

GREAT BRITAIN BIOCIDAL PRODUCT CERTIFICATE: SIMPLIFIED AUTHORISATION MINOR CHANGE

Product Name: 小島 BIRD FREE

Authorisation Holder: Bird Free Limited

This certificate is granted in exercise of the powers conferred by Articles 50 (2) and (3) 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 Article 7 (7) of Regulation (EU) No. 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No. 528/2012, as it has effect in Great Britain.

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 has determined that the conditions in Article 25 of Regulation 528/2012 GB are still met and amends this authorisation with the following terms and conditions:

1. Subject to compliance with paragraph 2 the Authorisation Holder is authorised to place on the market the biocidal product(s) detailed in the Summary of the Product Characteristics in Appendices 1 and 2, for the use(s) set out in Appendix 1.
2. The Authorisation Holder shall complete, within the stated timeframe, the actions set out in the table below. If the actions have not been completed by the relevant due date, the biocidal product(s) covered by this certificate of authorisation may no longer be placed on the market as of that date.

Description	Due Date

3. This certificate revokes and replaces certificate document reference number 2018/116974.
4. Notwithstanding paragraph 3 existing stock labelled in accordance with

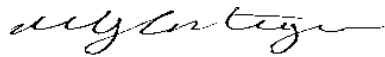
authorisation number UK-2018-1127 and document number 2018/116974, shall remain subject to the terms and conditions set out in document 2018/116974 and in accordance with Article 52 of Regulation 528/2012 GB may continue to be:

- a. made available on the market until 30 September 2023; and
 - b. used until 28 March 2024.
5. Without prejudice to the duties imposed on the Authorisation Holder by Article 69 of Regulation 528/2012 GB, the Authorisation Holder must include on the product label(s) the information contained in Appendix 1 for the biocidal product(s), other than,
- the list of all authorised trade names and their relevant suffix (however the relevant product trade name and suffix must be on the product label);
 - date of authorisation;
 - expiry date of the authorisation;
 - the name and address of the manufacturer(s) of the product (including site details);
 - the name and address of the manufacturer(s) of the active substance(s) (including site details);
 - 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);
 - any authorised uses outlined in Section 4 and 5 that are not relevant to the Authorisation Holder's current marketing strategy (however, for those uses which are included on the label, all the relevant conditions relating to those uses as outlined in the subsections of Sections 4 and 5 must be included in the labelling); and
 - the list of all authorised pack sizes and types (however the relevant pack size must be on the product label).
6. In accordance with Article 6 of Regulation (EU) No. 354/2013 (Changes Regulation), as it has effect in Great Britain, the Authorisation Holder may remove or update the information on the product label to implement Administrative Changes as defined in Section 2 of Title 1 of the Annex to Regulation (EU) No. 354/2013, as it has effect in Great Britain.

The Authorisation Holder must notify these Administrative Changes to the GB Competent Authority within 12 months of implementation.

7. This certificate of authorisation may be amended in accordance with Article 48 or 50 of Regulation 528/2012 GB.
8. This certificate of authorisation may be cancelled in the circumstances set out in Articles 48 or 49 of Regulation 528/2012 GB.
9. Subject to paragraphs 7 to 8, this certificate of authorisation remains in force until 11:59pm on 4 June 2028.

Issued by

A handwritten signature in black ink, appearing to read 'M. J. L. T. J.', is positioned below the 'Issued by' heading.

Date of issue: 3 April 2023

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. This authorisation is applicable/valid in Great Britain only (which means England, Scotland and Wales). This authorisation is not applicable/valid in Northern Ireland.
- iii. This certificate revokes and replaces the terms and conditions for Great Britain only. Certificate document reference number 2023/44099 revokes and replaces the terms and conditions for Northern Ireland only.
- iv. Following the submission of a minor change application by the Authorisation Holder, the following amendments have been made to this authorisation,
 - Authorisation holder details have been updated in Section 1.2. of the Summary of the Product Characteristics.
 - Authorisation number for Great Britain has been changed to GB-2018-1127 in Section 1.2. of the Summary of the Product Characteristics.
 - Extended efficacy period to 4 years.
- v. From 3 April 2023 any new stock of the biocidal product(s) must be placed on the market and used in accordance with the terms and conditions outlined in this document. Existing stocks of the biocidal product(s) can be phased off the GB market as outlined in this certificate of authorisation.
- vi. If the Authorisation Holder fails to comply with the action(s) as outlined in term/condition 2 they cannot place the biocidal product(s) on the GB market as of the date stated. Any stock of the biocidal product(s) they have already placed on the GB market prior to the date(s) stated in term/condition 2 can continue to be made available on the GB market by any company other than the Authorisation Holder and used in accordance with the terms and conditions of this authorisation.
- vii. While the information in term/condition 5 is not required to be included on the product label(s) by Regulation 528/2012 GB the Authorisation Holder may choose to include it if they wish.
- viii. The power to amend or cancel this certificate of authorisation is exercisable at any time by HSE where the conditions specified in Regulation 528/2012 GB are not met.

- ix. A failure to comply with any terms and/or conditions contained in this certificate of authorisation (or where term/condition 4 applies document 2018/116974) may result in cancellation of the authorisation under Article 48 of Regulation 528/2012 GB. Non-compliance with the law may result in enforcement action, including prosecution.
- x. Regulation 528/2012 GB does not allow for the renewal of Simplified Authorisations. This authorisation will expire on the date shown. No phase out will be given for making the biocidal product available on the market or using it in GB. The Authorisation Holder should manage the stocks of the biocidal product(s) to ensure none remains in the supply chain by the expiry date.

The Authorisation Holder may apply for a new authorisation in accordance with Article 26 of Regulation 528/2012 GB or Article 4a of Regulation (EU) No. 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) 528/2012, as it has effect in Great Britain.

Appendix 1: Summary of Product Characteristics for a Biocidal Product

1. Administrative information

1.1. Trade name(s) of the product

小島 BIRD FREE
Fire Gel
Optical Gel

1.2. Authorisation holder

Name and address of the authorisation holder

Authorisation holder name	Bird Free Ltd
Authorisation holder address	7 Purley Place, London, United Kingdom, N1 1QA

Authorisation number

GB-2018-1127

Suffixes to the authorisation number linked to trade names

小島 BIRD FREE: GB-2018-1127 -0001
Fire Gel: GB-2018-1127 -0002
Optical Gel: GB-2018-1127 -0003

Date of the authorisation

Authorised 5 June 2018
As amended 3 April 2023

Expiry date of the authorisation

4 June 2028

1.3. Manufacturer(s) of the product

Manufacturer 1

Name of manufacturer	EZFLEX Co Ltd
Address of manufacturer	902, Joongang Building, 44-21, Yeouido-dong, Yeongdeungpo-gu, Seoul, Korea

Location of manufacturing sites	300-35, Seokgye-ri, Sangbuk-myeon, Yangsan-si, Gyeongsangnam-do, South Korea
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1.4. Manufacturer(s) of the active substance(s)

Manufacturer 1

Active substance	Peppermint Oil
Name of manufacturer	Sigma-Aldrich Company Ltd
Address of manufacturer	The Old Brickyard NEW ROAD, Gillingham, Dorset, SP8 4XT, United Kingdom
Location of manufacturing sites	The Old Brickyard NEW ROAD, Gillingham, Dorset, SP8 4XT, United Kingdom

Manufacturer 2

Active substance	Citronellal
Name of manufacturer	Sigma-Aldrich Korea Ltd
Address of manufacturer	698-84 Maeng-ri, Wonsam-myun, Cheoin-gu, Yongin-city, Kyunggi-do, South Korea, 449-471
Location of manufacturing sites	698-84 Maeng-ri, Wonsam-myun, Cheoin-gu, Yongin-city, Kyunggi-do, South Korea, 449-471

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)
Peppermint Oil	Peppermint Extract	Active Substance	8006-90-4	616-900-7	0.53
Citronellal	3,7-dimethyloct-6-en-1-al	Active Substance	106-23-0	203-376-6	0.42
Confidential - see Appendix 2		Non-active substance			99.05

2.2. Type of formulation

RTU VP – Ready to use vapour releasing product

3. Hazard and precautionary statements

The following classification and labelling information was originally determined by the reference Member State, prior to IP completion day, in accordance with Regulation (EC) No. 1272/2008 of the 16 December 2008 (Classification, Labelling and Packaging of substances and mixtures Regulation) and the outcomes of the product risk assessment.

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	None
Hazard statement	None

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	None
Hazard statements	None
Precautionary statements	None
Note	EUH208- Contains citronellal. May cause an allergic reaction.

NB: It is the responsibility of the Authorisation Holder to label the product in accordance with Regulation (EC) No. 1272/2008 of the 16 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.

4. Authorised use(s)

4.1. Use description

Table1. Use #1 – Professional use

Product type	PT 19: Repellents and attractants
Where relevant, an exact description of the authorised use	Bird repellent for deterring pigeons from buildings and structures
Target organism(s) (including development stage)	Pigeons (<i>Columba livia</i>)
Field(s) of use	In, on and around buildings/structures
Application method(s)	Pre-packed covered plastic dishes
Application rate(s) and frequency	Space dishes (centre-to-centre) as follows: • Nesting sites 14-15cm • Night roosts 14-20cm • Day roosts 18-25cm Product will remain effective for a minimum period of 4 years.
Category(ies) of users	Professional
Pack sizes and packaging material	Round PET dish with cover (20 x 65 mm). Fifteen dishes of BIRDFREE (three columns of five) are packed in a cardboard box (200mm long x 70mm wide x 110mm high). Twenty of the 15-dish boxes are packed into an outer box (360mm long x 417mm wide x 238mm high).

4.1.1. Use-specific instructions for use – Use #1 – Professional use

Affix pre-packed covered plastic dishes to dry surfaces with silicone adhesive and remove covers from dishes.

It is essential to clean the application site of all nests, faeces and other organic

debris before the product is applied (failure to do so will compromise efficacy).

Allow cleaned surfaces to dry fully prior to treatment.

When replacing or removing, remove plastic dishes and clean surfaces with a disposable cloth soaked in soap and water. Avoid touching the gel when removing the dishes.

4.1.2. Use-specific risk mitigation measures – Use #1 – Professional use

For professional use only.

For use only as a repellent.

For use in, on and around buildings only.

To avoid risks to man and the environment, comply with the instructions for use.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Wash hands and exposed skin before meals and after use.

Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment – Use #1 – Professional use

In case of inhalation: Remove person to fresh air and keep comfortable for breathing.

In case of skin contact: Wash skin with plenty of water. Remove contaminated clothing and wash before re-use.

In case of eye contact: Rinse eyes with water as a precaution. Hold eye open and rinse slowly and gently with water for 20 minutes. Remove contact lenses, if present and easy to do so, then continue rinsing eye. Seek medical advice.

In case of ingestion: Call a poison centre or doctor if you feel unwell.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging – Use #1 – Professional use

This material and its container must be disposed of in a safe way.

Dispose of contents/container in accordance with local regulations.

4.1.5. Where-specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Use #1 – Professional use

Keep in a safe place.

Store in a well-ventilated place in original container.

Shelf-life: 12 months

5. General directions for use

5.1. Instructions for use

5.2. Risk mitigation measures

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

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

6. Other information

Appendix 2: Confidential Biocidal Product Characteristics

In accordance with Article 66 (2) of Regulation 528/2012 GB these biocidal product characteristics are considered to be confidential but are also part of the Summary of the biocidal Product Characteristics (SPC).

1. Product composition and formulation

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

<i>Common name</i>	<i>IUPAC name</i>	<i>Function</i>	<i>CAS number</i>	<i>EC number</i>	<i>Content (% w/w)</i>
Peppermint oil	Peppermint extract	Active Substance	8006-90-4	616-900-7	0.53
Citronellal	3,7-dimethyloct-6-en-1-al	Active Substance	106-23-0	203-376-6	0.42
Beeswax	N/A	Filler	8012-89-3	232-383-7	16.5
Polybutene	But-1-ene	Filler	9003-29-6	500-004-7	72.5
Polydimethylsiloxanes	Poly (dimethylsiloxane)	Resistance to ultraviolet	63148-62-9	613-156-5	10.05

2. Other confidential biocidal product characteristics

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