THE PRESIDENT
of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Warsaw, 22/04/2020

No PB/0841/TP/2020

PHD Premium sp. z o.o. sp. k.
ul. Rakowicka 6/3
31-511 Kraków

DECISION

Based on Article 55 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.06.2012, p.1, as amended.)

authorisation No. 0841/TP/2020 is Issued for making available on the market and use of the biocidal product MEDI CLEANER

1. **Trade name of the biocidal product:**
   MEDI CLEANER
2. **Biocidal product`s main group, type of formulation and its uses:**
   Cat. 1, gr. 1 according to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.06.2012, p.1, as amended.)
   Liquid, preparation intended for hand disinfection, it has bactericidal, fungicidal and viricidal effects
3. **The name and address of the authorisation holder:**
   PHD Premium sp. z o.o. sp. k, ul. Rakowicka 6/3, 31-511 Kraków
4. **The identity of active substance or active substances (or another that allows the identification of the active substance) and its concentration in biocidal product in metric units, its EC number and CAS number:**
   ethanol, EC: 200-578-6, CAS: 64-17-5, concentration: 750 g/kg
5. **Information on categories of users:**
   The product is intended for general use
6. **Other provisions of the decision:**
   The authorisation is valid for up to 180 days from the date of authorisation issuing

SUBSTANTIATION

On 10.04.2020, the application No DRB-RBE.4230.1204.2020.UC for registration of MEDI CLEANER the biocidal product was received by the authority.
According to Article 55 (1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.06.2012, p.1, as amended.) *"By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means."*
The above provision states that it is possible for the President of the Office to use the measure provided in Article 55 (1) of this Regulation, in relation to biocidal products non-compliant with requirements of Regulation No. 528/2012.

According to the indicated provision, by way of derogation from Article 17 and 19 of this Regulation, the competent authority may issue - for a period not exceeding 180 days – an authorization for making available on the market or use of a biocidal product not complying with the requirements of this Regulation regarding the issuing of an authorization, for the purposes of its limited and controlled use, under the supervision of the competent authority, if this type of measure is necessary due to the occurrence of public health threats. In addition, there must be a premise that this threat cannot be contained by other means. In the present case, the disposition of the above provision is met. Due to the spread of SARS-CoV-2 coronavirus causing COVID-19 disease and the related growing demand for disinfectants and their deficiencies, there is justified need to issue a permit for making available on the market or use of a biocidal product for disinfection purposes, based on Article 55(1) of Regulation No. 528/2012.

In addition, according to Article 69(2) of Regulation No. 528/2012, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show information referred to in Article 69(2), first subparagraph, points a-o of the Regulation No. 528/2012. By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (e), (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging, as referred to in Article 69(2), second subparagraph. In addition, authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the Regulation No. 528/2012 requirements, and also according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2) of Regulation No. 528/2012.

Bearing this in mind, decreed as in the beginning.

Advice:
Against this decision, pursuant to Article 127 § 3 and Article 129 § 2 of the Act of 14 June 1960, Code of Administrative Procedure (Journal of Laws of 2020, item 256), the party has the right to submit a request for re-examination of the case to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, within 14 days from the date of delivery of the decision.

If the party does not want to exercise their right to make a request to reconsider the case may, basing on Article 52 §3, in connection with Article 53 §1 of the Act of 30 August 2002, Law on proceedings before administrative courts (Journal of Laws of 2018, item 1302, as amended, hereinafter: l.p.a.c), lodge a complaint against the decision with the Voivodship Administrative Court in Warsaw within 30 days of the date of delivery of the decision. The complaint, pursuant to Article 54 §1 of the l.p.a.c is lodged through The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. A fee for the complaint is PLN 200. Based on Article 243 §1, in connection with Article 244 §1 of the l.p.a.c, a party may submit a request to the Voivodship Administrative Court for granting the fight for assistance in the area of exemption from court fees and the attribution of the lawyer.

Based on Article 127a §1 and 2, in connection with Article 127 §3 of the Code of Administrative Procedure during the time limit for lodging a request for reconsideration of the case a party may waive the right to lodge a request for re-examination of the case. On the day of delivery to a public administration body waiver statements to lodge a request for reconsideration of the case, the decision becomes final and unappealable.

Grzegorz Cessak

The President

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CC:
1: The party
2: file