

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

BROMAUS Grano

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2014/00244/AUT

R4BP asset number: IT-0008282-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	RATAN E GRANO BROMAUS Grano
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sepran sas
	Address	Via Brenta, 20 36033 Isola Vicentina Italy
Authorisation number	IT/2014/00244/AUT	
<i>R4BP asset number</i>	IT-0008282-0000	
Date of the authorisation	08/09/2014	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	Sepran S.a.s.
Address of manufacturer	Via Brenta, 20 36033 Isola Vicentina (VI) Italy
Location of manufacturing sites	Sepran S.r.l. - Via Brenta, 20 36033 Isola Vicentina (VI) Italy IMC Limited - F65 Hal Far Industrial Estate BBG 3000 Birzebbuga Malta Mayer Braun Deutschland S.r.l. - Via Brigata Marche, 129 31030 Carbonera (TV) Italy Industrialchimica S.r.l. - Via Sorgaglia, 40 35020 Arre Italy Vebi Istituto Biochimico S.r.l. - Via Desman, 43 35010 Borgoricco(PD) Italy Kollant S.r.l. - Via C.Colombo 7/7A 30030 Vigonovo (VE) Italy Colkim S.r.l. - Via Piemonte, 50 40064 Ozzano Emilia (BO) Italy

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

Active substance	Bromadiolone
Name of manufacturer	Activa Srl
Address of manufacturer	Via Feltre 32 20132 Milan Italy
Location of manufacturing sites	Tezza S.r.l.-via Tre Ponti 22 0000 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 (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	active substance	28772-56-7	249-205-9	0,05
Denatonium Benzoate	N-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate hydrate	Non-active substance	3734-33-6	223-095-2	0,001

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H372: Causes 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	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves. P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or a Doctor. P308+P313: IF exposed or concerned: Get medical advice. P501: Dispose of contents to according to the national rules.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice - professionals - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i></p> <p>Common name: house mouse</p> <p>Development stage: Juveniles to Adults</p>
Field(s) of use	<p>indoor use</p> <p>Other</p> <p>Indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: 40g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application: Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.</p>

Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p> <p>d) ready-for-use sealing stations of 250g (minimum quantity for professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>

4.1.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage:

House mouse (*Mus musculus*) 40 g per bait point

Check the quantity of bait in each container once every 2/3 days, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

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

MECHANISM OF ACTION: The active substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. **SYMPTOMS:** severe poisoning from ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Loading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature. Avoid light and sunlight exposure. Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

4.2. Use description

Table 2. Rats - professionals - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
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: 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: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p> <p>Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.</p>

Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p> <p>d) ready-for-use sealing stations of 250g (minimum quantity for professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>

4.2.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage:

Brown rat (*Rattus norvegicus*) 60-100 g x bait point

Black rat (*Rattus rattus*) 60-100 g x bait point

Check the quantity of bait in each container once a week, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

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

MECHANISM OF ACTION: The active substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. **SYMPTOMS:** severe poisoning from ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Leading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature.

Avoid light and sunlight exposure.

Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

4.3. Use description

Table 3. House mice and rats - professionals -outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: 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>Rattus rattus</i> Common name: roof rat Development stage: Juveniles to adults</p>
Field(s) of use	<p>outdoor use Other</p> <p>The product is intended to be applied outdoor around buildings and must be placed inside a suitable bait station.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: Dosage: House mouse (<i>Mus musculus</i>): 40g x Bait point; Brown rat (<i>Rattus norvegicus</i>): 60-100 g x Bait Point; Black rat (<i>Rattus rattus</i>): 60-100 g x bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p>

	Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p> <p>d) ready-for-use sealing stations of 250g (minimum quantity for professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>

4.3.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage:

Brown rat (*Rattus norvegicus*) 60-100 g x bait point

Black rat (*Rattus rattus*) 60-100 g x bait point

House mouse (*Mus musculus*) 40 g x bait point

Check the quantity of bait in each container once a week, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise

treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

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

MECHANISM OF ACTION: The active substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. SYMPTOMS: severe poisoning from ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Loading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature. Avoid light and sunlight exposure.
Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

4.4. Use description

Table 4. Rats - trained professionals - Outdoor open areas & waste dumps

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
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: Juveniles to Adults</p>
Field(s) of use	<p>outdoor use Other</p> <p>The product is intended to be applied in and around buildings, open areas and waste dumps. The rodenticide bait must be placed inside a suitable bait station or other covered and protect bait point.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: Low Infestations: Brown rat (<i>Rattus norvegicus</i>), Black rat (<i>Rattus rattus</i>): 40-60 g x bait point. High Infestations: Brown rat (<i>Rattus norvegicus</i>), Black rat (<i>Rattus</i></p>

	<p>rattus): 60-100 g x bait point If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p> <p>Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p> <p>d) ready-for-use sealing stations of 250g (minimum quantity for Trained professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>

4.4.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station or other covered and protect bait point, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage - Low Infestations for covered application (open areas):

Brown rat (*Rattus norvegicus*) 40-60g x bait point

Black rat (*Rattus rattus*) 40-60g x bait point

Dosage - High Infestations for covered application (open areas):

Brown rat (*Rattus norvegicus*) 60-100g x bait point

Black rat (*Rattus rattus*) 60-100g x bait point

Check the quantity of bait in each container once a week, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

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

MECHANISM OF ACTION: The active substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. **SYMPTOMS:** severe poisoning from ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Leading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature. Avoid light and sunlight exposure.
Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

4.5. Use description

Table 5. House mice and rats - trained professionals - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: 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>Rattus rattus</i> Common name: roof rat Development stage: Juveniles to Adults</p>
Field(s) of use	<p>indoor use</p> <p>The product is intended to be applied indoor buildings and must be placed inside a suitable bait station.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent.</p>

	<p>The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: House mice and Rats (Low infestation): 40-60g of bait per bait point. House mice and Rats (High infestation): 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p> <p>Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p> <p>d) ready-for-use sealing stations of 250g (minimum quantity for Trained professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>

4.5.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage - Low Infestations:

Brown rat (*Rattus norvegicus*) 40-60g x bait point

Black rat (*Rattus rattus*) 40-60g x bait point

House mouse (*Mus musculus*) 40-60g x bait point

Dosage - High Infestations :

Brown rat (*Rattus norvegicus*) 60-100g x bait point

Black rat (*Rattus rattus*) 60-100g x bait point

House mouse (*Mus musculus*) 60-100g x bait point

Check the quantity of bait in each container once a week, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.5.2. Use-specific risk mitigation measures

4.5.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

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

MECHANISM OF ACTION: The active substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. **SYMPTOMS:** severe poisoning from

ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Loading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature. Avoid light and sunlight exposure.
Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

4.6. Use description

Table 6. Mice and rats - trained professionals - outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready-to-use bait in grains based on bromadiolone.</p> <p>The product is effective against <i>Rattus rattus</i> (brown rat), <i>Rattus norvegicus</i> (roof rat, house rat), <i>Mus musculus</i> (house mouse).</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: 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>Rattus rattus</i> Common name: roof rat Development stage: Juveniles to Adults</p>
Field(s) of use	<p>outdoor use</p> <p>The product is intended to be applied outdoor around buildings and must be placed inside a suitable bait station.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.</p>
Application rate(s) and frequency	<p>Application rate: House mice and Rats (Low infestation): 40-60g of bait per bait point. House mice and Rats (High infestation): 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p> <p>Check the quantity of bait in each container once a week, replenishing it as necessary. The product is not intended for permanent use; organise treatments that last no more than 6 weeks.</p>
Category(ies) of users	<p>trained professional</p>
Pack sizes and packaging material	<p>Packages:</p> <p>a) sealed, pre-dosed sachets, each containing g10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25</p> <p>b) bags, cartons and buckets containing kg 1,5-2-2,5-3-4-5-8-10-12,5-15-20-25 of loose rodent bait</p> <p>c) cans and bags containing kg 1,5 2-2,5-3-4-5 of loose rodent bait</p>

	<p>d) ready-for-use sealing stations of 250g (minimum quantity for Trained professionals users kg 1,5, corresponding to n^6 ready-for-use sealing stations)</p> <p>pre-sealed sachets: paper;</p> <p>buckets in plastic/PET;</p> <p>bags in polyethylene and paper;</p> <p>cartons</p>
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4.6.1. Use-specific instructions

After having inspected the affected area, create bait points near the rodent's nests, along their routes, in the places where they are most often seen, with product quantities as explained in the dosages given below. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. Do not use the product as a tracing agent. The baits must be applied so as to minimize the risk of accidental ingestion by children or non-target animals. The rodenticide bait must be placed inside a suitable bait station or other covered and protect bait point, protected from the weather, ingestion by non-target species and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. This avoids the undesired dispersion of the bait in the environment.

Dosage - Low Infestations for covered application (open areas):

Brown rat (*Rattus norvegicus*) 40-60g x bait point

Black rat (*Rattus rattus*) 40-60g x bait point

Dosage - High Infestations for covered application (open areas):

Brown rat (*Rattus norvegicus*) 60-100g x bait point

Black rat (*Rattus rattus*) 60-100g x bait point

Check the quantity of bait in each container once a week, replenishing it as necessary. Remove dead animals every day, disposing of them in accordance with current legislation. Wear protective gloves and wash hands when removing dead bodies and uneaten bait. The product is not intended for permanent use; organise treatments that last no more than 6 weeks. At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract. Avoid touching the product with bare hands and wear appropriate gloves. The rodenticide bait must be placed inside a suitable bait station, protected from the weather, ingestion by non-target species

and dispersion in the environment. The container must bear the wording "Do not touch" and a warning explaining its content. The container must be suitably secured and have the access envisaged for the target animal only. The product is formulated with a bittering agent.

4.6.4. 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 substance contained in the product is a competitor Vitamin K antagonist and reduces hepatic synthesis of K-dependent factors. SYMPTOMS: severe poisoning from ingestion inhibits vitamin K, causing cutaneous and mucosal bleeding. Leading symptoms of other systems and equipment is mainly hemorrhagic. Avoid leakage or spillage, if this can be done without danger. Do not let product enter drains or water courses. Collect using gloves and put in a container for reuse if possible, or for disposal. Subsequent to collection, wash with soap and water the area and materials involved.

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

At the end of the treatment, dispose of the containers containing any remaining bait in accordance with current legislation.

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

Keep containers tightly closed and labelled with the name of the product. Store at room temperature. Avoid light and sunlight exposure.
Validity: 24 months (if stored in the original closed container, in a cool dry place, away from sunlight).

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

5.2. Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training

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

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