



*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

Ministero della Salute  
0034575-13/06/2019 DGDMF-MDS-P

DGDMF

0034575-P-13/06/2019



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I.5.i.d.2/508

Spett.le  
Mayer Braun Deutschland S.r.l.  
Via Brigata Marche, 129  
Carbonera (Treviso) Italia

**OGGETTO: Prodotto biocida BRODIMAX FORTE KING DIFE**  
**Trasmissione decreto di autorizzazione**

Si trasmette, in allegato, il D.D. di modifica del 11 GIU. 2019 relativo al prodotto biocida indicato in oggetto n. IT/2014/00251/MRA.

Si richiama l'attenzione in merito a quanto disposto dal Regolamento (UE) 1272/2008 del Parlamento europeo e del Consiglio relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze, delle miscele e successive modifiche e adeguamenti.

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

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# 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

I.5.i.d.2/2013/508

IT/2014/00251/MRA

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;

**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 30 settembre 2014;

**ATTESO** che la titolarità del biocida predetto è attribuita alla società Mayer Braun Deutschland S.r.l.

**VISTA** l’istanza inviata sul registro Europeo R4BP3 case number BC-BS032044-43 con cui la società istante suddetta ha richiesto la modifica tecnica maggiore al prodotto biocida;

**VISTA** la documentazione presentata dalla società richiedente a sostegno delle suddette istanze di modifica dell’autorizzazione;

**VISTO** il parere dell’Istituto Superiore di Sanità acquisito con prot.n.0056821 del 16/10/2018;

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

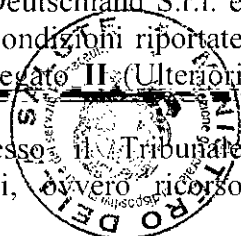
### DECRETA:

Le modifiche dell’autorizzazione del prodotto biocida:

<b>DENOMINAZIONE</b>	<b>BRODIMAX FORTE KING DIFE</b>
<b>TITOLARE DELL'AUTORIZZAZIONE E RESPONSABILE DELL'IMMISSIONE SUL MERCATO</b>	MAYER BRAUN DEUTSCHLAND S.r.l. Via Brigata Marche 129 31030 Carbonera (Treviso) Italia
<b>NUMERO DI AUTORIZZAZIONE</b>	<b>IT/2014/00251/MRA</b>
<b>NUMERO ASSET</b>	<b>IT-0008244-0000</b>
<b>SCADENZA AUTORIZZAZIONE</b>	<b>31/08/2020</b>

A far data dalla notifica del presente decreto, la società Mayer Braun Deutschland S.r.l. 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.

Roma, li

11 GIU. 2019

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



ND/FR

ALL. 1

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

## 1. Administrative information

### 1.1. Trade names of the product

Market area Italy Trade name(s) BRODIMAX FORTE KING DIFE

### 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 MAYER BRAUN DEUTSCHLAND SRL  
 Address of the manufacturer VIA BRIGATA MARCHE 129 31030 CARBONERA TV Italy  
 Location of manufacturing sites VIA BRIGATA MARCHE 129 31030 CARBONERA TV Italy

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

BAS number: 26

Name of the manufacturer Activa s.r.l

Address of the manufacturer Via Feltrè, 32 20132 Milano Italy

Location of manufacturing sites Dr. Tezza s.r.l - Via Tre Ponti, 22 37050 S. Maria di Zevio (VR) 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	Content (%)
26	259-978-4	56073-07-5	Difenacoum	3-(3-biphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active Substance	0.0029

### 2.2. Type of formulation

Ready-to-use bait: grain

## 3. Hazard and precautionary statements

### Hazard statements

May cause damage to organs through prolonged or repeated exposure.

### Precautionary statements

Keep out of reach of children.

Read label before use.

Do not

breathe *dust*.

Wear *protective*

*gloves*.

Get medical *advice* if you feel

unwell.

Get medical

*attention* if you feel

unwell.

Dispose of

*contents* to *national*

*legislation*

Dispose of *container* to *national*

*legislation*.

## 4. Authorised use(s)

### 4.1. Use 1– House mice and Brown rats– general public – 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>	General public (non-professional)		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Mus musculus	House mouse	Adults
	Mus musculus	House mouse	Juveniles
	Rattus norvegicus	Brown rat	Juveniles
	Rattus norvegicus	Brown rat	Adults
<b>Application method(s)</b>			
<b>Method</b>	In bait boxes		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations		
<b>Rate:</b>	Mice: bait boxes with 60g of product each 5-10m		
<b>; Rats: bait boxes with 100g of product each 5-10m</b>			
<b>Dilution:</b>	0%		
<b>Timing:</b>	Mice: bait boxes with 60g of product each 5-10m 60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10m (5m in case of strong infestation and 10m in case of weak infestation).		
	Rats: bait boxes with 100g of product each 5-10m  100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).		
<b>Pack sizes and packaging material</b>	Maximum pack size of 150g.		
<b>Number of packed bags per packaging, up to 150g Grams/kg of bait per packed bag: individual sachets from 10g to 100g</b>			
<b>Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE or HDPE or PVC</b>			

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

- The bait stations should be visited only 2 to 3 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.

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

See section Directions for use

#### 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

See section Directions for use

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

See section Directions for use.

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

See section Directions for use

### 4.2. Use 2– Brown Rats – general public – 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>	General public (non-professional)		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	Adults
	Rattus norvegicus		Juveniles

Brown  
rat

**Application method(s)**

**Method** In bait boxes

**Description** Ready-to-use bait to be used in tamper-resistant bait stations

**Rate:** Rats: bait boxes with 100g of product each 5-10m

**Dilution:** 0%

**Timing:** Rats: bait boxes with 100g of product each 5-10m  
100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation)

**Pack sizes and packaging material** Maximum pack size of 150g.

Number of packed bags per packaging up to 150g  
Grams/kg of bait per packed bag: individual sachets from 10g to 100g

**Packaging material:**  
Bags: Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.

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

- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt
- The bait stations should be visited 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.

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

See section Directions for use

**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**

See section Directions for use

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

See section Directions for use

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

See section Directions for use

**4.3. Use 3- House mice – 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

**use** Indoor

**Category(ies) of users** Professional

**Target organisms**

Scientific name	Common name	Development stage
Mus musculus	House mouse	Adults
Mus musculus	House mouse	Juveniles

**Application method(s)**

**Method** In bait boxes

**Description** Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose pellet

**Rate:** Mice: bait boxes with 60g of product each 5-10m

**Dilution:** 0%

**Timing:** Mice: bait boxes with 60g of product each 5-10m  
60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).

**Pack sizes and packaging material** Minimum pack size of 3 kg

Number of packed bags per packaging: up to 30 kg.  
Grams/kg of bait

per packed bag: individual sachets from 10g to 60g

Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

**4.3.1. 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.

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

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

See section Directions for use

**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 station closing to 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**

See section Directions for use

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

See section Directions for use

**4.4. Use 4 – Brown 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>use</b>	Indoor		
<b>Category(ies) of users</b>	Professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	Adults
	Rattus norvegicus	Brown rat	Juveniles

**Application method(s)**

<b>Method</b>	In bait boxes
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose pellet
<b>Rate: product each 5-10m</b>	Rat: bait boxes with 100g of
<b>Dilution:</b>	0%
<b>Timing:</b>	Rat: bait boxes with 100g of product each 5-10m  100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).

**Pack sizes and packaging material** Minimum pack size of 3 kg.

Number of packed bags per packaging: up to 30 kg.  
Grams/kg of bait per packed bag: individual nonwoven sachets from 10g to 100g.  
Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

**4.4.1. 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.

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

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



See section Directions for use

#### 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 station close to 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

See section Directions for use

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

See section Directions for use

### 4.5. Use 5 – House mice and/or brown 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 building		
<b>Category(ies) of users</b>	Professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	Adults
	Rattus norvegicus	Brown rat	Juveniles
	Mus musculus	House mouse	Adults
	Mus musculus	House mouse	Juveniles
<b>Application method(s)</b>			
<b>Method</b>	In bait boxes		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose pellet		

<b>Rate:</b>	Rats: bait boxes with 100 g of product each 5-10m ; Mice: bait boxes with 60g of product each 5-10m.
<b>Dilution:</b>	0%
<b>Timing:</b>	Rats: bait boxes with 100 g of product each 5-10m  100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).  Mice: bait boxes with 60g of product each 5-10m.  60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation)

**Pack sizes and packaging material** Minimum pack size of 3 kg.

Number of packed bags per packaging: up to 30 kg  
Grams/kg of bait per packed bag, individual sachets from 10g to 100g.  
Packaging material  
Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

#### 4.5.1. 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.

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

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

- Do not apply this product directly in the burrows

**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 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

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

See section Directions for use

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

See section Directions for use

**4.6. Use 6 - House mice and/or brown 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		
<b>Category(ies) of users</b>	indoor Trained professional		
<b>Target organisms</b>	<b>Scientific name</b>	<b>Common name</b>	<b>Development stage</b>
	Rattus norvegicus	Brown rat	Adults
	Rattus.norvegicus.	Brown rat	Juveniles
	Mus musculus	House mouse	Adults
	Mus musculus	House mouse	Juveniles
<b>Application method(s)</b>			
<b>Method</b>	In bait boxes		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations , in sachets or as loose pellet		
<b>Rate:</b> per baiting point; Mice: bait boxes with point	Rats: bait boxes with 100-200 g 60-80 g per baiting point		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Rats: bait boxes with 100-200 g per baiting point		
	Mice: bait boxes with 60-80 g per baiting point		
<b>Pack sizes and packaging material</b>	Minimum pack size of 3 kg.		
<b>Number of packed bags per packaging:</b>	up to 30 kg.		
<b>Grams/kg of bait per packed bag:</b>	individual sachets from 10g to 200g.		
<b>Packaging material:</b>	Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material. Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC		

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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

Remove the remaining product at the end of treatment period.

- 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.

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

- Do not use the product in pulsed baiting treatments.

- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

**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 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**

See section Directions for use

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

See section Directions for use

**4.7. Use 7 – House mice and/or brown 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	Adults
	Rattus norvegicus	Brown rat	Juveniles
	Mus musculus	House mouse	Juveniles
	Mus musculus	House mouse	Adults
<b>Application method(s)</b>			
<b>Method</b>	In bait boxes		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations , in sachets or as loose pellet		
<b>Rate:</b> per baiting point ; Mice, bait boxes with point	Rats: bait boxes with 100-200 g 60-80 g per baiting point		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-80 g per baiting point .		

**Pack sizes and packaging material** Minimum pack size of 3 kg.

Number of packed bags per packaging: up to 30 kg.

Grams/kg of bait per packed bag: individual sachets from 10g to 200g.

Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or, PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

**4.7.1. Use-specific instructions for use**

- Protect bait from the atmospheric conditions. Place the baiting points 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.

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

**4.7.3. 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.

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

See section Directions for use

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

See section Directions for use

**4.8. Use 8 – Brown Rats – trained professionals – Outdoor open areas & waste dumps**

<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>Outdoor waste dumps</b>	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	Adults
	Rattus norvegicus	Brown rat	Juveniles
<b>Application method(s)</b>			
<b>Method</b>	In bait boxes		
<b>Description</b>	Ready-to-use bait to be used in tamper-resistant bait stations , in sachets or as loose pellet		
<b>Rate: per baiting point.</b>	Rats: bait boxes with 100-200 g		
<b>Dilution:</b>	0%		
<b>Timing:</b>	Rats: bait boxes with 100-200 g per baiting point		
<b>Pack sizes and packaging material</b>	Minimum pack size of 3 kg.		
Number of packed bags per packaging: up to 30 kg.			
Grams/kg of bait per packed bag: individual sachets from 10g to 200g.			
Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC			
Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.			

**4.8.1. Use-specific instructions for use**

Protect bait from the atmospheric conditions. Place the baiting points 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.

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

#### 4.8.3. 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.

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

See section Directions for use

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

See section Directions for use

## 5. General directions for use

### 5.1. Instructions for use

General Public:

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- 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
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc)
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not open the sachets containing the bait - where relevant for the bait formulation in the product
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Do not place bait stations near water drainage systems where they can come into contact with water
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product
- Remove the remaining bait or the bait stations at the end of the treatment period.

Professionals:

- 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).
- 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.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations 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 rodents 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.

- Bait in sachets: Do not open the sachets containing the bait.

- Loose grain: Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

Trained professionals:

- 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.

- 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 during product handling phase (glove material to be specified by the authorisation holder within the product information).

- 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.

- Bait in sachets: Do not open the sachets containing the bait

- Loose grain: Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

## 5.2. Risk mitigation measures

General  
Public

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

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

- The product information (i.e. label and/or leaflet) shall clearly show that:

- The product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

- Users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations")

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

**Professionals:**

- 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
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities
- The product information (i.e. label and/or leaflet) shall clearly show that:
  - the product shall not be supplied to the general public (e.g. "for professionals only").
  - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
  - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not wash the bait stations with water between applications.
- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label]

**Trained Professionals:**

- 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
- 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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label]

**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, always check for and remove contact lenses, 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 [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].
- 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 [insert national phone number]"
- Hazardous to wildlife

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

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Use of gloves is recommended.

**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: two years

## 6. Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after 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

Post-authorization requirements:

- Long-term stability test within 2 years.





# Ministero della Salute

## 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; in particolare devono essere riportate le seguenti modalità applicative:
  1. USO NON PROFESSIONALE:
    - Uso interno di edifici per il controllo del Topolino domestico (*Mus Musculus*) e del Ratto grigio (*Rattus norvegicus*)
    - Uso intorno agli edifici per il controllo del Ratto grigio (*Rattus norvegicus*)
  2. USO PROFESSIONALE:
    - Uso interno di edifici per il controllo del Topolino domestico e del Ratto grigio
    - Uso intorno agli edifici per il controllo del Topolino domestico e del Ratto grigio
  3. USO PROFESSIONALE FORMATO:
    - Uso interno di edifici per il controllo del Topolino domestico e del Ratto grigio
    - Uso intorno agli edifici per il controllo del Topolino domestico e del Ratto grigio
    - Uso esterno in aree aperte e discariche per il controllo del Ratto grigio

Tutte le etichette del prodotto biocida devono riportare il numero di autorizzazione attribuito dal presente decreto, con la seguente dicitura:

**“*PRODOTTO BIOCIDA***  
***AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2014/00251/MRA*”**

- 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.