

Summary of product characteristics for a biocidal product

Product name: ZAGOR 25 rágcsálóirtó pép

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

Authorisation number: HU-2018-SP-14-00219-0000

R4BP 3 asset reference number: HU-0019405-0000

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Administrative information

1.1. Trade names of the product

ZAGOR 25 rágcsálóirtó pép
FACORAT 25 rágcsálóirtó pép
RODYKETT 25 rágcsálóirtó pép
LAMPORAT 25 rágcsálóirtó pép

1.2. Authorisation holder

**Name and address of the
authorisation holder**

Name	INDUPHARMA S.R.L
Address	VIA SORGAGLIA 40 35020 ARRE, PADOVA Italy
Authorisation number	HU-2018-SP-14-00219-0000
R4BP 3 asset reference number	HU-0019405-0000
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

INDUPHARMA S.r.l.

Address of the manufacturer

Via Sorgaglia 40 35020 Arre (PD) Italy

Location of manufacturing sites

Via Sorgaglia 40 35020 Arre (PD) 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 (blood) 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 attention.
Dispose of contents to according to national legislation..

4. Authorised use(s)

4.1 Use description

Use 1 - house mice – trained professional- indoors

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: Juvenils and adults
Field(s) of use	Indoor
Application method(s)	Method: Bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Application Rate: 20 g - 40 g pasta bait per bait point. Dilution (%): 0.0025 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	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/Polyesther

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

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

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- trained professional- indoors

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: Juvenils and adults

Field(s) of use

Indoor

Application method(s)

Method: Bait application
Detailed description:
Ready-to-use pasta bait to be used in tamper-resistant bait stations.

Application rate(s) and frequencies

Application Rate: 100 g - 200 g per bait station.
Dilution (%): 0,0025
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

Trained professional

Pack sizes and packaging material

From 1,5 Kg up to 25Kg (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

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

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 - House mice and Rats – trained professionals – 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)	<p>Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Juvenils and adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: Juvenils and adults</p>
Field(s) of use	<p>Outdoor</p> <p>Around buildings</p>
Application method(s)	<p>Method: Bait application Detailed description:</p> <p>Ready-to-use pasta bait to be used in tamper-resistant bait stations.</p>
Application rate(s) and frequencies	<p>Application Rate: House mice: 20 – 40 g pasta bait per bait point; Brown rat: 100 g - 200 g pasta bait per bait point Dilution (%): 0.0025 Number and timing of application: 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.</p>
Category(ies) of users	Trained professional
Pack sizes and packaging material	<p>Number of packed bags per packaging: Grams/kg of bait per packed bag: from 1,5 Kg up to 25Kg (containing rodenticide baits of 10-20 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.</p>

4.3.1 Use-specific instructions for use

- 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

Do not apply this product directly in the burrows.

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

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.

4.3.4 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- general public – indoors

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: Juvenils and adults
Field(s) of use	Indoor
Application method(s)	Method: Bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Application Rate: 20 g - 40 g pasta bait per bait point. Dilution (%): 0.0025 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

Pack sizes and packaging material

General public (non-professional)

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

4.4.1 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.

4.4.2 Use-specific risk mitigation measures

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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

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4.5 Use description

Use 5 - 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: Juvenils and adults

Field(s) of use

Indoor

Application method(s)

Method: Bait application
Detailed description:
Ready-to-use pasta bait to be used in tamper-resistant bait stations.

Application rate(s) and frequencies

Application Rate: 100 g - 150 g per bait point.
Dilution (%): 0.0025
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

General public (non-professional)

Pack sizes and packaging material

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

4.5.1 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.

4.5.2 Use-specific risk mitigation measures

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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

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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

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4.6 Use description

Use 6 - Rats – general public – 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: Juvenils and adults
Field(s) of use	Other Around buildings.
Application method(s)	Method: Bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Application Rate: 100 g - 150 g pasta bait per bait point. Dilution (%): 0.0025 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	General public (non-professional)
Pack sizes and packaging material	Up to 150g (containing rodenticide baits of 10-20 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.

4.6.1 Use-specific instructions for use

- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to

check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.6.2 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

4.6.3 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 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.

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

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

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5. General directions for use

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.

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.
- 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. 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:

- 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 (225/2015 (VIII.7.) Gov. Decree)

For general 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 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 (225/2015 (VIII.7.) Gov. Decree)

(Egészségügyi Toxikológiai Tájékoztató Szolgálat telefonszáma: 06 80 20 11 99).

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: "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.