



MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

Prague, 24 March 2020
Ref. No. MZDR 11853/2020-12/OBP



MZDRX019MNFE

DECISION

The Ministry of Health (hereinafter the “Ministry”), as the central administrative authority for the marketing of 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 on amendments to certain related acts (the Act on Biocides), **has decided** *ex officio* pursuant to Art. 55(1) 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 marketing of biocidal products **as follows**:

- I. **Due to the extraordinary reasons resulting from the unfavourable development of the epidemiological situation around the incidence of the COVID-19 disease, caused by the novel coronavirus identified as SARS-CoV-2, in Europe, it is permitted to market the biocidal product Anti-COVID designated for personal hygiene to disinfect the hands, containing the active substance ethanol, in the composition specified by the World Health Organisation as per the annex to this decision (a summary of properties of the biocidal product), for the duration of the state of emergency pursuant to Government Resolution No. 194 of 12 March 2020.**
- II. **All the affected entities are ordered to provide information to the Ministry of Industry and Trade, at seven-day intervals, about the volume of production, structure and volume of market supplies of personal hygiene products for hand disinfection, supplied to the market based on this decision.**
- III. **This decision is issued in order to expand the list of permit holders who are authorised to supply the Anti-COVID product to the market in the Czech Republic.**
- IV. **This decision cancels and replaces the decision of the Ministry of Health of 17 March 2020, ref. No. MZDR 11853/2020-5/OBP, PID: MZDRX019I3TS.**

Rationale:

This permit is being issued in connection with the adverse development of the epidemiological situation with regard to the occurrence of the COVID-19 disease caused by the new coronavirus designated as SARS-CoV-2 in Europe. The aim of the measure is to ensure enough crucial personal hygiene products in the Czech Republic so as to limit the spread of this disease, based on the initiative of the Ministry of Industry and Trade, which was authorised to procure disinfectant products pursuant to Government Regulation No. 196 of 12 March 2020.

Given the ongoing flu epidemic and the generally non-severe course of the illness, including the preliminary asymptomatic period, the disease may be expected to continue spreading significantly across the Czech Republic.

The Ministry has also taken into account the request from the Ministry of Industry and Trade of 24 March 2020 regarding the expansion of the number of permit holders. The request of the Ministry of Industry and Trade reflects the lasting shortage of hand disinfectant products on the market in the Czech Republic due to their increased consumption, for which reason the Ministry proceeded to permit biocidal products pursuant to ruling I of this decision 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, as amended, and to expand the list of permit holders authorised to supply this product to the market in the Czech Republic pursuant to ruling III of this decision.

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

Signed electronically

March 2020

Signature
author's
certificate:

Name: Mgr. et Mgr.
Adam Vojtěch,
MHA Issued by:
PostSignum
Qualified C...
Valid through: 25
December 2020
14:14:59+000 +01:0