



# Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO  
FARMACEUTICO

*Ufficio I Affari generali e Prodotti di interesse sanitario  
diversi dai dispositivi medici*

*Viale Giorgio Ribotta, 5 - 00144 Roma*

Classifica I.5.i.d.2/396

Ministero della Salute DGDMF-MDS-P

DGDMF

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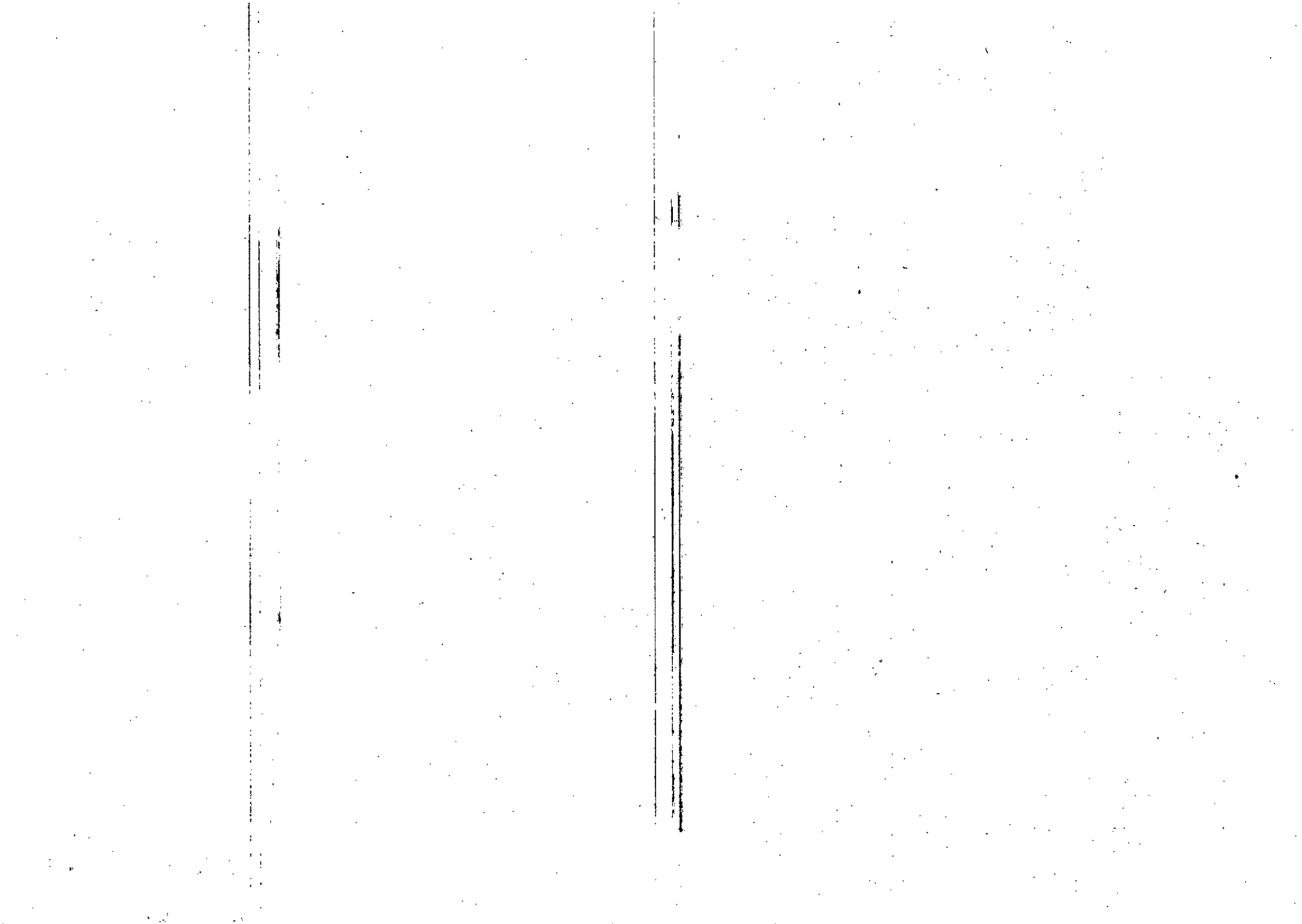
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Spett.le  
TECNOCHIMICA SAS  
Via Antoniana 218  
35011  
Campodarsego (PD)

**OGGETTO:** Prodotto biocida "BROM ESCA"  
Trasmissione decreto di rinnovo

Si trasmette in allegato, il decreto di autorizzazione all'immissione in commercio del biocida indicato in oggetto IT/2014/00206/AUT.

IL DIRETTORE DELL'UFFICIO I  
(Dott.ssa Paola D'Alessandro)





# Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO

UFFICIO I

I.5.i.d.2/2012/396

IT/2014/00206/AUT

IL DIRETTORE

**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 ed, in particolare, l'articolo 31 del riguardante il rinnovo delle autorizzazioni nazionali;

**VISTO** il Regolamento di esecuzione (UE) 2017/1381 della commissione del 25 luglio 2017 che stabilisce il rinnovo dell'approvazione del principio attivo BRODIFACOUM;

**VISTO** il decreto di prima autorizzazione del prodotto biocida di cui al dispositivo del presente decreto, rilasciato in data 27 maggio 2014;

**VISTA** l'istanza presentata sul Registro Europeo R4BP3 in data 14 luglio 2015 Case number BC-UT018538-03;

**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;

**CONSIDERATO** che il brodifacoum è un candidato alla sostituzione secondo quanto previsto dall'articolo 10 del Regolamento (UE) n.528/2012;

## DECRETA:

Il rinnovo dell'autorizzazione del prodotto biocida:

<b>DENOMINAZIONE</b>	<b>BROM ESCA</b>
<b>TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO</b>	<b>TECNOCHIMICA SAS</b> Via Antoniana 218A- 35011 – Campodarsego (PD) Italy
<b>NUMERO DI AUTORIZZAZIONE</b>	<b>IT/2014/00206/AUT</b>
<b>SCADENZA DELL'AUTORIZZAZIONE</b>	<b>5 ANNI DALLA DATA DEL PRESENTE DECRETO</b>
<b>ASSET NUMBER</b>	<b>IT-0005805-0000</b>

A far data dalla notifica del presente decreto, la società TECNOCHIMICA SAS è tenuta a produrre il prodotto sopra indicato 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

- 3 APR. 2019

IL DIRETTORE DELL'UFFICIO I  
(Dr.ssa Paola D'Alessandro)



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## 1. Administrative information

### 1.1. Trade names of the product

Market area Trade name(s)  
Italy BROM ESCA

### 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 Tecnochimica Sas

Address of the manufacturer Via Antoniana 218A 35011 Campodarsego (PD) Italy

Location of manufacturing sites  
FERBI S r.l. - Viale 1° Maggio 64023 Mosciano Sant'Angelo (TE) Italy  
VEBI ISTITUTO BIOCHIMICO S.r.l. - Via Desman 43 35010 Borgoricco (PD) Italy  
INDUSTRIALCHIMICA S.r.l. - Via Sorgaglia 25 35020 Arre (PD) Italy  
INDIA INDUSTRIE CHIMICHE Spa - Nona Strada 53/57 35100 Padova Italy

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

BAS number: 11

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 (%)
11	259-980-5	56073-10-0	Brodifacoum	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-naphthyl]-4-hydroxycoumarin		0.005

### 2.2. Type of formulation

RB - Bait (ready for use)

## 3. Hazard and precautionary statements

Hazard statements May damage the unborn child.  
May cause damage to organs fo

BLOOD 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		
<b>Category(ies) of users</b>	Indoor Industrial, Professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	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 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.		

#### Pack sizes and packaging material

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)

#### 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 Bottle

from 1.5 Kg - to 5 kg

Plastic composite (HDPE)

Bottle sealed

Professional, trained professional

Yes

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 Bucket

from 1.5 Kg -to 25 kg  
 Labelled plastic (HDPE) bucket  
 Rectangular or truncated cone bucket sealed  
 Professional, trained professional  
 Yes  
 Labelled Plastic 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		
<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>	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%		

**Timing:** If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.

**Pack sizes and packaging material**

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)

**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 Bottle

from 1.5 Kg- to 5 kg

Plastic composite (HDPE)

Bottle sealed

Professional, trained professional

Yes

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 Bucket

from 1.5 Kg -to 25 kg

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

LabelledPlastic 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. 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>			
<b>Bait product of</b>	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)

**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 Bottle

from 1.5 Kg- to 5 kg

Plastic composite (HDPE)

Bottle sealed

Professional, trained professional

Yes

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 Bucket

from 1.5 Kg -to 25 Kg.

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

Labelled Plastic 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

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.

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

Do not apply this product directly in the burrows.

#### 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 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.

#### 4.3.4. 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

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

Product type(s)	PT14 - Rodenticides (Pest control)		
Where relevant, an exact description of the authorised use	Not relevant for rodenticides		
Field(s) of use	Indoor		
Category(ies) of users	Trained professional		
Target organisms	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
Application method(s)			
Method	Bait application		
Description	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.		
Rate:	Rate Rats :- High		
infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. Mice 40 gr of bait per bait point			
Dilution:	0%		
Timing:	Rate Rats :- High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point.. Mice 40 gr of bait per bait point		
Pack sizes and packaging material	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)		
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 Bottle

from 1.5 Kg- to 5 kg

Plastic composite (HDPE)

Bottle sealed

Professional, trained professional

Yes

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 Bucket

from 1.5 Kg -to 25 kg

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

Labelled Plastic 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

Remove the remaining product at the end of treatment period.

**4.4.2. 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 reinvansion.

- 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.

- Do not use the product in pulsed baiting treatments

- do not use the product as permanent baits for the prevention of rodent infestation or monitoring activities

**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 points close to water drainage system, 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.

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.

**4.5. 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>	Bait application		
<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>	Rate:Rats :- High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. Mice 40 gr of bait per bait point		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Rate:Rats :- High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. Mice 40 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>			

**Intended user (e.g. professional, non-professional)**

**Compatibility of the product with the proposed packaging materials (Yes/No)**

Labelled or Printed Bottle

from 1.5 Kg- to 5 kg

Plastic composite (HDPE)

Bottle sealed

Professional, trained professional

Yes

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 Bucket

from 1.5 Kg -to 25 kg

Labelled plastic (HDPE) bucket

Rectangular or truncated cone bucket sealed

Professional, trained professional

Yes

Labelled Plastic 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

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

Remove the remaining product at the end of treatment period.

#### 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.
- Do not use the product in pulsed baiting treatments
- do not use this product directly in the burrows
- do not use the product as permanent baits for the prevention of rodent infestation or monitoring activities

#### 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 surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, 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.

## 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:

- Dermal 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

- At 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 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) BROM ESCA***

***AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2014/00206/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.