PREZES

Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

Warsaw, 26-11-2020 r.

Nr PB/3131/TP/2020

Hendi Polska Sp. z o.
o. ul. Magazynowa 5
62-023 Gÿdki

DECISION

Based on Article. 55 sec. 1 of the Regulation of the European Parliament and of the Council (EU) No 528/2012 of May 22, 2012 concerning the making available on the market and use of biocidal products (Journal of Laws UE L 167 of June 27, 2012, p. 1, as amended) .d.) it seems

permit No. 3131 / TP / 2020 for making available on the market and using a biocidal product Antiviral liquid for disinfecting the skin of the hands of Hendi

1. Name of the biocidal product:

Hendi antiviral liquid for disinfecting the skin of the

hands **2. Product group, application form of the biocidal product and its intended use:** cat.

1 gr. 1, cat. 1 group 2, cat. 1 group 4 according to Annex V to the Regulation of the European Parliament and of the Council (EU) No. 528/2012 of May 22, 2012 on the making available on the market and use of biocidal products, (Journal of Laws UE L 167 of June 27, 2012, p. 1, as amended); A liquid for

hygienic hand disinfection and disinfection of surfaces (also in contact with food), with bactericidal, virucidal and fungicidal properties.

3. Name and surname and address or name (company) and address of the registered office of the responsible entity: Hendi Polska Sp. z o. o., ul. Magazynowa 5, 62-023 Gÿdki

4. Chemical name of the active substance or substances (or any other identifiable active substance) and its content in metric units in the biocidal product, its EC number and CAS number:

Ethanol, EC: 200-578-6, CAS: 64-17-5, content: 70g / 100g

5. Information about the type of user:

The product is intended for general and professional use

6. Other provisions of the decision:

The permit is valid for 180 days from 10/12/2020, i.e. from the day following the expiry of the license No. 1704 / TP / 2020 of 12/06/2020 to make the biocidal product available on the market and use Hendi antiviral liquid for disinfecting the skin of the hands

JUSTIFICATION

On November 18, 2020, the authority received an application no. DRB-RBE.4230.3865.2020.AR for the registration of a biocidal product Hendi antiviral liquid for disinfecting the skin of the hands.

Pursuant to Art. 55 sec. 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 (hereinafter: Regulation No. 528/2012) *"By way of derogation from Art. 17 and 19, the competent authority may issue - for a period not exceeding 180 days - an authorization to make available on the market or use a biocidal product that does not comply with the requirements of this Regulation relating to the issuing of an authorization for the purposes of its limited and controlled use under the supervision of the competent authority, if such use measure is necessary because there is a risk to public health, animal health or the environment which cannot be stopped by other means. "*

The above provision states that in relation to biocidal products that do not meet the requirements of Regulation No. 528/2012, it is possible for the President of the Office to use the measure provided for in Art. 55 sec. 1 of this regulation. Pursuant to the said provision, by way of derogation from Art. 17 and 19 of this Regulation, the competent authority may issue - for a period not exceeding 180 days - an authorization to make available on the market or use a biocidal product that does not comply with the requirements of this Regulation relating to 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, inter alia, threats to public health. Additionally, there must be an indication that the threat cannot be stopped by other means.

In the case in question, the instruction of the above-mentioned the recipe is met. Due to the spread of the SARS-CoV-2 coronavirus causing the COVID-19 disease and the related growing demand for disinfectants and their shortages, there is a justified need to issue a permit for making available on the market or using a biocidal product for disinfection purposes, pursuant to Art. . 55 sec. 1 of Regulation No 528/2012.

At the same time, pursuant to Art. 69 sec. 2 of Regulation No 528/2012, authorization holders shall ensure that the labels are not misleading as regards the risk to human health, animal health or the environment of a given product or its effectiveness, and in no case contain the phrases "low biocidal product risks', 'non-toxic', 'harmless',' natural ',' environmentally friendly ',' animal friendly 'or similar phrases. In addition, the information referred to in Art. 69 sec. 2, first paragraph, point a about Regulation No 528/2012. By way of derogation from the first subparagraph, where necessary due to the size or activity of the biocidal product, the information referred to in Article 69 sec. 2, first paragraph, point e), g), h), j), k), l) and n) may be placed on the packaging or in a leaflet constituting an integral part of the packaging, as provided for in Art. 69 sec. 2, second paragraph. In addition, authorization holders ensure that biocidal products are classified, packaged and labeled in accordance with the requirements of Regulation No. 528/2012, as well as with Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling 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 for the hazard and precautionary statements referred to in Art. 22 sec. 2 lit. i) Regulation No 528/2012.

Given the above, it decides as at the outset.

Information:

From this decision, pursuant to Art. 127 § 3 and art. 129 § 2 of the Act of June 14, 1960. Administrative Procedure Code (Journal of Laws of 2020, item 256, as amended), the party has the right to submit an application for reconsideration 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 a party does not want to exercise the right to request reconsideration of the case, it may, pursuant to Art. 52 § 3 in connection with art. 53 § 1 of the Act of August 30, 2002, Law on proceedings before administrative courts (Journal of Laws of 2019, item 2325, as amended, hereinafter: ppsa), submit a complaint to the Provincial Administrative Court in Warsaw against the decision in 30 days from the date of delivery of the decision. The complaint, pursuant to Art. 54 § 1 of the PPSA shall be submitted through the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The entry fee for the complaint is PLN 200. Based on Article. 243 § 1 in connection with joke. 244 § 1 of the PPSA, a party may submit an application to the Provincial Administrative Court for granting the right of assistance in the scope of exemption from court costs and the appointment of an attorney or legal advisor.

Based on Article. 127a § 1 and 2 in connection with joke. 127 § 3 of the Code of Administrative Procedure, during the period for submitting an application for reconsideration of the case, a party may waive the right to submit an application for reconsideration of the case. The decision becomes final and binding on the day the public administration authority is served with the declaration of waiver of the right to file an application for reconsideration of the case.

Grzegorz Cessak

President

/ document signed electronically /

They receive:

1. Party represented by attorneys: Agata Gaca, Wojciech Obrzut 2. a / a