GREAT BRITAIN BIOCIDAL CRITICAL SITUATION PERMIT – EXTENSION

Biocidal Product Name: Biobor JF
Permit Holder: UK Civil Aviation Authority

This permit is issued in exercise of the powers conferred by Article 55 (1) of Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, as it has effect in Great Britain (referred to in this certificate as "Regulation 528/2012 GB") and following decisions made by the Secretary of State (as regards England) on 27 October 2022 (Critical Situation Extension Decision reference 2022/208312), the Scottish Ministers (as regards Scotland) on 14 October 2022 (Critical Situation Extension Decision reference 2022/205377) and the Welsh Ministers (as regards Wales) on 24 October 2022 (Critical Situation Extension Decision reference 2022/205380).

Regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 makes provision as to the appointment of competent authorities for the purposes of Article 81 of Regulation 528/2012 GB. These are, respectively, the Secretary of State (as regards England), the Scottish Ministers (as regards Scotland) and the Welsh Ministers (as regards Wales).

The Health and Safety Executive acts on behalf of the competent authorities, pursuant to Agency Agreements which came into force on 12 February 2021.

The Health and Safety Executive issues this permit with the following terms and conditions:

1. The making available and use notified to the Health and Safety Executive under Article 55 (1) of Regulation 528/2012 GB ("the critical use") and outlined in the application from the UK Civil Aviation Authority, dated 25 April 2022, reference 2022/81804, may take place subject to compliance with the terms and/or conditions listed below and in Appendix 1.

2. This permit applies from 30 October 2022.

3. The biocidal product shall only be made available in Great Britain by the suppliers listed in Section 1.5 of Appendix 1.

4. When the biocidal product(s) is made available as part of the critical use to someone other than the permit holder, the labelling or packaging shall include the information listed in Appendix 1 other than,

    - start date of the permit;

- expiry date of the permit;
- the name and address of the formulator of the biocidal product;
- the name and address of the supplier of the active substance(s);
- the name and address of all permitted suppliers of the biocidal product (however the relevant biocidal product supplier name and address must be on the product label);
- the non-active substances, (however details of non-active substances specifically listed in the table in Section 2.1 or specifically referenced in Sections 3, 4 or 5 should be included on the product label); and
- the list of all permitted pack sizes (however the relevant pack size must be on the product label).

5. When the biocidal product(s) is made available as part of the critical use to someone other than the permit holder, any relevant classification, packaging and labelling requirements of Regulation (EC) No 1272/2008, as it has effect in Great Britain (the Classification Labelling and Packaging Regulation) shall be complied with.

6. Labels should not be misleading in respect of the risks from the product to human health, animal health or the environment, or in relation to its efficacy, and shall not mention the following terms or any similar indications,

   - ‘low-risk biocidal product’;
   - ‘non-toxic’;
   - ‘harmless’;
   - ‘natural’;
   - ‘environmentally friendly’; and
   - ‘animal friendly’.

7. Any advertisement for the product shall, in addition to complying with Regulation (EC) No 1272/2008, as it has effect in Great Britain (the Classification Labelling and Packaging Regulation), include the sentences “Use biocides safely. Always read the label and product information before use.”. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

8. Advertisements shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health, or the environment, or its efficacy, and shall not mention the following terms or any similar indications,

   - ‘low-risk biocidal product’;
   - ‘non-toxic’;
   - ‘harmless’;
   - ‘natural’;
   - ‘environmentally friendly’; and
   - ‘animal friendly’.

9. The suppliers listed in Section 1.5 of Appendix 1 shall keep records of the quantities of the biocidal product they make available as part of the critical use, including quantities made available to the permit holder, in Great Britain. This information should be made available to the Health and Safety Executive upon request.

10. Users of the biocidal product(s), including the permit holder, shall keep records of each treatment undertaken as part of the critical use. This information should be made available to the Health and Safety Executive upon request.

11. On becoming aware of new data or information on adverse effects of the active substance or biocidal product on humans, in particular vulnerable groups, animals or the environment, the permit holder shall without delay inform the Chemicals Regulation Division of the Health and Safety Executive.

12. The permit holder shall work with the product manufacturer and other interested parties to ensure progress continues to be made towards approval of the active substance(s) and subsequent authorisation of the biocidal product in Great Britain.

13. The permit holder shall submit reports to the Chemicals Regulation Division of the Health and Safety Executive outlining the steps taken to comply with term/condition 12 by 30 April 2023 and 31 October 2024.

14. This permit remains in force until 11:59pm on 2 May 2024, unless it is revoked at an earlier date.

Issued by

Nicola Gregg

Date of issue: 28 October 2022

Chemicals Regulation Division, Health and Safety Executive,
Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, United Kingdom

Explanatory notes:

i. Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (and supplementary EU Regulations and EU Decisions) has been retained into Great Britain law by European Union (Withdrawal) Act 2018 (as amended). The retained Regulation (EU) No. 528/2012 has been amended by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 and the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

ii. HSE extended this permit following decisions taken by the Secretary of State (as regards England) on 27 October 2022, the Scottish Ministers (as regards Scotland) on 14 October 2022 and the Welsh Ministers (as regards Wales) on 24 October 2022.

iii. This permit is applicable/valid in Great Britain only (which means England, Scotland and Wales). This permit is not applicable/valid in Northern Ireland.

iv. This permit is to allow the making available and use of the biocidal product in Great Britain only, due to an absence of any other products permitted for use by aircraft and engine manufacturers to perform safety critical maintenance operations.

v. Making available on the market means any supply of a biocidal product, whether in return for payment or free of charge, at all stages of the supply chain. Some examples of this could include:

- manufacturer to distributor
- distributor to retail store
- retail store to user

vi. The list of suppliers in Section 1.5 of Appendix 1 has been provided by the permit holder. Suppliers may be added to, or removed from, this list at the request of the permit holder.

vii. The records kept of the quantities of the biocidal product made available by each supplier as part of the critical use shall include details of:

- the person(s) the biocidal product was supplied to
- the date of the supply

viii. The records kept of each treatment undertaken as part of the critical use shall include details of:

- the type of treatment undertaken
- the quantity of product used
- the aircraft treated
- the date of the treatment
- the location of the treatment

ix. The power to amend or cancel this permit is exercisable at any time by HSE following an adverse effects report, or where the terms and/or conditions specified in Regulation 528/2012 GB, Critical Situation Extension Decision references 2022/208312, 2022/205377 and 2022/205380, or this permit are not met.

x. A failure to comply with any terms and/or conditions contained in this permit may result in enforcement action, including prosecution.

xi. This permit will expire on the date shown. No phase out will be given for the making available and use of the biocidal product in Great Britain. Stocks of the biocidal product should be managed to ensure that none remains in the supply chain by the expiry date.

Appendix 1: Conditions for the Critical Use of a Biocidal Product

1. Administrative information

1.1. Trade name(s) of the biocidal product

Please provide all trade names of the product.

Biobor JF

1.2. Permit holder

Name and address of the permit holder

Permit holder name	UK Civil Aviation Authority
Permit holder address	Aviation House, Beehive Ringroad, Crawley, West Sussex RH6 0YR

Permit number

GBCSP-2022-01B

Suffixes to the permit number linked to trade names

Start date of the permit

30 October 2022

Expiry date of the permit

2 May 2024

1.3. Formulator(s) of the biocidal product

Formulator 1

Name of formulator	Hammonds Fuel Additives Inc.
Address of formulator	6951 West Little York, Houston, Texas, 77040

1.4. Supplier(s) of the active substance(s)

Supplier 1

Active substance	Reaction mass of 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]
Name of supplier	Hammonds Fuel Additives Inc.
Address of supplier	6951 West Little York, Houston, Texas, 77040

1.5. Supplier(s) of the biocidal product

Product supplier 1

Name of supplier	Aviall UK Inc.
Address of supplier	North Feltham Trading Estate, 680 River Gardens, Feltham, TW14 0RD

Product supplier 2

Name of supplier	Aerospheres UK Ltd.
Address of supplier	Unit 3 Barratt Way, Harrow, HA3 5TJ

Product supplier 3

Name of supplier	Aljac Fueling Components
Address of supplier	Pitfield House, Station Approach, Shepperton, TW17 8AN

Product supplier 4

Name of supplier	Sil-Mid Ltd
Address of supplier	Unit 1 and 2 Roman Park, Roman Way, Coleshill, B46 1HG

Product supplier 5

Name of supplier	Topcast Aviation Europe Ltd
Address of supplier	iMex Centre, 575-599 Maxted Road, Hemel Hempstead, HP2 7DX

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

Common name	*IUPAC name*	*Function*	*CAS number*	*EC number*	*Content (% w/w)*
Substituted dioxaborinanes	Reaction mass of 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]	Active substance	2665-13-6 and 14697-50-8	220-198-4 and 238-749-2	95.00
Confidential - see Appendix 2		Non-active substances			5.00

2.2. Type of formulation

Ready-for-use liquid

3. Hazard and precautionary statements

It is the responsibility of the permit holder to ensure that the product is labelled in accordance with Regulation (EC) No. 1272/2008 of the 16th December 2008 (Classification, Labelling and Packaging of substances and mixtures Regulation), as it has effect in Great Britain, and include the relevant classification and labelling information from this section. The following classification and labelling information has been provided by the product manufacturer.

Classification of the product according to Regulation (EC) No. 1272/2008 as it applies in Great Britain (GB) (GB Classification, Labelling and Packaging of substances and mixtures Regulation (GB CLP))

Hazard category	Flam. Liq. 3 Eye Dam. 1 Repr. 1B
Hazard statement	H226: Flammable liquid and vapour. H318: Causes serious eye damage. H360: May damage fertility or the unborn child.

Labelling of the product according to Regulation (EC) No. 1272/2008 as it applies in Great Britain (GB) (GB Classification, Labelling and Packaging of substances and mixtures Regulation (GB CLP))

Signal words	Danger
Hazard statements	H226: Flammable liquid and vapour. H318: Causes serious eye damage. H360: May damage fertility or the unborn child.
Precautionary statements	P201: Obtain special instructions before use. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P308+P313: IF exposed or concerned: Get medical advice/attention. P403+P235: Store in a well-ventilated place. Keep cool. P501: Dispose of contents in accordance with local, state or national legislation.

Note	

4. Permitted use

4.1. Use description

Table1. Use #1 – Aviation fuel biocide

Product type	PT06 – Preservatives for products during storage
Where relevant, an exact description of the permitted use	Only for use as an aviation fuel biocide to prevent or treat microbiological growth in aircraft fuel tanks and engines.
Target organism(s) (including development stage)	Micro-organisms such as bacteria, mould and yeast – including Cladosporium resinae and Pseudomonas aeruginosa
Field(s) of use	In aircraft fuel tanks and engines.
Application method(s)	As described by the relevant Aircraft Maintenance Manual (AMM).
Application rate(s) and frequency	As described by the relevant Aircraft Maintenance Manual (AMM).
Category(ies) of users	Only to be used by maintenance organisations approved in accordance with: • Regulation (EU) No 1321/2014, Annex II, Part 145 (Maintenance organisation regulations) • Regulation (EU) No 1321/2014, Annex I, Part M, sub Part MF (Smaller aircraft maintenance organisation regulations) • National regulations under BCAR (British Civil Airworthiness Requirements) Section A (CAP 553)
Pack sizes	0.946 litres (1 US quart) – 6 per case 3.8 litres (1 US gallon) – 4 per case 17.4 litres (4.6 US gallon pail) 194.6 litres (51.4 US gallon drum) 1249 litres (330 US gallon tote)

5. Directions for use

5.1. Instructions for use

Only to be used in accordance with the appropriate Aircraft Maintenance Manuals (AMM) and product label.

5.2. Risk mitigation measures

Eye protection, fuel resistant gloves and protective outerwear must be worn.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

In case of spillage, immediately contain the spill area and follow local procedures for clean-up and disposal of the material.

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

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Importers/suppliers/users of the biocidal product must comply with all relevant health and safety regulations, including those relating to transport, storage and use of the biocidal product.

6. Other conditions/restrictions

On becoming aware of any adverse effects of the active substance or biocidal product on humans, in particular vulnerable groups, animals or the environment, the user shall without delay inform the permit holder.

Appendix 2: Confidential Biocidal Product Characteristics

1. Product composition and formulation

1.1. Qualitative and quantitative confidential information on the composition of the biocidal product

Common name	*IUPAC name*	*Function*	*CAS number*	*EC number*	*Content (% w/w)*
Tributyleneglycol biborate	2,2'-[(1-methylpropane-1,3-diyl)bis(oxy]bis[4-methyl-1,3,2-dioxaborinane]	Active substance	2665-13-6	220-198-4	67.60
Hexyleneglycol biborate	2,2'-oxybis[4,4,6-trimethyl-1,3,2-dioxaborinane]	Active substance	14697-50-8	238-749-2	27.40
Low boiling point naptha	Naptha	None (residual)	64742-89-8	265-192-2	4.50
Water	Water	None (residual)	7732-18-5	231-791-2	0.50

2. Other confidential biocidal product characteristics