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

Belgium	
Competent Authority granting the temporary	derogation
Organisation	Email address
Federal Public Service Health, Food chain safety and Environment	
n case of repeated action: number of previous	as action(s)
Product name	
APESIN spray F	
Product type	
PT 2	
Active substance(s)	
Propan-1-ol (CAS-nr. 71-23-8)	
Propan-2-ol (CAS-nr. 67-63-0)	
Γarget organism(s)	_
SARS-CoV-2	
User category	
General public	
Professional user	
Starting date of the action based on Art. 55 (1)) of the BPR
08/10/2020	,
End data of the nation, based on Art 55 (1) o	f the DDD
End date of the action based on Art. 55 (1) o	I UIC DEK
06/04/2021	

Description of danger the derogation is intended to address ☑ danger to public health The wide spread of the SARS-CoV-2 Coronavirus has led to a shortage of disinfectants in Belgium. Disinfection products have become virtually unavailable in pharmacies and drugstore. In Belgium, alcohol based products are the most commonly used for disinfection products. However, because of the high demand stocks of alcohol based products have decreased dramatically and a sufficient supply cannot longer be guaranteed over a longer period of time. It should be noted that the number of people in Belgium diagnosed with SARS-CoV-2 infection is rapidly increasing. As a consequence of this development we expect a further grow of the demand for disinfectants for which shortage has been already notified. In order to secure the supply of disinfecting products a temporary exemption for the making available on the market and use of APESIN spray F product for surface disinfection has been granted for which a virucide activity has been demonstrated. \Box danger to animal health (describe briefly the danger, the area affected and the effects of the danger) \Box danger to environment (describe briefly the danger, the area affected and the effects of the danger) Geographical area of use Belgium Absence of any other means to contain the danger Because of the high demand Belgium is facing a shortage of disinfectant product that have been identified as essential to prevent SARS-Cov-2 spread. Limited and controlled use Applications submitted for the product and/or granted authorisations*

^{*} This section will be removed when publishing the notification in CIRCABC