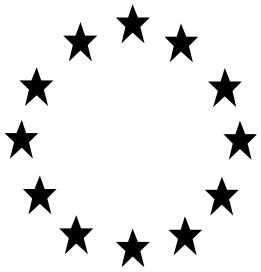
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATIONS

Amended for SA-MIC



小島 BIRD FREE

Product type 19

Peppermint oil and Citronellal

Case Number in R4BP: BC-ML054577-21, BC-PQ067026-20

Evaluating Competent Authority: FI

Date: 17 March 2022

Assessment history

Application type	**refMS/ eCA**	**Case number in the refMS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment / renewal)**	**Chapter/ page**
SA-APP	UK	BC-RG035397-31	05.06.2018	Initial assessment	
SA-APP	FI	BC-ML054577-21	12.02.2020	*New rMS for a SA-APP due to UK's withdrawal from the EU.* *Changes in the PAR:* - *reference to UK legislation removed* - *new applicant's name and contact details* - *ED assessment of coformulants* - *reference to COM decision (EU) 2019/1331 added*	6, 10 7 9, conf.ann 25
SA-MIC	FI	BC-PQ067026-20	17.03.2022	*Amendment: Update on efficacy claim, no update on shelf life*	4, 10, 12, 24-28, 30

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March 2022:

Minor change application. Applied changes: Increase in efficacy lifespan from 3 months to 4 years and increase in shelf life from 1 year to 2 years. The applicant has provided a new efficacy study, but no new data on storage stability.

All updates are highlighted with yellow.

1 CONCLUSION

1.1 Summary of decisions and restrictions

It is concluded after evaluation that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product in accordance with Article 25 of Regulation (EU) No 528/2012 subject to the following conditions:

1.1.1 Usage area

User	Usage Area
Professional	In, on and around buildings/structures

1.1.2 Pest and application rate

Authorisation is granted for use against pigeons (*Columba livia)*.

Application rate:
Space dishes (centre-to-centre) as follows:
- nesting sites 14-15cm
- night roosts 14-20cm
- day roosts 18-25cm

1.1.3 Active substance details

The concentration of the active substance peppermint oil in the biocidal product is 0.53 % w/w. The minimum purity of the active substance peppermint oil is 79 % w/w.
Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

The concentration of the active substance citronellal in the biocidal product is 0.42 % w/w. The minimum purity of the active substance citronellal is 95 % w/w.
Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

1.1.4 Eligibility for the simplified authorisation procedure

Following evaluation, 小島 BIRD FREE has been shown to meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012, i.e.:

1. The active substances peppermint oil and citronellal appear in Annex I of Regulation (EU) 528/2012 with no restrictions applied.
2. The biocidal product contains no substances of concern.
3. the biocidal product does not contain any nanomaterials.
4. The use pattern and associated label claims of the biocidal product have been judged sufficiently effective.
5. The handling of the biocidal product as part of its intended use does not require any PPE.

1.1.5 Comparative assessment and authorisation

A comparative assessment is not required since peppermint oil and citronellal are not considered candidates for exclusion in accordance with Article 5(1) or substitution in accordance with Article 10(1) of EU Regulation 528/2012.

Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.
Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

1.2 Necessary issues accounted for in the product label

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
This material and its container must be disposed of in a safe way.
Dispose of contents/container in accordance with local regulations.
Keep in a safe place.
Store in original container.

1.3 Requirement for further information

None.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
小島 BIRD FREE Fire Gel Optical Gel	EU EU EU

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bird Free Optical Gel Limited
	Address	No 3 The Square, Tralee, Kerry, V92 PR22, Ireland
Authorisation number	EU-0021836-0000	
Date of the authorisation	12 February 2020	
Expiry date of the authorisation	11 February 2030	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	EZFLEX Co Ltd
Address of manufacturer	RM.503, Yuwon Bldg, Seongnae1-dong, Gangdong-gu, Seoul, South Korea 457-22
Location of manufacturing sites	300-35, Seokgye-ri, Sangbuk-myeon, Yangsan-si, Gyeongsangnam-do, South Korea

2.1.1.4 Manufacturer(s) of the active substance(s)

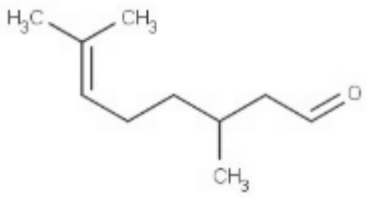
Active substance	Peppermint oil
Name of manufacturer	Sigma-Aldrich Company Ltd
Address of manufacturer	The Old Brickyard NEW ROAD, Gillingham, Dorset, SP8 4XT, United Kingdom
Location of manufacturing sites	The Old Brickyard NEW ROAD, Gillingham, Dorset, SP8 4XT, United Kingdom

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

2.1.2 Product composition and formulation

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Peppermint oil
IUPAC or EC name	Peppermint extract
EC number	616-900-7
CAS number	8006-90-4
Index number in Annex VI of CLP	Not available
Minimum purity / content	790 g/kg
Structural formula	N/A

Main constituent(s)	
ISO name	Citronellal
IUPAC or EC name	3,7-Dimethyloct-6-en-1-al
EC number	203-376-6
CAS number	106-23-0
Index number in Annex VI of CLP	Not available
Minimum purity / content	>950 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

Peppermint oil and citronellal are not candidates for substitution.
Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.
Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peppermint oil (Natural 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

The full formulation composition details are contained within the Confidential Annex Section 3.6.1. The biocidal product 小島 BIRD FREE does not contain nanomaterials.

2.1.2.4 Information on technical equivalence

Peppermint oil and citronellal are listed in Annex I of Regulation (EU) No 528/2012 and therefore technical equivelence is not required at this time.

2.1.2.5 Information on the substance(s) of concern

No substances of concern have been identified in the product formulation.

There were no indications of endocrine disruptive properties of active or non-active substances (co-formulants) in the product. Hence, the product is not an endocrine disruptor. For more details please see the confidential annex.

2.1.2.6 Type of formulation

RTU VP – Ready to use vapur releasing product

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	None
Hazard statement	None
Labelling	
Signal words	None
Hazard statements	None
Precautionary statements	None
Note	EUH208 – Contains citronellal. May cause an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Professional use

Product Type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Bird repellent for deterring pigeons from buildings and structures.
Target organism (including development stage)	Pigeons (*Columba livia*)

Field of use	In, on and around buildings
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 Products 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 小島 BIRD FREE (three columns of five) are packed into 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).

2.1.4.2 Use-specific instructions for 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.

2.1.4.3 Use-specific risk mitigation measures

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.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

This material and its container must be disposed of in a safe way. Dispose of contents/container in accordance with local regulations.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Keep in a safe place. Store in a well-ventilated place in original container. Shelf-life: 12 months

2.1.5 General directions for use

2.1.5.1 Instructions for use

See section 2.1.4.2

2.1.5.2 Risk mitigation measures

See section 2.1.4.3

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

See section 2.1.4.4

2.1.5.4 Instructions for safe disposal of the product and its packaging

See section 2.1.4.5

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

See section 2.1.4.6

2.1.6 Other information

None

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials
PET Dishes in cardboard box	-	PET	-	professional	Acceptable, no adverse interactions were observed in the accelerated and 2 year storage studies.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data has been submitted as part of this product application. Please see Annex 3.1 for the list of studies used.

March 2022: New efficacy data has been provided for the minor change application. Annex 3.1 has been updated.

2.1.8.2 Access to documentation

Peppermint oil and citronellal are listed in Annex I of Regulation (EU) No 528/2012 and no active substance dossiers are available, therefore no letter of access is required.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Professional use

Product Type(s)	PT19 (Repellent)
Where relevant, an exact description of the authorised use	Bird Repellent
Target organism (including development stage)	Birds (including feral pigeons; *Columba livia*, gulls or other nuisance bird species). Adults and fledged juveniles
Field of use	In, on and around buildings
Application method(s)	Placement of PET petri dishes (containing the polybutene based product) onto cleaned nesting and roosting sites
Application rate(s) and frequency	Affix pre-packed covered plastic dishes to dry surfaces with silicone adhesive and remove covers from dishes. For feral pigeons, dishes should be spaced (centre-to-centre) as follows: nesting sites 14-15cm; night roosts 14-20cm; day roosts 18-25cm. These spacings may also deter other nuisance bird species.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Round PET dish with cover (20 x 65mm). Fifteen dishes of 小島 BIRD FREE (three columns of five) are packed into 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).

2.2.2 Physical, chemical and technical properties

小島 BIRD FREE is a ready to use vapour releasing product. The physical and chemical and storage stability data submitted to support the formulation are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Physical state at 20 °C and 101.3 kPa	ISO 4630-1 Gardner colour scale	Peppermint oil 0.53% Citronellal 0.42 %	Solid	Harding, L. (2017a)	Acceptable
Colour at 20 °C and 101.3 kPa	ISO 4630-1 Gardner colour scale	Peppermint oil 0.53% Citronellal 0.42 %	Cream	Harding, L. (2017a)	Acceptable
Odour at 20 °C and 101.3 kPa	Olfactory assessment	Peppermint oil 0.53% Citronellal 0.42 %	Citrus/lemon	Harding, L. (2017a)	Acceptable
pH	-	-	No data submitted as the product is a wax block	-	Acceptable
Storage stability test – **accelerated storage** 2 weeks at 54 °C in proposed packaging (PET dish)	CIPAC MT 46.3	Peppermint oil 0.53% Citronellal 0.42 %	**Active substance content** Citronellal Initial: 0.42% After: 0.35% Peppermint oil Initial: 0.53% After: 0.53% Product appearance No change after storage Packaging No change after	Harding, L. (2017a)	Acceptable. Although the Citronellal falls by 17%, efficacy data are available that sufficiently demonstrate that the product remains efficacious after a storage period of 12 months. (See section 2.2.5). The applicant identified 3 possible causes for the loss in Citronellal content: 1. The complex matrix of the formulation (i.e. beeswax) thus makes extraction after storage difficult.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			storage <u>Weight loss</u> 0.54% after storage		2. Vapourisation due to volatility. 3. Degradation. There were no degradation products observed in the chromatogram during the determination of citronellal after storage, therefore degradation is considered an unlikely cause. The applicant considered vapourisation to be the most likely cause as citronellal odour was detected following storage. The UK CA accepts this explanation and reasons that no further consideration is necessary.
Storage stability test – **low temperature storage** 1 week at 0°C in proposed packaging (PET dish)	CIPAC MT 39.3	Peppermint oil 0.53% Citronellal 0.42%	<u>Product appearance</u> No change after storage <u>Packaging</u> No change after storage <u>Weight loss</u> 0.05% after storage	Harding, L. (2017a)	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Storage stability test – **long term storage at ambient temperature** 12 months at 25 °C in proposed packaging (PET dish)	In house method: SOP CEM-3249	Peppermint oil 0.53% Citronellal 0.42 %	**Active substance content** <u>Citronellal</u> Initial: 0.42% After 3 months: 0.34% After 12 months: 0.24% <u>Peppermint oil</u> Initial: 0.53% After 3 months: 0.52% After 12 months: 0.52% <u>Product appearance</u> No change after 12 months storage <u>Packaging</u> No change after 12 months storage <u>Weight loss</u> 0.54% after 12 months storage	Harding, L. (2017b)	Acceptable. Although the Citronellal falls by 19 and 43% after 3 and 12 months respectively, efficacy data are available that sufficiently demonstrate that the product remains efficacious after a storage period of 12 months. (See section 2.2.5). The applicant identified 3 possible causes for the loss in Citronellal content: 1. The complex matrix of the formulation (i.e. beeswax) thus makes extraction after storage difficult. 2. Vapourisation due to volatility. 3. Degradation. There were no degradation products observed in the chromatogram during the determination of citronellal after storage, therefore degradation is considered an unlikely cause. The applicant considered vapourisation to be the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
					most likely cause as citronellal odour was detected following storage. The UK CA accepts this explanation and reasons that no further consideration is necessary.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Case	Peppermint oil 0.53% Citronellal 0.42 %	-	-	No further data required as product stored in a cardboard box.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Case	Peppermint oil 0.53% Citronellal 0.42 %	-	-	See accelerated storage above.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Case	Peppermint oil 0.53% Citronellal 0.42 %	No adverse effects noted between the product and the commercial packaging after 12 months storage at 25 °C.		Acceptable.
Physical compatibility	-	-	-	-	The products are not designed to be used in conjunction with any other product. No claims of compatibility are made on the label.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Chemical compatibility	-	-	-	-	The products are not designed to be used in conjunction with any other product. No claims of compatibility are made on the label.
Surface tension	-	-	-	-	As the product is RTU VP, these data are not deemed necessary for the evaluation.
Viscosity	-	-	-	-	As the product is RTU VP, these data are not deemed necessary for the evaluation.

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties of 小島 BIRD FREE are acceptable for a ready to use vapour releasing product (RTU VP) with the exception of the storage stability of citronellal. The content in the formulation decreases by 19% and 43% after 3 and 12 months storage at 25°C respectively, however efficacy data support a shelf life of 12 months.

2.2.3 Physical hazards and respective characteristics

Property	Method	Purity of the test substance % (w/w)	Results/Remarks	Reference	UK CA comments
Explosives	-	Peppermint oil 0.53% Citronellal 0.42 %	-	-	The products do not contain any components that are classified as explosive making it highly unlikely that the formulation will require classification.
Flammable	-	Peppermint oil 0.53% Citronellal 0.42 %	-	-	The products do not contain any flammable components in amounts that are significant

Property	Method	Purity of the test substance % (w/w)	Results/Remarks	Reference	UK CA comments
					enough to have any impact on the flammability of the final product.
Oxidising	-	Peppermint oil 0.53% Citronellal 0.42 %	-	-	The products do not contain any components classified as oxidising. There are no chemical groups or bonds present in the product known to induce oxidising properties.
Auto-ignition temperatures of products	-	Peppermint oil 0.53% Citronellal 0.42 %	Not determined	-	Acceptable, based on justification for non-flammability

Conclusion on the physical hazards and respective characteristics of the product
All relevant physical hazards and respective characteristics for the product were found to be acceptable. The product is not considered to be explosive, oxidising or flammable.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

Not required.
Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin. Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

Analytical methods for the active substance in the biocidal product

Peppermint oil/Citronellal
A weighed portion of the formulation was diluted with dichloromethane and the resulting solution analysed by GC-FID, using a DB-WAXETR capillary column. Validation data are shown in the table below. Representative chromatograms were submitted and were acceptable.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peppermint Oil	GC-FID	0.32-0.81%	0.11-0.4 g/l (0.3-1%) (n=6) r=0.9999	Chromatograms of test sample, analytical standard and blank sample showed no interference at the retention times of interest (ca. 14.2, 14.4, 14.8, 15.6 and 16.2 mins).	96-106 (n=12)	100	1.4 (n=6)	N/A	Harding, L. (2016)
Citronellal	GC-FID	0.32-0.81%	0.11-0.41 g/l (0.3-1%) (n=6) r=0.9998		91-104 (n=12)	97	0.7 (n=6)	N/A	Harding, L. (2016)

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Not required.
Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin. Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

Conclusion on the methods for detection and identificationof the product
The analytical methods of analysis for the determination of Peppermint oil and Citronellal in the product is acceptable. The monitoring methods for water, sediment and soil are not required as both active substances are listed in Annex I of Regulation (EU) 528/2012.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

小島 BIRD FREE is a repellent (product type 19) for use in repelling nuisance birds.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

小島 BIRD FREE is used to control nuisance birds, notably pigeons.

The product is used to protect buildings, their contents and other structures/items that may be affected by nesting/roosting of nuisance birds.

2.2.5.3 Effects on target organisms, including unacceptable suffering

For pigeons, dishes should be spaced (centre-to-centre) as follows: nesting sites 14- 15cm; night roosts 14-20cm; day roosts 18-25cm.

The product is a repellent which prevents the nesting and roosting behaviour of birds in affected locations.

2.2.5.4 Mode of action, including time delay

The applicant has provided the following statement regarding the mode of action of the product:

'The mode of action is an olfactory repellent (peppermint oil and citronellal), and once placement has occurred, works immediately (no time delay) in deterring birds from roosting or nesting.'

The UK CA accepts the applicant's statement regarding the mode of action.

2.2.5.5 Efficacy data

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organisms</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>PT19 Repellent against nuisance birds</td>
<td>小島 BIRD FREE (stored under ambient conditions for 12 months)</td>
<td>Columba livia</td>
<td>Field study conducted on nesting sites in a donkey stable in Pisa, Italy.

16 nesting sites commonly used by pigeons within the stable were identified. Photographs of each site were taken before treatment, indicating that all contained nests/eggs/birds.

The areas were all cleared of nests and material and cleaned.

The product was then applied to 8 of the nesting sites (G1-8) according to the use instructions, 15 cm apart.

At the remaining 8 sites (E1-9), empty plastic trays were applied in the same way as a negative control.

The sites were monitored and photographs were taken 1, 2, 3, 7, 15, 30, 60 and 90 days after treatment.

Nest activity was recorded according to the following scale.

0: No new material.
1: Unstructured material.
2: Structured nest without eggs or eggs without a structured nest.
3: Eggs on structured nest.
4: Squabs on nest.
5: Fledglings on nest.

Scores 0 and 1 were considered to represent a lack of nesting activity (as the</td>
<td>Below is a summarized table of the results for each site.
N.B. Where 2 numbers are provided this indicates that multiple reproductive cycles took place during this period.
<table>
<tr><th colspan="2">Site</th><th>Pre-treatment Score</th><th>Post-treatment Score</th></tr>
<tr><td rowspan="8">Treated</td><td>G1</td><td>3</td><td>0</td></tr>
<tr><td>G2</td><td>4</td><td>0</td></tr>
<tr><td>G3</td><td>3</td><td>1</td></tr>
<tr><td>G4</td><td>3</td><td>1</td></tr>
<tr><td>G5</td><td>3</td><td>1</td></tr>
<tr><td>G6</td><td>3</td><td>1</td></tr>
<tr><td>G7</td><td>3</td><td>1</td></tr>
<tr><td>G8</td><td>3</td><td>1</td></tr>
<tr><td rowspan="8">Control</td><td>E1</td><td>3</td><td>2</td></tr>
<tr><td>E2</td><td>3</td><td>4</td></tr>
<tr><td>E3</td><td>3</td><td>4,3</td></tr>
<tr><td>E4</td><td>3</td><td>0</td></tr>
<tr><td>E5</td><td>4</td><td>3</td></tr>
<tr><td>E6</td><td>3</td><td>4,5</td></tr>
<tr><td>E7</td><td>3</td><td>5</td></tr>
<tr><td>E9</td><td>3</td><td>2</td></tr>
</table>
</td>
<td>Gagliardo (2017a) Nesting Site Report</td>
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<table>
<tr><td></td><td></td><td></td><td>building was a stable it was considered to be acceptable for unstructured straw and feathers to be present on) while scores ≥2 were considered to represent noteworthy nesting activity.</td><td></td><td></td></tr>
<tr><td>PT19 Repellent against nuisance birds</td><td>小島 BIRD FREE (stored under ambient conditions for 12 months)</td><td>Columba livia</td><td>Field study conducted on a day roost site in Pisa, Italy.

A suitable roost site, the south facing slope of the roof of a stable, was identified. Opposite ends of the same slope were used as treatment and control.

Video cameras were installed to monitor roosting activity before and after the treatment. Each camera was set up to record a picture every minute.

Both ends were monitored for roosting activity 3 days prior to treatment.
Both ends were then cleaned. The product was applied to the east end of the roof and empty dishes were applied to the west end. These were placed according to the use instructions, on the apexes of the corrugated material (18.5cm apart) and 25 cm apart on the slope.

The site was monitored using the video camera 1, 2, 3, 7, 14, 30, 60 and 90 days after treatment.

Temperature, wind speed and rainfall were also recorded at each time point.</td><td>Below is a summarised table of the results for the treated and control sites in terms of the number of occasions when birds occupied the site (A) and the total amount of time (hh:mm:ss) that the site was occupied by birds (B).

<table><tr><th>DAY</th><th colspan="2">Treated (BIRD FREE)</th><th colspan="2">Control (Empty Dishes)</th></tr><tr><th></th><th>A</th><th>B</th><th>A</th><th>B</th></tr><tr><td>-3</td><td>34</td><td>1:13:43</td><td>80</td><td>0:42:34</td></tr><tr><td>-2</td><td>65</td><td>1:45:20</td><td>81</td><td>1:07:52</td></tr><tr><td>-1</td><td>24</td><td>1:00:06</td><td>49</td><td>1:22:29</td></tr><tr><td>Pretreatment Average</td><td>41</td><td>01:19:43</td><td>70</td><td>01:04:18</td></tr><tr><td>1</td><td>8</td><td>0:01:11</td><td>26</td><td>0:26:21</td></tr><tr><td>2</td><td>1</td><td>0:04:55</td><td>46</td><td>0:34:17</td></tr><tr><td>3</td><td>1</td><td>0:02:19</td><td>35</td><td>0:11:38</td></tr><tr><td>7</td><td>1</td><td>0:00:06</td><td>31</td><td>0:19:02</td></tr><tr><td>14</td><td>1</td><td>0:01:29</td><td>21</td><td>0:26:07</td></tr><tr><td>30</td><td>5</td><td>0:03:42</td><td>30</td><td>0:29:23</td></tr><tr><td>60</td><td>1</td><td>0:00:22</td><td>20</td><td>0:31:53</td></tr><tr><td>90</td><td>0</td><td>0:00:00</td><td>10</td><td>0:04:25</td></tr><tr><td>Post-treatment Average</td><td>2</td><td>00:01:46</td><td>27</td><td>00:22:53</td></tr></table></td><td>Gagliardo (2017b) Day Roosting Site Report</td></tr>
<tr><td>PT19 Repellent against nuisance birds</td><td>小島 BIRD FREE (stored under ambient conditions for 10 months)</td><td>Columba livia</td><td>Field study conducted on a night roost site in Pisa, Italy.

A suitable roost site, the sheltered, warm area around a large vent on the roof of a veterinary building, was identified. Opposite sides of the roof vent were used as treatment and control.

Video cameras were installed to monitor roosting activity before and after the treatment. Each camera was set up to</td><td>Below is summarised table of the results for the treated and control sites in terms of the highest number of birds occupying the space at any time point that day.

<table><tr><th rowspan="2">Day</th><th colspan="2">Highest Number of Birds per day</th></tr><tr><th>Treated (BIRD FREE)</th><th>Control (Empty Dishes)</th></tr><tr><td>-3</td><td>48</td><td>52</td></tr><tr><td>-2</td><td>39</td><td>51</td></tr><tr><td>-1</td><td>37</td><td>29</td></tr></table></td><td>Gagliardo (2017c)</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>record a picture every minute.

Both sides were monitored for roosting activity 3 days prior to treatment.

Both sides were then cleaned. The product was applied to the south slope of the roof and empty dishes were applied to the north slope. These were placed according to the use instructions, on the apexes and grooves of the tiles (28 cm apart) and 20 cm on the slope. At the most sheltered point (closest to the vent where birds were found most frequently) a shorter distance of 14 cm was used. Dishes were also placed along the edge over the vent at 25 cm apart.

The site was monitored using the video cameras at sunrise, sunset, 12 noon and 14:30 at each of the following time points: 1, 2, 3, 7, 14, 30, 60 and 90 days after treatment.

Temperature, wind speed and rainfall were also recorded at each time point.</td>
<td>
<table>
<tr><td>Pre-treatment Average</td><td>41</td><td>44</td></tr>
<tr><td>1</td><td>0</td><td>35</td></tr>
<tr><td>2</td><td>0</td><td>25</td></tr>
<tr><td>3</td><td>0</td><td>36</td></tr>
<tr><td>7</td><td>0</td><td>41</td></tr>
<tr><td>14</td><td>0</td><td>48</td></tr>
<tr><td>30</td><td>0</td><td>35</td></tr>
<tr><td>60</td><td>0</td><td>41</td></tr>
<tr><td>90</td><td>0</td><td>47</td></tr>
<tr><td>Post-treatment Average</td><td>0</td><td>39</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>PT19 Repellent against nuisance birds</td>
<td>小島 BIRD FREE</td>
<td>Columba livia</td>
<td>A field trial was conducted comparing the effect of BIRDFREE on the night roosting activity of feral pigeons, to empty PET dishes (untreated) over a 4 year test period. The location of the pigeon night roost site was the corrugated roof of a building at the University of Pisa Veterinary Clinic, which housed the heating machinery. The site was chosen as it was observed to be a highly frequented night roost for pigeons (confirmed by a 3-day pre-treatment census and pre-treatment cleaning of the area which removed over 100 kg of pigeon faeces). Two roof areas adjacent to warm-air vents of approximately 16.2 m² (on opposite sides of the building) were chosen as the BIRDFREE 'treated' plot (south roof) and the Empty PET dishes 'untreated' plot (north roof). The test was unreplicated,</td>
<td>Over the whole 4-year test period, the BIRDFREE treated area (plot) maintained a 100% reduction in number of birds roosting (including at sunset and sunrise), compared to the untreated (empty PET dishes) area (plot). It is therefore concluded that the product 'BIRDFREE' is an effective deterrent to birds (pigeons) roosting over-night (on night roosting sites) for a minimum of 4 years following treatment with BIRDFREE.</td>
<td>Gagliardo (2021)</td>
</tr>
</table>

			but assessment of roosting activity was conducted eleven times during the test period, on Days 1, 2, 3, 7, 14, 30, 60, 90 and 1, 2, and 4 years after treatment. The BIRDFREE dishes (and the empty PET dishes) were placed at 140 mm centres across the respective plot areas (9.0 m x 1.8 m). Assessment was made at sunrise, sunset, 12:00 and 14:30 on each assessment date, using two video cameras overlooking the plot area (one per plot area). The number of birds within the plot area at each assessment time point was counted on each assessment date for the BIRDFREE treated plot and the untreated plot. The test areas were cleaned prior to placement of the BIRDFREE or empty PET dishes.		

Conclusion on the efficacy of the product

The label claims for the product are:

- *'For deterring feral pigeons from buildings and other structures when applied according to instructions'*
- *'will remain effective for a minimum period of 3 months'*

Efficacy against pigeons

3 field studies were provided to support the efficacy of the product against pigeons.

Gagliardo; 2017a investigated the efficacy of the product against pigeons at nesting sites. The results of this study clearly demonstrated that the product resulted in no nest building/egg laying at treated sights compared to substantial nesting activity in most of the untreated control sites (in some cases multiple reproductive cycles).

Gagliardo; 2017b and c investigated the efficacy of the product against pigeons at day and night roosting sites respectively. The results of the day roost site study demonstrate a substantial reduction in the number and duration of instances where pigeons occupy the space. The results of the night roost study demonstrated no roosting activity at the treated site compared to maintained roosting behaviour at the control site.

The UK CA considers that these data are, therefore, sufficient to support the use of the product against pigeons at the requested application rates.

NOTE: According to Commission Implementing Decision (EU) 2019/1331, the biocidal product 'Bird Free', identified by the case number BC-RG035397-31 in the Register for Biocidal Products, meets the condition laid down in Article 25(d) of Regulation (EU) No 528/2012.

Residual efficacy period

The product is claimed to remain effective for up to 3 months after application.

All of the above studies were conducted over a ninety day period and demonstrate that efficacy is maintained at similar levels throughout this time. The UK CA, therefore, considers that this period of residual efficacy is sufficiently supported.

March 2022:

The updated label claims for the product are:

- 'For deterring feral pigeons from buildings and other structures when applied according to instructions'
- 'will remain effective for a minimum period of 4 years'

The product is claimed to remain effective for 4 years after application.

Gagliardo; 2017c night roosting (field) study of feral pigeons has been continued and the results from 4 years were provided in a new study report (Gagliardo; 2021). In the study the effect of BIRDFREE was compared to empty PET dishes (untreated). The study shows that the product remains efficacious for 4 years. The results of the

night roost study demonstrated no roosting activity (including at sunset and sunrise) at the treated site compared to maintained roosting behaviour at the control site. The FI CA, therefore, considers that this period of residual efficacy is sufficiently supported.

Shelf life

The chemistry evaluation has identified that the quantity of one of the active substances, Citronellal, has reduced by more than 10 % during the storage stability study. For this reason, efficacy data are required to demonstrate that the product remains effective after storage.

The applicant has provided a letter to confirm that the samples used in the efficacy tests were manufactured and sent to the testing laboratory in Pisa in May 2016 and were stored under ambient conditions until used in the tests. The study reports, Gagliardo; 2017a and b, indicate that the treatment in these studies began in May 2017, one year later. The applicant has provided a statement to confirm this.

We, therefore, consider that the data sufficiently demonstrate that the product remains efficacious after a storage period of 12 months.

March 2022:

Applicant's justification for the change in shelf-life: *As the biocidal product remains effective for four years when exposed heat/light/wind/rain, it can be inferred that it would remain effective for at least two years when stored in accordance with storage guidelines.*

The document "CA-May14-Doc5.5-Final-Simplified Procedure stability data" indicates in point 3(7)(b): Stability data could be waived where the applicant demonstrates that the product is efficacious by the end of the proposed shelf-life (i.e. data from efficacy tests using aged/stored product).

The products used in the new 4-years efficacy test are about 10 months old. Therefore, the provided efficacy test does not demonstrate that products, aged for 24 months, would be efficacious. The conclusion is that the shelf life of the product cannot be increased from 12 months to 24 months.

2.2.5.6 Occurrence of resistance and resistance management

The applicant has provided the following statement about the occurrence of resistance.

'No occurrence of resistance was seen to the product 小島 BIRD FREE in feral pigeons (Columba livia) at any of the test sites for the duration of the studies. It is highly unlikely that resistance will occur in any 'nuisance bird species' to the product 小島 BIRD FREE, as it is an olfactory repellent, and mechanisms of resistance do not occur to this type of repellent in animal species. Therefore, no resistance management strategy is required for this product.'

The UK CA accepts the applicant's statement and agrees that, due to the mode of action as an olfactory repellent, occurrence of resistance is very unlikely. If the applicant becomes aware of any potential occurrences of resistance this should be reported to the relevant authority.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

March 2022: The label claims for the product which are supported by the data package are:

- *'For deterring feral pigeons from buildings and other structures when applied according to instructions'*
- *'will remain effective for a minimum period of 4 years'*

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

小島 BIRD FREE is not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Material safety data sheets have been submitted for each active substance and co-formulant of 小島 BIRD FREE; safety data sheets have been checked for classification and substances of concern.

Substances of Concern
There are no substances of concern present in the 小島 BIRD FREE formulation according to the criteria laid out in Annex A of the guidance on the BPR, Vol III, Parts B+C.

Classification
No data was provided; classification of the product was determined by the toxicity of the components. No classification is required for acute toxicity, irritation or sensitisation; however the active substance Citronellal is present in 小島 BIRD FREE at 0.42% and although this is below the 1% generic concentration limit for sensitisation, it is however above the 0.1% limit for elicitation. Therefore the phrase – EUH208 – 'Contains citronellal. May cause an allergic reaction' should be included on the product label.

2.2.6.2 Exposure assessment

There are no substances of concern present and the product is not classified, therefore the UK CA considers that a detailed exposure assessment is not relevant

under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

The UK CA accepts that personal protective equipment are not required for the use of 小島 BIRD FREE.

2.2.6.3 Risk characterisation for human health

There are no substances of concern present and the product is not classified, therefore the UK CA considers that authorisation of 小島 BIRD FREE under the Simplified Authorisation procedure according to Regulation (EU) 528/2012 is acceptable from a human health perspective.

2.2.7 Risk assessment for animal health

There are no substances of concern present and the product is not classified, therefore the UK CA considers that a risk assessment for animal health is not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.8 Risk assessment for the environment

There are no substances of concern present and the product is not classified, therefore the UK CA considers that authorisation of 小島 BIRD FREE under the Simplified Authorisation procedure according to Regulation (EU) 528/2012 is acceptable from an environmental perspective.

2.2.9 Measures to protect man, animals and the environment

Please see section 2.1.4.

2.2.10 Assessment of a combination of biocidal products

小島 BIRD FREE is not intended to be used in combination with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title	Testing Company	Report no.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
Harding, L	2017a	Accelerated Physical and Chemical Storage Stability Study on a Repellent Formulation containing Peppermint Oil and Citronellal	CEM Analytical Services Limited (CEMAS)	CEMR-7748	Y	N	Y	Bird Free Ltd.	3.4.1
Harding, L	2017b	Long Term Physical and Chemical Storage Stability Study on a Repellent Formulation containing Peppermint Oil and Citronellal	CEM Analytical Services Limited (CEMAS)	CEMR-7749	Y	N	Y	Bird Free Ltd.	3.4.1
Harding, L	2016	Analytical Method for the Determination of a Repellent Formulation containing Peppermint Oil and Citronellal	CEM Analytical Services Limited (CEMAS)	CEMR-7837	Y	N	Y	Bird Free Ltd	5
Gagliardo, A	2017a	Effect of 小島 BIRD FREE on nesting sites of feral pigeons	Department of Biology, University of Pisa	01	N	N	Y	Bird Free Ltd	6.7
Gagliardo, A	2017b	Effect of 小島 BIRD FREE on a day roost of feral pigeons	Department of Biology, University of Pisa	02	N	N	Y	Bird Free Ltd	6.7
Gagliardo, A	2017c	Effect of 小島 BIRD FREE on a night roost of feral pigeons	Department of Biology, University of Pisa	03	N	N	Y	Bird Free Ltd	6.7
Gagliardo, A	2021	Effect of 小島 BIRD FREE on a night roost of feral pigeons	Department of Biology, University of Pisa	04	N	N	Y	Bird Free Ltd	6.7

3.2 Output tables from exposure assessment tools

Not applicable as no exposure assessments performed.

3.3 New information on the active substance

No new information on the active substance has been provided in support of this biocidal product.
Peppermint oil is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.
Citronellal is listed in Annex I of Regulation (EU) No 528/2012 under Category 7 – Other.

3.4 Residue behaviour

Not relevant. The intended uses of 小島 BIRD FREE are not expected to lead to contamination of food/feedstuff.

3.5 Summaries of the efficacy studies

Please see section 3.1 above and the efficacy section 2.2.5 of this PAR which summarises these data.

3.6 Confidential annex

Please see the separate confidential annex.

3.7 Other
