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

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# Background

An application for a minor change was received (BC-VL068809-03). This minor change involves adding wipes/adding additional sizes/adding additional packaging material:

1. Adding the UDW2-Bio wipe:

25 pcs. 32 cm x 20 cm

20 pcs. 40 cm x 30 cm

Also for non-Professional use

1. Adding additional sizes of the UDW2-Bio wipe.

Professional / non-Professional:

In a Canister 50 pcs., 100 pcs; 17.8 cm x 19 cm

25 pcs., 20 cm x 30 cm

20 pcs., 43 cm x 30 cm

20 pcs., 18 cm x 18 cm

1. Adding additional sizes of the UDW2 wipe.

Professional / non-Professional:

25, 48 pcs., 20 cm x 30 cm

25 pcs., 20 cm x 32 cm

20 pcs., 43 cm x 30 cm

20 pcs., 18 cm x 18 cm

1. Adding additional packing materials for the wipes: OPP 20my/CPP 60 my and OPP 20 my/CPP 50 my

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

1. Adding new trade names for the UniBlue Universal Disinfection Fluid (UDF2):

UniBlue UDF2

1. Adding a manufacturing site in China for the wipes

Soshio Wet Tissue Co., Ltd.

NO.6, GongYe Road, BeiJiao ShunDe,

FoShan GuangDong, 528311

China

# APCP assessment

1. The UDW2-Bio wipe is already included in the original authorization of November 2020 and is thus acceptable.
2. The canister (HDPE with PP lid) is a new packaging type. Wet wipes are packed in flexible film (OPP/CPP) and inserted into the canister. The canister is secundary packaging and acceptable.

The additional sizes of the wipes do not affect the physical, chemical and technical properties and neither the stability of the product and are considered acceptable.

1. The additional sizes of the wipes do not affect the physical, chemical and technical properties and neither the stability of the product and are considered acceptable.
2. Information on the new packaging materials OPP 20my/CPP 60 my and OPP 20 my/CPP 50 my showed that the weight loss is less than for the already authorized laminate PET/PE packages. Furthermore, the products are aqueous, making extrapolation of packaging materials possible. Hence, the new packaging materials are acceptable.

The additional sizes of the wipes do not affect the physical, chemical and technical properties and neither the stability of the product and are considered acceptable

# Decision

All changes applied for were accepted by Ctgb NL.