Addendum to Product Assessment Report

**Universal Disinfection fluid and wipes**

September 2021

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

# Background

An application for a minor change was received (BC-QJ067708-17). This minor change involves two minor changes.

1. Adding an additional size of the Bio-wipe in four different packaging sizes.

UDW2-Bio 30, 40, 60, 80 pcs., 21 cm x 25 cm

1. Reinstates the wipe substrate material: 50% polyester & 50% viscose.

UDW2 80 pcs., 17.8 cm x 17.8 cm

A new test has been performed. The test is included into the IUCLID dataset under: Efficacy data to support bactericidal and yeasticidal claim EN 16615 1 minute - UDW2.A change in the pack size range

In addition to that, two administrative changes were included in this minor change application:

1. Adding new trade names for UniBlue Universal Disinfection Wipe (UDW2):

* UniBlue UDW2-Bio
* UniBlue UDW2
* Kruidvat reinigings en desinfectiedoekjes

1. Adding a new active substance manufacturer of Lactic acid:

Jungbunzlauer S.A.

ZI et Portuaire

BP 32

67390 Marckolsheim

France

# APCP assessment

1. The size of the new wipes does not affect the physical, chemical and technical properties and neither the stability of the product. The addition of the 4 different packaging sizes is considered acceptable.
2. According to Decision number: TAP-D-1403137-31-00/F, Case number: BC-HL044251-48 the source Jungbunzauler S.A. is considered technically equivalent compared to the reference source. The new active substance manufacturer for lactic acid is considered acceptable. The safety data sheet provided is according to the requirements.

# Efficacy assessment

#### Efficacy data:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| **Function and field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method/**  **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Disinfectant for use on non-porous hard surfaces in general, healthcare, veterinary and food/feed related areas – product types 2, 3 and 4. | UDW2 Wipe (300mm x 200mm, pack with 48 wipes) | Bacteria *- S. aureus, E. hirae, P aeruginosa*  Yeast *- C. albicans* | EN16615 (2015) – Phase 2 Step 2  Contact time: 1 minute  Temperature: 23 ˚C  Clean conditions 0.3 g/L BSA | Bactericidal at 1 minute  Clean conditions  Log reduction  *S. aureus, >6.34*  *E. hirae, >5.69*  *P aeruginosa>5.53*  Yeasticidal at 1 minute  Log reduction  *C. albicans: 4.64* | Efficacy data to support bactericidal and yeasticidal claim EN 16615 1 minute UDW2 XXXXX  XXXXX |

# Efficacy conclusion:

The EN16615 phase 2 step 2 test demonstrated that the ready-to-use wipe (UDW2) consisting of 50% polyester and 50% viscose is efficacious against bacteria and yeast with a contact time of 1 minute.

Efficacy is demonstrated for a product with a wipe size of 300mm x 200mm and a package volume of 48 wipes and contains 2.95x the weight of the wipe in liquid. The applicant declared that the requested wipe will contain 3.0 or 3.2 xweight of the dry wipe. Therefore, efficacy is substantiated for the requested addition of wipe with the size 17.8 cm x 17.8 cm and a package of 80 wipes against bacteria and yeast with a contact time of 1 minute.