



MINISTRY OF HEALTH  
OF THE CZECH REPUBLIC

Prague, 10 March 2020  
Ref. No. MZDR 10904/2020-1/OBP



MZDRX019E1UH

## DECISION

The Ministry of Health (hereinafter the “Ministry”), as the central administrative authority on marketing biocidal products and active substances and their use pursuant to Section 5(1)(i) of Act No. 324/2016 Coll., on biocidal products and active substances and amending certain related acts (Act on Biocides), **has decided** *ex offa* pursuant to Art. 55 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (hereinafter “Regulation No. 528/2012”), to permit the biocidal product **Alcohol-based pharmaceutical disinfectant** on the market, **as follows:**

- I. **The biocidal product *Alcohol-based pharmaceutical disinfectant* (hereinafter the “product”) is permitted for supply to the market in the Czech Republic under permit No. CZ-2020-55-02 and under the conditions specified in this decision and the conditions stipulated in the summarised properties of the biocidal product, which are attached to this decision, for a period of 180 days from the publication of this decision on the Ministry’s official bulletin.**
- II. **The product may be sold only to natural persons in the workplace of the pharmaceutical care provider which manufactured it.**

### Rationale:

This permit is been issued in connection with the adverse development of the epidemiological situation due to the COVID-19 disease caused by the new coronavirus designated SARS-CoV-2 in Europe. The aim of the measure is to ensure the availability of personal hygienic products for the public within the Czech Republic to prevent the spread of this disease.

Given the occurrence of cases of this disease in the Czech Republic, and given the gradual spread of the disease in neighbouring or nearby countries such as Italy, France, Germany, Austria, Switzerland, Poland and Croatia, and given the ongoing flu epidemic and generally mild course of the disease, including the initial asymptomatic period, this disease may be expected to continue spreading significantly within the Czech Republic.

Since it is not easy to identify a patient infected with the COVID-19 disease, it is crucial that sufficient personal hygienic products be available to help prevent the contagion of this disease to healthy individuals.

The Ministry has also taken into account the current lack of disinfectant hand products on the market in the Czech Republic due to their increased need and has therefore proceeded to permit the biocidal product **Alcohol-based pharmaceutical disinfectant** in accordance with the procedure under Art. 55 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, as amended, and thereby expedite the availability of disinfectant hand products from pharmaceutical care providers.

The composition of the product **Alcohol-based pharmaceutical disinfectant** corresponds to the recommendations of the World Health Organization.

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**Mgr. et Mgr. Adam Vojtěch, MHA**

Minister for Health

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