



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

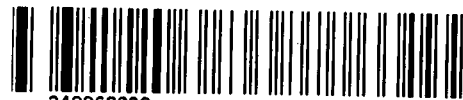
Classif: I.5.i.d.2/816

Allegati: 1 decreto + 2 allegati

Ministero della Salute

DGDMF

0051434-P-12/09/2019



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**MAYER BRAUN DEUTSCHLAND
S.r.l**

Via Brigata Marche 129

31030, Carbonera (Treviso),
Veneto

**OGGETTO: Prodotto biocida BRODIMAX STRONG TECNO FOOD KING, CAFERAT KING,
FISHRAT KING - Trasmissione decreto di rinnovo.**

Si trasmette, in allegato, il decreto di rinnovo dell'autorizzazione n. **IT/2016/00355/AUT** relativa al biocida indicato in oggetto.

Si richiama l'attenzione in merito a quanto previsto dal regolamento 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
dott.ssa Paola D'Alessandro

Referente tecnico: Raffaella Perrone – 06.5994 2520

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Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO I
IT/2016/00355/AUT
IL DIRETTORE

VISTO l'art. 15 della Legge del 06 agosto 2013, n. 97, 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, in particolare, l'articolo 31 del regolamento n. 528/2012 relativo al rinnovo delle autorizzazioni nazionali;

VISTO il decreto di prima autorizzazione del prodotto biocida di cui al dispositivo del presente decreto, rilasciato in data 28/09/2016;

VISTA l'istanza (NA-RNL) BC-TH053217-35 presentata sul Registro Europeo R4BP3 in data 2/08/2019;

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

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

DECRETA:

Il rinnovo dell'autorizzazione del prodotto biocida:

DENOMINAZIONE	BRODIMAX STRONG TECNO FOOD KING, CAFERAT KING, FISHRAT KING
TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO	MAYER BRAUN DEUTSCHLAND S.r.l Via Brigata Marche 129 31030, Carbonera (Treviso), Veneto
NUMERO DI AUTORIZZAZIONE	IT/2016/00355/AUT
SCADENZA DELL'AUTORIZZAZIONE	Autorizzazione valida per 5 anni dalla data del presente decreto
ASSET NUMBER	IT-0015069-0000

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 di questo Ufficio.

Roma, li 11 SET. 2019

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



ALL 1

Summary of product characteristics for a biocidal product

DM

1. Administrative information

1.1. Trade names of the product

Market area	Trade name(s)
Italy	BRODIMAX STRONG TECNO FOOD KING, CAFERAT KING, FISHRAT KING.

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 S.R.L.		
Address of the manufacturer	VIA BRIGATA MARCHE 129	31030	CARBONERA Italy
Location of manufacturing sites	VIA BRIGATA MARCHE 129	31030	CARBONERA Italy

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

BAS number: 11

Name of the manufacturer ACTIVA SRL- DR. TEZZA

Address of the manufacturer VIA FELTRE 22 20132 MILANO Italy

Location of manufacturing sites VIA TRE PONTI 22 37050 SANTA MARIA' DI ZEVIO VERONA 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 (%)
11	259-980-5	56073-10-0	Brodifacoum	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-naphyl]-4-hydroxycoumarin	Active Substance	0.0025

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements May cause damage to organs *blood* through prolonged or repeated exposure .

Precautionary statements If medical advice is needed, have product container or label at hand.

Keep out of reach of children.
Wear *protective gloves*.
Get medical *advice* if you feel unwell.

IF SWALLOWED:Immediately call a *POISON CENTER*.

Dispose of *contents* to national legislation.

4. Authorised use(s)

4.1. non professional use- general public

Product type(s)	PT14 - Rodenticides (Pest control)		
Where relevant, an exact description of the authorised use	The product is ready to use and must be used in accordance with the specific dosages reported below. Do not touch the product with bare hands and use appropriate gloves. The baits should be used only in appropriate containers tamper-proof and duly marked commercially available. The containers must be placed safely in order to minimize the risk of tampering and of accidental ingestion of the bait by children or non -target animals. Always make sure that the containers are secured in an appropriate manner and that the bait can not be dragged away by rodents. Observe the area of infestation and put the containers that include the bait at the dens along the route of rodents and in the places of greatest presence.		
Field(s) of use	Indoor, Other USO#1 interno per topi e ratti esca in pasta pronta all'uso che deve essere usata per la derattizzazione all'interno di ogni ambiente domestico e civile (abitazioni, cantine, garage, ripostigli, edifici rurali e giardini di proprietà) USO#2 interno ed intorno edifici per ratti esca in pasta pronta all'uso che deve essere usata per la derattizzazione all'interno ed intorno ogni ambiente domestico e civile (abitazioni, cantine, garage ripostigli edifici rurali e giardini di proprietà).		
Category(ies) of users	General public		
(non-professional)			
Target organisms	Scientific name	Common name	Development stage
	Mus musculus	House mouse	Adults
	Rattus norvegicus	Brown rat	Adults
Application method(s)			
Method	Bait application		
Description	<p>-Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.</p> <p>- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.</p> <p>- 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.</p> <p>- 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.).</p> <p>- Where possible, bait stations must be fixed to the ground or other structures.</p> <p>[Do not open the sachets containing the bait - where relevant for the bait formulation in the product].</p> <p>- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.</p> <p>- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.</p> <p>- Do not place bait stations near water drainage systems where they can come into contact with water.</p> <p>- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.</p> <p>- Remove the remaining bait or the bait stations at the end of the treatment period.</p> <p>- Do not open the sachets containing the bait.</p>		

Rate: g x 10 mq	Mus musculus: 50 g x 10 mq Rattus norvegicus: 100
Dilution: use.%	not applicable. The formulation is ready to
Timing:	see below instruction of use
Pack sizes and packaging material 10- 12.5-15-20 g	plastic bag/sack from 20 to 150 g containing heat sealed food paper bags of fresh paste rodenticide of

tamper resistant baitbox, plastic: ready to
use bait station from 20 to 150 g containing heat sealed food paper bags with
10- 12.5-15-20-25-50 g of fresh paste rodenticide.

4.1.1. Use-specific instructions for use

For indoor use against mouse:

- 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.

For indoor use against rats:

- 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

For around
buildings use against rats:

- 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

4.1.2. Use-specific risk mitigation measures

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

- Do not eat, drink or smoke when using this product.

- 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].

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

MECHANISM OF ACTION: the active ingredient of BRODIMAX STRONG TECNO FOOD KING is a long lasting anticoagulant chemical and decreases the hepatic synthesis of k-dependent factors.

SYMPTOMS: Severe poisoning by ingestion causes Vitamin K inhibition, causing dermal and mucous haemorrhages. Symptoms to occur in other systems is mainly haemorrhagic.
THERAPY: if large quantities are ingested, induce vomiting, perform gastric lavage and monitor prothrombin activity, if decreased Vitamin K1 should be administered. Follow the appropriate medical protocol.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "BRODIMAX STRONG TECNO FOOD KING or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre".

- Hazardous to wildlife.

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

Arrange disposal by incineration or with other approved suitable treatments. Elimination or recycling according with the local Authority Regulations. In a professional use containers even if completely empty must be clean up before to be disposed.

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

Use of gloves is recommended.

4.1.5. Where specific to the use, the 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 2 years

Conditions for safe storage included any incompatibilities: keep container tightly closed in cool and dry places far from unauthorized people far from foods and domestic animals. Protect from direct solar rays. Keep far from combustion fonts. Accurate ventilation/aspiration in work places.

4.2. professional and trained professionals

Product type(s)	PT14 - Rodenticides (Pest control)		
Where relevant, an exact description of the authorised use	The product is ready to use and must be used in accordance with the specific dosages reported below. Do not touch the product with bare hands and use appropriate gloves. The baits should be used only in appropriate containers tamper-proof and duly marked commercially available. The containers must be placed safely in order to minimize the risk of tampering and of accidental ingestion of the bait by children or non-target animals. Always make sure that the containers are secured in an appropriate manner and that the bait can not be dragged away by rodents. Observe the area of infestation and put the containers that include the bait at the dens along the route of rodents and in the places of greatest presence. The containers must be positioned at about 5-10 m away from each other.		
Field(s) of use	Indoor, Outdoor, Other Uso # 1 interno per topi e ratti Esca in pasta pronta all'uso che deve essere usata per la derattizzazione all'interno di ogni ambiente domestico, civile (abitazioni, cantine, garage, ripostigli, edifici rurali e giardini di proprietà), rurale ed edifici industriali (anche depositi merci e stive delle navi). Uso # 2 interno e intorno edifici per topi e ratti Esca in pasta pronta all'uso che deve essere usata per la derattizzazione all'interno e intorno ogni ambiente do-mestico, civile (abitazioni, cantine, garage, ripostigli, edifici rurali e giardini di proprietà), rurale ed edifici industriali (anche depositi merci e stive delle navi).		
Category(ies) of users	Industrial, Trained professional, Professional		
Target organisms	Scientific name	Common name	Development stage
	Mus musculus	House mouse	Adults
	Rattus norvegicus	Brown rat	Adults
Application method(s)			
Method	Bait application		
Description	<p>Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.</p> <p>- 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.</p> <p>- 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.</p> <p>- 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.</p> <p>-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.</p> <p>- 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.).</p> <p>- Where possible, bait stations must be fixed to the ground or other structures.</p> <p>Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.</p> <p>- 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.</p> <p>- Bait should be secured so that it cannot be dragged away from the bait station.</p>		

- 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.

- Do not open the sachets containing the bait.

Rate: Mus musculus: 50 g x 10 mq Rattus norvegicus: 100g x 10 mq
Dilution: the product is ready to use%
Timing: see below instruction of use

Pack sizes and packaging material sacchi da 1.5 a 25 kg

secchi da 1.5 a 25 kg

buste da 1.5 a 25 kg

secchielli da 1.5 a 25 kg

cartoni da 1.5 a 25 kg

barattoli da 1.5 a 5 kg

contenenti bustine pre-dosate sigillate da g 10-12,5-15-20 di esca rodenticida cadauna.

stazioni sigillate pronte all'uso da 250g (quantità minima per gli utilizzatori professionali 1.5 kg)

4.2.1. Use-specific instructions for use

For indoor use against mouse:

- 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.

- For indoor use against rats:

- 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.

For around buildings use:

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

- Mouse: 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.

- Rat: The bait stations should be 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.

4.2.2. Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

- Do not eat, drink or smoke when using this product.

- Wear protective gloves (professional use only).

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.

- 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

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

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"; "BRODIMAX STRONG TECNO FOOD KING or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre".

Hazardous to wildlife.

4.2.4. Where specific to the use, the 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

Use of gloves is recommended.

Arrange disposal by incineration or with other approved suitable treatments. Elimination or recycling according with the local Authority Regulations. In a professional use containers even if completely empty must be clean up before to be disposed

4.2.5. Where specific to the use, the 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 2 years

Conditions for safe storage included any incompatibilities: keep container tightly closed in cool and dry places far from unauthorized people far from foods and domestic animals. Protect from direct solar rays. Keep far from combustion fonts. Accurate ventilation/aspiration in work places.

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.).

- 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.

- 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.

- Do not open the sachets containing the bait.

5.2. Risk mitigation measures

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

- Do not eat, drink or smoke when using this product.

- Wear protective gloves (professional use only).

- 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.

- 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

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"; "BRODIMAX STRONG TECNO FOOD KING 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 uneaten bait and the packaging in accordance with local requirements

- Use of gloves is recommended.

Arrange disposal by incineration or with other approved suitable treatments. Elimination or recycling according with the local Authority Regulations. In a professional use containers even if completely empty must be clean up before to be disposed.

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 2 years

Conditions for safe storage included any incompatibilities: keep container tightly closed in cool and dry places far from unauthorized people far from foods and domestic animals. Protect from direct solar rays. Keep far from combustion fonts. Accurate ventilation/aspiration in work places

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.

Allegato II - Ulteriori Condizioni dell'Autorizzazione

ETICHETTATURA

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

PRODOTTO BIOCIDA (PT14)

AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2016/00355/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.