



**THE MINISTRY OF HEALTH
OF THE CZECH REPUBLIC**

Prague, 17 March 2020

Ref. No.: 11853/2020-5/OBP

MZDRX019I3TS

DECISION

The Ministry of Health (hereinafter referred to as the “Ministry”) as the central administrative authority for the placement of biocidal products and active ingredients on the market and their use pursuant to Section 5(1)(i) of Act No. 324/2016 Coll., on biocidal products and active ingredients and on amending certain related acts (Act on Biocides), **has decided**, by virtue of its official capacity, pursuant to Article 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 referred to as “Regulation No 528/2012”), to permit the placement of biocidal products on the market, **as follows** :

- I. For extraordinary reasons arising from the adverse development of the epidemiological situation due to the occurrence of the COVID-19 disease caused by the novel coronavirus designated as SARS-CoV-2 in Europe, it is hereby permitted to make available on the market the biocidal product Anti-COVID intended for personal hygiene for hand sanitation, containing the active ingredient ethanol, with the composition as specified by the World Health Organisation, enclosed with this Decision – summary of the properties of the biocidal product, for the duration of the state of emergency declared by Government Resolution No. 194 of 12 March 2020.**
- II. All entities concerned are hereby ordered to present to the Ministry of Industry and Trade, at seven-day intervals, information about the volume of production, structure, and volume of supplies to the market, of personal hygiene products for hand sanitation made available to the market pursuant to this Decision.**
- III. This Decision is being issued in order to expand the number of permit holders authorised to supply the permitted Anti-COVID product to the market in the Czech Republic.**
- IV. This Decision rescinds and supersedes Decision of the Ministry of Health of 15 March 2020, ref. no. MZDR 11853/2020-1/OBP, PID: MZDRX019GU5L.**

Rationale:

The permission is being issued in connection with the adverse development of the epidemiological situation in terms of the occurrence of the COVID-19 disease, caused by the novel coronavirus designated as SARS-CoV-2 in Europe. The objective of the measure is to ensure a sufficient volume of key personal hygiene products in the Czech Republic for preventing the spread of the

disease, and on the basis of an initiative of the Ministry of Industry and Trade which was authorised to secure disinfectant products pursuant to Government Resolution No. 196 of 12 March 2020.

Given the ongoing epidemic of influenza, the usual course of which is not especially serious, including an initial symptom-free period, it can be expected that the disease will continue to spread significantly throughout the Czech Republic.

Furthermore, the Ministry has taken into account the persisting shortage of hand disinfectant on the market in the Czech Republic due to their increased use, and hence has permitted biocidal products as stated in operative part I. of this Decision, pursuant to Article 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 to expand the list of holders of a permission to supply the said product to the market in the Czech Republic as stated in operative part III. of this Decision.

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