

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

- Notifying Member State¹

Bulgaria

- Competent Authority granting the temporary derogation

Organisation	Email address
Ministry of Health	biocides@mh.government.bg

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

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- Product name

Primasept / Примасепт

(WHO-recommended formulations
for hygienic hand disinfection
(formulation Ethanol)

- Product type

PT 1

- Active substance(s)

Formulation 1:
Ethanol
Glycerol
Hydrogen peroxide

- Target organism(s)

Bacteria, yeasts and enveloped
viruses

- User category

- General public
- Professional users

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

06/04/2020

- End date of the action based on Art. 55 (1) of the BPR
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03/10/2020

- Description of danger the derogation is intended to address

danger to public health

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

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

The use of disinfectants is essential to prevent the spread of novel coronavirus and the number of people in Bulgaria 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 the Primasept / Примасепт for hand disinfection have been granted in Bulgaria.

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

Bulgaria

- 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 Bulgaria.

It is therefore necessary to use the derogation possibility provided in Article 55(1) of Regulation No 528/2012 to ensure a stable, and if possible, increase the supply of hand rub disinfectants to contain the spread of the disease.

- Limited and controlled use

In accordance with Regulation (EU) No 528/2012, the authorizations are granted for a limited and controlled use, under the supervision of the competent authority. **Hence, the authorized biocidal products pursuant to Art. 55, para. 1 will only be available on the market in pharmacies, drugstores and medical establishments.**