



Translation from Hungarian

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NATIONAL PUBLIC HEALTH CENTRE

File number: 24812-3/2020/JIF
Official: Erika PARONAI-TREPÁK
Phone: +36 1 476-1351

Re: Revision of the trade permit for the disinfectant Immunetec antimicrobial hand and skin cream

Please state the foregoing number in your response.

Annexes: Licence Form (3 pages)

DECISION

The operative part of the trade permit for the disinfectant **Immunetec antimicrobial hand and skin cream** issued by Decision No. 54828-3/2019/JIF of the National Public Health Centre is hereby

revised

in the following terms. **Immunetec Proof Kft.** (5008 Szolnok, Krúdy Gyula u. 112.) as distributor is hereby authorised to trade in **Product Type 1** of the disinfectant **Immunetec antimicrobial hand and skin cream**

as follows:

- 1/ Trade in the product is subject to continuous compliance with the conditions prescribed in the "Licence Form" based on Expert Opinion No. **24812-2/2020/JIF** of the National Public Health Centre (hereinafter: NPHC).
- 2/ The trader must include the user's manual in each packaging unit as required by NPHC Expert Opinion No. **24812-2/2020/JIF** and attached to its application. Furthermore, the product's label and inscription must comply with the requirements of **Act XXV of 2000 on chemical security** and **Joint Decree 38/2003 (7 July) of the Minister of Health, Social and Family Affairs, the Minister of Agriculture and Rural Development, and the Minister of Environmental Protection and Water Management on the conditions of the manufacturing of and trade in biocidal products.**
- 3/ The trader shall apply for a permit to change the name, packaging, composition, effect spectrum, labelling and instruction for use of the disinfectant **Immunetec antimicrobial hand and skin cream.**
- 4/ The trader shall notify the National Chief Medical Officer in writing of the termination of trade.
- 5/ This permit shall not replace the licence of any other authority or the obligatory report of any hazardous material or hazardous mixture laid down in **Act XXV of 2000 on chemical security.**

Pursuant to Article 52 of **Regulation 528/2012/EU** of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (hereinafter: **Regulation**), the NPHC shall grant a **180 day period of grace** from the date when this decision becomes definitive for the making available on the market and use of existing stocks.

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In such period of grace, trade in and any use of the disinfectant **Immunetec antimicrobial hand and skin cream** shall be subject to the label containing the information specified in the Licence Form enclosed with the trade permit issued by Decision No. 54828-3/2019/JIF.

The applicant has paid HUF 25,000 of administrative service fee as required by Paragraph VI.34 of Annex 1 to **Decree 1/2009 (30 January) of the Minister of Health on the fees payable for certain public administrative procedures and administrative type services of the State Public Health and Medical Officer's Service**, and no other procedural costs have arisen, so the NPHC has not ordered any payment.

This decision shall become definitive when communicated.

The client may file an administrative action submitting a petition against this decision on the grounds of a legal infringement within 30 days of receipt. The petition shall be addressed to the Debrecen Regional Court but submitted to the NPHC. The party acting with a legal representative or a business organisation shall submit the petition by electronic means.

If the Regional Court finds any legal infringement, it shall alter, annul or repeal the definitive decision upon the client's request except for any procedural infringement that does not essentially affect the evaluation of the matter on the merits, and it shall order the authority to conduct a new procedure as necessary. In the absence of any legal infringement, the Regional Court shall dismiss the petition.

The submission of the petition shall not delay the coming into force of the decision.

The Regional Court shall evaluate the action without holding a trial but shall hold one at the request of either party. The petitioner client may request a trial in the petition. If the petitioner omits this, it may not file an application for a certificate. The action shall be subject to duty payment, made as decided by the Regional Court.

REASONS

Immunetec Proof Kft. (5008 Szolnok, Krúdy Gyula u. 112.) applied for a revision of the trade permit for the disinfectant **Immunetec antimicrobial hand and skin cream** issued by Decision No. 54828-3/2019/JIF of the National Public Health Centre due to a change in the manufacturing company and the distributor's seat.

The NPHC examined the application and its enclosures, and in Expert Opinion No. **24812-2/2020/JIF** it proposed a revision of the trade permit for the product within **Main Group I, Product Type 1** laid down in Annex V of the Regulation with the stipulations laid down in the operative part of this decision.

*Pursuant to Section 2(1) of **Decree 1/2009 (30 January) of the Minister of Health on the fees payable for certain public administrative procedures and administrative type services of the State Public Health and Medical Officer's Service**, "The party required to pay a fee shall pay the administrative service fee in the amount laid down in Annex 1 (hereinafter: fee)." The applicant has certified payment of the administrative service fee.*

Having examined the NPHC's Expert Opinion and the available documents, I have found that the product described in the application is eligible for trade as a disinfectant within **Product Type 1** in Annex V to the **Regulation** in compliance with the conditions laid down in the operative part.

This decision is based on Section 10 of **Joint Decree 38/2003 (7 July) of the Minister of Health, Social and Family Affairs, the Minister of Agriculture and Rural Development, and the Minister of Environmental Protection and Water Management on the conditions of the manufacturing of and trade in biocidal products.**

I have taken this decision within my powers laid down in Section 4(6)f) of **Act XI of 1991 on official and administrative health activities** and in Sections 24 and 24/D(4)a) of **Government Decree 316/2013 (28 August) on certain rules of the authorisation of and trade in biocidal products.** My competence is laid down in Section 13(3) of **Government Decree 385/2016 (2 December) on the performance of the public health responsibilities of the Budapest Metropolitan and County Government Offices and District (Budapest District) Offices and on the designation of the government agency of health.**

My procedure is based on Sections 50(2)b), 80, 81(1) and (4) of **Act CL of 2016 on general administrative procedure** (hereinafter: **GAP**) and on Article 52 of the **Regulation**. I have provided information on the definitive nature of this decision pursuant to **GAP** Section 82(1).

The right to seek redress has been granted by virtue of **GAP** Section 114(1) and its rules are laid down in Section 39 of **Act I of 2017 on administrative procedure** (hereinafter: **AP**). The jurisdiction and competence of the Debrecen Regional Court have been established by virtue of **AP** Sections 12(1), 13(1)b) and Annex 4 of **Act CLXXXIV of 2010 on the names and seats of courts and the determination of their areas of competence.**

The electronic submission of the petition is required by Sections 2(1), (4)e) and 9(1)a) and b) of **Act CCXXII of 2015 on the general rules of electronic administration and fiduciary services** pursuant to Section 608(1) of **Act CXXX of 2016 on civil procedure.**

The amount of procedural fees is regulated by Section 45/A of **Act XCIII of 1990 on duties.**

Budapest, 16 July 2020

In the name and by commission of
National Chief Medical Officer Dr. Cecília Müller:

Illegible signature
Dr. Ágnes Dánielisz
Head of Department

Seal: National Public Health Centre – 22

Copies to:

1. Immunetec Proof Kft. – 5008 Szolnok, Krúdy Gyula u. 112.
2. Archives

Translation from Hungarian

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This translation was done by "NYUGAT" Translation Bureau (H-1062 Budapest, Andrássy út 99., Trade Register No.: Cg. 0106-780534, Community Tax No.: HU28066862). We hereby certify that this translation is in full conformity with the attached Hungarian document.

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Budapest, 4 August 2020

