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)

REPULSIF CHIENS CHATS ET FOUINES LIQUIDE

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: [March 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	*FR CA*	BC-QS075908-95	07/04/2023	*Initial assessment*	

1 Conclusion

REPULSIF CHIENS CHATS ET FOUINES LIQUIDE is a liquid biocidal product containing peppermint oil, lavender oil and acetic acid as active substances, to be applied undiluted. The product is used as a reppellant *(PT19)* by general public and professionnals for the control of cats, dogs and weasels indoors and outdoors.

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 against cats, dogs and weasels indoors by the general public and professional users and against cats outdoors by the general public and professional, 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 are listed

[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

in section 1.4 of the SPC.

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 substancesareavailable. More information on the analytical methods for the active substance(s) 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 indoor against stone martens, cats and dogs, and outdoor against cats. More information is available in section 3.5 of the PAR.

Hazards/ Risk assessment for 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.

Hazard/ Risk assessment for the environment

No substance of concern regarding environment was identified.

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	*AL - other liquids to be applied undiluted*

2.2 Uses

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

Table 2.2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	*Repellent Indoor*	*19*	*Cats (Felis catus), Dogs (Canis lupus familiaris), Stone marten (Martes foina)*	*Spraying*	*3 mL/m²*	*Professional*	**A**	
2	*Repellent Outdoor*	*19*	*Cats (Felis catus)*	*Spraying*	*3 mL/m²*	*Professional*	**A**	
3	*Repellent Indoor*	*19*	*Cats (Felis catus), Dogs (Canis lupus familiaris), Stone marten (Martes foina)*	*Spraying*	*3 mL/m²*	*Non-Professional*	**A**	
4	*Repellent Outdoor*	*19*	*Cats (Felis catus)*	*Spraying*	*3 mL/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.

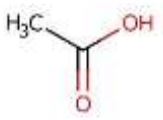
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

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%*
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%*
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%
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.Letter of access

2.9 Letter of access

A Letter of Access is not applicable for products eligible for simplified authorisation under

[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.

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

This section is 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[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)
PP	1L - 2L - 3L - 5L - 12.5L - 20L - 25L	White PP bottle	Spray gun or bottle cap/screw cap	Professional	Yes
PP	200 mL - 250 mL - 300 mL - 350 mL - 400 mL - 450 mL - 500 mL - 550 mL - 600 mL - 650 mL - 700 mL - 750 mL - 800 mL - 850 mL - 900 mL - 950 mL -1L - 2L	White PPbottle	Spray gun or bottle cap/screw cap	Non-professional	Yes
PE	1L - 2L - 3L - 5L - 12.5L - 20L - 25L	White PE bottle	Spray gun or bottle cap/screw cap	Professional	Yes
PE	200 mL - 250 mL - 300 mL - 350 mL - 400 mL - 450 mL - 500 mL - 550	White PE bottle	Spray gun or bottle cap/screw cap	Non-professional	Yes

	mL - 600 mL - 650 mL - 700 mL - 750 mL - 800 mL - 850 mL - 900 mL - 950 mL -1L - 2L				
PET	1L - 2L - 3L - 5L - 12.5L - 20L - 25L	White PET bottle	Spray gun or bottle cap/screw cap	Professional	Yes
PET	200 mL - 250 mL - 300 mL - 350 mL - 400 mL - 450 mL - 500 mL - 550 mL - 600 mL - 650 mL - 700 mL - 750 mL - 800 mL - 850 mL - 900 mL - 950 mL -1L - 2L	White PET bottle	Spray gun or bottle cap/screw cap	Non-professional	Yes
PEHD/F	1L - 2L - 3L - 5L - 12.5L - 20L - 25L	White PEHD/F bottle	Spray gun or bottle cap/screw cap	Professional	Yes
PEHD/F	200 mL - 250 mL - 300 mL - 350 mL - 400 mL - 450 mL - 500 mL - 550 mL - 600 mL - 650 mL - 700 mL - 750 mL - 800 mL - 850 mL - 900 mL - 950 mL -1L - 2L	White PEHD/F bottle	Spray gun or bottle cap/screw cap	Non-professional	Yes
Cardboard (plastic coated PE/PE	1L - 2L - 3L - 5L - 12.5L - 20L - 25L	Cardobard with inner coating PE/PE	Spray gun or bottle cap/screw cap	Professional	Yes
Cardboard (plastic coated PE/PE	200 mL - 250 mL - 300 mL - 350 mL - 400 mL - 450 mL - 460 mL - 500 mL - 550 mL - 600 mL - 650 mL - 700 mL - 750 mL - 800 mL - 850 mL - 900 mL - 950	Cardboard with inner coating PE/PE	Spray gun or bottle cap/screw cap	Non-professional	Yes

	mL -1L - 1850 mL - 2L - 2320 mL 950 mL -1L - 2L				

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

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
3.1.	Appearance at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191122	Clear colorless liquid	Report BAS122021.5	Acceptable
3.1.1.	Physical state at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191122	Liquid	Report BAS122021.5	Acceptable
3.1.2.	Colour at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191122	Colorless	Report BAS122021.5	Acceptable
3.1.3.	Odour at 20 °C and 101.3 kPa	Internal method based on observation	Batch: B191122	Slight	Report BAS122021.5	Acceptable
3.2.	pH value at 20°C Acidity at 20°C	CIPAC MT 75.3 CIPAC MT191	Batch: B191122	4.03 0.7861	Report BAS122021.5	Acceptable
3.3.	Relative density / bulk density (kg/L) at 20°C	CIPAC MT3.3	Batch: B191122	1.011	Report BAS122021.5	Acceptable
3.4.1.1.	Storage stability test – **accelerated storage** **Analytical method (Report BAS122021.1) for the determination of active substances in product is validated in paragraph 3.4**	CIPAC MT46.3	Batch: B220310	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 =**- 4.7836 % (Ci= 8,64g/L; Cf=8,23g/L) **Lavender oil=**- 0.9388 % (Ci= 8,49g/L; Cf=8,41g/L	Report BAS042022.1	Acceptable The product is stable 14 days at 54°C in white PE bottle.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
				Acetic acid=- 0.4755 % (Ci=8,52g/L; Cf=8,48g/L)		
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature** **Analytical method (Report BAS122021.1) for the determination of active substances in product is validated in paragraph 3.4**	Technical Monograph No.17, 2nd edition CropLife International	Batch: B191122	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 (200mL PET bottle, 500 mL PE bottle and 1L PEHD-F bottle) 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 =**- 1.9603 % (Ci= 8,78g/L; Cf=8,61g/L) **Lavender oil=**- 0.7339 % (Ci= 8,5; Cf=8,44g/L) **Acetic acid=**- 0.2456 % (Ci=8,51; Cf=8,49)	Report BAS122021.5	Acceptable The product is stable 2 years at ambient temperature in commercial packagings (PP bottle, PET bottle, PE bottle and PEHD-F bottle).
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived - No study performed. The sentence "Protect from frost" will be on the label.				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

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
						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 - Not required considering the formulation type.				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	**Content of dust/fines, attrition, friability:** Waived - Not required considering the formulation type. **Particle size distribution:** Waived - For simplified authorisation, this parameter is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Only chemical stability should be demonstrated. And this parameter is generally measured for exposure reasons (exposure to spray). As no risk assessment is to be conducted for simplified authorization, this parameter is not relevant.				Acceptable
3.5.7.	Persistent foaming	Waived - Not required considering the formulation type.				Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Comment
3.5.8.	Flowability/pourability/dustability	Waived - Not required considering the formulation type.				Acceptable
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	FEA 644	Batch: 191112	No blockage or deterioration of the nozzle was noted. **<u>Before the ambient storage (24 months):</u>** Shape: circular Mean size: 7.45 cm **<u>After the ambient storage (24 months):</u>** Shape: circular Mean size: 7.5 cm	Report BAS122021.5	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 - 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
3.9.	Viscosity	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

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
The product "Répulsif chiens, chats et fouines liquide" is an *AL* . All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable: the product is stable. Based on the conducted studies, it can be concluded the biocidal product is stable during 2 years at ambient temperature (20°C) in its commercial packagings. **Implications for labelling:** The sentence "Protect from frost" and "Protected from light" are included on the label.

3.3 Physical hazards and respective characteristics

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	Comment
4.1.	Explosives	Waived - All active substances are registered under the Annex I of the BPR and all other co-formulants in the product do not have any concerning chemical groups regarding the explosive properties. Therefore, it can be concluded that the product is not classified for this property without any further testing.			Acceptable
4.2.	Flammable gases	Waived - Not relevant because the product is a liquid.			
4.3.	Flammable aerosols	Waived - Not relevant because the product is a liquid, not applied as aerosols.			
4.4.	Oxidising gases	Waived - Not relevant because the product is a liquid.			
4.5.	Gases under pressure	Waived - Not relevant because the product is a liquid.			
4.6.	Flammable liquids	Regulation (EC) No. 1907/2006, Council Regulation (EC) No. 440/2008 EC A.9. method (2008) and ISO Standard 3679 (March 2015)	Batch 220214	No flash point was observed up to 110.0 °C (corrected value).	Acceptable The product is not flammable
4.7.	Flammable solids	Waived - Not relevant because the product is a liquid.			
4.8.	Self-reactive substances and mixtures	Waived - All active substances are registered under the Annex I of the BPR and all other co-formulants in the product do not have any concerning chemical groups regarding the self reactive properties. Therefore, it can be concluded that the product is not classified for this property without any further testing.			Acceptable
4.9.	Pyrophoric liquids	Waived - Experience in manufacture and handling shows that the liquid do not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time			Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Comment
		(days)). Therefore, the product do not need to be classified and the classification procedure does not need to be applied.			
4.10.	Pyrophoric solids	Waived - Not relevant because the product is a liquid.			
4.11.	Self-heating substances and mixtures	Waived - Not relevant because the product is liquid and liquids are not classified as self-heating.			
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waived - Not relevant because the product is a water-based formulation.			
4.13.	Oxidising liquids	Waived - No concerning chemical groups have been identified for the oxidizing properties in the ingredients of the product. Therefore, it can be concluded that the product is not classified for this hazard without any further testing.			
4.14.	Oxidising solids	Waived - Not relevant because the product is a liquid.			
4.15.	Organic peroxides	Waived - Not relevant because the products do not fall under the definition of organic peroxides.			
4.16.	Corrosive to metals	Manual of Tests and Criteria – 7th revised edition (2019) Method C.1. (Part III, Section 37.4) Regulation (EC) No. 1272/2008 (CLP); amendment 1 (2021)	LAB200422.1	Neither localised nor uniform corrosion was observed after the test; the test item is not classified as corrosive to metals according to Regulation EC No. 1272/2008 (CLP).	Acceptable
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waived - 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 oxidising properties, this property is considered not applicable.			Acceptable
4.17.2.	Relative self-ignition	Waived - Not relevant because the product is a liquid.			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Comment
	temperature for solids				
4.17.3.	Dust explosion hazard	Waived - Not relevant because the product is a liquid.			

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
This product is a liquid formulation. Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR, as well as the flash point test and corrosive to metals test, it can be concluded that the product presents no physical hazards.

3.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method: *The study objective is the validation, in accordance with SANCO/3030/99 rev.5, of the analytical methods (report BAS122021.5) for the determination of acetic acid (by HPLC), peppermint oil and lavender oil (By GC-FID) in PEO8v5LAO8v5ACE8v5AL.* *As explained in report BAS122021.5, peppermint oil and lavender oil being complex mixtures of molecules, it was impossible to measure directly "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 were back-calculated from contents in lead compounds and a multiplication factor obtained by analysis of pure essential oils. Thus, method validation was performed for menthone, menthol, linalool and linalyl acetate.*											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurity (y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		

Menthol from Peppermint oil	The linearity of menthol was determined 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	98,94% - 96,83%	97,89 %	C Horwitz= 0,0035% HorRat = 0,592%	0,3473% RDS= 1,8595%	5	/	Report BAS122021.1
Menthone from Peppermint oil	The linearity of linalool was determined from five injections of five levels of standard ranging from 0.1285 g/L to 0.0428 g/L r^2 = 0.99944	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	0,08mg /mL 0,17% w/w	2	99,34% - 96,06%	97,44 %	C Horwitz= 0,0017% HorRat= 0,457%	0.1675% RDS= 1,6032%	5	/	Report BAS122021.1

Linalool from Lavender oil	The linearity of linalool was determined 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	0,14mg /mL 0,29% w/w	2	100,29% - 98,79%	99.59 %	C Horwitz= 0,0026% HorRat= 0,282 %	0.2624% RDS= 0,9235%	5	/	Report BAS122021.1
Linalyl acetate from Lavender oil	The linearity of linalyl acetate was determined 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	96,55% - 95,11%	95.99 %	C Horwitz= 0,0028% HorRat= 0,496%	0.2755% RDS= 1,6154%	5	/	Report BAS122021.1
Acetic	determined	No peak in	1	2	101% -	100.8	C Horwitz=	0.9847	5	Not available	Report

acid	from five injections of five levels of standard ranging from 1.5630 g/L to 0.5210 g/L r^2 = 0.99999	the solvent blank and in the formulation blank near the retention time of Acetic acid, Retention times for Acetic acid match between reference stantard and test item, no interference observed	mg/mL 0.85% w/w		100,61%	1%	0,0086% HorRat= 0,346%	RDS= 0,9486%			BAS122021.3

Table 3.7 Analytical methods for soil

Analytical methods for soil
Not pertinent for a SA-APP

Table 3.8 Analytical methods for air

Analytical methods for air
Not pertinent for a SA-APP

Table 3.9 Analytical methods for water

Analytical methods for water
Not pertinent for a SA-APP

Table 3.10 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 3.11 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 3.12 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 available. Specificity, linearity, accuracy and precision were checked and found acceptable. 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 REPULSIF CHIENS, CHATS ET FOUINES LIQUIDE is intended to be used as a repellent against stone martens, cats and dogs (development stage over 3 months) and then avoid damages caused by them, indoor (weasels, cats and dogs) or outdoor (cats). 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 liquid acts as a repellent against weasels, 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 3.13 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&3&4: cats and dogs repellent</td>
<td>REPULSIF CHIENS, CHATS ET FOUINES LIQUIDE

Formulation code:
PEO8v5LAO8v5
ACE8v5AL</td>
<td>Cats (Felis catus)

Dogs (Canis lupus familiaris)

Males and females

Development stages:
Cats: 4 months to 20 years
Dogs: 4 months to 14 years

Spraying Application
Outdoor: seat, synthetic grass, cushion, seeds bag

Indoor: shelf, shower mat, door, sofa, garage, chimney, banister, storage box

3 ml/m²</td>
<td>Field test (in-house method) – France

Indoor and Outdoor

7 locations (16 cats: 6 outdoor/4 outdoor&indoor/6 indoor) and 10 dogs (indoor))

Weather data (outdoor):
<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>
Mean temperature (indoor): 19.5°C

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</td>
<td>Control period (Cats indoor) Average on 7 days:
<table>
<tr><td>Presence of animal in the future tested area</td><td>14.4</td></tr>
<tr><td>Presence of animal (sec)</td><td>280,5</td></tr>
<tr><td>Number of degradation in the future tested area</td><td>12.3
(no degradation outside the future treated area)</td></tr>
</table>
Efficacy (Cats indoor) :
<table>
<tr><th>T0 (average 7days)</th><th></th><th>% Efficacy</th></tr>
<tr><td>Presence of animal in the tested area</td><td>0.9</td><td>92.4</td></tr>
<tr><td>Presence of animal (sec)</td><td>7.3</td><td>97.6</td></tr>
<tr><td>Number of degradation</td><td>0.1</td><td>99.2</td></tr>
<tr><th>T1(average 7days)</th><th></th><th></th></tr>
<tr><td>Presence of animal in the tested area</td><td>0.6</td><td>96.3</td></tr>
<tr><td>Presence of animal (sec)</td><td>34</td><td>88.1</td></tr>
<tr><td>Number of degradation</td><td>0.4</td><td>97.8</td></tr>
<tr><th>T2 (average 7days)</th><th></th><th></th></tr>
<tr><td>Presence of animal in the tested area</td><td>0.4</td><td>95.6</td></tr>
<tr><td>Presence of animal (sec)</td><td>3.6</td><td>98.2</td></tr>
<tr><td>Number of degradation</td><td>0.3</td><td>98.2</td></tr>
<tr><th>T3 (average 7days)</th><th></th><th></th></tr>
</table>
</td>
<td> 

R.I:2</td>
<td>6.7.1.</td>
</tr>
</table>

made on 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

Presence of animal in the tested area	0.3	**97.7**
Presence of animal (sec)	2	**99.3**
Number of degradation	0	**100**

Control period (Cats outdoor):

Presence of animal in the future tested area	14.5
Presence of animal (sec)	300
Number of degradation in the future tested area	14.1 (no degradation outside the future treated area)

Efficacy (Cats outdoor) :

T0 (average 7days)		**% Efficacy**
Presence of animal in the tested area	0.9	**99.1**
Presence of animal (sec)	13.5	**95.5**
Number of degradation	0.6	**96.5**
T1(average 7days)		
Presence of animal in the tested area	0.7	**95.6**
Presence of animal (sec)	3.3	**98.9**
Number of degradation	0.6	**96.5**
T2 (average 7days)		
Presence of animal in the tested area	0.3	**97.1**
Presence of animal	1,8	**99.4**

(sec)		
Number of degradation	0	**100**
T3 (average 7days)		
Presence of animal in the tested area	0.1	**99.1**
Presence of animal (sec)	0,8	**99.7**
Number of degradation	0	**100**

Control period (Dogs indoor):

Presence of animal in the future tested area	15.7
Presence of animal (sec)	300
Number of degradation in the future tested area	15.6 (no degradation outside the future treated area)

Efficacy (Dogs indoor) :

T0 (average 7days)		**% Efficacy**
Presence of animal in the tested area	0.7	**94.7**
Presence of animal (sec)	5.7	**98.1**
Number of degradation	0	**100**
T1(average 7days)		
Presence of animal in the tested area	0.1	**99.5**
Presence of animal (sec)	0.7	**99.8**
Number of degradation	0	**100**
T2 (average 7days)		
Presence of animal in the tested area	0.5	**97.3**
Presence of animal (sec)	3.8	**98.7**
Number of degradation	0.1	**99.4**
T3 (average 7days)		
Presence of animal in the tested area	0.1	**98.6**

				<table><tr><td>Presence of animal (sec)</td><td>0.6</td><td>**99.8**</td></tr><tr><td>Number of degradation</td><td>0</td><td>**100**</td></tr></table> The product has demonstrated a good repellent effect up to 3 months, against cats and dogs, and then avoid degradation on treated sites.		
PT19 Uses 1&3: weasels repellent	REPULSIF CHIENS, CHATS ET FOUINES LIQUIDE Formulation code: PEO8v5LAO8v5 ACE8v5AL	Stone martens (*Martes fouina*) Spraying application 3 ml/m² (5 sprays/m²)	Field test (in-house method) – France Outdoor 5 locations harbouring one or several stone marten. <table><tr><th>Test site</th><th>Surface treated (m²)</th></tr><tr><td>Colmar (68000) – Youth and culture center</td><td>About 14</td></tr><tr><td>Haguenau (67500) – Particular house</td><td>About 9</td></tr><tr><td>Illzach (68110) – Particular house</td><td>About 6</td></tr><tr><td>Luneville (54300) – Particular house</td><td>About 5</td></tr><tr><td>Heimsbrunn (68990) – Particular house</td><td>About 6</td></tr></table> Pre-treatment:The sites were first monitored in order to detect the presence of stone marten (footprints, faeces) and to verify that it comprises an infestation of the target species. Post-treatment: Indications demonstrating the presence or non-presence of animals (recent indications, owner's complaint) at T+1month, T+2months and T+3months in order to study the reinfestation after treatment by stone martens.	<table><tr><th>TEST SITE</th><th>Initial indications of presence</th></tr><tr><td>1 Colmar (68000) REPULSIVE TEST ITEM</td><td>Stone Martens settled in an attic Noise at night and in the daytime and presence of a lot of excrement showing that these animals are settled for a very long time Strong smell « putoisie »</td></tr><tr><td>2 Haguenau (67500) REPULSIVE TEST ITEM</td><td>Stone Martens settled under the roof Degraded glass wool Noises heard during the night and located presence of a lot of excrement showing that these animals are settled for a very long time</td></tr><tr><td>3 Illzach (68110) REPULSIVE TEST ITEM</td><td>Stone Martens settled under the roof Degraded glass wool Noises heard during the night presence of a lot of excrement</td></tr><tr><td>4 Luneville (54300) REPULSIVE TEST ITEM</td><td>Stone Martens settled in the attic, presence of a lot of fresh excrement outside on the railways and scratches around the building and noise at night</td></tr><tr><td>5 Heimsbrunn (68990) REPULSIVE TEST ITEM</td><td>Stone Martens settled under the roof Noise at night and in the daytime Degraded glass wool presence of a lot of fresh excrement</td></tr></table> Table 1 : Faeces count for each test site during the study <table><tr><th></th><th>Address</th><th>Application</th><th>T1month</th><th>T2months</th><th>T3months</th></tr><tr><td>Test site 1</td><td>Colmar (68000)</td><td>138</td><td>138</td><td>138</td><td>138</td></tr><tr><td>Test site 2</td><td>Haguenau (67500)</td><td>79</td><td>79</td><td>79</td><td>79</td></tr><tr><td>Test site 3</td><td>Illzach (68110)</td><td>65</td><td>65</td><td>65</td><td>65</td></tr><tr><td>Test site 4</td><td>Luneville (54300)</td><td>184</td><td>184</td><td>184</td><td>184</td></tr><tr><td>Test site 5</td><td>Illzach (68110)</td><td>39</td><td>39</td><td>39</td><td>39</td></tr></table> From the day after the application, no more fresh excretion or damages/scratches noted. Animals left the test site, no more presence of animals 1, 2, 3 months after the treatment.	Evaluation of the efficacy of "REPULSIF FOUINES" For the control of STONE MARTENS infestations in a rural AND URBAN ZONE. [redacted] R.I :2	6.7.2

3.5.4 Efficacy assessment

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

- **Repellent Efficay against cats and dogs:**

Efficacy of the product REPULSIF CHIENS, CHATS, FOUINES LIQUIDE 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 (indoor and or outdoor) can be clearly defined. The owners then spray 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 outdoor (seat, synthetic grass, cushion, seeds bag) and indoor (shelf, shower mat, door, sofa, garage, leg of chair, chimney, banister, storage box) made of different materials (wood, plastic, synthetic fibres, steel, cotton, rubber, tiles, stone, paper…) 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), globally efficacy higher than almost 95 % is demonstrated for all the parameters "presence of animals in the treated zone' and "presence of degradation". Cats and dogs spend less time in the treated area and even if they frequent furtively the treated site, degradation almost disappear within 3 months.

- **Repellent Efficay against stone martens:**

Efficacy of the product REPULSIF CHIENS, CHATS, FOUINES LIQUIDE has been assessed in a field trial, performed in France (5 locations). Sites are particular houses or youth and culture center, harbouring one or several stone marten. Treatments took place in attic or under the tiles of roof.
The efficacy indicator was measured at T+1month, T+2months and T+3months by the persistence of the stone marten's presence after the treatment and in particular the noise caused by animals and perceived by test site owners, and the presence of fresh excrements.

For all treated test sites, animals leave their nests shortly after the application of the product and do not return on treated test sites, up to 3 months after the application of the product REPULSIF CHIENS, CHATS, FOUINES LIQUIDE.

3.5.5 Conclusion on efficacy

The product REPULSIF CHIENS, CHATS, FOUINES LIQUIDE has demonstrated a good repellent effect up to 3 months, at the application rate of 3 ml/m², applied indoor against stone martens, cats and dogs, and outdoor against cats.

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 substances and available information for the non-active substances.

The classification of the product REPULSIF CHIENS, CHATS, FOUINES LIQUIDE 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 the criterias for substitution nor exclusion]

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 Protection Claimed (Yes/No)**

[redacted]	[redacted]	4.6.1	Flash point test on PEO8v5LAO8v5ACE8v5AL	22-902007-005	Physico-chemical study	ARMOSA TECH	No	Yes
[redacted]	[redacted]	4.16.1	Study plan_Test methods for corrosion to metals on PEO8v5LAO8v5ACE8v5AL	On-going study	Physico-chemical study	ARMOSA TECH	No	Yes
[redacted]	[redacted]	3.4.1.2	BAS122021.5_Physical and chemical stability after a storage procedure at 20 °C +- 2 °C for 24 months of PEO8v5LAO8v5ACE8v5AL	BAS122021.5	Accelerated storage study	ARMOSA TECH	No	Yes
[redacted]	[redacted]	3.41.1	_Chemical stability after a storage procedure at 54 °C +- 2 °C for 14 days of PEO8v5LAO8v5ACE8v5AL	BAS042022.1	Ambient storage study	ARMOSA TECH	No	Yes
[redacted]	[redacted]	5.1	BAS122021.1_Validation of the analytical method for the determination of Peppermint oil and Lavender oil in PEO8v5LAO8v5ACE8v5AL	BAS122021.1	Method validation	ARMOSA TECH	No	Yes
[redacted]	[redacted]	5.2	BAS122021.3_Validation of the analytical method for the determination of Acetic acid in PEO8v5LAO8v5ACE8v5AL	BAS122021.3	Method validation	ARMOSA TECH	No	Yes

[redacted]	[redacted]	6.7.1	Field trial of the biocidal product PEO8v5LAO8v5ACE8v5AL	BAS160222.1	Efficacy study	ARMOSA TECH	No	Yes
[redacted]	[redacted]	6.7.2	EVALUATION OF THE EFFICACY OF "REPULSIF FOUINES" FOR THE CONTROL OF STONE MARTENS INFESTATIONS IN A RURAL AND URBAN ZONE.	21ARMMfF001	Efficacy study	ARMOSA TECH	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

– None

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.