquid onto the skin and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 60 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) foam pump, liquid pump or spray 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) foam pump, liquid pump or spray pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

2.1.4.110 Use-specific instructions for use for use #6.2

Hygienic body wash: Use only on skin that is not damaged and skin that will not be opened after disinfection. Treat body parts separately. For a complete body wash, apply appr. 60 ml of product (divided in portions of appr. 10 ml) onto wetted skin, rub for 30 seconds and rinse off with clean tap water. Ensure complete wetting.

2.1.4.111 Use-specific risk mitigation measures for use #6.2

None

2.1.4.112 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #6.2

None

2.1.4.113 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #6.2

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

2.1.4.114 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #6.2

See general directions for use.

2.1.4.115 Use description for use #6.3

Table 20 Use #6.3 – Scalp Disinfection with Body Wash application, PT01, foaming or spraying, professional and non-professional

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor. 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).
Application method(s)	Foaming or spraying: Dosing foam or liquid onto the skin and washing.
Application rate(s) and frequency	RTU Product. Dosage approximately 6 - 10 ml per use. Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)

Pack sizes and packaging material	- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) foam pump, liquid pump or spray 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) foam pump, liquid pump or spray pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

2.1.4.116 Use-specific instructions for use for use #6.3

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 30 seconds and rinse off with clean tap water.

2.1.4.117 Use-specific risk mitigation measures for use #6.3

None

2.1.4.118 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for use #6.3

None

2.1.4.119 Where specific to the use, the instructions for safe disposal of the product and its packaging for use #6.3

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

2.1.4.120 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage for use #6.3

See general directions for use.

2.1.5 General directions for use[1]

Meta SPC 1: Surface disinfection
(Representative product: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008)

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC.

2.1.5.1. Instructions for use

See use-specific instructions.

2.1.5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

None

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

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

2.1.5.5. 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.

Meta SPC 2: Surface disinfection
(Representative product: Hygienix Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022)

2.1.5.6. Instructions for use

See use-specific instructions.

2.1.5.7. Risk mitigation measures

See use-specific risk mitigation measures.

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

None

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

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

2.1.5.10. 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.

Meta SPC 3: Hand disinfection

(Representative product: Hygienix Disinfecting Foam Wash DFWG-L-06163)

2.1.5.11. Instructions for use

See use-specific instructions.

2.1.5.12. Risk mitigation measures

None

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

None

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

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

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

Shelf-life: 2 years. Store at room temperature. Protect from frost.

Meta SPC 4: Hand disinfection
(Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06161)

2.1.5.16. Instructions for use

See use-specific instructions.

2.1.5.17. Risk mitigation measures

None

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

None

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

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

2.1.5.20. 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.

Meta SPC 5: Hand disinfection (Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06163)

2.1.5.21. Instructions for use

See use-specific instructions.

2.1.5.22. Risk mitigation measures

None

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

None

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

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

2.1.5.25. 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.

Meta SPC 6: Hand disinfection (Representative product: Hygienix Disinfecting Foam Wash DFWS-L-06161)

2.1.5.26. Instructions for use

See use-specific instructions.

2.1.5.27. Risk mitigation measures

None

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

None

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

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

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

Shelf-life: 2 years. Store at room temperature. Protect from frost.

2.1.6 Other information

None

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Meta SPC 1 & 2					
Bottle (for direct use or as refill)	50 - 3000 ml	PET, PE or HDPE	- (PP/PVC/PE) spray pump, foam sprayer, trigger sprayer or pressurized sprayer - (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap	Professional and non-professional	Y
Jerry can	3000 - 30000 ml	PET, PE or HDPE	- (PP/PVC/PE) dosing valve, dosing pump or pressurized sprayer for direct use - (PP, PVC or PE) screw-cap to use as refill	Professional and non-professional	Y
Single wipe sachet	1 wipe	Laminated PET, PET/PE, PE or blends thereof	Not applicable	Professional and non-professional	Y

Flow pack	8 - 200 wipes	Laminated PET, PET/PE or PE	Resealable lid	Professional and non-professional	Y
Tub, canister or bucket	10 - 800 wipes	HDPE or PE	PET, PP or PE cap, screwcap or resealable lid	Professional and non-professional	Y
Wipe characteristic:	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. Wipe substrate weight ranges from 35 – 70 gr/m2.	Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/ viscose/pulp, Polypropylene/ viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/ viscose, Polyester, Polyester/ Polypropylene/ Viscose, Pulp (cellulose), and variations thereof	Not applicable	Professional and non-professional	Y
Meta SPC 3 & 6					
Bottle (for direct use or as refill)	100 - 4000 ml	PET, PE or HDPE	- (PP/PE) foam pump, liquid pump or spray pump - (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap	Professional and non-professional	Y

Jerry can (to refill bottles, or to be directly connected to an industrial (PP/PE) pump system to dose soap)	3000 - 30000 ml	PET, PE or HDPE	- (PP, PVC or PE) dosing valve - (PP, PVC or PE) screw-cap	Professional and non-professional	Y
Collapsible (laminated) bag, pouch or collapsible bottle (to refill bottles or for use in soap dispensers)	100 – 2500 ml	PET, PE or HDPE	- (PP/PVC/ PE) foam pump, liquid pump or spray pump - (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap	Professional and non-professional	Y
Meta SPC 4 & 5					
Bottle (for direct use or as refill)	100 - 4000 ml	PET, PE or HDPE	- (PP/PE) liquid pump - (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap	Professional and non-professional	Y
Jerry can (to refill bottles, or to be directly connected to an industrial (PP/PE) pump system to dose soap)	3000 – 30000 ml	PET, PE or HDPE	- (PP, PVC or PE) dosing valve - PP, PVC or PE screw-cap	Professional and non-professional	Y
Collapsible (laminated) bag, pouch or collapsible bottle (to refill bottles or for	100 – 2500 ml	PET, PE or HDPE	- (PP/PVC/ PE) liquid pump - (PP, PVC or PE) crew-, pull-, push-, flip-top or	Professional and non-professional	Y

use in soap dispensers)			press-top cap		

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

All submitted data is new

Physico-Chemical Characteristics

Biocidal Product	Meta SPC	Reference
Light Duty Cleaning and Disinfection Liquid LDL-L-0616008	1	1a, 1g
Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	2	1b, 1g
Disinfecting Foam Wash DFWG-L-06163	3	1c, 1h
Disinfecting Gel Wash DGWG-L-06161	4	1d, 1h
Disinfecting Gel Wash DGWG-L-06163	5	1e, 1h
Disinfecting Foam Wash DFWS-L-06161	6	1f, 1h

Physical hazards

Meta SPC	Reference
1 - 2	1j
3 - 6	1k

Method of Detection

Meta SPC	Reference
1 - 6	1i

Accelerated Stability Data

Biocidal Products	Meta SPC	Reference
Light Duty Cleaning and Disinfection Liquid LDL-L-0616008	1	2a
Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	2	2b
Disinfecting Foam Wash DFWG-L-06163	3	2c
Disinfecting Gel Wash DGWG-L-06161	4	2d
Disinfecting Gel Wash DGWG-L-06163	5	2e
Disinfecting Foam Wash DFWS-L-06161	6	2f

Room Temperature Stability Data

Biocidal Products	Meta SPC	Reference
Light Duty Cleaning and Disinfection Liquid LDL-L-0616008	1	3a, 3g
Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	2	3b, 3h
Disinfecting Foam Wash DFWG-L-06163	3	3c, 3i
Disinfecting Gel Wash DGWG-L-06161	4	3d, 3j
Disinfecting Gel Wash DGWG-L-06163	5	3e, 3k

Disinfecting Foam Wash DFWS-L-06161	6	3f, 3l

Efficacy Data

Biocidal Products	Meta SPC	Reference
Light Duty Cleaning and Disinfection Liquid LDL-L-0616008	1	4a – j, 10a - f
Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	2	4h, 5a - n, 11a - f
Disinfecting Foam Wash DFWG-L-06163	3	6a - c
Disinfecting Gel Wash DGWG-L-06161	4	7a - d
Disinfecting Gel Wash DGWG-L-06163	5	8a - c
Disinfecting Foam Wash DFWS-L-06161	6	9a - d

Hazard classification and labelling calculations/determinations

Meta SPC	Worst-case formulation	Reference
1	Light Duty Cleaning and Disinfection Liquid LDL-H-05181	12a
2	Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182	12b, 12c
3	Disinfecting Foam Wash DFWG-H-05183	12d, 12e
4	Disinfecting Gel Wash DGWG-H-05184	12f
5	Disinfecting Gel Wash DGWG-H-05185	12g
6	Disinfecting Foam Wash DFWS-H-05186	12h, 12i

Proposed label claims

Biocidal Products	Meta SPC	Reference
Light Duty Cleaning and Disinfection Liquid LDL-L-0616008	1	13a
Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	2	13b
Disinfecting Foam Wash DFWG-L-06163	3	13c
Disinfecting Gel Wash DGWG-L-06161	4	13d
Disinfecting Gel Wash DGWG-L-06163	5	13e
Disinfecting Foam Wash DFWS-L-06161	6	13f

2.1.8.2 Access to documentation

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR.
The applicant is the owner of all submitted data.

2.2 Assessment of the biocidal product (family)

2.2.1. Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are addressed in the following chapters and tables.

Use #	Meta SPC	Use Title
1.1 / 2.1	1, 2	Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, surface application followed by wiping, professional and non-professional
1.2 / 2.2	1, 2	Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, surface application followed by wiping, professional and non-professional
1.3 / 2.7	1, 2	Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional
1.4 / 2.8	1, 2	Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, wiping with ready-to-use wipe(s), professional and non-professional
2.3	2	Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, spraying or foaming, professional and non-professional
2.4	2	Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, spraying or foaming, professional and non-professional
2.5	2	Surface disinfection, PT02, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, pouring and spreading, professional and non-professional
2.6	2	Surface disinfection, PT04, activity against bacteria, yeasts, enveloped viruses, viruses and mycobacteria, pouring and spreading, professional and non-professional
3.1	3	Hand and skin disinfection, PT01, foaming or spraying, professional and non-professional
4.1	4	Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional
4.2	4	Body Wash Disinfection, PT01, pumping or squeezing, professional and non-professional
4.3	4	Scalp Disinfection with Body Wash application, PT01, pumping or squeezing, professional and non-professional
5.1	5	Hand and skin disinfection, PT01, pumping or squeezing, professional and non-professional
6.1	6	Hand and skin disinfection, PT01, foaming or spraying, professional and non-professional
6.2	6	Body Wash Disinfection, PT01, foaming or spraying, professional and non-professional
6.3	6	Scalp Disinfection with Body Wash application, PT01, foaming or spraying, professional and non-professional

Table 1 Use #1.1, 1.2, 2.1, 2.2 – Surface disinfection - Wiping with an unspecified wipe

Product Type	**Use 1.1, 2.1** PT02 **Use 1.2, 2.2** PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. **Use 1.1, 2.1** 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. **Use 1.2, 2.2** 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.
Application method(s)	Spraying, foaming or pouring, followed by wiping: Application to the surface followed by wiping with unspecified wipe.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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.

Table 2 Use #1.3, 1.4, 2.7, 2.8 – Surface disinfection - Wiping with an impregnated wet wipe

Product Type	**Use 1.3, 2.7** PT02 **Use 1.4, 2.8** PT04

Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. **Use 1.3, 2.7** 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. **Use 1.4, 2.8** 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.
Application method(s)	Wiping with an impregnated wet wipe: Wiping the surface with an impregnated wet wipe.
Application rate(s) and frequency	RTU Product. Use as many wipes as necessary to completely wet the surface (approximately one 18 cm x 20 cm wipe per m2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	Single (1) wipe sachet, made of laminated PET, PET/PE, PE or blends thereof, or; Flow pack made of laminated PET, PET/PE or PE with 8 - 200 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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. - Wipe substrate weight ranges from 35 – 70 gr/m2. - 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 variations thereof.

Table 3 Use #2.3, 2.4 – Surface disinfection - Spraying, or foaming with a foam sprayer or foam nozzle

Product Type	**Use 2.3** PT02 **Use 2.4**

	PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor. **Use 2.3** 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. **Use 2.4** 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.
Application method(s)	Spraying, or foaming with a foam sprayer or foam nozzle: Coarse spraying, or foaming with a foam sprayer or foam nozzle.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 50 - 3000 ml (PET, PE or HDPE) bottle for direct use or as refill. 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) pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

Table 4 Use #2.5, 2.6 – Surface disinfection - Pouring and spreading

Product Type	**Use 2.5** PT02 **Use 2.6** PT04
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Viruses Mycobacteria
Field of use	Indoor.

	Use 2.5 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. **Use 2.6** 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.
Application method(s)	Pouring and spreading: Pouring the liquid onto the surface and spreading with a cloth, towel, scrubber, mop, etc.
Application rate(s) and frequency	RTU Product. Use as much as needed to completely wet the surface (approximately 20 ml/m^2). Use when necessary, as frequently as necessary.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 3000 ml (PET, PE, or HDPE) bottle for direct use or as refill. 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 or PE) dosing valve for direct use, or with (PP, PVC or PE) screw-cap to use as refill.

Table 5 Use #3.1, 6.1, 6.2, 6.3 – Hand, skin and scalp disinfection - Foaming or spraying

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	**Use 3.1** Bacteria Yeasts **Use 6.1, 6.2, 6.3** Bacteria Yeasts Enveloped viruses
Field of use	Indoor. **Use 3.1, 6.1** 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). **Use 6.2** 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).

	Use 6.3 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).
Application method(s)	Foaming or spraying **Use 3.1, 6.1** Dosing foam or liquid onto the hands and washing. **Use 6.2** Dosing foam or liquid onto the skin and washing. **Use 6.3** Dosing foam or liquid onto the scalp and washing.
Application rate(s) and frequency	RTU Product. Use when necessary, as frequently as necessary. **Use 3.1, 6.1** Dosage approximately 3 ml per use. **Use 6.2** Dosage approximately 60 ml per use. **Use 6.3** Dosage approximately 6 - 10 ml per use.
Category(ies) of users	Professional and non-professional (general public)
Pack sizes and packaging material	- 100 - 4000 ml (PET, PE or HDPE) bottle for direct use or as refill. With (PP/PE) foam pump, liquid pump or spray 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) foam pump, liquid pump or spray pump, or with (PP, PVC or PE) screw-, pull-, push-, flip-top or press-top cap.

Table 6 Use #4.1, 4.2, 4.3, 5.1 – Hand, skin and scalp disinfection - Pumping or squeezing

Product Type	PT01
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	**Use 4.1, 4.2, 4.3** Bacteria Yeasts

	Enveloped viruses **Use 5.1** Bacteria Yeasts
Field of use	Indoor. **Use 4.1, 5.1** 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). **Use 4.2** 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). **Use 4.3** 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).
Application method(s)	Pumping or squeezing **Use 4.1, 5.1** Pumping, or squeezing bottle to dose soap onto the hands and washing. **Use 4.2** Pumping, or squeezing bottle to dose soap onto the skin and washing. **Use 4.3** Pumping, or squeezing bottle to dose soap onto the scalp and washing.
Application rate(s) and frequency	RTU Product. Use when necessary, as frequently as necessary. **Use 4.1, 5.1** Dosage approximately 3 ml per use. **Use 4.2** Dosage approximately 60 ml per use. **Use 4.3** Dosage approximately 6 - 10 ml per use.
Category(ies) of users	Professional and non-professional (general public)

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.

2.2.2 Physical, chemical and technical properties

Note on physical and chemical properties
This application is a simplified procedure for which only stability data is to be addressed. The applicant has provided more information, however.

The section on physical and chemical properties was designed to include general information in the first table, representing all products within the family. Then, in the remaining tables, physical and chemical properties per meta SPC are addressed.

Some data was provided for endpoints that are not to be evaluated within the scope of a simplified application procedure (e.g. surface tension and viscosity). These data were accepted as-is. This also counts for endpoints like the acidity, which was not correctly reported, but as this information is not used in a risk assessment (no exposure assessment is performed), it is not corrected. The measurements were performed adequately, according to an international standard.

The analytical method used for the storage stability studies is the same as reported in section 2.2.4 and is considered validated.

Finally, the shelf-life of the wipe-based products was not addressed with a storage stability study. Considering it was agreed in the Coordination Group (CG 30, 2018) that the shelf-life of products applied for in a simplified procedure can be addressed by means of efficacy data, the stability of wipes was investigated in efficacy studies with a number of representative wipes (see also efficacy section).

Table 2.1 Hygienix Biocidal Product Family

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1a-1f
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless to pale yellow (clear to slightly opaque)	1a-1f
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions, or, if fragranced, characteristic of fragrance used.	1a-1f
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	0.65-1.20	1a-1f

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4. The data is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability.				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	2.05-4.60	1a-1f
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.0-1.1 g/cm^3	1a-1f
eCA remark The density reported is not a relative density. The data is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability.				
Storage stability test – **accelerated storage**	CIPAC MT 46.3		See the evaluation per meta SPC below.	
Storage stability test – **long term storage at ambient temperature**			See the evaluation per meta SPC below.	
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			See the evaluation per meta SPC below. Based on the composition of the products, light is not expected to have an effect on the content of the active substance and technical characteristics of the products.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			See the evaluation per meta SPC below. The humidity is not relevant as the products are water based.	
Effects on content of the active substance and technical			See the evaluation per meta SPC below. Long term stability testing at	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product - **reactivity towards container material**			ambient temperature is ongoing for the current actual six biocidal products (one within each Meta SPC). No reactivity towards generally used plastic container materials is expected based on the composition and characteristics of the products.	
Wettability			Not applicable, all products within the family are aqueous liquids	
Suspensibility, spontaneity and dispersion stability			Not applicable, none of the products are suspensions/dispersion or are intended to form suspensions/ dispersions.	
Wet sieve analysis and dry sieve test			Not applicable, all products within the family are aqueous liquids which are ready for use.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable, all products within the family are aqueous liquids solution, which are not emulsions or intended to form emulsions.	
Disintegration time			Not applicable, all products within the family are aqueous liquids	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable, none of the products in the family are franules or powders.	
Persistent foaming			Not applicable, all products within the family are ready to use aqueous solutions	
Flowability/Pourability/Dustability			Not applicable, all products within the	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			family are aqueous liquids	
Burning rate — smoke generators			Not applicable, all products within the family are aqueous liquids	
Burning completeness — smoke generators			Not applicable, all products within the family are aqueous liquids	
Composition of smoke — smoke generators			Not applicable, all products within the family are aqueous liquids	
Spraying pattern — aerosols			Not applicable, no aerosol application	
Physical compatibility			Not applicable, no label recommendations are made to use the product in combination with other substances, mixtures or (non)-biocidal products	
Chemical compatibility			Not applicable, no label recommendations are made to use the product in combination with other substances, mixtures or (non)-biocidal products	
Degree of dissolution and dilution stability			Not applicable, all products within the family are ready to use aqueous solutions	
Surface tension	ASTM D 1331, ring method, 25 °C	100	Ca. 29-30 mN/m	1g, 1h
Viscosity	OECD Test Guideline 114 OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	5-16000 mPa.s	1a-1f
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product Family
See the evaluations by the eCA in the main table. For details on the conclusions with regard to the shelf-life per meta SPC, see the tables below.

Table 2.2 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 1: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1a
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless (clear to slightly opaque)	1a
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions	1a
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	0.75-1.10	1a
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	2.05-2.20	1a
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.00-1.05 g/cm^3	1a
Storage stability test – **accelerated storage**	CIPAC MT 46.3. (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content. (+) tartaric acid content (% w/w) T=0: 0.40 T=14 d: 0.40 (-0%) Sodium benzoate Content (%w/w) T=0: 0.40 T=14 d: 0.38 (-5%) pH T=0: 2.08	2a

			T=14 d: 2.01 Viscosity (mPa.s) content T=0: 7 T=14 d: 8	
Storage stability test – **long term storage at ambient temperature**		100%	Stored in PET & HDPE for 3 years at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (% w/w) T=0: 0.40 T=1yr PET: 0.40 T=1yr HDPE: 0.41 T=2 yr PET: 0.44 T=2 yr HDPE: 0.42 T=3 yr PET 0.41 T=3 yr HDPE 0.40 Sodium benzoate Content (%w/w) T=0: 0.40 T=1 yr PET: 0.41 T=1 yr HDPE: 0.38 T=2 yr PET: 0.44 T=2 yr HDPE: 0.42 T=3 yr PET 0.39 T=3 yr HDPE 0.36 pH T=0: 2.08 T=1 yr PET: 2.0 T=1 yr HDPE: 2.08 T=2 yr PET:	3a, 3g

			2.06 T=2 yr HDPE: 2.06 T=3 yr PET: 2.01 T=3 yr HDPE: 2.01 Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results in PET Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change 3-year results in HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change	
eCA remark Full 3 year data in PET and HDPE is available. The accelerated data is based on a study in glass. The study comprised of a 750 mL PE spray bottle and a 500 mL PET spray bottle, both equipped with trigger spray attachments. The discharge rate was approximately 1.30 g/actuation (HDPE) and 1.24 g/actuation (PET). The MMAD was not reported, which is an issue the eCA has not considered for the approval decision based on the toxicological risk assessment (it is not an input parameter) and the low-risk nature of the product. The wipes were not tested in regular storage stability trials. Therefore, the applicant has provided efficacy tests (see section 2.2.5.5 for more details), including data on aged				

samples in the appropriate packaging material variants (cellulose wipes in ziplock bags, polyester-viscose wipes in ziplop bags for Meta SPC 1). For Meta SPC 1 the product Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 with 0.4% sodium benzoate and 0.4% tartaric acid was tested (representative product with the lowest active substance contents). For this meta SPC, the shelf-life is therefore as follows: 3 years across all products.				
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		100%	The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products, light is not expected to have an effect.	3a, 3g
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			For temperature, refer to accelerated storage stability data (54 °C, 14 days) and ambient temperature storage data. Humidity is not applicable, all	2a, 3a, 3g

			products within the family are aqueous solutions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See long term shelf-life data.	3a, 3g
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				
Chemical compatibility				
Degree of dissolution and dilution stability				
Surface tension	ASTM D 1331, ring method, 25 °C		Ca. 30 mN/m (not measured, by analogy/read across)	1g
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	<10 mPa.s	1a
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	<10 mPa.s	1a

eCA remark
The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008
See the evaluations by the eCA in the main table. The shelf-life of Meta SPC 1 is 3 years.

Table 2.3 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 2: Hygienix Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1b
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless (clear to slightly opaque)	1b
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions	1b
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	0.90-1.20	1b
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4.				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	2.05-2.20	1b
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.00-1.05 g/cm³	1b
Storage stability test – **accelerated storage**	CIPAC MT 46.3. (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content. (+) tartaric acid content (% w/w) T=0: 0.48 T=14 d: 0.52 (+8%) Sodium benzoate Content (%w/w) T=0: 0.49 T=14 d: 0.50 (+2%) pH	2b

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=0: 2.08 T=14 d: 2.01 Viscosity (mPa.s) content T=0: 7 T=14 d: 8	
Storage stability test – **long term storage at ambient temperature**		100%	Stored in PET & HDPE for 3 years at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (% w/w) T=0: 0.48 T=1yr PET: 0.50 T=1yr HDPE: 0.52 T=2yr PET: 0.54 T=2yr HDPE: 0.53 T=3yr PET 0.51 T=3yr HDPE 0.49 Sodium benzoate Content (%w/w) T=0: 0.49 T=1yr PET: 0.50 T=1yr HDPE: 0.47 T=2yr PET: 0.53 T=2yr HDPE: 0.51 T=3yr PET 0.49 T=3yr HDPE 0.46 pH T=0: 2.08 T=1yr PET: 2.14 T=1yr HDPE: 2.14 T=2yr PET: 2.06 T=2yr HDPE: 2.17 T=3yr PET 2.09	3b, 3h

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=3yr HDPE 2.01 Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results in PET Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change 3-year results in HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change	
eCA remark Full 3-year data in PET and HDPE is available. The accelerated data is based on a study in glass. The study comprised of a 750 mL PE spray bottle and a 500 mL PET spray bottle, both equipped with trigger spray attachments. The discharge rate was approximately 1.43 g/actuation (HDPE) and 1.15 g/actuation (PET). The MMAD was not reported, which is an issue the eCA has not considered for the approval decision based on the toxicological risk assessment (it is not an input parameter) and the low-risk nature of the product. The wipes were not tested in regular storage stability trials. Therefore, the applicant has provided efficacy tests (see section 2.2.5.5 for more details), including data on aged				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
samples in the appropriate packaging material variants (polyester-viscose wipes in ziplock bags, cellulose wipes in ziplock bags for Meta SPC 2). For Meta SPC 2, Heavy Duty Cleaning and Disinfection Liquid LDL-L-0616022 was tested, with 0.5% sodium benzoate and 0.5% tartaric acid (representative product with the lowest active substance contents). For this meta SPC, the shelf-life is therefore as follows: 3 years across all products.				
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products, light is not expected to have an effect.	3b, 3h
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			For temperature, refer to accelerated storage stability data (54 °C, 14 days) and ambient temperature	2b 3b, 3h

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			storage data. Humidity is not applicable, all products within the family are aqueous solutions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See long term shelf-life data	3b, 3h
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				
Chemical compatibility				
Degree of dissolution and dilution stability				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	ASTM D 1331, ring method, 25 °C		Ca. 29 mN/m	1g
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	<10 mPa.s	1b
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	<10 mPa.s	1b
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Hygienix Heavy Duty Cleaning and Disinfection Liquid
See the evaluations by the eCA in the main table. The shelf-life of meta SPC 2 is 3 years.

Table 2.4 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 3: Hygienix Disinfecting Foam Wash DFWG-L-06163

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1c
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless to pale yellow	1c
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions, slightly flowery	1c
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	1.10-1.20	1c
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	3.10-3.40	1c
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.00-1.10 g/cm^3	1c
Storage stability test – **accelerated storage**	CIPAC MT 46.3. (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content. (+) tartaric acid content (% w/w) T=0: 0.84 T=14 d: 0.78 (-7%) Sodium benzoate Content (%w/w) T=0: 0.79 T=14 d: 0.78 (-1%)	2c

			pH T=0: 3.13 T=14 d: 3.21 Viscosity (mPa.s) content T=0: 10 T=14 d: 9	
Storage stability test – **long term storage at ambient temperature**	Hygienix's Disinfecting Foam Wash DFWG-L-06163	100%	Stored in PET & HDPE for 3 years days at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (% w/w) T=0: 0.84 T=1yr PET: 0.82 T=1yr HDPE: 0.81 T=2yr PET: 0.81 T=2yr HDPE: 0.80 T=3yr PET 0.79 T=3yr HDPE 0.86 Sodium benzoate Content (%w/w) T=0: 0.79 T=1yr PET: 0.81 T=1yr HDPE: 0.80 T=2yr PET: 0.82 T=2yr HDPE: 0.80 T=3yr PET 0.81 T=3yr HDPE 0.82 pH T=0: 3.25 T=1yr PET: 3.22 T=1yr HDPE: 3.30 T=2yr PET:3.32 T=2yr HDPE: 3.30 T=3yr PET 3.13 T=3yr HDPE 3.22	2c, 3c, 3i

			Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results PET Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change 3-year results HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change	

eCA remark
Full 3-year data in PET and PE is available.

The shelf-life study comprised of a 175 mL PE handheld foamer a 500mL PET foamer, both equipped with appropriate pumps. The discharge rate was approximately 1.04 g/actuation (HDPE) and 0.84 g/actuation (PET). The discharge rate in HDPE increased to 1.25 g/actuation and in PET the discharge rate decreased significantly to 0.32 g/actuation. This was caused by crystallization in the pump, in the case of the PET pack. No 'fresh' pack was used after 3 years, but the same pack was used after each iteration. A decline in discharge rate was also observed after 2 years, although this was somewhat minor. It is therefore unlikely a fresh pack would have crystallization occur in the spray head, but no direct evidence is available to support this. Therefore, the stability after 3 years is not proven and the increased shelf-life cannot be granted.

The MMAD is not considered relevant, as the pumps produce foam rather than a spray.

For this meta SPC, the shelf-life is 2 years.

Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products, light is not expected to have an effect.	3c, 3i
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			For temperature, refer to accelerated storage stability data (54 °C, 14 days) and ambient temperature storage data. Humidity is not applicable, all products within the family are aqueous solutions.	2c, 3c, 3i
Effects on content of the active substance			See long term shelf-life data.	3c, 3i

and technical characteristics of the biocidal product - **reactivity towards container material**				
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				
Chemical compatibility				
Degree of dissolution and dilution stability				
Surface tension	ASTM D 1331, ring method, 25 °C	100	Ca. 30 mN/m, not measured, read across	1h
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	<10 mPa.s	1c
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	<10 mPa.s	1c
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Hygienix Disinfecting Foam Wash DFWG-L-06163
See the evaluations by the eCA in the main table. The shelf-life of meta SPC 3 is 2 years.

Table 2.5 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 4: Hygienix Disinfecting Gel Wash DGWG-L-06161

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1d
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless	1d
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions,	1d
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	1.10-1.20	1d
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	3.10-3.40	1d
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.0-1.1 g/cm^3	1d
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content.	2d

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(+) tartaric acid content (% w/w) T=0: 0.61 T=14 d: 0.58 (-5%) Sodium benzoate Content (%w/w) T=0: 0.82 T=14 d: 0.81 (-1%) pH T=0: 3.27 T=14 d: 3.26 Viscosity (mPa.s) content T=0: 7360 T=14 d: 5860	
Storage stability test – **long term storage at ambient temperature**	Hygienix's Disinfecting Gel Wash DGWG-L-06161	100%	Stored in PET & HDPE for 3 years days at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (% w/w) T=0: 0.65 T=1yr PET: 0.63 T=1yr HDP: 0.64 T=2yr PET: 0.62 T=2yr HDPE: 0.62 T=3yr PET 0.61 T=3yr HDPE 0.59 Sodium benzoate Content (%w/w) T=0: 0.82 T=1yr PET: 0.84 T=1yr HDPE: 0.83	3d, 3j

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=2yr PET: 0.85 T=2yr HDPE: 0.83 T=3yr PET 0.85 T=3yr HDPE 0.80 pH T=0 PET: 3.23 T=0 HDPE: 3.25 T=1yr PET: 3.18 T=1yr HDPE: 3.22 T=2yr PET: 3.23 T=2yr HDPE: 3.23 T=3yr PET 3.35 T=3yr HDPE 3.18 Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results in PET Leakage: none Deformation: none Blockage: NA Amount delivered: NA Spray pattern: NA 3-year results in HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: NA	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark Full 3-year data in PET and PE is available. The accelerated data is based on a study in glass. The shelf-life study comprised of a 500 mL PE gel pump and a 300 mL PET gel table top (bottle). The HDPE pack is equipped with a dispenser pump. The discharge rate was approximately 1.10 g/actuation (HDPE). The MMAD is not considered relevant, as the pumps produce a gel rather than a spray, comparable to that of a hand soap dispenser. The shelf-life for this meta SPC is 3 years.				
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products, light is not expected to have an effect.	3d, 3j
Effects on content of the active substance and technical			For temperature, refer to accelerated	2d, 3d, 3j

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product – **temperature and humidity**			storage stability data (54 °C, 14 days) and ambient temperature storage data. Humidity is not applicable, all products within the family are aqueous solutions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See long term shelf-life data.	3d, 3j
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Chemical compatibility				
Degree of dissolution and dilution stability				
Surface tension	ASTM D 1331, ring method, 25 °C	100	Ca. 30 mN/m, not measured, read across	1h
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	6000-8000 mPa.s	1d
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	4500-6500 mPa.s	1d
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Hygienix Disinfecting Gel Wash DGWG-L-06161
See the evaluations by the eCA in the main table. The shelf-life of meta SPC 4 is 3 years.

Table 2.6 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 5: Hygienix Disinfecting Gel Wash DGWG-L-06163

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1e
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless	1e
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions,	1e
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	1.10-1.20	1e
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	3.10-3.40	1e
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.0-1.1 g/ml	1e
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content. (+) tartaric acid content (% w/w) T=0: 0.82 T=14 d: 0.76 (-7%) Sodium benzoate Content (%w/w) T=0: 0.79	2e

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=14 d: 0.79 (0%) pH T=0: 3,24 T=14 d: 3,20 Viscosity (mPa.s) content T=0: 7040 T=14 d: 5280	
Storage stability test – **long term storage at ambient temperature**	DISINFECTING GEL WASH DGWG-L-06163	100%	Stored in PET & HDPE for 3 years days at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (% w/w) T=0 PET: 0.82 T=0 HDPE: 0.82 T=1yr PET: 0.82 T=1yr HDPE: 0.80 T=2yr PET: 0.81 T=2yr HDPE: 0.78 T=3yr PET 0.78 T=3yr HDPE 0.80 Sodium benzoate Content (%w/w) T=0 PET: 0.79 T=0 HDPE: 0.79 T=1yr PET: 0.81 T=1yr HDPE: 0.79 T=2yr PET: 0.82 T=2yr HDPE: 0.80 T=3yr PET 0.81 T=3yr HDPE 0.77	3e, 3k

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH T=0: 3.25 T=1yr PET: 3.18 T=1yr HDPE: 3.30 T=2yr PET: 3.26 T=2yr HDPE: 3.27 T=2yr PET 3.21 T=2yr HDPE 3.22 Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results in PET Leakage: none Deformation: none Blockage: NA Amount delivered: NA Spray pattern: NA 3-year results in HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: NA	
eCA remark Full 3-year data in PET and PE is available. The accelerated data is based on a study in glass. The shelf-life study comprised of a 500 mL PE gel pump and a 300 mL PET gel table top (bottle). The HDPE pack is equipped with a dispenser pump. The discharge rate was				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
approximately 1.04 g/actuation (HDPE). The MMAD is not considered relevant, as the pumps produce a gel rather than a spray, comparable to that of a hand soap dispenser. The shelf-life for this meta SPC is 3 years.				
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		100%	The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products, light is not expected to have an effect.	3e, 3k
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		100%	For temperature, refer to accelerated storage stability data (54 °C, 14 days) and ambient temperature storage data. Humidity is not	2e, 3e, 3k

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			applicable, all products within the family are aqueous solutions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		100%	See long term shelf-life data.	3e, 3k
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				
Chemical compatibility				
Degree of dissolution and dilution stability				
Surface tension	ASTM D 1331, ring method, 25 °C	100	Ca. 30 mN/m, not measured, by	1h

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			analogy/read across	
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	6500-8000 mPa.s	2e
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	5000-7000 mPa.s	2e
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Hygienix Disinfecting Gel Wash DGWG-L-06163
See the evaluations by the eCA in the main table. The shelf-life of meta SPC 5 is 3 years.

Table 2.7 Biocidal Product belonging to the Hygienix Biocidal Product Family, Meta SPC 6: Hygienix Disinfecting Foam Wash DFWS-L-06161

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Liquid	1f
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Colourless	1f
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303; Organoleptic evaluation. RT (21-23 °C) and ambient atmospheric pressure.	100%	Characteristic of surfactant solutions,	1f
Acidity / ~~alkalinity~~	OECD Test Guideline 122; Titration with NaOH solution. RT (21-23 °C).	100%	0.85-1.10	1f
eCA remark The acidity data was not correctly calculated to OECD 112 and was erroneously expressed as NaOH rather than H_2SO_4				
Acidity / pH	OECD Test Guideline 122; pH meter. RT (21-23 °C)	100%	3.10-3.40	1f
Relative density / ~~bulk density~~	OECD Test Guideline 109; Pycnometer method. RT (21-23 °C).	100%	1.00-1.10 g/cm^3	1f
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (54 °C, 14 days)	100%	Stored in glass for 14 days at 54 °C. Tested parameters: Appearance, pH, viscosity, active substance content. (+) tartaric acid content (% w/w) T=0: 0.80 T=14 d: 0.78 (-3%) Sodium benzoate Content (%w/w) T=0: 0.79	2f

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=14 d: 0.78 (-1%) pH T=0: 3,17 T=14 d: 3.24 Viscosity (mPa.s) content T=0: 9 T=14 d: 9	
Storage stability test – **long term storage at ambient temperature**	Disinfecting Foam Wash DFWS-L-06161	100% Lot 200-063	Stored in PET & HDPE for 3 years days at 21 ± 2 °C. Tested parameters: active substance content and pH. (+) tartaric acid content (w/w) T=0: 0.80 T=1yr PET: 0.82 T=1yr HDPE: 0.82 T=2yr PET: 0.83 T=2yr HDPE: 0.81 T=3yr PET 0.80 T=3yr HDPE 0.81 Sodium benzoate Content (%w/w) T=0: 0.79 T=1yr PET: 0.81 T=1yr HDPE: 0.80 T=2yr PET: 0.82 T=2yr HDPE: 0.82 T=3yr PET 0.81 T=3yr HDPE 0.81 pH T=0: 3.24 T=1yr PET: 3.33	3f, 3l

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T=1yr HDPE: 3.26 T=2yr PET: 3.32 T=2yr HDPE: 3.30 T=3yr PET 3.16 T=3yr HDPE 3.35 Tested parameters: Leakage, packaging deformation, blockage, amount delivered upon dispensing, spray pattern. 3-year results in PET Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change 3-year results in HDPE Leakage: none Deformation: none Blockage: none Amount delivered: No change Spray pattern: no change	
eCA remark Full 3-year data in PET and PE is available. The accelerated data is based on a study in glass. The shelf-life study comprised of a 175 mL PE handheld foamer a 500 mL PET foamer, both equipped with appropriate pumps. The discharge rate was approximately 1.20 g/actuation				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
(HDPE) and 0.94 g/actuation (PET). The MMAD is not considered relevant, as the pumps produce foam rather than a spray. After three years, the discharge rate of the PET pack has decreased from 0.94g/actuation to 0.68g/actuation. Blockage of the pump was observed in both HDPE and PET, although in HDPE this did not results in a reducation of the discharge rate. It should be noted that in this report, the nature of the nozzle blockage is not discussed, in contrast to that for meta SPC 3. As the intended use suggest 3 mL should be used (approximately 3 trigger actuations), this decrease in discharge rate may cause issues with correctly dosing the product. After 2 years, the PET pack also showed a decrease in the discharge rate, but no blockage of the pump was observed. The eCA considers that, based on the data provided, it cannot be concluded that the packaging is stable for 3 years. Therefore, the shelf-life is 2 years. For this meta SPC, the shelf-life is 2 years.				
Storage stability test – **low temperature stability test for liquids**			Not applicable (packaging will list 'protect from frost')	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The characteristics of the stability storage room for stability testing at ambient (room) temperature is a room with 1 large window on the west, samples were continuously exposed during the day to daylight, but were not placed directly in sunlight. By the exposure to light during storage stability tests, the product was automatically tested against light influences. Based on the composition of the products,	3f, 3l

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			light is not expected to have an effect.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			For temperature, refer to accelerated storage stability data (54 °C, 14 days) and ambient temperature storage data. Humidity is not applicable, all products within the family are aqueous solutions.	2f, 3f, 3l
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See long term shelf-life data.	3f, 3l
Wettability			Please refer to the overall main table for waivers for these endpoints.	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dustability				
Burning rate — smoke generators				
Burning completeness — smoke generators				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility				
Chemical compatibility				
Degree of dissolution and dilution stability				
Surface tension	ASTM D 1331, ring method, 25 °C	100	Ca. 30 mN/m	1h
Viscosity	OECD Test Guideline 114. Rotational viscometer (dynamic), RT (21-23 °C)	100	<10 mPa.s	1f
Viscosity	OECD Test Guideline 114 Rotational viscometer (dynamic), 40 °C.	100	<10 mPa.s	1f
eCA remark The data with regard to surface tension and viscosity is accepted by the eCA as it does not affect the conclusions of the evaluation, nor is it used in the assessment of product stability (the data is not obligatory for simplified procedures).				

Conclusion on the physical, chemical and technical properties of the Biocidal Product: Disinfecting Foam Wash DFWS-L-06161
See the evaluations by the eCA in the main table. The shelf-life of meta SPC 6 is 2 years.

2.2.3. Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Not applicable/Non-explosive (all products within the biocidal product family fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Flammable gases			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Flammable aerosols			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Oxidising gases			Not applicable/non-oxidising (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Gases under pressure			Not applicable (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Flammable liquids			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Flammable solids			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			authorisation, i.e. do not have any hazard classification)	
Self-reactive substances and mixtures			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Pyrophoric liquids			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Pyrophoric solids			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Self-heating substances and mixtures			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Substances and mixtures which in contact with water emit flammable gases			Not applicable/not-classified (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Oxidising liquids			Not applicable/non-oxidising (all products within the biocidal product family fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Oxidising solids			Not applicable/non-oxidising (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Organic peroxides			Not applicable, none of the products within the biocidal product family is based on organic peroxides.	
Corrosive to metals	UN-MTC section 37 class 8,	Hygienix Disinfecting	7 days of testing at 55°C **Mass loss Steel**	1k

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	test C1 (2009)	Foam Wash: Tartaric acid: 0.5%w/w* Benzoic acid: 0.5%w/w* *specification	Fully immersed: 2.21% Half immersed: 1.15% Gas phase: 0.54% **Mass loss Aluminium** Fully immersed: 0.41% Half immersed: 0.31% Gas phase: -0.01% No localized corrosion was observed. The results remain below the threshold for classification as indicated in the UN-MTC. Conclusion: not corrosive to metals.	
	UN-MTC section 37 class 8, test C1 (2009)	Hygienix Heavy Duty Cleaning & Disinfection Liquid: Tartaric acid: 0.8%w/w* Benzoic acid: 0.8%w/w* *specification	7 days of testing at 55°C **Mass loss Steel** Fully immersed: 3.31% Half immersed: 0.31% Gas phase: 0.73% **Mass loss Aluminium** Fully immersed: 8.29% Half immersed: 3.02% Gas phase: -0.03% No localized corrosion was observed. The results remain below the threshold for classification as indicated in the UN-MTC. Conclusion: not corrosive to metals.	1j
Auto-ignition temperatures of products (liquids and gases)			Not applicable (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Relative self-ignition temperature for solids			Not applicable (all products within the biocidal product family are aqueous liquids and fulfil the conditions for simplified authorisation, i.e. do not have any hazard classification)	
Dust explosion hazard			Not applicable (all products within the biocidal product family are aqueous liquids and fulfil the conditions for	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			simplified authorisation, i.e. do not have any hazard classification)	

Conclusion on the physical hazards and respective characteristics of the product
None of the products in the Hygienix Biocidal Product Family have physical or chemical hazard classification.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance: Tartaric acid	HPLC-UV	20-400 µg/ml* /5 measurements	R^2=0,9996 (in water), R^2=0,9998 (low % surfactant matrix) and R^2=0,9993 (high % surfactant matrix) Slope 1043.64 Intercept 3542.0	Conforms All relevant parameters meet the acceptance criteria for specificity**	94,96-105.6	100.49	3.90	LOD: 1.07 µg/ml LOQ: 3.24 µg/ml	3
Active substance: Sodium Benzoate	HPLC-UV	20-400 µg/ml* /5 measurements	R^2=0,9999 (in water), R^2=0,9995 (low % surfactant matrix) and R^2=0,9998 (high % surfactant matrix) Slope 41649.02 Intercept 85185.12	Conforms All relevant parameters meet the acceptance criteria for specificity**	97.48-103.71	101.20	1.81	LOD: 0.51 µg/ml LOQ: 1.53 µg/ml	3

*This concentration range would correspond to a concentration of 0.1%-2% active substance in the final product (for a 1g sample prepared as indicated in the method).
**No interference of the active substance peaks and any peaks of the placebo. The placebo sample used for determining specificity contains all co-formulants that are listed at level 1 (see report nr 3 in paragraph 4.2: *"Placebo samples containing all of the ingredients except for the analytes").* No co-elution between peaks. Any peaks eluting from mobile phase, placebo solution and stressed sample must be well separated from the principal peak. The retention time of the active substance peak in the reference standard solutions matches with the retention time of the active substance peak in the sample solution. Sufficient resolution between peaks.

eCA remark
The exact composition of the placebo (blank formulation) was not provided. Two placebos were used, a high surfactant and a low surfactant version. The chromatograms show some potential for interference due to a raised baseline, but this is also observed when the standards for the actives are injected. An explanation is not included in the report, but the outcome of the recoveries and precision suggest the method is sufficiently accurate and precise. The method is considered acceptable by the eCA.

Accuracy was investigated at three levels: 30 – 50% of the target calibration range, 50-75% and 75 – 100%. Per fortification level, three replicates were analysed. The mean at the highest fortification level was 105.1%, 97.45% at the medium level and 98.88% at the low level for tartatic acid. For sodium benzoate, the recoveries were 98.49% at the highest level, 99.99% at the medium level and 101.15% at the low level. The mean recoveries should formally be within the range 95 – 105%. Although the high fortification level for tartaric acid is slightly outside this range, the eCA considers this to be too minor to reject the validation study, also because the recoveries at the other fortification levels are acceptable.

The system precision of the method was determined for three samples (three concentrations) and analysing samples 6 times each. The intermediate precision was also reported, but ignored by the eCA (same analysis, but on different days with different instruments, reagents, sample solutions and standard solutions). Precision was 0.33 – 1.45% for tartaric acid and 0.14 – 0.55% for sodium benzoate, all well within the Horwitz criterion (at 1% active substance, the RSDr is 2.68%).

Conclusion on the methods for detection and identification of the product

An analytical method for determining the concentration of the active substances in the biocidal products of the Hygienix Biocidal Product Family has been provided in accordance with the Guidance on the Biocidal Products Regulation, Volume I: Identity/physico-chemical properties/analytical methodology, Part A: Information Requirements (November 2014), p. 105.
The provided HPLC-UV method fulfils validation criteria of linearity, specificity, repeatability and recovery.
Linearity: R^2>0,99; The range over which linearity was demonstrated corresponds to concentration of 0.1-2% active substance in the final biocidal product, which well covers the nominal range of 0.40-0.90% for each of the active substances ((+)-Tartaric Acid and Sodium Benzoate) within the Hygienix Biocidal Product Family.
Recovery: Mean recovery within the required range of 95-105% for products containing <1% active, cf. p. 70 of the Guidance.
Repeatability was assessed by performing 6 determinations for each of three different formulations. %RSD ranged from 0.33-1.45 for (+)-Tartaric acid and 0.14-0.55 for Sodium Benzoate.
Specificity: The placebo sample used for determining specificity contains all co-formulants that are listed at level 1 (see report par 4.2: *"Placebo samples containing all of the ingredients except for the analytes")*
The conclusion is that the method conforms to the criteria for specificity:

- No interference of the active substance peaks and any peaks of the placebo.
- No co-elution between peaks.
- Any peaks eluting from mobile phase, placebo solution and stressed sample are well separated from the principal peak.
- The retention time of the active substance peak in the reference standard solutions matches with the retention time of the active substance peak in the sample solution.

- Sufficient resolution between peaks

Analytical methods for monitoring, soil, air, water, soil, animal and human body fluids and tissues, and for monitoring of active substances and residues in food and feeding stuff are not listed as requirements for biocidal products eligible for simplified authorisation according to Article 25 of the BPR.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Function	Field of use
Surface disinfectant	Indoor
Hygienic hand, skin and scalp wash	Indoor

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Organisms to be controlled	Products, organisms, objects to be protected
Bacteria	Surfaces; Human skin
Yeasts	Surfaces; Human skin
Enveloped viruses	Surfaces; Human skin
Viruses	Surfaces
Mycobacteria	Surfaces

2.2.5.3 Effects on target organisms, including unacceptable suffering

The Hygienix Biocidal Product Family contains disinfectant products which are intended to kill bacteria, yeast, enveloped viruses, viruses and mycobacteria on hard surfaces, and to kill bacteria, yeast and enveloped viruses on human skin.

2.2.5.4 Mode of action, including time delay

(+)-Tartaric Acid and Sodium Benzoate are active substances listed on Annex I of the BPR. They are well-known biocides and preservatives that are mainly used in the food industry. A Letter of Access is not required for biocides on Annex I within a Simplified Authorisation application. A great amount of supporting data for efficacy and mode of action for both compounds is found in the literature (see for instance [redacted]

Generally, the antimicrobial mode of action of both compounds is as follows:
The antimicrobial activity of tartaric acid is, like most weak organic acids, attributed to pH reduction, depression of internal pH of microbial cell by ionization of undissociated acid molecules, and disruption of substrate transport by altering cell membrane permeability [redacted] or reduction of proton motive force [redacted]

Sodium benzoate interferes with the utilization of acetate required for the function of energy rich compounds which results in blockage of cell metabolism [redacted]). Furthermore, benzoate compounds induce increased cell membrane permeability and membrane leakage [redacted]). Selective permeability of the plasma membrane

creates an ionic gradient, which changes the proton influx, resulting in reduced uptake of certain essential nutrients such as amino acids (Pores in the membrane result in dissipation of the proton gradient, loss of K+-ions from the cell (and the leakage of additional cytoplasmic constituents

Additional references, see

(Possible) occurrence of resistance:
No possible occurrence of resistance is known or reported. As both sodium benzoate and weak organic acids such as (+)-tartaric acid act via multiple pathways, resistance is not expected to develop.

Time delay: No time delay, the effect is immediate.

2.2.5.5 Efficacy data

According to the Note for Guidance, CA-Nov14-Doc.5.8 – Final; Implementing the new concept of biocidal product families, points (28), (30), and (31), the "worst case" assessment (i.e lowest efficacy and highest risk) may be done on the Meta SPC level, when an overall worst case for the whole family cannot readily be established and taking into consideration the composition of the products and the different uses described in each Meta SPC. In the Hygienix Biocidal Product Family the lowest efficacy (worst case) was determined by testing formulations containing the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of each Meta SPC.

In the confidential annex "*Product (family) structure and formulations*", more detailed information is provided on the qualitative and quantitative information of the composition of the biocidal product family, the meta-SPC's and qualitative and quantitative information of the composition of the biocidal products. This file contains more information on the overall family structure, the meta-SPC's within the family and the tested formulations with the actual ingredient concentrations and how these relate to the meta-SPC's.

The minimum efficacy was therefore assessed on the products with the minimum concentration of both active substances and with the minimum concentration of non-active substances (except for water) within each of the six Meta SPCs.
This can be considered the worst-case product per Meta SPC in terms of efficacy. The following 'worst case' products were identified, and efficacy studies were performed against each of the following 'worst case' products:

- Meta SPC 1: Hygienix Light Duty Cleaning and Disinfection Liguid LDL-L-0616008. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 1.
- Meta SPC 2: Hygienix Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 2.
- Meta SPC 3: Hygienix Disinfecting Foam Wash DFWG-L-06163. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 3.

- Meta SPC4: Hygienix Disinfecting Gel Wash DGWG-L-06161. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 4.
- Meta SPC 5: Hygienix Disinfecting Gel Wash DGWG-L-06163. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 5.
- Meta SPC 6: (Hygienix) Disinfecting Foam Wash DFWS-L-06161. This product contains the lowest possible level of both active substances and the lowest possible level of non-active substances within the formula range of Meta SPC 6.

These six products furthermore represent actual biocidal products within each of the Meta SPCs and within the Hygienix Biocidal Product Family. This means the "low" of each meta-SPC represents the actual biocidal product, being the worst-case product at the lower end of the spectrum. Thus, the whole potential range of products within the Meta SPCs and the Hygienix Biocidal Product Family is covered by the thus determined minimum level of efficacies.

Finally, as discussed in section 2.2.2, the shelf-life of the wipe-based products of the Hygienix Biocidal Product Family was not addressed with a storage stability study. Considering it was agreed in the Coordination Group (CG 30, 2018) that the shelf-life of products applied for in a simplified procedure can be addressed by means of efficacy data, the stability of wipes was investigated in efficacy studies with a number of representative wipes. In consultation with the Dutch eCA (Ctgb), it was decided and required that efficacy of the impregnated wipes must be tested on both cellulose and polyester-viscose wipes, to provide evidence for efficacy and stability on all wipe substrate types in the authorisation, and to have these performed with E. hirae as most limiting conservative test species to provide proof for the efficacy on all wipe material types during the 3-years of shelf life. These data are included in this section.

Experimental data on the efficacy of the biocidal products within the Hygienix Biocidal Product Family against target organism(s), representing the minimum level of efficacy of the Hygienix Biocidal Product Family

Function	Field of use envisaged	Biocidal Product/ Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericidal	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	P.aeruginosa ATCC 15442; S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions* / 10%, 80%, 97% / 30 s, 60 s	Log R >5.15 / 80% / 30 s	4a
Bactericidal/ yeasticidal	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid	P.aeruginosa ATCC 15442; S. aureus ATCC	EN 16615 (2015)	Dirty conditions*/ wipe / 1 min, 5 min	Log R > 5 on bacteria and Log R > 4 on yeast /	4b

		LDL-L-0616008 Standard wipe **Meta SPC 1**	6538; E. hirae ATCC 10541; C. albicans ATCC 10231			as wipe / 1 min	
Yeasticidal	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	C. albicans ATCC 10231	EN 13624 (2013)	Dirty conditions* / 97%, 80%, 50%, 10% / 1 min, 2 min, 5 min	Log R 4.33 / 80% / 2 min	4c
Activity against enveloped viruses	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10%, 0.1% / 1 min	Log R ≥ 4.13 ± 0.25 / 10% / 1 min	4d
Limited spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min, 30 min	Log R ≥ 4.38 ± 0.37 / 50% / 1 min	4e
Limited spectrum virucidal activity, MNV	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min	Log R ≥5.63 ± 0.45 / 80% / 1 min	4f
Full spectrum virucidal activity, Polio virus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Poliovirus type 1 strain LSc-2ab (Chiron-Behring)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min	Log R ≥5.00 ± 0.35 / 50% / 1 min	4g

Activity against enveloped viruses	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Viscose/PE wipes used for the test **Meta SPC 1**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 16615:2015	Dirty conditions*/ wipe / 1 min	Log R ≥ 4.5 as wipe / 1 min	4h
Activity against enveloped viruses	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Lyocell wipes used for the test **Meta SPC 1**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 16615:2015	Dirty conditions*/ wipe / 1 min	Log R ≥ 4.5 as wipe / 1 min	4h
Full spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Viscose/PE wipes used for the test **Meta SPC 1**	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 16615:2015	Dirty conditions*/ wipe / 5 min, 10 min	Log R ≥ 4.19 as wipe / 5 min **Not valid**	4h
Full spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Lyocell wipes used for the test **Meta SPC 1**	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 16615:2015	Dirty conditions*/ wipe / 5 min, 10 min	Log R ≥ 4.19 as wipe / 5 min **Not valid**	4h

Full spectrum virucidal activity, Murine norovirus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Viscose/PE wipes used for the test **Meta SPC 1**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16615:2015	Dirty conditions*/ wipe / 5 min, 10 min	Log R ≥ 5.13 as wipe / 5 min **Not valid**	4h
Full spectrum virucidal activity, Murine norovirus	Surface disinfection, indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 Lyocell wipes used for the test **Meta SPC 1**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16615:2015	Dirty conditions*/ wipe / 5 min, 10 min	Log R ≥ 5.00 as wipe / 5 min **Not valid**	4h
Mycobactericidal	Surface disinfection Indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Mycobacterium terrae (ATCC 15755), Mycobacterium avium (ATCC 15769)	EN 14348:2005	Clean*** and dirty conditions* / 97%, 80%, 10% / 30 min	Log R >4.25 / clean and dirty conditions / 97% / 30 min	4i
Mycobactericidal	Surface disinfection Indoor	Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 **Meta SPC 1**	Mycobacterium terrae (ATCC 15755), Mycobacterium avium (ATCC 15769)	EN 16615:2015	Clean*** and dirty conditions* / 100%, 10% as wipe / 30 min	Log R >5.06 / clean and dirty conditions / 100% as wipe / 30 min	4j
Shelf-life tests for Meta SPC 1							
-	Surface disinfection Indoor	LDL-L-0616008-Ce t0m wipes 0.4g sodium benzoate / 100g	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Carrier 1 logR = 5.72 (Start inoculum higher than standard; represents worst-case)	10a

		0.4g l-tartaric acid / 100g White Paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Fresh product Cellulose wipes Standard wipe used for the water control				Carrier 2 logR = 7.67 (Start inoculum higher than standard; represents worst-case)	
-	Surface Disinfection, Indoor	LDL-L-0616008-PV t0m wipes 0.4g sodium benzoate / 100g 0.4g l-tartaric acid / 100g White elastic wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Fresh product Polyester-Viscose wipes Standard wipe used for the	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Carrier 1 logR = 6.27 (Start inoculum higher than standard; represents worst-case) Carrier 2 logR = 5.95 (Start inoculum higher than standard; represents worst-case)	10b

		water control					
-	Surface Disinfection, Indoor	LDL-L-0616008-Ce t25m wipes 0.4g sodium benzoate / 100g 0.4g l-tartaric acid / 100g White Paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Period RT stability: 25 months Cellulose wipes used for the test Standard wipe used for the water control	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	2nd run of testing, Carrier 1: LogR = 7.36 2nd run of testing Carrier 2: logR = 7.36	10c
-	Surface Disinfection, Indoor	LDL-L-0616008-PV t25m wipes 0.4g sodium benzoate / 100g 0.4g l-tartaric acid / 100g White elastic type wipes: ca 22x19 cm; 25 wipes, repacked	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	2nd run of testing, Carrier 1: LogR = 7.36 2nd run of testing, Carrier 2: LogR = 6.48	10d

		in Ziplock bags for testing Period RT stability: 25 months Polyester-Viscose wipes Standard wipe used for the water control					
-	Surface Disinfection, Indoor	LDL-L-0616008-Ce t42m wipes 0.4g sodium benzoate / 100g 0.4g l-tartaric acid / 100g Period RT stability: 42 months Cellulose wipes, pre-soaked Standard wipe used for the water control	E. hirae ATCC 10541	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Test 1: Log R = 5.20 Test 2: Log R = 5.63	10e
-	Surface Disinfection, Indoor	LDL-L-0616008-PV t42m wipes 0.4g sodium benzoate / 100g 0.4g l-tartaric acid / 100g Period RT stability: 42 months	E. hirae ATCC 10541	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Test 1: Log R >= 5.81 Test 2: Log R >= 5.81	10f

		Polyester-Viscose wipes, pre-soaked Standard wipe used for the water control					

Bactericidal	Surface Disinfection, Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	P.aeruginosa ATCC 15442; S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions* / 10% 50%, 97% / 30 s, 60 s	Log R > 5.05 / 97% /30 s	5a
Bactericidal	Surface Disinfection, Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	P.aeruginosa ATCC 15442; E. coli ATCC 10536, S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13697 (2015)	Dirty conditions* / 100%, 80%, 10% / 2 min, 5 min	Log R 4.74 / 100% / 5 min	5b
Yeasticidal	Surface Disinfection, Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	C. albicans ATCC 10231	EN 13697 (2015)	Dirty conditions**/10%, 60%, 100% / 1 min, 2 min, 5 min	Log R >3.14 / 100% / 2min Log R >3.24 60% / 5 min	5c
Yeasticidal	Surface Disinfection, Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	C. albicans ATCC 10231	EN 13624 (2013)	Dirty conditions*/ 10%, 50%, 80%, 97% / 1 min / 2 min, 5 min	Log R >4.55 / 80%/2 min	5d
Bactericidal/ yeasticidal	Surface Disinfection, Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2** Standard wipe	P.aeruginosa ATCC 15442; S. aureus ATCC 6538; E. hirae ATCC 10541; C. albicans	EN 16615 (2015)	Dirty conditions* / wipe 1 min	Log R >6.33 on bacteria and Log R > 5.97 on yeast/as wipe /1 min	5e

			ATCC 10231				
Activity against enveloped viruses	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10%, 0.1% / 1 min	Log R ≥3.13 ± 0.25 / 10% / 1 min (due to cyto-toxicity, a log RF ≥ 4 could not be shown) Log R ≥4.97 ± 0.32 / 80% / 1 min	5f
Limited spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min, 30 min	Log R ≥4.38 ± 0.37 / 50% / 1 min	5g
Limited spectrum virucidal activity, MNV	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min	Log R ≥4.13 ± 0.45 / 50% / 1 min	5h
Full spectrum virucidal activity, Polio virus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Poliovirus type 1 strain LSc-2ab (Chiron-Behring)	EN 14476:2013+A2:2019	Dirty conditions* / 80%, 50%, 10% / 1 min, 2 min	Log R ≥5.00 ± 0.35 / 50% / 1 min	5i
Activity against enveloped viruses	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 16777:2018	Dirty conditions* / 100%, 50%, 10% / 5 min, 10 min, 15 min	Log R ≥4.06 ± 0.36 / 100% / 5 min	5j
Limited spectrum virucidal activity,	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022	Adenovirus type 5 strain adenoid 75	EN 16777:2018	Dirty conditions* / 100%, 50%, 10% / 15 min, 30 min, 45 min	Log R ≥4.09 ± 0.245 / 50% / 15 min	5k

Adeno virus		**Meta SPC 2**	(ATCC VR-5)				
Limited spectrum virucidal activity, MNV	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16777:2018	Dirty conditions* / 100%, 50%, 10% / 15 min, 30 min, 60 min	Log R ≥6.13 ± 0.34 / 100% / 30 min	5l
Activity against enveloped viruses	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Viscose/PE wipes used for the test **Meta SPC 2**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 16615:2015	Dirty conditions* / wipe / 1 min	Log R ≥ 4.5 as wipe / 1 min	4h
Activity against enveloped viruses	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Lyocell wipes used for the test **Meta SPC 2**	Modified vaccinia virus Ankara (MVA) ATCC VR-1508	EN 16615:2015	Dirty conditions* / wipe / 1 min	Log R ≥ 4.5 as wipe / 1 min	4h
Full spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Viscose/PE wipes used for the test **Meta SPC 2**	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 16615:2015	Dirty conditions* / wipe / 2 min, 5 min	Log R ≥ 4.06 as wipe / 2 min Not valid	4h
Full spectrum virucidal activity, Adeno virus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Lyocell wipes used for the test	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 16615:2015	Dirty conditions* / wipe / 2 min, 5 min	Log R ≥ 4.06 as wipe / 2 min Not valid	4h

		Meta SPC 2					
Full spectrum virucidal activity, Murine norovirus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Viscose/PE wipes used for the test **Meta SPC 2**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16615:2015	Dirty conditions* / wipe / 2 min, 5 min	Log R ≥ 5.00 as wipe / 2 min Not valid	4h
Full spectrum virucidal activity, Murine norovirus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Lyocell wipes used for the test **Meta SPC 2**	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16615:2015	Dirty conditions* / wipe / 2 min, 5 min	Log R ≥ 4.69 as wipe / 2 min Not valid	4h
Mycobactericidal	Surface disinfection Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Mycobacterium terrae (ATCC 15755), Mycobacterium avium (ATCC 15769)	EN 14348:2005	Clean*** and dirty conditions* / 80%, 97%, 10% / 60 min	Log R >4 / clean and dirty conditions / 80% / 60 min	5m
Mycobactericidal	Surface disinfection Indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 **Meta SPC 2**	Mycobacterium terrae (ATCC 15755), Mycobacterium avium (ATCC 15769)	EN 16615:2015	Clean*** and dirty conditions* / 100%, 10% / 60 min	Log R >5 / clean and dirty conditions / as wipe / 60 min	5n
Shelf-life tests for Meta SPC 2							
-	Surface Disinfection, Indoor	HDL-L-0616012-PV t0m wipes 0.5g sodium benzoate / 100g 0.5g l-tartaric acid / 100g	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Carrier 1 logR = 7.01 Carrier 2 logR = 7.01	11a

		White elastic type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Fresh product Polyester/viscose wipes used for the test Standard wipe used for the water control					
-	Surface Disinfection, Indoor	HDL-L-0616012-Cet0m wipes 0.5g sodium benzoate / 100g 0.5g l-tartaric acid / 100g White paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Fresh product Cellulose wipes Standard wipe used for the water control	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe /100% / 1 min	Carrier 1 Log R = 7.01 Carrier 2 logR = 7.01	11b
-	Surface Disinfection, Indoor	HDL-L-0616022-PVt25m wipes 0.5g sodium benzoate / 100g	E. hirae	EN 16615 (2015)	Dirty Conditions*/ wipe/ 100% / 1 min	Carrier 1 logR = 6.14 Carrier 2 logR = 7.01	11c

		0.5g l-tartaric acid / 100g White paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Period RT stability: 25 months Polyester/viscose wipes used for the test Standard wipe used for the water control					
-	Surface Disinfection, Indoor	HDL-L-0616022-CEt25m wipes 0.5g sodium benzoate / 100g 0.5g l-tartaric acid / 100g White paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Period RT stability: 25 months Cellulose wipes Standard wipe used for the water control	E. hirae	EN 16615 (2015)	Dirty Conditions*/ wipe/ 100% / 1 min	Carrier 1 logR = 5.11 Carrier 2 logR 7.01	11d

-	Surface Disinfection, Indoor	HDL-L-0616022-PV t42m wipes 0.5g sodium benzoate / 100g 0.5g l-tartaric acid / 100g White elastic type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Period RT stability: 42 months Polyester/viscose wipes Standard wipe used for the water control	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Carrier 1: Log R = 5.53 Carrier 2: Log R = 5.73	11e
-	Surface Disinfection, Indoor	HDL-L-0616022-CE t42m wipes 0.5g sodium benzoate / 100g 0.5g l-tartaric acid / 100g White paper type wipes: ca 22x19 cm; 25 wipes, repacked in Ziplock bags for testing Period RT stability: 42 months Cellulose wipes Standard wipe used for the	E. hirae	EN 16615 (2015)	Dirty Conditions* / wipe / 100% / 1 min	Test 1: Log R = 5.60 Test 2: Log R = 5.71	11f

		water control					
Bactericidal	Skin Disinfection, Indoor	Disinfecting Foam Wash DFWG-L-06163 **Meta SPC 3**	P.aeruginosa ATCC 15442; E. coli ATCC 10536, S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions*/ 10% 30%, 50%/ 30s, 60s	Log R≥ 5.03 / 10%/30s	6a
Yeasticidal	Skin Disinfection, Indoor	Disinfecting Foam Wash DFWG-L-06163 **Meta SPC 3**	C. albicans ATCC 10231	EN 13624 (2015)	Dirty conditions*/10 % 50%, 80%/ 30s, 60s	Log R 4.08/ 80%/30s Log R> 4.32 50% / 60 s LogR 2,89 50% /30s	6b
Bactericidal	Skin Disinfection, Indoor	Disinfecting Foam Wash DFWG-L-06163 **Meta SPC 3**	E. coli K12 NCTC 10538	EN 1499 (2013)	Dirty conditions*/50 %/30s	Log R = 4.39 3ml/30s >reference (statistically significant)	6c
Bactericidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06161 **Meta SPC 4**	P.aeruginosa ATCC 15442; E. coli ATCC 10536, S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions*/1% 10% 30%, 50%/ 30s, 60s	Log R ≥ 5.16 /50%/30s	7a
Yeasticidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06161 **Meta SPC 4**	C. albicans ATCC 10231	EN 13624 (2013)	Dirty conditions*/10 % 50%, 80%/ 30s, 60s	Log R ≥ 2,16 / 50%/60s Log R = 3.74 /80%/ 30s	7b

Bactericidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06161 **Meta SPC 4**	E. coli K12 NCTC 10538	EN 1499 (2013)	Dirty conditions*/50 %/30s	Log R = 3,87/ 3ml/30s >reference (statistically significant)	7c
Activity against enveloped viruses	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06161 **Meta SPC 4**	Modified vaccinia virus Ankara ATCC VR-1508	EN 14476 (2013 + A1 2015)	Dirty conditions*/0,5 %, 5%, 10%, 50%/20s, 30s, 60s, 30 min	Log R ≥4/ 50%/20s 100% /20s	7d
Bactericidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06163 **Meta SPC 5**	P.aeruginosa ATCC 15442; E. coli ATCC 10536, S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions*/1% 10% 30%, 50%/ 30s, 60s	Log R ≥4,98 / 10%/30s	8a
Yeasticidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06163 **Meta SPC 5**	C. albicans ATCC 10231	EN 13624 (2013)	Dirty conditions*/10 % 50%, 80%/ 30s, 60s	Log R=2,21 / 50%/30s/	8b
Bactericidal	Skin Disinfection, Indoor	Disinfecting Gel Wash DGWG-L-06163 **Meta SPC 5**	E. coli K12 NCTC 10538	EN 1499 (2013)	Dirty conditions*/50 %/30s	Log R=3,96/ 3ml/30s >reference (statistically significant)	8c
Bactericidal	Skin Disinfection, Indoor	Disinfecting Foam Was DFWS-L-06161 **Meta SPC 6**	P.aeruginosa ATCC 15442; E. coli ATCC 10536, S. aureus ATCC 6538; E. hirae ATCC 10541	EN 13727 (2015)	Dirty conditions*/1% 10% 30%, 50%/ 30s, 60s	Log R ≥4,57/10% /30s	9a
Yeasticidal	Skin Disinfection, Indoor	Disinfecting Foam Was DFWS-L-06161 **Meta SPC 6**	C. albicans ATCC 10231	EN 13624 (2013)	Dirty conditions*/10 % 50%, 80%/ 30s, 60s	Log R=2,34 50%/30s	9b

Bactericidal	Skin Disinfection, Indoor	Disinfecting Foam Was DFWS-L-06161 **Meta SPC 6**	E. coli K12 NCTC 10538	EN 1499 (2013)	Dirty conditions*/50 %/30s	Log R=4,04/ 3ml/30s >reference (statistically significant)	9c
Activity against enveloped viruses	Skin Disinfection, Indoor	Disinfecting Foam Was DFWS-L-06161 **Meta SPC 6**	Modified vaccinia virus Ankara ATCC VR-1508	EN 14476 (2013 + A1 2015)	Dirty conditions*/0,5 %, 5%, 10%, 50%/20s, 30s, 60s, 30 min	log R≥4/ 50%/20s	9d

*3.0 g/L bovine albumin + 3.0 g (ml)/L sheep erythrocytes
**3.0 g/L bovine albumin
*** 0.3 g/L bovine albumin

Conclusion on the efficacy of the biocidal products within the Hygienix Biocidal Product Family against target organisms

The efficacy of the products of the Hygienix Biocidal Product Family was assessed on the level of the six Meta SPCs. Minimum efficacy was assessed using the formulations with the lowest concentration of each active and non-active substance (except water) within the range of each Meta SPC. Tests were conducted conform the requirements as listed in the overview of (EN) standards, test conditions, and pass criteria as included in Appendix 4 to the BPR Guidance on the BPR Vol II B&C (V3 2018) as follows:

- Meta SPC 1 – PT02 – PT04 Hard Surfaces, use in healthcare and other than healthcare, wipe application and surface application followed by wiping. The tested formulation was Light Duty Cleaning and Disinfection Liquid LDL-L-0616008. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal), EN 13624 (yeasticidal) EN 14476 (full spectrum virucidal) and EN 14348 (mycobactericidal). Further, pass criteria were met for phase 2, step 2 tests EN 16615 (bactericidal, yeasticidal, mycobactericidal) and (adapted test method/field study) EN 16615 (full spectrum virucidal). All tests were performed under dirty conditions as required for healthcare. The following contact times apply: bacteria: 2 min., yeasts: 2 min., enveloped viruses: 2 min., mycobacteria: 30 min.
- Meta SPC 2 – PT02 – PT04 Hard Surfaces, use in healthcare and other than healthcare, wipe application and surface application followed by wiping, spray, foam, pour and spread applications. The tested formulation was Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal), EN 13624 (yeasticidal) EN 14476 (full spectrum virucidal) and EN 14348 (mycobactericidal). Further, pass criteria were met for phase, step 2 tests EN 13697 (bactericidal and yeasticidal), EN 16777 (full spectrum virucidal), EN 16615 (bactericidal, yeasticidal, mycobactericidal) and (adapted test method/field study) EN 16615 (full spectrum virucidal). All tests were performed under dirty conditions as required for healthcare. For wipe application and surface application followed by wiping the following contact times apply: bacteria: 2 min., yeasts: 2 min., enveloped viruses: 2 min., viruses: 30 min., mycobacteria: 60 min. For spray, foam, pour and spread applications the following contact times apply: bacteria: 5 min., yeasts: 5 min., enveloped viruses: 5 min., viruses: 30 min., mycobacteria: 60 min.
- Meta SPC 3 – PT01 – Hand and skin disinfection. The tested formulation was Disinfecting Foam Wash DFWG-L-06163. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal) and EN 13624 (yeasticidal). Further, pass criteria were met for the phase, step 2 test EN 1499 (bactericidal). For hygienic hand wash a dosage of 3 ml and a contact time of 30 sec. applies.
- Meta SPC 4 – PT01 – Hand and skin disinfection, body wash disinfection and scalp disinfection. The tested formulation was Disinfecting Gel Wash DGWG-L-06161. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal), EN 13624 (yeasticidal) and EN 14476 (activity against enveloped viruses). Further, pass criteria were met for the phase 2, step 2 test EN 1499 (bactericidal).
  Both skin and scalp disinfection are included as a possible area of use in the definition of product type 1 (PT1) according to the BPR Guidance on the BPR Vol II B&C (V3 2018). As skin disinfection is very similar to hand disinfection, the body wash application is considered as substantiated by the standard tests for hand disinfection. The same applies for scalp disinfection; as the use instructions specify that the product must be applied directly onto the scalp (by spreading the hair), this use is comparable to hand disinfection. The product was successfully tested under dirty conditions with 50% dilution which can also be considered as worst-case scenario for topic application on the hands, body and scalp.

For the hygienic handwash application a dosage of 3 ml and a contact time of 60 sec. applies. For the body wash application, a dosage of appr. 60 ml (divided in portions of appr. 10 ml) and a contact time of 60 sec. applies. For the scalp disinfection application, a dosage of 6 - 10 ml and a contact time of 60 sec. applies.

- Meta SPC 5 – PT01 – Hand and skin disinfection. The tested formulation was Disinfecting Gel Wash DGWG-L-06163. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal) and EN 13624 (yeasticidal). Further, pass criteria were met for the phase, step 2 test EN 1499 (bactericidal). The conclusion is that for the mentioned applications a dosage of 3 ml (hands) and a contact time of 30 sec. is required.
- Meta SPC 6 – PT01 – Hand and skin disinfection, body wash disinfection and scalp disinfection. The tested formulation was Disinfecting Foam Wash DFWS-L-06161. Pass criteria were met for phase 2, step 1 tests EN 13727 (bactericidal), EN 13624 (yeasticidal) and EN 14476 (activity against enveloped viruses). Further, pass criteria were met for the phase 2, step 2 test EN 1499 (bactericidal).
  Both skin and scalp disinfection are included as a possible area of use in the definition of product type 1 (PT1) according to the BPR Guidance on the BPR Vol II B&C (V3 2018). As skin disinfection is very similar to hand disinfection, the body wash application is considered as substanciated by the standard tests for hand disinfection. The same applies for scalp disinfection; as the use instructions specify that the product must be applied directly onto the scalp (by spreading the hair), this use is comparable to hand disinfection. The product was successfully tested under dirty conditions with 50% dilution which can also be considered as worst-case scenario for topic application on the hands, body and scalp.
  For the hygienic handwash application a dosage of 3 ml and a contact time of 30 sec. applies. For the body wash application, a dosage of appr. 60 ml (divided in portions of appr. 10 ml) and a contact time of 30 sec. applies. For the scalp disinfection application, a dosage of 6 - 10 ml and a contact time of 30 sec. applies.

eCA note:
Adapted EN16615 tests were provided to substantiate efficacy against viruses for uses that require wiping in metaSPCs 1 and 2. Since the test with mechanical action represents the claimed uses with wipes better than a standard surface test (EN16777), we agree to use the EN16615 to substantiate efficacy. Because the EN16615 is not validated for viruses we asked for an extensive explanation of the test procedure. The test report includes a clear explanation on how the tests were conducted. For MVA the eCA agrees that the test can be used to substantiate efficacy. However, for MNV and adenovirus the water controls show insufficient amounts of viruses on field 1 and the adjacent fields. Therefore, these tests are inconclusive on efficacy against these viruses.

- In metaSPC 1, no EN16777 tests were provided and only use against enveloped viruses will be authorized, based on EN14476 and adapted EN16615 for vaccinia virus.
- In metaSPC2, along the same lines as in metaSPC1 enveloped viruses will be authorized based on EN14476 and adapted EN16615. Since there are also non-wipe application methods in metaSPC 2, EN16777 tests were provided too. Full virucidal activity is substantiated by EN14476 and EN16777 tests, also for the uses where wiping is the application method. Since the tests without mechanical action are worst case compared with application with mechanical action and no validated test with mechanical action for viruses exists, this is acceptable. The contact time as tested in the EN16777 is taken as the substantiated contact time.

2.2.5.6 Occurrence of resistance and resistance management

No possible occurrence of resistance is known or reported. As both sodium benzoate and weak organic acids such as tartaric acid act via multiple pathways, resistance is not expected to develop.

2.2.5.7 Known limitations

No known limitations.

2.2.5.8 Evaluation of the label claims

Proposed label claims Meta SPC 1
(Representative product: Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008)

- Wiping with an unspecified wipe (use 1.1, 1.2) and wiping with an impregnated wet wipe (use 1.3, 1.4)

PT02, PT04
Disinfection of bacteria, yeasts, enveloped viruses and mycobacteria
Kills bacteria, yeasts and enveloped viruses in 2 minutes
Kills mycobacteria in 30 minutes
Cleans and disinfects in one step
Kills / Eliminates >99.999% of bacteria
Kills / Eliminates >99.99% of bacteria, yeasts, enveloped viruses and mycobacteria

Proposed label claims Meta SPC 2
(Representative product: Hygienix Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022)

- Wiping with an unspecified wipe (use 2.1, 2.2) and wiping with an impregnated wet wipe (use 2.7, 2.8)

PT02, PT04
Disinfection of bacteria, yeasts, viruses and mycobacteria
Kills bacteria, yeasts and enveloped viruses in 2 minutes
Kills all viruses in 30 minutes
Kills mycobacteria in 60 minutes
Cleans and disinfects in one step
Kills / Eliminates >99.999% of bacteria
Kills / Eliminates >99.99% of bacteria, yeasts, viruses and mycobacteria

- Spraying, or foaming with a foam sprayer or foam nozzle (use 2.3, 2.4) and pouring and spreading (use 2.5, 2.6)

PT02, PT04
Disinfection of bacteria, yeasts, viruses and mycobacteria
Kills bacteria, yeasts and enveloped viruses in 5 minutes
Kills all viruses in 30 minutes
Kills mycobacteria in 60 minutes

Cleans and disinfects in one step
Kills / Eliminates >99.99% of bacteria, mycobacteria and viruses
Kills / Eliminates >99.9% of yeasts

Proposed label claims Meta SPC 3
(Representative product: Hygienix Disinfecting Foam Wash DFWG-L-06163)

- Foaming or spraying (Use 3.1)

Disinfects
Cleans and disinfects in one step
Kills bacteria and yeasts in 30 seconds.
Eliminates >99% of bacteria and yeasts
Kills / Eliminates >99,9% of bacteria

Proposed label claims Meta SPC 4
(Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06161)

- Pumping or squeezing (Use 4.1, 4.2, 4.3)

Disinfects
Cleans and disinfects in one step
Kills bacteria, yeasts and enveloped viruses in 60 seconds.
Kills / Eliminates >99% of bacteria, yeasts and enveloped viruses
Kills / Eliminates >99,9% of bacteria and enveloped viruses
Kills / Eliminates >99,9% of enveloped viruses

Proposed label claims Meta SPC 5
(Representative product: Hygienix Disinfecting Gel Wash DGWG-L-06163)

- Pumping or squeezing (Use 5.1)

Disinfects
Cleans and disinfects in one step
Kills bacteria and yeasts in 30 seconds
Eliminates >99% of bacteria and yeasts
Kills / Eliminates >99,9% of bacteria

Proposed label claims Meta SPC 6
(Representative product: Hygienix Disinfecting Foam Wash DFWS-L-06161)

- Foaming or spraying (Use 6.1, 6.2, 6.3)

Disinfects
Cleans and disinfects in one step
Disinfection of bacteria, yeasts and enveloped viruses
Kills bacteria, yeasts and enveloped viruses in 30 seconds
Kills / Eliminates >99% of bacteria, yeasts and enveloped viruses
Kills / Eliminates >99,99% of bacteria and enveloped viruses
Kills / Eliminates >99,99% of enveloped viruses

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The products are not to be authorised for use with other (biocidal) product(s).

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

In the Hygienix Biocidal Product Family the worst case for classification and labeling purposes was determined for formulations containing the highest level of both active substances and non-active substances within the formula range of each Meta SPC. These "Highest concentrations" dummy formulas are always indicated with an extension indicator 'H' at the end of the formulation number.

Table for clarification

Registration application concerns product at Meta SPC level	Corresponding actual Biocidal Product identification (Best-case)	Associated "Highest Concentration" formulation with the meta SPC (Worst-case)*
Meta SPC 1 Light Duty Cleaning and Disinfection Liquid	LDL-L-0616008	LDL-H-05181
Meta SPC 2 Heavy Duty Cleaning and Disinfection Liquid	HDL-L-0616022	HDL-H-05182
Meta SPC 3 Disinfecting Foam Wash	DFWG-L-06163	DFWG-H-05183
Meta SPC 4 Disinfecting Gel Wash	DGWG-L-06161	DGWG-H-05184
Meta SPC 5 Disinfecting Gel Wash	DGWG-L-06163	DGWG-H-05185
Meta SPC 6 Disinfecting Foam Wash	DFWS-L-06161	DFWS-H-05186

* these codes refer to dummy products with the highest concentrations (=indicated by the 'H') in a meta SPCA

The classifications in this section of the PAR apply to the "Highest concentrated" formula in each meta SPC (i.e. the most concentrated formula), the "H" version of each meta SPC. Consequently, the below calculated formulations represent the "worst" case formulations for the whole meta SPC.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta SPC 1 - 6: Not classified
Justification for the value/conclusion	Rf (H315) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H315) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0

	Rf (H315) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0.78 Rf (H315) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0.78 Rf (H315) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0.78 Rf (H315) for Disinfecting Foam wash DFWS-H-05186 (Meta SPC 6): 0.65 The pH of the BPF is between 2 and 11.5 Meta SPC 1 - 6 contain ingredients with skin corrosion/irritation property, however, the concentrations are below the classification thresholds. See confidential Annex for calculations.
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification. Not classified for skin corrosion or irritation

Data waiving	
Information requirement	Meta SPC 1 - 6: not classified for skin corrosion or irritation.
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Additional explanation of non-classification of skin corrosion/irritation: See confidential Annex

Serious eye damage

Conclusion used in Risk Assessment – Eye Damage	
Value/conclusion	Meta SPC 1- 6: Not classified
Justification for the value/conclusion	Rf (H318) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H318) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0 Rf (H318) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0.40 Rf (H318) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0.40 Rf (H318) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0.40 Rf (H318) for Disinfecting Foam wash DFWS-H-05186 (Meta SPC 6): 0.33 The pH of the BPF is between 2 and 11.5

	Meta SPC 1 - 6 contain ingredients with eye damaging properties, however, the concentrations are below the classification thresholds. See for calculation the Confidential Annex.
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for eye damage

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for eye damage or eye irritation
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied

Additional explanation of non-classification of serious eye damage: See Confidential Annex.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Meta SPC 1 - 6: Not classified
Justification for the value/conclusion	Rf (H319) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H319) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0 Rf (H319) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0.94 Rf (H319) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0.94 Rf (H319) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0.94 Rf (H319) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): 0.65 The pH of the BPF is between 2 and 11.5 Meta SPC 1 - 6 contain ingredients with eye irritating properties, however, the concentrations are below the classification thresholds.
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for eye irritation

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for eye irritation.
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied

Additional explanation of non-classification of serious eye damage: See Confidential Annex.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Meta SPC 1 - 6: Not classified
Justification for the conclusion	Rf (H335) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H335) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0 Rf (H335) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0 Rf (H335) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0 Rf (H335) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0 Rf (H335) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): 0 The pH of the BPF is between 2 and 11.5
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for respiratory tract irritation

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for respiratory tract irritation.
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Skin sensitization

Value/conclusion	Meta SPC 1 - 6: Not classified
Justification for the value/conclusion	Rf (H317) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H317) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0 Rf (H317) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0 Rf (H317) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0 Rf (H317) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0 Rf (H317) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): 0

	Rf: is in this case not a summarised value but the highest calculated value for an individual substance
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified as a skin sensitizer

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for skin sensitization
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Meta SPC 1 - 6: Not classified
Justification for the value/conclusion	Rf (H334) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): 0 Rf (H334) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): 0 Rf (H334) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): 0 Rf (H334) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): 0 Rf (H334) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): 0 Rf (H334) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): 0 Rf: is in this case not a summarised value but the highest calculated value for an individual substance
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified as a respiratory sensitizer

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for inhalation sensitization
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Acute toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta SPC 1 - 6: Not classified

Justification for the selected value	ATE (oral) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): >2000 ATE (oral) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): >2000 ATE (oral) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): >2000 ATE (oral) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): >2000 ATE (oral) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): >2000 ATE (oral) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): >2000
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for Acute oral toxicity

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for acute oral toxicity
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Meta SPC 1 - 6: Not classified
Justification for the selected value	ATE (inh) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): >5 ATE (inh) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): >5 ATE (inh) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): >5 ATE (inh) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): >5 ATE (inh) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): >5 ATE (inh) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): >5
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for Acute inhalation toxicity

Data waiving	
Information requirement	Meta SPC 1 - 6: Not classified for acute inhalation toxicity
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Meta SPC 1 - 6: Not classified
Justification for the selected value	ATE (derm) for Light Duty Cleaning and Disinfection Liquid LDL-H-05181 (Meta SPC 1): >2000 ATE (derm) for Heavy Duty Cleaning and Disinfection Liquid HDL-H-05182 (Meta SPC 2): >2000 ATE (derm) for Disinfecting Foam Wash DFWG-H-05183 (Meta SPC 3): >2000 ATE (derm) for Disinfecting Gel Wash DGWG-H-05184 (Meta SPC 4): >2000 ATE (derm) for Disinfecting Gel Wash DGWG-H-05185 (Meta SPC 5): >2000 ATE (derm) for Disinfecting Foam Wash DFWS-H-05186 (Meta SPC 6): >2000
Classification of the product according to CLP and DSD	Conclusive but not sufficient for classification Not classified for Acute dermal toxicity

Data waiving	
Information requirement	Meta SPC 1 - 86: Not classified for acute dermal toxicity
Justification	Sufficient toxicological information is available for all the ingredients. Calculation method for CLP Classification is applied.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

There are no substance(s) of concern identified in this BPF, in accordance with CA-Nov14-Doc.5.11 - SoC guidance_final.doc. The evaluation is included in the Confidential Annex. Hygienix Biocidal Product Family

Assessment for endocrine disrupting properties for non-active substances

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed using the following methodorogy:

1) For each co-formulant, the exact GHS hazard classification is checked and identified whether the co-formulant has any CMR hazards statements
2) Each co-formulant is entered by way of its CAS number in the following 3 databases:
   A. Endocrine Active Substance Information system database (EU)
   B. Endocrine Disprusruption Screening Program for the 21st century (EPA)
   C. Endocrine disruptor knowledge database (FDA)
3) If data is found in the database, the data is presented in the table and a risk assessment is performed. In case no data on the ED properties is found in databases, a final check on the chemical/molecular structure is performed. A comparison is made with known ED chemicals and an assessment is done by Hygienix to evaluate the potential for ED properties based on the structure of each of the co-formulant.
4) An overall final risk evaluation and assessment is performed by a toxicology expert

After this screening it was concluded that none of the co-formulants shows an alert for endocrine disruptors. See the Confidential Annex for more information on the screening results.

2.2.7 Risk assessment for animal health

Risk assessment for animal health is a requirement for products not eligible for a simplified authorization as per Article 19, point 1. As this registration is submitted under the Art. 25 simplified authorization, this requirement is not relevant. Furthermore, Risk assessment for animal health is not defined as a requirement in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorization. Risk assessment for animal health is not part of the required summary of the biocidal product characteristics, for products submitted under the simplified authorization, as defined in points (a), (b) and (e) to (q) of Article 22(2). Therefore, the Risk assessment for animal health is not required for the current registration.

2.2.8 Risk assessment for the environment

Risk assessment for the environment is a requirement for products not eligible for a simplified authorization as per Article 19, point 1. As this registration is submitted under the Art. 25 simplified authorization, this requirement is not relevant. Furthermore, Risk assessment for the environment is this not defined as a requirement in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorization. This Risk assessment for the environment is not part of the required summary of the biocidal product characteristics, for products submitted under the simplified authorization, as defined in points (a), (b) and (e) to (q) of Article 22(2). Therefore, this Risk assessment for the environment is not required for the current registration.

2.2.9 Measures to protect man, animals and the environment

Measures to protect humans, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product, shelf-life of biocidal product
Store at room temperature. Protect from frost.
Shelf-life based on accelerated storage stability: 2 years (Meta SPC 4, 6), 3 years (Meta SPC 1, 2, 3, 5).
Storage stability studies at ambient temperature ongoing.

Recommended methods and precautions concerning handling and transport
No specific methods or precautions necessary. Follow use instructions.
The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous, nor do they require personal protection equipment.

Recommendations and precautions concerning fire, in case of fire nature of reaction products, combustion gases etc.
No specific recommendations or precautions necessary Products are non-flammable aqueous liquids and will not react with fire.

Particulars of likely direct or indirect adverse effects
No direct or indirect adverse effects expected. The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous, nor do they require personal protection equipment.

First aid instructions, antidotes.

Rinse with plenty of water. No antidotes necessary. The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous, nor do they require personal protection equipment.

Emergency measure to protect environment in case of accident.
No specific emergency measures necessary. The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only).
No specific control measures necessary. The products fulfil the criteria for simplified authorization and are based on active substances that are widely used in the food industry, activity against non-target organisms is not expected.

Possibility of destruction or decontamination following release in or on the following.

Air
The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous. Furthermore, all products are aqueous liquids. Contamination of air is therefore not possible and decontamination of air is therefore not applicable.

Water, including drinking water
The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous. All products are aqueous liquids that will be diluted quickly in water. Decontamination of water/drinking water is therefore not applicable.

Soil
The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous. All products are aqueous liquids that will be rinsed away or diluted in soil quickly. Decontamination of soil is therefore not applicable.

Procedures for waste management of active substance/biocidal product, and if appropriate, its packaging

Possibility of reuse or recycling
Packaging can be recycled. No special measures are necessary, packaging can be recycled similar to household waste.

Possibility of neutralisation of effects.
The products fulfil the criteria for simplified authorization and are therefore not classified as hazardous. The products are based on active substances that are widely used in the food industry and non-active substances that are widely used in the household and personal care industry. Neutralisation of the effects is therefore not necessary.

Conditions for controlled discharge including leachate qualities on disposal.
No specific conditions or controlled discharge necessary. The products fulfill the criteria for simplified authorization and are therefore not classified as hazardous. The products are based on active substances that are widely used in the food industry and non-active substances that are widely used in the household and personal care industry.

Conditions for controlled incineration.
No specific conditions necessary. The products fulfill the criteria for simplified authorization and are therefore not classified as hazardous.

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only).
None, the product and its packaging can be discarded with general (household) waste.

Procedures, if any, for cleaning application equipment (relevant for biocidal products only)
No specific procedures necessary. Product can be rinsed away with water.

2.2.10 Assessment of a combination of biocidal products

Not applicable, the biocidal products of the Hygienix Biocidal Product Family are not intended to be authorised for the use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product (family)

#	Title	Author	Year	Testing Laboratory	Report/study number	Company owner	Report date
1a			2016			Hygienix B.V.	Sep 23, 2016
1b			2016			Hygienix B.V.	Sep 23, 2016
1c			2016			Hygienix B.V.	Sep 23, 2016
1d			2016			Hygienix B.V.	Sep 23, 2016
1e			2016		9	Hygienix B.V.	Sep 23, 2016
1f			2016			Hygienix B.V.	Sep 23, 2016
1g			2016			Hygienix B.V.	Jul 25, 2016
1h		.	2016			Hygienix B.V.	Sep 13, 2016
1i	)		2016			Hygienix B.V.	Apr 12, 2016
1j		.	2021			Hygienix B.V.	May 6, 2021

1k	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	May 6, 2021
2a	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 19, 2016
2b	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 22, 2016
2c	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 25, 2016
2d	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 3, 2016
2e	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 25, 2016
2f	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 25, 2016,
3a	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019
3b	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019
3c	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019
3d	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019

3e	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019
3f	[redacted]	[redacted]	2019	[redacted]	[redacted]	Hygienix B.V.	Feb 12, 2019
3g	[redacted]	[redacted]	2020	[redacted]	[redacted]	Hygienix B.V.	Mar 20, 2020
3h	[redacted]	[redacted]	2020	[redacted]	[redacted]	Hygienix B.V.	Mar 21, 2020
3i	[redacted]	[redacted]	2020	[redacted]	[redacted]	Hygienix B.V.	Mar 21, 2020
3j	[redacted]	[redacted]	2020	[redacted]	[redacted]	Hygienix B.V.	Mar 21, 2020
3k	[redacted]	[redacted]	2020	[redacted]	[redacted] 1	Hygienix B.V.	Mar 21, 2020
3l	[redacted]	[redacted]	2020	[redacted]	[redacted]	Hygienix B.V.	Mar 21, 2020
4a	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 23, 2016
4b	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 20, 2016

4c	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 5, 2016
4d	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 16, 2021
4e	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 25, 2021
4f	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 1, 2021
4g	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Jan 19, 2021
4h	[redacted]	[redacted]	2022	[redacted]	[redacted]	Hygienix B.V.	May 5, 2022
4i	[redacted]	[redacted]	2021	[redacted]	[redacted]	Bode Chemie GmbH	Jun 24, 2021
4j	[redacted]	[redacted]	2021	[redacted]	[redacted]	Bode Chemie GmbH	Jun 24, 2021
5a	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 22, 2016
5b	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 22, 2016

	[redacted]	[redacted]		[redacted]			
5c	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 6, 2016
5d	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 5, 2016
5e	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 20, 2016
5f	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 16, 2021
5g	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 25, 2021
5h	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 1, 2021
5i	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Jan 19, 2021
5j	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Feb 24, 2021
5k	[redacted]	[redacted]	2022	[redacted]	[redacted]	Hygienix B.V.	Jul 6, 2022
5l	[redacted]	[redacted]	2021	[redacted]	[redacted]	Hygienix B.V.	Apr 12, 2021

5m			2021			Bode Chemie GmbH	Jun 24, 2021
5n			2021			Bode Chemie GmbH	Jun 24, 2021
6a			2016			Hygienix B.V.	Oct 31, 2016
6b			2016			Hygienix B.V.	Sep 13, 2016
6c	D		2016			Hygienix B.V.	Aug 12, 2016
7a			2016			Hygienix B.V.	Dec 19, 2019
7b			2016			Hygienix B.V.	Sep 13, 2016
7c			2016			Hygienix B.V.	Aug 12, 2016

7d	[redacted]	[redacted]	2016	[redacted]	[redacted].1	Hygienix B.V.	Sep 29, 2016
8a	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Dec 19, 2016
8b	[redacted]	[redacted].	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 13, 2016
8c	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 12, 2016
9a	[redacted]	[redacted].	2016	[redacted]	[redacted]	Hygienix B.V.	Oct 31, 2016
9b	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 13, 2016
9c	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Aug 12, 2016
9d	[redacted]	[redacted]	2016	[redacted]	[redacted]	Hygienix B.V.	Sep 29, 2016
10a	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018

10b	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
10c	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
10d	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
10e	[redacted]	[redacted]	2020	[redacted]	[redacted]	Aseptix B.V.	Mar 16, 2020
10f	[redacted]	[redacted]	2020	[redacted]	[redacted]	Aseptix B.V.	Mar 16, 2020
11a	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
11b	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
11c	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018

11d	[redacted]	[redacted]	2018	[redacted]	[redacted]	Hygienix B.V.	Dec 10, 2018
11e	[redacted]	[redacted]	2020	[redacted]	[redacted]	Aseptix B.V.	Mar 16, 2020
11f	[redacted]	[redacted]	2020	[redacted]	[redacted]	Aseptix B.V.	Mar 16, 2020
12a	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Sep 26, 2016
12b	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12c	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12d	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12e	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12f	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016

12g	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12h	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
12i	[redacted]	[redacted]	2016	[redacted]	n.a.	n.a.	Oct 6, 2016
13a	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13b	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13c	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13d	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13e	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13f	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13g	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.
13h	[redacted]	n.a.	2020	[redacted]	n.a.	n.a.	n.a.

3.2 Output tables from exposure assessment tools

Not part of the requirements for biocidal products eligible for simplified authorization as per Article 19, point 1, nor are they defined as requirements in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorization.

3.3 New information on the active substance

No new information has been provided on the active substances (+)-Tartaric Acid and Sodium Benzoate as such. New data is provided for the biocidal products containing these active substances.

3.4 Residue behaviour

Not part of the requirements for biocidal products eligible for simplified authorization as per Article 19, point 1, nor are they defined as requirements in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorization

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

See summary table in 2.2.5.5 and IUCLID file.

3.6 Confidential annex

See attached Confidential Annex with Qualitative and quantitative information on the composition of the biocidal product and Qualitative and quantitative information on the composition of the biocidal product family.

3.7 Other: Reference list

Literature references