

# 1 Decision by the Danish EPA

ECA Consortium applied at 24. April 2020 for a derogation according to article 55 of Regulation (EU) no. 528/2012 for the production and marketing of the biocidal product Neuthox by Danish Clean Water A/S.

The evaluation performed by the Danish Environmental Agency has shown that sufficient data has been provided to verify the outcome and conclusions, and justify derogation for use of Neuthox according to the following conditions:

Use area

| User             | Application method         | Product type         |
|------------------|----------------------------|----------------------|
| Non-professional | Hand hygienic disinfection | PT 1 (Human hygiene) |

Authorisation is granted for production and marketing of the biocidal product Neuthox to use as a hand hygienic disinfectant to prevent spread of bacteria and viruses through contact by professional and non-professional users.

Application rates and frequency:

3 mL biocidal product is applied to clean; dry hands and rubbed thoroughly for 60 seconds. Frequency depends on the actual need for hand disinfectant.

The concentration of the active substance active chlorine in the biocidal product is 500 ppm. The source of the formulated active substance is Danish Clean Water A/S. Danish Clean Water A/S is part of ECA Consortium A/S, which is listed on article 95 of Regulation (EU) no. 528/2012 as a product supplier. Additionally, Danish Clean Water A/S is listed here as substance and product supplier.

A safe use has been demonstrated for the intended use as a hand disinfectant by professional and non-professional users. Please refer to section 5 for the details of the exposure assessment and risk evaluation.

Stability

Stability data has not been provided for this application. The expiry date will be set to maximum 9 months after the production date following evaluating of stability data in the active substance Assessment Report.

RECOMMENDED ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

Recommended issues accounted for in the product label is provided in appendix 1 (“Etikettebrev”).