

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SANIFAR

Product type(s)

PT14: Rodenticides

Authorisation number: FR-2016-1020

R4BP asset number: FR-0014523-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	SANIFAR
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	SOFAR FRANCE
	Address	BP2 29190 PLEYBEN France
Authorisation number		FR-2016-1020
<i>R4BP asset number</i>		FR-0014523-0000
Date of the authorisation		05/07/2017
Expiry date of the authorisation		31/12/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	SOFAR
Address of manufacturer	BP 02 29190 Pleyben France
Location of manufacturing sites	BP 02 29190 Pleyben France

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

Active substance	Brodifacoum
Name of manufacturer	ACTIVA/TEZZA
Address of manufacturer	Via Feltre 32 20132 Milan Italy
Location of manufacturing sites	PM TEZZA SRL VIA TRE PONTI 22 37050 S. MARIA DI ZEVIO (VR) 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	0,005

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. 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	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P314: Get medical attention if you feel unwell. P405: Store locked up. P501: Dispose of container to in accordance with local regulation.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. HOUSE MICE AND/OR RATS-TRAINED PROFESSIONALS -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: Rattus norvegicus Common name: Rats Development stage: juveniles Scientific name: Rattus norvegicus Common name: Rats Development stage: adults Scientific name: Rattus rattus Common name: Rats Development stage: juveniles Scientific name: Rattus rattus Common name: Rats Development stage: adults Scientific name: Mus musculus Common name: Mice Development stage: juveniles Scientific name: Mus musculus Common name: Mice Development stage: adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequency	Application rate: - Dilution (%): 0 Number and timing of application: Bait products: Rats (Rattus Rattus & Rattus Norvegicus)

	<p>- High infestation: 180-200 g of bait per baiting point every 5 meters</p> <p>- Low infestation: 180-200 g of bait per baiting point every 10 meters</p> <p>Mice (<i>Mus Musculus</i>)</p> <p>- High infestation: 30-40 g of bait per baiting point every 1 meters</p> <p>- Low infestation: 30-40 g of bait per baiting point every 2 meters</p>
Category(ies) of users	industrial ; trained professional ; professional
Pack sizes and packaging material	<p>Minimum pack size of 5 kg.</p> <p>The product is supplied in individual PE/PP sachets (10-20-25-30-40-50-60-90-100-200g) wrapped in:</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10-15-20-25-30kg) - Bucket-Barrel (PE/PP) (5-10-15-18-20-25-30kg) - Cardboard box (5-10-12-15-20-25-30-50kg) - Bag-Film (PE/PP) (5-10-15-20-25kg) - Metal Box (5-10-15-20-25kg) - Bait box in PE/PP/PET/PVC <p>The product is supplied in bulk in :</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10kg) - Bucket-Barrel (PE/PP) (5-10kg) - Cardboard box (5-10kg) - Bag-Film (PE/PP) (5-10kg) - Metal Box (5-10kg) - Bait box in PE/PP/PET/PVC

4.1.1. Use-specific instructions

- Remove the remaining product at the end of treatment period.

4.1.2. Use-specific risk mitigation measures

4.1.3. 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.
- 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.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.

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 points 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

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4.1.6. 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

Table 2. HOUSE MICE AND/OR RATS-TRAINED PROFESIONALS -OUTDOOR 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)	<p>Scientific name: Rattus norvegicus Common name: Rats Development stage: juveniles</p> <p>Scientific name: Rattus norvegicus Common name: Rats Development stage: adults</p> <p>Scientific name: Rattus rattus Common name: Rats Development stage: juveniles</p> <p>Scientific name: Rattus rattus Common name: Rats Development stage: adults</p> <p>Scientific name: Mus musculus Common name: Mice Development stage: juveniles</p> <p>Scientific name: Mus musculus Common name: Mice Development stage: adults</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points</p>
Application rate(s) and frequency	<p>Application rate: -</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Bait products:</p> <p><u>Rats (Rattus Rattus & Rattus Norvegicus)</u></p> <p>- High infestation: 180-200 g of bait per baiting point every 5 meters</p> <p>- Low infestation: 180-200 g of bait per baiting point every 10 meters</p> <p><u>Mice (Mus musculus)</u></p>

	<ul style="list-style-type: none"> - High infestation: 30-40 g of bait per baiting point every 1 meter - Low infestation: 30-40 g of bait per baiting point every 2 meters
Category(ies) of users	industrial ; trained professional ; professional
Pack sizes and packaging material	<p>Minimum pack size of 5 kg.</p> <p>The product is supplied in individual PE/PP sachets (10-20-25-30-40-50-60-90-100-200g) wrapped in:</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10-15-20-25-30kg) - Bucket-Barrel (PE/PP) (5-10-15-18-20-25-30kg) - Cardboard box (5-10-12-15-20-25-30-50kg) - Bag-Film (PE/PP) (5-10-15-20-25kg) - Metal Box (5-10-15-20-25kg) - Bait box in PE/PP/PET/PVC <p>The product is supplied in bulk in :</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10kg) - Bucket-Barrel (PE/PP) (5-10kg) - Cardboard box (5-10kg) - Bag-Film (PE/PP) (5-10kg) - Metal Box (5-10kg) - Bait box in PE/PP/PET/PVC

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.2.2. Use-specific risk mitigation measures

4.2.3. 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.

- 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.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals.

- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- Do not use this product in pulsed baiting treatments.

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 points close to surface waters or 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

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4.2.6. 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

Table 3. HOUSE MICE AND/OR RATS-TRAINED PROFESIONALS -OUTDOOR OPEN AREAS AND WASTE DUMPS

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Rattus norvegicus</i> Common name: Rats Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: Rats Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Rats Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Rats Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: Mice Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: Mice Development stage: adults</p>
Field(s) of use	<p>outdoor use Other</p> <p>Outdoor open areas Waste dumps</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points</p>
Application rate(s) and frequency	<p>Application rate: -</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Bait products:</p> <p><u>Rats (<i>Rattus Rattus</i> & <i>Rattus Norvegicaus</i>)</u></p>

	<p>- High infestation: 180-200 g of bait per baiting point every 5 meters</p> <p>- Low infestation: 180-200 g of bait per baiting point every 10 meters</p> <p><u>Mice (Mus Musculus)</u></p> <p>- High infestation: 30-40 g of bait per baiting point every 1 meter</p> <p>- Low infestation: 30-40 g of bait per baiting point every 2 meters</p>
Category(ies) of users	industrial ; trained professional ; professional
Pack sizes and packaging material	<p>Minimum pack size of 5 kg.</p> <p>The product is supplied in individual PE/PP sachets (10-20-25-30-40-50-60-90-100-200g) wrapped in:</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10-15-20-25-30kg) - Bucket-Barrel (PE/PP) (5-10-15-18-20-25-30kg) - Cardboard box (5-10-12-15-20-25-30-50kg) - Bag-Film (PE/PP) (5-10-15-20-25kg) - Metal Box (5-10-15-20-25kg) - Bait box in PE/PP/PET/PVC <p>The product is supplied in bulk in :</p> <ul style="list-style-type: none"> - Bags (paper bags with or without plastic film in PE/PP inside) (5-10kg) - Bucket-Barrel (PE/PP) (5-10kg) - Cardboard box (5-10kg) - Bag-Film (PE/PP) (5-10kg) - Metal Box (5-10kg) - Bait box in PE/PP/PET/PVC

4.3.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.

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- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
 - Remove the remaining product at the end of treatment period.
 - For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.3.2. Use-specific risk mitigation measures

4.3.3. 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.

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 points close to surface waters 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

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4.3.6. 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 USE¹

5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 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
- 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.
- Do not open the sachets containing the bait.
- Place the bait in the bait station using a dosing device.

- Do not transfer the grain into a container other than the original one. If the transfer can not be avoided, wear an APF 10 respirator during the operation.

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

5.2. Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in appropriate collection center.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums.

In severe cases, there may be bruising and blood present in the faeces or urine.

- Antidote: Vitamin K1 administered by medical/veterinary personnel only.

- In case of:

- Dermal exposure, wash skin with water and then with water and soap.

- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed,

seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].

- 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 [insert national phone number]"

- 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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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.