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

Denmark	
ompetent Authority granting the tempor	ary derogation
Organisation	Email address
Danish Environmental Protection Agency	biocides@mst.dk
case of repeated action: number of pre-	vious action(s)
oduct name	
WHO, formulation 2	
oduct type	
PT 1	
ctive substance(s)	
Propan-2-ol	
arget organism(s)	
Virus	
ser category	
Professionals	
General public	
arting date of the action based on Art. 5	55 (1) of the BPR
23/03/2020	
nd date of the action based on Art. 55 (	1) of the BPR
30/06/2020	

 $<sup>^{1}</sup>$  In this form "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

## • Description of danger the derogation is intended to address

### ☑ danger to public health

Due to the outbreak of COVID-19, Denmark has experienced a shortage of biocidal products for disinfection of hands. Not only general stores, but also pharmacies and hospitals have experienced a lack of supply of these products.

The number of people diagnosed with this virus continues to increase in Denmark and therefore, it is expected that the availability of disinfectant products for hands will continue to be a challenge.

Therefore, a temporary derogation is possible for the making available on the market and use of biocidal products with the WHO formulation 2 (active substance: propan-2-ol). Furthermore, due to limitations in the availability of the active substances propan-2-ol and ethanol from article 95 suppliers, a temporary derogation is given for active substance suppliers, who are currently not listed in article 95 for propan-2-ol and ethanol in PT1.

☐ danger to animal health		
	danger to environment	
Geographical area of use		
	Denmark	

# Absence of any other means to contain the danger

The Danish EPA has been informed that there is a shortage of biocidal products for hand disinfection due to the outbreak of the COVID-19. Furthermore, supply of active substances from article 95 suppliers is insufficient to fulfil the demand at the moment.

In order to contain the spread of the virus and to ensure public health, these products are essential.

#### • Limited and controlled use

Manufacturers of biocidal products with the WHO formulation II has to apply for a temporary authorisation from the Danish EPA.

Manufacturers of biocidal products has to inform the Danish EPA of any alternative source of the active substance used in the biocidal product.