



MINISTRY OF HEALTH
of the Czech Republic

Prague, March 24, 2020
Reference No: MZDR 11853/2020-12/OBP

MZDRX019MNFE

DECISION

The Ministry of Health (hereinafter as the “Ministry”) as a central administrative authority for use and supply of biocidal products and active substances on the market pursuant to Section 5 (1) letter (i) of the Act No. 324/2016 Coll., on biocidal products and active substances and on amendments to certain related acts (“Biocides Act”), **decides** ex officio pursuant to Art. 55 (1) of the Regulation (EU) No. 528/2012 of the European Parliament and the Council, on use of and supply of biocidal products on market (hereinafter as the “Regulation”), on authorizations to supply biocidal products on the market as follows:

- I. For extraordinary reasons given by the adverse development of the epidemiologic situation with COVID-19 disease caused by new coronavirus SARS-CoV-2 in Europe, the biocidal product Anti-COVID designated for personal hygiene for hand disinfection containing the active substance ethanol in structure according to the specification of the World Health Organisation, as set out in the Annex to this Decision – summary of biocidal product, is approved to be delivered on the market for the duration of the state of emergency under Governmental Resolution No. 194 dated March 12, 2020.**
- II. Any and all affected entities are, within the period of 7 days, obliged to submit to the Ministry of Industry and Trade the information on the level of production, structure and level of supply of personal hygiene products designated for the disinfection of hands placed on the market on the basis of this Decision.**
- III. This Decision is issued due to the extension of the list of licence holders authorised to supply the authorised anti-COVID product on the market in the territory of the Czech Republic.**
- IV. This Decision repeals and replace the decision of the Ministry of Health dated March 17, 2020, ref. no.: MZDR 11853/2020-5/OBP, PID: MZDRX019I3TS.**

Rationale:

The authorization is issued in the context of adverse development of the epidemiological situation in the incidence of COVID-19 disease caused by the new coronavirus SARS-CoV-2 in Europe. The aim of the measure is to ensure the availability of key personal hygiene products in the territory of the Czech Republic to prevent the spread of this disease and, based on the initiative of the Ministry of Industry and Trade, which was instructed to ensure the disinfectants under Governmental Resolution No. 196 dated March 12, 2020.

Due to the fact that the ongoing flu epidemic and not serious course of the disease in general, including an initial symptom-free period, it may be expected that this disease will continue to spread significantly within the territory of the Czech Republic.

The Ministry further considered the request made by the Ministry of Industry and Trade dated March 24, 2020 to extend the list of license holders. The request of the Ministry of Industry and Trade reflects the continuing shortage of hands disinfectants on the market in the Czech Republic due to their increased need and therefore the Ministry has approached to the authorization of biocidal products as referred to in point I. of this Decision pursuant to the Art. 55 of the Regulation (EU) No. 528/2012 of the European Parliament and the Council, on the Conditions for Supply on the Market and Use of Biocidal Products, as amended, and to the extension of the list of licensed holders authorized to supply such product on the market in the territory of the Czech Republic, as set in point III. of this Decision.

Mgr. et Mgr. Adam Vojtěch, MHA
Minister of Health

Signed electronically