

**NOTIFICATION OF DEROGATION PURSUANT TO ARTICLE 55(1) OF REGULATION (EU) NO 528/2012**

- Notifying Member State<sup>1</sup>

Estonia

- Competent Authority granting the temporary derogation

Organisation	Email address
Health Board	KOOBiotsiid@terviseamet.ee

- In case of repeated action: number of previous action(s)

- Product name

WHO Formulation 2

- Product type

PT 1

- Active substance(s)

Propan-2-ol

- Target organism(s)

SARS-CoV-2

- User category

General public  
Professional user

- Starting date of the action based on Art. 55 (1) of the BPR

27/03/2020

- End date of the action based on Art. 55 (1) of the BPR

01/05/2020

The government of Estonia has declared an emergency situation due to the pandemic spread of the coronavirus in the world and the likely further spread of the virus within Estonia. Unless decreed otherwise by the government, the emergency situation remains in force until 1 May 2020.

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- Description of danger the derogation is intended to address

danger to public health

As a result of the wide spread of the SARS-CoV-2 coronavirus, disinfectants for hand disinfection are increasingly in demand across Estonia.

The number of confirmed cases of virus SARS-CoV-2 in Estonia is increasing rapidly.

Since the novel coronavirus SARS-CoV-2 is transmitted in a similar way to the flu virus, as a droplet infection, the recommendation to disinfect the hands and surfaces can also be transferred in case of contact with SARS-Cov-2.

Appropriate hand disinfectants are practically no longer available on the market but the need will grow for use in households, public areas, public health facilities and hospitals. There are shortages in supply chain for biocidal products.

In order to secure the supply of hand disinfection products a temporary derogation for the making available on the market and use of the hand disinfectants with the WHO formulation 2 (containing propan-2-ol) have been granted in Estonia.

danger to animal health

(describe briefly the danger, the area affected and the effects of the danger)

danger to environment

(describe briefly the danger, the area affected and the effects of the danger)

- Geographical area of use

Estonia

- Absence of any other means to contain the danger

Due to the urgent demand of the hand disinfectants the procedure according to the art 17 of BPR is too time consuming to get products on the market for the critical period.

- Limited and controlled use

Manufacturers of biocidal products with the WHO formulation II has to apply for a temporary registration via transitional measure from Health Board.