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 the applicant)

Termirepel™ TR0207

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-EQ050919-17

Evaluating Competent Authority: Lithuanian National Public Health Centre

Date: 04/10/2019

Table of Contents

1 CONCLUSION

The eCA considers that all the conditions for a simplified authorisation procedure of biocidal product Termirepel™ TR0207 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)**
Termirepel™ TR0207	/

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	European plast research & development (E.P.R.D.) sa
	Address	227 Rue Waassertrap L-4408 Belvaux Luxembourg
Authorisation number	(10-14 17.5)BSV-19452(A-08PSA1203395-19-296)	
Date of the authorisation	04/10/2019	
Expiry date of the authorisation	04/10/2029	

2.1.1.3 Manufacturer(s) 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
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. 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 ☒

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	/
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	/
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	/
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	4
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	5

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 statements	n/a
Note	

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use # 1 – Repellent masterbatch against termites

Product Type	19
Where relevant, an exact description of the authorised use	Masterbatch incorporated during the manufacturing process of construction film to endow a termite repellent quality to the construction film.
Target organism (including development stage)	Juvenile and adults from subterranean termite species.
Field of use	Indoor The product is mixed with the raw materials during the production process of plastic construction films.
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 indeed 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	Industrial
Pack sizes and packaging material	Please see the relevant section.

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

n/a

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

n/a

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

n/a

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

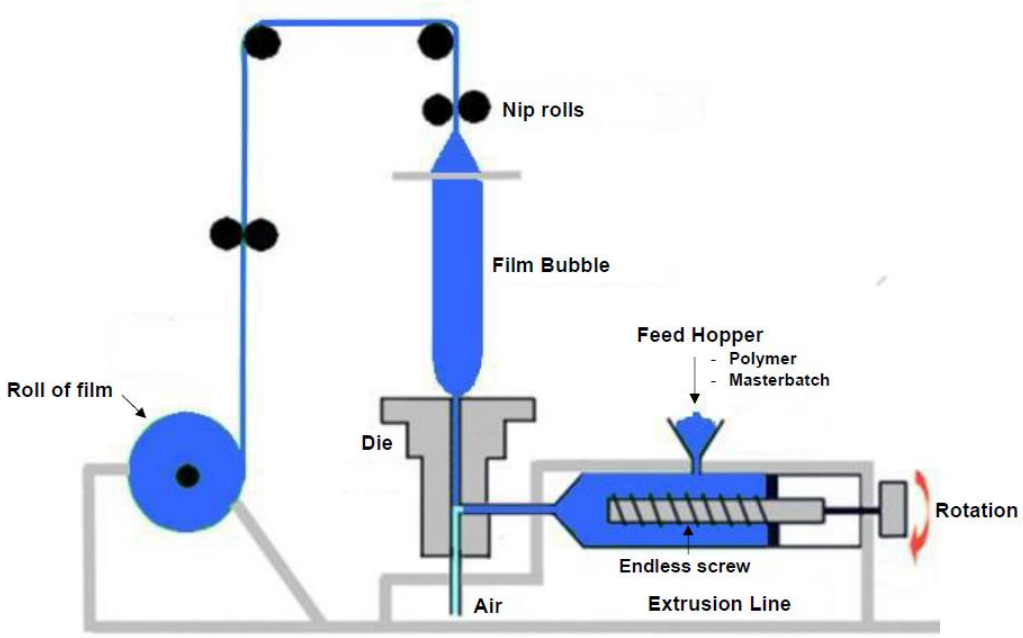
n/a

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 in 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

2.1.6 Other information

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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 EU 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 termites

Product Type	19
Where relevant, an exact description of the authorised use	Masterbatch incorporated during the manufacturing process of construction film to endow a termite repellent quality to the construction film.
Target organism (including development stage)	Juvenile and adults from subterranean termite species.
Field of use	Indoor The product is mixed with the raw materials during the production process of plastic construction films.
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 indeed 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	Industrial
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 EU 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 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 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 identificationof 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 termite repellent effect to construction 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:
Subterranean termites

Master batches (pellets) for incorporation into plastics (e.g plastic construction films), with the aim to protect the final treated articles against termites 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 this case the protected article is construction film used in foundations of houses and other buildings. The film's purpose is to protect the buildings from potentially damaging or hazardous water and gas seepages. Would the film be pierced by termites this protective function is of course compromised.

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 insects are repelled by the taste and/or smell of the active substances mixed with the plastic.

2.2.5.5 Efficacy data

With a view to prove the efficacy of the Termirepel repellent masterbatches a series of controlled trials has been performed by the BAM[1]. The trials included preliminary lab experiments, simulated use trials and a semi-field trial. The used protocols were developed by the BAM.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Repellency	*Outdoor: masterbatch for construction film*	*Termirepel treated film*	• *Reticulitermes flavipes* • *Coptotermes formosanus*	BAM designe protocol, choic test: 'Biotesting of plastic film for resistance against penetration by termites when exposed in the soil under semi-field conditions, according to BAM laboratory method (2010)'	Controlled lab experiment: Treated (3% termirepel) vs untreated film. 12 wks exposure >250 termites	Termirepel treated film was not damaged throughout the test	*BAM report VH 4547-2 20111118*
Repellency	*Outdoor: masterbatch for construction film*	*Termirepel treated film*	• *Reticulitermes flavipes*	BAM designe protocol: 'Biotesting of plastic film for resistance against penetration by termites when exposed	Controlled simulated use trial: Treated (3% termirepel) vs untreated film. 12 months	Termirepel treated film was not damaged by the termites during the experiment.	*BAM report VH 4547-5 20130109*

[1] Bundesanstalt für Materialforschung und -prüfung, Berlin, Germany

				in the soil under semi-field conditions, according to BAM laboratory method (2010)'. choice test			
Repellency	*Outdoor: masterbatch for construction film*	*Termirepel treated film*	*Wild subterranean termites*	BAM designe protocol: 'Biotesting of plastic film for resistance against penetration by naturally occurring termites when exposed on the ground under field conditions similar to EN 252'	Field trial: Treated (3% termirepel) vs untreated film. 16 months	Termirepel treated film was not damaged by the termites during the experiment.	*BAM report VH 4547-6 20150602*
Repellency	*Outdoor: masterbatch for construction film*	*Termirepel treated film*	*Wild subterranean termites*	BAM designe protocol: 'Biotesting of plastic film for resistance against penetration by naturally occurring termites when exposed on the ground under field conditions similar to EN 252'	Field trial: Treated (3% termirepel) vs untreated film. 5 years	Termirepel treated film was not damaged by the termites during the experiment.	*BAM report VH 4547-6 20150602 (follow-up)*

Conclusion on the efficacy of the product
Construction film treated with Termirepel™ remains undamaged by termites throughout the different tests. This is in contrast with the unprotected wood samples or wood samples only protected with untreated construction film. This marked difference is considered sufficient proof of the repellent effect present in the treated film, an effect which is entirely due to the addition of Termirepel™ during the fabrication process of the film.

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 'termites-repellent masterbatch for construction 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 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 masterbatch 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 masterbatch, 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.

Information requirement	All of the human health risk assessment
Justification	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.

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

2.2.8.1 Effects assessment on 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

1.1.1.1 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: minimally 2 years

1.1.1.2 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.

1.1.1.3 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.

1.1.1.4 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

1.1.1.5 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).

1.1.1.6 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
R. Plarre & Y. de Laval	2011	Test Report VH 4547-2	BAM facility Berlin-Lichterfelde	VH 4547-2	18/11/2011
H-J Kunte, R. Plarre & Y. De Laval	2013	Test Report VH 4547-5	BAM facility Berlin-Lichterfelde	VH 4547-5	09/01/2013
H-J Kunte & R. Plarre	2015	Test report VH 4547-6 (field test 1)	Field test site Soulac sur Mer, France	VH 4547-6	02/06/2015
H-J Kunte & R. Plarre	2019	Test report 19002482 Follow-up BAM test report of VH 4547-6 (field test 1).	Field test site Soulac sur Mer, France	VH 4547-6 (follow up)	12/02/2019

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)

Not applicable

3.6 Confidential annex

Please refer to separate file

3.7 Other

Not relevant