

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

- Notifying Member State¹

Belgium

- Competent Authority granting the temporary derogation

Organisation	Email address
Federal Public Service Health, Food chain safety and Environment	covid19.gestautor@health.fgov.be

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

0

- Product name

Aero-Sense Alcohol Hand Gel 70%

- Product type

PT 1

- Active substance(s)

Propan-2-ol (CAS-nr 67-63-0)

- 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

25/03/2020

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

21/09/2020

- Description of danger the derogation is intended to address
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- 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 Aero-Sense Alcohol Hand Gel 70% product for hand-disinfection has been granted.

- 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

Belgium

- Absence of any other means to contain the danger

Because of the high demand most of the products for hand disinfectants have been sold out. 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