

**EN**

***ANNEX***

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

**BROMIX**

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** IT/2014/00248/AUT

**R4BP asset number:** IT-0008334-0000

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## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	BROMIX
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	BAUER & BAUER S.N.C.
	Address	via Brigata Marche 129 31030 Carbonera (Treviso) Italy
Authorisation number	IT/2014/00248/AUT	
<i>R4BP asset number</i>	IT-0008334-0000	
Date of the authorisation	08/09/2014	
Expiry date of the authorisation	31/12/2026	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	BAUER & BAUER S.N.C.
Address of manufacturer	VIA BRIGATA MARCHE 129 31030 CARBONERA (TV) Italy
Location of manufacturing sites	VIA BRIGATA MARCHE 129 31030 CARBONERA (TV) Italy

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

Active substance	Bromadiolone
Name of manufacturer	ACTIVA/ DR. TEZZA
Address of manufacturer	VIA TRE PONTI 22 37050 SANTA MARIA DI ZEVIO (VR) Italy
Location of manufacturing sites	VIA TRE PONTI 22 37050 SANTA MARIA DI ZEVIO (VR) Italy

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## 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

RB Bait (ready for use)

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.  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: }.
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.  P270: Do not eat, drink or smoke when using this product.  P280: Wear protective gloves.  P308+P313: IF exposed or concerned: Get medical advice.  P308+P313: IF exposed or concerned: Get medical attention.  P501: Dispose of contents to national legislation.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. trained professional**

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 rattus</i> Common name: roof rat Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse 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: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles</p>
Field(s) of use	<p>indoor use outdoor use Other</p> <p>Indoor, outdoor around buildings, outdoor open areas, outdoor waste dumps, sewers</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Indoor Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Outdoor around buildings Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.- Direct application of ready-to-use bait into the burrow. Outdoor open areas and outdoor waste dumps - Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and</p>

	humans as tamper-resistant bait stations.- Direct application of ready-to-use bait into the burrow. Sewers - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.- [Covered and protected baiting points – only if authorised; see the corresponding additional elements to be considered in addendum 3].
Application rate(s) and frequency	Application rate: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point.  Dilution (%): N.A.  Number and timing of application: 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.
Category(ies) of users	trained professional
Pack sizes and packaging material	<ul style="list-style-type: none"> <li>a) bustine pre-dosate sigillate, in carta alimentare, contenenti g 10-12,5-15-20 di esca rodenticida cadauna, in confezioni a partire da 1.5 kg fino a 25 kg</li> <li>b) sacchetti, cartoni o secchielli a partire da 1.5 kg fino a 25 kg</li> <li>c) barattoli e buste a partire da 1.5 kg fino a 25 kg</li> <li>d) stazioni sigillate pronte all'uso da 250 g (quantità minima per gli utilizzatori professionali 1.5kg)</li> </ul>

#### 4.1.1. Use-specific instructions

##### Indoor

- Remove the remaining product at the end of treatment period

##### Outdoor around buildings

- 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 [Not applicable where explicitly authorised according to addenda 4].

##### Outdoor open areas and outdoor waste dumps

- Protect bait from the atmospheric conditions. Place the bait stations 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
- Follow any additional instructions provided by the relevant code of best practice.

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## Sewers

- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- [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**

#### Indoor

- During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- 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.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- 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.

#### Outdoor around buildings

- During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- 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, in line with the recommendations provided by the relevant code of best practice.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- 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.
- [Unless explicitly authorised according to addendum 4]:  
Do not apply this product directly in the burrows.

#### Outdoor open areas and outdoor waste dumps

- During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- 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.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- 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.

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Sewers

-During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”.

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.

- Do not use this 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**

Indoor

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

Outdoor around buildings

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.

Outdoor open areas and outdoor waste dumps

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.

Sewers

None

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

Indoor

None

Outdoor around buildings

None

Outdoor open areas and outdoor waste dumps

None

Sewers

None



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

##### Indoor

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

##### Outdoor around buildings

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

##### Outdoor open areas and outdoor waste dumps

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

##### Sewers

None

#### 4.2. Use description

**Table 2. professional use**

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 rattus</i>  Common name: roof rat  Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i>  Common name: house mouse  Development stage: adults</p>
Field(s) of use	<p>indoor use  outdoor use</p> <p>Indoor and outdoor around buildings</p>

Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: - for mice 40 g of bait per bait point - for rats 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): N.A.</p> <p>Number and timing of application:</p> <p>Indoor for mice - 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.</p> <p>Indoor for rats - 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.</p> <p>Outdoor around buildings for house mice and/or rats - 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.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>a) bustine pre-dosate sigillate, in carta alimentare, contenenti g 10-12,5-15-20 di esca rodenticida cadauna, in confezioni a partire da 1.5 kg fino a 25 kg</p> <p>b) sacchetti, cartoni o secchielli a partire da 1.5 kg fino a 25 kg</p> <p>c) barattoli e buste a partire da 1.5 kg fino a 25 kg</p> <p>d) stazioni sigillate pronte all'uso da 250 g (quantità minima per gli utilizzatori professionali 1.5kg)</p>

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### **4.2.1. Use-specific instructions**

Indoor for mice

- 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.

Indoor for rats

- 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.

Outdoor around buildings for house mice and/or rats

- 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.

### **4.2.2. Use-specific risk mitigation measures**

### **4.2.3. Use-specific risk mitigation measures**

Indoor

-During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”

Outdoor around buildings

-During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”.

- Do not apply this product directly in the burrows.

### **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**

Indoor

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

Outdoor around buildings

- 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.

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

None

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

Shelf life: 24 months

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## 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

### 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.
  
- Wear protective chemical resistant gloves during product handling phase
  
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

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

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- 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.

- Instructions for use that are "bait-specific":

grain: Place the bait in the baiting point by using a dosage device.

## **5.2. Risk mitigation measures**

-During loose grain transfer operations wear appropriate protective devices for the respiratory tract (respiratory mask disposable EN149 FFP2). Avoid touching the product with bare hands and wear appropriate gloves”

- 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 unless authorised for permanent baiting treatments.

- 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.

## **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:

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- 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: 24 months

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## **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.