



MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

Prague, 12 May 2020
Ref. No. MZDR 11853/2020-25/OBP

MZDRX01A8TJ9

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 amending 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**:

The deferral deadline for the delivery of the Anti-COVID product to the market, stipulated by decision Ref. No. MZDR 11853/2020-18/OBP, is extended until 15 August 2020.

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 hygiene products within the Czech Republic to prevent the spread of this disease.

The Ministry acknowledged the compiled survey of the market of personal hygiene disinfectants 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 via the procedure pursuant to Art. 55 of Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (hereinafter “Regulation (EU) 528/2012”).

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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 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 the remaining supplies of the biocidal product within fourteen days.

On 27 April 2020, the Ministry of Health decided to terminate 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 the biocidal product, which is possible until the end of the storage period indicated on the product label or packaging.

On 11 May 2020, the Ministry of Health received a request from the Ministry of Industry and Trade to extend the deferral period for supplying the Anti-COVID product to the market until 30 October 2020, with the justification that a substantial part of the existing inventory of the Anti-COVID product consists of inventory in the retail network and another part is still held in the inventory of the product manufacturers, whereas the selling off of this product cannot be realised by the originally expected deadline of 15 May 2020. The Ministry of Industry and Trade also argued with the assumption that consumption of the disinfectant products would remain high with the gradual easing of restrictive measures and the liquidation of existing inventories of the Anti-COVID product may thus have a negative impact on the availability of hand disinfectant products on the market in the Czech Republic.

The Ministry of Health is of the opinion that extending the deferral deadline until 30 October 2020 would exceed the 180-day deadline for supply to the market stipulated in Art. 55(1) of Regulation (EU) 528/2012 of the European Parliament and of the Council. The Ministry of Health also believes that the existing inventories of the Anti-COVID product, which were

permitted based on an exemption, should be sold off and consumed within the shortest possible period of time, so that the further consumption of biocidal products is based on products which meet the standard conditions stipulated by Regulation (EU) 528/2012 of the European Parliament and of the Council or by Act No. 324/2016 Coll.

The Ministry of Health, being aware of the conditions stipulated in Art. 55(1) of Regulation (EU) 528/2012 of the European Parliament and of the Council. and the reasons which led the Ministry of Industry and Trade to submit a request to extend the deferral deadline, partially accommodated the request and decided to extend the deferral deadline by a reasonable period, namely until 15 August 2020.

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

Signed electronically

Electronic
signature - 12
May 2020
Certificate of
signature author:
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Adam Vojtěch, MHA
Issued by:
PostSignum
Qualified C..
Valid through: 25
December 2020
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+01:00.