ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

RODITAN

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2017/00376/AUT

R4BP asset number: IT-0016313-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	RODITAN

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sepran sas
ivalue and address of the authorisation holder	Address	Via Brenta, 20 36033 Isola Vicentina Italy
Authorisation number		IT/2017/00376/AUT
R4BP asset number		IT-0016313-0000
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.r.1
Address of manufacturer	Via Brenta, 20 36033 Isola Vicentina (VI) Italy
Location of manufacturing sites	Via Brenta, 20 36033 Isola Vicentina (VI) Italy

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

Active substance	Bromadiolone
Name of manufacturer	ACTIVA SRL / Dr Tezza srl
Address of manufacturer	Via Feltre 32 20132 Milano Italy
Location of manufacturing sites	Via Tre Ponti 22 Santa Maria di Zevio 37050 Verona 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	0,0027

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs {0:or state all organs affected, if known:} through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.
Precautionary statements	P102: Keep out of reach of children. P501: Dispose of contents to according to national regulation.
	P202: Do not handle until all safety precautions have been read and understood.
	P260: Do not breathe dust.
	P314: Get medical advice if you feel unwell.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Non professional

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is a ready-to-use bait in grains based on bromadiolone. 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).
Target organism(s) (including development stage)	Scientific name: Rattus rattus Common name: roof rat Development stage: adults
	Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults
	Scientific name: Mus musculus Common name: house mouse Development stage: adults
Field(s) of use	indoor use Other
	The product is intended to be applied in and around buildings and must be placed inside a suitable bait station.
Application method(s)	Method: bait application 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. 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.
Application rate(s) and frequency	Application rate: Dosage: House mouse (Mus musculus) 50-60 g x 10 mq Brown rat (Rattus norvegicus) 80- 150 g x 10 mq Black rat (Rattus rattus) 80- 150 g x 10 mq Dilution (%): N.A 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.

Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Packages: a) sealed, pre-dosed sachets, each containing g 10-12,5-15-20 of rodent bait, in packages weighing a total of 50- 100-150 g b) ready-for-use sealing stations, each of 20-25-50-100-150 g (containing sealed, pre-dosed sachets each 10-12,5-15-20-25-50g) Pre-dosed sachets in paper. Bags: cellophan/polyethylene Can: PLT
	Box: carton

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. 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:

House mouse (Mus musculus) 50-60 g x 10 mq Brown rat (Rattus norvegicus) 80- 150 g x 10 mq Black rat (Rattus rattus) 80- 150 g x 10 mq

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.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

Keep out of reach of children. Avoid touching the product with bare hands and wear appropriate gloves. Avoid the contact with eyes, skin and clothes. 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.

4.1.4. 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. Professional

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is a ready-to-use bait in grains based on bromadiolone. 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).
Target organism(s) (including development stage)	Scientific name: Rattus rattus Common name: roof rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults

	Scientific name: Mus musculus Common name: house mouse Development stage: adults
Field(s) of use	indoor use Other
	The product is intended to be applied in and around buildings and must be placed inside a suitable bait station.
Application method(s)	Method: bait application
	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 (respiratory mask disposable EN149 FFP2). 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.
Application rate(s) and frequency	Application rate: Dosage: House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100-200 g x 10 mq Black rat (Rattus rattus) 100-200 g x 10 mq
	Dilution (%): N.A
	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.
Category(ies) of users	professional
Pack sizes and packaging material	Packages: a) sealed, pre-dosed sachets, each containing g 10-12,5-15-20 of rodent bait, in packages weighing a total of kg 1,5-2-3-5-10-15-20-25 b) bags, cartons and buckets containing kg 1,5-2-3-5-8-10-12,5-15-20-25 of loose rodent bait c) cans and bags containing kg 1,5 2-3-4-5 of loose rodent bait
	pre-sealed sachets: paper;
	buckets in plasic/PET;

	bags in polyethylene and paper;
	cartons

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 (respiratory mask disposable EN149 FFP2). 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:

House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100-200 g x 10 mq Black rat (Rattus rattus) 100-200 g x 10 mq

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 (respiratory mask disposable EN149 FFP2). 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. 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.

4.2.5. 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. Trained professional

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is a ready-to-use bait in grains based on bromadiolone. 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).
Target organism(s) (including development stage)	Scientific name: Rattus rattus Common name: roof rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults Scientific name: Mus musculus Common name: house mouse Development stage: adults
Field(s) of use	indoor use outdoor use 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.

Application method(s)	Method: bait application
	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 (respiratory mask disposable EN149 FFP2). 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.
Application rate(s) and frequency	Application rate: Dosage: House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100- 200 g x 10 mq Black rat (Rattus rattus) 100- 200 g x 10 mq Dosage for covered application (open areas): House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 80 g x 10 mq Black rat (Rattus rattus) 80 g x 10 mq Dilution (%): N.A 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.
Category(ies) of users	trained professional
Pack sizes and packaging material	Packages: a) sealed, pre-dosed sachets, each containing g 10-12,5-15-20 of rodent bait, in packages weighing a total of g 100-150-200-250-300-400-500-750-1000 and of kg 1,5-2-3-5-10-15-20-25 b) bags, cartons and buckets containing kg 1,5-2-3-5-8-10-12,5-15-20-25 of loose rodent bait c) cans and bags containing g 100, 200, 250, 300, 400, 500, 750 and kg 1-1,5-2-3-4-5 of loose rodent bait
	pre-sealed sachets: paper; buckets in plasic/PET;
	bags in polyethylene and paper;

	cartons	

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 (respiratory mask disposable EN149 FFP2). 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:

House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100- 200 g x 10 mq Black rat (Rattus rattus) 100- 200 g x 10 mq

Dosage for covered application (open areas):
House mouse (Mus musculus) 60 g x 10 mq
Brown rat (Rattus norvegicus) 80 g x 10 mq
Black rat (Rattus rattus) 80 g x 10 mq

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 (respiratory mask disposable EN149 FFP2). 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).

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

General public:

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. 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:

House mouse (Mus musculus) 50-60 g x 10 mq Brown rat (Rattus norvegicus) 80- 150 g x 10 mq Black rat (Rattus rattus) 80- 150 g x 10 mq

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

Professional:

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 (respiratory mask disposable EN149 FFP2). 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:

House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100-200 g x 10 mq Black rat (Rattus rattus) 100-200 g x 10 mq

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.

Trained Professional:

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 (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves. Do not

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

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:

House mouse (Mus musculus) 60 g x 10 mq Brown rat (Rattus norvegicus) 100- 200 g x 10 mq Black rat (Rattus rattus) 100- 200 g x 10 mq

Dosage for covered application (open areas):
House mouse (Mus musculus) 60 g x 10 mq
Brown rat (Rattus norvegicus) 80 g x 10 mq
Black rat (Rattus rattus) 80 g x 10 mq

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.

5.2. Risk mitigation measures

Keep out of reach of children. During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). 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.

5.3. 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.

5.4. 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.

5.5. 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).

6. OTHER INFORMATION