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)

REPULSIFS CHIENS ET CHATS GRANULES

Product type 19

Acetic acid, Lavender oil and peppermint oil as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-SU075909-87

Competent Authority: FR CA

Date: [June 2024]

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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	*FR CA*	BC-YH074113-35	07/04/2023	*Initial assessment*	
SA-ADC	*FR CA*	BC-QB088323-44	09/10/2023	*Addition of trade names*	
SA-AAT	*FR CA*	na	02/07/2024	Discussions with concerned members states in the frame of mutual recognition in sequence. Referral to CG: revised PAR and SPC.	

1 Conclusion

REPULSIFS CHIENS ET CHATS GRANULES is a granulated biocidal product containing peppermint oil, lavender oil and acetic acid as active substances. The product is used as a reppellant *(PT19)* against cats and dogs outdoors by general public and professionnals.

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 reppellant against cats and dogs for general public and professionnals, 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 lavender oil, peppermint oil and acetic acid are listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that acetic acid concentration in the product is limited to ensure 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 (a) substance(s) 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 is provided in the confidential annex. The manufacturer(s) of the biocidal product is listed in section 1.4 of the SPC.

[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

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer(s) of the active substance(s) are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended use(s) 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

No physical hazards were identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Analytical methods for monitoring, soil, air, water, animal and human body fluids and tisues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

Efficacy against target organisms

The biocidal product has been shown to be efficacious outdoor against cats and dogs. More information is available in section 3.5 of the PAR.

Human and animal health

No substances of concern regarding human health were identified.

The handling of the product and its intended use do not require personal protective equipment.

Risk assessment for the environment

No substance of concern regarding environment was identified.

It has to be noted that following of the conclusions of CG-61 meeting (22/04/2024), for the preparation of the dosage a dosing device capable of dosing the quantity of product required for treatment will be provided to the non-professional users.

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 number1	Use description2	PT3	Target organisms4	Application method5	Application rate6 (min-max)	User category7	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	*Repellent Outdoor*	*19*	*Cats (Felis catus), Dogs (Canis lupus familiaris)*	*Spreading Granule*	*30 g/m²*	*Professional*	**A**	
2	*Repellent Outdoor*	*19*	*Cats (Felis catus), Dogs (Canis lupus familiaris)*	*Spreading Granule*	*30 g/m²*	*Non-Professional*	**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.

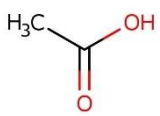
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substances

Main constituent	
Common name	*Peppermint oil*
Chemical name	*Peppermint oil (Natural oil)*
EC number	*616-900-7*
CAS number	*8006-90-4*
Index number in Annex VI of CLP	-
Minimum purity / content	*100% / 8.5 g/kg*
Structural formula	Not available

Main constituent	
Common name	*Lavender oil*
Chemical name	*Lavender oil (Natural oil)*
EC number	*616-770-1*
CAS number	*8000-28-0*
Index number in Annex VI of CLP	-
Minimum purity / content	*100% / 8.5 g/kg*
Structural formula	Not available

Main constituent	
Common name	*Acetic acid*
Chemical name	*Acetic acid*
EC number	*200-580-7*
CAS number	*64-19-7*
Index number in Annex VI of CLP	-
Minimum purity / content	*99.85% / 8.5 g/kg*
Structural formula	

2.5 Information on the source(s) of the active substance(s)

The information on the source(s) of the active substance(s) 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 2.4 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code		
Hazard Pictograms		
Signal word(s)		
Hazard statements		
Precautionary statements*		The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	*EUH208 - Contains DL Menthone (CAS 1074-95-9) and Linalool (CAS 78-70-6) - May produce an allergic reaction*	
Notes	*[Where necessary, add a justification for excluding certain P-statements.]*	

*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

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR (category 4).
The applicant is the owner of all submitted data.

2.10 Data submitted in relation to product authorisation

Not relevant

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
PP	1 kg, 2kg, 3kg, 5kg, 10kg, 20kg, 25kg	White PP bottle	Screw cap	Professional	Yes
PP	200g, 240g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 1kg, 1.5 kg, 2kg	White PPbottle	Screw cap	Non-professional*	Yes
PE	1 kg, 2kg, 3kg, 5kg, 10kg, 20kg, 25kg	White PE bottle	Screw cap	Professional	Yes
PE	200g, 240g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 1kg, 1.5 kg, 2kg	White PE bottle	Screw cap	Non-professional*	Yes
PET	200g, 240g, 250g, 300g,	White PET bottle	Screw cap	Professional	Yes

	350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 1kg, 1.5 kg, 2kg				
PET	1 kg, 2kg, 3kg, 5kg, 10kg, 20kg, 25kg	White PET bottle	Screw cap	Non-professional*	Yes
PEHD/F	1 kg, 2kg, 3kg, 5kg, 10kg, 20kg, 25kg	White PEHD/F bottle	Screw cap	Professional	Yes
PEHD/F	200g, 240g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 1kg, 1.5 kg, 2kg	White PEHD/F bottle	Screw cap	Non-professional*	Yes
Cardboard (plastic coated PE/PET	1 kg, 2kg, 3kg, 5kg, 10kg, 20kg, 25kg	Cardobard with PE/PET inner coating	Screw cap	Professional	Yes
Cardboard (plastic coated PE/PET	200g, 240g, 250g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 1kg, 1.5 kg, 2kg	Cardboard with PE/PET inner coating	Screw cap	Non-professional*	Yes

***** These packagings have to include a dosing device for non professional uses.

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	Comment
3.1.	Appearance at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191123	Brown granules	Report BAS122021.6	Acceptable
3.1.1.	Physical state at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191123	Solid	Report BAS122021.6	Acceptable
3.1.2.	Colour at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191123	Brown	Report BAS122021.6	Acceptable
3.1.3.	Odour at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191123	Slight	Report BAS122021.6	Acceptable
3.2.	pH value at 20°C	CIPAC MT 75.3	Batch: B191123	4.12	Report BAS122021.6	Acceptable
3.3.	Bulk density (kg/L) at 20°C Tap density (kg/L) at 20°C	CIPAC MT 186	Batch: B191123	Bulk density: 0.124 Tap density: 0.126	Report BAS122021.6	Acceptable
3.4.1.1.	Storage stability test– **accelerated storage** **Analytical method (Report BAS122021.2) for the determination of active substances in product is validated in paragraph 3.4**	CIPAC MT46.3	Batch: B220311	The appearance of the test item was considered to be stable after 14 days of storage procedure at 54 °C ± 2 °C; no significant change of aspect and weight was observed. **Deviation from T0: Peppermint oil =**- 0,3935 % (Ci= 8,46g/L; Cf=8,43g/L) **Lavender oil=**- 2,6059 % (Ci= 8,59g/L; Cf=8,37g/L	Report BAS042022.2	Acceptable The product is stable 14 days at 54°C in white PE bottle of 500g.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
				Acetic acid=- 0.8254 % (Ci=8,49g/L; Cf=8,42g/L)		
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature** **Analytical method (Report BAS122021.2) for the determination of active substances in product is validated in paragraph 3.4**	Technical Monograph No.17, 2nd edition CropLife International	Batch: B191123	The appearance of the test item was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C. The packaging material (500g, White PE bottle with screw cap)was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C; no significant change of weight was observed. **Deviation from T0: Peppermint oil =**- 4,9329 % (Ci= 8,86g/L; Cf=8,42g/L) **Lavender oil=**- 0,2523 % (Ci= 8,68g/L; Cf=8,66g/L **Acetic acid=**- 0.4812 % (Ci=8,499g/L; Cf=8,46g/L) **pH at 1%:** 4.12 (before) 4.15 (after) **Bulk density:** 0.124 (before) 0.128 (after) **Tap density:** 0.126 (before) 0.127 (after)	Report BAS122021.6	Acceptable The product is stable 2 years at ambient temperature in white PE bottle of 500g.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived - No study performed.				Acceptable
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waived - No study performed but not relevant since the container is opaque and thus is blocking the light.				Acceptable The sentence "Protect from light" will be added on the label for the HDPE bottles.
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived - No study performed. Humidity is not relevant considering that the packaging is water-resistant (plastic).				Acceptable
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waived - No study performed. Both the product and the packaging material are inert.				Acceptable
3.5.1.	Wettability	Waived - Not required considering the formulation type.				Acceptable
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Waived - Not required considering the formulation type.				Acceptable
3.5.3.	Wet sieve analysis and dry sieve test	Waived - For simplified authorisation, this parameter is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Indeed, only efficacy and chemical stability should be demonstrated.				Acceptable
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Waived - Not required considering the formulation type.				Acceptable
3.5.5.	Disintegration time	Waived - Not required considering the formulation type.				Acceptable
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	Waived - For simplified authorisation, this parameter is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Indeed, only				Acceptable

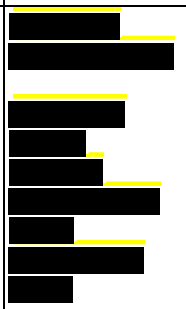
Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
		efficacy and chemical stability should be demonstrated.				
3.5.7.	Persistent foaming	Waived - Not required considering the formulation type.				Acceptable
3.5.8.	Flowability/pourability/dustability	Waived - For simplified authorisation, this parameter is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Indeed, only efficacy and chemical stability should be demonstrated.				Acceptable beacause not sold in bulk
3.5.9.	Burning rate — smoke generators	Waived - Not required considering the formulation type.				Acceptable
3.5.10.	Burning completeness — smoke generators	Waived - Not required considering the formulation type.				Acceptable
3.5.11.	Composition of smoke — smoke generators	Waived - Not required considering the formulation type.				Acceptable
3.5.12.	Spraying pattern — aerosols / spray	Waived - Not required considering the formulation type.				Acceptable
3.6.1.	Physical compatibility	Waived - Not relevant because the formulation is not used in combination with another product.				Acceptable
3.6.2.	Chemical compatibility	Waived - Not relevant because the formulation is not used in combination with another product.				Acceptable
3.7.	Degree of dissolution and dilution stability	Waived - Not required considering the formulation type.				Acceptable
3.8.	Surface tension	Waived - Not required considering the formulation type.				Acceptable
3.9.	Viscosity	Waived - Not required considering the formulation type.				Acceptable

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
The product "Répulsif chiens et chats granules" is an *GR- Ready-to-use granule* . All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable: the product is stable. The biocidal product is stable 2 weeks at 54°C and 2 years at ambient temperature (20°C) with commercial packaging. **Implications for labelling:** The sentence "Protect from light" is included on the label.

3.3 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	Comment
4.1.	Explosives	Waived - All active substances and all other co-formulants in the product do not have any concerning chemical groups regarding the explosive properties and the carrier of the product is an inert material which is stable up to 1000°C. Moreover, the high water content and the composition of essential oils (confidential part) in the product mitigates the risks linked with explosive properties. Therefore, it can be concluded that the product is not classified for this property without any further testing.				Acceptable More detail is included in confidential part.
4.2.	Flammable gases	Waived - Not required considering the formulation type.				-
4.3.	Flammable aerosols	Waived - Not required considering the formulation type.				-
4.4.	Oxidising gases	Waived - Not required considering the formulation type.				-
4.5.	Gases under pressure	Waived - Not required considering the formulation type.				-
4.6.	Flammable liquids	Waived - Not required considering the formulation type.				-
4.7.	Flammable solids	UN Test N.1	"Répulsif chiens et chats granules" Batch LAB270422.1	Neither ignition nor propagation was observed. The test item was not classified as a flammable solid of Division 4.1 and thus was not assigned to any packing group, under the experimental conditions used. According to Regulation (EC) No. 1272/2008 (CLP), the test item was not classified.	[redacted]	Acceptable The product is not flammable
4.8.	Self-reactive substances and mixtures	Waived - All active substances and other co-formulants in the product do not have any concerning chemical groups regarding the self reactive properties and the carrier of the product is an inert substance. Therefore, it can be concluded that the product is not classified for this property without any further testing.				Acceptable More detail is included in confidential part.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	Comment
4.9.	Pyrophoric liquids	Waived - Not required considering the formulation type.				-
4.10.	Pyrophoric solids	Waived - Experience in manufacture and handling shows that the solid do not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the solid is known to be stable at room temperature for prolonged periods of time (days)). Therefore, the product do not need to be classified and the classification procedure does not need to be applied.				Acceptable
4.11.	Self-heating substances and mixtures	In compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Seventh revised edition (2019) - Test N.4 (Part III, Section 33.4.6) Regulation EC No. 1272/2008 (CLP)	LAB270422.1	No self-ignition of the test item was recorded and the temperature of the sample did not exceed the oven temperature by 60 °C.		Acceptable
4.12.	Substances and mixtures which in contact with water emit flammable gases	The formulation does not contain any metals nor metalloids and experience in manufacture and handling shows that the product does not react with water.				-
4.13.	Oxidising liquids	Waived - Not required considering the formulation type.				-
4.14.	Oxidising solids	Waived - No concerning chemical groups have been identified for the oxidizing properties in the ingredients of the product and the carrier is an inert material. Therefore, it can be concluded that the product is not classified for this hazard without any further testing				-
4.15.	Organic peroxides	Waived - Not relevant because the products do not fall under the definition of organic peroxides				-
4.16.	Corrosive to metals	Waived - The product is not diluted in water and the carrier of the product is know to not melt under 1000°C. Therefore, the product is not classified for this hazard				-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	Comment
		without any further testing.				
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waived - Not required considering the formulation type.				-
4.17.2.	Relative self-ignition temperature for solids	Waived - Considering the composition of the product and the fact that the product is non flammable.				Acceptable
4.17.3.	Dust explosion hazard	Waived - The product is not a powder. Furthermore, considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for dust explosion, this property is considered not applicable.				Acceptable

Table 3.4 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
This product is a solid formulation. Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR, it can be concluded that the product presents no physical hazards.

3.4 Methods for detection and identification

Table 3.5 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 : Following SANCO/3030/99 rev.5, the methods of analysis of peppermint oil, lavender oil and and acetic acid in PEO8v5LAO8v5ACE8v5GR (report BAS122021.6) were validated during this study by definition of the specificity, the linearity, the precision and the accuracy of the method. As explained in report BAS122021.6, peppermint oil and lavender oil being complex mixtures of molecules, it was impossible to analyze "peppermint oil" and/or "lavender oil". The chosen strategy is to quantify two representative molecules for each essential oil (lead compounds): - menthone and menthol for peppermint oil, - linalool and linalyl acetate for lavender oil.

Contents in essential oil could be back-calculated from contents in lead compounds and a multiplication factor obtained by analysis of pure essential oils (explained in report BAS122021.6).
Thus, method validation was performed for menthone, menthol, linalool, linalyl acetate and acetic acid.

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**	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Menthol from Peppermint oil	from five injections of five levels of standard ranging from 0.2470 g/L to 0.0823 g/L r^2 = 0.99923	No peak in the solvent blank and in the formulation blank near the retention time of menthol, Retention times for menthol match between reference stantard and test item, no interference observed	0,16 mg/mL 0,35% w/w	2	98,28 %- 97,59 %	97.93 %	C Horwitz= 0,0035% HorRat = 0,5023%	0,3454% RDS= 1,5797%	5	/	Report BAS122021.2
Menthone from Peppermint oil	determined from five injections of five levels of standard ranging from 0.1285 g/L to 0.0428 g/L	No peak in the solvent blank and in the formulation blank near the retention time of menthone, Retention times for menthone match between reference stantard and test item, no interference observed	0,08 mg/mL 0,18% w/w	2	98,42 %- 99,44 %	98.93 %	C Horwitz= 0,0017% HorRat= 0,6326%	0.1685% RDS= 2,1851%	5	/	Report BAS122021.2

	r^2 = 0.99944										
Linalool from Lavender oil	from five injections of five levels of standard ranging from 0.1976 g/L to 0.0659 g/L r^2 = 0.99933	No peak in the solvent blank and in the formulation blank near the retention time of linalool, Retention times for linalool match between reference stantard and test item, no interference observed	0,14 mg/mL 0,3% w/w	2	100,52%-98,08 %	99.30 %	C Horwitz= 0,0026% HorRat= 0,5033 %	0.2611% RDS= 1,6509%	5	/	Report BAS122021.2
Linalyl acetate from Lavender oil	from five injections of five levels of standard ranging from 0.1918 g/L to 0.0639 g/L r^2 = 0.99973	No peak in the solvent blank and in the formulation blank near the retention time of linalyl acetate, Retention times for linalyl acetate match between reference stantard and test item, no interference observed	0,14 mg/mL 0,3% w/w	2	99,93 %-99,27 %	99.60 %	C Horwitz= 0,0027% HorRat= 0,386%	0.2722% RDS= 1,2582%	5	/	Report BAS122021.2
Acetic acid	determined from five injections of five levels of standard ranging	No peak in the solvent blank and in the formulation blank near the retention time of Acetic acid, Retention times for Acetic acid match	1 mg/mL 0,85% w/w	2	100,11%-99,73 %	99,92 %	C Horwitz= 0,0086% HorRat= 0,3395%	0.8637% RDS= 0,9301%	5	/	Report BAS122021.4

	from 1.5630 g/L to 0.5210 g/L r^2 = 0.99999	between reference stantard and test item, no interference observed									

Table 3.6 Analytical methods for soil

Analytical methods for soil
Not pertinent for a SA-APP

Table 3.7 Analytical methods for air

Analytical methods for air
Not pertinent for a SA-APP

Table 3.8 Analytical methods for water

Analytical methods for water
Not pertinent for a SA-APP

Table 3.9 Analytical methods for animal and human body fluids and tissues

Analytical methods for animal and human body fluids and tissues
Not pertinent for a SA-APP

Table 3.10 Analytical methods for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Not pertinent for a SA-APP

Table 3.11 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical method(s) for the determination of Peppermint oil, Lavender oil and Acetic acid are acceptable. The analytical methods have been validated for the linearity, precision, accuracy and specificity. Analytical methods for monitoring, soil, air, water, animal and human body fluids and tisues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

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)

The product REPULSIFS CHIENS ET CHAT GRANULES is intended to be used as a repellent against cats and dogs (development stage over 3 months) and then avoid exterior damages caused by them. They are bothered by the smell of the product and will therefore delimit their territory elsewhere than in the treated area.

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

The mixture is based on olfactory repulsion. The smell of the granules acts as a repellent against cats and dogs.
Its effects lasts up to 3 months in dry weather. There is no time delay for the product to be effective.

3.5.3 Efficacy data

Table 3.12 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

Uses 1&2: cats and dogs repellent</td>
<td>REPULSIFS CHIENS ET CHATS GRANULE

Formulation code: PEO8v5LAO8v5ACE8v5GR</td>
<td>Repellent

Cats (Felis catus)

Dogs (Canis lupus familiaris)

Males and females

Development stage:
Cats: 1 to 16 years
Dogs: 4 months to 14 years

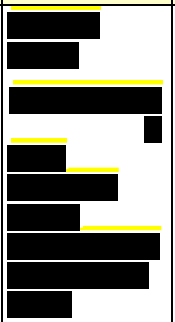
Spreading application (around the plants, in the vegetable garden, on flower plantations, site fence line, flowerpots)

30 g/m²</td>
<td>Field test (in-house method) – France

Outdoor

7 locations (10 cats and 10 dogs)

Weather data:
<table>
<tr><th></th><th>Mean Temp (°C)</th><th>Cumulative rain (mm)</th></tr>
<tr><td>25-31/08</td><td>19.6</td><td>0</td></tr>
<tr><td>1-30/09</td><td>19.5</td><td>61</td></tr>
<tr><td>1/31/10</td><td>14.2</td><td>32.4</td></tr>
<tr><td>1-30/11</td><td>8.1</td><td>71.6</td></tr>
<tr><td>1-13/12</td><td>7.8</td><td>116</td></tr>
</table>
For each location, one-week observation periods (several times a day) were performed:
7 days before application,
T0=immediately after application,
T1=1 month after application,
T2=2 months after application,
T3=3 months after application

A control period of 7 days is carried out before using the product. During this period, the owner first completes a form and notes the observations made on</td>
<td>Control period (Cats outdoor) Average on 7days:
<table>
<tr><td>Presence of animal in the future tested area</td><td>14.8</td></tr>
<tr><td>Presence of animal (sec)</td><td>300</td></tr>
<tr><td>Number of degradation in the future tested area</td><td>14.7
(no degradation outside the future treated area)</td></tr>
</table>
Efficacy (Cats outdoor) :
<table>
<tr><th>T0 (average 7days)</th><th></th><th>% Efficacy</th></tr>
<tr><td>Presence of animal in the tested area</td><td>1.1</td><td>92.1</td></tr>
<tr><td>Presence of animal (sec)</td><td>74.5</td><td>75.2</td></tr>
<tr><td>Number of degradation</td><td>0.1</td><td>98.8</td></tr>
<tr><td colspan="3">T1(average 7days)</td></tr>
<tr><td>Presence of animal in the tested area</td><td>0.6</td><td>96.5</td></tr>
<tr><td>Presence of animal (sec)</td><td>3</td><td>99.0</td></tr>
<tr><td>Number of degradation</td><td>0</td><td>100</td></tr>
<tr><td colspan="3">T2 (average 7days)</td></tr>
<tr><td>Presence of animal in the tested area</td><td>0.2</td><td>98.6</td></tr>
<tr><td>Presense of animal (sec)</td><td>1.9</td><td>99.4</td></tr>
<tr><td>Number of degradation</td><td>0</td><td>100</td></tr>
<tr><td colspan="3">T3 (average 7days)</td></tr>
<tr><td>Presence of animal in the tested area</td><td>0</td><td>100</td></tr>
<tr><td>Presence of animal (sec)</td><td>0</td><td>100</td></tr>
<tr><td>Number of degradation</td><td>0</td><td>100</td></tr>
</table>
</td>
<td> 

R.I:2</td>
<td>6.7.1./ Field trial of the biocidal product PEO8v5LAO8v5ACE8v5GR</td>
</tr>
</table>

his animal in the defined area and during the defined times. By completing this form, different treatment areas (exterior) can be clearly defined. The owners then spread the product on the defined areas and then observed for 1 week each month for a period of three months.

The parameters to be checked for the control period and the test period are the following:

- Presence of the animal in the treated zone (binary response 1/0)
- Presence of the animal in seconds in the treated zone (until 300sec)
- Presence of degradation in the area and outside the treated zone (number of holes, scratching, excrement, paw prints, damaged plants, barking)

The treated area has not been be mowed, trimmed, treated or watered during the trial.

For each period of observation, the efficacy of the product was calculated for each parameter by comparison with the control period

Control period (Dogs outdoor):

Presence of animal in the future tested area	11.1
Presence of animal (sec)	300
Number of degradation in the future tested area	10.7 (no degradation outside the future treated area)

Efficacy (Dogs outdoor) :

T0 (average 7days)		**% Efficacy**
Presence of animal in the tested area	0.4	**95.0**
Presence of animal (sec)	64.2	**78.6**
Number of degradation	0.2	**97.2**
T1 (average 7days)		
Presence of animal in the tested area	0.4	**96.7**
Presence of animal (sec)	32.1	**89.3**
Number of degradation	0.1	**99.2**
T2 (average 7days)		
Presence of animal in the tested area	0.3	**97.7**
Presence of animal (sec)	32.1	**89.3**
Number of degradation	0.1	**99.2**
T3 (average 7days)		
Presence of animal in the tested area	0.3	**97.6**
Presence of animal (sec)	2.9	**99.0**
Number of degradation	0.1	**99.1**

The product has demonstrated a good repellent effect up to 3 months, against cats and dogs and then avoid degradation on treated sites.

3.5.4 Efficacy assessment

Currently, no guidelines are available for efficacy testing of such repellents against cats and dogs. According to the applicant, conducting conclusive laboratory tests on cats and dogs is difficult and the applicant provided only field trial.

Efficacy of the product REPULSIFS CHIENS ET CHATS GRANULES has been assessed in a field trial, performed in France (7 locations). The field test was carried out by the owners of animals (dogs and/or cats) which caused damage. Owners are required to first complete a form relating to the general information and habits of their animal. By completing this form, different treatment areas (exterior) can be clearly defined. The owners then spread the product on the defined areas and then observed for 1 week each month for a period of three months.
A range of diverse surfaces (around the plants, in the vegetable garden, site fence line, flowerpots and door) were tested with the product with the objective to repel cats and dogs and keep them away from the area to be protected.

The efficacy of the product was performed by analyzing the average efficacy for each animal in each house compared to the control period before application.
From T0 and confirmed by following observations (T1, T2 and T3), efficacy higher than 95 % is demonstrated for the parameters "presence of animals in the treated zone' and "presence of degradation". The time of presence of the animals in the treated area decreases as observations are made, to finally achieve almost 90% from T1. Cats and dogs spend less time in the treated area and even if they frequent treated site, degradation almost disappear.

3.5.5 Conclusion on efficacy

The product REPULSIFS CHIENS ET CHATS GRANULES has demonstrated a good repellent effect up to 3 months, at the application rate of 30 g/m², applied outdoor, against cats and dogs.

3.5.6 Occurrence of resistance and resistance management

Up to now, no concern of resistance is described in the literature for the active substances peppermint oil, lavender oil and acetic acid, acting as repellent.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA)

3.5.7 Known limitations

none

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

none

3.6 Risk assessment for human health

According to Article 25 and Article 20 (1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the biocidal product family fulfills all conditions for a simplified authorisation procedure.

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substance(s) and available information for the non-active substances.

The classification of the product REPULSIFS CHIENS ET CHATS GRANULES has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

The biocidal product is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization and acute toxicity.

Refer to Confidential Annex for further details.

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

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

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.

3.6.4 Dietary exposure

Not relevant

3.7 Risk assessment for Animal health

Not relevant

3.8 Risk assessment for Environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.8.1. Classification

Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified for the environment. The active substances are listed in Annex I of Regulation (EU) No 528/2012 without any restriction for the environment and there is no need for risk mitigation measure to protect the environment.

3.8.1.1 Substance(s) of concern

The product does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.8.1.2 Screening for endocrine disruption relating to non-target organisms

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

3.9 Assessment of a combination of biocidal products

Not relevant

3.10 Comparative assessment

Not relevant as the active substances do not meet te substitution nor the exclusion criterias.

4 Appendices

4.1 Calculations for exposure assessment

Not relevant

4.1.1 Human health

Not relevant

4.1.2 Dietary assessment

Not relevant

4.1.3 Environment

Not relevant.

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

No new information on the active substances 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 Prote Claim (Yes/**

[redacted]	[redacted]	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa)	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA	not specified	no
[redacted]	[redacted]	3.2 Acidity, alkalinity	pH	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA		no
[redacted]	[redacted]	3.3 Relative density (liquids) and bulk, tap density (solids)	Bulk density	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In	not specified	no

				Report number: BAS122021.6		compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA		
[redacted]	[redacted]	3.3 Relative density (liquids) and bulk, tap density (solids)	Tap density	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA	not specified	no
[redacted]	[redacted]	3.4.1 Storage stability tests	Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International	not specified	no

						ARMOSA SA: ARMOSA SA		
[redacted]	[redacted]	3.4.1 Storage stability tests	Chemical stability after a storage procedure at 54 °C ± 2 °C for 14 days of PEO8v5LAO8v5ACE8v5GR	Title: Chemical stability after a storage procedure at 54 °C ± 2 °C for 14 days of PEO8v5LAO8v5ACE8v5GR Report number: BAS042022.2	study report	CIPAC MT46.3: CIPAC MT46.3 ARMOSA SA: ARMOSA SA	not specified	no
[redacted]	[redacted]	4.2 Flammability	Flammable solids	Title: Test method for self-heating substances on RÉPULSIF CHIENS ET CHATS SOLIDE Report number: 22-902007-012	study report	In compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of tests and Criteria Seventh revised edition (2019) - Test N.1 (Part III, Section 33.2.4) EC No. 1272/2008 (CLP), Amendment No. 1 (2021): In compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of tests and Criteria Seventh revised	not specified	no

						edition (2019) - Test N.1 (Part III, Section 33.2.4) EC No. 1272/2008 (CLP), Amendment No. 1 (2021) ARMOSA TECH: ARMOSA TECH		
[redacted]	[redacted]	4.17 Additional physical indicators for hazards	Self-heating substances and mixtures	Title: Test method for self-heating substances on REPULSIFS CHIENS ET CHATS SOLIDE Report number: 22-902007-010	study report	In compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Seventh revised edition (2019) - Test N.4 (Part III, Section 33.4.6) Regulation EC No. 1272/2008 (CLP): In compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Seventh revised edition (2019) - Test N.4 (Part III, Section 33.4.6)	yes	no

						Regulation EC No. 1272/2008 (CLP) ARMOSA TECH: ARMOSA TECH		
[redacted]	[redacted]	5 Methods of detection and identification	Methods of detection and identification Lavender oil & Peppermint oil	Title: Validation of the analytical method for the determination of Peppermint oil and Lavender oil in PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.2	study report	SANCO/3030/99 rev.5 from 22/03/2019: SANCO/3030/99 rev.5 from 22/03/2019 Armosa Tech SA: Armosa Tech SA	not specified	no
[redacted]	[redacted]	5 Methods of detection and identification	Methods of detection and identification Lavender oil & Peppermint oil	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA	not specified	no
[redacted]	[redacted]	5 Methods of detection and identification	Methods of detection and identification Acetic acid	Title: Validation of the analytical method for the determination of Acetic acid in PEO8v5LAO8v5ACE8v5GR	study report	SANCO/3030/99 rev.5 from 22/03/2019: SANCO/3030/99 rev.5 from 22/03/2019	not specified	no

				Report number: BAS122021.4		ARMOSA SA: ARMOSA SA		
[redacted]	[redacted]	5 Methods of detection and identification	Methods of detection and identification Acetic acid	Title: Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.6	study report	In compliance with Technical Monograph No. 17, 2nd edition CropLife International: In compliance with Technical Monograph No. 17, 2nd edition CropLife International ARMOSA SA: ARMOSA SA	not specified	no
[redacted]	[redacted]	6.7 Efficacy data to support these claims	Efficacy data cats and dogs	Title: Field trial of the biocidal product PEO8v5LAO8v5ACE8v5GR Report number: BAS122021.2	study report			no

4.4 References

4.4.1 References other than list of studies for the biocidal product

– not relevant

4.4.2 Guidance documents

See biocidal product reference guidances : web site: Orientation relative à la législation des biocides - ECHA (europa.eu)

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR)
- 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.