



**MINISTRY OF HEALTH
OF THE CZECH REPUBLIC**

Praha, March 17, 2020
Reference No: MZDR 11853/2020-5/OBP
MZDRX019I3TS

DECISION

The Ministry of Health (the “Ministry”) as a central administrative authority in the field of introduction of biocidal products and active substances onto the market and their use pursuant to Section 5 par. 1 letter i) of the Act No. 324/2016 Coll., on Biocidal Products and Active Substances, amending certain related acts (the “Act on Biocides”), **decided** *e x o f f i c i o* pursuant to Article 55 of the Regulation of the European Parliament and of the Council (EU) No. 528/2012, concerning the making available on the market and use of biocidal products (the “Regulation No. 528/2012”), on permission to introduce biocidal products onto the market **as follows**:

- I. **Due to extraordinary reasons caused by the adverse development of the epidemiologic situation concerning the spread of the COVID-19 disease caused by the new coronavirus SARS-CoV-2 in Europe, it is allowed to introduce onto the market the biocidal product Anti-COVID intended for personal hygiene for hand disinfection, containing the active substance ethanol in composition according to the specification of World Health Organization, according to the annex to this decision – the summary of the composition of biocidal product, for the period of duration of the state of emergency pursuant to Governmental Resolution No. 194 from March 12, 2020.**
- II. **All affected subjects are instructed to provide the Ministry of Industry and Trade with information regarding the amount of production, structure and supply to the market of the products for personal hygiene intended for hand disinfection introduced onto the market on the grounds of this decision, in the frequency of each 7 days.**
- III. **This decision is issued in order to increase the amount of authorisation holders who are authorised to import the product Anti-COVID to the market in the territory of the Czech Republic.**
- IV. **This decision repeals and replaces the decision of the Ministry of Health from March 15, 2020, Ref. No. MZDR 11853/2020-1/OBP, PID: MZDRX019GU5L.**

Rationale:

The authorization is issued in relation to the adverse development of the epidemiologic situation concerning the spread of the COVID-19 disease caused by the new coronavirus SARS-CoV-2 in Europe. The aim of the measure is to ensure sufficient amount of crucial personal hygiene products in the territory of the Czech Republic in order to prevent this disease from spreading, and is issued on the basis of an initiative of the Ministry of Industry and Trade which was entrusted with securing disinfectant products pursuant to Governmental Resolution No. 196 from March 12, 2020.

Regarding the ongoing flu epidemic and, generally, the non-serious course of the disease, including the initial asymptomatic period, it is expected that this disease is going to spread in the territory of the Czech Republic in a significant manner.

The Ministry further took into account the ongoing lack of hand disinfection products for their increased demand on the market in the territory of the Czech Republic and thus decided for allowing biocidal products pursuant to paragraph I. of this decision pursuant to Article 55 of the Regulation of the European Parliament and of the Council (EU) No. 528/2012, concerning the introduction of biocidal products on the market and their use, and for increasing the amount of authorization holders who are authorized to import the product Anti-COVID to the market in the territory of the Czech Republic pursuant to paragraph III. of this decision.