

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

- Notifying Member State¹

Germany

- Competent Authority granting the temporary derogation

Organisation	Email address
Federal Institute for Occupational Safety and Health	chemg@baua.bund.de

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

- Product name

Products for hygienic hand disinfection

- Product type

PT 1

- Active substance(s)

Propan-2-ol; Propan-1-ol; Ethanol

- Target organism(s)

SARS-CoV-2

- User category

Professional user

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

13/03/2020

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

09/09/2020

- Description of danger the derogation is intended to address

¹ In this form "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

danger to public health

The spread of the SARS-CoV-2 virus strongly increases demand for disinfectants for hygienic hand disinfection in Germany.

Suppliers of disinfectant products that can be made available on the market and used in accordance with a granted authorisation cannot meet the current demand.

The use of disinfectants is essential to prevent the spread of novel coronavirus and the number of people in Germany who have been diagnosed with such an infection is increasing. Therefore, in order to secure the supply of disinfection products a temporary exemption according to Article 55(1) of Regulation No 528/2012 for the making available on the market and use of products for hygienic hand-disinfection have been granted in Germany.

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

Germany

• Absence of any other means to contain the danger

As a result of the spread of the SARS-CoV-2 virus, disinfectants for hygienic hand disinfection are increasingly in demand in Germany.

The shortage of disinfectant products will remain or further increase in the near future because of the difficulties of formulators to source biocidal active substances and the continuously increasing demand due to the spread of the SARS-CoV-2 coronavirus.

It is therefore necessary to use the derogation possibility provided in Article 55(1) of Regulation No 528/2012 to increase the supply of hygienic hand disinfectants to contain the spread of the disease.

• Limited and controlled use

The formulations in question may only be manufactured and placed on the market by pharmacies, the pharmaceutical and chemical industry and legal entities under public law and may only be distributed to professional users.