

Summary of product characteristics for a biocidal product

Product name: UniBlue Universal Disinfection Fluid (UDF2)

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

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PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0020556-0000

R4BP 3 asset reference number: EU-0020556-0001

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Administrative information

1.1. Trade names of the product

UniBlue Universal Disinfection Fluid (UDF2)
UniBlue UDF2

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Wiping Systems ApS
	Address	Mileparken 10 D 2740 Skovlunde Denmark
Authorisation number	EU-0020556-0000 1-1	

R4BP 3 asset reference number

EU-0020556-0001

Date of the authorisation

04/12/2020

Expiry date of the authorisation

31/12/2028

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Fluid: Dreiturm GmbH
Address of the manufacturer	Dr.-Rudolf-Hedler-Straße 136396 Steinau an der Straße Germany
Location of manufacturing sites	Dr.-Rudolf-Hedler-Straße 136396 Steinau an der Straße Germany

Name of the manufacturer	Fluid: ReAgent Chemical Services Ltd
Address of the manufacturer	11b-13, Whitehouse Industrial Estate, Aston Fields Rd, WA7 3DL Runcorn United Kingdom
Location of manufacturing sites	11b-13, Whitehouse Industrial Estate, Aston Fields Rd, WA7 3DL Runcorn United Kingdom

Name of the manufacturer	Fluid: Nordcoll A/S
Address of the manufacturer	Egeskovvej 12 3490 Kvistgaard Denmark
Location of manufacturing sites	Egeskovvej 12 3490 Kvistgaard Denmark

Name of the manufacturer	Fluid: CIP4 S.r.l
Address of the manufacturer	Via Mario Idiomi, 6 20057 Assago (MI) Italy
Location of manufacturing sites	Via Mario Idiomi, 6 20057 Assago (MI) Italy

Name of the manufacturer	Fluid: Rockline Industries Ltd
Address of the manufacturer	Heming Rd B98 0DH Redditch United Kingdom
Location of manufacturing sites	Heming Rd B98 0DH Redditch United Kingdom

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

Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Tartaros Gonsalo Castello. S.L.
Address of the manufacturer	Carrer Concepción Arenal, 32, Novelda 03660 Alacant Spain
Location of manufacturing sites	Carrer Concepción Arenal, 32, Novelda 03660 Alacant Spain

Active substance	1424 - (+)-Tartaric acid
Name of the manufacturer	Distillerie Mazzari SpA
Address of the manufacturer	Via Giardino 6 48020 (RA) Sant'Agata sul Santerno Italy
Location of manufacturing sites	Via Giardino 6 48020 (RA) Sant'Agata sul Santerno Italy

Active substance	1421 - Lactic acid
Name of the manufacturer	Mushashino Chemical Company
Address of the manufacturer	Yaesu Daibiru Bldg.7th Fl.1-1, Kyobashi 1-chome 104-0031 Chuo-ku, Tokyo Japan
Location of manufacturing sites	Yaesu Daibiru Bldg.7th Fl.1-1, Kyobashi 1-chome 104-0031 Chuo-ku, Tokyo Japan

Active substance	1421 - Lactic acid
Name of the manufacturer	Jungbunzlauer S.A.
Address of the manufacturer	Z.I. et Portuaire, BP 32 67390 Marckolsheim France
Location of manufacturing sites	Z.I. et Portuaire, BP 32 67390 Marckolsheim France

Active substance	1429 - Lavender oil (Natural oil)
Name of the manufacturer	Naissance NNI
Address of the manufacturer	Unit 11, Milland Road Industrial Estate SA11 1NJ Neath, Wales United Kingdom
Location of manufacturing sites	Unit 11, Milland Road Industrial Estate SA11 1NJ Neath, Wales United Kingdom

Active substance	1430 - Peppermint oil (Natural oil)
Name of the manufacturer	Naissance NNI
Address of the manufacturer	Unit 11, Milland Road Industrial Estate SA11 1NJ Neath, Wales United Kingdom
Location of manufacturing sites	Unit 11, Milland Road Industrial Estate SA11 1NJ Neath, Wales United Kingdom

2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
(+)-Tartaric acid		Active Substance		201-766-0	0,616
Lactic acid		Active Substance		200-018-0	0,36
Lavender oil (Natural oil)		Active Substance	8000-28-0		0,099
Peppermint oil (Natural oil)		Active Substance	8006-90-4		0,099

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Precautionary statements

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 – PT 2 - Disinfection of non-porous hard surfaces within healthcare

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeast
Development stage:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Disinfection of non-porous hard surfaces in healthcare areas that are frequently touched and cannot be kept precluded from touching, by patients and/or staff, longer than 5 minutes.

Application method(s)

Method: Pouring or application by pump or triggerspray
Detailed description:
-

Application rate(s) and frequencies

Application Rate: -
Dilution (%): Ready-to use liquid.
Number and timing of application:

Disinfection with prior cleaning
The rate of application must be sufficient to keep the intended area covered with fluid during the contact time :
Contact time:
Bacteria and yeast: 5 minutes
Viruses: 2 minutes

The product can be used as often as it is found necessary.

Category(ies) of users

Professional

Pack sizes and packaging material

IBC (intermediate bulk container)
Plastic: HDPE, professional – 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum),
Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml, 750 ml, 500 ml.
Trigger spray: 1000 ml, Trigger spray/ pump: 750 ml, 500 ml, 250 ml, 200 ml, 150 ml, 125 ml, 100 ml, 50 ml.

4.1.1 Use-specific instructions for use

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Apply the ready-to-use product by pouring, pumping or spraying directly to the surface, make sure to wet the surface completely. The surface should be kept wet during the contact time. Reapplication may be necessary to achieve the full contact time.

4.1.2 Use-specific risk mitigation measures

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

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

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

4.2 Use description

Use 2 - Use # 2 – PT 2 - Disinfection of non-porous hard surfaces within healthcare, no patient/medical staff contact

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Mycobacteria
Development stage:

Scientific name:
Common name: Yeast
Development stage:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Disinfection of non-porous hard surfaces in healthcare areas that can easily be precluded from touching by patients or medical staff during the contact time, e.g. by locking a room.

Application method(s)

Method: Pouring or application by pump or trigger spray
Detailed description:
-

Application rate(s) and frequencies

Application Rate: -
Dilution (%): Ready-to use liquid.
Number and timing of application:

Disinfection with prior cleaning
The rate of application must be sufficient to keep the intended area covered with fluid during the contact time. Contact time:
Bacteria and yeast: 5 minutes
Mycobacteria: 10 minutes
Viruses: 2 minutes

The product can be used as often as it is found necessary.

Category(ies) of users

Professional

Pack sizes and packaging material

IBC (intermediate bulk container)
Plastic: HDPE, professional – 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum),
Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml 750 ml, 500 ml.

Trigger spray: 1000 ml, Trigger spray/ pump: 750 ml, 500 ml, 250 ml, 200 ml, 150 ml, 125 ml, 100 ml, 50 ml.

4.2.1 Use-specific instructions for use

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Apply the ready-to-use product by pouring, pumping or spraying directly to the surface, make sure to wet the surface completely. When a contact time longer than 5 minutes is necessary, the surface should be precluded from touching by medical staff and/or patients.
 The surface should be kept wet during the contact time.
 Reapplication may be necessary to achieve the full contact time.

4.2.2 Use-specific risk mitigation measures

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

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

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

4.3 Use description

Use 3 - Use # 3 – PT 2 - Disinfection of non-porous hard surfaces

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

Scientific name:
 Common name: Bacteria
 Development stage:

Scientific name:
 Common name: Mycobacteria
 Development stage:

Scientific name:
 Common name: Yeast
 Development stage:

	<p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of all water tolerant non-porous hard surfaces in e.g. kindergartens, nursing homes, offices, private homes.</p>
Application method(s)	<p>Method: Pouring or application by pump or triggerspray Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): Ready-to use liquid. Number and timing of application:</p> <p>Disinfection with prior cleaning The rate of application must be sufficient to keep the intended area covered with fluid with a contact time for: Bacteria: 1 minute Yeast: 5 minutes Viruses: 2 minutes Mycobacteria: 10 minutes The product can be used as often as it is found necessary. -</p>
Category(ies) of users	<p>Professional</p> <p>General public (non-professional)</p>
Pack sizes and packaging material	<p>IBC (intermediate bulk container) Plastic: HDPE, non-professional - Container: 5 L, 4 L, 1000 ml, 750 ml, 500 ml. Trigger spray: 1000 ml, Trigger spray/ pump: 750 ml, 500 ml, 250 ml, 200 ml, 150 ml, 125 ml, 100 ml, 50 ml.</p> <p>Professional - 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum), Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml, 500 ml. Trigger spray: 1000 ml, Trigger spray/ pump: 750 ml, 500 ml.</p>

4.3.1 Use-specific instructions for use

4.3.1 Use-specific instructions for use

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Apply the ready-to-use product by pouring, pumping or spraying directly to the surface, make sure to wet the surface completely. The surface should be kept wet during the contact time.

4.3.2 Use-specific risk mitigation measures

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

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

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

4.4 Use description

Use 4 - Use # 4 – PT 2 - Disinfection of instruments by immersion or filling

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeast Common name: Yeast Development stage:

<p>Scientific name: Viruses Common name: Viruses Development stage:</p> <p>Scientific name: Mycobacteria Common name: Mycobacteria Development stage:</p>

Field(s) of use

<p>Indoor</p> <p>Disinfection of instruments by immersion or filling. E.g. within healthcare (except medical devices), hospitals, nursing homes, institutions, kindergartens, private homes.</p>
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Application method(s)

<p>Method: Immersion Detailed description: -</p>
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Application rate(s) and frequencies

<p>Application Rate: - Dilution (%): Ready-to use liquid Number and timing of application:</p> <p>Disinfection with prior cleaning The rate of application must be sufficient to keep the intended area covered with fluid with a contact time for: Bacteria, and yeast: 5 minute s Viruses: 2 minutes Mycobacteria: 10 minutes The product can be used as often as it is found necessary.</p>
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Category(ies) of users

<p>Professional</p> <p>General public (non-professional)</p>
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Pack sizes and packaging material

<p>IBC (intermediate bulk container) Plastic: HDPE, Non-professional - Container: 5 L, 4 L, 1000 ml, 750 ml, 500 ml. Professional – 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum), Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml, 750 ml, 500 ml.</p>

4.4.1 Use-specific instructions for use

<p>Thoroughly clean and rinse the instrument. Dry the instrument before applying the disinfectant. Immerse instruments into the ready-to-use product and leave it immersed according to contact time or fill the instruments with the ready-to-use product and leave it there according to contact time.</p>
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4.4.2 Use-specific risk mitigation measures

Zie sectie 5

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

Zie sectie 5

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

Zie sectie 5

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

Zie sectie 5

4.5 Use description

Use 5 - Use # 5 – PT 3 - Disinfection of non-porous hard surfaces within veterinary

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeast Common name: Yeast Development stage: Scientific name: Viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of non-porous hard surfaces within veterinary hygiene. All surfaces associated with housing of animals.

Application method(s)

Method: Pouring or application by pump or triggerspray
Detailed description:
-

Application rate(s) and frequencies

Application Rate: -
Dilution (%): Ready-to use liquid
Number and timing of application:

Disinfection with prior cleaning
The rate of application must be sufficient to keep the intended area covered with fluid with a contact time for:
Bacteria, yeast and viruses: 30 minutes
The product can be used as often as it is found necessary.

Category(ies) of users

Professional

Pack sizes and packaging material

IBC (intermediate bulk container)
Plastic: HDPE, professional – 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum),
Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml, 750 ml. Trigger spray: 1000 ml,
Trigger spray/ pump: 750 ml, 500 ml.

4.5.1 Use-specific instructions for use

Thoroughly clean and rinse the surface. The surface should be dry before applying the disinfectant. Apply the ready-to-use product by pouring, pumping or spraying directly to the surface, make sure to wet the surface completely.
The surface should be kept wet during the contact time.
Surfaces should remain out of use for the duration of the treatment process .
Reapplication may be necessary to achieve the full contact time.

4.5.2 Use-specific risk mitigation measures

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

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

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

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4.6 Use description

Use 6 - Use # 6 – PT 4 - Food industry - Disinfection of non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Mycobacteria Common name: Mycobacteria Development stage:</p> <p>Scientific name: Yeast Common name: Yeast Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking within the food industry.</p>
Application method(s)	<p>Method: Pouring or application by pump or triggerspray, CIP, immersion Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): Ready-to use liquid Number and timing of application:</p> <p>Disinfection with prior cleaning The rate of application must be sufficient to keep the intended area covered with fluid with a contact time for: Bacteria and yeast: 5 minutes</p>

	Viruses: 2 minutes Mycobacteria: 10 minutes The product can be used as often as it is found necessary.
Category(ies) of users	Professional
Pack sizes and packaging material	IBC (intermediate bulk container) Plastic: HDPE, professional – 1000 L (IBC), 500 L (IBC), 250 L (IBC), 200 L (Drum), Container: 125 L, 100 L, 50 L, 25 L, 5 L, 4 L, 1000 ml, 750 ml, 500 ml. Trigger spray: 1000 ml. Trigger spray/ pump: 750 ml, 500 ml.

4.6.1 Use-specific instructions for use

<p>Thoroughly clean and rinse the surface. The surface should be dry before applying the disinfectant. Apply the ready-to-use product by pouring, pumping or spraying directly to the surface or to inner surfaces by CIP, make sure to wet the surface completely. The surface should be kept wet during the contact time. Reapplication may be necessary to achieve the full contact time.</p> <p>Thoroughly clean and rinse the instrument. Dry the instrument before applying the disinfectant. Immerse equipment into the ready-to-use product and leave it immersed according to contact time.</p>
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4.6.2 Use-specific risk mitigation measures

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

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

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

5. General directions for use

5.1. Instructions for use

The product is applied directly to the surface which must remain covered and wet for the full contact time. Cleaning prior to disinfection is required.

Apply
fluid or wipe to the surface and leave for the required contact times depending on the target organisms – see the contact time table on the product label.

Reapplication may be necessary to achieve the full contact time.

5.2. Risk mitigation measures

For indoor use only.
Wash hands and exposed skin before meals and after use.

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

IF INHALED: Call a POISON CENTRE/doctor if you feel unwell.
IF ON SKIN: Wash with soap and water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing .
IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.

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

This material and its container must be disposed of in a safe way.
Dispose of contents/container in accordance with local regulations.

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

To be stored in a dry frost-free place at 5-30°C

Do not store in direct sunlight.

Shelf life: 3 years

6. Other information