

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

RATIBROM 2 PELLETT

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2019/0098/MRA/IT/2013/00144/AUT

R4BP asset number: RO-0008493-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	RATIBROM 2 PELLETT
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Kollant S.r.l.
	Address	Via C.Colombo, 7/7A 30030 Vigonovo Italy
Authorisation number	RO/2019/0098/MRA/IT/2013/00144/AUT	
<i>R4BP asset number</i>	RO-0008493-0000	
Date of the authorisation	14/12/2012	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	KOLLANT SRL
Address of manufacturer	VIA TRIESTE, 49/53 35121 PADOVA Italy
Location of manufacturing sites	VIA C.COLOMBO, 7/7A 30030 VIGONOVO (VE) Italy

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

Active substance	Bromadiolone
Name of manufacturer	ACTIVA SRL
Address of manufacturer	VIALE LOMBARDIA, 22 20131 MILANO Italy
Location of manufacturing sites	Dr TEZZA, 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 % (w/w)

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	EUH401: To avoid risks to human health and the environment, comply with the instructions for use.
Precautionary statements	P102: Keep out of reach of children. P273: Avoid release to the environment. P233: Keep container tightly closed. P234: Keep only in original packaging.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Professional use

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is ready to use and must be used according to the doses below. Do not touch the product with bare hands, but wear suitable gloves. When pouring the bait use suitable gloves and ab antiduct filter face mask FFP2. Place the rodenticide bait in the suitable bait box with proper calibrated dispenser (20 g), protected from the atmospheric agents, the ingestion of non-target species and dispersion in the environment. Observe the area of infestation and place the bait box that contains the bait at the dens, along their routes and places of major attendance. The bait box must be placed at 5-10 meters from each other.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: all Scientific name: Rattus rattus Common name: roof rat Development stage: all Scientific name: Mus musculus Common name: house mouse Development stage: all
Field(s) of use	indoor use outdoor use
Application method(s)	Method: bait application Detailed description: Bait boxes should be placed in a secure manner, in order to minimize the risk oftampering and accidental ingestion of the bait by children or non-targetanimals. Always ensure that Bait boxes are secured properly and that the bait can not be dragged away byrodents. Avoid treatments in the presence of not protected food or feed. Not touse in agriculture. In case of contamination wash hands thoroughly with soap and plenty of water. Do not reuse the bait box and not release to theenvironment, but disposed of in accordance with current rules. In case of suspected ingestion consult a Poison Control Center. The product can bedangerous if ingested by pets or other non-target animals. If swallowed, inducevomiting. Contact your veterinarian immediately and show this container or label.
Application rate(s) and frequency	Application rate: House mouse: 2 dosers (40 g) x 100 sqm Brown rat: 3-5 dosers (60-100 g) x 100sqm Black rat: 3-5 dosers (60-100 g) x 100 sqm Dilution (%): 0 Number and timing of application:

	House mouse: 2 pre-dosed packing (about 40g) x 10 mBrown rat: 3-5 pre-dosed packing (about 60-100g) x 10 mBlack rat: 3-5 pre-dosed packing (about 60-100g) x 10 mReplaced weekly the bait boxes, if necessary. The product is not intended for permanent use, organize treatments lasting up to 6 weeks.
Category(ies) of users	professional
Pack sizes and packaging material	Plastic: composite:, Bag /Sack, 1-3-5-10-20-25 kg Plastic: composite:, Box, 1-3-5-10-20-25 kg

4.1.1. Use-specific instructions

see Directions for use

4.1.2. Use-specific risk mitigation measures

see Directions for use

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

see Directions for use

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

see Directions for use

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

see Directions for use

4.2. Use description

Table 2. Non Professional Use

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is ready to use and must used according to the doses below. The rodenticide bait is placed in an appropriate bait box with proper calibrated dispenser (20g), protected from

	the atmospheric agents, the ingestion of non-target species and dispersion in the environment.
Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: all</p> <p>Scientific name: Rattus rattus Common name: roof rat Development stage: all</p> <p>Scientific name: Mus musculus Common name: house mouse Development stage: all</p>
Field(s) of use	indoor use outdoor use
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait boxes should be placed in a secure manner, in order to minimize the risk of tampering and accidental ingestion of the bait by children or non-target animals. Always ensure that bait boxes are secured properly and that the bait can not be dragged away by rodents. Avoid treatments in the presence of not protected food or feed. Not to use in agriculture. In case of contamination wash hands thoroughly with soap and plenty of water. Do not reuse the bait box and not release to the environment, but disposed of in accordance with current rules. In case of suspected ingestion consult a Poison Control Center. The product can be dangerous if ingested by pets or other non-target animals. If swallowed, induce vomiting. Contact your veterinarian immediately and show this container or label.</p>
Application rate(s) and frequency	<p>Application rate: House mouse: 2 pre-dosed packing x 10 m Brown rat: 3-5 pre-dosed packing x 10 m Black rat: 3-5 pre-dosed packing x 10 m</p> <p>Dilution (%): 0</p> <p>Number and timing of application: House mouse: 2 pre-dosed packing (about 40g) x 10 m Brown rat: 3-5 pre-dosed packing (about 60-100g) x 10 m Black rat: 3-5 pre-dosed packing (about 60-100g) x 10 m Replaced weekly the bait boxes, if necessary. The product is not intended for permanent use, organize treatments lasting up to 6 weeks.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Plastic: composite:, Box, 100-160-200-260-500g Plastic: composite:, Bag /Sack, 100-160-200-260-500g</p>

4.2.1. Use-specific instructions

See Direction for use

4.2.2. Use-specific risk mitigation measures

see Directions for use

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

see Directions for use

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

see Directions for use

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

see Directions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Ready to use product. Observe the are of infestation and place the bait box that contains the bait at the dens, along their routes and places of major attendance.

5.2. Risk mitigation measures

Avoid touching the bait with bare hands and use appropriate gloves.

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

MECHANISM OF ACTION: The active substance in the product is an antagonist competitor of vitamin K and decreases the hepatic synthesis of K-dependent factors.**SYMPTOMS:** severe poisoning from ingestion inhibits vitamin K, causing bleeding skin and mucous haemorrhagies membranes. The symptomatology of the other systems and apparatus is mainly hemorrhagic. **TREATMENT:** In case of ingestion of large quantities, induce vomiting, perform gastric lavage and monitor prothrombin activity, if reduced, administered vitamin K. Follow proper medical protocol.**CONTRAINDICATIONS:** anticoagulants.**Warning:** consult a Poison Control Center.Bait boxes should be placed in a secure manner, in order to minimize the risk of tampering and accidental ingestion of the bait by children or non-target animals. Always ensure that bait boxes are secured properly and that the bait can not be dragged away by rodents. Avoid treatments in the presence of not protected food or feed . Not to use in agriculture. In case of contamination wash hands thoroughly with soap and plenty of water. Do not reuse the bait box and not release to the environment, but disposed of in accordance with current rules. In case of suspected ingestion consult a Poison Control Center. The product can be dangerous if ingested by pets or other non-target animals. If swallowed, induce vomiting. Contact your veterinarian immediately and show this container or label.

5.4. Instructions for safe disposal of the product and its packaging

Keep out of the reach of children. Keep container tightly closed. \Keep away from food, drink and animal feed stuffs.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Keep in a cool, dry, well ventilated areaShelf life of up to 2 years

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

6. OTHER INFORMATION