Addendum to Product Assessment Report

**Universal Disinfection fluid and wipes**

Augustus 2022

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

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# Background

An application for a minor change was received (BC-JS076389-03). This minor change involves the application for changing the shelf-life for the UniBlue Universal Disinfection Fluid (UDF2) from 2 years to 3 years.

In addition to that a new tradename for the UniBlue Universal Disinfection Wipe (UDW2) was added. Plus two additional manufacturing sites for UniBlue UDF2 and UniBlue UDW2 were added.

#### 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. | UDF2 - After three years storage period. | Bacteria:  *S. aureus,*  *E. hirae*  *P. aeruginosa* | EN 13727 – Phase 2 Step 1  Contact time: 1 minute  Temperature: 20 ˚C  Clean conditions 0.3 g/L BSA  Concentration tested: 50, 80, 97% UDF2 liquid | Bactericidal with 50% UDF2 liquid  At 1 minute  Clean conditions  Log reduction  *S. aureus, >5.06*  *E. hirae>5.35*  *P. aeruginosa>5.54* | XXXXXXXXXXXXX |
| Yeast: *Candida albicans* | EN 1657 – Phase 2 Step 1  Contact time: 30 minutes  Temperature: 10 ˚C  Clean conditions (veterinary) – 3 g/L BSA  Concentration tested: 25, 50, 80, 97% UDF2 liquid | Yeasticidal with 97% UDF2 liquid  30 minutes  Clean conditions  Log reduction  *C. albicans> 4.00* | XXXXXXXXXXXXX |

# Conclusion concerning the change of the shelf life period from 2 to 3 years

**APCP (05-08-2022)**

No long term stability at ambient temperature study report was provided for the test items. 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 below. Based on the efficacy tests carried out on the product UniBlue UDF2 (representative for the BPF) stored for 3 years, the eCA considers that the extension of the shelf-life to 3 years is justified.

**EFFICACY (04-08-2022)**

**Assessment of two efficacy tests after storage:**

In the original PAR an explanation and justification have been provided to substantiate a shelf life of 2 years. Two phase 2, step 1 tests were provided, one with bacteria and one with yeasts:

* Bacteria (en13727, 1 min, clean (PT2), 20 °C): results with fresh product 50% product efficacious, after two years storage 50% product efficacious, after three years 50% product efficacious.
* Yeasts (en1657, 30 min, clean (PT3), 10 °C): results with fresh product 97% product efficacious, after two years storage 97% product efficacious, after three years 97% product efficacious.

In case efficacy has been shown with the fresh product than phase 2, step 1 tests are acceptable to substantiate efficacy after storage (see e-consultation WGV2018 EFF 9-1c Efficacy testing of stored product). The justification and testing for shelf life was accepted in the original PAR. As a similar strategy has been employed for a three years shelf life we agree with this strategy. The provided tests fulfil the validation criteria and prove efficacy after storage. Based on these tests the shelf life of UniBlue Universal Disinfection Fluid (UDF2) can be adapted from 2 to 3 years.