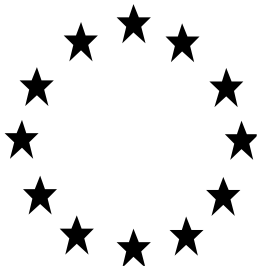
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR SIMPLIFIED AUTHORISATION APPLICATIONS



Universal Disinfection Fluid and Wipes

Product types 2, 3, 4

Lavender Oil, Peppermint Oil, Lactic Acid and (+)-Tartaric Acid as included in the Annex I of Regulation (EU) No 528/2012

Asset number: EU-0020556-0000

Evaluating Competent Authority: NL CA

Date:4 December 2020

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1 CONCLUSION

1.1 SUMMARY OF DECISIONS AND REQUIREMENTS

Suffient data have been provided to verify the outcome and conlusions of the UK CA. However the NL CA will only permit an authorisation of the biocidal product family, in accordance with Article 25 of the BPR, if the post authorisation requirement (added at 1.4 ACTIVE SUBSTANCE DETAILS - eCA note) will be dealt within the post authorisation period.

The application will be authorised based on the following conclusions:

1.2 USAGE AREA

UniBlue Universal Disinfection Fluid (UDF2)

User	Usage Area
Non-professional - indoor	PT 2 • Disinfection of non-porous hard surfaces • Disinfection of instruments by immersion or filling
Professional - indoor	PT 2 • Disinfection of non-porous hard surfaces with or without patient/medical staff contact within healthcare • Disinfection of non-porous hard surfaces • Disinfection of instruments by immersion or filling PT 3 • Disinfection of non-porous hard surfaces within veterinary PT 4 • Food industry - Disinfection of non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking

UniBlue Universal Disinfection Wipes (UDW2)

User	Usage Area
Non-professional - indoor	PT 2 • Disinfection of non-porous hard surfaces, wipes
Professional - indoor	PT 2 • Disinfection of non-porous hard surfaces with or without patient/medical staff contact within healthcare, wipes • Disinfection of non-porous hard surfaces, wipes PT 4 • Food industry - Disinfection of non-porous hard surfaces, wipes

1.3 PEST AND APPLICATION RATE

Efficacy is sufficiently demonstrated against bacteria, yeasts, viruses and mycobacteria.

The following contact times (in minutes) have been demonstrated by the data and can be claimed on the label.

UniBlue Universal Disinfection Fluid (UDF2)

UDF2	Bacteria	Viruses	Yeast	Mycobacteria
Non-porous hard surfaces, healthcare, patient/medical staff contact (PT2)	5	2	5	-
Non-porous hard surfaces, healthcare, no patient/medical staff contact (PT2)	5	2	5	10
Non-porous hard surfaces (PT2)	1	2	5	10
Instrument by immersion or filling (PT2) (no medical devises)	5	2	5	10
Veterinary and farming; Non-porous hard surfaces (PT3)	30	30	30	-
Food industry; Non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking (PT4)	5	2	5	10

UniBlue Universal Disinfection Wipes (UDW2)

UDW2-	Bacteria	Viruses	Yeast	Mycobacteria
Non-porous hard surfaces, healthcare, patient/medical staff contact, wipes (PT2)	5	2	5	-
Non-porous hard surfaces, healthcare, no patient/medical staff contact, wipes (PT2)	5	2	5	10
Non-porous hard surfaces, wipes (PT2)	1	2	5	10
Food industry; non-porous hard surfaces, wipes (PT4)	5	2	5	10

1.4 ACTIVE SUBSTANCE DETAILS

The concentration of the active substance lactic acid in the biocidal product is 0.360% w/w. The source of lactic acid is Mushashino Chemical Company.

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012 under Category 1 – Substances authorised as food additives according to Regulation (EC) No. 1333/2008.

The concentration of the active substance (+)-tartaric acid in the biocidal product is 0.616% w/w. The source of (+)-tartaric acid is Tartaros Gonsalo Castello. S.L..

(+)-Tartaric acid is listed in Annex I of the Regulation (EU) No 528/2012 under Category 1 – Substances authorised as food additives according to Regulation (EC) No. 1333/2008.

The concentration of the active substance peppermint oil in the biocidal product is 0.099% w/w. The source of peppermint oil is Naissance NNI.

Peppermint oil is listed in Annex I of the Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

The concentration of the active substance lavender oil in the biocidal product is 0.099% w/w. The source of lavender oil is Naissance NNI.
Lavender oil is listed in Annex I of the Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

eCA note: The method of analysis used to determine the content of active substances is not considered sufficiently validated for specificity, linearity, accuracy and precision according to SANCO 3030/99 rev. 4. This would indicate a data gap and therefore a direct rejection of the application. See conclusion on the methods for detection and identification of the product.

However, due to the nature of the requested data and the Brexit history of the dossier, the NL CA will make an exception with regards to post authorisation requirements.
Within 12 months (after authorisation) the applicant will need to provide the NL CA a full report on the validation of the method(s) used to determine the content of all active substances. This report should fulfil with all the requirements of the SANCO/3030/99 rev.4.

If the applicant fails to deliver the requested study, within the set timeframe, the whole authorisation will be rejected and all biocidal products will need to be removed from the EU market.

1.5 ELIGIBILITY FOR THE SIMPLIFIED AUTHORISATION PROCEDURE

Following evaluation, the product Universal Disinfection Fluid and Wipes has been shown to meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012, i.e.:

1. The active substances lactic acid and (+)-tartaric acid appear in Annex I of 528/2012 with the restriction 'concentration to be limited so that each bioicidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No. 1272/2008' that is met.
2. The active substances peppermint oil and lavender oil appear in Annex I of 528/2012 with no restrictions applied.
3. The biocidal product contains no substances of concern.
4. The biocidal product does not contain any nanomaterials.
5. The use pattern and associated label claims of the biocidal product have been judged sufficiently effective.
6. The handling of the biocidal product as part of its intended use does not require any PPE.

1.6 COMPARATIVE ASSESSMENT AND AUTHORISATION

Lactic acid, (+)-tartaric acid, peppermint oil and lavender oil do not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and therefore are not considered as candidates for substitution.

1.7 ENDOCRINE DISRUPTION ASSESSMENT

A targeted determination of whether any non-active substances ('co-formulants') in the biocidal product 'Universal Disinfection Fluid and Wipes' are an endocrine disruptor (ED) or have "indications" of endocrine disrupting properties based on whether a decision has already been made within the EU programmes of work has been conducted. Please see section 3.5 for further details.

1.8 NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

For indoor use only.
This material and its container must be disposed of in a safe way.
Cleaning prior to disinfection is required.
Wash hands and exposed skin before meals and after use.
The surface must remain covered and wet for the full contact time.
Reapplication may be necessary to achieve the full contact time.
Surfaces should remain out of use for the duration of the treatment process.
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.
Dispose of contents/container in accordance with local regulations.
To be stored in a dry frost-free place at 5-30 degrees Celsius.
Do not store in direct sunlight.
After opening of the packet wipes can be used for 30 days when keeping the packet closed.
Shelf life: 2 years

1.9 REQUIREMENT FOR FURTHER INFORMATION

N/A

2 ASSESSMENT REPORT

2.1 SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1 ADMINISTRATIVE INFORMATION

2.1.1.1 IDENTIFIER OF THE PRODUCT / PRODUCT FAMILY

Identifier	**Country (if relevant)**
Universal Disinfection Fluid and Wipes	

2.1.1.2 AUTHORISATION HOLDER

Name and address of the authorisation holder	**Name**	Wiping System APS
	Address	Mileparken 10 D, DK-2740, Skovlunde, Denmark
Authorisation number	EU-0020556-0000	
Date of the authorisation	4 December 2020	
Expiry date of the authorisation	31 December 2028	

2.1.1.3 MANUFACTURER OF THE PRODUCTS OF THE FAMILY

UniBlue Universal Disinfection Fluid (UDF2):

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

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

UniBlue Universal Disinfection Wipes (UDW2):

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

Name of manufacturer	CIP4 S.r.l.
Address of manufacturer	Via Idiomi, 6, 20090, Assago (MI), Italy
Location of manufacturing sites	Via Idiomi, 6, 20090, Assago (MI), Italy

2.1.1.4 MANUFACTURER OF THE ACTIVE SUBSTANCE

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

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

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

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

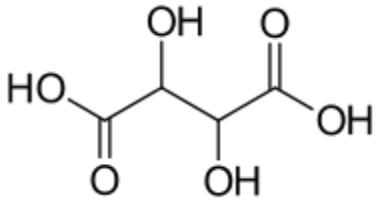
2.2 PRODUCT COMPOSITION AND FORMULATION

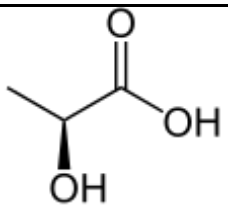
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

No ☒

2.2.1 IDENTITY OF THE ACTIVE SUBSTANCES

Main constituent	
ISO name	Tartaric acid
IUPAC or EC name	2,3-Dihydroxybutanedioic acid
EC number	201-766-0
CAS number	87-69-4
Index number in Annex VI of CLP	Not allocated
Minimum purity / content	99.5 %
Structural formula	

Main constituent(s)	
ISO name	Lactic acid
IUPAC or EC name	2-Hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	Not allocated
Minimum purity / content	95%
Structural formula	

Main constituent(s)	
ISO name	Lavender oil
IUPAC or EC name	Not applicable - mixture
EC number	Not allocated
CAS number	8000-28-0
Index number in Annex VI of CLP	Not allocated

Minimum purity / content	100% (UVCB)
Structural formula	Not applicable - mixture

Main constituent(s)	
ISO name	Peppermint oil
IUPAC or EC name	Not applicable – mixture
EC number	Not allocated
CAS number	8006-90-4
Index number in Annex VI of CLP	Not allocated
Minimum purity / content	100% (UVCB)
Structural formula	Not applicable – mixture

2.2.2 CANDIDATE(S) FOR SUBSTITUTION

Lactic acid, (+)-tartaric acid, peppermint oil and lavender oil do not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and are therefore not considered as candidates for substitution.
Lactic acid and (+)-tartaric acid are listed in Annex I of the Regulation (EU) No 528/2012 under Category 1 – Substances authorised as food additives according to Regulation (EC) No. 1333/2008.
Peppermint oil and lavender oil are listed in Annex I of the Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

2.2.3 QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Tartaric acid	2,3-Dihydroxybutanedioic acid	Active substance	87-69-4	201-766-0	0.616 (technical) 0.613 (pure)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	0.360 (technical) 0.356 (pure)
Lavender oil	Not applicable - mixture	Active substance	8000-28-0	Not allocated	0.099 (technical) 0.099 (pure)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peppermint oil	Not applicable - mixture	Active substance	8006-90-4	Not allocated	0.099 (technical) 0.099 (pure)

The full formulation composition details are contained within the confidential annex 3.6.1 of this PAR.

2.2.4 INFORMATION ON TECHNICAL EQUIVALENCE

The active substances lactic acid, (+)-tartaric acid, peppermint oil and lavender oil are included in Annex I of Regulation (EU) No. 528/2012 and therefore technical equivalence is not required at this time.

2.2.5 INFORMATION ON THE SUBSTANCE(S) OF CONCERN

Universal Disinfection Fluid and Wipes does not contain substances of concern. Please see the confidential annex of this PAR for further details.

2.2.6 TYPE OF FORMULATION

RTU AL – ready to use aqueous liquid RTU wipe

2.3 AUTHORISED USE

UniBlue Universal Disinfection Fluid (UDF2)

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

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Viruses
Field 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)	Pouring or application by pump or triggerspray
Application rate(s) and frequency	Ready-to use liquid. 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.

Use-specific instructions for use #1

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.

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

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Mycobacteria Yeast Viruses
Field 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)	Pouring or application by pump or trigger spray
Application rate(s) and frequency	Ready-to use liquid. 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.

Use-specific instructions for use #2

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 staf and/or patients. The surface should be kept wet during the contact time. Reapplication may be necessary to achieve the full contact time.

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

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Mycobacteria Yeast Viruses
Field of use	Indoor Disinfection of all water tolerant non-porous hard surfaces in e.g. kindergartens, nursing homes, offices, private homes.
Application method(s)	Pouring or application by pump or triggerspray
Application rate(s) and frequency	Ready-to use liquid. 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.
Category(ies) of users	Non-professional, Professional
Pack sizes and packaging material	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.

	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.

Use-specific instructions for use #3

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.

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

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria Yeast Viruses
Field of use	Indoor Disinfection of instruments by immersion or filling. E.g. within healthcare (except medical devices), hospitals, nursing homes, institutions, kindergartens, private homes.
Application method(s)	Immersion
Application rate(s) and frequency	Ready-to use liquid 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 Viruses: 2 minutes Mycobacteria: 10 minutes The product can be used as often as it is found necessary.
Category(ies) of users	Non-professional, Professional
Pack sizes and packaging material	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.

Use-specific instructions for use #4

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.

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

Product Type	PT 3 - Veterinary hygiene
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Viruses
Field of use	Indoor Disinfection of non-porous hard surfaces within veterinary hygiene. All surfaces associated with housing of animals.
Application method(s)	Pouring or application by pump or triggerspray
Application rate(s) and frequency	Ready-to use liquid 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.

Use-specific instructions for use #5

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 contacttime.

Table 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	PT 4 – Food and feed area
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Mycobacteria Yeast

	Viruses
Field of use	Indoor Disinfection of non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking within the food industry.
Application method(s)	Pouring or application by pump or triggerspray, CIP, immersion
Application rate(s) and frequency	Ready-to use liquid 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 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.

Use-specific instructions for use #6

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. 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.

UniBlue Universal Disinfection Wipes (UDW2)

Table 7. Use # 7 – PT 2 - Disinfection of non-porous hard surfaces within healthcare, wipes

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Viruses

Field 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)	Wiping with RTU pre-wetted wipes
Application rate(s) and frequency	Ready-to use pre-wetted wipe Disinfection with prior cleaning Keep the surface wet during contact time for: 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	Packet with closing lid. Pack: Laminate – PET 12 my /PE 60 my Flap: PP or synthetic paper 25 pcs., 32 cm x 20 cm 20 pcs., 40 cm x 30 cm

Use-specific instructions for use #7

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Wipe the surface to be disinfected. Make sure to wet surfaces completely. Allow to take effect for the contact time. Reapplication may be necessary to achieve a wet surface for the full contact time.

Table 8. Use # 8– PT 2 - Disinfection of non-porous hard surfaces within healthcare, no patient/medical staff contact, wipes

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Mycobacteria Yeast Viruses
Field 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)	Wiping with RTU pre-wetted wipes
Application rate(s) and frequency	Ready-to use pre-wetted wipe Disinfection with prior cleaning Keep the surface wet during contact time for: Bacteria and yeast 5 minutes 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	Packet with closing lid. Pack: Laminate – PET 12 my /PE 60 my Flap: PP or synthetic paper 25 pcs., 32 cm x 20 cm 20 pcs., 40 cm x 30 cm

Use-specific instructions for use #8

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Wipe the surface to be disinfected. Make sure to wet surfaces completely. Allow to take effect for the contact time. When a contact time longer than 5 minutes is necessary, the surface should be precluded from touching by medical staf and/or patients. Reapplication may be necessary to achieve a wet surface for the full contact time.

Table 9. Use # 9 – PT 2 - Disinfection of non-porous hard surfaces, wipes

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Mycobacteria Yeast Viruses
Field of use	Indoor Disinfection of all water tolerant non-porous hard surfaces. E.g. in kindergartens, nursing homes, offices, private homes.
Application method(s)	Wiping with RTU pre-wetted wipe
Application rate(s) and frequency	Ready-to use pre-wetted wipe Disinfection with prior cleaning Keep the surface wet during contact time for: Bacteria: 1 minutes Yeast: 5 minutes Viruses: 2 minutes Mycobacteria: 10 minutes The product can be used as often as it is found necessary.
Category(ies) of users	Non-professional, Professional
Pack sizes and packaging material	Packet with closing lid. Pack: Laminate – PET 12 my /PE 60 my Flap: PP or synthetic paper Professional: 25 pcs., 32 cm x 20 cm 20 pcs., 40 cm x 30 cm Non-professional:

	10 pcs., 19 cm x 17 cm 40 pcs., 19 cm x 17 cm 80 pcs., 19 cm x 17 cm

Use-specific instructions for use #9

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Wipe the surface to be disinfected. Make sure to wet surfaces completely. Allow to take effect for the contact time. Reapplication may be necessary to achieve a wet surface for the full contact time.

Table 10. Use # 10 – PT 4 - Food industry; Disinfection of non-porous hard surfaces, wipes

Product Type	PT 4 – Food and feed area
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria Yeast Viruses
Field of use	Indoor Disinfection of non-porous hard surfaces within the food industry.
Application method(s)	wiping with RTU pre-wetted wipe
Application rate(s) and frequency	Ready-to use pre-wetted wipe Disinfection with prior cleaning Keep the surface wet during contact time for: Bacteria and yeast: 5 minutes 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	Packet with closing lid. Pack: Laminate – PET 12 my /PE 60 my Flap: PP or synthetic paper 25 pcs., 32 cm x 20 cm 20 pcs., 40 cm x 30 cm

Use-specific instructions for use #10

Thoroughly clean and rinse the surface. Dry the surface before applying the disinfectant. Wipe the surface to be disinfected. Make sure to wet surfaces completely. Allow to take effect for the contact time. Reapplication may be necessary to achieve a wet surface for the full contact time.

2.4 HAZARD AND PRECAUTIONARY STATEMENTS

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

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-
Precautionary statements	-
Note	-

2.5 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**	**Compatibility of the product with the proposed packaging materials**
UniBlue Universal Disinfection Fluid (UDF2): IBC (intermediate bulk container)					
IBC	1000 L	HDPE	Type of closure: Regular lid Trigger spray Pump Material: PP	Professional	Acceptable, no adverse interactions were observed in the accelerated storage study using PET pack (also product is water based).
IBC	500 L	HDPE		Professional	
IBC	250 L	HDPE		Professional	
Drum	200 L	HDPE		Professional	
Container	125 L	HDPE		Professional	
Container	100 L	HDPE		Professional	
Container	50 L	HDPE		Professional	
Container	25 L	HDPE		Professional	
Container	5 L	HDPE		Professional	
Container	4 L	HDPE		Professional	
Container/ Trigger spray	1000 ml	HDPE		Professional/ Non-professional	
Container/ Trigger spray/ pump	750 ml	HDPE		Professional/ Non-professional	
Container/ Trigger spray/ pump	500 ml	HDPE		Professional/ Non-professional	
Bottle/Trigger spray/ pump	250 ml	HDPE		Professional/ Non-professional	
Bottle/Trigger spray/ pump	200 ml	HDPE		Professional/ Non-professional	
Bottle/Trigger spray/ pump	150 ml	HDPE		Professional/ Non-professional	

Bottle/Trigger spray/ pump	125 ml	HDPE		Professional/ Non-professional	
Bottle/Trigger spray/ pump	100 ml	HDPE		Professional/ Non-professional	
Bottle/Trigger spray/ pump	50 ml	HDPE		Professional/ Non-professional	
UniBlue Universal Disinfection Wipe (UDW2-Bio): UDW2-Bio 80% cellulose & 20% Rayon					
UDW2-Bio: 60gsm, 320% UDF2 fluid of weight of wipe = 12g/wipe, covering 1m^2 surface disinfection per wipe.	25 pcs. 32 cm x 20 cm	Pack: Laminate PET/PE	Flap: PP or Synthetic paper	Professional	
UDW2-Bio: 60gsm, 330% UDF2 fluid of weight of wipe = 24g/wipe, covering 2m^2 surface disinfection per wipe	20 pcs. 40 cm x 30 cm	Pack: Laminate PET/PE	Flap: PP or Synthetic paper	Professional	Acceptable, no adverse interactions were observed in the accelerated storage study, using PET/PE sales pack.
UDW2-Bio: 60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m^2 surface disinfection per wipe	40 pcs. 19 cm x 17 cm	Pack: Laminate PET/PE	Flap: PP or Synthetic paper	Non-professional	
UDW2-Bio: 60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m^2 surface disinfection per wipe	80 pcs. 19 cm x 17 cm	Pack: Laminate PET/PE	Flap: PP or Synthetic paper	Non-professional	

UDW2-Bio: 60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m^2 surface disinfection per wipe	10 pcs. 19 cm x 17 cm	Pack: Laminate PET/PE	Flap: PP or Synthetic paper	Non-professional	

2.6 DIRECTIONS FOR USE

2.6.1 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.
Surfaces should remain out of use for the duration of the treatment process.
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.

2.6.2 RISK MITIGATION MEASURES

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

2.6.3 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.

2.6.4 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.

2.6.5 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: 2 years.

2.7 OTHER INFORMATION

The applicant should monitor resistance on a continuous basis by requesting that any ineffective treatment be reported to them. Should the authorisation holder be made aware of any occurrence of resistance, this should be reported to the relevant competent authorities.

2.8 ASSESSMENT OF THE BIOCIDAL PRODUCT

2.8.1 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

Tartaric acid/Lactic acid/Lavender oil/Peppermint oil are the active substances in the biocidal product family Universal Disinfection Fluid and Wipes which is a RTU AL (Ready To Use Any Other Liquid) product family. The physical, chemical and storage stability data submitted to support the individual products in the biocidal product family are summarised in the following table. Data have been provided on UDF2 (RTU AL in an IBC) and UDW2 (RTU AL on wipes in a PET/AL/PE packet). Data are available for products from either the neat solution (UDF2) or the solution from wipes (UDW2).

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
Physical state at 20 °C and 101.3 kPa	ISO 4630-1 Gardner colour scale	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%	Solution	[redacted]	Acceptable.
Colour at 20 °C and 101.3 kPa	ISO 4630-1 Gardner colour scale ISO 4630-1 Gardner colour scale	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%	Clear	[redacted]	Acceptable.
Odour at 20 °C and 101.3 kPa	Olfactory assessment	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%	-	-	No data submitted or required due to the safety implications of what is being requested.
eCA note: No classification regarding any hazard by inhalation is assigned to the BPF hence odour should be investigated. Nevertheless it is expected that the products would have either a lavender or peppermint odour.					
pH	ASTM D1293-12 Using a glass	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil	2.3 (neat)	[redacted]	Acidity test missing, however Mammalian tox assessment has no issue with this low pH (see section 2.10).

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	electrode as sensor	0.099%/Peppermint oil 0.099%			
Storage stability test – **accelerated storage**	CIPAC MT 46.3	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%)	Storage for 2 weeks at 54 °C. **Active substance content** Density: 0.99 g/ml <u>Tartaric acid</u> Initial: 0.412% After: 0.430% (4.4 % increase) <u>Lactic acid</u> Initial: 0.246% After: 0.242% (1.62% decrease) <u>Lavender oil</u> Initial: 0.0704% After: 0.0754% 7.1 % increase) <u>Peppermint oil</u> Initial: 0.0627% After: 0.0716% (14.2 % increase) <u>Product appearance</u> No change after storage <u>pH of neat solution</u> Initial: 2.4 After: 2.4	[redacted]	Acceptable, however the target amounts in the formulation are:- Tartaric acid = 6.16 g/l Lactic acid = 3.6 g/l Lavender oil = 0.99 g/l Peppermint oil = 0.99 g/l The Lavender and Peppermint oil content increased on storage, but was not considered significant based on the quantities in the product (less than 0.1%), but were low compared to the target amount. The tartaric and lactic acid contents were low and inconsistent, compared to the target content. This was due to interference from the other co-formulants according to the applicant, however acceptable Efficacy data were submitted before and after 2 years storage of the product (see section
	LC-MS method				
	LC-MS method				
	GC-MS method				
	GC-MS method			[redacted]	
	Visual assessment				
	ASTM D1293-12 Using a glass electrode as sensor				

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	CIPAC MT 191 Visual assessment		Acidity Initial: No data submitted After: No data submitted Packaging PET/AL/PE sales pack no change after storage		2.9.1.4) and a new method was requested. In addition, three of the four active substance contents increased - this may have been due to the loss of water as a result of the high temperature in the study.
	CIPAC MT 46.3 GC-MS method	**UDW2** (RTU AL - Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%)	Storage for 2 weeks at 54 °C. **Active substance content** Tartaric acid Initial: 0.428% After: 0.493% (15.2 % increase) Lactic acid Initial: 0.261% After: 0.263% (0.8 % decrease) Lavender oil Initial: 0.0628% After: 0.0502% (20.1 % decrease) Peppermint oil Initial: 0.0475% After: 0.0375% (21.05 % decrease)	[redacted]	Acceptable (see above), the low levels of Peppermint oil may be due to low recovery from the wipes, however, acceptable efficacy data were submitted before and after two years storage of the product (see section 2.9.1.4).
eCA note: The accelerated storage stability test is not considered acceptable. The study report is not complete, as requested by the eCA, as it does not contain information on the materials and methods used (e.g.: test items and batches analysed, packaging used for storage, CIPAC or other recognized methodology). Information is also unclear on which fluids the determination of the content of active substances was performed as the study states "experiments were carried out on the UDF2 fluid sample". Furthermore, in the study only results on the concentration of tartaric acid and lactic acid are					

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
presented so the above summarizaed data on lavender oil and peppermint oil are not included in the report. The increase and decrease (>10%) in the concentration of active substances has also not been explained.					
Storage stability test – **long term storage at ambient temperature**	-	**RTU AL** (Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099%	-	-	
eCA note: No study report was provided for the long term storage at ambient temperature. No results were provided addressing the technical characteristics of the triggers sprayers. This is considered acceptable by the eCA based on the CA agreement on the simplified procedure (Doc. CA-May14-Doc.5.5 – Final) which states "Stability data could be waived where the applicant demonstrates that the product is efficacious by the end of the proposed shelf-life (i.e. data from efficacy tests using aged/stored product)." For the efficacy evaluation see section 2.9.1.4. Based on the efficacy test carried out on the product UDW2 wipes stored for 2 years, the eCA considers that the shelf-life of 2 years is justified.					
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Case	All products of the BPF	-	-	No further data required as label states to store in a dry frost-free place at 5-30ºC and not in direct sunlight.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Case	All products of the BPF	-	-	See accelerated storage above.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Case	All products of the BPF	No adverse effects noted between the product and the commercial packaging after 2 weeks storage at 54 °C.	-	Acceptable.
eCA note: The packaging material for UDW2 wipe and UDW2-Bio is the same (Pack: Laminate PET/PE). The efficacy test was performed with UDW2 wipes (product included in the intended authorization similar with UDW2-Bio) which were stored for two years at ambient temperature.					
Physical compatibility	-	All products of the BPF	-	-	The products are not designed to be used in conjunction with any other product. No claims of

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
					compatibility are made on the label.
Chemical compatibility	-	All products of the BPF	-	-	The products are not designed to be used in conjunction with any other product. No claims of compatibility are made on the label.
Surface tension	-	-	-	-	As the products are ready to use aqueous solution or aqueous solution on wipes, these data are not deemed necessary for the evaluation.
Viscosity	-	-	-	-	As the products are ready to use aqueous solution or aqueous solution on wipes, these data are not deemed necessary for the evaluation.

Conclusion on the physical, chemical and technical properties of the product

Data have been provided on the individual products UDF2 (RTU AL in an IBC) and UDW2 (RTU AL on wipes in a PET/AL/PE packet).

The physical, chemical and technical properties of the RTU AL were submitted and acceptable. The Lavender and Peppermint oil content increased on storage, but was not considered significant based on the quantities in the product (less than 0.1%), but were low compared to the target amount. This was due to only determining the major constituents in the oils (Borneol and Menthol). The tartaric and lactic acid contents were low and inconsistent compared to the target content. This was due to interference from the other co-formulants according to the applicant, however acceptable Efficacy data are available before and after two years storage and a new fully validated method has been submitted.

Therefore under Regulation (EU) No 528/2012 an **authorisation may be recommended**, with no further data required, due to acceptable Efficacy data being available before and after two years storage (see section 2.9.1.4) and the authorisation being granted under the simplified authorisation procedure.

eCA note: The physical, chemical and technical characteristics of the products within the BPF have not been addressed satisfactorily but considering the efficacy studies performed which show that the products are still efficacious after storage at ambient conditions the eCA considers that no additional data is required.

2.8.2 PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Explosives	-	All products of the BPF	-	-	The products do not contain any components that are classified as explosive making it highly unlikely that the formulations will require classification.
Flammable gases			Not applicable. The biocidal products are aqueous liquids.		
Flammable aeosols			Not applicable. The biocidals products are not aerosols.		
Oxidising gases			Not applicable. The bioxidal products are aqueous liquids.		
Flammable liquids	EU A.9 (Pensky-Martens Closed cup tester)	UniBlue® Universal Disinfection Fluid (UDF2) Batch No.: CH20021801	Flash point: 45.5°C No sustained combustibility occurred during test. Three	[redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	UN L2 (Open Cup Flash Point Tester for sustained combustility)		replicates were tested and the ignition observed at 74.5 °C was not sustained longer than 2-3s. The products are not classified as Category 3 flammable liquids.		
Flammable solids			Not applicable. The biocidal products are aqueous liquids.		
Self-reactive substances and mixtures			Not applicable. The biocidal products do not contain any thermally unstable substances.		
Pyrophoric liquids			Not applicable. Experience in manufacturing and handling shows that the biocidal products do not		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			ignite spontaneously on coming in contact with air at normal temperatures. See also the auto-ignition temperature.		
Pyrophoric solids			Not applicable. The biocidal products are aqueous liquids.		
Self-heating substances and mixtures			Not applicable. The biocidal products are aqueous liquids.		
Substances and mixtures which in contact with water emit flammable gases			Not applicable. The biocidal products are aqueous liquids.		
Oxidising liquids	-	All products of the BPF	-	-	The products do not contain any components classified as oxidising. There are no chemical groups or bonds present in the product known to induce oxidising properties.
Oxidising solids			Not applicable.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			The biocidal products are aqueous liquids.		
Organic peroxides			Not applicable. The products do not generate H_2O_2.		
Corrosive to metals	According to ASTM guideline		Not corrosive	Corrosive to metals	
eCA note: The study report is not considered acceptable as it was not performed according to the UN Test C.1. Furthermore, the report does not contain clear information on the tested items and batches, no data on minimum weight loss and minimum intrusion depth was included. The eCA NL considers that the product is not likely to be corrosive to metals hence accepts the proposal of the applicant with a mention that this end-point has not been fully covered by the required testing.					
Auto-ignition temperatures of products	EU A.15 (DIN 51794 and DIN EN 14522)	UniBlue® Universal Disinfection Fluid (UDF2)All products of the BPF Batch No.: CH20021801	495°C The value is based on the lowest measured value after three independent measurements.	[redacted]	
Relative self-ignition temperature for solids			Not applicable. The biocidal products are aqueous liquids.		
Dust explosion hazard			Not applicable. The biocidal products are		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			aqueous liquids.		

Conclusion on the physical hazards and respective characteristics of the product
The individual products are not explosive, flammable or oxidising, therefore a non-classification of the biocidal product family is acceptable from a chemistry perspective. The applicant has confirmed that the product is not classified in accordance with Regulation 1272/2008. The eCA agrees that no classification and labelling for physical hazards are required for the biocidal product family "Universal Disinfection Fluid and Wipes". **eCA note:** This is no data requirement for an application in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012 however the autorisation holder has to ensure that the biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008. The applicant has sufficiently shown that the biocidal products are not flammable liquids. It is expected that the products do not have corrosive properties but the endpoint corrosive to metals has not been addressed satisfactory.

2.8.3 METHODS FOR DETECTION AND IDENTIFICATION

2.8.3.1 ANALYTICAL METHODS FOR THE ACTIVE AND IMPURITIES IN THE TECHNICAL MATERIAL

The active substances lactic acid, (+)-tartaric acid, peppermint oil and lavender oil are included in Annex I of Regulation (EU) No. 528/2012 and therefore no further consideration is required.

2.8.3.2 ANALYTICAL METHODS FOR THE ACTIVE SUBSTANCE IN THE BIOCIDAL PRODUCT

RTU AL (ready to use any other liquid)

Original Methods

Tartaric acid and Lactic acid
The aqueous solution from the HDPE container or the aqueous solution from the wipes were analysed using LC-MS, with the determination made by comparison to standards.
Only limited details of the method were submitted, and with regards to validation data only chromatograms.

Lavender oil and Peppermint oil
The aqueous solution from the HDPE container or the aqueous solution from the wipes were analysed using GC-MS, with the determination made by comparison to standards. Only limited details of the method were submitted, and with regards to validation data only chromatograms.

New Methods

Lactic acid
A sample of the product (aqueous solution from the HDPE container or the aqueous solution from the wipes) was diluted with water and analysed by LC-MS (monitoring for m/z 89), using a Stabilwax-DA capillary column. Acceptable validation data were submitted.

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		
					Range	Mean	RSD
Lactic Acid	LC/MS-DAD	0.3%	0.2-0.8% (n=3) y = 6.753+03x + 1.46e+03	No interference (comparison of blank formulation	93-106 (n=2)	99	Precision %RSD: 1.7

		0.6%	r^2 = 0.998	and formulation with active)	96-97 (n=2)	96	(n=5) %RSD$_{Horwitz}$ = 3.1 Acceptable

Tartaric acid

A sample of the product (aqueous solution from the HDPE container or the aqueous solution from the wipes) was diluted with water and analysed by LC-MS (monitoring for m/z 149), using a Stabilwax-DA capillary column. Acceptable validation data were submitted.

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		
					Range	Mean	RSD
Tartaric Acid	LC/MS-DAD	0.45% 0.9%	0.3-1.2% (n=3) y = 6.93e+4x + 2.82e+04 r^2 = 0.995	No interference (comparison of blank formulation and formulation with active)	97-109 (n=2) 97-105 (n=2)	103 101	Precision: %RSD: 1.1 (n=5) %RSD$_{Horwitz}$ = 2.9 Acceptable

Peppermint Oil

A sample of the product (aqueous solution from the HDPE container or the aqueous solution from the wipes) was extracted with DCM and the resulting extract analysed by GC-MS, using a RP18 column. Acceptable validation data were submitted.

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		
					Range	Mean	RSD
Peppermint Oil	GC/MS	0.074% 0.15%	0.05-0.2% (n=3) y = 3.94e+09x + 1.98e+07 r^2 = 0.97	No interference (comparison of blank formulation and formulation with active)	103-108 (n=2) 96-97 (n=2)	106 96	Precision: %RSD: 4.1 (n=5) %RSD$_{Horwitz}$ = 4.1

							Acceptable

Lavender Oil
A sample of the product (aqueous solution from the HDPE container or the aqueous solution from the wipes) was extracted with DCM and the resulting extract analysed by GC-MS, using a RP18 column. Acceptable validation data were submitted.

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		
					Range	Mean	RSD
Lavender Oil	GC/MS	0.074% 0.15%	0.05-0.2% (n=3) y = 1.58e+9x + 1.92e+07 r^2 = 0.971	No interference (comparison of blank formulation and formulation with active)	104-109 (n=2) 96-97 (n=2)	107 96	Precission: %RSD: 4.2 (n=5) $\%RSD_{Horwitz}$ = 4.4 Acceptable

2.8.3.3 ANALYTICAL METHODS FOR THE MONITORING OF RESIDUES (SOIL, WATER, AIR, BODY FLUIDS AND TISSUES AND FOOD)

Monitoring methods are not required as lactic acid, (+)-tartaric acid, peppermint oil and lavender oil are included in Annex I of Regulation (EU) No. 528/2012.

Conclusion on the methods for detection and identification of the product
The new methods of analysis for the determination of Tartaric acid/Lactic acid/Lavender oil and Peppermint oil in the RTU AL (ready to use any other liquid) product have been fully validated and are acceptable. **eCA note:** The method of analysis used to determine the content of active substances is not considered validated for specificity, linearity, accuracy and precision according to SANCO 3030/99 rev. 4. The study report provided does not comply with the requirements on the following points: - method description is incomplete: no information is provided on the test item used for analysis (was the liquid extracted/squeezed out of the wipes, how much liquid was used in the study); no information was included on the composition and purity of the samples

H76648 (WSUDF2 (UDF2) CH18072301) and H76649 (WSUDF2-4 Biocides (UDF2-4) CH18072302); it is not clear for which purposes sample H76649 (WSUDF2-4 Biocides (UDF2-4) CH18072302) was used; sample preparation is restricted to little and unclear information (no description on how the samples for calibration, for the two fortification levels and for precision were prepared); representative chromatograms including peak assignments are missing; no information was provided on the DAD function in determining the concentration of lactic acid and tartaric acid; no information on how the calculations were performed was included;
- the specificity for the two oils, peppermint and lavender, is not sufficiently addressed. The oil standards used, appear to have a different composition than the oil mixtures included in the composition of the biocidal products. The justification provided is not considered satisfactory by the eCA as also the standards measured for this purpose seem to have a different composition based on the TICs provided. It is expected that, for mixtures such as the oils used as active substances, for the biocidal products individual characteristic peaks which have a stable concentration are clearly identified and subsequently can be used to determine the individual components present in the matrix. This could possibly explain the discrepancies observed for the measurements performed to determine the content of a.s. before and after storage.
The full report on the validation of the method(s) used to determine the content of active substances should be provided within 12 months in order to support the authorization.

2.9 EFFICACY AGAINST TARGET ORGANISMS

2.9.1 FUNCTION AND FIELD OF USE

The products in the family are disinfectants for use on non-porous hard surfaces in general, healthcare, veterinary and food/feed related areas – product types 2, 3 and 4.

2.9.1.1 ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

The products in the family are intended to kill bacteria, yeasts and viruses.

In some cases the products are also intended to kill mycobacteria all in object to protect humans and animals.

2.9.1.2 EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The products kill bacteria, viruses, yeasts and mycobacteria on non-porous hard surfaces.

2.9.1.3 MODE OF ACTION, INCLUDING TIME DELAY

The applicant has provided a very detailed description of the mode of action of the products in the product family. This includes details of the formulation components and their purpose in the product. The applicant's full statement is included in the confidential annex of this PAR.

In summary,:

'*The high antimicrobial efficacies of the Universal Disinfection formulations of Wiping Systems are based on*
1. Perforation of microbial cell walls
2. Permeabilisation of cell membranes and
3. Acidic hydrolysis of microbial cell structures, proteins and enzymes.'

2.9.1.4 EFFICACY DATA

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant for use on non-porous hard surfaces in general, healthcare, veterinary and food/feed related areas – product types 2, 3 and 4.	UDW2-Bio – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – *Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa.*	EN 1276 (2009) – Phase 2 Step 1 Contact time: 1 minutes. Temperature: 20 °C Clean conditions – 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Bactericidal at 50% wipe liquid 1 minutes Clean conditions Log reduction *S. aureus, >5.06* *E. hirae, >5.21* *E. coli, >5.24* *P aeruginosa>5.15*	[redacted]
	UDW2-Bio – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria - *S. aureus, E. hirae, E. coli, P aeruginosa* Yeast - *Candida albicans*	EN 13697 (2015) – Phase 2 Step 2 Contact time: bacteria: 1minute Yeast 5 minutes Temperature: 24.4 °C Clean conditions - 0.3 g/L BSA Concentration tested: 50, 80, 100% wipe liquid	Bactericidal at 50% wipe liquid 1 minute Clean conditions Log reduction for: *S. aureus, >4* *E. hirae, >4* *E. coli, >4* *P aeruginosa>4* Yeasticidal at 50% wipe liquid 5 minutes Clean conditions Log reduction for *C. albicans*, >3	[redacted]
	UDW2-Bio – Liquid squeezed from the wipe (this is identical to UDF2)	Yeast – *C. albicans*	EN 1650 (2008 + A1 2013) – Phase 2 step 1 Contact time: 5 minutes Temperature 20 °C Clean conditions – 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Yeasticidal at 80% wipe liquid 5 minutes Clean conditions Log reduction: C. *albicans* > 4	[redacted]
	UDW2 – Liquid	Yeast – *C. albicans*	EN 13624 – Phase 2 Step 1 (Medical/healthcare area test)	Yeasticidal at 80% wipe liquid 5 minutes	[redacted]

	squeezed from the wipe (this is identical to UDF2)		Contact time: 5 minutes Temperature: 20 °C Clean conditions – 0.3 g/L BSA Concentration tested: 50,80, 97% wipe liquid	Clean conditions Log reduction C. albicans >4.04	
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – *S. aureus, E. hirae, P aeruginosa*	EN 13727 – Phase 2 Step 1 (Medical/healthcare area test) Contact time: 1 minute Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50,80 en 97 % wipe liquid	Bactericaidal et 50% product at 1 minute Clean conditions Log reduction for: *S. aureus, >5.22* *E. hirae, >5.13* *P aeruginosa>5.34*	[redacted]

	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Mycobacteria – *Mycobacterium terrae, Mycobacterium avium*	EN14348 (2005) – Phase 2 Step 1 Contact time: 10 minutes Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Mycobactericidal at 97% wipe liquid At 10 minutes Clean conditions Log reduction *M. terrae*> 5.08 *M. avium* >5.35	[redacted]
	UDW2– (2014) UDW2-Bio (2019) Liquid squeezed from the wipe (this is identical to UDF2)	Virus – Adenovirus. Poliovirus and Murine Norovirus	EN 14476 (2013) – Phase 2 Step 1 Contact time: 2 minutes Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Virucidal at 80% wipe liquid At 2 minutes Clean conditions Log reduction Adenovirus:>6.17 Poliovirus:>4.17 Murine norovirus:>4.5	[redacted]
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – *S. aureus, E. hirae, P aeruginosa*	EN 14561 (2006) – Phase 2 Step 2 (Medical instrument test) Contact time: 1 minute Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 100% wipe liquid	Bactericidal at 80% wipe liquid 1 minute Clean conditions Log reduction *S. aureus, >5.57* *E. hirae, >5.60* *P aeruginosa>5.08*	[redacted]
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Yeast – *C. albicans*	EN 14562 – Phase 2 Step 2 (Medical instrument test) Contact time: 5 minutes Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 100% wipe liquid	Yeasticidal at 100% wipe liquid 5 minutes Clean conditions Log reduction C. albicans: 4	[redacted]
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Mycobacteria – *M. terrae, M. avium*	EN 14563 (2009) – Phase 2 Step 2 (Medical instrument test) Contact time: 10 minutes Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 100% wipe liquid	Mycobactericidal at 80% wipe liquid At 10 minutes Clean conditions Log reduction *M. terrae,>5.08* *M. avium >5.03*	[redacted]

	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – *S. aureus, E. hirae, Proteus. hauseri (*formally *vulgaris), P. aeruginosa*	EN 1656 – Phase 2 Step 1 (Veterinary area) Contact time: 30 minutes Temperature: 10 °C Clean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 97% wipe liquid	Bactericida at 50% wipe liquid 30 minutes Clean conditions Log reduction *S. aureus, >5.36* *E. hirae,>5.35* *Proteus. hauseri (*formally *vulgaris),>5.35* *P. aeruginosa >5.30*	[redacted]

	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Yeast – *C. albicans*	EN 1657(2014) – Phase 2 Step 1 (Veterinary area) Contact time: 30 minutes Temperature: 10 °C Clean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 97% wipe liquid	Yeasticidal at 97% wipe liquid 30 minutes Clean conditions Log reduction *C. albicans*> 4.52	[redacted]
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – *S. aureus, E. hirae, P. hauseri (*formally *vulgaris), P. aeruginosa*	EN 14349(2013) – Phase 2 Step 2 (Veterinary area) Contact time: 30 minutes Temperature: 10 °C Clean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 100% wipe liquid	Bactericidal at 50% wipe liquid. 30 minutes Clean conditions Log reduction *S. aureus, >4* *E. hirae,>4* *Proteus. hauseri (*formally *vulgaris),>4* *P. aeruginosa >4*	[redacted]
	UDW2-(2014) UDW2-Bio (2020) Liquid squeezed from the wipe (this is identical to UDF2)	Virus – Bovine Enterovirus	EN 14675 (2015) – Phase 2 Step 1 (Veterinary area) Contact time: 2 minutes Temperature: 10 °C Clean conditions 0.3 g/L BSA Concentration tested: 10, 50, 80% wipe liquid	Virucidal at 80% 30 minutes Clean conditions Log reduction Bovine Enterovirus: >4.6	[redacted]
	UDW2-Bio– Liquid squeezed from the wipe (this is	Yeast – *C. albicans*	EN 16438 (2014) – Phase 2 Step 2 Contact time: 30 minutes Temperature: 10 °C	Yeasticidal at 50% wipe liquid 30 minutes Clean conditions.	[redacted]

	identical to UDF2)		Clean conditions 3 g/L BSA Concentration tested: 10, 50, 100% wipe liquid		
	UDW2 Wipe	Bacteria - *S. aureus, E. hirae, P aeruginosa* Yeast - *C. albicans*	EN16615 (2015) – Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 °C Clean conditions 0.3 g/L BSA	Bactericidal at 5 minutes Clean conditions Log reduction *S. aureus, >5.78* *E. hirae, >5.75* *P aeruginosa>5.08* Yeasticidal at 5 minutes Log reduction *C. albicans>4.5*	[redacted]
	UDW2-Bio Wipe	Bacteria - *S. aureus, E. hirae, P aeruginosa* Yeast - *C. albicans*	EN16615 (2015) – Phase 2 Step 2 Contact time: 1 minute Temperature: 23.5-23.6 °C Clean conditions 0.3 g/L BSA	Bactericidal at 1 minute Clean conditions Log reduction *S. aureus, >5.97* *E. hirae, >5.85* *P aeruginosa>5.06* Yeasticidal at 1 minute Log reduction *C. albicans>4.58*	[redacted]
	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2). After a 2 year storage period	Bacteria: *S. aureus,* *E. hirae* *P. aeruginosa*	EN 13727 – Phase 2 Step 1 Contact time: 1 minute Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Bactericidal with 50% wipe liquid At 1 minute Clean conditions Log reduction *S. aureus, >5.25* *E. hirae>5.11* *P. aeruginosa>5.24*	[redacted]
		Yeast: *Candida albicans*	EN 1657 – Phase 2 Step 1 Contact time: 30 minutes Temperature: 10 °C Clean conditions (veterinary) – 3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid	Yeasticidal with 97% wipe liquid 30 minutes Clean conditions Log reduction *C. albicans> 4.52*	[redacted]
Study report to determine	100% ethanol,	bacteria: *E. coli* (DSM 498)	In this study 100% and 80% ethanol concentrations were used	The study shows that for ethanol concentrations at 20% and below no biocidal activity was found	[redacted]

the Minimum Biocidal Concentration (MBC) of ethanol.	p.a. or 80% Ethanol p.a. for serial dilutions	yeast: *Candida parapsilosis* (DSM 70125)	for serial dilutions to determine the MBC values for biocidal activities using a standard method. Concentrations applied: 100% 50% 25% 12.5% 6.25% 3.12 1.56% 0.78% Exposure time: 5 min *Escherichia coli* Concentrations applied: 80% 40% 20% 10% 5% Exposure times: 5 min. 20 min. 30 min. *Escherichia coli* and *Candida parapsilosis*	for the tester strains even after longer residence times of 30 minutes. Therefore, ethanol is not effective at the concentration used in the UDF2/UDW2 product.	
Efficacy comparison test between two different wipe materials. UDF2 liquid was squeezed from UDW2 and UDW2-Bio.	UDW2 – Liquid squeezed from the wipe (this is identical to UDF2) and UDW2- Bio – Liquid squeezed from the wipe (this is identical to UDF2)	Bacteria – Staphylococcus aureus	EN 13727 (2012+A2:2015) – Phase 2 Step 1 - comparison test UDW2 UDW2-Bio) Contact time: 30 seconds Temperature: 20 °C Clean conditions 0.3 g/L BSA Concentration tested: 1, 5, 10, 25, 50, 80, 97 %	Bactericaidal et 10% product at 30 seconds. UDW2 Log reduction for: S. aureus, > 5.33 UDW2-Bio Log reduction for: S. aureus, > 5.33	[redacted]
Expert Opinion on comparison test performed on efficacy according to EN 13727 between two		Bacteria – Staphylococcus aureus	EN 13727 comparison test	Aim of the tests was to check on the influence of modifications of the excipients in the test sample UDW2 and the test sample UDW2-Bio in regarding to the bactericidal activity in the test run. The results show that there were only slight differences in the reduction factors between the two different wipes.	[redacted]

wipe materials.					

Conclusion on the efficacy of the product

The products in the family are disinfectants for use on non-porous hard surfaces in general, healthcare, veterinary and food/feed related areas – product types 2, 3 and 4. The products are intended to kill bacteria, yeasts and viruses and, in some cases, mycobacteria. The applicant has provided tests, tables of contact times (in minutes), target organisms and use areas for the wipes and RTU fluids.

It should be noted that the fluid product (UDF2) and the liquid in the wipe product (UDW2(-bio)) are identical. All of the data provided was generated using the liquid squeezed from the wipe product, with the exception of EN16615 for which the wipe itself was used. Any effect of the wipe matrix on the formulation will be taken into account by this. The first efficacy tests that was provided was done on fluid squeezed from the wipe UDW2 consisting of 50% polyester & 50% Rayon. A new biodegradable wipe UDW2-Bio have been introduced consisting of 80% cellulose and 20% Rayon. A comparison test has been provided between the two wipe materials. The liquid was squeezed from both wipes and an efficacy test EN 13727 was performed. The results show that there were only slight differences in the reduction factors between the two different wipes. The liquid squeezed from the wipe product can be considered as a worst case. Therefore, the data generated using the liquid squeezed from UDW2 can be used to support both wipe and fluid products.

The tests below have been conducted in clean conditions, using the low level of soiling recommended for the relevant product type. The use instructions state that surfaces should always be cleaned prior to disinfection.

Use 1: PT2 Healthcare, non-porous hard surfaces with patient/medical staff contact
For PT2 disinfection within healthcare of non-porous hard surfaces that are likely to come in contact with the patient and/or the medical staff which are frequently touched by different people have proven to have bactericidal (EN 1276, EN 13727, EN 13697) activity with a contact time 1 minute, yeasticidal (EN 1650, EN 13624, EN 13697) activity with a contact time of 5 minutes and virucidal (14476) activity with a contact time of 2 minutes.

Use 2: PT2 Healthcare, non-porous hard surfaces with NO patient/medical staff contact
For PT2 disinfection within healthcare of non-porous hard surfaces that are not likely to come in to contact with the patient and/or medical staff and are not frequently touched by different people have proven to have bactericidal (EN 1276, EN 13727, EN 13697) activity with a contact time 1 minute, yeasticidal (EN 1650, 13624, EN 13697) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Use 3: PT2 Non-porous hard surfaces
For PT2 disinfection on all water tolerant non-porous hard surfaces used by both professionals within institutional areas e.g. kindergartens, nursing homes etc. and in private homes, have proven to have bactericidal (EN 1276, EN 13727, EN 13697) activity with a contact time 1 minute, yeasticidal (EN 1650, EN 13624, EN 13697) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Use 4: PT2 Instruments by immersion or filling
For PT2 disinfection of instruments by immersion or filling within healthcare (except medical devices) in hospitals, kindergartens, nursing homes, private homes etc. have

proven to have bactericidal (EN 13727, EN 14561) activity with a contact time 1 minute, yeasticidal (EN 13624, EN 14562) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348, EN 14563) activity with a contact time of 10 minutes.

Use 5. PT3 Non-porous hard surfaces within veterinary areas.
For PT3 disinfection of non-porous hard surfaces within veterinary areas have proven to have bactericidal (EN 1656, EN 14349) activity with a contact time of 30 minutes, yeasticidal (EN 1657, EN 16438) activity with a contact time of 30 minutes, virucidal (14675) activity with a contact time of 30 minutes.

Use 6. PT4 Areas within food industry.
For PT4 disinfection of non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking has proofed to have bactericidal (EN 1276, EN 13697) activity with a contact time of 1 minute, yeasticidal (EN 1650, EN13697) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Use 7. PT2 Healthcare, non-porous hard surfaces with patient/medical staff contact, wipes.
For PT2 disinfection within healthcare of non-porous hard surfaces that are likely to come in contact with the patient and/or the medical staff which are frequently touched by different people have proven to have bactericidal (EN13727, EN 1276, EN 16615) activity with a contact time 1 minute, yeasticidal (N 1650, EN 13624, EN 16615) activity with a contact time of 5 minutes and virucidal (EN 14476) activity with a contact time of 2 minutes.

Use 8: PT2 Healthcare, non-porous hard surfaces with NO patient/medical staff contact, wipes
For PT2 disinfection within healthcare of non-porous hard surfaces that are not likely to come in to contact with the patient and/or medical staff and are not frequently touched by different people have proven to have bactericidal (EN 1276, EN 13727, EN 16615) activity with a contact time 1 minute, yeasticidal (EN 1650, 13624, EN 16615) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Use 9: PT2 Non-porous hard surfaces, wipes
For PT2 disinfection on all water tolerant non-porous hard surfaces used by both professionals within institutional areas e.g. kindergartens, nursing homes etc. and in private homes, have proven to have bactericidal (EN 1276, EN 13727, EN 16615) activity with a contact time 1 minute, yeasticidal (EN 1650, EN 13624, EN 16615) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Use 10: PT4 Non-porous hard surfaces within food industry, wipes
For PT4 disinfection of non-porous hard surfaces have proven to have bactericidal (EN, 1276, EN 16615) activity with a contact time of 1 minute, yeasticidal (EN 1650, EN 16615) activity with a contact time of 5 minutes, virucidal (14476) activity with a contact time of 2 minutes and mycobactericidal (EN 14348) activity with a contact time of 10 minutes.

Review of contact times

In all cases for general, medical, veterinary and food areas, the contact times for the fluid product adhere to the limits specified in the guidance (Guidance on the BPR: Volume II Parts B+C version 3.0 April 2018) and are therefore considered to be acceptable.

The longest contact time for the wipe products is 10 minutes against mycobacteria. After discussion with Member States (e-consultation initiated January 2018) about the acceptability of longer contact times than 1 minute, and in light of the applicant's reasoned case, this contact time is considered to be acceptable. When it is clearly specified in the use instructions that surfaces must remain wet for the full contact time and that reapplication may be required to achieve this.

Shelf life

As the storage stability assessment of the product indicated that the concentration of the active substances was below the target amount of active substances in the product both before and after the storage for two weeks at 54 °C.

The applicant has provided additional efficacy studies to demonstrate that the product remains sufficiently efficacious after two years at room temperature. This study was agreed among the Member States.
In order to address this two phase 2 step 1 studies have been provided. These are conducted on bacteria and yeasts according to EN13727 and EN1657 respectively.

A justification for why the selected tests represent a worst case. The full justification can be found in the annex of this PAR (section 3.5.3). Furthermore, an e-consultation was also initiated between the Member States.
The results of both studies demonstrated the necessary log reductions to pass the tests at the relevant contact times for those organisms. The efficacy of the product is maintained after the maximum storage period of 2 years.

Additional information - the Lavender and Peppermint oil content increased on storage, but was not considered significant based on the quantities in the product (less than 0.1%), but were low compared to the target amount. This was due to only determining the major constituents in the oils (Borneol and Menthol). The tartaric and lactic acid contents were low and inconsistent compared to the target content. This was due to interference from the other co-formulants, however as already stated acceptable Efficacy data are available before and after two years storage and a new fully validated method has been submitted.

Decision label claim

eCA NL concludes that sufficient data have been provided to verify the label claims (contact times in minutes) as presented in the table below.

UniBlue Universal Disinfection Fluid (UDF2)

UDF2	Bacteria	Viruses	Yeast	Mycobacteria
Non-porous hard surfaces, healthcare, patient/medical staff contact (PT2)	5	2	5	-
Non-porous hard surfaces, healthcare, no patient/medical staff contact (PT2)	5	2	5	10
Non-porous hard surfaces (PT2)	1	2	5	10
Instrument by immersion or filling (PT2)	5	2	5	10
Veterinary and farming; Non-porous hard surfaces (PT3)	30	30	30	-
Food industry; Non-porous hard surfaces, inner surfaces without circulation, inner surfaces by CIP and equipment disinfection by soaking (PT4)	5	2	5	10

UniBlue Universal Disinfection Wipes (UDW2)

UDW2(-Bio)	Bacteria	Viruses	Yeast	Mycobacteria
Non-porous hard surfaces, healthcare, patient/medical staff contact, wipes (PT2)	5	2	5	-
Non-porous hard surfaces, healthcare, no patient/medical staff contact, wipes (PT2)	5	2	5	10
Non-porous hard surfaces, wipes (PT2)	1	2	5	10
Food industry; non-porous hard surfaces, wipes (PT4)	5	2	5	10

2.9.1.5 OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

In relation to resistance, the applicant has stated the following:

'On the basis of available data, there is no evidence that the use of organic acids in combination with essential oils is leading to an increase in resistant bacterial populations or that there is any increased risk to humans regarding antibiotic resistance. The combination of use of actives with a different mode of action used at the same time is reducing the risk of development of antimicrobial resistance within the treated populations'.

The UK CA accepts the applicant's statement and agrees that, as there are no known occurrences of resistance, this should not be an issue at present. However, the UK CA notes that, as with all products, the applicant should monitor resistance on a continuous basis by requesting that any ineffective treatment be reported to them. Should the authorisation holder be made aware of any occurrence of resistance, this should be reported to the relevant competent authorities.

2.9.1.6 KNOWN LIMITATIONS

There are no known limitations for the product family.

2.9.1.7 EVALUATION OF THE LABEL CLAIMS

The label claims in terms of targets and contact times have been based on the presented studies, please see the result under the efficacy conclusion.

2.9.1.8 RELEVANT INFORMATION IF THE PRODUCT IS INTENDED TO BE AUTHORISED FOR USE WITH OTHER BIOCIDAL PRODUCT(S)

Not applicable.

2.10 RISK ASSESSMENT FOR HUMAN HEALTH

eCA note NL CA: The text included for human health is the original authorisation provided by UK CA. Due to Brexit, NL CA has taken over this dossier and added their conclusions to the respective sections in a note.

2.10.1 ASSESSMENT OF EFFECTS ON HUMAN HEALTH

"Universal Disinfection Fluid and Wipes" contains lactic acid, (+)-tartaric acid, peppermint oil, lavender oil and no substances of concern. The UK CA therefore considers that the biocidal product "Universal Disinfection Fluid and Wipes" does not meet the classification criteria for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitisation, respiratory sensitisation (ADS), or acute toxicity.

Update December 2019 after referral to Co-ordination Group:

Following notification for placing on the market in a Member State, the product "Universal Disinfection Fluid and Wipes" was referred to the Coordination Group (CG) as per Article 35 of Reg. 528/2012. It was suggested that the product should be classified and labelled with Eye Irrit. 2, H319 and that two co-formulants contained in the product should be considered substances of concern (please refer to this PAR's Confidential Annex 3.5.5 for further details).

The CG members agreed on 13 December 2019 by consensus that:

- The two co-fomulants are not considered as SoCs.

eCA note NL CA: No studies with the product are performed. Based on the classification and labelling rules according to CLP, the BPF is not classified for human health endpoints.

2.10.2 EXPOSURE ASSESSMENT

The Applicant has not provided information regarding biocidal product "Universal Disinfection Fluid and Wipes" exposure on human health.

Taking into account that there are no substances of concern present, that the biocidal product "Universal Disinfection Fluid and Wipes" is not classified, and based on the data requirements for the Simplified procedure according to Regulation (EU) 528/2012, the UK CA considers that a detailed exposure assessment is not relevant.

The UK CA accepts that personal protective equipment are not required for the use of the biocidal product "Universal Disinfection Fluid and Wipes".

eCA note NL CA:
Based on the BPR guidance on substances of concern, no SoCs are identified; the product is not classified therefore none of the co-formulants add to the classification, none of the co-formulants are biocidal active sutbstances for which final limit values exist, none of the co-formulants are considered ED or synergists, and for none of the co-formulants EU OEL values exist. As the BPF is not classified and does not contain SoCs and considering the data requirements for a simplified authorisation, NL CA agrees with UK CA that a detailed

exposure assessment is not relevant. Furthermore, NL CA agrees with UK CA that no personal protective equipment is required.

However, considering the composition of the BPF, NL CA noted a co-formulant for which national occupational exposure limits exists. However, as the substance does not lead to classification of the BPF and based on the performed risk assessment by NL CA safe use can be concluded, NL CA considers that the substance is not a substance of concern as it does not meet the criteria of the SoC definition as included in definition in Article 3(1)(f) of the BPR. For more information, please be referred to the Confidential Annex, section 3.5.6.

2.10.3 RISK CHARACTERISATION FOR HUMAN HEALTH

The formulation "Universal Disinfection Fluid and Wipes" has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25). An assessment of potential SOC's (Substances of Concern) has been made. The co-formulants are either not classified as hazardous to human health under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification on their own. Therefore no SOC's are considered to be present in the formulation "Universal Disinfection Fluid and Wipes". On this basis, "Universal Disinfection Fluid and Wipes" can be authorised from a human health perspective under the simplified authorisation procedure (Reg. (EU) 528/2012, chapter V, article 25).

eCA note NL CA:
We agree with UK CA that "Universal Disinfection Fluid and Wipes" can be authorised from a human health perspective under the simplified authorisation procedure (Reg. (EU) 528/2012, chapter V, article 25).

2.11 RISK ASSESSMENT FOR THE ENVIRONMENT

The formulation "Universal Disinfection Fluid and Wipes" has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25). An assessment of potential SOC's (Substances of Concern) has been made. The co-formulants are either not classified as hazardous to the environment under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification on their own. Therefore no SOC's are considered to be present in the formulation "Universal Disinfection Fluid and Wipes". On this basis, "Universal Disinfection Fluid and Wipes" can be authorised from an environmental perspective under the simplified authorisation procedure (Reg. (EU) 528/2012, chapter V, article 25).

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for Universal Disinfection Fluid and Wipes. The product was not tested for potential endocrine disruption properties. Universal Disinfection Fluid and Wipes contains the active substances lavender oil, peppermint oil, lactic acid and (+)-tartaric acid and various co-formulants (see confidential annex).

For lavender oil, peppermint oil, lactic acid and (+)-tartaric acid no ED assessment is required because for active substances which have been approved, the EU assessment should be followed.

For the co-formulants the data included in Section 3.5.4.2 are considered, as well as additional databases relevant for non-target organisms including:
• Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
• UN factsheet (https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
• Denmark EPA (http://cend.dk/files/DK_ED-list-final_2018.pdf)
• Japan ED database (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.htm)

Based on these databases, none of the co-formulants triggered an alert for ED property for non-target organisms from a environmental exposure and risk point of view.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Author(s)	Year	Title and publication	Confidential
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
[redacted]	[redacted]	[redacted]	Yes
		Guideline for Disinfection Centers for Disease Control and Prevention USA, 2008	

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Not applicable as BPF contains only active substances listed on Annex 1 of the BPR and no substances of concern.

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new information on the active substance has been provided in support of this biocidal product.

3.4 RESIDUE BEHAVIOUR

Not relevant.

3.5 CONFIDENTIAL ANNEX