



*Ministero della Salute*

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL  
SERVIZIO FARMACEUTICO  
Ufficio I – Prodotti di interesse sanitario diversi dai dispositivi medici  
Viale Giorgio Ribotta, 5 - 00144 Roma

Class.: I.5.i.d.2/258

Ministero della Salute

DGDMF

0091827-P-22/12/2021

I.5.i.d.2/2011/258



481701582

**INDUPHARMA S.R.L.**

Via Sorgaglia 40  
35020 Arre (PD)

**OGGETTO: Prodotto biocida: TOPIN 2B – RACUMIN BM  
Trasmissione decreto di trasferimento di titolarità.**

Si trasmette, in allegato, il decreto di trasferimento di titolarità dell'autorizzazione n. **IT/2013/00160/AUT** relativa al biocida indicato in oggetto.

Si richiama l'attenzione di codesta società su quanto disposto dal Regolamento (CE) n. 1272/2008 del Parlamento europeo e del Consiglio, del 16 dicembre 2008, relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze e delle miscele e ss.mm.ii..

Si rammenta, inoltre, che codesta società ha l'obbligo di adeguare autonomamente gli stampati del prodotto alla vigente normativa in materia di etichettatura e sue eventuali modifiche, ai sensi dell'articolo 6 del decreto del Ministero della salute del 10 febbraio 2015, recante, *“Disciplina dell'iter procedimentale ai fini dell'adozione dei provvedimenti autorizzativi da parte dell'autorità competente previsti dal Regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi”*.

IL DIRETTORE GENERALE  
Dott. Achille Jachino





IMPOSTA DI BOLLO ASSOLTA

# Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO  
UFFICIO I  
IT/2013/00160/AUT

IL DIRETTORE GENERALE

**VISTO** l'art. 15 della Legge n. 97 del 06 agosto 2013 recante "Disposizioni per l'adempimento degli obblighi derivanti dall'appartenenza dell'Italia all'Unione europea – Legge europea 2013";

**VISTO** il Regolamento (UE) 528/2012 del Parlamento Europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi, in particolare gli artt.19 e ss.;

**VISTA** l'istanza NA-TRS con case number BC-YN070420-26 presentata sul Registro Europeo R4BP3 in data 07 ottobre 2021;

**VISTA** la documentazione presentata dalla società richiedente a sostegno della suddetta istanza;

**RITENUTA** la conformità di detta documentazione alla normativa vigente in materia di immissione sul mercato di biocidi;

## DECRETA:

Il trasferimento di titolarità del prodotto biocida:

<b>DENOMINAZIONE</b>	<b>TOPIN 2B – RACUMIN BM</b>
<b>PRINCIPIO ATTIVO:</b>	<b>Bromadiolone</b>
<b>TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO</b>	<b>INDUPHARMA S.R.L.</b> Via Sorgaglia 40 35020 Arre (PD)
<b>NUMERO DI AUTORIZZAZIONE</b>	<b>IT/2013/00160/AUT</b>
<b>ASSET NUMBER</b>	<b>IT-0003076-0000</b>
<b>SCADENZA DELL'AUTORIZZAZIONE</b>	<b>31 dicembre 2022</b>

A far data dalla notifica del presente decreto, la società INDUPHARMA S.R.L. è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato I (SPC – Sommario delle Caratteristiche del Prodotto) e nell'allegato II (Ulteriori Condizioni dell'Autorizzazione). Avverso il presente atto è ammesso ricorso giurisdizionale presso il Tribunale Amministrativo Regionale competente entro il termine di sessanta giorni, ovvero ricorso straordinario al Capo dello Stato entro il termine di centoventi giorni.

Il presente decreto viene redatto in duplice originale, di cui un esemplare è notificato in via amministrativa alla ditta interessata e l'altro è conservato agli atti di questo Ufficio.

Roma, li **20 DIC, 2021**

IL DIRETTORE GENERALE  
Dott. Achille Iachino



**Summary of product characteristics for a biocidal product**



## 1. Administrative information

### 1.1. Trade names of the product

Market area	Trade name(s)
Italy	TOPIN 2B
Italy	RACUMIN BM

### 1.2. Authorisation holder

Authorisation number	Not defined	
Date of the authorisation	Not defined	
Expiry date of the authorisation	Not defined	
Name and address of the authorisation holder	Name Address	Not defined Not defined

### 1.3. Manufacturers of the product

Name of the manufacturer	INDUPHARMA S.r.l.		
Address of the manufacturer	Via Sorgaglia 40	35020	Arre (PD) Italy
Location of manufacturing sites	Via Sorgaglia 40	35020	Arre (PD) Italy

### 1.4. Manufacturer(s) of the active substance(s)

BAS number:	12		
Name of the manufacturer	ACTIVA SRL		
Address of the manufacturer	Via Feltre 32	20132	Milan Italy
Location of manufacturing sites	Tezza S.r.l.-via Tre Ponti 22	37050	S. Maria di Zevio Italy

## 2. Product composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the product

BAS number	EC number	CAS number	Common name	IUPAC name	Function Active Substance	Content (%)
12	249-205-9	28772-56-7	Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	stabilizer	0.005
-		1305-62-0	calcium hydroxide			0.375

### 2.2. Type of formulation

RB - Bait (ready for use)

## 3. Hazard and precautionary statements

Hazard statements	May damage the unborn child. Causes damage to organs ( <i>BLOOD</i> ) through prolonged or repeated exposure .
-------------------	---

Precautionary statements	Keep out of reach of children.
--------------------------	--------------------------------

Do not handle until all safety precautions have been read and understood.

Wear protective gloves.

IF exposed or concerned: Get medical advice.  
Dispose of contents to in accordance with national and international regulations.





## 4. Authorised use(s)

### 4.1. House mice - professionals - indoor

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)						
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides						
<b>Field(s) of use</b>	Indoor Indoor						
<b>Category(ies) of users</b>	Industrial, Professional						
<b>Target organisms</b>	<table border="0"> <thead> <tr> <th>Scientific name</th> <th>Common name</th> <th>Development stage</th> </tr> </thead> <tbody> <tr> <td>Mus musculus</td> <td>House mouse</td> <td>juveniles to adult</td> </tr> </tbody> </table>	Scientific name	Common name	Development stage	Mus musculus	House mouse	juveniles to adult
Scientific name	Common name	Development stage					
Mus musculus	House mouse	juveniles to adult					
<b>Application method(s)</b>							
<b>Method</b>	Bait application						
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations						
<b>Rate:</b> station is needed, the minimum distance between bait stations should be of 5 meters.	40g of bait per bait point. If more than one bait						
<b>Dilution:</b>	0%						
<b>Timing:</b>	If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.						
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units						
Minimum pack size of 1.5 kg up to 25 kg.							
Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.							
Packaging material: plastic composite-triple layer (polyester/ PET met/polyethylene)							
<b>Type of packaging</b>							
<b>Size/volume of the packaging</b>							
<b>Material of the packaging</b>							
<b>Type and material of closure(s)</b>							
<b>Intended user (e.g. professional, non-professional)</b>							
<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>							
Labelled or Printed Bag/Sack							
from 1.5 Kg - to 25 kg							
Plastic composite							
Prefabricated bags or serial production bags , both thermal welded							
Professional, trained professional							
Yes							
Labelled or Printed Bag/Sack - with Inner plastic liner							
from 1.5 Kg - to 10 kg - max size inner liner 10 Kg							
Plastic composite							
Prefabricated bags or serial production bags , both thermal welded							
Professional, trained professional							
Yes							
Labelled plastic (HDPE) bucket							
from 1.5 Kg -to 25 kg							
Labelled plastic (HDPE) bucket							
Rectangular or truncated cone bucket sealed							
Professional, trained professional							
Yes							



Labelled plastic (HDPE)  
bucket- with inner plastic liner

from 1.5 - to 10 kg - max  
size inner liner 10 Kg

Labelled plastic (HDPE)  
bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled or Printed  
Carton sachet with plastic inner liner

from 1,5 - to 10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated bags or serial production  
bags , both thermal welded

Professional, trained  
professional

Yes

Labelled or Printed  
Cardboard with inner plastic liner

1,5-10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated  
cardboard

Professional, trained  
professional

Yes

#### 4.1.1. Use-specific instructions for use

The  
bait stations should be visited at least every 2 to 3 days at the beginning of  
the treatment and at least weekly afterwards, in order to check whether the bait  
is accepted, the bait stations are intact and to remove rodent bodies. Re-fill  
bait when necessary.

#### 4.1.2. Use-specific risk mitigation measures

#### 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

When placing bait  
stations close to water drainage systems, ensure that bait contact with water is  
avoided.

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

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

Shelf life: 24  
months

## 4.2. Rats - professionals - indoor

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)		
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides		
<b>Field(s) of use</b>	Indoor Indoor		
<b>Category(ies) of users</b>	Industrial, Professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	juvenile to adult
	Rattus rattus	Roof rat	other: juvenile to adult
<b>Application method(s)</b>			
<b>Method</b>	Bait application		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations		
<b>Rate:</b> bait station is needed, the minimum distance between bait stations should be of 5 meters.	60-100g of bait per bait point. If more than one		
<b>Dilution:</b>	0%		
<b>Timing:</b>	If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.		
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units		
Minimum pack size of 1.5 kg up to 25 kg.			



Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.

**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)**

Labelled or Printed Bag/Sack

from 1.5 Kg - to 25 kg

Plastic composite

Prefabricated bags or serial production bags , both thermal welded

Professional, trained professional

Yes

Labelled or Printed Bag/Sack - with Inner plastic liner

from 1.5 Kg - to 10 kg - max size inner liner 10 Kg

Plastic composite

Prefabricated bags or serial production bags , both thermal welded

Professional, trained professional

Yes

Labelled plastic (HDPE) bucket

from 1.5 Kg -to 25 kg

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

Labelled plastic (HDPE) bucket- with inner plastic liner

from 1.5 - to 10 kg - max size inner liner 10 Kg

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

Labelled or Printed Carton sachet with plastic inner liner

from 1,5 - to 10 kg single inner plastic bags of up to 10 Kg each

Carton + Plastic composite

Prefabricated bags or serial production bags , both thermal welded

Professional, trained professional

Yes

Labelled or Printed Cardboard with inner plastic liner

1,5-10 kg single inner plastic bags of up to 10 Kg each

Carton + Plastic composite

Prefabricated cardboard

Professional, trained professional

Yes



#### 4.2.1. Use-specific instructions for use

The bait stations should be visited at least every 5 to 7 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

#### 4.2.2. Use-specific risk mitigation measures

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

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

#### 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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

Shelf life: 24 months

### 4.3. Mice and rats - trained professionals - outdoor around buildings

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)		
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides		
<b>Field(s) of use</b>	Outdoor		
<b>buildings</b>	outdoor around		
<b>Category(ies) of users</b>	Trained professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	juvenile to adult
	Rattus rattus	Roof rat	other: juvenile to adult
	Mus musculus	House mouse	other: juvenile to adult
<b>Application method(s)</b>			
<b>Method</b>	Bait application		
<b>Description</b>	Bait formulations:- Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations		
<b>Rate:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.		
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units		
Minimum pack size of 1.5 kg up to 25 kg.			
Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.			
Packaging material: plastic composite-triple layer (polyester/PET met/polyethylene)			
<b>Type of packaging</b>			
<b>Size/Volume of the packaging</b>			
<b>Material of the packaging</b>			
<b>Type and material of closure(s)</b>			
<b>Intended user (e.g. professional, non-professional)</b>			
<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>			
<b>Labelled or Printed Bag/Sack</b>			
<b>from 1.5 Kg - to 25 kg</b>			
<b>Plastic composite</b>			
<b>Prefabricated bags or serial production bags, both thermal welded</b>			
<b>Professional, trained professional</b>			





Yes

Labelled or  
Printed Bag/Sack - with Inner plastic liner

from 1.5 Kg - to  
10 kg - max size inner liner 10 Kg

Plastic  
composite

Prefabricated bags or serial production bags ,  
both thermal welded

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket

from 1.5 Kg -to 25 kg

Labelled  
plastic (HDPE) bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket- with inner plastic liner

from 1.5 - to 10 kg - max  
size inner liner 10 Kg

Labelled plastic (HDPE)  
bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled or Printed  
Carton sachet with plastic inner liner

from 1.5 - to 10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated bags or serial production  
bags , both thermal welded

Professional, trained  
professional

Yes

Labelled or Printed  
Cardboard with inner plastic liner

1,5-10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated  
cardboard

Professional, trained  
professional

Yes

#### 4.3.1. Use-specific instructions for use

Remove  
the remaining product at the end of treatment period.

For permanent  
baiting :

- Where possible, it is recommended that the treated area is  
revisited every 4 weeks at the latest in order to avoid any selection of a  
resistant population.

- Follow any additional instructions provided by  
the relevant code of best practice. For application in covered and protected  
bait points:- For outdoor use, baiting points must be covered and placed in  
strategic sites to minimise the exposure to non-target species.

- Follow  
any additional instructions provided by the relevant code of best  
practice.

#### 4.3.2. Use-specific risk mitigation measures

-  
Where possible, prior to the treatment inform any possible bystanders (e.g.  
users of the treated area and their surroundings) about the rodent control  
campaign

- Consider preventive control measures (e.g. plug holes, remove  
potential food and drinking as far as possible) to improve product intake and  
reduce the likelihood of reinvasion.



- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.

- Do not use the product in pulsed baiting treatments.

- do not apply this product directly in the burrows

In case of permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.

- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

#### 4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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

Shelf life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

### 4.4. House mice and rats - professionals -outdoor around buildings

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)		
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides		
<b>Field(s) of use</b>	Outdoor outdoor around buildings		
<b>Category(ies) of users</b>	Industrial, Professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	juvenile to adult
	Rattus rattus	Roof rat	other: juvenile to adult
	Mus musculus	House mouse	other: juvenile to adult
<b>Application method(s)</b>			
<b>Method</b>	Bait application		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations		
<b>Rate:</b>	House mouse: 40g of bait per bait point. Rattus: 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.		
<b>Dilution:</b>	0%		
<b>Timing:</b>	If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.		
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units		
Minimum pack size of 1.5 kg up to 25 kg.			
Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.			
<b>Type of packaging</b>			
<b>Size/volume of the packaging</b>			
<b>Material of the packaging</b>			
<b>Type and material of closure(s)</b>			
<b>Intended user (e.g. professional, non-professional)</b>			
<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>			



Labelled or  
Printed Bag/Sack

from 1.5 Kg - to 25  
kg

Plastic composite

Prefabricated bags  
or serial production bags , both thermal welded

Professional,  
trained professional

Yes

Labelled or  
Printed Bag/Sack - with Inner plastic liner

from 1.5 Kg - to  
10 kg - max size inner liner 10 Kg

Plastic  
composite

Prefabricated bags or serial production bags ,  
both thermal welded

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket

from 1.5 Kg -to 25 kg

Labelled  
plastic (HDPE) bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket- with inner plastic liner

from 1.5 - to 10 kg - max  
size inner liner 10 Kg

Labelled plastic (HDPE)  
bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled or Printed  
Carton sachet with plastic inner liner

from 1,5 - to 10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated bags or serial production  
bags , both thermal welded

Professional, trained  
professional

Yes

Labelled or Printed  
Cardboard with inner plastic liner

1,5-10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated  
cardboard

Professional, trained  
professional

Yes

#### 4.4.1. Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

#### 4.4.2. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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



When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

#### 4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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

Shelf life: 24 months

### 4.5. House mice and rats - trained professionals - indoor

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)												
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides												
<b>Field(s) of use</b>	Indoor indoor												
<b>Category(ies) of users</b>	Trained professional												
<b>Target organisms</b>	<table border="0"> <thead> <tr> <th>Scientific name</th> <th>Common name</th> <th>Development stage</th> </tr> </thead> <tbody> <tr> <td>Rattus norvegicus</td> <td>Brown rat</td> <td>juvenile to adult</td> </tr> <tr> <td>Rattus rattus</td> <td>Roof rat</td> <td>other: juvenile to adult</td> </tr> <tr> <td>Mus musculus</td> <td>House mouse</td> <td>other: juvenile to adult</td> </tr> </tbody> </table>	Scientific name	Common name	Development stage	Rattus norvegicus	Brown rat	juvenile to adult	Rattus rattus	Roof rat	other: juvenile to adult	Mus musculus	House mouse	other: juvenile to adult
Scientific name	Common name	Development stage											
Rattus norvegicus	Brown rat	juvenile to adult											
Rattus rattus	Roof rat	other: juvenile to adult											
Mus musculus	House mouse	other: juvenile to adult											
<b>Application method(s)</b>													
<b>Method</b>	Bait application												
<b>Description</b>	Bait formulations: Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.												
<b>Rate:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.												
<b>Dilution:</b>	0%												
<b>Timing:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.												
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units												
Minimum pack size of 1.5 kg up to 25 kg.													
Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.													
Packaging material: plastic composite-triple layer (polyester/ PET met/polyethylene)													
<b>Type of packaging</b>													
<b>Size/volume of the packaging</b>													
<b>Material of the packaging</b>													
<b>Type and material of closure(s)</b>													
<b>Intended user (e.g. professional, non-professional)</b>													
<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>													
Labelled or Printed Bag/Sack													
from 1.5 Kg - to 25 kg													
Plastic composite													
Prefabricated bags or serial production bags , both thermal welded													
Professional, trained professional													
Yes													
Labelled or Printed Bag/Sack - with Inner plastic liner													
from 1.5 Kg - to 10 kg - max size inner liner 10 Kg													
Plastic composite													
Prefabricated bags or serial production bags , both thermal welded													
Professional, trained professional													





Yes

Labelled plastic (HDPE)  
bucket

from 1.5 Kg -to 25 kg

Labelled  
plastic (HDPE) bucket

Reclangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket- with inner plastic liner

from 1,5 - to 10 kg - max  
size inner liner 10 Kg

Labelled plastic (HDPE)  
bucket

Reclangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled or Printed  
Carton sachet with plastic inner liner

from 1,5 - to 10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated bags or serial production  
bags , both thermal welded

Professional, trained  
professional

Yes

Labelled or Printed  
Cardboard with inner plastic liner

1,5-10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated  
cardboard

Professional, trained  
professional

Yes

#### 4.5.1. Use-specific instructions for use

Remove  
the remaining product at the end of treatment period.

For permanent  
baiting :

- Where possible, it is recommended that the treated area is  
revisited every 4 weeks at the latest in order to avoid any selection of a  
resistant population.

- Follow any additional instructions provided by  
the relevant code of best practice.

#### 4.5.2. Use-specific risk mitigation measures

-

Where possible, prior to the treatment inform any possible bystanders (e.g.  
users of the treated area and their surroundings) about the rodent control  
campaign

- Consider preventive control measures (e.g. plug holes, remove  
potential food and drinking as far as possible) to improve product intake and  
reduce the likelihood of reinvasion.

- To reduce risk of secondary  
poisoning, search for and remove dead rodents during treatment at frequent  
intervals, in line with the recommendations provided by the relevant code of  
best practice.

- Products may only be used in permanent treatments at  
those sites with a high potential for reinvasion when other methods of control  
have proven insufficient.

- Do not use the product in pulsed baiting  
treatments.

In case of permanent baiting:

- Permanent baiting  
is strictly limited to sites with a high potential for reinvasion when other  
methods of control have proven insufficient.-

The permanent  
baiting strategy shall be periodically reviewed in the context of integrated  
pest management (IPM) and the assessment of the risk for re-infestation.

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

When  
placing bait points close to water drainage system, ensure that bait contact  
with water is avoided.



#### 4.5.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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

Shelf  
life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

#### 4.6. Rats - trained professionals - Outdoor open areas

<b>Product type(s)</b>	PT14 - Rodenticides (Pest control)		
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides		
<b>Field(s) of use areas</b>	Outdoor outdoor open areas		
<b>Category(ies) of users</b>	Trained professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	juvenile to adult
	Rattus rattus	Roof rat	other; juvenile to adult
<b>Application method(s)</b>			
<b>Method</b>	Bait application		
<b>Description</b>	Bait formulations:- Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations		
<b>Rate:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.		
<b>Pack sizes and packaging material</b>	Bait product of 20 gr units		
Minimum pack size of 1.5 kg up to 25 kg.			
Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.			
Packaging material: plastic composite-triple layer (polyester/ PET met/polyethylene)			
<b>Type of packaging</b>			
<b>Size/volume of the packaging</b>			
<b>Material of the packaging</b>			
<b>Type and material of closure(s)</b>			
<b>Intended user (e.g. professional, non-professional)</b>			
<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>			
Labelled or Printed Bag/Sack			
from 1.5 Kg - to 25 kg			
Plastic composite			
Prefabricated bags or serial production bags , both thermal welded			
Professional, trained professional			
Yes			
Labelled or Printed Bag/Sack - with Inner plastic liner			
from 1.5 Kg - to 10 kg - max size inner liner 10 Kg			
Plastic composite			
Prefabricated bags or serial production bags , both thermal welded			



Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket

from 1.5 Kg -to 25 kg

Labelled  
plastic (HDPE) bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled plastic (HDPE)  
bucket- with inner plastic liner

from 1.5 - to 10 kg - max  
size inner liner 10 Kg

Labelled plastic (HDPE)  
bucket

Rectangular or truncated cone bucket  
sealed

Professional, trained  
professional

Yes

Labelled or Printed  
Carton sachet with plastic inner liner

from 1,5 - to 10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated bags or serial production  
bags , both thermal welded

Professional, trained  
professional

Yes

Labelled or Printed  
Cardboard with inner plastic liner

1,5-10 kg  
single inner plastic bags of up to 10 Kg each

Carton +  
Plastic composite

Prefabricated  
cardboard

Professional, trained  
professional

Yes

#### 4.6.1. Use-specific instructions for use

-Protect  
bait from the atmospheric conditions. Place the bait stations in areas not  
liable to flooding.

- Replace any bait in baiting points in which bait has  
been damaged by water or contaminated by dirt.

- Remove the remaining  
product at the end of treatment period

- Follow any additional  
instructions provided by the relevant code of best practice.

For permanent baiting :

- Where possible, it is recommended that  
the treated area is revisited every 4 weeks at the latest in order to avoid any  
selection of a resistant population.

- Follow any additional instructions  
provided by the relevant code of best practice.

For  
application in covered and protected bait points:

- For outdoor use,  
baiting points must be covered and placed in strategic sites to minimise the  
exposure to non-target species.

- Follow any additional instructions  
provided by the relevant code of best practice.

#### 4.6.2. Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g.  
users of the treated area and their surroundings) about the rodent control  
campaign



- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.
- do not apply this product directly in the burrows

**In case of permanent baiting:**

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

**4.6.4. Where specific to the use, the instructions for safe disposal of the product and its packaging**

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

Shelf life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

## 5. General directions for use

### 5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
  - Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
  - The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
  - Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
  - The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
  - Where possible, bait stations must be fixed to the ground or other structures.
  - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
  - When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits
  - Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
  - Wear protective chemical resistant gloves (rubber) during product handling phase





- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.- Instructions for use that are "bait-specific":- Bait in sachets: Do not open the sachets containing the bait.

## 5.2. Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment unless authorised for permanent baiting treatments.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
  - Dermat exposure, wash skin with water and then with water and soap.
  - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
  - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. Contact a veterinary surgeon in case of ingestion by a pet
  - Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre
  - Hazardous to wildlife.

## 5.4. Instructions for safe disposal of the product and its packaging

A1  
the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements

## 5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 24 months

## 6. Other information

- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.







## Allegato I SPC

## Allegato II - Ulteriori Condizioni dell'Autorizzazione

### ETICHETTATURA

- L'etichetta del prodotto biocida oggetto della presente autorizzazione dovrà essere redatta nel rispetto delle disposizioni di cui all'articolo 69 del Regolamento (UE) n.528/2012 riportando le informazioni di cui al sommario delle caratteristiche del prodotto riportato in Allegato I.
- Tutte le etichette del prodotto biocida devono riportare il numero di autorizzazione attribuito dal presente decreto, con la seguente dicitura:

***“PRODOTTO BIOCIDA (PT14)  
AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2013/00160/AUT”***

- Per ogni categoria di utilizzatore autorizzata (Professionisti/ Professionisti formati/ Utilizzatori non professionisti) deve essere predisposta una etichetta distinta.
- L'etichetta dovrà contenere l'indicazione dell'officina di produzione e sito produttivo del formulato autorizzato.
- Nell'etichetta l'esatta denominazione del biocida dovrà comunque essere individuabile attraverso una colorazione e un carattere unici in contrasto con le altre eventuali colorazioni e caratteri usati nel testo degli stampati autorizzati.
- L'etichetta del prodotto non contiene le formule «biocida a basso rischio», «non tossico», «innocuo», «naturale», «rispettoso dell'ambiente», «rispettoso degli animali» o indicazioni analoghe comportanti una sottovalutazione degli effetti potenziali del prodotto da parte dell'utilizzatore e non devono riportare dizioni riferite al prodotto che possano generare confusione per quanto concerne i rischi che il prodotto comporta per l'uomo o l'ambiente.

E' consentita l'immissione sul mercato dei biocidi a condizione che le indicazioni dell'etichetta siano redatte in lingua italiana.

