MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

In Prague on July 14, 2022
No. MZDR 20900/2022-1/OBP

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# DECIDED

The Ministry of Health (hereinafter referred to as the "Ministry") as the central administrative authority in the field of placing biocidal products and active substances on the market and their use pursuant to § 5 paragraph 1 letter i) of Act No. 324/2016 Coll., on biocidal products and active substances and on the amendment of some related laws (Biocide Act), **decided** on the basis of the regulation on airworthiness No. 2020-0176 of 05/08/2020 of the European Union Aviation Safety Agency pursuant to Article 55, paragraph 1 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council, on the supply of biocidal products to the market and their use (hereinafter referred to as "Regulation No. 528/2012"), for permission to place the biocidal product **BIOBOR JF** on the market in the Czech Republic and its use, **as follows:**

I. The preparation BIOBOR JF can be supplied to the market in the territory of the Czech Republic and used under the conditions set out in the summary of properties of the biocidal product, which is attached to this decision.

II. The permit for delivery to the market in the territory of the Czech Republic and use is valid until the date indicated in the summary of properties of the biocidal product.

III. The preparation BIOBOR JF can be used for the purpose of treating aviation fuel to prevent the development of microbial contamination, if specified in the maintenance manual aircraft (Aircraft Maintenance Manual), or the relevant regulation for maintaining airworthiness (EASA Airworthiness Directive) and can only be used in this way by a person who, as part of his profession, ensures the airworthiness of aircraft.

IV. Before the first use of the BIOBOR JF preparation, the employer of the person mentioned in point III is obliged to notify the Ministry of Health of the Czech Republic in writing that the BIOBOR JF preparation will be used for the purpose of treating aviation fuel.

V. In order to comply with the conditions of controlled use, each company is required to report to the Ministry of Health of the Czech Republic the quantity of the biocidal product

BIOBOR JF supplied to the market in the territory of the Czech Republic, quantity used biocidal product BIOBOR JF, the amount of fuel treated with this product and also the number of aircraft in which fuel treated with BIOBOR JF was used, always once every 60 days.

**Justification:**

Aircraft manufacturers impose on operators a procedure for the long-term shutdown of aircraft aimed at preventing damage to aircraft, aircraft components, or their equipment in order to ensure the safety of air traffic.
One such measure is preventing the growth of micro-organisms in jet fuel and limiting it risks of fuel system failure as a result of fuel paths being blocked by a cluster of microbial contamination when returning aircraft to normal service.

On August 5, 2020, the European Union Aviation Safety Agency issued Airworthiness Directive No. 2020-0176, which requires the use of BIOBOR JF in certain types of aircraft for the above-mentioned purposes.

The preparation BIOBOR JF contains the active substances 2,2'-[(1-methylpropane-1,3-diyl)bis(oxy)]bis[4-methyl-1,3,2-dioxaborinane] and 2,2'-oxybis[4,4,6-trimethyl-1,3,2-dioxaborinane], none of the listed active substances being permitted for use in biocidal products according to Regulation of the European Parliament and of the Council (EU) No. 528/2012 on the conditions for the supply of biocidal products to the market and their use, as amended, nor is it included in the review program according to Commission Implementing Regulation (EU) No. 1062/2014, concerning the work of the systematic review program of all existing active substances contained in biocidal products, which are listed in Regulation (EU) No. 528/2012 of the European Parliament and of the Council, as amended.

Considering the fact that this preparation is the only one prescribed by some manufacturers specific types of aircraft, or ordered to be used for these purposes on the basis of Airworthiness Regulation No. 2020-0176 of 05/08/2020 of the European Union Aviation Safety Agency, and also with regard to the need to ensure a high standard of air traffic safety, the Ministry proceeded to grant an exemption according to the procedure Article 55 paragraph 1
Regulation of the European Parliament and of the Council (EU) No. 528/2012 on the conditions for the supply of biocidal products to the market and their use, as amended, and the use of the biocidal product BIOBOR JF was permitted under the conditions specified in this decision.

When determining the conditions of the permit, the Ministry took into account the dangerous properties of the product, in particular the reproductive toxicity of category 2 with the assigned standard hazard phrase H361d, and decided that, in order to review the use of this product, an obligation should be imposed on all users of the product that the Ministry

health authorities announced their intention to use this biocidal product and at the same time regularly reported in an interval of 60 days the amount of the product delivered to the market in the Czech Republic, the amount of the product used, the amount of treated fuel and the number of aircraft on which it was used fuel treated with biocidal product BIOBOR JF.

The Ministry of Health draws attention to the fact that if the reasons for issuing this authorization no longer apply, the Ministry of Health may cancel or change the authorization for the supply to the market in the territory of the Czech Republic and the use of the product BIOBOR JF. The Ministry of Health also considers it appropriate to draw attention to the possibility of extending the validity of this permit for a period not exceeding 550 days, if the reasons that led to the issuance of this permit continue to persist. The European Commission decides on the extension of the validity of the authorization in accordance with Article 55, paragraph 1 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council on the conditions for supplying biocidal products to the market and their use, as amended.

The Ministry of Health recommends all importers of the biocidal product to notify the General Directorate of Customs, Department 21 Customs, in writing of this fact when importing the product BIOBOR JF from third countries, in order to release the product into free circulation without any problems.

**MUDr. Pavla Svrÿinová, Ph.D.**
deputy for the protection and promotion of public health
and chief hygienist of the Czech Republic

signed electronically