

ADDENDUM TO PRODUCT ASSESSMENT REPORT

Hygienix Biocidal Product Family

February 2023

Addendum to biocidal product assessment report
related to product authorisation under Regulation (EU)
528/2012

1 BACKGROUND

An application for a minor change was received (BC-JP082555-18). The minor change involves the following changes:

- The number of wipes per flow pack has been adjusted from maximum 200 to maximum 250 wipes. Further, a new packaging material (PP) for wipes (single wipe sachet and flow pack) has been added (uses 1.3, 1.4, 2.7, 2.8).
- New efficacy studies are presented to demonstrate efficacy at a contact time of 2 minutes upon wiping (uses 2.1, 2.2, 2.7 and 2.8).

In addition to that, the following administrative changes were also applied for:

- Various Italian trade names of the brand Lysoform Salviette have been deleted (product Hygienix Light Duty Cleaning and Disinfection Liquid LDL-L-0616008 (wipes)).
- One Italian trade name has been added to product Hygienix Light Duty Cleaning and Disinfection Lidquid LDL-L-0616008 (wipes).
- Change in the name or address of the authorisation holder and Change in the name, the administrative details or the formulating location of the biocidal product formulator: The address of Hygienix B.V. has changed to: Boslaan 4, 1217 CV Hilversum.

2 CONCLUSION

The change in packaging material and number of wipes is considered acceptable.
The change in contact time for viruses in Meta SPC 2 is acceptable.

3 ASSESSMENT REPORT

Authorised use(s)

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

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 or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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/m ² . - Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester,

Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.
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2.1.4.14 Use-specific instructions for use #1.3

<p>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.</p> <p>Contact times (min): Bacteria, yeasts and enveloped viruses - 2 Mycobacteria - 30</p>
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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.
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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

Ctgb
Hygienix Biocidal Product Family
PT01, PT02, PT04

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 or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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/m ² . - Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester, Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.

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	<p>- 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.</p> <p>- 3000 - 30000 ml (PET, PE or HDPE) jerry can with (PP/PVC/PE) dosing pump or pressurized sprayer for direct use, or with (PP, PVC or PE) screw-cap to use as refill.</p>
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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 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, enveloped viruses and viruses - 2

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
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Ctgb
Hygienix Biocidal Product Family
PT01, PT02, 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, enveloped viruses and viruses - 2

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.

2.1.4.61 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 or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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/m ² .

- Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester, Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.

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, enveloped viruses and viruses - 2

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
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Ctgb
Hygienix Biocidal Product Family
PT01, PT02, 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 or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof, or; Flow pack made of laminated or single-layer PET, PET/PE, PE or PP (including CPP and OPP) with 8 - 250 wipes per pack, or; HDPE or PE Plastic tub, canister or bucket with 10 - 800 wipes per package. - 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/m ² . - Wipe material can consist of Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose mix, Viscose/Pulp (cellulose) mix, Polyethylene, Polyethylene/viscose, Polyester, Polyester/Polypropylene/Viscose, Pulp (cellulose), and any variations thereof.

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, enveloped viruses and viruses - 2

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.

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	Professional and non-professional	Y

Ctgb
Hygienix Biocidal Product Family
PT01, PT02, PT04

			press-top cap		
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 or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof	Not applicable	Professional and non-professional	Y
Flow pack	8 - 250 wipes	laminated or single-layer PET, PET/PE, PE, PP (including CPP and OPP) or blends thereof	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	Polypropylene, Polypropylene/pulp (cellulose), Polypropylene/viscose/pulp, Polypropylene/viscose	Not applicable	Professional and non-professional	Y

Ctgb
Hygienix Biocidal Product Family
PT01, PT02, PT04

	liquid weight to the wipe weight. Wipe substrate weight ranges from 35 – 70 gr/m2.	mix, Viscose/Pulp (cellulose) mix, Polyethylene , Polyethylene / viscose, Polyester, Polyester/ Polypropylene/ Viscose, Pulp (cellulose), and any variations thereof			
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Assessment of the biocidal product (family)

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

Ctgb
Hygienix Biocidal Product Family
PT01, PT02, PT04

Full spectrum virucidal activity, Adenovirus	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Standard wipe (soaked) used for the test Meta SPC 2	Adenovirus type 5 strain adenoid 75 (ATCC VR-5)	EN 16615:2015	Dirty conditions* / wipe / 100%, 1% / 2 min	Log R \geq 4.22 as wipe / 100% / 2 min	5o
Full spectrum virucidal activity, Murine noroviruses	Surface disinfection, indoor	Heavy Duty Cleaning and Disinfection Liquid HDL-L-0616022 Standard wipe (soaked) used for the test Meta SPC 2	Murine norovirus (S99; FLI registration no. RVB-0651)	EN 16615:2015	Dirty conditions* / wipe / 100%, 10% / 2 min	Log R \geq 5.06 as wipe / 2 min	5p

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

4 ANNEXES

List of studies for this minor change

#	Title	Author	Year	Testing Laboratory	Report/study number	Company owner	Report date
5o			2021			Bode Chemie GmbH	Nov 3, 2021
5p			2021			Bode Chemie GmbH	Jul 7, 2021