



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

Prague, 27 March 2020
Ref. No. MZDR 11853/2020-
18/OBP

MZDRX01A28JI

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) and (f) of Act No. 324/2016 Coll., on Biocidal Products and Active Substances and amendments to certain related acts (the Act on Biocides) **has decided** *ex offio* pursuant to Art. 55 and 52 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. **This decision amends the validity period of license No. CZ-2020-55-04 until 30 April 2020.**
- II. **A deferral period is provided in accordance with Art. 52 of the Regulation on Biocidal Products until 15 May 2020. The use of existing supplies of biocidal products is possible until the end of the storage period indicated on the product label or packaging.**

Rationale:

The product Anti-COVID was granted a license by the Ministry of Health, No. CZ-2020-55-04, based on a suggestion from the Ministry of Industry and Trade. Based on Government Resolution No. 196 of 12 March 2020, the Ministry of Industry and Trade was commissioned to ensure disinfectant products in relation to the adverse development of the epidemiological situation regarding the incidence of COVID-19 disease, caused by the novel coronavirus called SARS-CoV-2 across Europe. The aim of the adopted measure was to ensure a sufficiency of key personal hygienic products within the Czech Republic to prevent the spreading of this disease.

The Ministry acknowledged the compiled survey of the market of personal hygienic disinfectant products in the Czech Republic and their shortage on the market in the Czech Republic due to increased demand, and therefore proceeded to permit the Anti-COVID biocidal product, proceeding in accordance with Art. 55 of Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products (hereinafter “Regulation (EU) No. 528/2012”).

In order to fulfil the conditions stipulated in Art. 55 of Regulation (EU) No. 528/2012, namely the permitting of a product for limited and controlled use under the supervision of the respective authority, the Government of the Czech Republic adopted Resolution No. 301 of 26 March 2020, which ordered the Ministry of Industry and Trade to collect and evaluate information about the extent of production, structure and volume of the delivery of personal hygiene products for hand disinfection to the market, supplied to the market based on decisions issued by the Ministry of Health during the state of emergency in accordance with 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, as amended, in order to assess the lasting need for the decisions issued pursuant to Art. 55(1) of Regulation (EU) No. 528/2012 of the European Parliament and of the Council, based on information provided by the license holders pursuant to ruling No. II of license No. CZ-2020-55-04, and to subsequently inform the Minister of Health immediately about the fact that the sufficient availability of personal hygiene products for hand disinfection has been ensured.

Based on the suggestion of the Ministry of Industry and Trade and given the capacity requirements for the production of the Anti-COVID product, the range of license holders authorised to manufacture the biocidal product was expanded under Decision Ref. No. MZDR 11853/2020- 5/OBP.

In a letter from the Ministry of Industry and Trade dated 20 April 2020, it was recommended to the Ministry of Health, in accordance with Government Resolution No. 301 of 26 March 2020, to cancel license No. CZ- 2020-55-04 as at 30 April 2020 and to stipulate a deferral period to sell of the remaining supplies of the biocidal product within fourteen days.

For the aforementioned reasons, the Ministry of Health has amended the validity period of license No. CZ-2020-55-04 as at 30 April 2020, and stipulated a deferral period for delivery to the market until 15 May 2020 via the procedure pursuant to Art. 52 of Regulation (EU) No. 528/2012, and also stipulated a deadline for the use of existing supplies of biocidal products, which is possible until the end of the storage period indicated on the product label or packaging.

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

Signed electronically

Electronic signature - 27 April
2020 Signature author's
certificate:

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