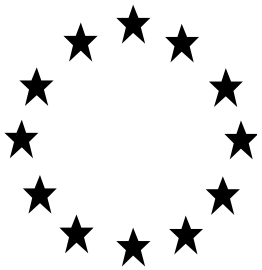
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the eCA)



Repellent Masterbatches Antitermite/Multirepel BPF

Product type 19

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

Case Number in R4BP: [BC-WX027468-91]

Evaluating Competent Authority: Ctgb

Date: 12/04/2018

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1 CONCLUSION

For this dossier, the eCA considers that all the conditions for a simplified authorisation procedure in accordance with Art.25 of EU 528/2012 are met :

a) all the active substances contained in the BPF are listed on Annex I

b) the products in the BPF does not contain a substance of concern

c) the products in the BPF does not contain any nanomaterials

d) the products in the BPF are sufficiently effective

e) the handling of the products does not require personal protective equipment. According to the safety data sheets of the producer of the masterbatches, the products are not classified in accordance with Regulation 1272/2008.

Regarding the pellets of the masterbatch product, the active substances 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 with the pellets is required.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Repellent Masterbatches Antitermite/Multirepel BPF	/

There are two meta SPCs in this family: meta SPC 1, containing products with a combined use against termites and rats, and meta SPC 2, containing products intended to be used against termites only.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	PolyOne Belgium
	Address	Rue Melville Wilson, 2 B-5330 Assesse Belgium
Pre-submission phase started on	/	
Pre-submission phase concluded on	/	
Authorisation number	EU-0015409-0000	
Date of the authorisation	1-6-2018	
Expiry date of the authorisation	30-5-2028	

2.1.1.3 Manufacturer(s) of the products of the family

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

1 Please fill in here the identifying product name from R4BP 3.

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

Active substance nr. 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
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 (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 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?

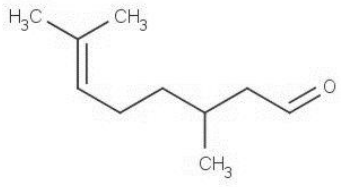
Yes ☐
No ☒

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 family[2]

Please refer to the confidential annex

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. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

Other : XX

These masterbatches are pellets based on EVA or LDPE polymer carriers, for incorporation into plastics (e.g. cables, wires). The active substances are embedded into and bound to the polymer matrix, with the aim to protect the final treated articles against attacks from rodents or termites by repelling them.

2.1.3 Hazard and precautionary statements[2]

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

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

2.1.4 Authorised use(s)

2.1.4.1 Use description

Meta SPC 1

Table 1. Use # 1.1 – Masterbatches for repelling rats and termites

Product Type	PT 19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Rats - adults and juveniles Termites (genus *Reticulitermes*) – adults Termites (genus *Coptotermes*) - adults Termites (genus *Odontotermes*) - adults Termites (genus *Mastotermes*) - adults
Field of use	Indoor Master batches with repellent properties for incorporation in plastic cable and wire coatings, with the aim to protect the final treated articles against gnawing damage from rats and termites by repelling them. Protection should be understood as a protection from gnawing damage which could potentially affect the operating ability of the cable.
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

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

	from around 150°C to 200°C for flexible PVC compounds and from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. As soon as the molten plastic is applied in the crosshead part of the extruder onto the cable core, the extruded plastic and cable move into a cooling through, and are immediately cooled down in water. 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; therefore no direct contact with the pellets is required and the exposure can be considered negligible.
Application rate(s) and frequency	The concentration of the master batch in the final compound is in the range 2 – 4 %.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section

4.1.1. Use-specific instructions for use

Please refer to general directions for use for meta SPC 1.

4.1.2 Use-specific risk mitigation measures

Please refer to general directions for use below.

4.1.3 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 directions for use below.

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

Please refer to general directions for use below.

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

Please refer to general directions for use below.

Meta SPC 2

Table 2. Use # 2.1 – Masterbatches for repelling termites

Product Type	PT 19 - Repellents and attractants

Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Termites (genus *Reticulitermes*) – adults Termites (genus *Coptotermes*) - adults Termites (genus *Odontotermes*) - adults Termites (genus *Mastotermes*) - adults
Field of use	Indoor Master batches with repellent properties for incorporation in plastic cable and wire coatings, with the aim to protect the final treated articles against gnawing damage from termites by repelling them. Protect should be understood as a protection from gnawing damage which could potentially affect the operating ability of the cable.
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 150°C to 200°C for flexible PVC compounds and from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. As soon as the molten plastic is applied in the crosshead part of the extruder onto the cable core, the extruded plastic and cable move into a cooling through, and are immediately cooled down in water. 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; therefore no direct contact with the pellets is required and the exposure can be considered negligible.
Application rate(s) and frequency	The concentration of the master batch in the final compound is in the range 3 – 4 %.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section

2.1.4.2 Use-specific instructions for use[3]

Please refer to general directions for use for meta SPC 2.

2.1.4.3 Use-specific risk mitigation measures

Please refer to general directions of 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 directions of 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 directions of 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 directions of use

3 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5 General directions for use meta SPC 1 and 2

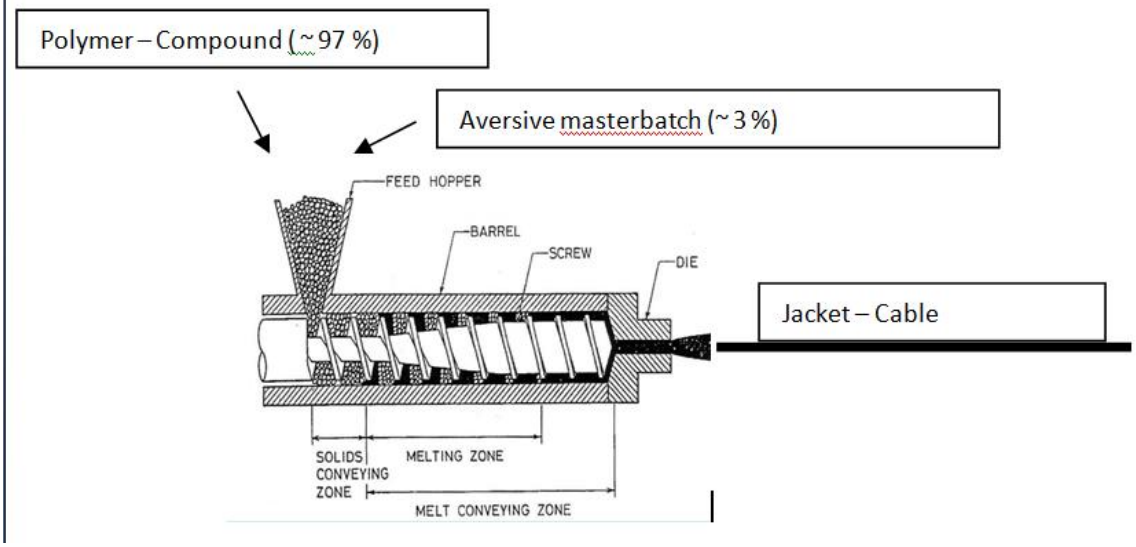
2.1.5.1 Instructions for use

Instructions for use Meta SPC 1

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 2 – 4 % range.

The form itself of the pellets is designed to enable their homogeneous dispersion in the plastics pellets in which they will be added. The masterbatch products are currently only based on EVA or LDPE polymers. EVA based masterbatches can be used in most matrices, LDPE specifically in polyolefins. The masterbatches based on ethylene vinyl acetate or polyethylene as the plastic matrix of the masterbatch can therefore be used in all commonly used cable cover materials.

Extrusion image



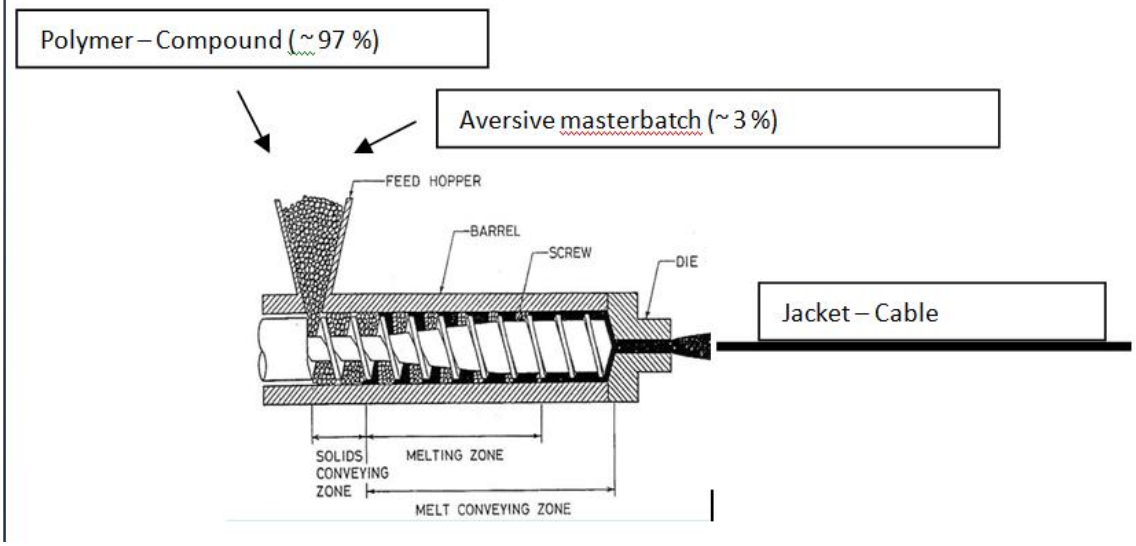
The generation of waste should be avoided or minimized wherever possible.

Instructions for use Meta SPC 2

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 – 4 % range.

The form itself of the pellets is designed to enable their homogeneous dispersion in the plastics pellets in which they will be added. The masterbatch products are currently only based on EVA or LDPE polymers. EVA based masterbatches can be used in most matrices, LDPE specifically in polyolefins. The masterbatches based on ethylene vinyl acetate or polyethylene as the plastic matrix of the masterbatch can therefore be used in all commonly used cable cover materials.

Extrusion image



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

/

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 were performed on the products. All of these data are submitted within the current application. No other studies have been performed in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.

2.1.8.2 Access to documentation

All studies are owned by the applicant or the producer of the product

2.2 Assessment of the biocidal product family

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

The uses below are the ones applied for by the applicant and revised after first evaluation, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

Table 3. Use # 1 – masterbatches for repelling rats/termites (Multirepel)

Product Type	PT 19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent against rats and termites
Target organism (including development stage)	Termites (genus *Reticulitermes*) – adults Termites (genus *Coptotermes*) - adults Termites (genus *Odontotermes*) - adults Termites (genus *Mastotermes*) - adults Rats (*Rattus sp.*) – adults and young
Field of use	Indoor Master batches with repellent properties for incorporation in plastic articles such as cables and wires, with the aim to protect the final treated articles against attacks from rats by repelling them. Protect should be understood as a protection from damage which could potentially affect the operating conditions of the cables
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 150°C to 200°C for flexible PVC compounds and from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. As soon as the molten plastic is applied in the crosshead part of the extruder onto the cable core, the extruded plastic and cable move into a cooling through, and are immediately cooled down in water. 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; therefore no direct contact with the pellets is required and the exposure can be considered negligible.

Application rate(s) and frequency	Typical dosing of the master batch in the final compound is in the range 2 – 4 %.; minimum dosage for Multirepel masterbatches it is 2%.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section

Table 4. Use # 2 – masterbatches for repelling termites (Antitermite)

Product Type	PT 19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent against termites
Target organism (including development stage)	Termites (genus *Reticulitermes*) – adults Termites (genus *Coptotermes*) - adults Termites (genus *Odontotermes*) - adults Termites (genus *Mastotermes*) - adults
Field of use	Indoor Master batches with repellent properties for incorporation in plastic articles such as cables and wires, with the aim to protect the final treated articles against attacks from rats by repelling them. Protect should be understood as a protection from damage which could potentially affect the operating conditions of the cables
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 150°C to 200°C for flexible PVC compounds and from around 160°C up to 250°C for PE compounds. The heating lasts for about 3 to 5 minutes. As soon as the molten plastic is applied in the crosshead part of the extruder onto the cable core, the extruded plastic and cable move into a cooling through, and are immediately cooled down in water. 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; therefore no direct contact with the pellets is required and the exposure can be considered negligible.
Application rate(s) and frequency	Typical dosing of the master batch in the final compound is in the range 3 – 4 %.; minimum dosage for Antitermite

	masterbatches is 3%.
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 EU 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
However, an evaluation on storage stability is included.
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.
For the semi-field efficacy test conducted with rats by Vetagro Sup / INRA (Lattard V. : Avenant N°1 à la convention cadre n°149VAL0914 (Vetagro Sup / INRA, USC1233, 2015), with a similar masterbatch product (Antirat masterbatch), the pellets were produced in March 2012. The addition of the pellets into the cables and the initiation of the efficacy test was only done in 2014. The test showed that the treated cables were not attacked for at least 2 months, contrary to the untreated cables which were attacked fairly rapidly; therefore the the >2 year old pellets can be considered sufficiently stable.
For the BAM efficacy test against termites (Plarre, R. : Test Report - 2% 107079 EVA ANTITERMITE (CC10107079BG) tested in polyethylene resin, 2016), the time between production of the Antitermite masterbatch and the exposure of the termites to the treated product was almost 7 months.
Furthermore, the stability of the masterbatch pellets is supported by the available accelerated ageing tests. In the dossier, several efficacy tests (4 in total; 2 with the Antirat product and 2 with the Antitermite product) are presented carried out on treated cables that were submitted to accelerated ageing before being used in the efficacy testing. The efficacy tests showed that after the accelerated ageing, the product still effectively protected the cables from rodent attack.
Based on the efficacy test by Vetagro Sup / INRA (Lattard V. : Avenant N°1 à la convention cadre n°149VAL0914 (Vetagro Sup / INRA, USC1233, 2015), carried out on a similar product (Antirat masterbatch) stored for 2 years, the applicant considers that a shelf-life of 2 years is justified.
This is in line with the Commission Document CA-May14-Doc.5.5– on consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure which mentions : "Stability data could be waived where the applicant demonstrates that the product is efficacious by the end of the proposed shelf-life (i.e. data from efficacy tests using aged/stored product)."
According to the applicant, in principle the pellets masterbatches can be used without any problem after several years of storage : the active substances are fully encapsulated in the masterbatches. This is also supported by the accelerated ageing tests (see also

Conclusion on efficacy – age of the products.) Nevertheless, as a precautionary approach, a shelf life of 2 years is defined based on efficacy testing on a similar product stored for 2 years. Since masterbatches are mostly tailor-made, longer shelf lifes are not required.

The proposed packaging material (LDPE) is fully compatible with the product, which consists of masterbatch pellets based on and LDPE or an EVA matrix with the active substances tightly encapsulated. Both type of polymers (LDPE/EVA) are by their chemical nature fully compatible.

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 EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012.

Nevertheless, the products do not need to be classified for physico-chemical hazards based on their constituents.

2.2.4 Methods for detection and identification

This is no data requirement for an application in accordance with Art.25 of EU 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

The products of the BPF are intended for indoor use by industrial users only.
The masterbatch pellets are incorporated into plastic treated articles such as cables and wires) with the aim to protect the final treated articles against gnawing damage from rats or termites by repelling them. "Protect" should be understood as a protection from gnawing damage which could potentially affect the operating conditions of the treated articles. In cable applications, scratches and some weight loss are permitted as long as they don't impair the cable function, which might result from the piercing of the sheath layer. Damage needs to be limited to surface scratches. Thickness of protective or insulating layers usually includes a safety margin to allow for some surface damage; indeed cables need to be installed in the ground and are therefore subject to be in contact with stones and other obstacles in the soil.
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 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 cable 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.

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

Target organisms :

Meta SPC 1

Termites (Isoptera) :
- Reticulitermes sp
- Coptotermes sp.
- Mastotermes sp.
- Ondontotermes sp.

Rats: general claim (efficacy tests on *Rattus norvegicus* and *Rattus rattus*).

Meta SPC 2

Termites (Isoptera) :
- Reticulitermes sp
- Coptotermes sp.
- Mastotermes sp.
- Ondontotermes sp.

Objects to be protected : Plastic cable and wire coating. The claim is to protect the treated articles from gnawing damage that can affect the operating conditions of the treated article. In cables, scratches and some weight loss are permitted as long as they don't impair the cable function, which might result from the piercing of the sheath layer.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Repelling the target organisms from the treated plastic material.

A masterbatch as such is not "effective" as the active substance is embedded in the polymer(s) and in this particular case, the active substances are also fully encapsulated. The efficacy is tested with the treated article as only there the active substance becomes biologically active. 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.
In the final treated product the active substances will not be detected until the surface is touched or very closely approached by the termite or the rodent. Upon touching/very light biting of the cables, the target organisms are prevented from biting again by the taste/smell (as they have very sensitive olfactory receptors) and they will remember to not try to gnaw on the plastic cables again

As the products simply act as repellents, there is no unacceptable suffering. This is also demonstrated in the efficacy test where behaviour and health of the rats was monitored (Test 1, 5 and 6).

2.2.5.4 Mode of action, including time delay

As for most currently approved repellents, the mode of action is not clarified. The efficacy is shown experimentally. It is expected the target animals are repelled by the taste/smell (as they have very sensitive olfactory receptors) of the active substance.

2.2.5.5 Efficacy data

There are two meta SPCs in this family: one containing products with a combined use against termites and rats (meta SPC 1) and one containing products intended to be used against termites only (meta SPC 2). The proposed minimum dosage into the final treated articles (cables) is 2% for meta SPC 1 and 3% for the meta SPC2, leading to the same end concentration of active substances in the treated article.
Efficacy tests against termites on both types of products are provided. Taking into account the proposed different dosage in the treated articles, the total active substance content of both types of products in the final treated articles is comparable.
For rats, tests based on products not included in this family (Antirat masterbatches) are included as well. See the confidential Annex for a justification.

There are currently no specific guidelines to test the efficacy of these type of masterbatch products. The applicant considers that both the efficacy testing and the ageing tests are carried out in accordance with "industry best practice", which was accepted by the e-CA. All tests are simulated-use tests. In the tests the efficacy is assessed visually in combination with weight loss assessments, in both biocide treated and non-treated (control) cables. This allows to conclude whether the product effectively protects the cables from gnawing damage that can affect the operating conditions of the cables (comparison between biocide and control treatment).

In terms of species tested, a variety of rats was tested, including EU species (TEST 5 with *Rattus rattus* and TEST 2 and 6 with *Rattus norvegicus*), but also with wild rats as found in the field in India (TESTS 1, 3 and 4). The latter may include *Bandicota bengalensis* (the lesser bandicoot rat), *Tatera indica* (the Indian gerbil), *Millardia meltada* (the Indian soft furred field rat) and *Rattus rattus* (black rat). The Indian labs that carried out the tests state that these four species are the most widely distributed and abundantly found in most of the geographical regions in India and other parts of southern Asia. These wild rats are considered to mimic the behaviour of the rats in real life.

The efficacy Guidance for PT14 (rodenticides) mentions a general claim against rats in EU will only require testing against *Rattus norvegicus*, unless there are country specific requirements. Some countries require also testing on *Rattus rattus*. As tests on *Rattus norvegicus* and *Rattus rattus* species have been performed, a general claim for rats is considered acceptable.

For termites, the efficacy Guidance document for PT18/19 mentions: "A product against termites in Europe should normally be tested on termites belonging to the genus *Reticulitermes*. For European tropical overseas regions, the product should normally be tested at least against termites belonging to the genus *Coptotermes* and on every genus claimed by the applicant." Based on this, the species claimed for termites are: *Reticulitermes* sp., *Coptotermes* sp., *Ondontotermes* sp and *Mastotermes* sp..

Also, to give a good indication on the performance of the product, the aggressiveness of the species is taken into account. E.g. for termites, tests on *Mastotermes darwinienis* are included. This giant termite species is by far the most destructive termite in Australia (Gay and Calaby, 1970). The submitted tests show that even for such aggressive species, the product works well.

AVAILABLE TESTS AGAINST RATS	
TEST 1 : Chowdhary, A : Evaluation of anti rodent activity of cable against rodents (Haffkine Institute)	
Guideline	RDSO/SPN/204/2011 Annex G (Indian national standard for anti-rodent testing of railway signalling cables)
Final product tested	Cables dosed with Combirepel 9518 = 9518 PE Multirepel (LDPE matrix) at a dose of both 2% and 3%
Test species	Wild rats, captured in different zones of Mumbai, India. The Indian labs that carried out the tests state that these species may include : *Bandicota bengalensis* (the lesser bandicoot rat), *Tatera indica* (the Indian gerbil), *Millardia meltada* (the Indian soft furred field rat) and *Rattus rattus* (black rat). These four species are the most widely distributed and abundantly found in most of the geographical regions in India and other parts of southern Asia.
Effects investigated	- Clinical signs (mortalilty, morbidity recorded twice a day and all visible signs/symptoms recorded daily) - Damage to cables (visual assessment) at the end of the test (after 4 weeks) - Weight of the test samples (gnawing factor) at the end of the test (after 4 weeks)
Main test conditions	TEST CHAMBER / DEVICE : Polypropylene cages provided with sterile bedding material. The rodents were provided with ad libitum water and pellet feed. TEST CONDITIONS : 5 cable samples were used per group (G1 = control = cables without additive; G2 = cables dosed with 2% Combirepel 9518; G3 = cables dosed with 3% Combirepel 9518). NUMBERS OF TARGET ORGANISMS : Initial density / numbers in test system: 5 rodents per group EXPOSURE PERIOD : 30 days
Results	-Clinical signs : No clinical signs were observed throughout the trial period -Visual assessment of damage to cables : More significant attack in control group as compared to treated group. In the control group, some of the cables are attacked to the point where the core cable is visible. For the treated cables, attack is limited to maximum slight "surface nibbling". See tables below for detailed results. **Damage scale :**

Degree of damage	Description	Rating
OK	Undamaged	100
SN (surface nibbling)	Gnaw/bite marks on the surface, 10 or less (core of the cable must not be seen)	75
SA (slight attack)	Gnaw/bite marks on the surface, more than 10 (core of the cable	50

	must not be seen)	
A (attack)	The core cable can be seen in 2 or less regions of the sample	25
D (destroyed)	The core cable can be seen in more than 2 regions of the sample	0

Results :

Group	**sample number**	**OBSERVATION**		
		initial observation	**degree of damage after fourth week**	**rating R**
G1 (control)	1	OK	OK	100
	2	OK	A	25
	3	OK	OK	100
	4	OK	SN-OK	75
	5	OK	A	25
G2	1	OK	OK	100
	2	OK	SN-OK	75
	3	OK	SN-OK	75
	4	OK	SN-OK	75
	5	OK	OK	100
G3	1	OK	OK	100
	2	OK	OK	100
	3	OK	SN-OK	75
	4	OK	SN-OK	75
	5	OK	OK	100

-Weight change of cables : Significant weight change in control group as compared to treated group. The difference is about a factor 10 : 2% in control group vs. 0.2% in treated group. Results of a t-test (unpaired) carried out on all individual percentages of control vs. treated showed a significant difference in the weight loss percentages for the untreated (M=2.2, SD=2.39) and treated (M=0.19, SD=0.26) conditions; t=2.72, p = 0.018. See table below for details.

Weight change of cables (mean of 5 samples per group) :

	<table><tr><th>Group</th><th>Initial weight (g)</th><th>Final weight (g)</th><th>Weight loss (%)</th><th>G factor*</th></tr><tr><td>G1(control)</td><td>10.997</td><td>10.757</td><td>2.177</td><td>0.022</td></tr><tr><td>G2</td><td>11.541</td><td>11.516</td><td>0.216</td><td>0.00218</td></tr><tr><td>G3</td><td>11.270</td><td>11.251</td><td>0.168</td><td>0.0016</td></tr></table> * G-factor (gnawing factor) = weight loss test sample / initial weight test sample Note: The report mentions that the entire data of weight loss did not reveal any statistical significance when compared with the initial readings. This may be true, however, it does not impact the conclusions of the test, since the claim is not to protect the cables from weight loss, but from biting damage that can affect the operating conditions of the cables. In addition, clinical signs were monitored and none were noted.
Conclusion	This efficacy test is a "choice test" (i.e. rats are not starved during the test, they can find food in the cages) with a duration of 1 month, carried out in the laboratory at Haffkine Institute. The efficacy is evaluated based on a visual assessment and weight loss recordings. The claim of the products is to protect the cables from biting damage that can affect the operating ability of the cables. In cables, scratches and some weight loss are permitted as long as they don't impair cable function, i.e no piercing of the sheath layer. Therefore, for an appropriate assessment of the efficacy for these kind of products, both weight loss and visual assessment can provide important information on the efficacy of the product. Conclusion: Based on the difference between control and treated for the visual assessment and the weight loss data it can be concluded that the product effectively protects the cables from biting damage of rats.
TEST 2 : Lattard V. : Avenant N°1 à la convention cadre n°149VAL0914 (Vetagro Sup / INRA, USC1233)	
Guideline	In-house method, with the aim to develop in the long term an official standard test for evaluating the resistance of cables to rodents. Rats captured in the field reproduce and multiply in captivity (large enclosures referred to as terrariums), until an equilibrium state is reached (around 150 to 200 rats in the enclosure). Statement by applicant IUCLID 3.4.1: "For the semi-field efficacy test conducted with rats by Vetagro Sup / INRA (Lattard V. : Avenant N°1 à la convention cadre n°149VAL0914 (Vetagro Sup/ INRA, USC1233, 2015)), the Antirat masterbatch pellets were produced in March 2012. The addition of the pellets into the cables and the initiation of the efficacy test was only done in 2014." According to the test report the test is performed in July-August 2015. Therefore, the test can be considered to be done with aged product.

Final product tested	Cables dosed with 9028 PE Antirat at a dose of 2%
Test species	*Rattus norvegicus*
Effects investigated	Visual assessment of damage
Main test conditions	TEST CHAMBER / DEVICE : Terrarium containing brown rats (semi-field situation) TEST CONDITIONS : The rods were tied to a metallic frame (8 cables in parallel) measuring 2 meter in length by 0.9 metres in width. These frames were put on the soil in the terrariums containing the rats. In experiment 1, the control (metal frame with non-treated rods) and test (metal frame with treated rods) samples were placed in a different terrarium, whereas in experiment 2 they were place in the same terrarium. Untreated controls : rods without additive.  NUMBERS OF TARGET ORGANISMS : about 150 (experiment 2) to 200 rats (experiment 1) EXPOSURE PERIOD : ca. 2 months
Results	EXPERIMENT 1 (control and test samples in different terrarium): After about 1 month (day 40), the first changes were detected in the the control samples, where the rods were attacked and cut, whereas the treated rods were still intact. Also after 56 days (close to two months), the treated rods were intact.

J56'
Terrarium'23'
non,treated'polyethylene'
rods''

J56'
Terrarium'12'
polyethylene'rods'treated'with'master'batch'9028'PE'
Anti'rodent'at'2'%'

EXPERIMENT 2 (control and test samples in same terrarium):

At day 15, the non-treated rods were cut in 3 different places, whereas the treated cables were not attacked

J15'
non,treated'polyethylene'rods''

Rupture'of'rod'

J15'
polyethylene'rods'treated'with'master'
batch'9028'PE'Anti'rodent'at'2'%%'

:

	At day 21, all the non-treated rods were cut and a large part of the cables had disappeared. The treated rods were still not attacked, even not after about 2 months **J21**' non,treated'polyethylene' rods''  **J21**' polyethylene'rods'treated'with'master' batch'9028'PE'Anti'rodent'at'2'%' 
Conclusion	This test was set up as a semi-field test, with 150-200 brown rats (*Rattus norvegicus*) in a very large terrarium and carried out by VetAgro Sup Institute. The visual assessment in this test shows a very clear difference between the untreated and treated conditions. Especially in experiment 2 (control and treated group in the same terrarium), in which on day 21 all of the untreated rods were cut and many disappeared, whereas even after two months, the treated rods were intact. Although based on visual assessment it is not possible to calculate statistical significance, the pictures clearly show the very big difference between treated (intact) and untreated (almost completely destroyed/disappeared). Conclusion: This test shows that the product effectively prevents rats from damaging treated plastic cables.
TEST 3 :Anonymous : Testing of Rodrepel RR0306 EVA effectiveness on accelerated aged cables (C Tech - Hyderabad Testing Facility)	

<table>
<tr><td>Guideline</td><td>In-house method</td></tr>
<tr><td>Final product tested</td><td>Cables dosed with Rodrepel 0306 EVA = 87477 EVA Antirodent at a dose of 3% and submitted to an accelerated ageing procedure before the efficacy test.

AGEING PROCEDURE : The samples were aged at a temperature of 90°C for 90 days. These cables were then submitted to forced cooling, temperature being brought down to -15°C for a period of 90 days. The final run of tests is submitting the cable samples to salt spray, the process being done in a standard salt spray cabinet.</td></tr>
<tr><td>Test species</td><td>Various rat species, captured from the wild. The Indian labs that carried out the tests state that these species may include: Bandicota bengalensis (the lesser bandicoot rat), Tatera indica (the Indian gerbil), Millardia meltada (the Indian soft furred field rat) and Rattus rattus (black rat). These four species are the most widely distributed and abundantly found in most of the geographical regions in India and other parts of southern Asia.</td></tr>
<tr><td>Effects investigated</td><td>Weight loss and visual inspection after 60, 120 and 180 days of exposure</td></tr>
<tr><td>Main test conditions</td><td>TEST CHAMBER / DEVICE: Semi-field conditions : plexiglas enclosure comprised of sand up to a height of 6 feet.
TEST CONDITIONS: Three replicate bundles of cables were used for the test and the control samples (each bundle consisting of 4 cables). The bundles of aged cables were placed on the surface and at various depths within the sand pit. The rodents were pre-acclimatized for a period of 15 days within the sand pit.
Untreated controls : cables without additive
EXPOSURE PERIOD : 180 days</td></tr>
<tr><td>Results</td><td>Visual assessment of damage to cables : Visual inspection revealed that there was significant surface abrasion leading to pit like formation in the control samples at 60, 120 and 180 days whereas the Rodrepel RR0306 EVA containing samples were smooth in finish at every time-point.

Weight change of cables : Significant weight change for control samples (between 12-21% for each 60-day evaluation period) as compared to samples dosed with Rodrepel RR0306 EVA (between 0.8-2 %) for each 60-day evaluation period); about a factor 10 difference. See table below for further information.
<table>
<tr><th>Group</th><th>Initial weight (g)</th><th>Final weight (g)</th><th>Weight loss (%)</th></tr>
<tr><td colspan="4">Readings after 60 days</td></tr>
<tr><td>Control bundle 1</td><td>400</td><td>344</td><td>14</td></tr>
<tr><td>Control bundle 2</td><td>400</td><td>352</td><td>12</td></tr>
<tr><td>Control bundle 3</td><td>400</td><td>344</td><td>14</td></tr>
<tr><td colspan="4">Average weight loss : 13.34%</td></tr>
<tr><td>Test bundle 1</td><td>400</td><td>395</td><td>1.25</td></tr>
</table>
</td></tr>
</table>

		Test bundle 2	400	393	1.75	
		Test bundle 3	400	396	1.0	
		Average weight loss : 1.3%				
		Readings after 120 days				
		Control bundle 1	344	293.5	14.67	
		Control bundle 2	352	298.4	15.1	
		Control bundle 3	344	293.7	14.6	
		Average weight loss : 14.79%				
		Test bundle 1	395	390	1.2	
		Test bundle 2	393	385	2.0	
		Test bundle 3	396	390	1.5	
		Average weight loss : 1.07%				
		Readings after 180 days				
		Control bundle 1	293.5	244.6	16.7	
		Control bundle 2	298.4	250	16.2	
		Control bundle 3	293.7	232.2	20.9	
		Average weight loss : 17.9%				
		Test bundle 1	390	386	1.02	
		Test bundle 2	385	381	1.03	
		Test bundle 3	390	387	0.77	
		Average weight loss : 0.94%				
Conclusion	This test was set up as a simulated use test in the laboratory of C-Tech Hydrabad Testing Facility, with artificially aged cables. In terms of species tested, this test is conducted with rats found in the field (India), in order to mimic their response in real life. The efficacy is evaluated based on a visual assessment and weight loss recordings Based on the difference between control and treated for the visual assessment (pit formation in the control group, treated cables are smooth in finish) and the weight loss data (significant difference between control and treated; about factor 10) it can be concluded that the product effectively protects the cables from biting damage, also after submitting them to accelerated ageing processes. Conclusion: Based on the difference between control and treated for the visual assessment and the weight loss data it can be concluded that the product effectively protects the cables from biting damage by rats, also after submitting them to accelerated ageing processes.					

<table>
<tr><th colspan="2">TEST 4 : Anonymous : Testing of Rodrepel RR 0315 LDPE effectiveness on accelerated aged cables (C Tech - Hyderabad Testing Facility)</th></tr>
<tr><td>Guideline</td><td>In-house method</td></tr>
<tr><td>Final product tested</td><td>Cables dosed with Cables dosed with Rodrepel 0315 LDPE = 9028 PE Antirodent at a dose of 3% and submitted to an accelerated ageing procedure before the efficacy test.
AGEING PROCEDURE: The samples were aged at a temperature of 90°C for 90 days. These cables were then submitted to forced cooling, temperature being brought down to -15°C for a period of 90 days. The final run of tests is submitting the cable samples to salt spray, the process being done in a standard salt spray cabinet.</td></tr>
<tr><td>Test species</td><td>Various species , captured from the wild. The Indian labs that carried out the tests state that these species may include: Bandicota bengalensis (the lesser bandicoot rat), Tatera indica (the Indian gerbil), Millardia meltada (the Indian soft furred field rat) and Rattus rattus (black rat). These four species are the most widely distributed and abundantly found in most of the geographical regions in India and other parts of southern Asia.</td></tr>
<tr><td>Effects investigated</td><td>Weight loss and visual inspection after 60, 120 and 180 days of exposure</td></tr>
<tr><td>Main test conditions</td><td>TEST CHAMBER / DEVICE: Semi-field conditions: plexiglas enclosure comprised of sand up to a hight of 6 feet.
TEST CONDITIONS: Three replicate bundles of cables were used for the test and the control samples (each bundle consisting of 4 cables). The bundles of aged cables were placed on the surface and at various depths within the sand pit. The rodents were pre-acclimatized for a period of 15 days within the sand pit.
Untreated controls : cables without additive
EXPOSURE PERIOD : 180 days</td></tr>
<tr><td>Results</td><td>Visual assessment of damage to cables : Visual inspection revealed that there was significant surface abrasion leading to pit like formation in the control samples at 60, 120 and 180 days whereas the Rodrepel RR0306 LDPE containing samples were smooth in finish at every time-point.
Weight change of cables : Significant weight change for control samples (between 10-18% for each 60-day evaluation period) as compared to samples dosed with Rodrepel 0315 LDPE (between 0.7-3 %) for each 60-day evaluation period); about a factor 10 difference. See table below for further information.
<table>
<tr><th>Group</th><th>Initial weight (g)</th><th>Final weight (g)</th><th>Weight loss (%)</th></tr>
<tr><td colspan="4">Readings after 60 days</td></tr>
<tr><td>Control bundle 1</td><td>400</td><td>340</td><td>15</td></tr>
<tr><td>Control bundle 2</td><td>400</td><td>345</td><td>13.75</td></tr>
<tr><td>Control bundle 3</td><td>400</td><td>361</td><td>9.75</td></tr>
<tr><td colspan="4">Average weight loss : 12.83%</td></tr>
<tr><td>Test bundle 1</td><td>400</td><td>393</td><td>1.75</td></tr>
<tr><td>Test bundle 2</td><td>400</td><td>390</td><td>2.5</td></tr>
</table></td></tr>
</table>

		Test bundle 3	400	389	2.75
		Average weight loss : 2.33%			
		Readings after 120 days			
		Control bundle 1	340	300	11.7
		Control bundle 2	345	298	16.23
		Control bundle 3	361	300	16.89
		Average weight loss : 14.94%			
		Test bundle 1	393	380	3.3
		Test bundle 2	390	387	0.7
		Test bundle 3	389	381	2.0
		Average weight loss : 2%			
		Readings after 180 days			
		Control bundle 1	300	245	18.33
		Control bundle 2	298	240	16.95
		Control bundle 3	300	246	18
		Average weight loss : 17.76%			
		Test bundle 1	380	373	1.8
		Test bundle 2	387	381	1.5
		Test bundle 3	381	377	1.04
		Average weight loss : 1.4%			
Conclusion	This test was set up as a simulated use test in the laboratory of C-Tech Hydrabad Testing Facility, with artificially aged cables. In terms of species tested, this test is conducted with rats found in the field (India), in order to mimic their response in real life. The efficacy is evaluated based on a visual assessment and weight loss recordings. Conclusion: Based on the difference between control and treated for the visual assessment and the weight loss data it can be concluded that the product effectively protects the cables from biting damage, also after submitting them to accelerated ageing processes.				
TEST 5: Grover P (2012): Observation and examination report of Anti-rodent test conducted on test cables in field condition supplied by CTECH CORPORATION MUMBAI (Indian Institute of Chemical Technology - IICT)					
Guideline	In-house method				
Final product tested	Cables dosed with product Rodrepel = Antirat masterbatch at a dose of 3%				
Test species	*Rattus rattus*				
Effects investigated	Weight loss and visual inspection.				

<table>
<tr><td></td><td>Monitoring rodent health status (physically as well as by Infrared Camera for 24 hours/day)</td></tr>
<tr><td>Main test conditions</td><td>TEST CHAMBER / DEVICE: Choice test in field conditions. Test animals are kept in plexiglass enclosure filled with mud and gravel, with a window for inlet/outlet of food/water. The enclosure is kept in an open environment subject to natural climatic conditions. An infra-red camera is fixed in the enclosure to monitor rodent movement and behaviour.
TEST CONDITIONS: Three test (T1, T2 and T3) and three control samples (C1, C2 and C3); over-ground and buried/underground. The rodents (5/6 rats per experiment) were captured from the wild and were pre-acclimatized for a period of 7 days in laboratory cages.
Untreated controls : cables without additive
EXPOSURE PERIOD : 90 days</td></tr>
<tr><td>Results</td><td>-Weight loss at the end of exposure period (90 days): Significant weight change for control samples (average about 40%) as compared to samples dosed with Rodrepel (around 1 %); about a factor 40 difference. See table below for further information

<table>
<tr><th>Group</th><th>Initial weight (g)</th><th>Final weight (g)</th><th>Weight loss (%)</th><th>G factor*</th></tr>
<tr><td>C1</td><td>340</td><td>180</td><td>47.05</td><td>0.4705</td></tr>
<tr><td>C2</td><td>340</td><td>233</td><td>31.87</td><td>0.3187</td></tr>
<tr><td>C3</td><td>340</td><td>205</td><td>40.57</td><td>0.4057</td></tr>
<tr><td colspan="5">Average weight loss control : 39.83%</td></tr>
<tr><td>T1</td><td>344</td><td>340</td><td>1.17</td><td>0.0117</td></tr>
<tr><td>T2</td><td>346</td><td>344</td><td>0.57</td><td>0.0057</td></tr>
<tr><td>T3</td><td>343</td><td>340</td><td>0.94</td><td>0.0094</td></tr>
<tr><td colspan="5">Average weight loss treated: 0.8933%</td></tr>
</table>
* G-factor (gnawing factor) = weight loss test sample / initial weight test sample

-Weight loss per 4 weeks

<table>
<tr><th>Group</th><th>Weight loss (grams)
WEEK 1-4</th><th>Weight loss (grams)
WEEK 4-8</th><th>Weight loss (grams)
WEEK 8-12</th></tr>
<tr><td>C1</td><td>85</td><td>40.8</td><td>34.2</td></tr>
<tr><td>C2</td><td>54.72</td><td>30.7</td><td>23.5</td></tr>
<tr><td>C3</td><td>68.8</td><td>41.4</td><td>29.8</td></tr>
<tr><td>T1</td><td>2.06</td><td>1.37</td><td>0.57</td></tr>
<tr><td>T2</td><td>1.04</td><td>0.59</td><td>0.37</td></tr>
</table>
</td></tr>
</table>

T3	1.8	1.02	0.49

-Visual assessment of damage:
The samples were removed from the exposed area and observed carefully under a magnifying glass to find any marks like nibbling, scraping, pitting and perforation. Ratings are given based on such visual observation per sample. A perfect cable will be rated at 100 whereas a totally damaged one will be 0 by this lab. With 3 replicates, a total score below 150 (which is 3 times only 50 in average) is considered as unprotected or ineffective whereas a score above 150 is considered as protected or effective. The results are shown in below table.

Group	Rating	Cumulative rating	Result
C1	5	13	Fail
C2	8		
C3	-		
T1	100	289	Pass
T2	99		
T3	90		

- Rat behavior : all the rodents were healthy and no unusual behavior was noted

Conclusion

This test was set up as a choice test in field conditions at the Indian Institute of Chemical Technology – IICT. This test is conducted with the species *Rattus rattus* using cables treated with a Rodrepel = Antirodent masterbatch.

The efficacy is evaluated based on a visual assessment and weight loss recordings.

Based on the difference between control and treated for the visual assessment and the weight loss data it can be concluded that the product effectively protects the cables from biting damage by rats.

TEST 6: Grover P. (2010): Observation and examination report of Anti-rodent test conducted on test cables in field condition supplied by CTECH CORPORATION MUMBAI (Indian Institute of Chemical Technology - IICT)

Guideline	In-house method
Final product tested	Cables dosed with Rodrepel = Antirodent masterbatch at a dose of 3%
Test species	*Rattus norvegicus*
Effects investigated	Weight loss and visual inspection. Monitoring rodent health status (physically as well as by Infrared Camera for 24 hours/day)
Main test conditions	TEST CHAMBER / DEVICE: Choice test in field conditions. Test animals are kept in plexigalss enclosure filled with mud and

<table>
<tr><td></td><td>gravel, with a window for inlet/outlet of food/water. The enclosure is kept in an open environment subject to natural climatic conditions. An infra-red camera is fixed in the enclosure to monitor rodent movement and behaviour.
TEST CONDITIONS: Three test (T1, T2 and T3) and three control samples (C1, C2 and C3); overground and buried/underground. The rodents (5/6 rats per experiment) were captured from the wild and were pre-acclimatized for a period of 7 days in laboratory cages.
Untreated controls : cables without additive
EXPOSURE PERIOD : 90 days</td></tr>
<tr><td>Results</td><td>Weight loss at the end of exposure period (90 days): Significant weight change for control samples (average about 25%) as compared to samples dosed with Rodrepel (around 2 %); about a factor 10 difference. See table below for further information

<table>
<tr><th>Group</th><th>Initial weight (g)</th><th>Final weight (g)</th><th>Weight loss (%)</th><th>G factor*</th></tr>
<tr><td>C1</td><td>340</td><td>260</td><td>23.52</td><td>0.2352</td></tr>
<tr><td>C2</td><td>342</td><td>259</td><td>24.26</td><td>0.2426</td></tr>
<tr><td>C3</td><td>345</td><td>253</td><td>26.66</td><td>0.2666</td></tr>
<tr><td colspan="5">Average weight loss control : 24.82%</td></tr>
<tr><td>T1</td><td>344</td><td>338.38</td><td>1.63</td><td>0.0163</td></tr>
<tr><td>T2</td><td>346</td><td>339.75</td><td>1.8</td><td>0.018</td></tr>
<tr><td>T3</td><td>343</td><td>335.77</td><td>2.1</td><td>0.021</td></tr>
<tr><td colspan="5">Average weight loss treated: 1.84%</td></tr>
</table>
* G-factor (gnawing factor) = weight loss test sample / initial weight test sample

-Weight loss per 4 weeks

<table>
<tr><th>Group</th><th>Weight loss (grams)
WEEK 1-4</th><th>Weight loss (grams)
WEEK 4-8</th><th>Weight loss (grams)
WEEK 8-12</th></tr>
<tr><td>C1</td><td>40</td><td>26.61</td><td>13.39</td></tr>
<tr><td>C2</td><td>43.38</td><td>26.57</td><td>13.05</td></tr>
<tr><td>C3</td><td>37</td><td>30</td><td>25</td></tr>
<tr><td>T1</td><td>3.1</td><td>2.05</td><td>0.47</td></tr>
<tr><td>T2</td><td>3.29</td><td>2.03</td><td>0.93</td></tr>
<tr><td>T3</td><td>3.43</td><td>2.04</td><td>1.76</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>-Visual assessment of damage:
The samples were removed from the exposed area and observed carefully under a magnifying glass to find any marks like nibbling, scraping, pitting and perforation. Ratings are given based on such visual observation per sample. A perfect cable will be rated at 100 whereas a totally damaged one will be 0 by this lab. With 3 replicates, a total score below 150 (which is 3 times only 50 in average) is considered as unprotected or ineffective whereas a score above 150 is considered as protected or effective. The results are shown in below table

<table>
<tr><th>Group</th><th>Rating</th><th>Cumulative rating</th><th>Result</th></tr>
<tr><td>C1</td><td>10</td><td rowspan="3">35</td><td rowspan="3">Fail</td></tr>
<tr><td>C2</td><td>25</td></tr>
<tr><td>C3</td><td>-</td></tr>
<tr><td>T1</td><td>100</td><td rowspan="3">265</td><td rowspan="3">Pass</td></tr>
<tr><td>T2</td><td>90</td></tr>
<tr><td>T3</td><td>75</td></tr>
</table>

-Rat behavior : all the rodents were healthy and no unusual behavior was noted</td></tr>
<tr><td>Conclusion</td><td>This test was set up as a choice test in field conditions at the Indian Institute of Chemical Technology – IICT. This test is conducted with the species Rattus norvegicus using cables treated with a Rodrepel = Antirodent masterbatch.

The efficacy is evaluated based on a visual assessment and weight loss recordings

Based on the difference between control and treated for the visual assessment and the weight loss data it can be concluded that the product effectively protects the cables from biting damage by rats.</td></tr>
</table>

AVAILABLE TESTS AGAINST TERMITES	
TEST 7 : Chowdhary, A : Evaluation of antitermite activity of cable against subterranean termites (Odontotermes obesus & Coptotermes formosanus) (Haffkine Institute)	
Guideline	GB 2951.38-86 (Chinese national standard for termite test methods for wires)
Final product tested	Cables dosed with Combirepel 9518 = 9518 PE Multirepel at a dose of both 2% and 3%
Test species	*Coptotermes formosanus* *Odontotermes obesus*

<table>
<tr><td>Effects investigated</td><td>- Clinical signs (mortalilty, morbidity recorded twice a day and all visible signs/symptoms recorded daily)
- Damage to cables (visual assessment) at the end of the test (after 4 weeks)
- Weight of the test samples (gnawing factor) at the end of the test (after 4 weeks)</td></tr>
<tr><td>Main test conditions</td><td>TEST CHAMBER / DEVICE: Experimental glass containers, layered with soil and wood scrapings. The termites were provided wood scrapings and cotton wool soaked in water.
TEST CONDITIONS: 5 cable samples were used per group (G1 = control = cables without additive; G2 = cables dosed with 2% Combirepel 9518; G3 = cables dosed with 3% Combirepel 9518).
NUMBERS OF TARGET ORGANISMS : Initial density / numbers in test system: 200 termites per group
EXPOSURE PERIOD : 30 days</td></tr>
<tr><td>Results</td><td>-Clinical signs : No clinical signs were observed throughout the trial period
-Visual assessment of damage to cables: No attack of cables treated with Combirepel; some attack in control group (nest building/surface nibbling). See tables below for detailed results.
<u>Damage scale :</u>

<table>
<tr><th>Degree of damage</th><th>Description</th><th>Rating</th></tr>
<tr><td>OK</td><td>Undamaged</td><td>100</td></tr>
<tr><td>Nest building</td><td>Formation of nest building on the surface of the test samples</td><td>75</td></tr>
<tr><td>Surface nibbling</td><td>Surface roughened by the termites but not pitted</td><td>50</td></tr>
<tr><td>Slight attack</td><td>Surface with shallow pits and only in a few restricted regions</td><td>25</td></tr>
<tr><td>Attack</td><td>Surface deeply pitted, shallowly pitted over extensive areass</td><td>10</td></tr>
<tr><td>Destroyed</td><td>Sample perforated</td><td>0</td></tr>
</table>
Results :

<table>
<tr><th colspan="4">ODONTOTERMES OBESUS</th></tr>
<tr><th rowspan="2">Group</th><th colspan="3">OBSERVATION</th></tr>
<tr><th>initial observation</th><th>degree of damage
after fourth week</th><th>rating R</th></tr>
<tr><td>G1 (control)</td><td>OK</td><td>SN-NB</td><td>55</td></tr>
<tr><td>G2</td><td>OK</td><td>OK</td><td>100</td></tr>
</table>
</td></tr>
</table>

G3	OK	OK	100

COPTOTERMES FORMOSANUS			
Group	**OBSERVATION**		
	initial observation	**degree of damage**	**rating R**
		after fourth week	
G1 (control)	OK	SN-NB	70
G2	OK	OK	100
G3	OK	OK	100

-Weight change of cables: No weight change for cables dosed with Combirepel; weight change of about 10% in control group. See below table for further details

Weight change of cables (mean of 5 samples per group) :

ODONTOTERMES OBESUS				
Group	**Initial weight (g)**	**Final weight (g)**	**Weight loss (%)**	**G factor***
G1(control)	11.09	10.00	9.83	0.0983
G2	11.69	11.69	0	0
G3	11.27	11.27	0	0

COPTOTERMES FORMOSANUS				
Group	**Initial weight (g)**	**Final weight (g)**	**Weight loss (%)**	**G factor***
G1(control)	11.01	10.06	8.62	0.0862
G2	11.26	11.26	0	0
G3	10.82	10.82	0	0

	* G-factor (gnawing factor) = weight loss test sample / initial weight test sample In addition, clinical signs were monitored and none were noted.
Conclusion	This efficacy test is carried out in the laboratory, at Haffkine Institute, one of the oldest biomedical research institutes in India.. It is carried out against two types of species, O*dontotermes obesus* and C*optotermes formosanus*. The efficacy is evaluated based on a visual assessment and weight loss recordings. The claim of the products is to protect the cables from damage that can affect the operating conditions. Therefore, for an appropriate assessment of the efficacy for these kind of products, both weight loss and visual assessment can provide important information on the efficacy of the product. Based on the difference between control and treated for the visual assessment (in the control group, nest building/surface nibbling is oberved. For the treated cables, the samples are undamaged) and the weight loss data (10% weight loss control and no weight loss in treated samples) it can be concluded that the product effectively protects the cables from biting damage.
TEST 8 : Plarre, R. : Test Report - 2% 107079 EVA ANTITERMITE (CC10107079BG) tested in polyethylene resin	
Guideline	DIN EN 117:2013
Final product tested	Polyethylene resin dosed with 107079 EVA Antitermite at a dose of 2%
Test species	*Reticulitermes* sp.
Effects investigated	Visual examination of the test material between the wooden plates and termite survival rate
Main test conditions	TEST CHAMBER / DEVICE: Type and design of test chamber / device: plastic containers (9 cm height; 7x7cm2 surface area), filled with 35g Vermiculite and 8g pine sapwood saw dust. Vermiculite and saw dust were mixed and moistened with approximately 80mL of water. TEST CONDITIONS: In this test, the resistance against termites of the test sample (polyethylene resin dosed at 2% with 107079 EVA ANTITERMITE master batch) was determined by pressing it between 2 wooden plates of pine sapwood (sandwich-method). Test specimens (appox. 5cm x 4.5cm x 0.2cm) are placed between two wooden plates of pine sapwood (size 5cm x 5cm x 0.5cm) and tightened with a rubber band (sandwich method). All samples were buried in the vermiculite. Controls are set up in the same way, but without the test product between the plates. Test samples were set up in 6 replicates; controls in 3 replicates. NUMBERS OF TARGET ORGANISMS : 250 worker termites together with 2 soldier termites EXPOSURE PERIOD : 58 days

Results	In all parallels, the wooden plates next to the test specimen were completely attacked. The tested polyethylene resin was resistant against attack by the termite species *Reticulitermes santonensis*. The test product showed no toxic effect against termites.
Conclusion	As in the control treatment no cable with an EVA coating without product was used, the efficacy of the product cannot be assessed based on this test. This test is only providing supplementary information regarding the non-toxicity of the product.
TEST 9 :Anonymous : Testing of Termirepel 0315 LDPE MB effectiveness on accelerated aged cables (C Tech - Hyderabad Testing Facility)	
Guideline	In-house method
Final product tested	Cables dosed with Termirepel 0315 LDPE = 143510 PE Antitermite at a dose of 3% and submitted to an accelerated ageing procedure before the efficacy test. AGEING PROCEDURE: The samples were aged at a temperature of 90°C for 90 days. These cables were then submitted to forced cooling, temperature being brought down to -15°C for a period of 90 days. The final run of tests is submitting the cable samples to salt spray, the process being done in a standard salt spray cabinet.
Test species	*Mastotermes darwinienis*
Effects investigated	Weight loss and visual inspection after 30, 60, 120, 150 and 180 days of exposure
Main test conditions	TEST CHAMBER / DEVICE: Semi-field conditions : Termites were kept in their natural environment which was artificially created by the research team. The test method has been developed so as to imitate as closely as possible real life conditions in a replicated environment. This would ensure that the vicinity replicates closely the natural vicinity conditions of the termite and ensuring that other parameters such as availability of nourishment are taken care of. TEST CONDITIONS: Three replicate bundles of cables were used for the test and the control samples (each bundle consisting of 3 cables). The cable samples i.e. test and control samples were buried underground at a depth of 1.5 feet. Untreated controls : cables without additive EXPOSURE PERIOD : 180 days
Results	Visual assessment of damage to cables : Visual inspection revealed that there was significant surface abrasion leading to pit like formation in the control samples after 30, 60, 90, 120, 150 and 180 days of exposure, whereas the TermirepelTM 0315 LDPE MB containing samples were smooth in finish after 30, 60, 90, 120, 150 and 180 days of exposure. Weight change of cables : Significant weight change for control samples (between 10-25% for each 30-day evaluation period) as compared to samples dosed with Termirepel^{TM} 0315 LDPE MB (between 0.4-2.2 %) for each 30-day evaluation period); about a factor 10 difference

Conclusion	This test was set up as a simulated use test in the laboratory of C-Tech Hydrabad Testing Facility. The test is carried out on *Mastotermes darwinienis*. This giant termite species is by far the most destructive termite in Australia (Gay and Calaby, 1970). The submitted tests show that even for such aggressive species, the products work well, and even when the cables have been submitted to accelerated ageing processes. The efficacy is evaluated based on a visual assessment and weight loss recordings Based on the difference between control and treated for the visual assessment (pit formation in the control group, treated cables are smooth in finish) and the weight loss data (significant difference between control and treated) it can be concluded that the product effectively protects the cables from biting damage, also after submitting them to accelerated ageing processes.
TEST 10: Anonymous : Testing of Termirepel 0306 EVA MB effectiveness on accelerated aged cables (C Tech - Hyderabad Testing Facility)	
Guideline	In-house method
Final product tested	Cables dosed with Cables dosed with Termirepel 0306 EVA = 107079 EVA Antitermite at a dose of 3% and submitted to an accelerated ageing procedure before the efficacy test. AGEING PROCEDUR : The samples were aged at a temperature of 90°C for 90 days. These cables were then submitted to forced cooling, temperature being brought down to -15°C for a period of 90 days. The final run of tests is submitting the cable samples to salt spray, the process being done in a standard salt spray cabinet.
Test species	*Mastotermes darwinienis*
Effects investigated	Weight loss and visual inspection after 30, 60, 120, 150 and 180 days of exposure
Main test conditions	TEST CHAMBER / DEVIC : Semi-field conditions: Termites were kept in their natural environment which was artificially created by the research team. The test method has been developed so as to imitate as closely as possible real life conditions in a replicated environment. This would ensure that the vicinity replicates closely the natural vicinity conditions of the termite and ensuring that other parameters such as availability of nourishment are taken care of. TEST CONDITION : Three replicate bundles of cables were used for the test and the control samples (each bundle consisting of 3 cables). The cable samples i.e. test and control samples were buried underground at a depth of 1.5 feet. Untreated controls : cables without additive EXPOSURE PERIOD: 180 days
Results	Visual assessment of damage to cables: Visual inspection revealed that there was significant surface abrasion leading to pit like formation in the control samples after 30, 60, 90, 120, 150 and 180 days of exposure, whereas the Termirepel 0306 EVA MB containing samples were smooth in finish after 30, 60, 90, 120, 150 and 180 days of exposure. Weight change of cables: Significant weight change for control samples (cumulative 57.5% after 180 days) as compared to

	samples dosed with Termirepel 0306 EVA MB (cumulative 5.1% after 180 days) for each 30-day evaluation period); about a factor 10 difference
Conclusion	This test was set up as a simulated use test in the laboratory of C-Tech Hydrabad Testing Facility. The test is carried out on *Mastotermes darwinienis*. This giant termite species is by far the most destructive termite in Australia (Gay and Calaby, 1970). The submitted tests show that even for such aggressive species, the products work well, and even when the cables have been.submitted to accelerated ageing processes. The efficacy is evaluated based on a visual assessment and weight loss recordings Based on the difference between control and treated for the visual assessment (pit formation in the control group, treated cables are smooth in finish) and the weight loss data (significant difference between control and treated) it can be concluded that the product effectively protects the cables from biting damage, also after submitting them to accelerated ageing processes.
TEST 11 : Chowdary, A, EVALUATION OF ANTI TERMITE ACTIVITY OF CABLE SHEATH AGAINST R. SANTONENSIS TERMITES (Haffkine Instuitute)	
Guideline	GB 1986: GB 2951.38-86 guideline + in-house standardized method of determining the bio efficacy of antitermite doping compounds.
Final product tested	Cables dosed with Termirepel = Antitermite masterbatch at 3%
Test species	R. *santonensis (now flavipes)* termite, imported from western France
Effects investigated	- Clinical signs (mortality, morbidity recorded twice a day and all visible signs/symptoms recorded daily) - Damage to cables (visual assessment) at the end of the test (30 days) - Weight of the test samples (gnawing factor) at the end of the test (30 days)
Main test conditions	TEST CHAMBER / DEVICE: Experimental glass containers layered with soil and wood scrapings. Cages were kept in a stainless steel tray containing water to avoid escape of termites. Termites were provided wood scrapings ad libitum and cotton wool soaked in water TEST CONDITIONS: 3 cable samples were used per group (G1 = control = cables without additive; G2 = cables dosed with 3% Termireple). NUMBERS OF TARGET ORGANISMS: approximately 200 termites per group per week EXPOSURE PERIOD : 30 days
Results	Clinical signs : No clinical signs were observed throughout the trial period -Visual assessment of damage to cables: No attack in treated samples, where control samples showed slight attack. See tables

below for detailed results.

Damage scale :

Degree of damage	Description	Rating
OK	Undamaged	100
Nest building	Formation of nest building on the surface of the test samples	75
Surface nibbling	Surface roughened by the termites but not pitted	50
Slight attack	Surface with shallow pits and only in a few restricted regions	25
Attack	Surface deeply pitted, shallowly pitted over extensive areas	10
Destroyed	Sample perforated	0

Results (mean of 3 samples per group) :

Group	OBSERVATION		
	initial observation	degree of damage after fourth week	Mean rating
G1 (control)	OK	SA-OK	25
G2	OK	OK	100

-Weight change of cables: No weight change in control group; close to 10% weight change in treated group. See table below for details.

Weight change of cables (mean of 3 samples per group) :

Group	Initial weight (g)	Final weight (g)	Weight loss (%)	G factor*
G1(control)	10.61	9.823	7.42	0.0742
G2	10.45	10.45	0	0

* G-factor (gnawing factor) = weight loss test sample / initial weight test sample

Conclusion	This efficacy test is a "choice test" with a duration of 1 month, carried out in the laboratory, at Haffkine Institute, one of the oldest and most knowledgeable biomedical research institutes in India. It is carried out on a EU relevant species : R. *santonensis (now flavipes)* termite, imported from western France The efficacy is evaluated based on a visual assessment and weight loss recordings. The claim of the products is to protect the cables from biting damage that can affect the operating conditions of the cables. In cables, scratches and some weight loss are permitted as long as they don't impair cable function, i.e. no piercing of the sheath layer. Therefore, for an appropriate assessment of the efficacy for these kind of products, both weight loss and visual assessment can provide important information on the efficacy of the product. Based on the difference between control and treated for the visual assessment (in the control group, slight attack is observed; no attack in treated group) and the weight loss data (significant difference between control and treated) it can be concluded that the product effectively protects the cables from biting damage. In addition, clinical signs were monitored and none were noted.
TEST 12 : Chowdary, A, EVALUATION OF ANTI TERMITE ACTIVITY OF CABLE SHEATH AGAINST R. CLYPEATUS TERMITES (Haffkine Instuitute)	
Guideline	GB 1986: GB 2951.38-86 guideline + in-house standardised and validated method of anti-termite activity against *R. clypeatus* termite.
Final product tested	Cables dosed with Termirepel = Antitermite masterbatch at 3%
Test species	R. *clypeatus,* imported from Israel
Effects investigated	- Clinical signs (mortality, morbidity recorded twice a day and all visible signs/symptoms recorded daily) - Damage to cables (visual assessment) at the end of the test (30 days) - Weight of the test samples (gnawing factor) at the end of the test (30 days)
Main test conditions	TEST CHAMBER / DEVICE: Experimental glass containers layered with soil and wood scrapings. Cages were kept in a stainless steel tray containing water to avoid escape of termites. Termites were provided wood scrapings ad libitum and cotton wool soaked in water TEST CONDITIONS: 3 cable samples were used per group (G1 = control = cables without additive; G2 = cables dosed with 3% Termirepel). NUMBERS OF TARGET ORGANISMS : approximately 200 termites per group per week

	EXPOSURE PERIOD : 30 days
Results	Clinical signs : No clinical signs were observed throughout the trial period -Visual assessment of damage to cables: No attack in treated samples, where control samples showed slight attack. See tables below for detailed results. **Damage scale :**

Degree of damage	Description	Rating
OK	Undamaged	100
Nest building	Formation of nest building on the surface of the test samples	75
Surface nibbling	Surface roughened by the termites but not pitted	50
Slight attack	Surface with shallow pits and only in a few restricted regions	25
Attack	Surface deeply pitted, shallowly pitted over extensive areas	10
Destroyed	Sample perforated	0

Results (mean of 3 samples per group) :

Group	OBSERVATION		
	initial observation	degree of damage after fourth week	Mean rating
G1 (control)	OK	SA-OK	15
G2	OK	OK	100

-Weight change of cables: No weight change in control group; close to 10% weight change in treated group. See table below for details.

Weight change of cables (mean of 3 samples per group) :

Group	Initial weight (g)	Final weight (g)	Weight loss (%)	G factor*
G1(control)	13.16	11.88	9.726	0.09726
G2	13.2	13.2	0	0

	* G-factor (gnawing factor) = weight loss test sample / initial weight test sample
Conclusion	This efficacy test is a "choice test" with a duration of 1 month, carried out in the laboratory, at Haffkine Institute, one of the oldest and most knowledgeable biomedical research institutes in India. It is carried out on R. *clypeatus,* imported from Israel The efficacy is evaluated based on a visual assessment and weight loss recordings. The claim of the products is to protect the cables from biting damage that can affect the operating conditions of the cables. In cables, scratches and some weight loss are permitted as long as they don't impair cable function, i.e. no piercing of the sheath layer. Therefore, for an appropriate assessment of the efficacy for these kind of products, both weight loss and visual assessment can provide important information on the efficacy of the product. Based on the difference between control and treated for the visual assessment (in the control group, slight attack is observed; no attack in treated group) and the weight loss data (significant difference between control and treated) it can be concluded that the product effectively protects the cables from biting damage. In addition, clinical signs were monitored and none were noted.

Conclusion on the efficacy of the product

Meta SPC 1: Multirepel masterbatch:

Repellence against rats:

Six efficacy tests with rats have been submitted. Four out of six tests are carried out with Antirat masterbatches and two on the Multirepel products. Taking into account the proposed dosages, read-across between both types of products is possible (see confidential Annex). In all of the tests, the efficacy of the product was shown. 2% masterbatch in final cable is proposed as the minimum dosage for the masterbatches in meta SPC 1.

Species tested: Two tests were provided on *Rattus norvegicus* (TEST 2 and TEST 6), and one test was carried out specifically on the *Rattus rattus* species (TEST 5). By means of visual observations and/or weight loss recordings, these tests demonstrated a very clear difference between control and treated samples; i.e. contrary to the untreated cables, damage in the treated cables was never beyond the point where it would affect the operating ability of the cable. Therefore, the efficacy of the products against the European rat species has been demonstrated. In addition, three tests (TEST 1, TEST 3 and TEST 4) were carried out on various rat species captured from the field in India. These tests can be used as supporting data, demonstrating a similar effect against a broader range of rats species.

Type of carrier: The masterbatches are produced based on either a LDPE or an EVA carrier. Both types of carrier have been tested in

the efficacy trials. In all cases, a good efficacy was observed. TEST 3 and TEST 4 are similar tests, the only difference being the type of carrier. The results of these tests are very similar, therefore showing that the type of carrier does not have any influence on the active substance and consequently on the efficacy of the product. This is fully in line with what one would expect: Its molecules completely melt inside the extruder in which the masterbatch is processed at elevated temperature together with the polymer being extruded. Only the active substances, at the required dosing, play a role in the efficacy in the treated article.

Age of product: Efficacy tests have been carried out on treated cables that were fabricated with masterbatches of various ages, up to an age of 2 years (TEST 2). In addition, accelerated ageing tests were also provided in the dossier (TEST 3 and 4). In both cases a good efficacy is observed; i.e. the weight loss recorded for the treated cable is a factor 10 less than for control cables. When comparing this to TEST 1 (similar (various) species, see above), which is done on a non-aged product, it can be seen that also for TEST 1 the difference between control and treated cables is about a factor 10 .
In reality, the active substances can be considered to keep their intended function for a very long period of time.

In conclusion, the tests demonstrate sufficient efficacy of masterbatches in meta SPC 1, as repellent against rats when incorporated in plastic cable and wire coatings.

Repellence against termites:
Please see meta-SPC 2 below. 2% masterbatch in final cable is proposed as the minimum dosage for the masterbatches in meta SPC1.

Meta SPC 2: Antitermite masterbatch:
Six efficacy tests with termites have been submitted; five with the Antitermite masterbatch (meta SPC 2) and one on Multirepel (meta SPC 1). Taking into account the proposed different dosage in the treated articles, the total active substance content of both types of products is comparable; therefore read-across between the Antitermite and Multrepel products is possible. In all of the tests, the efficacy of the product was shown. 3% masterbatch in final cable is proposed as the minimum dosage for the masterbatches in meta SPC2 and 2% for meta SPC 1.

Species tested: A test on Reticutilitermes *santonensis (now flavipes)* is included, which is a relevant termite species for EU (France). In addition, tests with R. *clypeatus,* (imported from Israel) and the species *Odontotermes*, C*optotermes* and *Mastotermes* were included. The latter is a giant termite species which is by far the most destructive termite in Australia (Gay and Calaby, 1970). The submitted tests show that the products work well, for EU relevant species as well as very aggressive species worldwide

Type of carrier: The masterbatches are produced based on a LDPE or EVA carrier. Both types of carrier have been tested in the efficacy trials. In all cases, a good efficacy was observed. TEST 9 and TEST 10 are similar tests, the only difference being the type of carrier. The

results of these tests are very similar, therefore showing that the type of carrier does not have any influence on the active substance and consequently on the efficacy of the product. This is fully in line with what one would expect: Its molecules completely melt inside the extruder in which the masterbatch is processed at elevated temperature together with the polymer being extruded. Only the active substances, at the required dosing, play a role in the efficacy in the treated article.

Age of product:
Accelerated ageing tests were also provided in the dossier (TEST 9 and 10). In both tests a good efficacy is observed; i.e. the weight loss recorded for the treated cable is a factor 10 less than for control cables. This is obtained under very worst case conditions: aged cables and a very aggressive termite species (Mastotermes). These can be used as read-across studies for the other termite species.

In conclusion, the tests demonstrate sufficient efficacy of masterbatches in meta SPC 1 and 2, as repellent against termites when incorporated in plastic cable and wire coatings.

2.2.5.6 Occurrence of resistance and resistance management

No knowledge of occurrence of resistance. Resistance is less likely to occur with repellents than with insecticides or rodenticides.

2.2.5.7 Known limitations

No limitations known.

2.2.5.8 Evaluation of the label claims

The label claims as stated in the SPC are all supported by results of efficacy tests of representative products.
The following claim can be used on the label:

Meta-SPC 1:
Repellent against rats
Repels rats form treated cable and wire coatings
Repellent against termites
Repels termites form treated cable and wire coatings

Meta-SPC 2:

Repellent against termites

Repels termites form treated cable and wire coatings

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Repellent Masterbatches in meta SPC 1 and 2 are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

This is no data requirement for an application in accordance with Art.25 of EU 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 any of the criteria defined in the EU SoC 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, Peppermint oil and Citronellal 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 effect is activated in treated articles as only there the active substance becomes 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 master batch as a sensitizer and H317 is not applicable.

2.2.6 Risk assessment for animal health

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

2.2.7 Risk assessment for the environment

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

2.2.8 Measures to protect man, animals and the environment

2.2.8.1 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

2.2.8.2 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.

2.2.8.3 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.

2.2.8.4 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

2.2.8.5 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).

2.2.8.6 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.

2.2.9 Assessment of a combination of biocidal products

Not relevant

2.2.10 Comparative assessment

Not relevant

3 Annexes[4]

3.1 List of studies for the biocidal product (family)

Author	Year	Title	Testing laboratory	Report no.	Report date
Chowdhary A	2013	Evaluation of anti rodent activity of cable against rodents	Haffkine Institute	HI/ZNS_VAU/RES-012A/12	15/02/2013
Lattard V.	2016	Avenant N°1 à la convention cadre n°149VAL0914	Vetagro Sup / INRA, USC1233	-	-
Anonymous	2016	Testing of Rodrepel RR0306 EVA effectiveness on accelerated aged cables	C Tech - Hyderabad Testing Facility	-	01/08/2016
Anonymous	2016	Testing of Rodrepel RR 0315 LDPE effectiveness on accelerated aged cables	C Tech - Hyderabad Testing Facility	-	01/08/2016
Grover P.	2012	Observation and examination report of Anti-rodent test conducted on test cables in field	Indian Institute of Chemical Technology - IICT	-	-

4 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

		condition supplied by CTECH CORPORATION MUMBAI			
Grover P.	2012	Observation and examination report of Anti-rodent test conducted on test cables in field condition supplied by CTECH CORPORATION MUMBAI	Indian Institute of Chemical Technology - IICT	-	-
Chowdhary A	2013	Evaluation of antitermite activity of cable against subterranean termites (Odontotermes obesus & Coptotermes formosanus	Haffkine Institute	HI/ZNS_VAU/RES-012A/12	15/02/2013
Plarre R.	2016	Test Report - 2% 107079 EVA ANTITERMITE (CC10107079BG) tested in polyethylene resin	BAM	15052864 Te D	25/02/2016
Anonymous	-	Testing of Termirepel 0315 LDPE MB effectiveness on accelerated aged cables	C Tech - Hyderabad Testing Facility	-	01/08/2016

Anonymous	2016	Testing of Termirepel 0306 EVA MB effectiveness on accelerated aged cables	C Tech - Hyderabad Testing Facility	-	01/08/2016
Chowdhary A	-	EVALUATION OF ANTI TERMITE ACTIVITY OF CABLE SHEATH AGAINST R. SANTONENSIS TERMITES	Haffkine Institute	-	-
Chowdhary A	-	EVALUATION OF ANTI TERMITE ACTIVITY OF CABLE SHEATH AGAINST R. CLYPEATUS	Haffkine Institute	-	-

3.2 Output tables from exposure assessment tools

Not relevant (simplified procedure)

3.3 New information on the active substance

Not relevant (simplified procedure)

3.4 Residue behaviour

Not relevant (simplified procedure)

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[5]

Not relevant (studies sufficiently summarized in Section 2.2.5.5)

3.6 Confidential annex

See separate document

3.7 Other

None

5 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.