

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

WHO Formulation 2; 70% (v/v)
Propan-2-ol in aqueous solution

- Product type

PT 1

- Active substance(s)

Propan-2-ol

- Target organism(s)

SARS-CoV-2

- User category

Non-professional user
Professional user

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

04/03/2020

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

31/08/2020

¹ 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

As a result of the spread of the SARS-CoV-2 coronavirus, disinfectants for hygienic hand disinfection are increasingly in demand in Germany. Appropriate preparations are practically no longer available in pharmacies and drugstores.

Since the novel coronavirus SARS-CoV-2 is transmitted in a similar way to the flu virus, namely as a droplet infection, the recommendation to disinfect the hands can also be transferred to contact with people who are infected with SARS-Cov-2. The number of people in Germany who have been diagnosed with such an infection is currently still very small, but a shortage of disinfectants has already occurred. With the expected increase in households in which sick people are located, the objective need for hand disinfection will also increase.

There is also a need for preventive use in households with defensively weakened people with an increased risk of infection or people in need of care to protect them. In addition to the products with the active ingredient ethanol, the supply of products with the active ingredient isopropanol must also be ensured.

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 coronavirus, disinfectants for hygienic hand disinfection are increasingly in demand in Germany. Appropriate, authorized preparations (or preparations for which the evaluation as biocidal products is ongoing) are practically no longer available in pharmacies and drugstores. The pharmacopeia grade ingredients used for authorized preparations will soon no longer be available in the required quantities either.

- Limited and controlled use

The two preparations in question are only to be manufactured and placed on the market by pharmacies and the pharmaceutical industry