



Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE, DEI DISPOSITIVI MEDICI, DEL
FARMACO E DELLE POLITICHE IN FAVORE DEL SERVIZIO SANITARIO
NAZIONALE
EX DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL
SERVIZIO FARMACEUTICO
Ufficio 8 – Biocidi e cosmetici
Viale Giorgio Ribotta, 5 - 00144 Roma
PEC: dgfdm@postacert.sanita.it

I.5.i.d.2/1173

<Spazio riservato per l'apposizione
dell'etichetta di protocollo>

Spett.le
FERBI S.r.l.
Via I Maggio
64023 Mosciano Sant'Angelo (TE)
regulatory@ferbi.it
ferbi@legalmail.it

OGGETTO: Prodotto biocida: FERBLOCK BRODI 50
Case number: BC-EJ094114-45
Trasmissione decreto di modifica amministrativa dell'autorizzazione
n. IT/2018/00522/AUT

Si trasmette, in allegato, il decreto di modifica amministrativa relativo al prodotto 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 e ss.mm.ii., relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze e delle miscele.

Si rammenta, inoltre, che codesta società, fermo restando quanto previsto dall'articolo 6 del Regolamento (UE) 354/2013 e dalla sezione 2 del titolo I, punto 11 del relativo allegato, 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 DELL'UFFICIO
dott.ssa Raffaella Perrone*

*Firma autografa sostituita a mezzo stampa, ai sensi dell'art. 3, comma 2, del D. Lgs. 39/1993

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Ministero della Salute

**DIPARTIMENTO DELLA PROGRAMMAZIONE, DEI DISPOSITIVI MEDICI, DEL FARMACO E
DELLE POLITICHE IN FAVORE DEL SERVIZIO SANITARIO NAZIONALE
EX DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO 8
IT/2018/00522/AUT
IL DIRETTORE DELL'UFFICIO**

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 e, in particolare, gli artt.19 e ss.;

VISTO il Regolamento di esecuzione (UE) N. 354/2013 della Commissione del 18 aprile 2013 sulle modifiche dei biocidi autorizzati a norma del regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio;

VISTO il decreto di prima autorizzazione del prodotto biocida di cui al dispositivo del presente decreto, rilasciato in data 11 ottobre 2018;

VISTA l'istanza NA-ADC, case number BC-EJ094114-45, presentata sul Registro Europeo R4BP3 in data 10 aprile 2024;

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

DECRETA

la modifica amministrativa dell'autorizzazione del prodotto biocida:

DENOMINAZIONE	FERBLOCK BRODI 50, BRODIFAST BLOCK PRO, NECORAT WAX PROFESSIONAL, ENDERAT BLOCK PRO, IKURAT BLOCK PRO, FIGHTER BLOCK PRO, APTIRAT BLOCK PRO, ALTRAT BRODI BLOCK PRO, FERRAT BRODI BLOCK PRO, SPECIALTOP BRODI BLOCK PRO, TABULA RASA BRODI BLOCK PRO, TRATRAT BLOCK PRO, ULTRABRODI BLOCK PRO, MIDABRODI BLOCK, RODOR FACOUM BLOCK, SHOCK PRO BLOCK PLUS
PRINCIPIO ATTIVO:	Brodifacoum
TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO	FERBI S.r.l. Via I Maggio 64023 Mosciano Sant'Angelo (TE)
NUMERO DI AUTORIZZAZIONE	IT/2018/00522/AUT
SCADENZA DELL'AUTORIZZAZIONE	31 dicembre 2026
TIPOLOGIA DI PRODOTTO	PT14

La società **FERBI S.r.l.** è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato 1 SPC - sommario delle caratteristiche del prodotto, aggiornato e caricato nel Registro Europeo.

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 entra in vigore il quindicesimo giorno successivo alla data di notifica.

Roma

IL DIRETTORE DELL'UFFICIO
dott.ssa Raffaella Perrone

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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

FERBLOCK BRODI 50

Product type(s)

PT14: Rodenticides

Authorisation number:

R4BP asset number:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	BRODIFAST BLOCK PRO NECORAT WAX PROFESSIONAL ENDERAT BLOCK PRO IKURAT BLOCK PRO FIGHTER BLOCK PRO APTIRAT BLOCK PRO ALTRAT BRODI BLOCK PRO FERRAT BRODI BLOCK PRO SPECIALTOP BRODI BLOCK PRO TABULA RASA BRODI BLOCK PRO TRATRAT BLOCK PRO ULTRABRODI BLOCK PRO MIDABRODI BLOCK RODOR FACOUM BLOCK SHOCK PRO BLOCK PLUS
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	
	Address	
Authorisation number		
<i>R4BP asset number</i>		
Date of the authorisation		
Expiry date of the authorisation		

1.3. Manufacturer(s) of the product

Name of manufacturer	FERBI S.r.l.
Address of manufacturer	Viale I Maggio 64023 Mosciano Sant'Angelo (TE) Italy
Location of manufacturing sites	FERBI S.r.l. site 1 FERBI S.r.l. - Viale I Maggio 64023 Mosciano Sant'Angelo (TE) Italy FERBI S.r.l. site 2 BÁBOLNA BIOENVIRONMENTAL CENTRE Ltd. - X. Szállás u. 6 H-1107 Budapest Hungary FERBI S.r.l. site 3 BIOSOL ITALIA S.r.l. - Via Nettunense Km 23,400 04011 Aprilia (LT) Italy FERBI S.r.l. site 4 COLKIM S.r.l. - Via Piemonte 50 40064 Ozzano dell'Emilia (BO) Italy FERBI S.r.l. site 5 D'ORTA S.p.A. - Via Provinciale Pianura, Loc. S. Martino 18 80078 Pozzuoli (NA) Italy FERBI S.r.l. site 6 G.M.B. INTERNACIONAL S.A. - Avenida de la Cova 144 46940 Manises, Valencia Spain

	<p>FERBI S.r.l. site 7 INDUSTRIALCHIMICA S.r.l. - Via Sorgaglia 25 35020 Arre (PD) Italy</p> <p>FERBI S.r.l. site 8 REA S.r.l. - SS87 Km20700 81025 Marcianise (CE) Italy</p> <p>FERBI S.r.l. site 9 VEBI ISTITUTO BIOCHIMICO S.r.l. - Via Desman 43 35010 Borgoricco (PD) Italy</p>
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1.4. Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	Activa Srl
Address of manufacturer	Via Feltre 32 20132 Milan Italy
Location of manufacturing sites	Activa Srl site 1 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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,005

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H373: May cause damage to organs BLOOD through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P102: Keep out of reach of children. P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P501: Dispose of contents to in accordance with national and international regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice professional indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles to adults
Field(s) of use	indoor use indoor
Application method(s)	Method: bait application Detailed description: Ready-to use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: 40 gr of bait per bait point. if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres Dilution (%): 0 Number and timing of application: if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres
Category(ies) of users	industrial ; professional
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 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 LLabelled 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
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4.1.1. Use-specific instructions

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. Use-specific risk mitigation measures

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4.1.4. 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.

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

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4.1.6. 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. Use description

Table 2. rats-professional- indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles to adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: other juveniles to adults</p>
Field(s) of use	<p>indoor use</p> <p>indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: 60-100 gr of bait per bait point. if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres</p> <p>Dilution (%): 0</p> <p>Number and timing of application: if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres</p>
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>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)</p> <p>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</p>

	<p>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</p>
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4.2.1. Use-specific instructions

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. Use-specific risk mitigation measures

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4.2.4. 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.

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

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4.2.6. 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. Use description

Table 3. House mice and rats-professional-outdoor around building

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles to adults</p> <p>Scientific name: Rattus rattus Common name: roof rat Development stage: other juveniles to adults</p> <p>Scientific name: Mus musculus Common name: house mouse Development stage: juveniles to adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around building</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: House mouse 40 gr of bait per bait point. Rats: 60-100 gr of bait per bait point. if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres</p> <p>Dilution (%): 0</p> <p>Number and timing of application: if more than one bait station is needed, the minimum distance between bait stations should be of 5 metres</p>
Category(ies) of users	industrial ; professional
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 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

4.3.1. Use-specific instructions

- 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

4.3.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

4.3.4. 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..

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

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4.3.6. 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. Use description

Table 4. House mice and rats -trained professionals-indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: other juveniles to adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles to adults Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles to adults
Field(s) of use	indoor use

	indoor
Application method(s)	Method: bait application Detailed description: 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
Application rate(s) and frequency	Application 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 Number and timing of application: <i>Rats</i> - High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. <i>Mice</i> - 40 gr of bait per baiting point
Category(ies) of users	trained professional
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 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
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4.4.1. Use-specific instructions

Remove the remaining product at the end of treatment period

4.4.2. Use-specific risk mitigation measures

4.4.3. 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 [in accordance with the applicable code of good practice, if any].
- 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 the product as permanent baits for the prevention of rodent infestation or monitoring activities

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

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

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

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4.4.6. 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. Use description

Table 5. Mice and rats-trained professionals-outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: other juveniles to adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles to adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles to adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: 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.</p>
Application rate(s) and frequency	<p>Application rate: Bait products Rats - High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. Mice - 40 g of bait per baiting point.</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Bait products <i>Rats</i> - High infestation: 100 g of bait per baiting point. - Low infestation: 60 g of bait per baiting point. <i>Mice</i> - 40 g of bait per baiting point.</p>

Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Bait product of 20 gr units</p> <p>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)</p> <p>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)</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>

	Professional, trained professional Yes
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4.5.1. Use-specific instructions

Remove the remaining product at the end of treatment period

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.

4.5.2. Use-specific risk mitigation measures

4.5.3. 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 [in accordance with the applicable code of good practice, if any].- 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 apply this product directly in the burrows.

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

4.5.4. 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.

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

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4.5.6. 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 USE¹

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.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

-Remove the remaining bait or the bait stations at the end of the treatment period

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.