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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT A SIMPLIFIED AUTHORISATION APPLICATION

(submitted by eCA)



Combirepel™ CR8181

Product type 19

Lavender oil, citronellal and peppermint oil as included on Annex I of the Biocidal Products Regulation (BPR)

Case Number in R4BP: BC-AQ050918-23
Evaluating Competent Authority: Lithuanian National
Public Health Centre

Date: 04/10/2019

Table of Contents

1	CONCLUS	SION	4
2	ASSESSM	ENT REPORT	5
	2.1 SUM	MARY OF THE PRODUCT ASSESSMENT	5
	2.1.1	Administrative information	
	2.1.1.1	Identifier of the product	
	2.1.1.2	Authorisation holder	
	2.1.1.3	Manufacturer of the product	
	2.1.1.4	manufacturer(s) of the active substance(s)	
	2.1.2	Product composition and formulation	
	2.1.2.1	Identity of the active substance	
	2.1.2.2	Candidate(s) for substitution	
	2.1.2.3	Qualitative and quantitative information on the composition of the biocidal product	7
	2.1.2.4	Information on technical equivalence	7
	2.1.2.5	Information on the substance(s) of concern	7
	2.1.2.6	Type of formulation	
	2.1.3	Hazard and precautionary statements	
	2.1.4	Authorised use(s)	8
	2.1.4.1	Use description	
	2.1.4.2	Use-specific instructions for use	
	2.1.4.3	Use-specific risk mitigation measures	9
	2.1.4.4	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and	
	_	ncy measures to protect the environment	
	2.1.4.5	Where specific to the use, the instructions for safe disposal of the product and its packaging	
	2.1.4.6	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditio	ns
	of stora		
	2.1.5	General directions for use	
	2.1.5.1 2.1.5.2	Risk mitigation measures	
	2.1.5.2	Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the	
		ment	
	2.1.5.4	Instructions for safe disposal of the product and its packaging	
	2.1.5.5	Conditions of storage and shelf-life of the product under normal conditions of storage	
	2.1.6	Other information	
	2.1.7	Packaging of the biocidal product	
	2.1.8	Documentation	
	2.1.8.1	Data submitted in relation to product application	
	2.1.8.2	Access to documentation	
	2.2 ASSE	SSMENT OF THE BIOCIDAL PRODUCT	
		Intended use(s) as applied for by the applicant	
	2.2.2	Physical, chemical and technical properties	
	2.2.3	Physical hazards and respective characteristics	
	2.2.4	Methods for detection and identification	
	2.2.5	Efficacy against target organisms	
	2.2.5.1	Function and field of use	
	2.2.5.2	Organisms to be controlled and products, organisms or objects to be protected	
	2.2.5.3	Effects on target organisms, including unacceptable suffering	
	2.2.5.4	Mode of action, including time delay	
	2.2.5.5	Efficacy data	
	2.2.5.6	Occurrence of resistance and resistance management	
	2.2.5.7	Known limitations	
	2.2.5.8	Evaluation of the label claims	17
	2.2.5.9	Relevant information if the product is intended to be authorised for use with other biocidal product(s)	17
	2.2.5.10	Product is not intended to be used with other biocides	17
	226	Risk assessment for human health	18

	2.2.7	Risk assessment for animal health	18
	2.2.8	Risk assessment for the environment	18
	2.2.9	Measures to protect man, animals and the environment	18
	2.2.9.1 life	Recommended methods and precautions concerning storage of active substance/biocidal product; s 18	helf-
	1.1.1.1	Recommended methods and precautions concerning handling and transport	19
	1.1.1.2	Recommended methods and precautions concerning fire	19
	1.1.1.3	First aid instructions	19
	1.1.1.4	Emergency measures to protect environment in case of an accident	19
	1.1.1.5	Instructions for safe disposal of the biocidal product and its packaging for different groups of users	19
	2.2.10	Assessment of a combination of biocidal products	19
	2.2.11	Comparative assessment	
3	ANNEXE:	S	20
	3.1 LIST	OF STUDIES FOR THE BIOCIDAL PRODUCT	20
	3.2 OUT	PUT TABLES FROM EXPOSURE ASSESSMENT TOOLS	20
	3.3 NEW	/ INFORMATION ON THE ACTIVE SUBSTANCE	20
	3.4 RESII	DUE BEHAVIOUR	20
	3.5 SUM	MARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)	20
		FIDENTIAL ANNEX	
		ER	

1 CONCLUSION

The eCA considers that all the conditions for a simplified authorisation procedure of biocidal product Combirepel™ CR8181 in accordance with Article 25 of Regulation (EU) No. 528/2012 are met:

- a) all the active substances contained in the biocidal product are listed on Annex I;
- b) the biocidal product does not contain any substance of concern;
- c) the biocidal product does not contain any nanomaterials;
- d) the biocidal product is sufficiently effective;
- e) the handling of the biocidal product and its intended use do not require personal protective equipment.

The biocidal product is not classified in accordance with Regulation 1272/2008.

The active substances in masterbatch pellets are embedded into and bound to the polymer matrix. Furthermore, the incorporation of the pellets into the polymer material is an industrial process during which the pellets are mechanically conveyed to the enclosed and hermetic space of the extruder barrel; therefore, no direct contact of operator with the pellets is required and the exposure is negligible.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Combirepel™ CR8181	/

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	European plast research & development (E.P.R.D.) sa
		227 Rue Waassertrap L-4408 Belvaux Luxembourg
Authorisation number	(10-14 17.	5)BSV-19475(A-08PSA1203394-19-295)
Date of the authorisation	04/10/201	9
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	C Tech Corporation
Address of manufacturer	5-b, Himgiri, 1277 Hatiskar Marg, Prabhadevi, Mumbai-400025, India
Location of manufacturing sites	C Tech Corporation Unit No.162, Plot No.259 Surat Special Economic Zone Surat SEZ, Sachin, Gujarat, India 394230

2.1.1.4 manufacturer(s) of the active substance(s)

Active substance 1	Lavender Oil (Lavendula Angustifolia)
Name of manufacturer	Ishanee Chemical Private Limited
Address of manufacturer	No.1 New Anand Bhawan Shivaji Park Road No.4 Dadar, India 400028
Location of manufacturing sites	See above

Active substance nr. 2	Peppermint Oil (Mentha piperita)
Name of manufacturer	Ishanee Chemical Private Limited
	No.1 New Anand Bhawan Shivaji Park Road No.4 Dadar, India

	400028
Location of manufacturing sites	See above

Active substance nr. 3	Citronellal (3,7-dimethyloct-6-enal)
Name of manufacturer	Ishanee Chemical Private Limited
Address of manufacturer	No.1 New Anand Bhawan Shivaji Park Road No.4 Dadar, India 400028
Location of manufacturing sites	See above

2.1.2 Product composition and formulation

The full composition of the product is provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes	
No	\boxtimes

2.1.2.1 Identity of the active substance

Main constituent(s)		
ISO name	Lavender oil	
IUPAC or EC name	Lavendula Angustifolia	
EC number	616-770-1	
CAS number	8000-28-0	
Index number in Annex VI of CLP	n/a	
Minimum purity / content	Not relevant	
Structural formula	Not relevant	

Main constituent(s)		
ISO name	Peppermint oil	
IUPAC or EC name	Mentha piperita	
EC number	616-900-7	
CAS number	8006-90-4	
Index number in Annex VI of CLP	n/a	
Minimum purity / content	Not relevant	

Structural formula	Not relevant

Main constituent(s)			
ISO name	Citronellal		
IUPAC or EC name	3,7-dimethyloct-6-enal		
EC number	203-376-6		
CAS number	106-23-0		
Index number in Annex VI of CLP	n/a		
Minimum purity / content	Not relevant		
Structural formula			

2.1.2.2 Candidate(s) for substitution

Not applicable

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lavender Oil	Lavendula Angustifolia	Active substance	8000-28-0	616-770-1	5
Peppermint oil	Mentha piperita	Active substance	8006-90-4	616-900-7	4
Citronellal	3,7- dimethyloct- 6-enal	Active substance	106-23-0	203-376-6	4

Please refer to the confidential annex for the full composition of the product.

2.1.2.4 Information on technical equivalence

Not relevant

2.1.2.5 Information on the substance(s) of concern

There are no substances of concern (requirement for simplified authorisation). Please see the confidential annex for the details.

2.1.2.6 Type of formulation

Other: XX	
-----------	--

Masterbatch pellets based on LDPE polymers, specifically intended for incorporation in polyolefins products.

2.1.3 Hazard and precautionary statements

Classification and labelling of the biocidal product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	n/a
Hazard statement	n/a
Labelling	
Signal words	n/a
Hazard statements	n/a
Precautionary	n/a
statements	
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Repellent masterbatch against rats and birds

Product Type	19		
Where relevant, an exact description of the authorised use	Masterbatch used during the manufacturing process of agricultural films (bale wrap film, silage film and silage bag) to convey a bird- and rat-repellent quality to the film.		
Target organism (including development stage)	Juvenile and adults from following species: Birds (mostly from the crow-family) Common European rats: • Rattus rattus • Rattus norvegicus		
Field of use	Indoor Master batches with repellent properties for incorporation in films. The goal is to protect the final treated articles against biting and pecking damage from birds and rats by repelling them. The ultimate goal is to protect the silage contained in the film (bale wrap film, silage fim and silage bag).		
Application method(s)	The masterbatch pellets are incorporated into the plastic material through an extrusion dosing device to obtain a fine and homogeneous dispersion in the final macromolecular matrix. The temperature during the extrusion process goes from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. The limited temperature range combined with the very short exposure		

time ensure incorporation of the active substances without degradation.

The incorporation of the pellets into the polymer material is an industrial process during which the pellets are mechanically conveyed to the enclosed and hermetic space of the extruder barrel. The bags are opened with a pair of science or a knife and a suction tube is inserted into the bag.

scissors or a knife and a suction tube is inserted into the bag (with no contact of the pellets by the operator). This tube goes straight to the hopper and there is a gauge to stop the flow when the hopper is sufficiently filled. In some production plants, operators just lift the open bag above the hopper and discharge the content in the hopper, without touching the pellets. Therefore no direct contact with the pellets is required and the exposure can be considered negligible.

The form itself of the pellets is designed to enable their homogeneous dispersion in the plastics pellets in which they will be added: a fine and homogeneous dispersion in the final macromolecular matrix is indeed of paramount importance. The masterbatch products are currently only based on LDPE polymers specifically intended for incorporation in polyolefins products.

	!
	3% w/w. Masterbatches are added continuously during the film's manufacturing process
Category(ies) of users	Industrial
Pack sizes and packaging material	25 kg, LDPE bag

2.1.4.2 Use-specific instructions for use

Please refer to general instructions for use.

2.1.4.3 Use-specific risk mitigation measures

Please refer to general instructions for use.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to general instructions for use.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general instructions for use.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

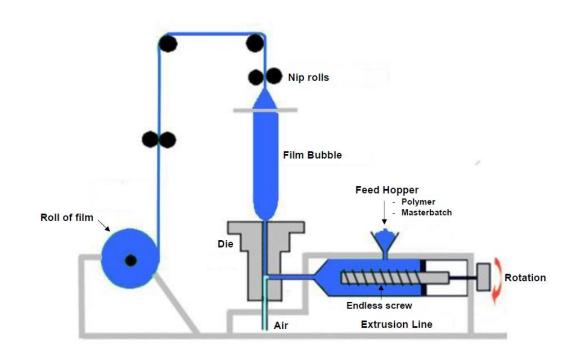
Please refer to general instructions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Add the plastics pellets to the plastic material through an extrusion dosing device to obtain a fine and homogeneous dispersion in the final macromolecular matrix. Dosing of the master batch in the final compound is 3%.

The form itself of the pellets is designed to enable their homogeneous dispersion in the bulk of raw material pellets to which they will be added. The masterbatch products are based on LDPE polymers specifically intended for use in polyolefins.



The generation of waste should be avoided or minimized wherever possible.

2.1.5.2 Risk mitigation measures

No specific hazards identified. Chemicals are not readily available as they are bound within the polymer matrix. No specific measures required.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No specific hazards identified. General procedures apply.

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in accordance with local regulations. Store in original bag protected from direct sunlight in a dry, cool and well- ventilated area, away from incompatible materials and food and drink. Keep bag tightly closed and sealed until ready for use. Bags that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled bags. Use appropriate containment to avoid environmental contamination.

Shelf life: 2 years

_	-		77+	har	INTO	rmat	100
		•					

_			

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non- professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
bags	25kg	LDPE	Bags are sealed	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Efficacy tests have been performed on the product. All of these data are submitted within the current application.

Additional studies performed on a similar product have been submitted for read-across purposes of the shelf-life claim.

No other studies have been performed in accordance with Art.25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of Regulation 528/2012.

2.1.8.2 Access to documentation

The studies are owned by the applicant or the manufacturer.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Repellent masterbatch against rats and birds

Product Type	19
Where relevant, an exact description of the authorised use	Masterbatch used during the manufacturing process of agricultural films (bale wrap film, silage film and silage bag) to convey a bird- and rat-repellent quality to the film.
Target organism (including development stage)	Juvenile and adults from following species: Birds (mostly from the crow-family)
	Common European rats:
	Rattus rattus
	Rattus norvegicus
Field of use	Indoor Master batches with repellent properties for incorporation in films. The goal is to protect the final treated articles against biting and pecking damage from birds and rats by repelling them. The ultimate goal is to protect the silage contained in the film (bale wrap film, silage fim and silage bag).
Application method(s)	The masterbatch pellets are incorporated into the plastic material through an extrusion dosing device to obtain a fine and homogeneous dispersion in the final macromolecular matrix. The temperature during the extrusion process goes from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. The limited temperature range combined with the very short exposure time ensure incorporation of the active substances without degradation. The incorporation of the pellets into the polymer material is an industrial process during which the pellets are mechanically conveyed to the enclosed and hermetic space of the extruder barrel. The bags are opened with a pair of scissors or a knife and a suction tube is inserted into the bag (with no contact of the pellets by the operator). This tube goes straight to the hopper and there is a gauge to stop the flow when the hopper is sufficiently filled. In some production plants, operators just lift the open bag above the hopper and discharge the content in the hopper, without touching the

	pellets. Therefore no direct contact with the pellets is required and the exposure can be considered negligible. The form itself of the pellets is designed to enable their homogeneous dispersion in the plastics pellets in which they will be added: a fine and homogeneous dispersion in the final macromolecular matrix is of paramount importance. The masterbatch products are currently only based on LDPE
	polymers specifically intended for incorporation in polyolefins products.
Application rate(s) and frequency	3% w/w. Masterbatches are added continuously during the film's manufacturing process
Category(ies) of users	Industiral
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of Regulation 528/2012.

In the specific case of applications for product authorisation submitted through the simplified procedure, The Commission considered that data on storage stability, stability and shelf-life as requested in point 3.4 of Annex III to BPR shall also be included because the conditions of storage, the stability and shelf-life of the product directly affect the efficacy of the product (Doc. CA-May14-Doc.5.5 – Final). Generally, for biocidal products storage stability is assessed by chemical analysis of the concentration of active substance(s) at various time points after storage. However, in the case of these masterbatch products, it is not technically possible to extract the actives from the pellets after incorporation. Based on the above, it is therefore considered to be an acceptable approach to assess the storage stability through the efficacy of the product.

The technical dossier (IUCLID) contains studies and statements addressing the storage stability by means of assessment of the efficacy of artificially aged plastic materials containing repellent masterbatches.

The masterbatch can be used without any problem after several years of storage: the active substances are fully encapsulated in the masterbatch. Nevertheless, as a precautionary approach, a shelf life of two years is proposed based on efficacy testing results on a similar product. Since masterbatches are mostly tailor-made, longer shelf lifes are not required.

Conclusion on the physical, chemical and technical properties of the product

Shelf life of the masterbatch products: 2 years.

Packaging material (LDPE) is compatible with the product.

2.2.3 Physical hazards and respective characteristics

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

Conclusion on the physical hazards and respective characteristics of the product

This is no data requirement for an application in accordance with Art. 25 of Regulation (EU) No 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of Regulation 528/2012.

2.2.4 Methods for detection and identification

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.

Conclusion on the methods for detection and identification of the product

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Indoor use.

The purpose of the masterbatch is to convey a rat and bird repellent effect to agricultural film. The product is mixed with the raw materials (and other additives) during the manufacturing process of plastic films.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Target organisms of the repellent effect:

Birds (predominantly species from the *Corvidae* family)

European rats: Rattus rattus and Rattus norvegicus

Master batches (pellets) for incorporation into plastics (e.g plastic films for bale wrapping), with the aim to protect the final treated articles against bird and rodent attacks through an acquired repellent effect. Protect should be understood as a protection from damage which could potentially affect the operating conditions of the treated article. In the case of the bale wrapping film, it is ultimately the contents of the plastic wrapping, the cattle feed, that needs to be protected from scavenger attacks. The intended protection is not only from mere loss through scavenging but much more importantly loss of quality via the breach of the ear-tight sealing that the bale wrapping provides. For the quality of the anaerobic digestion processes that optimize the feed it is of paramount importance that the silage remains shielded from air throught its storage. If the the wrapping is pierced this could mean important nutritional and economical loss.

2.2.5.3 Effects on target organisms, including unacceptable suffering Repellent effect

2.2.5.4 Mode of action, including time delay

As is the case with many repellents the exact mode of action is not fully elucidated. It's quite likely that after initially touching the plastic with the intention to pierce it the animals are repelled by the taste and/or smell of the active substances mixed with the plastic. Through repetition and an learning effect the protection extends beyond the initially attacked bales. Possibly even beyond the first animal to try and pierce them.

2.2.5.5 Efficacy data

With a view to prove the efficacy of the Compirepel repellent masterbatches a series of field trials has been performed with treated vs. untreated bale-wraps. The field trials have been performed in 2015 and 2018 at various farms in Belgium. All cooperating farmers stated that 15-20% of the bales are attacked by rodents and/or birds on an annual basis, which results in a significant loss of cattle feed.

The field trials revealed that in all cases the bird and rat attacks were significantly reduced when the treated film was used (0-3% attacks only). In two of the trials no relevant differences were observed between treated and untreated film. The two other trials did reveal a repellent effect in the treated film whereas the untreated film suffered a significant number of bird and/or rodent attacks.

All trials basically consisted of observation of damaged bales 1-6 months after the bales had been wrapped. No actual observation of attacks were recorded nor was a census of the pest animal pressure performed before the trials started.

A learning effect may occur in the population and animals may avoid the bales without having tried to attack them first themselves. It has already been observed that untreated bales, in the vicinity of treated bales are avoided by the animals as well.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisage d	Test substance	Test organism(s)	Test metho d	Test system / concentration s applied / exposure time	Test results: effects	Referenc e
Repellenc y	Outdoor: bale-wrap protection	Agrirepel bale wraping film treated with Combirepel masterbatc h	Rats and birds (wild)	No guidelin e	Field trial. Attacks by target organisms compared between treated vs untreated bales as well as comparison with historical data	Little differenc e in test. 15-20% reduction compare d with historical data	Field trial 20180219
Idem	Idem	Idem	Idem	Idem	Idem	Ca. 25% reduction compare d to untreated	Field trial 20150917

						film in test. Ca. 20% reduction compare d to historical data	
Idem	Idem	Idem	Idem	Idem	Idem	Ca. 75% reduction compare d to untreatte d film In test 15-20% reduction compare d to historical data	Field trial 20151002
Idem	Idem	Idem	Idem	Idem	Idem	No differenc e in test Ca. 15% reduction compare d to historical data	Field trial 20151009

Conclusion on the efficacy of the product

Bale wrap film treated with Combirepel show a significant reduction in attacks by birds and or rodents compared to untreated film. This repellent effect equates with an economical gain for the farmer through an increased amount of high quality cattle feed.

2.2.5.6 Occurrence of resistance and resistance management

Not recorded.

2.2.5.7 Known limitations

None known

2.2.5.8 Evaluation of the label claims

The product's principal claim 'bird- and rat-repellent masterbatch for bale wrap film' is sufficiently supported by the available test results.

- 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)
- 2.2.5.10 Product is not intended to be used with other biocides.

2.2.6 Risk assessment for human health

A human health risk assessment is not required for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

According to Article 25 a simplified authorization procedure may be applied where the product does not contain any substance of concern (SoC), and the handling of the biocidal product and its intended use do not require personal protective equipment (PPE).

Regarding SoC, the product does not contain substances that meet the SoC criteria defined in the EU guidance (CA-Nov14-Doc.5.11).

The use of PPE is not required as the products are not classified in accordance with Regulation 1272/2008.

According to the ECHA's C&L inventory the active substances Lavender oil and Peppermint oil are often classified as skin sensitizer (H317). As the concentrations of these active substances are above the generic concentration limit of 1%, the master batch also may be classified as skin sensitizer if the calculation method stipulated by the CLP regulation is applied. However, there is no need to classify the product as no exposure is expected to the active substances contained in master batch. In master batch itself the active substances are embedded in the polymer(s) and in this particular case, the active substances are also fully encapsulated. The biocidal effect is activated in treated articles as only there the active substances become biologically available. The master batch is added to the other ingredients and melted/mixed and during this process the active substances are distributed in the article in a way that they have biological activity. As the active substances are not biologically available in the master batch, they will also not be able to exert their potential sensitizing properties. It is therefore not required to classify the masterbatch as a sensitizer hence the H317 phrase is not applicable.

2.2.7 Risk assessment for animal health

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

2.2.8 Risk assessment for the environment

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

2.2.9 Measures to protect man, animals and the environment

2.2.9.1 Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Shelf life: 2 years

1.1.1.1 Recommended methods and precautions concerning handling and transport

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

1.1.1.2 Recommended methods and precautions concerning fire

In case of fire, use water spray (fog), foam, dry chemical or CO2. Decomposition products may include the following materials: carbon dioxide carbon monoxide.

1.1.1.3 First aid instructions

No specific hazards identified; General procedures apply.

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur

1.1.1.4 Emergency measures to protect environment in case of an accident

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

1.1.1.5 Instructions for safe disposal of the biocidal product and its packaging for different groups of users

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

2.2.10 Assessment of a combination of biocidal products

Not applicable

2.2.11 Comparative assessment

Not applicable.

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title	Testing laboratory	Report no.	Report date
E.PR.D.	2017- 2018	TEST REPORT WRAPPING FILM TEST - COMBIREPEL™	Field trial, performed by the manufacturer	n.a.	19-02-2018
E.P.R.D.	2015	TEST REPORT WRAPPING FILM TEST – COMBIREPEL™	Field trial, performed by the manufacturer	n.a.	17/09/2015
E.P.R.D.	2015	TEST REPORT WRAPPING FILM TEST - COMBIREPEL™	Field trial, performed by the manufacturer	n.a.	09/10/2015
E.P.R.D.	2015	TEST REPORT WRAPPING FILM TEST – COMBIREPEL™	Field trial, performed by the manufacturer	n.a.	02/10/2015

3.2 Output tables from exposure assessment tools

Not applicable

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not applicable

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

See studies summaries in Section 2.2.5.5. and in IUCLID

3.6 Confidential annex

Please refer to separate file

3.7 Other

None