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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

BROMAFAR

Product type(s)

PT14: Rodenticides

Authorisation number: FR-2015-0050

R4BP asset number: FR-0001335-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	BROMAFAR
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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-2015-0050
<i>R4BP asset number</i>		FR-0001335-0000
Date of the authorisation		19/06/2013
Expiry date of the authorisation		31/12/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	SOFAR FRANCE
Address of manufacturer	ZA DU DREVERS BP02 29190 PLEYBEN France
Location of manufacturing sites	ZA DU DREVERS BP02 29190 PLEYBEN France

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

Active substance	Bromadiolone
Name of manufacturer	PM TEZZA SRL
Address of manufacturer	Via tre ponti 22 37050 S. MARIA DI ZEVIO (VR) Italy
Location of manufacturing sites	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 (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	active substance	28772-56-7	249-205-9	0,005

2.2. Type(s) of formulation

Grain bait, ready to use

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H360D: May damage the unborn child.</p> <p>H372: Causes 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: }.</p>
Precautionary statements	<p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P260: Do not breathe dust.</p> <p>P264: Wash ... thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...</p> <p>P308+P313: IF exposed or concerned: Get medical advice/attention.</p> <p>P314: Get medical advice/attention if you feel unwell.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of {0:....:contents container} to {1:....}.</p>

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)	<p>Scientific name: <i>Mus musculus</i> Common name: house mice Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mice Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles</p>
Field(s) of use	<p>indoor use</p> <p>Indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: - 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: Rats: 200 g of bait per bait station separated by 5 to 10 meters, Mice: 40 g of bait per bait station separated by 1 to 2 meters</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Bait products:</p> <p>Rats (<i>Rattus norvegicus</i> & <i>Rattus rattus</i>):</p> <p>- High infestation: 200 g of bait per bait station separated by 5 meters.</p>

	<ul style="list-style-type: none"> - Low infestation: 200 g of bait per bait station separated by 10 meters. <p>House mice (<i>Mus musculus</i>):</p> <ul style="list-style-type: none"> - High infestation: 40 g of bait per bait station separated by 1 meter.. - Low infestation: 40 g of bait per bait station separated by 2 meters.
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>(<i>In France only</i> : <i>minimum pack size of 5 kg</i>)</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits.</p> <p>PE sachets (25-100g) are packed in:</p> <ul style="list-style-type: none"> - Bags (paper/PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-50 kg) - Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg) <p>Loose baits are packed in:</p> <ul style="list-style-type: none"> - Bags (paper/PE) (5-10 kg)

	<ul style="list-style-type: none">- Bucket (PE) (5-10 kg)- Carton box (carton) (5-10 kg)
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4.1.1. Use-specific instructions

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

- [When available] Follow any additional instructions provided by the relevant code of best practice.

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 [in accordance with the applicable code of good practice, if any].

- 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, in line with the recommendations provided by the relevant code of best practice.

- 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. (not relevant in France) – House mice – 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: <i>Mus musculus</i> Common name: house mice Development stage: adults Scientific name: <i>Mus musculus</i> Common name: house mice Development stage: juveniles
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations - [Covered and protected baiting points]
Application rate(s) and frequency	Application rate: 40 g of bait per bait station. Dilution (%): 0 Number and timing of application: House mice (<i>Mus musculus</i>): 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (In France only : <i>minimum pack size of 5 kg</i>) PE sachets (25-100g) are packed in:

	<ul style="list-style-type: none"> - Bags (paper/PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-50 kg) - Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg) <p>Loose baits are packed in:</p> <ul style="list-style-type: none"> - Bags (paper/PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg)
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4.2.1. 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.

- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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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

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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. (not relevant in France) – Rats – 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)	<p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: black or roof rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: black or roof rat Development stage: juveniles</p>
Field(s) of use	<p>indoor use</p> <p>Indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: - 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: 200 g of bait per bait station</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Rats (<i>Rattus norvegicus</i> & <i>Rattus rattus</i>): 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4 meters.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>(</p>

	<p>In France only</p> <p>:</p> <p><i>minimum pack size of 5 kg</i></p> <p>)</p> <p>PE sachets (25-100g) are packed in:</p> <ul style="list-style-type: none"> - Bags (paper/PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-50 kg) - Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg) <p>Loose baits are packed in:</p> <ul style="list-style-type: none"> - Bags (paper/PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg)
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4.3.1. 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.

- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

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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 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).

- [If national policy or legislation requires it] 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.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

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

FOR TRAINED PROFESSIONAL ONLY- 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. Where other elements have been excluded, it is likely that there are resistant rodent 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.

FOR PROFESSIONNALS ONLY 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.

FOR PROFESSIONNALS ONLY Remove the remaining bait or the bait stations at the end of the treatment period.

Instructions for use that are "bait-specific":

- Bait in sachets: [For non-emptiable sachets - Do not open the sachets containing the bait].

- Loose pellets-granules, grains: Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).

- Loose pellets-granules, grains: Decanting is to be avoided. In case decanting cannot be avoided, an RPE of APF 10 has to be used.

5.2. Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [in accordance with the applicable code of good practice, if any].

- 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").

- FOR TRAINED PROFESSIONAL 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.

- FOR TRAINED PROFESSIONAL ONLY 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 accordance with local requirements

- FOR PROFESSIONAL ONLY To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week)..

- FOR PROFESSIONAL ONLY Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- FOR PROFESSIONAL ONLY. 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").

- FOR PROFESSIONAL ONLY 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.

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"

- 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

- Shelf life: 2 years.

- Do not store biocide product above 30°C

- Keep away from light.

- Store in places prevented from the access of children, birds, pets and farm animals.

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.