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

Germany	
ompetent Authority granting the tempo	orary derogation
Organisation	Email address
Federal Institute for Occupational Safety and Health	chemg@baua.bund.de
case of repeated action: number of pro	evious action(s)
roduct name	٦
Formulations A-G	
roduct type	
PT 1	
ctive substance(s)	
Propan-2-ol; Ethanol	
arget organism(s)	
SARS-CoV-2	
ser category	_
Non-professional user]
Professional user	
tarting date of the action based on Art.	55 (1) of the BPR
07/10/2020	
nd date of the action based on Art. 55	(1) of the BPR
	٦

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

Due to rapid and comprehensive infection prevention measures and the involvement of the population, the number of new cases of COVID-19 in Germany has initially fallen. At present, however, the number of new cases is increasing again and – depending on numerous factors that are still uncertain – must be expected that the number of cases may continue to rise. In addition, public companies and public institutions are increasingly resuming their business activities and the use of public transport is increasing. In addition, following a decision by the Conference of Education Ministers, schools have returned to regular school operations after the summer holidays. Although hand hygiene through thorough hand washing is sufficient for the general population in everyday life to prevent the transmission of infections with the coronavirus SARS-CoV-2 via the hands, hygiene concepts of institutions and businesses often provide for the supply and use of disinfectants for personal hand hygiene. Under these conditions, it must be expected that – based on the current already increased level of demand – the demand for disinfectants for the prevention of COVID-19 infections may increase again in the coming months.

Manufacturers of disinfectants that have been proven to meet the requirements for use in the medical sector have considerably expanded their production capacities in recent months. These disinfectants, which have a spectrum of activity appropriate to the needs of medical institutions and which meet the requirements of the recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO), are available for the supply of the health care system in sufficient quantities. However, in order to meet the additional needs of public institutions and businesses as well as private consumers, supporting production capacities for the manufacture of disinfectants for the prevention of infections with the coronavirus SARS-CoV-2 need to be activated once again after the biocidal derogation granted for the first wave of COVID-19 expires on 6 October 2020.

☐ 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 in high demand in Germany. Appropriate, authorized preparations (or preparations for which the evaluation as biocidal products is ongoing) are not expected to be sufficiently available.

• Limited and controlled use

The preparations in question are only to be manufactured and placed on the market by pharmacies, the chemical and pharmaceutical industry and corporate bodies under public law in Germany. Amounts manufactured or imported have to be reported on a monthly basis.