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 1272/2008¹ 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 respective sections, refer to the respective sections of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Use number ¹	Use description ²	PT ³	Target organisms⁴	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 (<i>Talpa europaea) –</i> 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 (<i>Canis</i> <i>lupus</i> <i>familiaris</i>) – all developmental stages and Cat (<i>Felis catus</i>) – 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

А	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
Ν	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)

Mai	n 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	HO

Table 2.3 Identity of the active substance

Table 2.4 Identity of the active substance

Mai	n 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	CH ₃ CH ₃ CH ₃

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

	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	

Table 2.5 Classification and labelling of the biocidal product

*P-statements that are excluded based on the risk assessment or the intended use of the product², 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 <u>https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b</u>.

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/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

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

Numberin					
g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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%)	Characterist ic	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%)		BR-011/19 (2022)

Table 3.2 Physical, chemical, and technical properties

Numberin					
g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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%)	procedure. 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/MD C 55 LQ/2609- 31102022 (2022); TROJSTIG/MD C 55 LQ/18102022 (2022)

Numberin					
g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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 assessme nt	BROS Odstrasza krety psy i koty. Batch: C-03 (propionic acid 4%, citronellal 0.09%)	The package stability was checked and confirmed	BR-011/19 (2022)

Numberin					
g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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/dustabi lity	Waived	-	Not required. Technically not feasible	-

Numberin					
g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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	-

Numberin g according to Annex III of BPR	Property	Guideline and Method	Tested product/batc h (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 0°C. 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

Ana	alytical meth	nods for the analysis	s of the pr	oduct as	such in	cluding	the a	ctive subs	tance, im	ourities, and resid	dues
was weighed 50 g of crus of the suspe centrifuged.	d into the tare hing and grin ension was tra The liquid fro	SPB-FA/11 and SANCC ed grinding vessel. 45 ding balls were added ansferred to a test tub om the tube was filter e-ionization detector e	±2 g of me to the ves containin ed through	thanol ma sel and th g about 0 a syringe	ass was a le vessel .25 g of a filter inte	dded to was clos anhydro o a chro	the ve sed. Th us sodi matogi	essel and w e sample w ium sulpha raphic vial.	<i>eighed with vas ground te. The tub The analys</i>	n an accuracy to 0. in a ball mill for 1 e was shaken and sis was conducted v	01 g. About hour. 1.5 mL then
Analyte (type of analyte	Linearity	Specificity	Fortific range, le numb measure at each	vel and er of ements	Recove	ery rate	(%)	Precisi	on (%)	Limit of Quantification LOQ - only for	Reference
e.g. active substance)			Level	Number of measure ments	Range	Mean	RSD	Concentr ation tested	Number of replicates	impurit(y/ies)	
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	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	
Propionic acid	y=448.318x -83769.8 r ² =0.999 (0.022- 0.136 % w/w); n=5	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	(3.15% w/w); Level II (4.70%	N = 2	97.1 - 98.7	98	0.6	3.49	5	Not determined	0001/0224/ FA (2023)

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

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

Estonia

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 areas selected for the study, with the order treatment with the tested presence of the target animals before treatment with the tested presence of the target animals before treatment with the tested preparation. 28 25 4 1 26 0 100.0 14 24 2 21 28 21 26 583.9 Comments: The effective for active molehills before treatment with the tested preparation.Replication 1 13 28 26 583.9 The effector for target animals before treatment with the tested preparation.The test is considered valid and reliable as it showed significant difference between the final number of repelled moles in comparing the assessing and comparing the active molehills before and after 28 days. No changes were observed.The effective field on the last the index field as effect and the law forming vegetation surrounding the mound after 28 days. No changes were observed.The orduct is effective for at least 4 weeks after application.The effectivenessThe orduct is effective for at least 4 weeks after application.	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 controls were the same areas selected for the study, with the controls were the same areas selected for the study, with the controls were the same areas selected for the study area in active mound. The controls were the same areas selected for the study with the controls were the controls were the controls were the same areas selected for the study with the controls were the controls were the controls were the controls were the controls were the same areas selected for the study with the controls were the controls were the same areas selected for the study with the controls were the same areas selected for the study. with the controls were the controls were the same areas selected for the study. with the controls were the controls were the controls were the controls were the target animals before treatment with the tested preparation. 0 0 26 0 0.0 The efficacy of the product was determined by assessing and comparing the active molehils before and after application of the preduct. 0 0 1 10 0.0 0	 		_					
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	of the tested		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	The test is con- difference betw comparison with The product, at to repel moles phytotoxic efference mound after 28 Conclusion: The BROS Pele high efficacy at for use - it reper- percentage of e	veen the final th the control fter being app out of the pro oct on the lawn 3 days. No cha tab eemale m fter being used els the moles the effectiveness v	number of rep period. lied to the mo tected area, o -forming veg inges were ob utte, koeri ja d in accordand from the treat vas always hi	pelled moles ole mound and did not show etation surro oserved. kasse produ ce with the i ted area. Th i gher than a	in nd corridors any bunding the nct showed nstructions e 80%.	

	day trea hou app pro afte 14, day app giv For ass % o calo Env cor - te 0.2 - hi 68. 97. - pl	sessed on the y of the atment - 8 urs after the plication of the oduct, and then er 1, 3, 7, 10, , 21 and 28 ys from the plication in a ven location. r each sessment, the efficacy was culated. vironmental nditions: emperature: 26°C - 18.63°C umidity: .98% - .40% RH precipitation: 20 mm - 3.02								
Eur	pellent/ Fie ropean ble (<i>Talpa</i> ronaea) 5 te	eld test		eri ja kass			<u>ambie</u>	tab eemale nt conditions	Report No.: TROJSTIG/ MDC55LQ/ 2609-	6.7. – Field- test against moles (3 years aged
On	ly sele	0 m ² were ected 7 days fore the		treatment (DAT)	active molehills (Nk)	Active molehills	W (%)		31102022 (2022)	sample) and influence of coffee husk
fro pop diff sex	ividuals m the wild pulation of ferent xes and of foront	plication of the sted product. ese sites were proughly spected to minate any risk	Replication - I	0 1 3 7 10 14 21	0 21 21 21 21 21 21 21 21	21 0 0 0 0 0 0 0	0.0 100.0 100.0 100.0 100.0 100.0 100.0			on repelling efficacy of tested product on moles/ Testing the

BROS Peletab eemale mutte, koeri ja kasse

PT19

in areas,	to non-target		28	19	2	90.5	1	effectiveness
where they	animals. The area		0	0	23	0.0		of the
are not	occupied by		1	23	0	100.0		preparation
protected by	moles was		3	23	0	100.0		'BROS
applicable	assessed and a	Replication	7	23	0	100.0		odstrasza
		П	10	23	0	100.0		
law.	schematic plan of		14	21	2	91.3		krety, psy i
- 5	the site was		21	20	3	87.0		koty II'
replications	sketched, on		28	19	4	82.6		(MDC 55 LQ)
(five	which areas with		0	0	21	0.0		designed to
separate	molehills, near-		1	21	0	100.0		repel moles.
locations at	surface channels,		3	21	0	100.0		
least 1 km	active mounds	Replication	7	21	0	100.0		
apart)	leading to	Ш	10	21	0	100.0		
aparcy	burrows were		14	18	3	85.7		
	marked with		21	17	4	81.0		
	sticks. The		28	17	4	81.0		
	product was		0	0	25	0.0		
	applied to the		1	25	0	100.0		
	active molehills		3	25	0	100.0		
	located in the	Replication	7	25	0	100.0		
	tested area in	IV	10	24	1	96.0		
	accordance with		14	24	1	96.0		
	the directions for		21	23	2	92.0		
	use and in		28	21	4	84.0		
	amount of 20g		0	0 24	24	0.0		
	per mound. The		1 3	24 24	0	100.0 100.0		
	control was	Doplication	7	24	0	100.0		
	performed in the	Replication V	10	24	3	87.5		
	same areas	v	10	21	3	87.5		
	selected for	·	21	20	4	83.3		
	testing with the		28	20	4	83.3		
	confirmed		Avera			85.28		
			Aven	ige		05.20]	
	presence of the	Comment	c'					
	moles, but before			valid and	roliable a	c it chow	ed significant	
	treating it with		between the					
	the 3-year sample					peneu m	ioles III	
	of BROS Peletab	companso	n with the c	ontroi.				
	eemale mutte,	The produc	t, aged for	3 years, w	when appli	ed to a i	molehill, is not	
	koeri ja kasse		to the surr					
	product.			5.	5	5		
		Conclusio	ns:					

	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	3 years, s with the la treated ard than 80% The produ 4 weeks at The carrie <u>repelling</u>	ct, aged for fter applicat er (coffee	-					
	product was assessed on the 1 st , 3 rd , 7 th , 10 th , 14 th , 21 st and 28 th	Replication	Day after treatment (DAT)	Non- active molehills (Nk)	Active molehills	W (%)			
	day after the		0	0	24	0.0			
	application in a		1	0	24	0.0			
	given location.		3	0	24	0.0			
	For each	Replication	7	0	24	0.0	4		
	assessment %		10	0	24	0.0	4		
	efficacy was		14	0	24	0.0	-		
	calculated.		21	0	24	0.0	-		
	calculated.		28	0	24	0.0	_		
	The carrier of the		0	0	20	0.0			
	active substances		1	0	20	0.0			
	of the BROS		3	0	20	0.0			
	Peletab eemale	Replication	7	0	20	0.0	-		
	mutte, koeri ja	II	10	0	20	0.0	4		
	kasse product is		14 21	0	20 20	0.0	4		
	coffee husk,		21	0	20	0.0	4		
	brown in color		28	0	20 18	0.0	4		
	with a mild coffee		1	0	18	0.0	4		
	aroma. Additional		3	0	18	0.0	1		
	study was carried	Replication	7	0	18	0.0	1		
	out in the same	III	10	0	18	0.0	4		
	way as described		10	0	18	0.0	1		
	above to test		21	0	18	0.0	1		
			28	0	18	0.0	1		
			0	0	27	0.0	1		
		Replication	1	0	27	0.0	1		
	product has any effect on the	IV	3	0	27	0.0	1		

I	1										
			product efficacy.		7	0	27	0.0			
					10	0	27	0.0			
					14	0	27	0.0			
			Environmental		21	0	27	0.0			
			conditions:		28	0	27	0.0			
					0	0	17	0.0			
			 temperature: 		1	0	17	0.0			
			10°C – 15°C		3	0	17	0.0			
			humidity, 6E0/	Replication	7	0	17	0.0			
			- humidity: 65%	V	10	0	17	0.0			
			– 75% RH		14	0	17	0.0			
					21	0	17	0.0			
					28	0	17	0.0			
					Avera	age		0.0			
				Conclusion	s:						
				Coffee buck	the court	ar af tha a		octopoco of t			
				Coffee husk,							
				Peletab eem							
				the efficacy.							
									vas not found		
				to attract or							
							umber o	f mounds die	d not change		
				at the select	ed treated	l sites.					
PT19	BROS	Repellent/	Field test	Efficacy resu	ilts of the	biocidal p	roduct B	ROS Peleta	b eemale	Report	6.7. – Field-
	Peletab	Dogs (Canis		mutte, koe	ri ja kass	e (produ	ct aged	in ambient	<u>conditions</u>	No.:	test against
USE 2:	eemale	lupus	5 separate test	for 3 years			_			TROJSTIG/	dogs and
Solid	mutte,	familiaris)	sites for dogs	-					7	MDC55LQ/	cats (3
repellent	koeri ja	and cats	and 5 separate	Replication	Day afte		ber of	W (%)		18102022	years aged
against	kasse –	(Felis catus	locations for cats		treatmen		with			(2022)	sample) and
	granule	domesticus)	were selected in		(DAT)		nimal			(2022)	influence of
dogs and		uomesticus)	a closed housing	D I' I'		activ			4		coffee husk
cats	repellent		estate (one	Replication	0		0	0.0	4		
			location = one	I	1		5	100.0	4		on repelling
		Dogs and	replication),		2		5	100.0	4		efficacy of
	0.09%	cats, of	where at least		3		5	100.0	4		tested
	Citronellal	different	two of signs of		7		5	100.0	4		product on
	(w/w)	sexes and of	dog or cat		10		5	100.0	4		dogs and
	40/	different	activities were	Deuliseti	14		5	100.0	4		cats/
	4%	ages, of any		Replication	0		0	0.0	4		Efficacy
	propionic	breed,	found. In the	II	1		5	100.0	4		Efficacy test
		,	morning and in		2		5	100.0			report of the

Estonia

BROS Peletab eemale mutte, koeri ja kasse

PT19

Г	1-l	and a star of the			2		100.0			La construction
	acid	entering the	the evening,		3	5	100.0			product
((w/w)	area, where	inspections were		7	5	100.0			'BROS
		they cause	carried out to		10	5	100.0			odstrasza
		damage or	confirm the		14	5	100.0			krety, psy i
		their	presence of at	Replication	0	0	0.0			koty II'
		presence is a	least two of signs	III	1	5	100.0			(MDC 55 LQ)
		nuisance.	of activity of		2	5	100.0			intended to
			dogs and cats in		3	5	100.0			repel dogs
		- 5 separate	the previously		7	5	100.0			(Canis lupus
		locations for	selected study		10	5	100.0			familiaris)
		dogs and 5	areas.		14	5	100.0			and cats
		separate	areas.	Replication	0	0	0.0			(Felis catus
		locations for	The product was	IV	1	5	100.0			
		cats (one	applied in the		2	5	100.0			domesticus)
		location =	selected places		3	5	100.0			
		one	by scattering 40		7	5	100.0			
		replicate).	g of product per		10	5	100.0			
		replicate).			14	5	100.0			
			1 m ² onto the	Replication	0	0	0.0			
			surface (grass	V	1	5	100.0			
			fields or flower		2	5	100.0			
			beds).		3	5	100.0			
			The efficacy of		7	5	100.0			
			,		10	5	100.0			
			BROS Peletab		14	5	100.0			
			eemale mutte,				100.0			
			koeri ja kasse							
			was determined							
			by evaluating and				BROS Peleta			
			comparing the				<u>l in ambient</u>	conditions		
			number of signs	<u>for 3 years)</u>	against cats:	• •				
			of activity of dogs	Replication	Day after	Number of	W (%)]		
			and cats before	Replication	treatment	sites with	W (70)			
			and after		(DAT)	no animal				
			application of the		(B/(I)	activity				
			test product. The	Replication	0	0	0.0			
			effectiveness of	I	1	5	100.0			
				-	2	5	100.0			
			the product was		3	5	100.0			
			assessed on the		7	5	100.0			
			1st, 2nd, 3rd,		10	5	100.0			
			7th, 10th and		14	5	100.0			
			14th day after the	Replication	0	0	0.0			
			application in a	II	1	5	100.0			
				11	L T	J	100.0			

BROS Peletab eemale mutte, koeri ja kasse

PT19

	de la casti a c		2	-	100.0		
	jiven location.	-	2	5	100.0		
	For each	-	3	5	100.0		
	assessment %	-	7 10	5	100.0		
	efficacy of the	-		5	100.0		
	product was	Deplication	14 0	4	80.0 0.0		
c	calculated.	Replication III	1	05	100.0		
	The environ of the		2	5	100.0		
	The carrier of the	-	3	5	100.0		
	active	-	7	5	100.0		
	substances of	-	10	5	100.0		
	the product is	-	10	5	100.0		
	coffee husk,	Replication	0	0	0.0		
	brown in color	IV	1	5	100.0		
	with a mild		2	5	100.0		
	coffee aroma.		3	5	100.0		
	Additional study		7	5	100.0		
	was carried out		10	5	100.0		
	in the same way		14	5	100.0		
	as described	Replication	0	0	0.0		
	above to test	V	1	5	100.0		
	whether this		2	5	100.0		
	component of		3	5	100.0		
	the product has		7	5	100.0		
	an effect on the		10	5	100.0		
	product efficacy.		14	5	100.0		
	. ,				96.0		
	Environmental						
	conditions:						
		Conclusions					
	- temperature:	The test is co	nsidered valio	l and reliable	as it showed	significant	
		difference bet					
		comparison w			repence anni		
	– 75% RH	companson w		<i>.</i>			
	<i>y</i> b <i>y</i> b <i>t</i> t t t	The product B	BROS Peletab	eemale mutt	e, koeri ja ka	sse, aged for	
		3 years, show					
		the label-instr					
		protected surf					
		or higher th					
		-		•			
		The biocidal p					
		effective in th	e field for at	least 2 weeks	s after applica	ation.	

	The	carrier ((coffee hus	k) effect on	product effic	acv in	<u> </u>	
		lling do						
		lication	Day after treatment (DAT)	Number of sites with no animal activity	W (%)			
	Repl	lication	0	0	0.0			
	I		1	0	0.0			
			2	0	0.0			
			3	0	0.0			
			7	0	0.0			
			10	0	0.0			
			14	0	0.0			
		lication	0	0	0.0			
	II		1	0	0.0			
			2	0	0.0			
			3	0	0.0			
			7	0	0.0			
			10	0	0.0			
			14	0	0.0			
	Repl	lication	0	0	0.0			
	III		1	0	0.0			
			2	0	0.0			
			3	0	0.0			
			7	0	0.0			
			10	0	0.0			
			14	0	0.0			
	Repl	lication	0	0	0.0			
	IV		1	0	0.0			
			2	0	0.0			
			<u>3</u> 7	0	0.0			
				0	0.0			
			10	0	0.0			
	Deal	icotica	14	0	0.0			
	Kepi	lication	0	0	0.0			
			2	0	0.0			
			<u> </u>	0	0.0			
			10	0	0.0			
			14	0	0.0 0.0			
				1	0.0	l		
 1 1	J						1	

			L-) - 661		•	
	The carr	ier (cottee hus	<u>k) effect on</u>	product efficacy	<u>ın</u>	
	repelling	<u>cats:</u>				
	Replicatio	on Day after	Number of	W (%)		
		treatment	sites with			
		(DAT)	no animal			
			activity			
	Replicatio	on O	0	0.0		
	I	1	0	0.0		
		2	0	0.0		
		3	0	0.0		
		7	0	0.0		
		10	0	0.0		
		14	0	0.0		
	Replicatio		0	0.0		
	II	1	0	0.0		
		2	0	0.0		
		3	0	0.0		
		7	0	0.0		
		10	0	0.0		
		14	0	0.0		
	Replicatio	on O	0	0.0		
	III	1	0	0.0		
		2	0	0.0		
		3	0	0.0		
		7	0	0.0		
		10	0	0.0		
		14	0	0.0		
	Replicatio		0	0.0		
	IV	1	0	0.0		
		2	0	0.0		
		3	0	0.0		
		7	0	0.0		
		10	0	0.0		
		14	0	0.0		
	Replicatio		0	0.0		
	V	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		
I						

	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 m²

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 0°C. 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 nonactive 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)
	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
	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.	Νο	Yes
	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				
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
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.