

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Kenolox 10

Product type(s)

PT04: Food and feed area

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

Authorisation number: see authorisation letter

R4BP asset number: AT-0030676-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Kenolox 10 Ultra DES Spezial FOD Kenoxylac Kenoxilac MiQro Derolox AIR DES 100 HG desinfectie reiniger HG nettoyant de désinfection HG Desinfektionsreiniger
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	CID LINES NV
	Address	Waterpoortstraat 2 8900 Ieper Belgium
Authorisation number	see authorisation letter	
<i>R4BP asset number</i>	AT-0030676-0000	
Date of the authorisation	05/03/2024	
Expiry date of the authorisation	31/05/2032	

1.3. Manufacturer(s) of the product

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

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkselsedijk 46 4206 Gorinchem Netherlands (the)
Location of manufacturing sites	Arkselsedijk 46 4206 Gorinchem Netherlands (the)

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. et Portuaire, B.P. 32 67390 Marckolsheim France
Location of manufacturing sites	Z.I. et Portuaire, B.P. 32 67390 Marckolsheim France

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Degussa Antwerpen NV
Address of manufacturer	Tijsmanstunnel Wes 2040 Antwerpen Belgium
Location of manufacturing sites	Tijsmanstunnel West 2040 Antwerpen Belgium

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	1
Hydrogen peroxide		active substance	7722-84-1	231-765-0	1

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H315: Causes skin irritation. H319: Causes serious eye irritation.
Precautionary statements	P264: Wash hands thoroughly after handling. P280: Wear protective gloves. P280: Wear eye/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice. P337+P313: If eye irritation persists: Get medical advice. P362+P364: Take off contaminated clothing and wash it before reuse. P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1: hard surface disinfection for professional use PT4

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: other: bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: other: yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: other: viruses Common name: Viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Food and Feed industries Disinfection of hard/non-porous surfaces with prior cleaning</p>
Application method(s)	<p>Method: By spraying (with possibly wipe dry with a towel after the contact time); automated spraying in closed system (for knives); immersion or fogging</p> <p>Detailed description: -spraying with a (low pressurized) back pack sprayer and letting the surface/object air dry, or wiping the surface/object dry with a towel after the contact time.-spraying with a trigger sprayer and letting the surface/object air dry, or wiping the surface/object dry with a towel after the contact time.-automatic spraying of knives in closed systems.-immersion and letting the surface/object air dry, or wiping the surface/object dry with a towel after the contact time.-fogging.</p>
Application rate(s) and frequency	<p>Application Rate: 40 ml/m² for spraying; immersed in a bath; 30 ml/m³ for fogging</p> <p>Dilution (%): -</p> <p>Number and timing of application: Daily use With undiluted product at Room Temperature <u>By spraying or by immersion:</u> For an effect on bacteria and on yeasts: 2 min contact time For an effect on bacteria, yeasts and viruses: 5 min contact time <u>By fogging:</u> For an effect on bacteria, on yeasts and on viruses: 30 mL/m³ - in 3h contact time (after fogging) In rooms with a volume between 30 & 2000 m³</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>500 mL, 750 mL, 1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L</p> <p>1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg</p>

4.1.1. Use-specific instructions for use

Please refer to general directions for use.

By Spraying with a (low pressurized) back pack sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:

Kenolox 10 by spraying is used to disinfect surfaces and material in kitchens, canteens and food or feed industry where food is prepared, f.i. floors, walls, kitchen worktops, food processing machinery, cutting boards and hand contact surfaces (f.i. touch screens, handles, switches).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted with a (low pressurized) back pack sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see number and timing of application section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

By Spraying trigger sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:

Kenolox 10 by trigger spraying is used to disinfect small surfaces and material in kitchens, canteens and food or feed industry where food is prepared, f.i. kitchen worktops, food processing machinery, cutting boards and hand contact surfaces (f.i. touch screens, handles, switches).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted by trigger sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see number and timing of application section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

By automatic spraying of knives in closed systems:

Before application of the product, the knives should be cleaned thoroughly and rinsed with clean water. Apply the product undiluted by automatic spraying in closed systems. For the appropriate contact time, see number and timing of application section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed.

By immersion and letting objects air dry or wiping dry with a towel after the contact time:

Kenolox 10 by immersion is used to disinfect material in kitchens and food and feed industry, f.i. knives.

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Immerse the objects in a Kenolox 10 bath (+20°C). The treated objects need to stay wet during the appropriate contact time (see number and timing of application section). Final rinsing is not needed. Let the treated objects air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time

Disposal of used solution is poured into a drainage.

By Fogging

Kenolox 10 by fogging is used for room disinfection of kitchens and rooms in the entire food and feed industry.

Kenolox 10 is intended to be used for cold fogging. Surfaces, equipment and material in the room to be disinfected should first be cleaned thoroughly and rinsed with clean water.

The following operations must be performed prior to disinfection:

- Remove excess water
- Remove or protect sensitive electronic equipment and other objects that are sensitive to moisture
- Open drawers and cupboard doors
- Switch of ventilation and close windows and ventilation openings
- Close toilet bowls (only for PT2 applications)

Rinsing is not necessary.

For detailed instructions on fogging procedures, please see general directions for use.

Microbiological validation: please see general directions for use

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

Re-entering the room: The room can only be released for use if the measured concentration of hydrogen peroxide < 1,25 mg/m³ (0,86 ppm).

4.1.2. Use-specific risk mitigation measures

For mixing and loading, low-pressure spraying, hand-held trigger spraying, immersion/dipping, wiping dry after disinfection, cleaning of equipment, maintenance and repair:

The use of eye protection during handling of the product is mandatory. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034, 13962, 14605 or 943) shall be worn. Textiles used for wiping dry disinfected surfaces are to be kept in a closed container.

Respiratory protection:

For application by low-pressure, coarse spraying of large surfaces in Food & Feed industry:

in cleanrooms: Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

In institutional kitchens and canteens, industrial kitchens, industrial production rooms and cleanrooms with increased ventilation (20/h or up): Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by low-pressure, coarse spraying of small surfaces in Food & Feed industry (e.g. surface size 1 m² or food processing machine): respiratory protection is not required.

For application by hand-held trigger spray of large surfaces (surface size 10 m²) in Food & Feed industry: In institutional kitchens and canteens: Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by hand-held trigger spray of small surfaces in Food & Feed industry (e.g. surface size 1 m² or food processing machine): respiratory protection is not required.

For application by immersion/dipping in Food & Feed industry: respiratory protection is not required.

For application during knife disinfection by automated spraying, and during the fogging application phase in Food & Feed industry (user does not come in contact with the biocidal product): respiratory protection is not required.

For wiping dry of disinfected surfaces in Food & Feed: the same RPE as during the application phase is required.

For cleaning of equipment, maintenance and repair: respiratory protection is not required.

RMM for bystanders and professionals without protective equipment:

Small surface treatment: The general public is not allowed to touch or use items that have been disinfected until they are dry.

Large surface treatment: No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Fogging:

During disinfection people, animals, plants, medicines or food should not be present in the room. No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Ventilation times after disinfection of large surfaces by spraying:

-ventilation rates of 8/h and up: a re-entry time of 30 mins after the application phase has ended is required.

-ventilation rates of 3/h and up: a re-entry time of 90 mins after the application phase has ended is required.

-ventilation rates of 1.5/h and up: a re-entry time of 3h after the application phase has ended is required.

-low ventilation rates, below 1.5/h: a re-entry time of 6h after the application phase has ended is required.

-in cases where these waiting times cannot be respected:

For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

Ventilation times after disinfection by fogging:

-ventilation rates of 8/h and up: a re-entry time of 45 mins after the contact time has ended is required.

-ventilation rates of 3/h and up: a re-entry time of 2h after the contact time has ended is required.

-ventilation rates of 1.5/h and up: a re-entry time of 4h after the contact time has ended is required.

-low ventilation rates, below 1.5/h: a re-entry time of 10h after the contact time has ended is required.
 - in cases where these waiting times cannot be respected:
 For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

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

See general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2. Use description

Table 2. Use 2: RTU hard surface disinfection for non-professional use PT4

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: other: bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: other: yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: other: viruses Common name: Viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>In private houses/kitchens: Disinfection of hard/non-porous surfaces with prior cleaning</p>
Application method(s)	<p>Method: By spraying (with possibly wipe dry with a towel after the contact time)</p> <p>Detailed description: Spraying with a trigger sprayer and letting the surface/object air dry, or wiping the surface/object dry with a towel after the contact time.</p>
Application rate(s) and frequency	<p>Application Rate: 40 ml/m²</p> <p>Dilution (%): -</p> <p>Number and timing of application: Daily use With undiluted product at Room Temperature For an effect on bacteria and on yeasts: 2 min contact time For an effect on bacteria, yeasts and viruses: 5 min contact time</p>
Category(ies) of users	general public (non-professional)

Pack sizes and packaging material	500 mL, 750 mL and 1L Trigger spray HDPE (High Density Polyethylene)
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4.2.1. Use-specific instructions for use

Please refer to general directions for use.

Comply with the instructions for use.

By Spraying with a trigger sprayer and let it air dry or wipe dry with a towel after the contact time:

Kenolox 10 by spraying is used to disinfect small surfaces in kitchens in households, f.i. kitchen worktops, cutting boards and knives.

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess of water should be removed.

Apply the product undiluted with a trigger sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see number and timing of application section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

4.2.2. Use-specific risk mitigation measures

Wash hands thoroughly after handling. Do not spray in the direction of people. After disinfection, provide adequate ventilation (open windows and doors). Treated surfaces should be inaccessible to infants, children, companion animals and non-target animals until these surfaces are dry.

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

See general directions for use. If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use. Keep out of reach of children and non-target animals/pets.

4.3. Use description

Table 3. Use 3: hard surface disinfection in healthcare areas for professional use PT2

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: other: bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: other: yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: other: viruses Common name: Viruses Development stage: no data</p>
Field(s) of use	indoor use

	In HEALTHCARE (medical and non-medical areas). Disinfection of hard/non-porous surfaces with prior cleaning.
Application method(s)	Method: By spraying (with possibly wipe dry with a towel after the contact time) or fogging Detailed description: -spraying with a (low pressurized) back pack sprayer and letting the surface/object air dry or wiping the surface/object dry with a towel after the contact time.-spraying with a trigger sprayer and letting the surface/object air dry or wiping the surface/object dry with a towel after the contact time.-fogging
Application rate(s) and frequency	Application Rate: 40 ml/m ² for spraying; 30 ml/m ³ for fogging Dilution (%): - Number and timing of application: Daily use With undiluted product at Room Temperature <u>By spraying:</u> For an effect on bacteria and on yeasts: 2 min contact time For an effect on bacteria, yeasts and viruses: 5 min contact time <u>By fogging:</u> For an effect on bacteria, on yeasts and on viruses: 30 mL/m ³ - in 3h contact time (after fogging) In rooms with a volume between 30 & 2000 m ³
Category(ies) of users	professional
Pack sizes and packaging material	500 mL, 750 mL, 1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

4.3.1. Use-specific instructions for use

Please refer to general directions for use.

By Spraying with a (low pressurized) back pack sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:

Kenolox 10 by spraying is used to disinfect surfaces in healthcare/hospitals, f.i. walls, floors, bathrooms, toilet seat, toilet flush and hand contact surfaces (f.i. touch screens, handles, switches, trolleys, hospital beds, remote controls).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted with a (low pressurized) back pack sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see application rate and frequency section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

By Spraying with a trigger sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:
Kenolox 10 by trigger spray is used to disinfect small surfaces and material in healthcare/hospitals, f.i. furniture, bathrooms, toilet seat and toilet flush, hand contact surfaces (f.i. touch screens, handles, switches, trolleys, hospital beds, remote controls).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted by trigger sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see application rate and frequency section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel

after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

By Fogging

Kenolox 10 by fogging is used for room disinfection in healthcare.

Kenolox 10 is intended to be used for cold fogging. Surfaces, equipment and material in the room to be disinfected should first be cleaned thoroughly and rinsed with clean water.

The following operations must be performed prior to disinfection:

- Remove excess water
- Remove or protect sensitive electronic equipment and other objects that are sensitive to moisture
- Open drawers and cupboard doors
- Switch off ventilation and close windows and ventilation openings
- Close toilet bowls (only for PT2 applications)

Rinsing is not necessary.

For detailed instructions on fogging procedures, please see general directions for use.

Microbiological validation: please see general directions for use

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

Re-entering the room: The room can only be released for use if the measured concentration of hydrogen peroxide < 1,25 mg/m³ (0,86 ppm).

4.3.2. Use-specific risk mitigation measures

For mixing and loading, low-pressure spraying, hand-held trigger spraying, wiping dry after disinfection, cleaning of equipment, maintenance and repair:

The use of eye protection during handling of the product is mandatory.

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 6, EN 13034, 13962, 14605 or 943) shall be worn.

Textiles used for wiping dry disinfected surfaces are to be kept in a closed container.

Respiratory protection:

For application by low-pressure, coarse spraying of large surfaces in healthcare:

in laboratories and biotechnology, cleanrooms, pharmaceutical and cosmetics manufacturing facilities, operation theatres, medical practices, in epidemic cases: Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

in sanitary rooms, hospital rooms: Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). Ensure that the ventilation rate during and after disinfection is minimum 3ACH.

In cleanrooms with increased ventilation (20/h or up): Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

In large public areas: Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by low-pressure, coarse spraying of small surfaces in healthcare (e.g. surface size 1 m²): respiratory protection is not required.

For application by hand-held trigger spray of large surfaces (surface size 8-10 m²) in healthcare:

In cleanrooms, sanitary rooms: Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

In cleanrooms with increased ventilation (20/h or up), pharmaceutical and cosmetics manufacturing facilities, laboratories and biotechnology, medical practices: Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by hand-held trigger spray of small surfaces in healthcare (e.g. surface size 0.5-2 m²): respiratory protection is not required.

For application during the fogging application phase in healthcare (user does not come in contact with the biocidal product): respiratory protection is not required.

For wiping dry of disinfected surfaces in healthcare: the same RPE as during the application phase is required.

For cleaning of equipment, maintenance and repair: respiratory protection is not required.

RMM for bystanders and professionals without protective equipment:

Small surface treatment: The general public is not allowed to touch or use items that have been disinfected until they are dry.

Large surface treatment: No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Fogging:

During disinfection people, animals, plants, medicines or food should not be present in the room. No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Ventilation times after disinfection of large surfaces by spraying:

- ventilation rates of 8/h and up: a re-entry time of 30 mins after the application phase has ended is required.
- ventilation rates of 3/h and up: a re-entry time of 90 mins after the application phase has ended is required.
- ventilation rates of 1.5/h and up: a re-entry time of 3h after the application phase has ended is required.
- low ventilation rates, below 1.5/h: a re-entry time of 6h after the application phase has ended is required.

-in cases where these waiting times cannot be respected:

For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

Ventilation times after disinfection by fogging:

- ventilation rates of 8/h and up: a re-entry time of 45 mins after the contact time has ended is required.
- ventilation rates of 3/h and up: a re-entry time of 2h after the contact time has ended is required.
- ventilation rates of 1.5/h and up: a re-entry time of 4h after the contact time has ended is required.
- low ventilation rates, below 1.5/h: a re-entry time of 10h after the contact time has ended is required.

- in cases where these waiting times cannot be respected:

For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

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

See general directions for use.

4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.4. Use description

Table 4. Use 5: hard surface disinfection in areas other than healthcare areas, for professional use PT2

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: other: bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: other: yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: other: viruses Common name: Viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>In other areas than in healthcare. Disinfection of hard/non-porous surfaces with prior cleaning.</p>
Application method(s)	<p>Method: By spraying (with possibly wipe dry with a towel after the contact time) or fogging</p> <p>Detailed description: -spraying with a (low pressurized) back pack sprayer and letting the surface/object air dry or wiping the surface/object dry with a towel after the contact time.-spraying with a trigger sprayer and letting the surface/object air dry or wiping the surface/object dry with a towel after the contact time.-fogging</p>
Application rate(s) and frequency	<p>Application Rate: 40 ml/m² for spraying; 30 ml/m³ for fogging</p> <p>Dilution (%): -</p> <p>Number and timing of application: Daily use With undiluted product at Room Temperature <u>By spraying:</u> For an effect on bacteria and on yeasts: 2 min contact time For an effect on bacteria, yeasts and viruses: 5 min contact time <u>By fogging:</u> For an effect on bacteria, on yeasts and on viruses: 30 mL/m³ - in 3h contact time (after fogging) In rooms with a volume between 30 & 2000 m³</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>500 mL, 750 mL, 1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)</p>

4.4.1. Use-specific instructions for use

Please refer to general directions for use.

By Spraying with a (low pressurized) back pack sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:

Kenolox 10 by spraying is used to disinfect surfaces in houses and public areas, f.i. walls, floors, bathrooms, toilet seat, toilet flush, lockers, changing rooms and hand contact surfaces (f.i. touch screens, handles, switches, remote controls).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted with a (low pressurized) back pack sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see number and timing of application section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

By Spraying with a trigger sprayer and letting surfaces air dry or wiping dry with a towel after the contact time:

Kenolox 10 by spraying is used to disinfect small surfaces in houses and public areas, f.i. bathrooms, toilet seat, toilet flush and hand contact surfaces (f.i. touch screens, handles, switches, remote controls).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted with a trigger sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see application rate and frequency section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

By Fogging

Kenolox 10 by fogging is used for room disinfection in public areas.

Kenolox 10 is intended to be used for cold fogging. Surfaces, equipment and material in the room to be disinfected should first be cleaned thoroughly and rinsed with clean water.

The following operations must be performed prior to disinfection:

- Remove excess water
- Remove or protect sensitive electronic equipment and other objects that are sensitive to moisture
- Open drawers and cupboard doors
- Switch of ventilation and close windows and ventilation openings
- Close toilet bowls (only for PT2 applications)

Rinsing is not necessary.

For detailed instructions on fogging procedures, please see general directions for use.

Microbiological validation: please see general directions for use

The user is expected to prepare the exact quantity needed for disinfection. Disposal of remaining solution if there is any, is poured into a drainage. Clean equipment used after application.

Re-entering the room: The room can only be released for use if the measured concentration of hydrogen peroxide < 1,25 mg/m³ (0,86 ppm).

4.4.2. Use-specific risk mitigation measures

For mixing and loading, low-pressure spraying, hand-held trigger spraying, wiping dry after disinfection, cleaning of equipment, maintenance and repair:

The use of eye protection during handling of the product is mandatory.

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 6, EN 13034, 13962, 14605 or 943) shall be worn.

Textiles used for wiping dry disinfected surfaces are to be kept in a closed container.

Respiratory protection:

For application by low-pressure, coarse spraying of large surfaces in non-healthcare:

in laboratories and biotechnology, cleanrooms, pharmaceutical and cosmetics manufacturing facilities, operation theatres, medical practices, in epidemic cases: Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

in sanitary rooms, hospital rooms: Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder

within the product information). Ensure that the ventilation rate during and after disinfection is minimum 3ACH.

In cleanrooms with increased ventilation (20/h or up), industrial production rooms: Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

In large public areas: Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by low-pressure, coarse spraying of small surfaces in non-healthcare (e.g. surface size 1 m²): respiratory protection is not required.

For application by hand-held trigger spray of large surfaces (surface size 8-10 m²) in non-healthcare:

In cleanrooms, sanitary rooms: Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

In cleanrooms with increased ventilation (20/h or up), pharmaceutical and cosmetics manufacturing facilities, laboratories and biotechnology, medical practices: Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

For application by hand-held trigger spray of small surfaces in non-healthcare (e.g. surface size 0.5-2 m²): respiratory protection is not required.

For application during the fogging application phase in non-healthcare (user does not come in contact with the biocidal product): respiratory protection is not required.

For wiping dry of disinfected surfaces in non-healthcare: the same RPE as during the application phase is required.

For cleaning of equipment, maintenance and repair: respiratory protection is not required.

RMM for bystanders and professionals without protective equipment:

Small surface treatment: The general public is not allowed to touch or use items that have been disinfected until they are dry.

Large surface treatment: No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Fogging:

During disinfection people, animals, plants, medicines or food should not be present in the room. No access of the general public during treatment and until surfaces have dried and the treated area has been ventilated sufficiently.

Ventilation times after disinfection of large surfaces by spraying:

-ventilation rates of 8/h and up: a re-entry time of 30 mins after the application phase has ended is required.

-ventilation rates of 3/h and up: a re-entry time of 90 mins after the application phase has ended is required.

-ventilation rates of 1.5/h and up: a re-entry time of 3h after the application phase has ended is required.

-low ventilation rates, below 1.5/h: a re-entry time of 6h after the application phase has ended is required.

-in cases where these waiting times cannot be respected:

For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

Ventilation times after disinfection by fogging:

-ventilation rates of 8/h and up: a re-entry time of 45 mins after the contact time has ended is required.

-ventilation rates of 3/h and up: a re-entry time of 2h after the contact time has ended is required.

-ventilation rates of 1.5/h and up: a re-entry time of 4h after the contact time has ended is required.

-low ventilation rates, below 1.5/h: a re-entry time of 10h after the contact time has ended is required.

- in cases where these waiting times cannot be respected:

For re-entry, the undercut of AEC_{inhalation} of 1.25 mg/m³ H₂O₂ shall be ensured with technical and organisational measures (e.g. sensor, ventilation period defined by measurements).

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

See general directions for use.

4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.5. Use description

Table 5. Use 6: hard surface disinfection in areas other than healthcare areas, for non-professional use PT2

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: other: bacteria Common name: Bacteria Development stage: no data Scientific name: other: yeasts Common name: Yeasts Development stage: no data Scientific name: other: viruses Common name: Viruses Development stage: no data
Field(s) of use	indoor use In other areas than in healthcare. Disinfection of hard/non-porous surfaces with prior cleaning
Application method(s)	Method: By spraying (with possibly wipe dry with a towel after the contact time) Detailed description: Spraying with a trigger sprayer and letting the surface/object air dry or wiping the surface/object dry with a towel after the contact time.
Application rate(s) and frequency	Application Rate: 40 ml/m ² Dilution (%): - Number and timing of application: Daily use With undiluted product at Room Temperature For an effect on bacteria and on yeasts: 2 min contact time For an effect on bacteria, yeasts and viruses: 5 min contact time
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	500 mL, 750 mL and 1L Trigger spray HDPE (High Density Polyethylene)

4.5.1. Use-specific instructions for use

Please refer to general directions for use.

Comply with the instructions for use.

By Spraying with a trigger sprayer and letting surfaces air dry or wiping dry with a towel after the contact time: Kenolox 10 by spraying is used to disinfect smaller surfaces in houses or public areas, such as small surfaces in bathrooms (f.i. taps, sinks), toilet seat, toilet flush and hand contact surfaces (f.i. touch screens, handles, switches, remote controls).

Before application of the product, the surfaces and materials to be disinfected should be cleaned thoroughly and rinsed with clean water. Excess water should be removed.

Apply the product undiluted with a trigger sprayer on the surface or object which is to be disinfected. For the appropriate contact time, see application rate and frequency section. The treated surfaces need to stay wet during the contact time. Final rinsing is not needed. Let the treated surfaces/material air dry or wipe dry with a towel after the contact time. Keep bystanders/general public away from surfaces when surfaces are drying. If it's not possible, dry the surfaces with a towel after contact time.

4.5.2. Use-specific risk mitigation measures

Wash hands thoroughly after handling. Do not spray in the direction of people. After disinfection, provide adequate ventilation (open windows and doors). Treated surfaces should be inaccessible to infants, children, companion animals and non-target animals until these surfaces are dry.

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

See general directions for use. If medical advice is needed, have product container or label at hand.

4.5.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.5.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use. Keep out of reach of children and non-target animals/pets.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See use-specific instructions for use.

- All the surfaces to be disinfected must be cleaned before the disinfection procedure.

The following precautionary sentence will be added on the product label : “Thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected”.

- Disinfection cycle :

- The product is intended to be used undiluted

- Contact time depends on the use considered. Please refer to the description of application method related to each use.

- Final rinsing (with potable water) : not required.

Disinfection procedures by spraying: the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

Disinfection procedures by immersion : The bath is not intended to be re-used. Use the bath only once, empty it immediately after use & replace it by a fresh solution just before each use.

Disinfection procedures by fogging :

During disinfection, no people, animals or food can be present in the room.

The product **KENOLOX 10** is a ready-to-use liquid disinfectant to be applied by fogging for airborne surface disinfection (in rooms with volume between 30 and 2000 m³) and to be used by professional users only.

Always check compatibility with the materials to be disinfected.

The disinfection must be carried out in enclosed spaces.

Airborne disinfection should be done only after cleaning and rinsing. The surfaces to be disinfected should be dried before the disinfection procedure.

Please pay attention to open the cupboard doors.

Please check the temperature and the relative room humidity (to be set between 40 and 80%) to obtain an optimal level for the product efficiency.

Please check the temperature and the relative room humidity (to be set between 40 and 80%) to obtain an optimal level for the product efficiency.

The room where the fogging activity takes place is tightly sealed during fogging, no user is present :

Before the start of the disinfection cycle by fogging, the treated room is sealed. All the safety tasks for the implementation of decontamination are entrusted to an user who has completed the necessary training. Among them, first step is shutting down the air handling units and closing the air intake and return, so the product is not spread in the other rooms. The door or doors to the outside of the area are then locked and, if the joints are not tight enough, they are taped to seal. An orange tape, or bright color, is preferably chosen to attract attention and a sign "*Access ban, room disinfection in progress*" is put on. Only for use in areas that are inaccessible to the general public and companion animals”.

The product **KENOLOX 10** has been developed to be used for example with the NEBULO-NEBURATOR atomizers. The number of devices (or nozzles) has to be adapted to the volume to be treated.

However, the use of other atomizers is possible. They must be designed to ensure a fog production able to stay suspended in the air and provided that these devices meet following characteristics :

- Particle size: 10 µm
- Flow rate : 0.3 – 15 L/h
- Application rate : 30 mL/m³
- Room volume between 30 and 2000 m³

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. Each device or specific installation is systematically validated when it is set up.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use. The shelf-life of the products is 2 years.

6. OTHER INFORMATION

No other information.