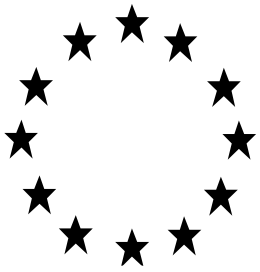
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR SIMPLIFIED AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



BYEPEST1

Product type(s) 19

Peppermint oil and Lavender oil

Case Number in R4BP: BC-GU027195-22

Evaluating Competent Authority: SPAIN

Date: June 2021

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Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
SA-APP	ES	EU-0015316-0000	December 2018	Initial assessment.
SA-AAT	ES	BC-FX048389-01	January 2019	Confidential claims requested by the applicant
SA-AAT	ES	Bc-WJ048690-23	January 2019	Confidential claims requested by the applicant.
SA-AAT	ES	BC-KY062701-12	November 2020	Ammendment
SA-AAT	ES	BC-JQ065298-13	May 2021	Post-authorisation
SA-AAT	ES	BC-NF066758-24	June 2021	Confidential claims requested by the applicant

The information added or modified is marked in gray.

1 CONCLUSION

The assessment presented in this report is in relation to the application submitted by the applicant for the authorisation of a biocidal product family contained lavander oil and peppermint oil as a active substances, both of them listed in the Annex I of Regulation (EU) nº 528/2012, as PT19 (repellent of birds).
This applicantion has been submitted according to the article 26 of Regulation (EU) nº528/2012. According to the the applicant the condition established in article 25 are met:

- The active substances contained in the family are listed in the Annex I of BPR,
- Does not contain any substance of concern,
- Does not contain any nanomaterials,
- Is sufficiently effective
- the handling of the biocidal product and its intended use do not require personal protective equipment.

The ES CA has detected during the evaluation the presence of a substance which is now notified as an active substance in relation to food and feed derogation. At the time of the dossier submission, this substance is not included in the Review Programme and the function in the biocidal product is as a colorant and the applicant has submitted a scientific justification. The ES CA has checked the information and it has been accepted. Therefore, the biocidal product family met the conditions of article 25.

Post-authorisation:
The applicant has provided new information related to the shelf-life.
It is concluded that the product can be authorized with an shlef-life of 2 years.
All information is found in the physicochemical properties (2.2.2), efficacy (2.2.5) sections and in Confidential Annex (6) section.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	Country (if relevant)
BYEPEST1	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BYEPEST ECOLABORATORIES SL
	Address	EL INGENIO 1, 3A, 39012, SANTANDER, SPAIN
Authorisation number	EU-0015316-0000	
Date of the authorisation	14/12/2018	
Expiry date of the authorisation	14/12/2028	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	BYEPEST ECOLABORATORIES SL
Address of manufacturer	EL INGENIO 1, 3A, 39012, SANTANDER, SPAIN
Location of manufacturing sites	POL. INDUSTRIAL DE GUARNIZO, CENTRO DE NEGOCIOS, NAVE 3, 39611, GUARNIZO, CANTABRIA, SPAIN

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

Active substance	PEPPERMINT OIL (NATURAL OIL)
Name of manufacturer	ESENCIAS MARTINEZ LOZANO SA
Address of manufacturer	CTRA. LORCA KM 7, 30400, CARAVACA DE LA CRUZ, MURCIA, SPAIN
Location of manufacturing sites	CTRA. LORCA KM 7, 30400, CARAVACA DE LA CRUZ, MURCIA, SPAIN

2.1.2 Product FAMILY composition and formulation

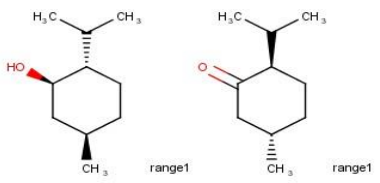
Active substance	LAVENDER OIL (NATURAL OIL)
Name of manufacturer	ESENCIAS MARTINEZ LOZANO SA
Address of manufacturer	CTRA. LORCA KM 7, 30400, CARAVACA DE LA CRUZ, MURCIA, SPAIN
Location of manufacturing sites	CTRA. LORCA KM 7, 30400, CARAVACA DE LA CRUZ, MURCIA, SPAIN

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Peppermint oil
IUPAC or EC name	(1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol; (2R,5S)-5-methyl-2-(propan-2-yl)cyclohexan-1-one
EC number	282-015-4
CAS number	8006-90-4
Index number in Annex VI of CLP	-
Minimum purity / content	-
Structural formula	
Main constituent(s)	
ISO name	Lavender oil.
IUPAC or EC name	-
EC number	289-995-2
CAS number	8000-28-0
Index number in Annex VI of CLP	-
Minimum purity / content	-
Structural formula	N/A

2.1.2.2 Candidate for substitution

Peppermint oil and Lavender oil are not candidate for substitution in accordance with Article 10(1) of Regulation 528/2012.
Peppermint oil and Lavender oil are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peppermint oil	(1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol; (2R,5S)-5-methyl-2-(propan-2-yl)cyclohexan-1-one	Active substance	8006-90-4	282-015-4	0,01	0,4
Lavender oil	-	Active substance	8000-28-0	289-995-2	0,01	0,2
-	-	Non-active substance	-	-	-	-

The full formulation composition details are contained within the Confidential Annex

2.1.2.4 Information on technical equivalence

Peppermint oil and Lavender oil 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. Infomation on the substance(s) of concern

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

2.1.2.6. Type of formulation

GS - Grease

2.1.3. Hazard and precautionary statements

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

Classification	
Hazard category	n/a
Hazard statement	n/a
Labelling	
Signal words	n/a
Hazard statements	n/a
Precautionary statements	n/a
Note	**-**

2.1.4. Authorised use(s)

2.1.4.1. Use description

Table 1. Use # 1 – Bird repellent – Outdoor.

Product Type	19 - bird repellent.
Where relevant, an exact description of the authorised use	This product should be used on buildings and adyacent structures such as: windows, roof lines, roof tops, cornices, protusions, facades, surfaces and similar structures on terraces, houses, signs, lights guardrails, handle bars, billboards, bridges, churches, monuments, etc.. to repel or deter away birds.
Target organism (including development stage)	- Common Pigeons (*Columba livia*). - Common seagull (*Larus canus*)
Field of use	Outdoor
Application method(s)	The product is applied on trays on surfaces to be treated.
Application rate(s) and frequency	According to the level of infestation: Common pigeons: - Area with nest: 20-30 g each 15 cm. - High infestation: 20-25 g each 15 cm. - Medium infestation: 20 g each 20-25cm. - Low infestation: 20 g each 25-30cm. Commo seagull: - Low infestation: 20 g each 25-30cm. No periodic application is required, once the pest has been controlled, removed the trays afeter a period of 6 months.
Categories of users-	General public. Professional. Trained professional.
Pack sizes and packaging material	Plastic (HDPE) cartridge of 280 g. Plastic (PP) cartridge of 400 g. Pre-filled tray (PA) with 20g of product: box of 8 or 32 prefilled tray. The trays are closed. Two trays close together one against the other, so there are no disposable parts. The boxes are made of carton SBS 380g

2.1.4.1.1. Use-specific instructions for use

See section 2.1.5.1.

2.1.4.1.2. Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.4.2. Use description

Table 2. Use # 2 – Bird repellent – Indoor.

Product Type	19 - bird repellent.
Where relevant, an exact description of the authorised use	This product should be used in covered structures such as:structures under roofs or terraces, cornices or covered windows, interior sgructures underneath roofs or open decks such as train stations, parking lots, bus stops, airports, metro stations, warehouses, factories, stadiums, etc.. to repel or deter away birds.
Target organism (including development stage)	- Common Pigeons (*Columba livia*). - Common seagull (*Larus canus*)
Field of use	Indoor (for covered areas with bird infestation problems)
Application method(s)	The product is applied on trays on surfaces to be treated.
Application rate(s) and frequency	According to the level of infestation: Common pigeon: - Area with nest: 20-30 g each 15 cm. - High infestation: 20-25 g each 15 cm. - Medium infestation: 20 g each 20-25cm. - Low infestation: 20 g each 25-30cm. Common seagull: - -Low infestation: 20 g each 25-30cm. No periodic application is required, once the pest has been controlled, removed the trays after a period of 6 months.
Category(ies) of users	General public. Professional. Trained professional.
Pack sizes and packaging material	Plastic (HDPE) cartridge of 280 g. Plastic (PP) cartridge of 400 g. Pre-filled tray (PA) with 20g of product: box of 8 or 32 prefilled tray. The trays are closed. Two trays close together

	one against the other, so there are no disposable parts. The boxes are made of carton SBS 380g

2.1.4.2.1. Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2.2. Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.5. General directions for use

2.1.5.1. Instructions for use

Keep out of reach of children and pets. Read label before use. Prior the treatment establish the level of infestation: • Low / Small: 1-10 birds and 0 nests. • Medium: 1-10 birds and 1-2 nests. • High / Severe: more than 10 birds and 1 or more nests. Apply the product only against seagulls when the first signs of infestation or few individuals appear and only using low doses. It is important to consider the size of the site as this is also decisive for establishing the level of infestation. A small place with a low bird population may actually be a severe problem. The application method is based on the installation of trays. They are of 6cm of diameter and are adhered to the surface to be treated with silicone glue at the recommended distance. Then they are filled with product. If trays get emptied, replace them with new ones.

Add a second line for severe cases.

If after 2 weeks from the installation, some birds remain in the treated area, add more quantity in those affected areas. This is due to insufficient amount of product or unattached trays.

No periodic application is required. Once the birds relocate, they do not need to return to the place treated with the product, being able to remove the remains of product after security period of at least 6 months.

For non-professional users: if the pest persists after 6 months that the product has been properly installed, contact with PCO.

2.1.5.2. Risk mitigation measures

The surface must be clean and dry before the application.

Do not apply the product in rainy days to avoid problems of adhesion of the silicone with the surface.

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

First aid measures:

- In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.
- Skin contact; wash affected area with plenty of water and soap, without scrubbing.

Advice for medical and healthcare personnel:

- Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ☎ [*INSERT LOCAL NUMBER HERE*].

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

Trained professional:
Deliver empty containers, unused product and other waste generated during the treatment to a registered establishment or undertaking, in accordance with current regulations
Code the waste according to Decision 2014/955 / EU.

General public and professional:
Empty containers should be deposited in separate collection containers according to the material of the containers.

Unused product and other waste generated during the treatment must be deposited in the residual fraction or in the collecting facilities.

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

Keep container closed when not in use.

Store in original container, out of reach of food.

Keep in a cool, dry, well ventilated place, at room temperature, and out of the reach of children and pets.

Shelf life: 2 years.

2.1.6. Other information

A new test against seagulls with high infestation should be provided at the renewal.

Definitions:
Trained professional: pest control operators, having received specific training in insecticide control according to the national legislation in force.

Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

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 (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Cartridge	400g	PP	n/a	Trained professional/ Professional/ General public	n/a
Cartridge	280g	HDPE	n/a	Trained professional/ Professional/ General public	n/a
Pre-filled trays	20g	PA	n/a	Trained professional/ Professional/ General public	n/a

NOTE: The trays are closed. Two trays close together one against the other, so there are no disposable parts. The boxes are made of carton SBS 380g.

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.

2.1.8.2. Access to documentation

Peppermint, ext and Lavender, Lavandula angustifolia, ext 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 FAMILY

2.2.1. Intended uses as applied for by the applicant

Table 2. Intended use # 1 – BIRD REPELLENT OUTDOOR

Product Type(s)	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	This product should be used on buildings and adyacent structures such as windows, roof lines, seawage pipes/edges, roof tops, cornices, protrusions, facades and similar structures on terraces, gardens, houses, signs, guardrails, billboards, bridges, churches, monuments, etc. to repel or deter away birds.
Target organism (including development stage)	Columba livia - Feral pigeon Passer domesticus - House sparrow Sturnus vulgaris - Starling Larus canus - Common gull Birds- Birds
Field of use	Outdoor
Application method(s)	Own - Profesional: The application method is based on the installation of 6cm trays that adhere to the surface to be treated with silicone glue and that are filled with product when they are used in cartridges of 280g or of 400g and using a common caulking gun for the dosage. When they are used in pre-filled dishes/trays of 20g, these will be adhered with silicone glue directly to the surface. The placing distance between trays depends on the population density of the birds, the nest and perching sites, and the specific characteristics of the place to treat. Own -

	No Profesional/ General Public The application method is based on the installation of 6 cm trays that adhere to the surface to be treated with silicone glue and that are filled with product when they are used in cartridges of 280g or of 400g and using a common caulking gun for the dosage. When they are used in pre-filled dishes/trays of 20g, these will be adhered with silicone glue directly to the surface. The placing distance between trays depends on the population density of the birds, the nest and perching sites, and the specific characteristics of the place to treat.
Application rate(s) and frequency	Other - Not required – - To determine the type of problem it is recommended to establish the degree of infestation: • Low / Small: 1-10 birds and 0 nests • Medium: 1-10 birds and 1-2 nests • High / Severe: More than 10 birds and 1 or more nests * Note: it is very important to consider the size of the site as this is also decisive for classification. A small place with a low bird population may actually be a severe problem. Hence, good judgment and experience for interpretation are important in classifying the problem. - The distance between trays should be: 400g and 280g Cartridges: Place about 20g(±4g) at a distance of: • Nest places: ~10-15cm • High problem areas: ~15cm • Medium problem areas: ~20-25cm • Low problem areas: ~25-30cm 20g Pre-filled Trays • Nest places: ~10-15cm • High problem areas: at a distance of ~15cm • Medium problem areas: at a distance of ~20-25cm • Low problem areas: at a distance of ~25-30cm - If necessary; the product dose can be increased by adding more product per tray or reducing the distance between trays according to the case. - No periodic application is required, once the pest has been controlled, the trays can be removed after a period of at least 6 months.

	- Each installation site is different and needs to be considered and studied taking into account all environmental and structural conditions. - The distance between trays can be increased or decreased accordingly. - For larger surfaces sometimes it may be necessary to add more lines for severe cases. - To treat problems with small birds such as sparrows, it is recommended to make a strip/line shape of about ~ 1cm of product thickness instead of the use with trays. Support materials such as plastic gutters can be used to adhere on the structure. * Notes for Professionals Follow-ups are recommended for installations where the problem persists after 2 weeks of placement to determine the cause. This may be due to: • Insufficient quantity per m2. Solution: Add more trays with product. • Incorrect estimation of the number of birds (less than the actual). Solution: Reduce the distance between trays by adding more. • Inefficient adhesion of the tray. Solution: fix trays again with good quality silicon. • Larger birds: add more quantity per tray using the cartridge. • Incorrect estimation of nests. Solution: Add trays with product at a shorter distance. * Note for Non-Professionals - If trays get emptied, replace them with new ones. - Add a second line for severe cases. - In the case that the plague persists after 2 weeks of placement, add more trays, it is due to an insufficient amount per m2. - If the pest persists after 6 months that the product has been properly installed, contact a professional. - For larger surfaces or with difficult access contact a professional.
Categories of user	PT19 - Repellents and attractants (Pest control)
Pack sizes and packaging material	This product should be used on buildings and adyacent structures such as windows, roof lines, seawage pipes/edges, roof tops, cornices, protrusions, facades and similar structures on terraces, gardens, houses, signs, guardrails, billboards, bridges, churches, monuments, etc. to repel or

	deter away birds.

Table 2. Intended use # 2 – BIRD REPELLENT INDOOR

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	This product should be used in covered structures such as: structures under roofs or terraces, cornices or covered windows, interior structures underneath roofs or open decks such as train stations, parking lots, bus stops, barns, warehouses, factories, ports, industrial warehouses, stadiums, airports, metro stations, etc. To repel or deter away birds.
Target organism (including development stage)	Columba livia - Feral pigeon Passer domesticus - House sparrow Sturnus vulgaris - Starling Larus canus - Common gull Birds- Birds
Field of use	Indoor
Application method	Own - Profesional: The application method is based on the installation of 6cm trays that adhere to the surface to be treated with silicone glue and that are filled with product when they are used in cartridges of 280g or of 400g and using a common caulking gun for the dosage. When they are used in pre-filled dishes/trays of 20g, these will be adhered with silicone glue directly to the surface. The placing distance between trays depends on the population density of the birds, the nest and perching sites, and the specific characteristics of the place to treat. Own - No Profesional/ General Public The application method is based on the installation of 6 cm trays that adhere to the surface to be treated with silicone glue and that are filled with product when they are used in cartridges of 280g or of 400g and using a common caulking gun for the dosage. When they are used in pre-filled dishes/trays of 20g, these will be adhered with silicone glue directly to the surface. The placing distance between trays depends on the population density of the birds, the nest and perching sites, and the specific characteristics of the place to treat.
Application rate and frequency	Other - Not required – **- To determine the type of problem it is recommended to establish the degree of infestation:**

	• Low / Small: 1-10 birds and 0 nests • Medium: 1-10 birds and 1-2 nests • High / Severe: More than 10 birds and 1 or more nests * Note: it is very important to consider the size of the site as this is also decisive for classification. A small place with a low bird population may actually be a severe problem. Hence, good judgment and experience for interpretation are important in classifying the problem. **- The distance between trays should be:** <u>400g and 280g Cartridges:</u> Place about 20g(±4g) at a distance of: • Nest places: ~10-15cm • High problem areas: ~15cm • Medium problem areas: ~20-25cm • Low problem areas: ~25-30cm <u>20g Pre-filled Trays</u> • Nest places: ~10-15cm • High problem areas: at a distance of ~15cm • Medium problem areas: at a distance of ~20-25cm • Low problem areas: at a distance of ~25-30cm - If necessary; the product dose can be increased by adding more product per tray or reducing the distance between trays according to the case. - No periodic application is required, once the pest has been controlled, the trays can be removed after a period of at least 6 months. - Each installation site is different and needs to be considered and studied taking into account all environmental and structural conditions. - The distance between trays can be increased or decreased accordingly. - For larger surfaces sometimes it may be necessary to add more lines for severe cases. - To treat problems with small birds such as sparrows, it is recommended to make a strip/line shape of about ~ 1cm of product thickness instead of the use with trays. Support materials such as plastic gutters can be used to adhere on the structure. <u>* Notes for Professionals</u>

	Follow-ups are recommended for instalations where the problem persists after 2 weeks of placement to determine the cause. This may be due to: • Insufficient quantity per m^2. Solution: Add more trays with product. • Incorrect estimation of the number of birds (less than the actual). Solution: Reduce the distance between trays by adding more. • Inefficient adhesion of the tray. Solution: fix trays again with good quality silicon. • Larger birds: add more quantity per tray. • Incorrect estimation of nests. Solution: Add trays with product at a shorter distance. * Note for Non-Professionals - If trays get emptied, replace them with new ones. - Add a second line for severe cases. - In the case that the plague persists after 2 weeks of placement, add more trays, it is due to an insufficient amount per m2. - If the pest persists after 6 months that the product has been properly installed, contact a professional. - For larger surfaces or with difficult access contact a professional.
Categories of users	Industrial Trained profesional Professional General public (non-professional)
Pack sizes and packaging material	- 280g Cartridges, HDPE - 400g Cartridges, PP - 20g pre-filled trays, PA (2 trays closed together forming a capsule) • Box of 8 pre-filled trays (4 capsules) • Box of 16 pre-filled trays (8 capsules) • Box of 32 pre-filled trays (16 capsules)

2.2.2. Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	n/a	n/a	n/a	n/a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Colour at 20 °C and 101.3 kPa	n/a	n/a	n/a	n/a
Odour at 20 °C and 101.3 kPa	n/a	n/a	n/a	n/a
Acidity / alkalinity	n/a	n/a	n/a	n/a
Relative density / bulk density	n/a	n/a	n/a	n/a
Storage stability test – **accelerated storage**	CIPAC 4956/m MT 46.3 (54ºC for 14 days) Gravimetric Analysis (internal procedure)	Active substances: Pepermint oil (0.37%) Lavender oil (0.12%) Rest: Inactive Components	Satisfactory Loss of active components < 10%	Report 17C001
	-	-	Storage conditions: 15 days at 54ºC Parameters: Visual Inspection: t(0d) and t(15d): no changes Organoleptic properties: t(0d) and t(15d): no changes pH: t(0d)= 5,2 and t(15d)= 5,2 Density(g/ml): t(0d)= 0,963 and t(15d)= 0,965 Chemical composition: t(0d) and t(15d): <10% Molecular structure:	Informe Técnico 20C001_02

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			t(0d) and t(15d): no changes Loss of mass packaging (for both active substances): t(0d) and t(15d): <2%	
Storage stability test – **long term storage at ambient temperature**	n/a -	n/a -	n/a Storage conditions: 36 months at 23,2ºC Parameters: Inspection: t(0m) and t(36m): no changes Organoleptic properties: t(03) and t(36m): no changes pH: t(0m)= 5,2 and t(36m)= 5,2 Density(g/ml): t(0m)= 0,963 and t(36m)= 0,965 Chemical composition: t(0m) and t(36m): <10% Molecular structure: t(0m) and t(36m): no changes Loss of mass packaging (for	n/a Informe Técnico 20C001_02

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			both active substances): t(0m) and t(36m): <2%	
Storage stability test – **low temperature stability test for liquids**	n/a	n/a	n/a	n/a
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	n/a	n/a	n/a	n/a
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	n/a	n/a	n/a	n/a
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	n/a	n/a	n/a	n/a
Wettability	n/a	n/a	n/a	n/a
Suspensibility, spontaneity and dispersion stability	n/a	n/a	n/a	n/a
Wet sieve analysis and dry sieve test	n/a	n/a	n/a	n/a
Emulsifiability, re-emulsifiability and emulsion stability	n/a	n/a	n/a	n/a
Disintegration time	n/a	n/a	n/a	n/a
Particle size distribution, content of dust/fines, attrition, friability	n/a	n/a	n/a	n/a
Persistent foaming	n/a	n/a	n/a	n/a
Flowability/Pourability/Dustability	n/a	n/a	n/a	n/a
Burning rate — smoke generators	n/a	n/a	n/a	n/a
Burning completeness — smoke generators	n/a	n/a	n/a	n/a
Composition of smoke — smoke generators	n/a	n/a	n/a	n/a
Spraying pattern — aerosols	n/a	n/a	n/a	n/a
Physical compatibility	n/a	n/a	n/a	n/a
Chemical compatibility	n/a	n/a	n/a	n/a
Degree of dissolution and dilution stability	n/a	n/a	n/a	n/a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	n/a	n/a	n/a	n/a
Viscosity	-	-	42 cSt (40ºC)	Technical Data Sheet Supplier

Conclusion on the physical, chemical and technical properties of the product

The applicant has submitted a technical data sheet of the BASE used in the composition of the biocidal product. The viscosity is 42 cSt (40ºC) and therefore is not necessary to classify the product as H304, Cat. 1

The long term stability test is ongoing. A post-authorisation condition is included in the terms and conditions of the authorization certificate.

Post-authorisation (April 2021):

There is sufficient scientific and technical justification to affirm that the product is stable and does not suffer any degradation that affect its repellency characteristics that are actually based in the essential oils organoleptic properties.

Furthermore, considering the efficacy trials presented together with the physical and chemical test, we grant a shelf-life of 2 years.

It is not possible to directly analyse the mixture with any known technique as in order to recover the active ingredients, the final product would have to be heated up to the melting/flash point of >150°C in order to obtain a sample for testing. In consequence, the mixture will be pushed into a phase change where, most of the properties of the active substances will be lost. The structural part of the active substances will brake and since they are essential oils, they would rapidly degrade after they pass their flash point (65°C-70°C). Moreover, this would translate into losing all of the more than 200 compounds found in the already low concentrated natural essential oils.

2.2.3. Physical hazards and respective characteristics

Conclusion on the physical hazards and respective characteristics of the product

No data were submitted regarding the physical hazards and respective characteristics of the product.

The active substance was not found to be explosive, oxidising or flammable. In the SDS provided by the applicant, neither BYEPEST1, nor any of the coformulants were described as being explosive, oxidising or flammable.

2.2.4. Methods for detection and identification

Conclusion on the methods for detection and identificationof the product

No data were submitted regarding the methods for detection and identification of the product.

2.2.5. Efficacy against target organisms

2.2.5.1. Function and field of use

ByePest 1 is a repellent (PT19) to be used against birds.

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

ByePest1 is used to control mainly urban pigeons (*Columba livia*) although othe kind of birds can also be controlled like seagulls (*Larus carnus*).

The product is used to protect building or structures, indoor and outdoor, such as: windows, roof lines, roof tops, cornices, protusions, facades, surfaces and similar structures on terraces, houses, signs, lights guardrail, handle bars, billboards, bridges, churches, monuments, train stations, parking lots, bus stops, barns, warehouses, factories, industrial warehouses, stadiums, airports, metro stations, etc.

2.2.5.3. Effects on target organisms, including unacceptable suffering

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 mode of action is an olfactory repellent due to natural oils.

According to the applicant: " *The product acts as a deterreen and habits modifier in birds, intimidating them by means of the smell and the freshness that the active substances produce. The freshness produced by peppermint, temporarily disturbs the orientation ability of the bird. The product has an inmmediatley effect on birds. After the placement, birds will try to approach the place but will be deterred by the smell and the look of the product. During the following days some birds make various attempts to return to the place treated, but they feel surrounded by an uncomfortable sensation that displeaces them, and they end up leaving the place, looking for a new one where they can continue with their lives without being harassed. Once they get used to the new place, they do not return to the place treated, since they do not feel the need anymore*".

2.2.5.5. Efficacy data

The following table summaries the efficacy tests submitted by the applicant:

<table>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>PT 19 Repellent against nuisance birds</td><td>Byebirds</td><td>Columbia Livia (common pigeon)</td><td>Field test conducted in a flour company in Colombia.

Two areas are compared in the same building: one to be treated with tested product and a second one with no treatment.

Preatment: visually determination during 2 week. Number of birds: 10. The level of infestation is classified as low.

Test period: 20 g of product are applied every 25 cm.</td><td>After 21 days of the application, the treated area is pigeon free.

The trays were removed six months after the application and the area remained pigeons free.</td><td>Colombia</td></tr>
<tr><td></td><td>Byebirds IVORY</td><td>Columbia Livia (common pigeon)

Seagull</td><td>Field test conducted in advertising signs in an office building, Santander, Spain.

Three areas are compared: one to be treated with the tested product, a second one with product without active substances and another one with no treatment.

Pretreatment: visual determination during 2</td><td>
<table>
<tr><th>CONTROL – WITH NO ACTIVE SUBSTANCE</th><th>Number of birds in the area</th><th>Droppings in the area</th><th>Nest in the area</th></tr>
<tr><td>1st visit</td><td>2</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 1</td><td>4</td><td>YES</td><td>NO</td></tr>
<tr><td>Weekly visit 2</td><td>2</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 1</td><td>2</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 2</td><td>4</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 3</td><td>2</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 4</td><td>2</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 5</td><td>3</td><td>YES</td><td>1</td></tr>
<tr><td>Monthly visit 6</td><td>2</td><td>YES</td><td>1</td></tr>
</table>
<table>
<tr><th>TREATED</th><th>Number</th><th>Droppings</th><th>Nest</th></tr>
</table>
</td><td>Santander</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>weeks. Number of birds: 6 pigeons and 4 seagulls and 2 pigeon nests. The level of infestation is classified as medium.

Test period: 20 g of product are applied every 20 cm except in nest sites where the product was applied every15 cm, according to the label claim.

Post-treatment: sites are checked weekly during the first two weeks and then monthly during the first 6 months.</td>
<td>
<table>
<tr><th>AREA WITH TESTED PRODUCT</th><th>of birds in the area</th><th>in the area</th><th>in the area</th></tr>
<tr><td>1st visit</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 3</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 4</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 5</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 6</td><td>0</td><td>NO</td><td>NO</td></tr>
</table>
<table>
<tr><th>CONTROL – AREA WITHOUT TREATMENT</th><th>Number of birds in the area</th><th>Droppings in the area</th><th>Nest in the area</th></tr>
<tr><td>1st visit</td><td>6</td><td>YES</td><td>0</td></tr>
<tr><td>Weekly visit 1</td><td>4</td><td>YES</td><td>0</td></tr>
<tr><td>Weekly visit 2</td><td>6</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 1</td><td>6</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 2</td><td>4</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 3</td><td>6</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 4</td><td>6</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 5</td><td>3</td><td>YES</td><td>0</td></tr>
<tr><td>Monthly visit 6</td><td>6</td><td>YES</td><td>0</td></tr>
</table>
</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Byebirds</td>
<td>Columbia Livia (common pigeon)</td>
<td>Field test conducted in house of the Eagle and the Vine, Santillana del Mar, Spain.

Two areas are compared: onte to be treated with the tested product and a second one adjacent with no treatment.

Pretreatment: visual determination during 2 weeks. Number of birds:</td>
<td>
<table>
<tr><th>TREATED AREA WITH TESTED PRODUCT</th><th>Number of birds in the area</th><th>Droppings in the area</th><th>Nest in the area</th></tr>
<tr><td>1st visit</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 3</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 4</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 5</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 6 (removal of</td><td>0</td><td>NO</td><td>NO</td></tr>
</table>
</td>
<td></td>
<td>Santillana</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 pigeons and 2 pigeon nests. The level of infestation is classified as medium.

Test period: 20 g of product are applied every 20 cm except in nest sites where the product was applied every15 cm, according to the label claim.

Post treatment: sites are checked weekly during the first two weeks and then monthly during the first 6 months. In addition, two more visits were done after the removal of the product.</td>
<td>
<table>
<tr><td>the product)</td><td></td><td></td><td></td></tr>
<tr><td>Monthly visit 7</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 8</td><td>0</td><td>NO</td><td>NO</td></tr>
</table>
<table>
<tr><th>CONTROL – AREA WITHOUT TREATMENT</th><th>Number of birds in the area</th><th>Droppings in the area</th><th>Nest in the area</th></tr>
<tr><td>1st visit</td><td>5</td><td>YES</td><td>2</td></tr>
<tr><td>Weekly visit 1</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Weekly visit 2</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 1</td><td>5</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 2</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 3</td><td>5</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 4</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 5</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 6 (removal of the product)</td><td>4</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 7</td><td>3</td><td>YES</td><td>2</td></tr>
<tr><td>Monthly visit 8</td><td>5</td><td>YES</td><td>2</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Byebirds</td>
<td>Sparrow</td>
<td>Field test in private house in Tequisquiapan, Queretaro, Mexico.

Pretreatment: visual determination during 2 weeks. Number of birds: 8 sparrows and 2 nests. The level of infestation is classified as medium.

Test period: 20 g of product are applied every 20 cm, according to the label claim

Post treatment: site was checked weekly during the first two weeks and</td>
<td>
<table>
<tr><th>TREATED AREA WITH TESTED PRODUCT</th><th>Number of birds in the area</th><th>Droppings in the area</th><th>Nest in the area</th></tr>
<tr><td>1st visit</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 3</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 4</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 5</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 6 (removal of the product)</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 7</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 8</td><td>0</td><td>NO</td><td>NO</td></tr>
</table>
</td>
<td></td>
<td>Tequisquiapan</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>then monthly during the first 6 months. In addition, two more visits were done after the removal of the product.</td><td></td><td></td></tr>
<tr><td></td><td>Byebirds</td><td>Columbia Livia (common pigeon)</td><td>Field test conducted on the Yoshizuka brigde, Fukuoka, Japan.

Pretreatment: bird monitoring and census tecniques were used during a week for daily visits at dawn. Four nests and 11 pigeons were found. The level of infestation is classified as high.

Test period: 20 g of product was applied every 20cm in perching sites and every 15 cm in nesting areas.
The application was divided into 3 zones: zone A: abutment; zone B: pillars and zone C: small pillar and wyo stretches of the bridge joist.

Post treatment: site was checked weekly during the first two weeks and then monthly during the first 6 months. In addition, two more visits were done after the removal of the product.</td><td>
<table>
<tr><th>TREATED AREA WITH TESTED PRODUCT</th><th>Number of birds in the treated zones</th><th>New droppings in the treated zones?</th><th>New nest in the treated zones?</th></tr>
<tr><td>1st visit</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Weekly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 1</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 2</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 3</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 4</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 5</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 6</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 7</td><td>0</td><td>NO</td><td>NO</td></tr>
<tr><td>Monthly visit 8</td><td>0</td><td>NO</td><td>NO</td></tr>
</table>
</td><td>Yoshizuka</td></tr>
</table>

<table>
<tr>
<td>PT 19
Repellent against nuisance birds</td>
<td>Byebirds
Manufactured: 2017.</td>
<td>Bubulcus ibis
(Cattle egret)</td>
<td>Field test on a conveyor of milling plant.
Pretreatment: bird monitoring and census tecniques were used during a week for daily visits at dawn.
More than 200 calltes egrest were found. The level of infestation is classified as severe.
1 control.
Sites:
- Baranda: 50 tray (20g /tray). 15 cm distance between trays.
- Upper structure 50m: 334 trays (20g/tray).
Total numbers of meters: 57.5m
Total number of trays: 384
Quantyty of product: 7.68Kg
Time duration of installed tays: 6 months.</td>
<td>The result of application was rate 100% satisfactory.
The egrets left the conveyor number 1 on the same day of application. Some tried to perch but then left the place upon perceivin the product.
Out of the more than 200 egrets, only 10 egrets were observed on conveyor number 1 the day after the application. They perched along a conveyor number 1, flying frm the treated area to the untreated area back and fort.

No extra application was perforked or required.
No post-treatment has been required.
<table>
<tr><th></th><th>Nº of egrets In the treated area. (Conveyor 1)</th><th>Nº of egrets near the treated area (Converyor 1)</th><th>Nº egrets in areas non treated.</th></tr>
<tr><td>1st visit</td><td>0</td><td>10</td><td>≥200</td></tr>
<tr><td>Week 1</td><td>0</td><td>0</td><td>≥200</td></tr>
<tr><td>Week 2</td><td>0</td><td>0</td><td>≥200</td></tr>
<tr><td>Month 3</td><td>0</td><td>0</td><td>≥200</td></tr>
<tr><td>Month 6 (removal of the product)</td><td>0</td><td>0</td><td>≥200</td></tr>
<tr><td>Month 12</td><td>0</td><td>0</td><td>≥200</td></tr>
</table>
</td>
<td>2019-2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Columbia livia
(common pigeon)</td>
<td>Field test
Pretreatment: bird monitoring and census tecniques were used during a week for daily visits at dawn.
More than 40 pigeons were found. The level of infestation is classified as severe.
Sites:
- Ridge 5m: 35 tray (20g /tray). 15 cm distance between</td>
<td>The result of application was rated as 100% satisfactory.
The pigeons left the warehouse roof on the sane day of the application. It was observed how the pigeons flew over the warehouse, approaching and moving away from the treated area. Some tried to perch but then left the place upon perceiving the product.
The pigeons change their habit of perching in the roof and began to do it in the buildings behind and beside the warehouse plus in the truck washing area right in front of the treated warehouse.

No post-treatment has been required.
<table>
<tr><th></th><th>Nº pigneons in the roof treated.</th><th>Nº pingeons in other areas not</th></tr>
</table>
</td>
<td></td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>trays.
- Ledge 5m: 35 trays (20g/tray).
Total numbers of meters: 10m
Total number of trays: 70
Quantyty of product: 1.4Kg
Time duration of installed tays: 6 months</td>
<td>
<table>
<tr><td></td><td></td><td>treated.</td></tr>
<tr><td>1st visit</td><td>0</td><td>≥40</td></tr>
<tr><td>Week 1</td><td>0</td><td>≥40</td></tr>
<tr><td>Week 2</td><td>0</td><td>≥40</td></tr>
<tr><td>Month 3</td><td>0</td><td>≥40</td></tr>
<tr><td>Month 6 (removal of the product)</td><td>0</td><td>≥40</td></tr>
<tr><td>Month 12</td><td>0</td><td>≥40</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

Conclusion on the efficacy of the product

The applicant has submitted 5 field tests in order to proved the efficacy of the product against birds.

The BYEPEST family has two products, the difference between them is the presence of one particular non-active substance in the BYEBIRDS product. The main study "SANTANDER" has been made with the BYEBIRS YVORY product.
The applicant has justified that the presence / absence of that co-formulant does not affect efficacy.
We accept this justification. (See confidential annex to more information. Section 3)

The dosage used in these field trials are related to the infestation level according to the next table provided by the applicant:

Infestation Level	Number of Birds	Number of nests
Low/Small	1 to 10	0
Medium	1 to 10	1-2
High/Severe	More than 10	1 or more nests

And after deciding the infestation level, the application dosage is determine by the following guidelines:

Infestation level	Amount of product	Distance between trays
Nest sites	20g-30g	10cm-15cm
High	20g-25g	15cm-20cm
Medium	16g-20g	20cm-25cm
Low	16g-20g	25cm-30cm

The tested product used in the efficacy studies is a product contained in the family, so ES CA considers acceptable this product as a representative of the product contained within the family.

Although the product contains *a particular non-active substance* as a coformulant, the applicant has submitted a justification in relation to its function in the biocidal product, the ES CA considers this justification acceptable. Please see annex confidential. (Section 4)

The ES CA considers the test reference: Santander as a key study in order to proved the efficacy of the product. In this field trial three areas are compared: one of them treated with the product, a second one treated with the product without active substances and another one without any treatment. As a standard method for performing this kind of study does not exist, the applicant has followed the general rules for the design of field trial. The pretreatment period during two weeks permits to know the level of infestation and so, during the test period the tested product is applied as the label claim recommendation. After one day of product application, the number of birds in the treated areas is zero while in the other two areas (treated with product without active substances and with any treatment), the birds number is similar to the pretreatment period. This is mantained during the post-treatment until 6 weeks.

Test Reference: Colombia and Santillana are also demonstrated that the product is efficacious when it is applied at the recommended dosage. Both of them included a control

site in order to compare the results obtained and the tests reflects that the number of birds in the treated area is zero since the application.

Test Reference: Tequisquiapan and Yoshizuka are considered by ES CA as an additional information in order to support the other studies submitted. In both studies are also showed that the birds number in the treated area is reduced but these studies do not include a control area therefore the effect of the biocidal product cannot be compared.

Aged product (post-authorisation):
The applicant has submitted a new trail (2019-2020) to support the self-life. According to the test, the product has been manufactured and stored for more than 2 years. It was kept in a warehouse under normal ambient conditions with no direct light or humidity.
The test follows the same methodology as the previous tests and it has shown a repellent efficacy of 100%, both in egrets and pigeons.

Conclusion

ES CA considers that the BPF ByePest1 is efficacious as bird repellent according to the information provided.
However, the dosage used in the field trials for low and medium infestation was 20g, therefore the lower dose proposed by the applicant (16 g) has not been demonstrated. ES CA considers that in order to align the dosage of the product with the efficacy studies the lower dosage for low and medium infestation is 20 g.
Overall efficacy against seagulls has only been demonstrated in one trial with 4 adults. That is why we consider that the efficacy has only been demonstrated for low infestations, so the phrase will be included in the SPC: *Apply the product only against seagulls when the first signs of infestation appear and few individuals*.
Likewise, we consider that for renewal a new test against seagulls for high infestation should be provided.

2.2.5.6. Occurrence of resistance and resistance management

Due to the mode of action, the occurrence of resistance is very unlikely. However, 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

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

- *'For deterring common pigeons and common seagull from buildings and other structures when applied according to instructions'*
- *'Remaining effective for a period of 6 months'*

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

BYEPEST1 is not intended to be used in combination with other biocidal products.

2.2.6. Risk assessment for human health

This is no data requirement for an application in accordance with Art.25 of Regulation (EU) 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.

According to Article 25 a simplified authorization procedure may be applied where the product does not contain any substance of concern (SoC), and the handling of the biocidal product and its intended use do not require personal protective equipment (PPE).

Material safety data sheets (SDS) have been submitted for each active substance and co-formulant of "BYEPEST1". SDS have been checked for classification.

No classification is required for acute toxicity, irritation or sensitisation. However, according to SDS, the active substances *Lavender oil* and *Peppermint oil* are classified as skin sensitizer (H317) due to the presence of some components which are classified as sensitizer. Thus, the composition certificates of the active substances have been required and submitted by the applicant. According to this, the allergen components are below the 0.1% limit for elicitation. Therefore, the phrase EUH208 should not be included on the product labels.

There are no substances of concern present and the BYEPEST1 family is not classified, therefore the ES CA considers that a detailed exposure assessment is not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.7. Risk assessment for animal health

There are no substances of concern present and the product is not classified, therefore the ES 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

The formulation "BYEPEST1" has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25). An assessment of potential SOC's (Substances of Concern) has been made. The co-formulants are either not classified as hazardous to the environment under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification on their own. Therefore no SOC's are considered to be present in the formulation "BYEPEST1". On this basis approval of "BYEPEST1" can be authorised from an environmental perspective under the simplified authorisation procedure (Reg. (EU) 528/2012, chapter V, article 25).

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

BYEPEST1 is not intended to be used in combination with other biocidal products.