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 eCA)

Repellent Masterbatches Antirat BPF

Product type 19

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

Case Number in R4BP: BC-YL027467-15

Evaluating Competent Authority: Ctgb

Date: 12/4/2018

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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 do not contain a substance of concern

c) the products in the BPF do 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 products, 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 Antirat BPF	/

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-0015777-0000	
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

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)

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

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

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 rats 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

Table 1. Use # 1 – masterbatches for repelling rats

Product Type	PT 19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Rats (*Rattus spp.*) – adults and juveniles
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 by repelling them. Protection should be understood as a protection from 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

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).

	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 masterbatch 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 the general directions of use below.

2.1.4.3 Use-specific risk mitigation measures

Please refer to the general directions of use below.

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 the general directions of use below.

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

Please refer to the general directions of use below.

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 the general directions of use below.

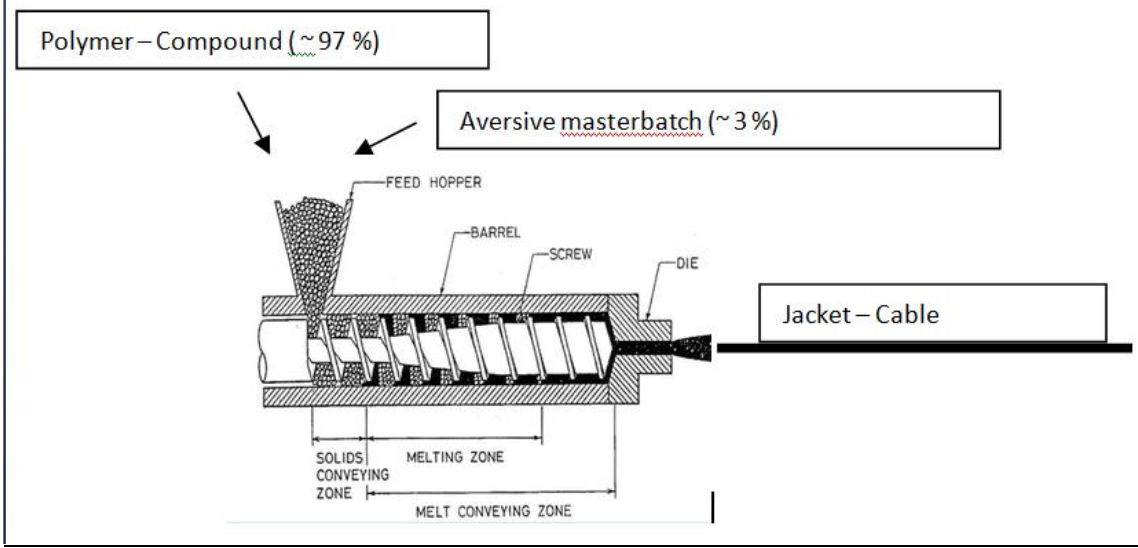
[3] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area 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

2.1.5.1 Instructions for use[4]

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. Typical 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

[4] 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.

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 of the BPF or related 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, 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 2. Use # 1 – masterbatches for repelling rats

Product Type	PT 19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent against rats
Target organism (including development stage)	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 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	Typical dosing of the master batch in the final compound is in the range 3 – 4 %.; minimum dosage 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 technically not 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 efficacy evaluation: see 2.2.5.4.
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 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 >2 year old pellets can be considered sufficiently stable.
Furthermore, the stability of the masterbatch pellets is supported by the available accelerated ageing tests. In this dossier, two efficacy tests with the Antirat 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 product 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 states : "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.
Nevertheless, as a precautionary approach, a shelf life of 2 years is defined based on efficacy testing on 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 masterbatches in this BPF contain active substances with a repellent action against rats. The masterbatch pellets are incorporated into plastic treated articles such as cable and wire coatings, with the aim to protect the final treated articles against gnawing damage from rats by repelling them. Protection should be understood as a protection from damage which could potentially affect the operating conditions of the treated article.
The product is intended for indoor use by industrial users only.
The proposed minimum dosage into the final treated articles is 3%.

The products are currently based on 2 types of carriers: ethyl vinyl acetate (EVA) and low-density polyethylene (LDPE). EVA based masterbatches can be used in most matrices, LDPE specifically in polyolefins. For example: EVA is a plastic ethylene-vinyl acetate copolymer with polar vinyl acetate groups which will interact and link very well with e.g. PVC compounds. Polyethylene is a non-polar polymer; for which an EVA based masterbatch can be used (as it contains an ethylene part) but it is harder to mix. 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. The type of polymer in the masterbatches is not affecting the efficacy as they simply function as carriers. It completely melts inside the extruder in which the masterbatch (e.g. 3%) is processed at elevated temperature together with the polymer being extruded (e.g. 97%). After melting and mixing in the extruder it is no longer possible to distinguish between the molecules of the carrier and the molecules of the polymer. Only the active substances, at the required dosing, play a role in the efficacy in the treated article. The selection of the carrier type is made with the sole purpose of enabling the best possible dispersion, mixture and homogeneity of the active substances in the final product.

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

Target organisms :

Rats : general claim .

Objects to be protected : Plastic cable and wire coatings. The claim is to protect the treated articles from gnawing damage that can affect the operating conditions of the articles.

2.2.5.3 Effects on target organisms, including unacceptable suffering
Repelling the target organisms from the treated plastic material.

A master batch 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 rat. Upon touching/very light gnawing of the cables, the target organisms are repelled 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 treated 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).

2.2.5.3 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.

2.2.5.4 Efficacy data

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 biting damage that can affect the operating conditions of the cables (comparison between biocide and control treatment).

Efficacy tests were performed with cables treated with products within this family but also with one other product (Multirepel masterbatches, combi-product against rats and termites). They are considered to support the current dossier as well. See the confidential Annex for a justification.
Efficacy tests are carried out on "fresh" treated cables and on treated cables that have been submitted to an (accelerated) ageing process.

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.

<table>
<tr><th colspan="2">AVAILABLE TESTS AGAINST RATS</th></tr>
<tr><th colspan="2">TEST 1 : Chowdhary, A : Evaluation of anti rodent activity of cable against rodents (Haffkine Institute)</th></tr>
<tr><td>Guideline</td><td>RDSO/SPN/204/2011 Annex G (Indian national standard for anti-rodent testing of railway signalling cables)</td></tr>
<tr><td>Final product tested</td><td>Cables dosed with Combirepel 9518 = 9518 PE Multirepel (LDPE matrix) at a dose of both 2% and 3%</td></tr>
<tr><td>Test species</td><td>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.</td></tr>
<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 : 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</td></tr>
<tr><td>Results</td><td>-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.
<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>SN (surface nibbling)</td><td>Gnaw/bite marks on the surface, 10 or less (core of the cable must not be seen)</td><td>75</td></tr>
<tr><td>SA (slight attack)</td><td>Gnaw/bite marks on the surface, more than 10 (core of the cable must not be seen)</td><td>50</td></tr>
<tr><td>A (attack)</td><td>The core cable can be seen in 2 or less regions of the sample</td><td>25</td></tr>
<tr><td>D (destroyed)</td><td>The core cable can be seen in more than 2 regions of the sample</td><td>0</td></tr>
</table>
</td></tr>
</table>

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) :

Group	Initial weight (g)	Final weight (g)	Weight loss (%)	G factor*
G1(control)	10.997	10.757	2.177	0.022
G2	11.541	11.516	0.216	0.00218
G3	11.270	11.251	0.168	0.0016

* 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>
</table>
</td></tr>
</table>

	Control bundle 2	400	352	12
	Control bundle 3	400	344	14
	Average weight loss : 13.34%			
	Test bundle 1	400	395	1.25
	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			

<table>
<tr><td></td><td>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.</td></tr>
<tr><td colspan="2">TEST 4 : Anonymous : Testing of Rodrepel RR 0315 LDPE effectiveness on accelerated aged cables (C Tech - Hyderabad Testing Facility)</td></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>
</table>
</td></tr>
</table>

		Control bundle 1	400	340	15
		Control bundle 2	400	345	13.75
		Control bundle 3	400	361	9.75
		Average weight loss : 12.83%			
		Test bundle 1	400	393	1.75
		Test bundle 2	400	390	2.5
		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)					

<table>
<tr><td>Guideline</td><td>In-house method</td></tr>
<tr><td>Final product tested</td><td>Cables dosed with product Rodrepel = Antirat masterbatch at a dose of 3%</td></tr>
<tr><td>Test species</td><td>Rattus rattus</td></tr>
<tr><td>Effects investigated</td><td>Weight loss and visual inspection.
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>
</table></td></tr>
</table>

T2	1.04	0.59	0.37
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 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

Results

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

Group	Initial weight (g)	Final weight (g)	Weight loss (%)	G factor*
C1	340	260	23.52	0.2352
C2	342	259	24.26	0.2426
C3	345	253	26.66	0.2666
Average weight loss control : 24.82%				
T1	344	338.38	1.63	0.0163
T2	346	339.75	1.8	0.018
T3	343	335.77	2.1	0.021
Average weight loss treated: 1.84%				

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

-Weight loss per 4 weeks

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

-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><td></td><td>
<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>

Conclusion on the efficacy of the product
Six efficacy tests with rats have been submitted. In all of the tests, the efficacy of the product was shown. Four out of six tests were carried out with Antirat masterbatches at a dose of 3% and two on the Multirepel products. Taking into account the proposed dosages, read-across between both types of products is possible (see confidential Annex). 3% masterbatch in final cable is proposed as the minimum dosage for the Antirat masterbatches. **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 in line with what one would expect: Its molecules 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 conclusion, the tests demonstrate sufficient efficacy of Antirat masterbatches, as repellent against rats when incorporated in plastic cable and wire coatings.

2.2.5.5 Occurrence of resistance and resistance management

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

2.2.5.6 Known limitations

No limitations known.

2.2.5.7 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:

Repellent against rats.

Repels rats form treated cable and wire coatings.

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

Repellent masterbatches Antirat are not intended to be used in combination with other biocidal products.

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 and Peppermint oil are often classified as skin sensitizer (H317). As the concentrations of these active substances are above the generic concentration limit of 1%, the master batch also may be classified as skin sensitizer if the calculation method stipulated by the CLP regulation is applied. However, there is no need to classify the product as no exposure is expected to the active substances contained in master batch. In master batch itself the active substances are embedded in the polymer(s) and in this particular case, the active substances are also fully encapsulated. The biocidal effect is activated in treated articles as only there the active substances become biologically available. The masterbatch 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[5]

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 condition supplied by CTECH CORPORATION MUMBAI	Indian Institute of Chemical Technology - IICT	-	-
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	-	-

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)[6]

See studies summaries in Section 2.2.5.5 and in IUCLID

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

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

3.6 Confidential annex

See separate document

3.7 Other

None