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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

NEW SEPRARAT PELLETT / COMPO RODIX PELLETT

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2018/00524/AUT

R4BP asset number: IT-0019924-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	NEW SEPRARAT PELLETT / COMPO RODIX PELLETT
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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/2018/00524/AUT	
<i>R4BP asset number</i>	IT-0019924-0000	
Date of the authorisation	30/01/2014	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	Sepran S.r.l.
Address of manufacturer	Via Brenta, 20 36033 Isola Vicentina (VI) Italy
Location of manufacturing sites	KOLLANT S.r.l - via C. Colombo 7/A 30030 Vigonovo (VE) Italy IMC Limited - HF65 Hal Far Industrial Estate BBG 3000 Birzebbuga Malta INDUSTRIAL CHIMICA S.r.l. - Via Sorgaglia, 40 35020 Arre (PD) Italy VEBI ISTITUTO BIOCHIMICO S.r.l. - Via Desman, 43 35010 S.Eufemia di Borgoricco (PD) Italy

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

Active substance	Brodifacoum
Name of manufacturer	Activa s.r.l
Address of manufacturer	via Feltre 32 20132 Milano Italy
Location of manufacturing sites	Tezza S.r.l - via Tre Ponti 22 37050 S. Maria Di Zevio Italy

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0025

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P102: Keep out of reach of children. 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 – professional – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations ¹ .
Application rate(s) and frequency	Application rate: 20 g - 40 g pellets per bait point. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	From 1,5 Kg up to 25Kg (containing rodenticide baits in pellets). Packaging material: PE/Aluminium/Polyester

4.1.1. Use-specific instructions

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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

4.2. Use description

Table 2. Rats – professional – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations .
Application rate(s) and frequency	Application rate: 100 g - 200 g per bait station. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	From 1,5 Kg up to 25Kg (containing rodenticide baits in pellets) Packaging material: PE/Aluminium/Polyester

4.2.1. Use-specific instructions

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

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

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

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

4.3. Use description

Table 3. House mice and Rats – professionals – around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Juveniles to adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	Other Around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: House mice: 20 – 40 g pellet per bait point; Brown rat: 100 g - 200 g pellet per bait point. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	From 1,5 Kg up to 25Kg (containing rodenticide baits in pellets) Packaging material: PE/Aluminium/Polyester

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4.3.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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

When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

4.4. Use description

Table 4. House mice – general public – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: 20 g - 40 g pellet bait per bait point.

	Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	Up to 150 g (containing rodenticide baits in pellets in predosed inner packs about 10-15-20 g). Packaging material: PE/Aluminium/Polyester

4.4.1. Use-specific instructions

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

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

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

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

4.5. Use description

Table 5. Rats –general public – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations.

Application rate(s) and frequency	Application rate: 100 g - 200 g per bait station Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	Up to 150g (containing rodenticide baits in pellets in predosed inner packs about 10-15-20 g) Packaging material: PE/Aluminium/Polyester

4.5.1. Use-specific instructions

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.

4.5.2. Use-specific risk mitigation measures

4.5.3. Use-specific risk mitigation measures

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

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

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

4.6. Use description

Table 6. Rats – general public – around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	Other Around buildings

Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: 100 g - 200 g pellet bait per bait point. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	Up to 150g (containing rodenticide baits in pellets in predosed inner packs about 10-15-20 g) Packaging material: PE/Aluminium/Polyester

4.6.1. Use-specific instructions

- 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.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

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

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

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Professional 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.

- Place the bait in the bait station by using a dosage device

General public 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.

- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

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

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- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
 - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
 - Where possible, bait stations must be fixed to the ground or other structures.
 - Do not open the sachets containing the bait
 - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
 - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
 - Do not place bait stations near water drainage systems where they can come into contact with water.
 - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
 - Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

For professional use:

- 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.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any]".
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:

the product shall not be supplied to the general public (e.g. "for professionals only").

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

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

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

- Do not wash the bait stations with water between applications.

- Dispose dead rodents in accordance with local requirements.

For general public use

- 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.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

For professional and general public use:

- 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.

Further instruction for professional use:

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- 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: 2 years

6. OTHER INFORMATION

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.