MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

In Prague on March 21, 2024
No. MZDR 7331/2024-2/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) 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 specified 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 delivered 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 supplying 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 in accordance with the procedure Article 55, paragraph 1 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council 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 allowed 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

the 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 exist, 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, of this fact in writing 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.
chief hygienist of the Czech Republic with the position of senior director
public health protection and promotion section

signed electronically

SUMMARY OF THE PROPERTIES OF THE BIOCIDAL PREPARATION

Biobor JF

Product type: 6

Permit number 1 : CZ-2024-55-01

1 The permit was issued in accordance with Article 55 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.

1. ADMINISTRATIVE INFORMATION

1.1. **Trade name(s) of the preparation**

Business name	Biobor JF

1.2. **Permit holder**

Permit number	CZ-2024-55-01
Period of validity of the permit	15.09.2024

1.3. **Manufacturer(s) of the preparation**

Manufacturer's name	Hammonds Fuel Additives, Inc.
Manufacturer's	6951 W Little York | Houston | Texas | 77040 USA
address Location of manufacturing plants	6951 W Little York | Houston | Texas | 77040 USA

1.4. **Manufacturer(s) of active ingredient(s).**

Active substance	--
Manufacturer name	--
Manufacturer's address	--
Location of manufacturing plants	--

2. COMPOSITION OF THE PREPARATION AND ITS TYPE OF COMPOSITION

2.1. **Qualitative and quantitative information about the composition of the preparation**

Common name	Title by IUPAC	Function	CAS number	EC number	Contents (%)
2,2'-[(1-methylpropan-1,3-diyl)bis(oxy)]bis[4-methyl-1,3,2-dioxaborinan]		active ingredient 2	665-13-6	220-198-4	67,6
2,2'-oxybis[4,4,6-trimethyl-1,3,2-dioxaborinan]		active substance 1	4697-50-8 238-749-2		27,4
Solvent naphtha (petroleum), light aliphatic			64742-89-8 265-192-2		4,5

2.2. **Type of product composition**

AL - Any other liquid

3. STANDARD HAZARD PHRASES AND INSTRUCTIONS FOR SAFE HANDLING

Standard hazard statements	Flammable liquid and vapors. Harmful if swallowed. Harmful in contact with skin. Causes serious eye damage.

	Suspected impairment of reproductive capacity. Suspicion of damage to the fetus in the mother's body.
Instructions for safe handling	Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. – No smoking. Use safety glasses. Use protective gloves. Use protective clothing. IF IN EYES: Rinse carefully with water for several minutes. Remove contact lenses, if worn and if they can be removed easily. Continue rinsing. Call a doctor immediately.

4. **PERMITTED USE(S).**

4.1. **Description of use**

Table 1. Use #1 – Aviation Fuel Additive

Product type	Product type 06 - Preservatives for products during storage (Preservatives)
If necessary, provide a precise description of the permitted use	Preventive and curative use
Target organism(s) (including developmental stage)	Cladosporium resin Pseudomonas aeruginosa
Fields of application	Outdoor
Method(s) of application	Mixing with fuel See instructions for use
Application dose(s) and frequency	Curative: 1 liter of preparation per 5000 liters of fuel. Preventive: 1 l of product per 10,000 l of fuel - 0.01-0.02% vol. Recommended duration of action for curative use 24-36 hours
User categories	professional
Package size and packaging material	Plastic containers 8 oz - 330 gallon

4.1.1. Instructions for the given method of use

See general guidelines

4.1.2. Risk mitigation measures for the given use

See general guidelines

4.1.3. Data on likely direct or indirect effects, first aid instructions and environmental emergency measures for the intended use

See general guidelines

4.1.4. Instructions for the safe disposal of the product and its packaging for the given method of use

See general guidelines

4.1.5. Storage conditions and shelf life of the product under normal storage conditions for the given method of use

See general guidelines

5. GENERAL RULES FOR USE[2]

5.1. **Instructions for use**

For contaminated aircraft fuel tank or storage systems where microbial growth has already occurred, the product should be used as a curative treatment to eradicate and control microorganisms in the tank. The product can also be used regularly in sterile systems as a preventive treatment to avoid contamination.

Dosage for curative treatment: 1 liter of product per 5000 liters of fuel

Dosage for preventive treatment: 1 liter of product per 10,000 liters of fuel

Before application, drain the water settled at the bottom of the tank and keep the tanks dry. The preparation may only be mixed into the fuel, not into the water settled at the bottom of the tank.

The recommended method of achieving the recommended concentration of the preparation is metered injection directly into the flowing fuel stream when refueling the aircraft. This ensures mixing and thus prevents a local high concentration of the preparation. If metered injection is not available and batch mixing is the only option, care should be taken to add the product only to clean, dry fuel. When mixing in batches, add the preparation to the highest possible amount of fuel, i.e. the tank while filling it. Start adding product when the tank is half full, never to an empty tank.
When applying the product, follow the relevant maintenance instructions. Do not exceed the volume concentration of the preparation in the fuel of 0.10%, a higher concentration can lead to the formation of solid particles.
For best results in curative use, fill tank completely and leave for 24 to 36 hours.

After applying biocide, monitor filters, remove water from tanks and replace filters at recommended intervals.

5.2. **Risk mitigation measures**

Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No smoking.

Wear safety glasses or a face shield, chemical-resistant gloves (e.g. rubber) and protective clothing when working with the product.

After working with the product, wash your hands carefully with soap and water.

Remove contaminated clothing and wash before reuse.

Avoid release to the environment.

5.3. **Data on likely direct or indirect effects, first aid instructions and urgent cases**

First aid instructions

IF IN EYES: Immediately flush eyes with plenty of water. Remove contact lenses, if worn and if they can be removed easily. Continue rinsing. Seek medical attention immediately.

IF ON SKIN: Wash with plenty of water. If you feel unwell, call the Poison Control Center.

IF SWALLOWED: Call the Poison Control Center. Do not induce vomiting.

[2] The directions for use, risk mitigation measures, and other directions for use in this section apply to permitted uses.

Note to physician: Probable mucosal damage may contraindicate gastric lavage.

Toxicological information center: tel. 224 91 92 93 or 224 91 54 02

Measures to protect the environment in the event of an accident

Collect the spilled product using a suitable absorbent material, store in a tightly closed container and dispose of it as hazardous waste. Keep away from heat and sources of ignition. Use appropriate personal protective equipment. Avoid release to sewers, surface water or soil.

In case of leakage of a large amount of product into surface water, underground water or sewerage, inform the relevant authorities.

5.4. **Instructions for the safe disposal of the product and its packaging**

Dispose of the product and empty packaging as hazardous waste.

5.5. **Storage conditions and shelf life of the product under normal storage conditions**

Store in well-ventilated areas.

Keep the package tightly closed. Protect contents from moisture. Long-term exposure to atmospheric moisture can cause the formation of solid particles and loss of effectiveness.

Combustible. Keep away from heat and sources of ignition.

Store only in original packaging.

Do not use the product if it is cloudy or contains solid particles.

Shelf life: 3 years

6. **OTHER INFORMATION**

Telephone number for emergency situations: Toxicology Information Center, Clinic of Occupational Medicine VFN and 1st Faculty of Medicine, University of Applied Sciences, Na Bojišti 1, 120 00, Prague 2, phone: 224 919 293 and 224 915 402