|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-MIC | *NL* | [BC-UE065537-28](https://r4bp-main.echa.europa.eu/r4bp-web-authority/case/sa-mic.xhtml?id=BC-UE065537-28)  | 21-5-2021 | Post authorisation requirement fulfilled | - |
| SA-MIC | *NL* | BC-QJ067708-17 | 10-9-2021 | -Adding an additional size of the Bio-wipe in four different packaging sizes.-Reinstates the wipe substrate material-Adding new trade names for UniBlue Universal Disinfection Wipe (UDW2)-Adding a new active substance supplier of Lactic acid | See addendum 20210910\_NL-0020556-0000\_Addendum |
| SA-MIC | *NL* | BC-VL068809-03 | 24-9-2021 | - Adding the UDW2-Bio wipe: 25 pcs. 32 cm x 20 cm20 pcs. 40 cm x 30 cmAlso for non-Professional use- Adding additional sizes of the UDW2-Bio wipe. - Adding additional sizes of the UDW2 wipe.- Adding additional packing materials for the wipes- Adding new trade names for UniBlue Universal Disinfection Fluid (UDF2)-Adding a new manufacturer site for the wipes | See addendum 20210924\_NL-0020556-0000\_Addendum |

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:September 2021Table of Contents

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# CONCLUSION

## 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. Update:The applicant has fulfilled the post authorisation requirement in May 2021, this is within the time frame of the requirement that was given by the Dutch competent authority.

The application will be authorised based on the following conclusions:

## 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
 |

## 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 |

## 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.

## 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.

## 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.

## 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.

## 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

## Requirement for further information

N/A

# ASSESSMENT REPORT

## summary of the product assessment

### ADMINISTRATIVE INFORMATION

#### IDENTIFIER of the product / PRODUCT FAMILY

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

#### 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 |

#### 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 |

#### 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** | Tartaric acid |
| **Name of manufacturer** | Distillerie Mazzari SpA |
| **Address of manufacturer** | Via Giardino, 6, Sant’Agata sul Santerno, 48020 (RA), Italy |
| **Location of manufacturing sites** | Via Giardino, 6, Sant’Agata sul Santerno, 48020 (RA), Italy |

|  |  |
| --- | --- |
| **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 |

## 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 [x]

### 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** | Tartaric acid.svg |

|  |
| --- |
| **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** | Skeletal formula of L-lactic acid |

|  |
| --- |
| **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 |

### 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.

### 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) |
| 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.

### 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.

### 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.

### Type of formulation

|  |
| --- |
| RTU AL – ready to use aqueous liquidRTU wipe |

## 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)** | BacteriaYeastViruses |
| **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 minutesViruses: 2 minutesThe 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 YeastViruses |
| **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 minutesMycobacteria: 10 minutesViruses: 2 minutesThe 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)** | BacteriaMycobacteriaYeastViruses |
| **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 minuteYeast: 5 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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, MycobacteriaYeastViruses |
| **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 liquidDisinfection 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 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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)** | BacteriaYeastViruses |
| **Field of use** | IndoorDisinfection 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 liquidDisinfection 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 minutesThe 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 contact time. |

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 YeastViruses |
| **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 liquidDisinfection 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 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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)** | BacteriaYeastViruses |
| **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 wipeDisinfection with prior cleaning Keep the surface wet during contact time for:Bacteria and yeast: 5 minutesViruses: 2 minutesThe 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 myFlap: PP or synthetic paper25 pcs., 32 cm x 20 cm20 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)** | BacteriaMycobacteria YeastViruses |
| **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 wipeDisinfection with prior cleaning Keep the surface wet during contact time for:Bacteria and yeast 5 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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 myFlap: PP or synthetic paper25 pcs., 32 cm x 20 cm20 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)** | BacteriaMycobacteria YeastViruses |
| **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 wipeDisinfection with prior cleaning Keep the surface wet during contact time for:Bacteria: 1 minutesYeast: 5 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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 myFlap: PP or synthetic paperProfessional:25 pcs., 32 cm x 20 cm20 pcs., 40 cm x 30 cmNon-professional:10 pcs., 19 cm x 17 cm40 pcs., 19 cm x 17 cm80 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 YeastViruses |
| **Field of use** | IndoorDisinfection 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 wipeDisinfection with prior cleaning Keep the surface wet during contact time for:Bacteria and yeast: 5 minutesViruses: 2 minutesMycobacteria: 10 minutesThe 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 myFlap: PP or synthetic paper25 pcs., 32 cm x 20 cm20 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. |

## 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 | **-** |

## 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 lidTrigger sprayPump 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-Bio80% cellulose & 20% viscose | 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 = 12g/wipe, covering 1m2 surface disinfection per wipe. | 25 pcs.32 cm x 20 cm | Pack: Laminate PET/PE | Flap: PP orSynthetic paper | Professional |
| UDW2-Bio:60gsm, 330% UDF2 fluid of weight of wipe = 24g/wipe, covering 2m2 surface disinfection per wipe | 20 pcs.40 cm x 30 cm | Pack: Laminate PET/PE | Flap: PPorSynthetic paper | Professional |
| UDW2-Bio:60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m2 surface disinfection per wipe | 40 pcs.19 cm x 17 cm | Pack: Laminate PET/PE | Flap: PP orSynthetic paper | Non-professional |
| UDW2-Bio:60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m2 surface disinfection per wipe | 80 pcs.19 cm x 17 cm | Pack: Laminate PET/PE | Flap: PPor Synthetic paper | Non-professional |
| UDW2-Bio:60gsm, 320% UDF2 fluid of weight of wipe = 6g/wipe, covering 0.5m2 surface disinfection per wipe | 10 pcs.19 cm x 17 cm | Pack: Laminate PET/PE | Flap: PPor Synthetic paper | Non-professional |

## Directions for use

### 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. |

### Risk mitigation measures

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

### 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. |

### 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. |

### 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. |

## Other information

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| --- |
| 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.  |

## Assessment of the biocidal product

### 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 | XXXXXXXXXXXXX | Acceptable.  |
| Colour at 20 °C and 101.3 kPa | ISO 4630-1 Gardner colour scaleISO 4630-1 Gardner colour scale | **RTU AL**(Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099% | Clear  | XXXXXXXXXXXXX | 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 electrode as sensor | **RTU AL**(Tartaric acid 0.616%/Lactic acid 0.36%/Lavender oil 0.099%/Peppermint oil 0.099% | 2.3 (neat) | XXXXXXXXXXXXX | Acidity test missing, however Mammalian tox assessment has no issue with this low pH (see section 2.10). |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3LC-MS methodLC-MS methodGC-MS methodGC-MS methodVisual assessmentASTM D1293-12 Using a glass electrode as sensorCIPAC MT 191Visual assessment | **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/mlTartaric acidInitial: 0.412%After: 0.430%(4.4 % increase)Lactic acidInitial: 0.246%After: 0.242%(1.62% decrease)Lavender oilInitial: 0.0704%After: 0.0754%7.1 % increase)Peppermint oilInitial: 0.0627%After: 0.0716%(14.2 % increase)Product appearanceNo change after storagepH of neat solutionInitial: 2.4After: 2.4AcidityInitial: No data submittedAfter: No data submittedPackagingPET/AL/PE sales pack no change after storage | XXXXXXXXXXXXX | Acceptable, however the target amounts in the formulation are:-Tartaric acid = 6.16 g/lLactic acid = 3.6 g/lLavender oil = 0.99 g/lPeppermint oil = 0.99 g/lThe 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 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 46.3GC-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 acidInitial: 0.428%After: 0.493%(15.2 % increase)Lactic acidInitial: 0.261%After: 0.263%(0.8 % decrease)Lavender oilInitial: 0.0628%After: 0.0502%(20.1 % decrease)Peppermint oilInitial: 0.0475%After: 0.0375%(21.05 % decrease) | XXXXXXXXXXXXX | 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 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. |  |  |  | XXXXXXXXXXXXX |
| 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 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. |

### 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)UN L2 (Open Cup Flash Point Tester for sustained combustility) | UniBlue® Universal Disinfection Fluid (UDF2)Batch No.: CH20021801 | Flash point:45.5°CNo sustained combustibility occurred during test. Three 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.  | XXXXXXXXXXXXX |  |
| 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 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.The biocidal products are aqueous liquids. |  |  |
| Organic peroxides |  |  | Not applicable.The products do not generate H2O2. |  |  |
| 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 BPFBatch No.: CH20021801 | 495°CThe value is based on the lowest measured value after three independent measurements. | XXXXXXXXXXXXX |  |
| Relative self-ignition temperature for solids |  |  | Not applicable.The biocidal products are aqueous liquids. |  |  |
| Dust explosion hazard |  |  | Not applicable.The biocidal products are 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. |

### Methods for detection and identification

#### 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.

#### Analytical methods for the active substance in the biocidal product

Lactic acid and Tartaric acid

For the determination of the content of Lactic acid and Tartaric acid in UDF2, high performance liquid chromatography with MS detection (ESI/negative ionization)) was used.

Detection at 89.0 m/z Lactate and at 148.5 m/z Tartrate.

Lavender oil and Peppermint oil

For the determination of the content of Lavender oil and Peppermint oil in UDF2, gas chromatography with MS detection (GC/MS) in SIM mode was used.

Mass fragments observed: m/z 55, 80, 93, 112, 121, 123, 136, 138, 139, 154.

The contents of Linalool and Linalyl acetate was used as the representative marker substances for the active substance Lavender oil.

The contents of Menthone and Menthol was used as the representative marker substances for the active substance Peppermint oil.

Lactic acid

The product was analysed by HPLC/MS (89.0 m/z Lactate) using a Zorbax Eclipse Plus C18 (3.5 µm) 150 mm x 3.0 mm i.d. column with 5mM ammonium formate and methanol as eluents.

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| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** |
| Range | Mean | RSD  |
| Lactic Acid | HPLC/MS | ~70% - 130%/0.259% (n=3x3)0.370% (n=3x3)0.481% (n=3x3) | n = 6y =281.8385x + 422.5535 R2= 0.9976Range: 414.0 – 3312 ng/mL | 1.90 % interference from other substances.  | 104.2-108.2 100.0-108.3 100.6-104.8 | 105.9104.4102.1 | 2.04.02.3 |

The determined method precision is 1.80 % for lactic acid and the determined HorRat value is 0.58. This result meets the acceptance criterion Hr ≤ 1.

Tartaric acid

The product was analysed by HPLC/MS (148.5 m/z Tartrate) using a Zorbax Eclipse Plus C18 (3.5 µm) 150 mm x 3.0 mm i.d. column with 5mM ammonium formate and methanol as eluents.

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| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** |
| Range | Mean | RSD  |
| Tartaric Acid | HPLC/MS | ~70% - 130%/0.433% (n=3x3)0.618% (n=3x3)0.804% (n=3x3) | n = 6y =747.8976x -270440.8445R2= 0.9996Range: 692.4 – 5539 ng/mL | 1.41 % interference from other substances.  | 103.9-104.5102.4-102.9 100.7-102.8 | 104.3102.6101.5 | 0.30.31.1 |

The determined method precision is 5.03 % for tartaric acid and the determined HorRat value is 1.74. This result meets the acceptance criterion Hr ≤ 2 with an explanation. Tartaric acid is quantified as sum of the monotartrate and ditartrate ions by HPLC and there may be pH-dependent equilibrium shifts between the monotartrate and ditartrate during chromatography and the two ions may have different responses. Therefore, small additional deviations in the tartrate contents may result from this.

Peppermint Oil

The product was analysed by GC/MS (m/z 55, 80, 93, 112, 121, 123, 136, 138, 139, 154) using a Phenomenex ZB-5-MS or equivalent column.

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| **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 | 0.060%-0.111%0.060% (n=3x3)0.085% (n=3x3)0.111% (n=3x3) | n = 6y = 0.0073x2 -67.7292x + 1195182.2335\*R2= 0.9942Range: 5738 – 28700 ng/mL | No interference from other substances. | 102- 106.5 96.8 – 99.4 90.0-96.3 | 104.898.393.0 | 2.31.43.4 |

\* the sensitivity of the mass selective detector was not constant over large ranges, so quadratic interpolation was used.

The determined method precision is 2.39 % for menthol and menthone (representing Peppermint oil) and the determined HorRat value is 0.63. This result meets the acceptance criterion Hr ≤ 1.

Lavender Oil

The product was analysed by GC/MS (m/z 55, 80, 93, 112, 121, 123, 136, 138, 139, 154) using a Phenomenex ZB-5-MS or equivalent column.

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| **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 | 0.020%-0.037%0.020% (n=3x3)0.028% (n=3x3)0.037% (n=3x3) | n = 6y = 186.3079x -316279.9188R2= 0.9943Range: 3527 – 48490 ng/mL | No interference from other substances. | 99.6- 103.4 96.9- 101.2 91.7-96.7 | 101.599.394.3 | 1.92.22.6 |

The determined method precision is 1.79 % for linalool and linalyl acetate (representing Lavender oil) and the determined HorRat value is 0.47. This result meets the acceptance criterion Hr ≤ 1.

#### 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.

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| **Conclusion on the methods for detection and identification of the product** |
| An HPLC-UV and GC-MS analytical method to determine the concentration of the active substances in UDF2 have been required to be validated according to the Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0. May 2018 and SANCO/3030/99 rev 5 22/03/2019. Concentration of the active substances in UDF2 determined according to test. In parentheses the accepted range.Lactic acid: 0.326 % w/w - (required 0.306-0.414 % w/w) Tartaric acid: 0.574 % w/w - (required 0.524-0.708 % w/w)Lavender oil: 0.027 % w/w - (required 0.084-0.114 % w/w)\* Peppermint oil: 0.089 % w/w - (required 0.084-0.114 % w/w) \*The low amount of Lavender oil (Linalool and Linalyl acetate) 0.027% found in the product, is due to the reaction of Linalool and Linalyl acetate with Lactic acid in the product by esterification or trans-esterification. The reaction product Linalyl lactate has been identified by mass spectrometry in the product. The 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 according to SANCO/3030/99 rev 5 22/03/2019 and are acceptable. |

## Efficacy against target organisms

### 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.

#### 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.

#### Effects on target organisms, including unacceptable suffering

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

#### 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.’*

#### Efficacy data

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| **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 ˚CClean conditions – 0.3 g/L BSAConcentration tested: 50, 80, 97% wipe liquid  | Bactericidal at 50% wipe liquid1 minutesClean conditionsLog reduction*S. aureus, >5.06**E. hirae, >5.21**E. coli, >5.24**P aeruginosa>5.15*  | XXXXXXXXXXXXX |
| 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: 1minuteYeast 5 minutes Temperature: 24.4 ˚C Clean conditions - 0.3 g/L BSAConcentration tested: 50, 80, 100% wipe liquid | Bactericidal at 50% wipe liquid1 minuteClean conditionsLog reduction for:*S. aureus, >4**E. hirae, >4**E. coli, >4**P aeruginosa>4*Yeasticidal at 50% wipe liquid5 minutesClean conditionsLog reduction for*C. albicans*, >3 | XXXXXXXXXXXXX |
| 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 minutesTemperature 20 ˚C Clean conditions – 0.3 g/L BSAConcentration tested: 50, 80, 97% wipe liquid | Yeasticidal at 80% wipe liquid5 minutesClean conditionsLog reduction:C. *albicans* > 4 | XXXXXXXXXXXXX |
| UDW2 – Liquid squeezed from the wipe (this is identical to UDF2) | Yeast *– C. albicans*  | EN 13624 – Phase 2 Step 1 (Medical/healthcare area test)Contact time: 5 minutes Temperature: 20 ˚CClean conditions – 0.3 g/L BSAConcentration tested: 50,80, 97% wipe liquid  | Yeasticidal at 80% wipe liquid5 minutesClean conditionsLog reductionC. albicans >4.04 | XXXXXXXXXXXXX |
| 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 minuteTemperature: 20 ˚C Clean conditions 0.3 g/L BSA Concentration tested: 50,80 en 97 % wipe liquid | Bactericaidal et 50% product at 1 minuteClean conditionsLog reduction for: *S. aureus, >5.22**E. hirae, >5.13**P aeruginosa>5.34* | XXXXXXXXXXXXX |

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|  | 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 ˚CClean conditions 0.3 g/L BSAConcentration tested: 50, 80, 97% wipe liquid | Mycobactericidal at 97% wipe liquidAt 10 minutesClean conditionsLog reduction*M. terrae*> 5.08*M. avium* >5.35  | XXXXXXXXXXXXX |
| 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 liquidAt 2 minutesClean conditionsLog reductionAdenovirus:>6.17Poliovirus:>4.17Murine norovirus:>4.5 | XXXXXXXXXXXXX |
| 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 BSAConcentration tested: 50, 80, 100% wipe liquid | Bactericidal at 80% wipe liquid1 minuteClean conditionsLog reduction*S. aureus, >5.57**E. hirae, >5.60**P aeruginosa>5.08* | XXXXXXXXXXXXX |
| 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 liquid5 minutesClean conditionsLog reductionC. albicans: 4  | XXXXXXXXXXXXX |
| 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 liquidAt 10 minutesClean conditionsLog reduction *M. terrae,>5.08* *M. avium >5.03*  | XXXXXXXXXXXXX |
| 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 minutesTemperature: 10 ˚CClean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 97% wipe liquid | Bactericida at 50% wipe liquid30 minutesClean conditionsLog reduction *S. aureus, >5.36**E. hirae,>5.35**Proteus. hauseri (*formally *vulgaris),>5.35* *P. aeruginosa >5.30* | XXXXXXXXXXXXX |

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|  | 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 minutesTemperature: 10 ˚CClean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 97% wipe liquid | Yeasticidal at 97% wipe liquid30 minutesClean conditionsLog reduction*C. albicans*> 4.52 | XXXXXXXXXXXXX |
| 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 minutesTemperature: 10 ˚CClean conditions (veterinary) 3 g/L BSA Concentration tested: 10, 50, 100% wipe liquid | Bactericidal at 50% wipe liquid*.*30 minutesClean conditionsLog reduction*S. aureus, >4**E. hirae,>4**Proteus. hauseri (*formally *vulgaris),>4* *P. aeruginosa >4* | XXXXXXXXXXXXX |
| 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 minutesClean conditionsLog reductionBovine Enterovirus: >4.6  | XXXXXXXXXXXXX |
| UDW2-Bio– Liquid squeezed from the wipe (this is identical to UDF2) | Yeast – *C. albicans*  | EN 16438 (2014) – Phase 2 Step 2 Contact time: 30 minutesTemperature: 10 ˚CClean conditions 3 g/L BSA Concentration tested: 10, 50, 100% wipe liquid | Yeasticidal at 50% wipe liquid30 minutesClean conditions*.*  | XXXXXXXXXXXXX |
| UDW2 Wipe  | Bacteria *- S. aureus, E. hirae, P aeruginosa*Yeast *- C. albicans* | EN16615 (2015) – Phase 2 Step 2Contact time: 5 minutesTemperature: 20 ˚C Clean conditions 0.3 g/L BSA  | Bactericidal at 5 minutes Clean conditionsLog reduction *S. aureus, >5.78**E. hirae, >5.75**P aeruginosa>5.08*Yeasticidal at 5 minutesLog reduction*C. albicans>4.5* | XXXXXXXXXXXXX |
| UDW2-Bio Wipe  | Bacteria *- S. aureus, E. hirae, P aeruginosa*Yeast *- C. albicans* | EN16615 (2015) – Phase 2 Step 2Contact time: 1 minuteTemperature: 23.5-23.6 ˚C Clean conditions 0.3 g/L BSA  | Bactericidal at 1 minuteClean conditions Log reduction *S. aureus, >5.97**E. hirae, >5.85**P aeruginosa>5.06*Yeasticidal at 1 minuteLog reduction*C. albicans>4.58* | XXXXXXXXXXXXX |
| 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 1Contact time: 1 minuteTemperature: 20 ˚C Clean conditions 0.3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid  | Bactericidal with 50% wipe liquidAt 1 minuteClean conditionsLog reduction*S. aureus, >5.25**E. hirae>5.11**P. aeruginosa>5.24* | XXXXXXXXXXXXX |
| Yeast: *Candida albicans*  | EN 1657 – Phase 2 Step 1 Contact time: 30 minutesTemperature: 10 ˚CClean conditions (veterinary) – 3 g/L BSA Concentration tested: 50, 80, 97% wipe liquid | Yeasticidal with 97% wipe liquid30 minutesClean conditionsLog reduction*C. albicans> 4.52* | XXXXXXXXXXXXX |
| Study report to determine the Minimum Biocidal Concentration (MBC) of ethanol. | 100% ethanol, p.a. or 80% Ethanol p.a. for serial dilutions | bacteria: *E. coli* (DSM 498) yeast: *Candida parapsilosis* (DSM 70125) | In this study 100% and 80% ethanol concentrations were used 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*  | The study shows that for ethanol concentrations at 20% and below no biocidal activity was found 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. | XXXXXXXXXXXXX |
| 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 testUDW2 UDW2-Bio )Contact time: 30 secondsTemperature: 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.UDW2Log reduction for: S. aureus, > 5.33UDW2-BioLog reduction for: S. aureus, > 5.33 | XXXXXXXXXXXXX |
| Expert Opinion on comparison test performed on efficacy according to EN 13727 between two wipe materials.  |  | 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. | XXXXXXXXXXXXX |

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| **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% viscose. A new biodegradable wipe UDW2-Bio have been introduced consisting of 80% cellulose and 20% viscose. 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 contactFor 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 contactFor PT2 disinfection within healthcare of non-porous hard surfaces that are notlikely 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 surfacesFor 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 fillingFor 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, wipesFor PT2 disinfection within healthcare of non-porous hard surfaces that are notlikely 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, wipesFor 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, wipesFor 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 |

 |

#### 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.

#### Known limitations

There are no known limitations for the product family.

#### 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.

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

Not applicable.

## 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.

### 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.

### 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.

### 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).

## 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.

# Annexes

## List of studies for the biocidal product

| **Author(s)** | **Year** | **Title and publication** | **Confidential** |
| --- | --- | --- | --- |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
| XXXXXXXXXXXXXXXXXXXXXXXX | XXXXX | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | Yes |
|  |  | Guideline for Disinfection Centers for Disease Control and Prevention USA, 2008 |  |

## 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.

## New information on the active substance

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

## Residue behaviour

Not relevant.

## Confidential annex