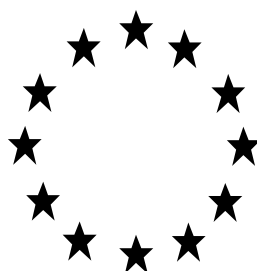


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR SIMPLIFIED
AUTHORISATION APPLICATION**

(submitted by the competent authority)



DIFFUSEUR ANTI MITES

Product type 19

Peppermint oil as included in the Annex I of Regulation (EU)
No 582/2012

Case Number in R4BP: BC-VW082288-89

Competent Authority: FR CA

Date: 24/03/2023

Table of Contents

1 Conclusion.....	5
2 Information on the biocidal product	7
2.1 Product type(s) and type(s) of formulation.....	7
2.2 Uses.....	7
2.3 Identity and composition	9
2.4 Identity of the active substance(s)	9
2.5 Information on the source(s) of the active substance(s)	9
2.6 Candidate(s) for substitution	9
2.7 Assessment of the endocrine-disrupting properties of the biocidal product	10
2.8 Classification and labelling	10
2.9 Letter of access	11
2.10 Data submitted in relation to product authorisation	11
2.11 Similar conditions of use across the Union	11
3 Assessment of the biocidal product.....	11
3.1 Packaging	11
3.2 Physical, chemical, and technical properties	12
3.3 Physical hazards and respective characteristics.....	18
3.4 Methods for detection and identification.....	24
3.5 Assessment of efficacy against target organisms	27
3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)	27
3.5.2 Mode of action and effects on target organisms, including unacceptable suffering	27
3.5.3 Efficacy data.....	28
3.5.4 Efficacy assessment.....	32
3.5.5 Conclusion on efficacy.....	32
3.5.6 Occurrence of resistance and resistance management	32
3.5.7 Known limitations.....	32
3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products.....	32
3.6 Human health	33
Assessment of effects on human health.....	33
Available toxicological data relating to substance(s) of concern	33
Available toxicological data relating to endocrine disruption	33
Dietary exposure	33
3.7 Animal health.....	33
3.8 Environment	34
Classification	34

Substance(s) of concern	34
Screening for endocrine disruption relating to non-target organisms	34
3.9 Assessment of a combination of biocidal products	34
3.10 Comparative assessment	35
4 Appendices	36
4.1 New information on the active substance(s) and substance(s) of concern	36
4.2 List of studies for the biocidal product	37
4.3 References.....	38
References other than list of studies for the biocidal product.....	38
Guidance documents.....	38
Legal texts.....	38
4.4 Confidential information.....	38

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-VW082288-89	15/06/2023	Initial assessment	

1 Conclusion

DIFFUSEUR ANTI MITES is a vapour releasing biocidal product containing peppermint oil. The product is used as a repellents and attractants (PT19) by general public for the control of adult cloth moths (*Tineola bisselliella*).

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 cloth moth repellent against adult textile attacking moths by non-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 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 substance peppermint oil is listed in Annex I of Regulation (EU) 528/2012 with no restrictions applied
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008¹ is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

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

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

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 of the biocidal product is listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions

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

of the assessments for each area are summarised below.

Physical, chemical and technical properties

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

Physical hazards and respective characteristics

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

Methods for detection and identification

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

Efficacy against target organisms

The product DIFFUSEUR ANTI MITES is effective to repel clothes moths adults at the application rate of 5 ml/0.049 m³ (i.e 5 ml in approximately 0,05 m³ or 50 L), after 7 days of product opening and up to 2 months.

With regard to the pack size claimed (box of 50 ml or 100 ml), application rates validated are the following:

- 1 box of 50 ml for 0,5 m³
- 1 box of 100 ml for 1 m³

Hazards/Risk assessment for human and animal health

No substances of concern regarding human health are identified.

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

Dietary risk assessment

Considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for the environment

No substances of concern regarding environment were 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	VP – (Vapour releasing product) : wax-based diffuser

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	Cloth moth repellent against adult textile attacking moths	PT19	Cloth moths <i>Tineola bisselliella</i> Adults	Wax-based diffuser	1 box of 50 mL for 0.5 m ³ 1 box of 100 mL for 1 m ³	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 category(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 evaluated in connection with the inclusion of the active substance 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(s)	
Common name	Peppermint oil (Natural oil)
Chemical name	-
EC number	-
CAS number	8006-90-4
Index number in Annex VI of CLP	-
Minimum purity / content	Not applicable
Structural formula	Not applicable

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

The information on the source(s) of the active substance is not applicable.

2.6 Candidate(s) for substitution

The active substance is included in Annex I (cat. 4 - Traditionally used substances of natural origin) of the BPR and thus is not considered as candidate for substitution.

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	Aquatic Chronic Cat.3	Aquatic Chronic Cat. 3
Hazard Pictograms	None	None
Signal word(s)	None	None
Hazard statements	H412 - Harmful to aquatic life with long lasting effects.	H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements*	P273 - Avoid release to the environment. P501 - Dispose of contents and container to an approved hazardous waste collection centre, in accordance with local, regional, national and/or international regulations.	P273 - Avoid release to the environment. P501 - Dispose of contents and container to an approved hazardous waste collection centre, in accordance with local, regional, national and/or international regulations.
Supplemental hazard statements	EUH208 - Contains isomenthone, 1,8 cineole (eucalyptol), beta-caryophyllene, limonene, alpha pinene and beta pinene. May produce an allergic reaction.	
Notes		

*P-statements that are excluded based on the risk assessment or the intended use of the product², are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

² Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at <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

No new data on the active substance has been submitted.

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)
Box	50 mL	Aluminium without varnish	Aluminium cap	Non-professional	Yes
Box	100 mL	Aluminium without varnish	Aluminium cap	Non-professional	Yes

¹ Type of packaging e.g. bottle, rolls, can, barrel, tank.

² Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.

For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.

³ For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.

⁴ Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	eCa comments	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	Visual Organoleptic	Diffuseur Anti Mites Batch 4124 3.5352% w/w menthol 2.8620% w/w menthone (nominal content of peppermint oil: 9.9% w/w)	Yellow waxy solid with a mint odour before and after 24 months of storage at 20 ± 2°C.	Acceptable	Biocidal alternative solutions SA, Hans M., 2022, report No. BAS082022.1
3.1.1.	Physical state at 20 °C and 101.3 kPa					
3.1.2.	Colour at 20 °C and 101.3 kPa					
3.1.3.	Odour at 20 °C and 101.3 kPa					
3.2.	Acidity, alkalinity and pH value	Not applicable. The product is a wax-based diffuser (VP).		Acceptable		
3.3.	Relative density / bulk density	Not required as part of the simplified procedure according to Article 20(1)(b) of Regulation (EU) No.528/2012).		Acceptable		
3.4.1.1.	Storage stability test – accelerated storage	CIPAC MT46.3	Batch: 4124	Aluminium container Before storage Weight : 52.01 g After storage Weight : 51.85 and no modification of the aspect of the packaging 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	Acceptable The product is stable 14 days at 54°C in its packaging	Report BAS072020.2

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	eCa comments	Reference
				<p>of aspect and weight was observed.</p> <p>Deviation from T0: Peppermint oil = -1.2349% (Ci= 95.9596 g/kg; Cf=94.7746 g/kg)</p>		
3.4.1.2.	Storage stability test – long-term storage at ambient temperature	Technical Monograph No.17, 2nd edition CropLife International	Batch: 4124	<p>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 was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C; no significant change of weight was observed.</p> <p>Deviation from T0: Peppermint oil = -0.5304% (Ci= 98.2339</p>	Acceptable	Report BAS082022.1

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	eCa comments	Reference
				g/kg; Cf=97.7129 g/kg)		
3.4.1.3.	Storage stability test – low temperature stability test for liquids	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – light	Not determined as the product is packed in opaque packagings (aluminium), so that the effects of light can be excluded.			Acceptable	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	- Effect of temperature and humidity: negligible as the commercial packagings are hermetically sealed and leak-tight.			Acceptable	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	Refer to the sections on the storage stability tests.			Acceptable	
3.5.1.	Wettability <i>[indicate the concentration tested]</i>	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.2.	Suspensibility, spontaneity, and dispersion stability <i>[indicate the concentration tested]</i>	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.3.	Wet sieve analysis and dry sieve test <i>[indicate the concentration</i>	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	eCa comments	Reference
	<i>tested]</i>					
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability <i>[indicate the concentration tested]</i>	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.5.	Disintegration time	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability <i>[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]</i>	Not required as part of the simplified procedure according to Article 20(1)(b) of Regulation (EU) No.528/2012).			Acceptable	
3.5.7.	Persistent foaming <i>[indicate the concentration tested]</i>	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.8.	Flowability/pourability/dustability	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.9.	Burning rate – smoke generators	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.10.	Burning completeness – smoke generators	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.11.	Composition of smoke – smoke generators	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.5.12.	Spraying pattern – aerosols / spray	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.6.1.	Physical compatibility	Not applicable. The product is not intended to be used in conjunction with any other products or active substances.			Acceptable	
3.6.2.	Chemical compatibility	Not applicable. The product is not intended to be used in conjunction with any other products or active substances.			Acceptable	
3.7.	Degree of dissolution and dilution stability	Not applicable. The product is a wax-based diffuser (VP).			Acceptable	
3.8.	Surface tension	Not required as part of the simplified procedure according to Article 20(1)(b) of Regulation (EU) No.528/2012).			Acceptable	
3.9.	Viscosity	Not required as part of the simplified procedure according			Acceptable	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	eCa comments	Reference
		to Article 20(1)(b) of Regulation (EU) No.528/2012).				

Table 3.3 Conclusion on physical, chemical, and technical properties**Conclusion on physical, chemical, and technical properties**

The product DIFFUSEUR ANTI MITES is a vapour releasing product (VP). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

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 packaging.

Implications for labelling:

- Shelf-life: 2 years

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	eCA comments
4.1.	Explosives	Justification for non-classification	n.a.	<p>The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding explosiveness. Moreover, menthol and menthone (substances contained in peppermint oil) have no chemical group associated with explosive properties. In addition, the main component of the product Diffuseur Anti Mites contains substances with no chemical group associated with explosive properties and is not classified for explosive properties according to its safety data sheet.</p> <p>As a result, the product Diffuseur Anti Mites is not expected to be explosive and test is considered as unnecessary.</p>	Based on the composition of the product, no explosive properties are expected
4.2.	Flammable gases	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.3.	Flammable aerosols	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.4.	Oxidising gases	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.5.	Gases under pressure	Justification for non-	n.a.	Not required as it is a solid product.	/

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	eCA comments
		classification			
4.6.	Flammable liquids	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.7.	Flammable solids	Justification for non-classification	n.a.	<p>The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding flammability. Its flash point is 72°C according to its safety datasheet.</p> <p>In addition, the main component of the product Diffuseur Anti Mites has a flash point > 175°C according to its safety datasheet.</p> <p>Therefore, the product Diffuseur Anti Mites is not expected to be flammable and flammability test is considered as unnecessary.</p>	Acceptable, the product is not considered as flammable
4.8.	Self-reactive substances and mixtures	Justification for non-classification	n.a.	<p>The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding self-reactivity. Moreover, menthol and menthone (substances contained in peppermint oil) have no chemical group associated with self-reactive properties.</p> <p>In addition, the main component of the product Diffuseur Anti Mites contains substances with no chemical group associated with self-reactive properties and is not classified for self-reactive properties according to its safety data</p>	Based in the composition, no self-reactive properties are expected

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	eCA comments
				sheet. Therefore, the product Diffuseur Anti Mites is not expected to present self-reactive properties and test is considered as unnecessary.	
4.9.	Pyrophoric liquids	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.10.	Pyrophoric solids	Justification for non-classification	n.a.	Test is not required as the product Diffuseur Anti Mites does not contain any components classified as pyrophoric according to their safety data sheets. Moreover, experience in manufacture and handling shows that the product Diffuseur Anti Mites does not ignite spontaneously on coming into contact with air at normal temperature. The product Diffuseur Anti Mites is not expected to be a pyrophoric solid and test is not required.	Acceptable
4.11.	Self-heating substances and mixtures	Justification for non-classification	n.a.	The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding self-heating. It has no self-heating properties according to its safety datasheet. In addition, the main component of the product Diffuseur Anti Mites is not expected to have self-heating properties according to its safety datasheet.	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	eCA comments
				Therefore, the product Diffuseur Anti Mites is not expected to present self-heating properties and test is considered as unnecessary.	
4.12.	Substances and mixtures which in contact with water emit flammable gases	Justification for non-classification	n.a.	Test is not required as the product Diffuseur Anti Mites does not contain any components classified as substances which in contact with water emit flammable gases. Therefore, the product Diffuseur Anti Mites is not expected to emit flammable gases in contact with water and test is not required.	Acceptable
4.13.	Oxidising liquids	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.14.	Oxidising solids	Justification for non-classification	n.a.	<p>The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding oxidising properties. Moreover, menthol and menthone (substances contained in peppermint oil) contain oxygen atoms but these elements are only chemically bonded to carbon and/or hydrogen atoms. Therefore the classification procedure for the hazard class "oxidising solids" shall not apply.</p> <p>In addition, the main component of the product Diffuseur Anti Mites contains substances with no highly electronegative atoms or with oxygen atoms but only bonded to carbon and/or</p>	Based on the composition, no oxidizing properties are expected

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	eCA comments
				hydrogen atoms. As a result, the product Diffuseur Anti Mites is not expected to be oxidising and test is considered as unnecessary.	
4.15.	Organic peroxides	Justification for non-classification	n.a.	Not required as the components are not expected to form or contain organic peroxides.	/
4.16.	Corrosive to metals	Justification for non-classification	n.a.	<p>The product Diffuseur Anti Mites is not concerned by the physical hazard "corrosive to metals" as it is a solid product.</p> <p>According to the classification criteria, only mixtures for which the application of the UN Test C.1 (described in part III, Section 37.4.1.1 of the UN-MTC) is relevant need to be considered. Application of classification criteria in the UN-MTC, Section 37.4 excludes solids, while 'liquids and solids that may become liquids (during transport)', have to be considered for such a classification. Solids having a melting point lower than 55°C (which is the test temperature required in UN Test C.1) must then be taken into consideration.</p> <p>As the melting point of the main component of Diffuseur Anti Mites is > 55°C (61 - 65°C according to its safety datasheet), the melting point of the product Diffuseur Anti Mites is expected to be more than 55°C.</p> <p>Therefore, the classification procedure for corrosive properties does not apply to the product Diffuseur Anti Mites.</p>	As the product if a solid, the croosive to metal properties are not required.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	eCA comments
				The product Diffuseur Anti Mites is not expected to be corrosive to metals and test is not required.	
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Justification for non-classification	n.a.	Not required as it is a solid product.	/
4.17.2.	Relative self-ignition temperature for solids	Justification for non-classification	n.a.	The active substance contained in the product Diffuseur Anti Mites (peppermint oil) is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding auto-flammability In addition, the main component of the product Diffuseur Anti Mites is not expected to have self-ignition properties according to its safety datasheet. Therefore, the product Diffuseur Anti Mites is not expected to present a significant hazard for relative self-ignition and test is not required.	Acceptable
4.17.3.	Dust explosion hazard	Justification for non-classification	n.a.	Not required as it is a wax-based product without dust.	/

Table 3.5 Conclusion on physical hazards and respective characteristics

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

3.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
<p>Principle of the method [reference method]: [Describe the analytical methods used for the analysis of the active substance(s), relevant impurity(ies) and substance(s) of concern in the biocidal product, e.g. "5 mg sample are taken and dissolved in 20 mL mobile phase (methanol/water 5/95 v/v) in a 50 mL volumetric flask, sonicated and filled up to the mark. Analysis is done by HPLC-UV at 254 nm with a C18 column and mobile phase using gradient/isocratic elution (specify gradient)."]</p>											
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(ies)	Reference
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Menthol	The linearity of menthol was determined from five injections of five levels of standard ranging from 0.2111 to 0.0704 g/L $r = 0.99942$	No peak in the solvent blank and in the formulation blank near the retention time of menthol, Retention times for menthol match between reference standard and test item, no interference observed	0.1407 mg/mL, 3.39 % w/w	2	90% - 110%	97,4 1%		3.392% RDS= 1.6051 % C Horwitz = 0.0339, Horrat equal to 0.72	5	/	Report BAS072020 .1

Menthone	The linearity of linalool was determined from five injections of five levels of standard ranging from 0.1752 to 0.0584 g/L r = 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 standard and test item, no interference observed	0.1168 mg/mL, 2.57 % w/w	2	90% - 110%	99.38%		2.5705 % RSD=2.1301 C Horwit= 0.0257, Horrat equal to 0.92.	5	/	Report BAS072020 .1
----------	---	--	-----------------------------	---	------------	--------	--	---	---	---	---------------------

Table 3.7 Conclusion on methods for detection and identification**Conclusion on methods for detection and identification**

Analytical methods for the determination of menthol and menthone in the biocidal product Diffuseur Anti Mites are available. Specificity, linearity, accuracy and precision were checked and found acceptable.

Methods for the detection of menthol and menthone in soil, air, water, animal and human body fluids and tissues and in food/feed of plant and animal origins are no data requirement for simplified procedures according to Article 20(1)(b) of the BPR.

- There are no available analytical methods for menthol and menthone residues in soil, air, water, and human body fluids and tissues.

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 DIFFUSEUR ANTI MITES is intended to be used as a repellent used against clothes moths adults, *Tineola bisselliella*, indoor, by non-professional users. It is applied in wardrobes/clothes closet and drawers to repel clothes moths. A residual effect of 2 months is claimed.

The application rate claimed is 1 box of 50 ml per drawer and 1 box of 100 ml per wardrobes or clothes closet.

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

Essential oils are complex mixtures of volatile organic compounds (Kalita et al., 2013). They are constituted by hydrocarbons (terpenes and sesquiterpenes) and oxygenated compounds (alcohols, esters, ethers, aldehydes, ketones, lactones and phenols). Being volatile in nature they act as chemical messengers for insects and other animals, serving as a signal of relatively short duration. For example, literature cites that hairs on the mosquito antennae are temperature and moisture sensitive. The repellent molecules thus interact with the female mosquito olfactory receptors thereby blocking the sense of smell which therefore comes as an hurdle in the recognition of host by the mosquitoes.

According to the applicant, essential oils act at a vapor phase and are generally effective when freshly applied as they usually dissipate quickly within a short period of time due to their high volatility. However this property can be improved through the development of formulations that enable controlled release of these volatile compounds.

However, no data in the scientific literature regarding the mode of action of peppermint oil against clothes moths.

3.5.3 Efficacy data

The applicant has submitted a simulated-use test to demonstrate the efficacy of the product DIFFUSEUR ANTI MITES. The study was performed with the trade name CIRE 9.9% HEM, which is identical to the product DIFFUSEUR ANTI MITES.

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects [address here results related to efficacy of the test product and validity of the test]	Reference	Number in IUCID section 6.7/Test report title																																																																
PT19 Use 1: Clothes moth	DIFFUSEUR ANTI MITES 9.9% w/w peppermint oil	Repellent <i>Tineola bisselliella</i> (adults) 50 adults mixed sex 50% males 50 % females	Simulated-use test In a specific test device made of two 50 L (0.049 m ³) communicating cylinders, the product is set for evaporating during 7 days in the first cylinder with a piece of wool as attractant target. After 7 days, clothes moths are released in the second cylinder, and the opening between both volumes is opened. The behaviour and location of the moths in the	<p>The trial is first done without the test product to check the attractiveness of the wool for the insects.</p> <p style="text-align: center;">Time of exposure (in minutes)</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>1</th> <th>5</th> <th>10</th> <th>15</th> <th>30</th> <th>60</th> <th>% activity after 1 hour</th> </tr> </thead> <tbody> <tr> <td>Replicate</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>1</td> <td>38</td> <td>50</td> <td>50</td> <td>50</td> <td>50</td> <td>50</td> <td>100</td> </tr> <tr> <td>2</td> <td>12</td> <td>50</td> <td>50</td> <td>50</td> <td>50</td> <td>50</td> <td>100</td> </tr> <tr> <td>3</td> <td>27</td> <td>41</td> <td>49</td> <td>49</td> <td>50</td> <td>50</td> <td>100</td> </tr> <tr> <td>4</td> <td>16</td> <td>47</td> <td>48</td> <td>48</td> <td>48</td> <td>48</td> <td>96</td> </tr> <tr> <td>Mean</td> <td>23,25</td> <td>47</td> <td>49,25</td> <td>49,25</td> <td>49,5</td> <td>49,5</td> <td>99</td> </tr> </tbody> </table> <p>After this validation (> 80% attracted by the wool without the product within 60 minutes), the trial is conducted with new insects (see results in table below).</p> <p>Number of clothes moths on the wool (treated and untreated) and % repellency after 1 hour exposure</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Date</th> <th>Treated*</th> <th>Untreated*</th> <th>Mean*(%)</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>1</td> <td>49.5</td> <td>98</td> </tr> </tbody> </table>		1	5	10	15	30	60	% activity after 1 hour	Replicate								1	38	50	50	50	50	50	100	2	12	50	50	50	50	50	100	3	27	41	49	49	50	50	100	4	16	47	48	48	48	48	96	Mean	23,25	47	49,25	49,25	49,5	49,5	99	Date	Treated*	Untreated*	Mean*(%)	Fresh	1	49.5	98	<p>Report 2594c-PER/0920</p>	<p>6.7_01 Laboratory assessment of the repellent efficacy of a product against clothe moth. Diffuseur anti mites HEM 9.9% RI = 1</p>
	1	5	10	15	30	60	% activity after 1 hour																																																															
Replicate																																																																						
1	38	50	50	50	50	50	100																																																															
2	12	50	50	50	50	50	100																																																															
3	27	41	49	49	50	50	100																																																															
4	16	47	48	48	48	48	96																																																															
Mean	23,25	47	49,25	49,25	49,5	49,5	99																																																															
Date	Treated*	Untreated*	Mean*(%)																																																																			
Fresh	1	49.5	98																																																																			

			<p>2 cylinders are then recorded during one hour. The number of insects is recorded on both cylinders of the device after 1, 5, 10, 15, 30 and 60 minutes. An untreated control has been conducted in the same experimental device and conditions. The insecticidal effect of the product has been assessed by leaving the insects inside the device one more hour once being taken out of the device. The knockdown is recorded from 0 to 2 hours and mortality after 24H. Efficacy is calculated by comparing the number of moths in the 2 parts of</p>	<table border="1"> <tr> <td>30 days aged</td> <td>4</td> <td>49.75</td> <td>92</td> </tr> <tr> <td>60 days aged</td> <td>9.25</td> <td>49.5</td> <td>81</td> </tr> <tr> <td>90 days aged</td> <td>14.5</td> <td>49.5</td> <td>71</td> </tr> </table> <p>(*) mean of 4 replicates</p> <p>% Kd after 2 h exposure to the product and mortality after 24 hours:</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Kd*</th> <th>Mortality*</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>0</td> <td>0</td> </tr> <tr> <td>30 days aged</td> <td>0</td> <td>0</td> </tr> <tr> <td>60 days aged</td> <td>0</td> <td>0</td> </tr> <tr> <td>90 days aged</td> <td>0</td> <td>0</td> </tr> </tbody> </table> <p>(*) mean of 4 replicates</p> <p>Efficacy criteria: $\geq 80\%$ repellence of adults within the test period and until the end of the residual period</p> <p>The product Diffuseur Anti Mites is effective to repel clothes moth adults (<i>Tineola bisselliella</i>) at the application rate of 5 ml/0.049m³ (102 ml/m³) up to 2 months, after 7 days of the diffusion of product inside the treated volume</p>	30 days aged	4	49.75	92	60 days aged	9.25	49.5	81	90 days aged	14.5	49.5	71	Date	Kd*	Mortality*	Fresh	0	0	30 days aged	0	0	60 days aged	0	0	90 days aged	0	0				
30 days aged	4	49.75	92																																
60 days aged	9.25	49.5	81																																
90 days aged	14.5	49.5	71																																
Date	Kd*	Mortality*																																	
Fresh	0	0																																	
30 days aged	0	0																																	
60 days aged	0	0																																	
90 days aged	0	0																																	

			<p>the device. Percentage of repellency = [(nb of moths in the untreated cylinder with wool - nb of moths in the treated cylinder with wool and product)/ nb of moths in the untreated cylinder with wool] *100</p> <p>30, 60 and 90 days aged products (opened product put in a 60 cm side cube opened 30 seconds each day) have been tested in the same condition than fresh product.</p> <p>Test conditions: 25°C ±2°C, 65% ±5%, light 1500 lux.</p> <p>Four replicates for both treated and untreated</p>		
--	--	--	---	--	--

			devices. Application rate: 5ml/0.049m ³ (102 ml/m ³)			
--	--	--	--	--	--	--

3.5.4 Efficacy assessment

At the submission of the dossier, no specific guidance is available for a repellent against clothes mites. The applicant has submitted a simulated-use test in order to mimic a practical situation. eCA agrees that this kind of the test is sufficient for the time being. Note that new guidance for PT19 claims (December 2021) requests a simulated-use test also.

Efficacy criteria have been based on this new guidance (i.e at least 80%)

To demonstrate the repellent effect of the product, a simulated use test has been conducted in a volume of 0.049 m³ (approximately 50 L) against clothes moths adults (*Tineola bisselliella*) in presence of wool piece as attractant for clothes moths. A fresh product, and aged products (30, 60 and 90 days) have been tested with comparison to an untreated control in the same experimental device and conditions. The results showed a repellency > 80% against clothes moths adults at the application rate of 5 ml/0.049 m³ with fresh product and up to 60 days, after 7 days of product diffusion inside the experimental device.

3.5.5 Conclusion on efficacy

The product DIFFUSEUR ANTI MITES is effective to repel clothes moths adults at the application rate of 5 ml/0.049 m³ (i.e 5 ml in approximately 0,05 m³ or 50 L), after 7 days of product opening and up to 2 months.

With regard to the pack size claimed (box of 50 ml or 100 ml), application rates validated are the following:

- 1 box of 50 ml for 0,5 m³
- 1 box of 100 ml for 1 m³

3.5.6 Occurrence of resistance and resistance management

No resistance has been identified in the literature review for clothes moths attracted by peppermint oil.

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

3.5.7 Known limitations

Time delay of the product is 7 days.

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

The product is not intended to be used with other biocidal products.

3.6 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.

Assessment of effects on human health

There are no human health data available for the product. The 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 DIFFUSEUR ANTI MITES 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.

However, due to the presence of 6 ingredients at a content above the elicitation threshold, the EUH208 labelling statement is required.

EUH208 - Contains isomenthone, 1,8 cineole (eucalyptol), beta-caryophyllene, limonene, alpha pinene and beta pinene. May produce an allergic reaction.

Refer to Confidential Annex for further details.

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)).

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.

Dietary exposure

The product does not come into contact with food when application follows the label instructions. Therefore, exposure to residues in food is not considered relevant. Taking into account authorized use residues in food are not considered relevant. Therefore, no further assessment is considered necessary.

3.7 Animal health

Not relevant

3.8 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.

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 classified Aquatic Chronic 3 (H412) based on the active substance properties. The active substance is listed in Annex I of Regulation (EU) No 528/2012, without any restriction for the environment. The coformulants are not classified and are not identified as substances of concern. There is no need for risk mitigation measure to protect the environment.

Substance(s) of concern

The product DIFFUSEUR ANTI MITES 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).

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. The active substance is not candidate for substitution.

4 Appendices

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

No new information on the active substance(s) is available

No new information on the substance(s) of concern is available

4.2 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. / 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)
██████	2020	IUCLID Section 3.4.1	3.4.1.2. Storage stability test (14 days at 54°C ± 2°C)	Physical and chemical stability after a storage procedure at 54 °C ± 2 °C for 14 days of PEO99WAX In compliance with CIPAC MT 46.3	Study report	Biocidal alternative solutions SA ARMOSA SA	No	Yes
██████	2022	IUCLID Section 3.4.1	3.4.1.1. Storage stability test (24 months at 20°C ± 2°C)	Physical and chemical stability after a storage procedure at 20 °C ± 2 °C for 24 months of PEO99WAX In compliance with Technical Monograph No. 17, 2nd edition CropLife International	Study report	Biocidal alternative solutions SA ARMOSA SA	No	Yes
██████	2020	IUCLID Section 5	5.3. Method of detection and identification of Peppermint Oil	Validation of the analytical method for the determination of Peppermint oil in PEO99WAX In compliance with SANCO/3030/99 rev.5 from 22/03/2019	Study report	Biocidal alternative solutions SA ARMOSA SA	No	Yes
██████	2021	IUCLID Section 6.7	6.7_01_Simulated-use test	Laboratory assessment of the repellent efficacy of a product against clothe moth. Cire HEM 9.9% Report No. 2594c-PER/0920	Study report	TEC Laboratory (Anglet, France) Spring	No	Yes

4.3 References

References other than list of studies for the biocidal product

No references other than studies are used.

Guidance documents

References to guidance documents are presented in the relevant PAR section when this guidance is needed.

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.

4.4 Confidential information

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