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 APPLICATION

(submitted by the competent authority)

BROS Peletab eemale mutte, koeri ja kasse

Product type 19

Propionic acid and Citronellal as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-BH086232-52

Competent Authority: Estonia

Date: 27.09.2023

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	Estonia	BC-BH086232-52	29.09.2023	Initial authorisation	

1 Conclusion

BROS Peletab eemale mutte, koeri ja kasse is a granule formulation biocidal product containing propionic acid and citronellal as active substances. The product is used as a product type 19 by non-professional users (general public) to repel moles, dogs and cats where they can be a nuisance to people.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses as repellent against moles, dogs and cats by non-professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substances propionic acid and citronellal are listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that propionic acid concentration in the product is limited so that the product is not classified;
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary.

The biocidal product does not contain any non-active substance(s) (so called "co-formulant(s)") which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity and quantity requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substances is available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

Analytical methods for monitoring of soil, air, water, animal, and human body fluids, and food and feeding stuff are not required for simplified authorisations according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against moles (*Talpa europaea*), dogs (*Canis lupus familiaris*) and cats (*Felis catus*) for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

Human health risk assessment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. The product contains active substances propionic acid and citronellal which are listed in Annex I of Regulation (EU) 528/2012 and no substances of concern.

Risk assessment for animal health

The product does not contain any substances of concern regarding animal health.

Risk assessment for the environment

No substance of concern regarding environment was identified. Environmental risk assessment is not required according to Article 25 and Article 20(1)(b) of Regulation

(EU) No 528/2012.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	PT19
Type(s) of formulation	GR - granule

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	Solid repellent against moles	PT 19	European mole (*Talpa europaea)* – all developmental stages	Manual application into the entrance of mole tunnel	20 g (approx. 2 tablespoons) per molehill To be used every 4 weeks or after rainfall	General public (non-professional)	A	
2	Solid repellent against dogs and cats	PT 19	Dog (*Canis lupus familiaris*) – all developmental stages and Cat (*Felis catus*) – all developmental stages	Manual application onto the surface	40 g (approx. 4 tablespoons) per 1 m^2 To be used every 2 weeks or after rainfall		A	

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance

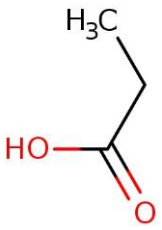
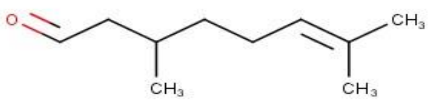
Main constituent(s)	
Common name	Propionic acid
Chemical name	Propionic acid
EC number	201-176-3
CAS number	79-09-4
Index number in Annex VI of CLP	607-089-00-0
Minimum purity / content	≥ 99.5%
Structural formula	

Table 2.4 Identity of the active substance

Main constituent(s)	
Common name	Citronellal
Chemical 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 applicable
Minimum purity / content	≥ 96%
Structural formula	

2.5 Information on the sources of the active substances

The information on the sources of the active substances propionic acid and citronellal is not applicable.

2.6 Candidate(s) for substitution

Not relevant.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

2.8 Classification and labelling

Table 2.5 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code	No hazard phrases assigned.	not applicable
Hazard Pictograms	No hazard pictograms assigned	not applicable
Signal word(s)	not applicable	not applicable
Hazard statements	not applicable	not applicable
Precautionary statements*	not applicable	not applicable
Supplemental hazard statements	not applicable	
Notes	not applicable	

***P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

Letter of access is not applicable for simplified authorisations according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. The active substances are included in Annex I of BPR.

2.10 Data submitted in relation to product authorisation

Not applicable. No new data on the active substance has been submitted.

2.11 Similar conditions of use across the Union

Not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	50g, 100g, 120g, 150g, 200g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g, 1000g	High density polyethylene (HDPE), low density polyethylene (LDPE), polyethylene (PE), polyethylene terephthalate (PET), polypropylene (PP)	PE, PP, PET, HDPE, LDPE	Non-professional	YES
Bucket	50g, 100g, 120g, 150g, 200g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g, 1000g	HDPE, LDPE, PE, PET, PP	PE, PP, PET, HDPE, LDPE	Non-professional	YES
Container	50g, 100g, 120g, 150g, 200g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g, 1000g	PE, PP, PET, HDPE, LDPE	PE, PP, PET, HDPE, LDPE	Non-professional	YES
Bag	50g, 100g, 120g, 150g, 200g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g,	PET/metallized polyethylene terephthalate (PETMET)/PE, PET/ALU/PE, PET/PE, polyamide (PA)/PE, PE, PE/PE, PE/ethylene-	Not applicable.	Non-professional	YES

	1000g	vinyl acetate (EVM), LDPE, PETMET/PE, PET/PE(ethylene-vinyl alcohol copolymer (EVOH))			
Sachet	50g, 100g, 120g, 150g, 200g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g, 1000g	PET/PE	Not applicable.	Non-professional	YES

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	OPPTS 830.6302 to 04.	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Solid	BR-011/19 (2022)
3.1.1.	Physical state at 20 °C and 101.3 kPa		BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Solid	BR-011/19 (2022)
3.1.2.	Colour at 20 °C and 101.3 kPa		BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Brownish	BR-011/19 (2022)
3.1.3.	Odour at 20 °C and 101.3 kPa		BROS Odstrasza krety psy i koty.Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Characteristic	BR-011/19 (2022)
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	1% solution: 5.5	BR-011/19 (2022)
3.3.	Relative density / bulk density	OECD 109 / CIPAC MT 186	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Relative density: 0.98 g/ml Bulk density: Pour 0.437 g/ml, Tapped:	BR-011/19 (2022)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				0.585 g/ml	
3.4.1.1.	Storage stability test – **accelerated storage**	Waived		The accelerated storage is not required. Storage stability is based on the efficacy results after 3 years of storage at ambient temperature according to BPR Guidance Vol II (Parts B+C) 2022 and document CA-May14-Doc.5.5-Final on the shelf-life data under the simplified procedure.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Based on efficacy results	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	Product is efficacious after 3 years of storage at ambient temperature based on efficacy results with stored product according to the BPR Guidance Vol II (Parts B+C) 2022 and document CA-May14-Doc.5.5-Final on the shelf-life	TROJSTIG/MDC 55 LQ/2609-31102022 (2022); TROJSTIG/MDC 55 LQ/18102022 (2022)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				data under the simplified procedure.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived	-	Not required	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waived	-	The product is stored in the package that precludes the effect of light.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived	-	Storage stability is based on the efficacy results after 3 years of storage at ambient temperature according to BPR Guidance Vol II (Parts B+C) 2022 and document CA-May14-Doc.5.5-Final on the shelf-life data under the simplified procedure.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual assessment	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	The package stability was checked and confirmed its suitability. There is no leakage or deformation of the packaging material	BR-011/19 (2022)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				after 3 years of storage	
3.5.1.	Wettability	Waived	-	The product is not intended to be mixed with water.	-
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Waived	-	The product is not intended to be mixed with water.	-
3.5.3.	Wet sieve analysis and dry sieve test	Waived	-	Not required the product is a granule formulation and will not go through the sieves	-
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	Not required the product is a granule formulation.	-
3.5.5.	Disintegration time	Waived	-	Not required the product is not a tablet.	-
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	Waived	-	Not required. Technically not feasible to perform such a study	-
3.5.7.	Persistent foaming	Waived	-	Not relevant. The product is a granule and not intended to be mixed with water.	-
3.5.8.	Flowability/pourability/dustability	Waived	-	Not required. Technically not feasible	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				to perform such a study	
3.5.9.	Burning rate — smoke generators	Waived	-	Not required the product is not a smoke generator.	-
3.5.10.	Burning completeness — smoke generators	Waived	-	Not required the product is not a smoke generator.	-
3.5.11.	Composition of smoke — smoke generators	Waived	-	Not required the product is not a smoke generator.	-
3.5.12.	Spraying pattern — aerosols / spray	Waived	-	Not required the product is not an aerosol.	-
3.6.1.	Physical compatibility	Waived	-	Not applicable since the product is not intended to be used with other products.	-
3.6.2.	Chemical compatibility	Waived	-	Not applicable since the product is not intended to be used with other products.	-
3.7.	Degree of dissolution and dilution stability	Waived	-	The product is not intended to be mixed with water.	-
3.8.	Surface tension	Waived	-	Not required the product is a granule formulation.	-
3.9.	Viscosity	Waived	-	Not required the product is a	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				granule formulation.	

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
BROS Peletab eemale mutte, koeri ja kasse is a granule (GR) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The biocidal product is stable after 3 years of storage in ambient conditions based on efficacy assessment with stored product. **Implications for labelling:** Reapply the product after rainfall. Do not use in the winter, or on snow and below 0ºC. Do not treat plant's leaves and grass as it may cause temporary yellowing caused by the contact with the active substance, which passes after about 2-3 weeks.

3.3 Physical hazards and respective characteristics

The product BROS Peletab eemale mutte, koeri ja kasse, which is applied for under the simplified application procedure, does not have physical hazards.

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	Waived	-	Not required for simplified authorization
4.2.	Flammable gases	Waived	-	Not required for simplified authorization
4.3.	Flammable aerosols	Waived	-	Not required for simplified authorization
4.4.	Oxidising gases	Waived	-	Not required for simplified authorization
4.5.	Gases under pressure	Waived	-	Not required for simplified authorization
4.6.	Flammable liquids	Waived	-	Not required for simplified authorization
4.7.	Flammable solids	Waived	-	Not required for simplified authorization
4.8.	Self-reactive substances and mixtures	Waived	-	Not required for simplified Waived authorization
4.9.	Pyrophoric liquids	Waived	-	Not required for simplified authorization
4.10.	Pyrophoric solids	Waived	-	Not required for simplified

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				authorization
4.11.	Self-heating substances and mixtures	Waived	-	Not required for simplified authorization
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waived	-	Not required for simplified authorization
4.13.	Oxidising liquids	Waived	-	Not required, product is not a liquid.
4.14.	Oxidising solids	Waived	-	Not required for simplified authorization
4.15.	Organic peroxides	Waived	-	Not required for simplified authorization
4.16.	Corrosive to metals	Waived	-	Not required, product is not a liquid.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waived	-	Not required, product is not a liquid.
4.17.2.	Relative self-ignition temperature for solids	Waived	-	Not required for simplified authorization
4.17.3.	Dust explosion hazard	Waived	-	Not required for simplified authorization

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method *(SPB-FA/11 and SANCO/3030/99 rev.5 guideline): The specified quantity of the test item with an accuracy to 0.01 g was weighed into the tared grinding vessel. 45±2 g of methanol mass was added to the vessel and weighed with an accuracy to 0.01 g. About 50 g of crushing and grinding balls were added to the vessel and the vessel was closed. The sample was ground in a ball mill for 1 hour. 1.5 mL of the suspension was transferred to a test tube containing about 0.25 g of anhydrous sodium sulphate. The tube was shaken and then centrifuged. The liquid from the tube was filtered through a syringe filter into a chromatographic vial. The analysis was conducted with gas chromatograph with flame-ionization detector equipped with the column Zebron ZB-5 (30 m x 0.25 mm x 0.25 µm).*											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Citronellal	*y=687.859x -4820.44 r^2=0.999 (0.022–0.136 %w/w); n=5*	*In the analysis conditions, active substances retention times in standard solution and test item solution are comparable. No interfering peaks on chromatograms with area larger than 3% of the value of active substance peak area in test item solution at the place of active substance peak*	Level I (0.069 % w/w) Level II (0.11% w/w)	N = 2	110.8 – 115.5	113	0.6	0.036	5	Not determined	0001/0224/ FA (2023)
Propionic acid	*y=448.318x -83769.8 r^2=0.999 (0.022–0.136 % w/w); n=5*		Level I (3.15% w/w); Level II (4.70% w/w)	N = 2	97.1 – 98.7	98	0.6	3.49	5	Not determined	

Analytical methods for monitoring soil, air, water, animal and human body fluids and tissues, and for monitoring of active substances and residues in food and feeding stuff are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Validated analytical methods for the determination of propionic acid and citronellal in the biocidal product are available. Specificity, linearity, accuracy and precision were checked and found acceptable.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Main group 3: Pest control.
Product type 19: Repellents and attractants

The biocidal product BROS Peletab eemale mutte, koeri ja kasse repels moles, dogs and cats. It is a repellent in granule formulation, designed to be used by general public outdoors. The organisms to be repelled are all developmental stages of moles (*Talpa europaea*), dogs (*Canis lupus familiaris*) and cats (*Felis catus*). The objects to be protected are the areas where the presence of target organisms is a nuisance to humans.

The biocidal product BROS Peletab eemale mutte, koeri ja kasse is designed to repel moles where allowed by applicable law, and not forbidden by plant protection or animal welfare regulations (grassy airfields, hydrotechnical constructions, sport facilities, paths and alleys on private properties, fenced gardens, etc.). The biocidal product is designed to repel dogs and cats around buildings, in the gardens, around playgrounds and sports fields.

The biocidal product BROS Peletab eemale mutte, koeri ja kasse becomes effective immediately after application. In favourable weather conditions (no rainfall), it remains effective for up to 2 weeks against dogs and cats, and up to 4 weeks against moles. It must be reapplied after rainfall.
The product is intended to be used by general public (non-professional user).

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The mode of action is an olfactory repellent (propionic acid and citronellal). The product starts working immediately after application (no time delay).

The active substances of the biocidal product BROS Peletab eemale mutte, koeri ja kasse are olfactory repellents. Their effect fades out as soon as the affected target organism leave the treated area. Therefore they do not cause any unacceptable suffering to the target organisms.

3.5.3 Efficacy data

Table 3.8 Efficacy data

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects
[address here results related to efficacy of the test product and validity of the test]</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr>
<td>PT19
USE 1:
Solid repellent against moles</td>
<td>BROS Peletab eemale mutte, koeri ja kasse–granule repellent
0.09% Citronellal (w/w)
4% propionic acid (w/w)</td>
<td>Repellent/ European mole (Talpa europaea)
Only individuals from the wild population. Field experiments were carried out only where moles were harmful and a procedure was required to repel them.
- 5 replications (five separate locations with a minimum distance of 1 km from</td>
<td>Field test
The locations for the test were selected 7 days before the application of the repellent product. These sites were carefully inspected to eliminate any risk to non-target animals. Active mounds were located, counted and marked with sticks. The molehills were opened and after 24 it was checked which of them were closed by moles (active mounds). Five locations with an area of more than 500 m^2 with at least 5 active mounds were selected for the</td>
<td>Efficacy results of the biocidal product BROS Peletab eemale mutte, koeri ja kasse <u>(fresh product):</u>
<table>
<tr><th>Replication</th><th>Day after treatment (DAT)</th><th>Non-active molehills (Nk)</th><th>Active molehills</th><th>W (%)</th></tr>
<tr><td rowspan="8">Replication I</td><td>0</td><td>0</td><td>27</td><td>0.0</td></tr>
<tr><td>1</td><td>27</td><td>0</td><td>100.0</td></tr>
<tr><td>3</td><td>27</td><td>0</td><td>100.0</td></tr>
<tr><td>7</td><td>27</td><td>0</td><td>100.0</td></tr>
<tr><td>10</td><td>27</td><td>0</td><td>100.0</td></tr>
<tr><td>14</td><td>27</td><td>0</td><td>100.0</td></tr>
<tr><td>21</td><td>26</td><td>1</td><td>96.3</td></tr>
<tr><td>28</td><td>24</td><td>3</td><td>88.9</td></tr>
<tr><td rowspan="8">Replication II</td><td>0</td><td>0</td><td>25</td><td>0.0</td></tr>
<tr><td>1</td><td>25</td><td>0</td><td>100.0</td></tr>
<tr><td>3</td><td>24</td><td>1</td><td>96.0</td></tr>
<tr><td>7</td><td>24</td><td>1</td><td>96.0</td></tr>
<tr><td>10</td><td>23</td><td>2</td><td>92.0</td></tr>
<tr><td>14</td><td>23</td><td>2</td><td>92.0</td></tr>
<tr><td>21</td><td>23</td><td>2</td><td>92.0</td></tr>
<tr><td>28</td><td>22</td><td>3</td><td>88.0</td></tr>
<tr><td rowspan="8">Replication III</td><td>0</td><td>0</td><td>29</td><td>0.0</td></tr>
<tr><td>1</td><td>29</td><td>0</td><td>100.0</td></tr>
<tr><td>3</td><td>29</td><td>0</td><td>100.0</td></tr>
<tr><td>7</td><td>29</td><td>0</td><td>100.0</td></tr>
<tr><td>10</td><td>27</td><td>2</td><td>93.1</td></tr>
<tr><td>14</td><td>26</td><td>3</td><td>89.7</td></tr>
<tr><td>21</td><td>26</td><td>3</td><td>89.7</td></tr>
</table>
</td>
<td>Report No.: TROJSTIG/ MDC55LQ/ 2210-20112020 (2021)</td>
<td>6.7. – Field-test against moles (fresh sample)/
Efficacy study of the product ’BROS odstrasza krety, psy i koty’ (MDC 55 LQ) intended to repel moles</td>
</tr>
</table>

		each other)	study. All closed (active) mounds were reopened. The next day, the product was applied to the active mounds located in the study area in accordance with the method of use and in the amount consistent with the dosage 20g per mound. The controls were the same areas selected for the study, with the confirmed presence of the target animals before treatment with the tested preparation. The efficacy of the product was determined by assessing and comparing the activity of the active molehills before and after application of the tested product. The effectiveness of the tested product was						

	28	25	4	**86.2**
Replication IV	0	0	26	0.0
	1	26	0	100.0
	3	26	0	100.0
	7	26	0	100.0
	10	24	2	91.7
	14	24	2	91.7
	21	23	3	88.5
	28	21	5	**80.8**
Replication V	0	0	31	0.0
	1	31	0	100.0
	3	31	0	100.0
	7	31	0	100.0
	10	28	3	90.3
	14	27	4	87.1
	21	26	5	83.9
	28	26	5	**83.9**
Average				**85.56**

Comments:
The test is considered valid and reliable as it showed significant difference between the final number of repelled moles in comparison with the control period.

The product, after being applied to the mole mound and corridors to repel moles out of the protected area, did not show any phytotoxic effect on the lawn-forming vegetation surrounding the mound after 28 days. No changes were observed.

Conclusion:
The BROS Peletab eemale mutte, koeri ja kasse product showed high efficacy after being used in accordance with the instructions for use - it repels the moles from the treated area. The percentage of effectiveness was always **higher than 80%.**

The product is effective for at least 4 weeks after application.

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>assessed on the day of the treatment - 8 hours after the application of the product, and then after 1, 3, 7, 10, 14, 21 and 28 days from the application in a given location. For each assessment, the % efficacy was calculated.

Environmental conditions:

- temperature: 0.26°C – 18.63°C

- humidity: 68.98% – 97.40% RH

- precipitation: 0.00 mm – 3.02 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repellent/ European mole (Talpa europaea)

Only individuals from the wild population of different sexes and of different ages, living</td>
<td>Field test

5 test sites with an area of over 500 m^2 were selected 7 days before the application of the tested product. These sites were thoroughly inspected to eliminate any risk</td>
<td>Efficacy results of the biocidal product BROS Peletab eemale mutte, koeri ja kasse <u>(product aged in ambient conditions for 3 years):</u>
<table>
<tr><th>Replication</th><th>Day after treatment (DAT)</th><th>Non-active molehills (Nk)</th><th>Active molehills</th><th>W (%)</th></tr>
<tr><td rowspan="8">Replication I</td><td>0</td><td>0</td><td>21</td><td>0.0</td></tr>
<tr><td>1</td><td>21</td><td>0</td><td>100.0</td></tr>
<tr><td>3</td><td>21</td><td>0</td><td>100.0</td></tr>
<tr><td>7</td><td>21</td><td>0</td><td>100.0</td></tr>
<tr><td>10</td><td>21</td><td>0</td><td>100.0</td></tr>
<tr><td>14</td><td>21</td><td>0</td><td>100.0</td></tr>
<tr><td>21</td><td>21</td><td>0</td><td>100.0</td></tr>
</table>
</td>
<td>Report No.: TROJSTIG/ MDC55LQ/ 2609-31102022 (2022)</td>
<td>6.7. – Field-test against moles (3 years aged sample) and influence of coffee husk on repelling efficacy of tested product on moles/

Testing the</td>
</tr>
</table>

		in areas, where they are not protected by applicable law. - 5 replications (five separate locations at least 1 km apart)	to non-target animals. The area occupied by moles was assessed and a schematic plan of the site was sketched, on which areas with molehills, near-surface channels, active mounds leading to burrows were marked with sticks. The product was applied to the active molehills located in the tested area in accordance with the directions for use and in amount of 20g per mound. The control was performed in the same areas selected for testing with the confirmed presence of the moles, but before treating it with the 3-year sample of BROS Peletab eemale mutte, koeri ja kasse product.				effectiveness of the preparation 'BROS odstrasza krety, psy i koty II' (MDC 55 LQ) designed to repel moles.

	28	19	2	**90.5**
Replication II	0	0	23	0.0
	1	23	0	100.0
	3	23	0	100.0
	7	23	0	100.0
	10	23	0	100.0
	14	21	2	91.3
	21	20	3	87.0
	28	19	4	**82.6**
Replication III	0	0	21	0.0
	1	21	0	100.0
	3	21	0	100.0
	7	21	0	100.0
	10	21	0	100.0
	14	18	3	85.7
	21	17	4	81.0
	28	17	4	**81.0**
Replication IV	0	0	25	0.0
	1	25	0	100.0
	3	25	0	100.0
	7	25	0	100.0
	10	24	1	96.0
	14	24	1	96.0
	21	23	2	92.0
	28	21	4	**84.0**
Replication V	0	0	24	0.0
	1	24	0	100.0
	3	24	0	100.0
	7	24	0	100.0
	10	21	3	87.5
	14	21	3	87.5
	21	20	4	83.3
	28	20	4	**83.3**
Average				**85.28**

Comments:
The test is considered valid and reliable as it showed significant difference between the final number of repelled moles in comparison with the control.

The product, aged for 3 years, when applied to a molehill, is not phytotoxic to the surrounding vegetation forming the lawn.

Conclusions:

The effectiveness of the product was determined by evaluating and comparing the activity of mounds before and after application of the tested product. The effectiveness of the tested product was assessed on the 1st, 3rd, 7th, 10th, 14th, 21st and 28th day after the application in a given location. For each assessment % efficacy was calculated.

The carrier of the active substances of the BROS Peletab eemale mutte, koeri ja kasse product is coffee husk, brown in color with a mild coffee aroma. Additional study was carried out in the same way as described above to test whether this component of the product has any effect on the

The BROS Peletab eemale mutte, koeri ja kasse product, aged for 3 years, showed high efficacy after being used in accordance with the label-instructions for use -it repels the moles from the treated area. The percentage of effectiveness was always **higher than 80%.**

The product, aged for 3 years, is effective in the field for at least 4 weeks after application.

<u>The carrier (coffee husk) effect on product efficacy in repelling moles:</u>

Replication	Day after treatment (DAT)	Non-active molehills (Nk)	Active molehills	W (%)
Replication I	0	0	24	0.0
	1	0	24	0.0
	3	0	24	0.0
	7	0	24	0.0
	10	0	24	0.0
	14	0	24	0.0
	21	0	24	0.0
	28	0	24	0.0
Replication II	0	0	20	0.0
	1	0	20	0.0
	3	0	20	0.0
	7	0	20	0.0
	10	0	20	0.0
	14	0	20	0.0
	21	0	20	0.0
	28	0	20	0.0
Replication III	0	0	18	0.0
	1	0	18	0.0
	3	0	18	0.0
	7	0	18	0.0
	10	0	18	0.0
	14	0	18	0.0
	21	0	18	0.0
	28	0	18	0.0
Replication IV	0	0	27	0.0
	1	0	27	0.0
	3	0	27	0.0

			product efficacy. Environmental conditions: - temperature: 10°C – 15°C - humidity: 65% – 75% RH	<table><tr><td rowspan="5"></td><td>7</td><td>0</td><td>27</td><td>0.0</td></tr><tr><td>10</td><td>0</td><td>27</td><td>0.0</td></tr><tr><td>14</td><td>0</td><td>27</td><td>0.0</td></tr><tr><td>21</td><td>0</td><td>27</td><td>0.0</td></tr><tr><td>28</td><td>0</td><td>27</td><td>0.0</td></tr><tr><td rowspan="9">Replication V</td><td>0</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>1</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>3</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>7</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>10</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>14</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>21</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td>28</td><td>0</td><td>17</td><td>0.0</td></tr><tr><td colspan="4">Average</td><td>0.0</td></tr></table> **Conclusions:** Coffee husk, the carrier of the active substances of the BROS Peletab eemale mutte, koeri ja kasse product, has no effect on the efficacy. When coffee husk without active substance was used in a similar manner to the biocidal product, it was not found to attract or repel moles. After 4 weeks from the application of the coffee husk (DAT 28), the number of mounds did not change at the selected treated sites.		
PT19 USE 2: Solid repellent against dogs and cats	BROS Peletab eemale mutte, koeri ja kasse – granule repellent 0.09% Citronellal (w/w) 4% propionic	Repellent/ Dogs (*Canis lupus familiaris*) and cats (*Felis catus domesticus*) Dogs and cats, of different sexes and of different ages, of any breed,	**Field test** 5 separate test sites for dogs and 5 separate locations for cats were selected in a closed housing estate (one location = one replication), where at least two of signs of dog or cat activities were found. In the morning and in	Efficacy results of the biocidal product **BROS Peletab eemale mutte, koeri ja kasse <u>(product aged in ambient conditions for 3 years)</u>** <u>against dogs:</u> <table><tr><th>Replication</th><th>Day after treatment (DAT)</th><th>Number of sites with no animal activity</th><th>W (%)</th></tr><tr><td rowspan="8">Replication I</td><td>0</td><td>0</td><td>0.0</td></tr><tr><td>1</td><td>5</td><td>100.0</td></tr><tr><td>2</td><td>5</td><td>100.0</td></tr><tr><td>3</td><td>5</td><td>100.0</td></tr><tr><td>7</td><td>5</td><td>100.0</td></tr><tr><td>10</td><td>5</td><td>100.0</td></tr><tr><td>14</td><td>5</td><td>100.0</td></tr><tr><td rowspan="3">Replication II</td><td>0</td><td>0</td><td>0.0</td></tr><tr><td>1</td><td>5</td><td>100.0</td></tr><tr><td>2</td><td>5</td><td>100.0</td></tr></table>	Report No.: TROJSTIG/ MDC55LQ/ 18102022 (2022)	6.7. – Field-test against dogs and cats (3 years aged sample) and influence of coffee husk on repelling efficacy of tested product on dogs and cats/ Efficacy test report of the

	acid (w/w)	entering the area, where they cause damage or their presence is a nuisance. - 5 separate locations for dogs and 5 separate locations for cats (one location = one replicate).	the evening, inspections were carried out to confirm the presence of at least two of signs of activity of dogs and cats in the previously selected study areas. The product was applied in the selected places by scattering 40 g of product per 1 m^2 onto the surface (grass fields or flower beds). The efficacy of BROS Peletab eemale mutte, koeri ja kasse was determined by evaluating and comparing the number of signs of activity of dogs and cats before and after application of the test product. The effectiveness of the product was assessed on the 1st, 2nd, 3rd, 7th, 10th and 14th day after the application in a				product 'BROS odstrasza krety, psy i koty II' (MDC 55 LQ) intended to repel dogs (*Canis lupus familiaris*) and cats (*Felis catus domesticus*)

	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication III	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication IV	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication V	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
			100.0

Efficacy results of the biocidal product **BROS Peletab eemale mutte, koeri ja kasse <u>(product aged in ambient conditions for 3 years)</u>** <u>against cats:</u>

Replication	Day after treatment (DAT)	Number of sites with no animal activity	W (%)
Replication I	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication II	0	0	0.0
	1	5	100.0

			given location. For each assessment % efficacy of the product was calculated. The carrier of the active substances of the product is coffee husk, brown in color with a mild coffee aroma. Additional study was carried out in the same way as described above to test whether this component of the product has an effect on the product efficacy. Environmental conditions: - temperature: 10°C – 15°C - humidity: 65% – 75% RH					

	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	4	80.0
Replication III	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication IV	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
Replication V	0	0	0.0
	1	5	100.0
	2	5	100.0
	3	5	100.0
	7	5	100.0
	10	5	100.0
	14	5	100.0
			96.0

Conclusions:

The test is considered valid and reliable as it showed significant difference between the final number of repelled animals in comparison with the control.

The product BROS Peletab eemale mutte, koeri ja kasse, aged for 3 years, showed high efficacy after being used in accordance with the label-instructions for use - it repels dogs and cats from the protected surface. The percentage of effectiveness was equal to or **higher than 80%** in all replicates of the test.

The biocidal product aged for 3 years in ambient conditions is effective in the field for at least 2 weeks after application.

The carrier (coffee husk) effect on product efficacy in repelling dogs:

Replication	Day after treatment (DAT)	Number of sites with no animal activity	W (%)
Replication I	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication II	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication III	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication IV	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication V	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
			0.0

The carrier (coffee husk) effect on product efficacy in repelling cats:

Replication	Day after treatment (DAT)	Number of sites with no animal activity	W (%)
Replication I	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication II	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication III	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication IV	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
Replication V	0	0	0.0
	1	0	0.0
	2	0	0.0
	3	0	0.0
	7	0	0.0
	10	0	0.0
	14	0	0.0
			0.0

				Conclusions: Coffee husk, the carrier of the active substances of the product, has no effect on the efficacy. 2 weeks from the application of the coffee husk, the number of activity sites of dogs and cats did not change.		

3.5.4 Efficacy assessment

Three field studies were conducted in support of the efficacy of the biocidal product BROS Peletab eemale mutte, koeri ja kasse to demonstrate its' repellent effect. The tests were conducted according to applicant's own methods B/RA/02/2019 and B/RA/04/2019 and were notified to the Office for Registration of Medical Products, Medical Devices and Biocidal Products (Polish Competent Authority) on 12.02.2020 and 04.12.2019 under numbers: DIB-IBW.0013.110.2019.KB.2 and DIB-IBW.0013.111.2019.KB, respectively.
One study against moles was conducted with the fresh sample of the biocidal product. The product sample stored in ambient conditions for 3 years was used in a study against moles, and against dogs and cats to demonstrate the efficacy of BROS Peletab eemale mutte, koeri ja kasse after the claimed shelf life period. Compared to the fresh sample there was no decrease in efficacy of the aged sample against moles. The tested product shows very high efficacy against dogs and cats after 3 years of storage in ambient conditions. Based on these results it can be expected that the fresh product is also efficacious against dogs and cats.
In these 2 field studies against moles, either fresh or stored product was applied to active molehills (20 g per molehill) in 5 separate test sites and proved efficacious in repelling moles from the test areas for 4 weeks as over 80% of the molehills remained inactive during the observed 28 days.
The field study with dogs and cats were carried out using animals that were owned by the residents of the properties were the tests were carried out. The selection of the location of sites for testing (5 locations for dogs and 5 locations for cats) was based on the observation of the animals by their owners as places where signs of animal presence and damage caused by them were reported and confirmed by property owners as undesirable activity. In the conducted studies, aged product was applied to areas which were observed by the owners of the animals as sites visited (and damaged) by their pets. After application of the product, no new signs of animal activity in the treated sites were observed during 14 days, therefore confirming the repellent efficacy as nearly 100% for 2 weeks.

3.5.5 Conclusion on efficacy

The results summarised in the table 3.8 Efficacy data confirmed that the biocidal product BROS Peletab eemale mutte, koeri ja kasse with 4 % (w/w) propionic acid and 0.09% (w/w) citronellal as active substances will be effective for the intended use for up to 4 weeks against moles and up to 2 weeks against dogs and cats after application. The biocidal product has a shelf-life of 3 years.

The label claims for the product which are supported by the data package are:
- The biocidal product BROS Peletab eemale mutte, koeri ja kasse is effective in repelling moles up to 4 weeks at the application rate of 20 g per molehill
- The biocidal product BROS Peletab eemale mutte, koeri ja kasse is effective in repelling dogs and cats up to 2 weeks at the application rate of 40 g per 1 m^2

3.5.6 Occurrence of resistance and resistance management

No resistance has occurred in the conducted tests. There are no reported cases of resistance developing in the literature so far. As the active substances (propionic acid and citronellal) are repellents (no killing action) and do not give rise to selection pressure, no resistance can be developed. Management strategies to avoid resistance are not applicable.

3.5.7 Known limitations

Reapply the product after rainfall. Do not use in the winter, or on snow and below 0ºC.
Do not treat plant's leaves and grass as it may cause temporary yellowing caused by the contact with the active substance, which passes after about 2-3 weeks.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

The biocidal product BROS Peletab eemale mutte, koeri ja kasse is not intended for use in combination with other biocidal products.

3.6 Risk assessment for human health

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, this requirement is not applicable for simplified authorization. No substances of concern were identified regarding human health.

3.6.1 Assessment of effects on human health

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, this requirement is not applicable for simplified authorization.

3.6.2 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified.

3.6.3 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of (the) non-active substance(s), refer to the respective section of the confidential annex.

3.7 Risk assessment for animal health

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, this requirement is not applicable for simplified authorization. No substances of concern were identified regarding animal health.

3.8 Risk assessment for the environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, this requirement is not applicable for simplified authorization. No substances of concern were identified regarding the environment.

3.8.1.1 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)).

3.8.1.2 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substances, refer to the respective section of the confidential annex.

3.9 Assessment of a combination of biocidal products

Not applicable as the biocidal product is not intended to be authorised for the use with other biocidal products.

3.10 Comparative assessment

The biocidal product contains citronellal and propionic acid which do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered as a candidates for substitution. Therefore, a comparative assessment of the biocidal product is not required.

4 Appendices

4.1 Calculations for exposure assessment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, this requirement is not applicable for simplified authorization.

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the active substances is available.

No new information on the substances of concern is available.

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2021 14.01.21	6.7/6.7	BROS odstrasza krety, psy i koty - report MOLES ENG 15.04.21.pdf Annex to the study TROJSTIG MDC 55 LQ 2210 26.06.23.pdf	Efficacy study of the product 'BROS odstrasza krety, psy i koty' (MDC 55 LQ) intended to repel moles Report No.: TROJSTIG/MDC 55 LQ/ 2210-20112020	Full study report	BROS sp. z o.o.	No	Yes
[redacted]	2022 03.11.22	6.7/6.7	BROS odstrasza krety, psy i koty EN Moles 3 years plus coffee husk 14.12.2022.pdf Annex to the study TROJSTIG MDC 55 LQ2609 26.06.23.pdf	Testing the effectiveness of the preparation „BROS odstrasza krety, psy i koty II" (MDC 55 LQ) designed to repel moles Report No.: TROJSTIG/ MDC 55 LQ/2609-31102022	Full study report	BROS sp. z o.o.	No	Yes
[redacted]	2022 18.10.22	6.7/6.7	BROS odstrasza krety, psy i koty EN Dogs	Efficacy test report of the product „BROS odstrasza krety,	Full study report	BROS sp. z o.o.	No	Yes

			and cats 3 years plus coffee husk 14.12.2022.pdf Annex to the study TROJSTIG MDC 55 LQ 18102022 26.06.23.pdf	psy i koty II" (MDC 55 LQ) intended to repel dogs (Canis lupus familiaris) and cats (Felis catus domesticus) Report No.: TROJSTIG/MDC 55 LQ/18102022				
[redacted]	2022 15.10.2022	3.1 – 3.3	BROS Odstrasza krety psy i koty 16.04.23.pdf	BROS Odstrasza krety psy i koty. Determination of physicochemical properties of test item Report: BR-011/19	Full study report	BROS sp. z o.o.	No	Yes
[redacted]	2023	5.0	0001_0224_FA Report.pdf 0001_0224_FA Amendment no 1 to Final Report.pdf	Odstrasza krety psy i koty. Validation of analytical method for determination of active substances citronellal and propionic acid content in the test item	Full Study report	BROS Sp. z o.o.	Yes	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

Not applicable.

4.4.2 Guidance documents

- Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018.
- Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 5.0, November 2022.
- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2018
- Field-test method to assess efficacy of biocidal product in the form of repellent intended to repel dogs and cats (B/RA/02/2019), accepted by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB) on December 12th 2019 under number: DIB-IBW.0013.110.2019.KB.2.
- Field-test method to assess efficacy of biocidal product in the form of repellent intended to repel European moles (B/RA/04/2019), accepted by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB) on December 4th 2019 under number: DIB-IBW.0013.111.2019.KB.

4.4.3 Legal texts

- Regulation (EU) No 528/2021 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.