

Summary of product characteristics for a biocidal product

Product name: BRORAT PASTA 25 rágcsálóirtó pép

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: HU-2018-SP-14-00225-0000

R4BP 3 asset reference number: HU-0019993-0000

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Administrative information

1.1. Trade names of the product

BRORAT PASTA 25 rágcsálóirtó pép

1.2. Authorisation holder

Name and address of the authorisation holder	Name	REA srl
	Address	S.S. 87 -Km 20.700 81025 Marcianise Italy
Authorisation number	HU-2018-SP-14-00225-0000	
R4BP 3 asset reference number	HU-0019993-0000	
Date of the authorisation	05/02/2014	
Expiry date of the authorisation	31/12/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	REA S.r.l.
Address of the manufacturer	S.S.87 km. 20,700 81025 Marcianise (CE) Italy
Location of manufacturing sites	S.S.87 km. 20,700 81025 Marcianise (CE) Italy
	FERBI S.r.l. - Viale I° Maggio 64023 Mosciano S. Angelo (TE) Italy
	BIOSOL ITALIA S.r.l.s., S.S. Nettunense Km 23,400 04011 Aprilia (LT) Italy
	D'ORTA S.p.A. – Via Provinciale Pianura, Loc. S. Martino, 18 80078 Pozzuoli (NA) Italy

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

Active substance	11 - Brodifacoum
Name of the manufacturer	Activa S.rl
Address of the 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 biocidal 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 of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements

May cause damage to organs , through prolonged or repeated exposure (blood).

Precautionary statements

Keep out of reach of children.
IF SWALLOWED:Immediately call a POISON CENTER.
IF exposed or concerned:Get medical advice.
Get medical attention if you feel unwell.
Dispose of contents to according to the local rules.

4. Authorised use(s)

4.1 Use description

Use 1 - House mice – general public – indoor

Product type	PT14 - Rodenticides (Pest control)
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: adults and juveniles
Field(s) of use	Indoor Indoors
Application method(s)	Bait application - Ready-to-use bait to be used in tamper-resistant bait stations. The "feeding station" in this manual is a device that has the following features: Usually black or translucent plastic box to safely dispose of the rodenticide. When refilling the dispenser, the box can be opened and closed using the enclosed key. It has one or two openings through which rodents can climb inside the box and consume the pesticide placed there and then climb out of the box. The size of the entrance opening ensures to prevent animals larger than rodents from gaining access to the pesticide. The rodenticide can be placed inside the box so that it is not dispersed on the ground and protected from sunlight, rain, ground water and wind. It may include a spike / hook / tray to fix the pesticide so that it is not or more difficult for rodents to remove from the box. If you do not have such a tool available, contact your pesticide dealer for assistance.
Application rate(s) and frequencies	- - - - 20 to 40 g of bait per bait station. High infestation – bait stations every 2 metres. Low infestation – bait stations every 5 metres
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Up to 150 g (containing rodenticide baits of 10-20 g in sachets of pasta bait). Packaging material: PE/Aluminium/Polyester

4.1.1 Use-specific instructions for use

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

4.1.2 Use-specific risk mitigation measures

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

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

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

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4.2 Use description

Use 2 - Rats – general public – indoor

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

Not relevant for rodenticides

Target organism(s) (including development stage)

Scientific name: Rattus norvegicus
Common name: Brown rat
Development stage: adults and juveniles

Field(s) of use

Indoor

Indoors

Application method(s)

Bait application -

Ready-to-use bait to be used in tamper-resistant bait stations.
 The "feeding station" in this manual is a device that has the following features:
 Usually black or translucent plastic box to safely dispose of the rodenticide.
 When refilling the dispenser, the box can be opened and closed using the enclosed key.
 It has one or two openings through which rodents can climb inside the box and consume the pesticide placed there and then climb out of the box. The size of the entrance opening ensures to prevent animals larger than rodents from gaining access to the pesticide.
 The rodenticide can be placed inside the box so that it is not dispersed on the ground and protected from sunlight, rain, ground water and wind.
 It may include a spike / hook / tray to fix the pesticide so that it is not or more difficult for rodents to remove from the box.

If you do not have such a tool available, contact your pesticide dealer for assistance.

Application rate(s) and frequencies

 100 to 200 g of bait per bait station. High infestation – bait stations every 5 metres. Low infestation – bait stations every 10 metres.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

Up to 150 g (containing rodenticide baits of 10-20 g in sachets of pasta bait).
 Packaging material: PE/Aluminium/Polyester

4.2.1 Use-specific instructions for use

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

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

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

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

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4.3 Use description

Use 3 - Rats – general public – outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Brown rat Development stage: adults and juveniles
Field(s) of use	Outdoor Outdoor around buildings
Application method(s)	Bait application - Ready-to-use bait to be used in tamper-resistant bait stations. The "feeding station" in this manual is a device that has the following features: Usually black or translucent plastic box to safely dispose of the rodenticide. When refilling the dispenser, the box can be opened and closed using the enclosed key. It has one or two openings through which rodents can climb inside the box and consume the pesticide placed there and then climb out of the box. The size of the entrance opening ensures to prevent animals larger than rodents from gaining access to the pesticide. The rodenticide can be placed inside the box so that it is not dispersed on the ground and protected from sunlight, rain, ground water and wind. It may include a spike / hook / tray to fix the pesticide so that it is not or more difficult for rodents to remove from the box. If you do not have such a tool available, contact your pesticide dealer for assistance.
Application rate(s) and frequencies	----- 100 to 200 g of bait per bait station. High infestation – bait stations every 5 metres. Low infestation – bait stations every 10 metres.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Up to 150 g (containing rodenticide baits of 10-20 g in sachets of pasta bait). Packaging material: PE/Aluminium/Polyester

4.3.1 Use-specific instructions for use

Place the feeding stations in a place protected from rain and groundwater.
Replace any baits in the feeding station that have been damaged or contaminated by water.
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.

4.3.2 Use-specific risk mitigation measures

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

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

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

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4.4 Use description

Use 4 - House mice and/or rats – trained professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
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

	<p>Development stage: adults and juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: adults and juveniles</p>
Field(s) of use	<p>Indoor</p> <p>Indoors</p>
Application method(s)	<p>Bait application - Ready-to-use pasta bait to be used in tamper-resistant bait stations.</p>
Application rate(s) and frequencies	<p>----</p> <p><u>For mice:</u> 20 to 40 g of bait per bait station. High infestation – bait stations every 2 metres. Low infestation – bait stations every 5 metres</p> <p><u>For rats:</u> 100 to 200 g of bait per bait station. High infestation – bait stations every 5 metres. Low infestation – bait stations every 10 metres.</p>
Category(ies) of users	<p>Trained professional</p>
Pack sizes and packaging material	<p>From 1,5 kg up to 25 kg (containing rodenticide baits of 10-20 g in sachets of pasta bait) Packaging material: PE / Aluminium / Polyesther</p>

4.4.1 Use-specific instructions for use

Remove the remaining product at the end of treatment period.

4.4.2 Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

Consider preventive protective measures (plugging holes, removing rodents' food source as much as possible) so that rodents consume more of the product and are less likely to re-establish themselves in the area.

Do not use the product in pulsed / rhythmic dispensing amounts.

Do not use the product for a long period of time (in a permanent position).

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

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

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

-

4.5 Use description

Use 5 - House mice and/or rats – trained professionals – outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)
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: adults and juveniles Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: adults and juveniles
Field(s) of use	Outdoor Outdoor around buildings
Application method(s)	Bait application - Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	--- <u>For mice:</u> 20 to 40 g of bait per bait station. High infestation – bait stations every 2 metres. Low infestation – bait stations every 5 metres <u>For rats:</u> 100 to 200 g of bait per bait station. High infestation – bait stations every 5 metres. Low infestation – bait stations every 10 metres.

Category(ies) of users

Trained professional

Pack sizes and packaging material

From 1,5 kg up to 25 kg (containing rodenticide baits of 10-20 g in sachets of pasta bait)
Packaging material: PE / Aluminium / Polyester

4.5.1 Use-specific instructions for use

Place the feeding stations in a place protected from rain and groundwater.
Replace any baits in the feeding station that have been damaged or contaminated by water.
Remove the remaining product at the end of treatment period.

4.5.2 Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
Consider preventive protective measures (plugging holes, removing rodents' food source as much as possible) so that rodents consume more of the product and are less likely to re-establish themselves in the area.

Do not use the product in pulsed / rhythmic dispensing amounts.
Do not use the product for a long period of time (in a permanent position).

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

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

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

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



5. General directions for use

5.1. Instructions for use

For 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.

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.

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.

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.

During collecting baits, avoid skin contact with the pesticide.

Instructions for use that are "bait-specific":

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

For trained 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).

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.

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.

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 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.

When using the product do not eat, drink or smoke.

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.

If the efficacy of the product is inadequate - and all other reasons are ruled out - rodents resistant to anticoagulants are likely to occur in the area. Therefore, consider using a non-anticoagulant rodenticide, if available, or a stronger 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.

5.2. Risk mitigation measures

For public use:

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 should be used in a suitable, closed bait station. The following information must appear on the label of bait stations: „it must not be moved or opened“; „contains rodenticide“; „product name or authorization number“; „active substance (s)“; „name of the antidote or medicine“ and „in case of an accident contact the Toxicology Center“ (Egészségügyi Toxikológiai Tájékoztató Szolgálat telephone number: 06 80 20 11 99).

Using this product should eliminate rodents within 35 days.

The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service. Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

Dispose dead rodents in accordance with local requirements.

The dead rodents should be collected with protective gloves or with turned plastic bag inside out, then placed in an additional bag and sealed. The double bags containing dead rodents should be placed in a closed waste container and then treated as communal waste.

For trained professional use:

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.

Do not use in areas where resistance to the active substance can be suspected.

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

Trained professional users are obliged to dispose of the dead rodents as hazardous waste in accordance with the provisions of the Government decree 225/2015. (VIII.7.).

The following information must appear on the label of bait stations: „it must not be moved or opened“; „contains rodenticide“; „product name or authorization number“; „active substance (s)“ and „in case of an accident contact the Toxicology Center“ (Egészségügyi Toxikológiai Tájékoztató Szolgálat telephone number: 06 80 20 11 99).

Furthermore: „the name of rodenticide“; „active substance (s)“; „antidote or medicine“; in addition the „name and address and telephone number of the pest control service“ must be appear on the label of bait station in accordance with provisions the EMMI decree 16/2017. (VIII.7.).

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.

Bait stations must be labelled with the following information: „it must not be moved or opened“; „contains rodenticide“; „product name or authorization number“; „active substance (s)“ and „in case of an accident contact the Toxicology Center“ (Egészségügyi Toxikológiai Tájékoztató Szolgálat telephone number: 06 80 20 11 99).

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.

It is recommended to wear protective gloves when collecting rodenticide.

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 may take from 4 to 10 days to be effective after effective 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.

The label includes:

BRORAT PASTA 25 rágcsálóirtó pép

Active substance: brodifacoum
Authorisation holder: REA S.r.l. (Italy)
Biocid license number: HU-2018-SP-14-00225-0000

as well as the following sections of this document, depending on the scope of users:
for general public: 2.2, 3, 4.1-4.3. (excluding packaging) and 5, 6 parts
for trained professional users: 2.2, 3, 4.4-4.5. (excluding packaging), and 5, 6 parts.
In addition the label on filter paper or on plastic bag containing the rodenticide include:

BRORAT PASTA 25 rágcsálóirtó pép
Active substance: brodifacoum
Antidote: K1-vitamine