ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

BROMOTOP Bucati Crocante de Ceara

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2019/0097/MRA/IT/2013/00138/AUT

R4BP asset number: RO-0008359-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	BROMOTOP Bucati Crocante de Ceara
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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/2019/0097/MRA/IT/2013/00138/AUT
R4BP asset number		RO-0008359-0000
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 S.r.l.
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 S.r.l.
Address of manufacturer	Viale Lombardia, 22 20131 Milano Italy
	Dr.Tezza, Via Tre Ponti, 22 37059 Santa 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-ph enylpropyl]-4-hy droxy-2H-1-benz opyran-2-one		28772-56-7	249-205-9	0,005 % (w/w)

2.2. Type(s) of formulation

other - Wax Block

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. The rodenticide bait is placed in an appropriate bait box, protected from the atmospheric agents, the ingestion of nontarget 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. Avoid touching the product with bare hands and use appropriate gloves.
Target organism(s) (including development	Scientific name: Rattus norvegicus
stage)	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 station
	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 to use in agriculture. In case ofcontamination wash hands thoroughly with soap and plenty of water. Do not reusethe bait box and not release to theenvironment, but disposed of in accordance with current rules. In case ofsuspected 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 orlabel.
Application rate(s) and frequency	Application rate: House mouse: 2 bait boxes x 100 qm Brown rat: 3-5 bait boxes x 100 qm Black rat: 3-5 bait boxes x 100 qm Dilution (%): 0 Number and timing of application: House mouse: 2 bait boxes x 100 qm Brown rat: 3-5 bait boxes x 100 qm Black rat: 3-5 bait boxes x 100 qm

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 be used according to the doses below. The rodenticide bait is placed in an appropriate bait box, protected from the atmospheric agents, the ingestion of nontarget species and of dispersal 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. Avoid touching the product with bare hands and use appropriate gloves.

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
indoor use
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 soapand plenty of water. Do not reuse the bait box and not release to theenvironment, but disposed of in accordance with current rules. In case ofsuspected ingestion consult a Poison Control Center. The product can bedangerous if ingested by pets or other nontarget animals. If swallowed, inducevomiting. Contact your veterinarian immediately and show this container or label.
Application rate: House mouse: 2 bait boxes x 100 qm Brown rat: 3-5 bait boxes x 100 qm Black rat: 3-5 bait boxes x 100 qm
Dilution (%): 0
Number and timing of application:
House mouse: 2 bait boxes x 100 qm
Brown rat: 3-5 bait boxes x 100 qm
Black rat: 3-5 bait boxes x 100 qm
general public (non-professional)
Plastic: composite:, Bag /Sack, 100-160-200-260-500g Plastic: composite:, Box, 100-160-200-260-500g

4.2.1. Use-specific instructions

See Directions 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 inst	ructions 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

The product is ready to use and must be used according to the doses indicated.

Replaced weekly the bait boxes, if necessary. Remove as soon as possible dead animals and discarded according to local rules. The product is not intended for permanent use, organize treatments lasting up to 6 weeksAt the end of treatment eliminate bait boxes containing the bait remained, according to current rules. Read carefully the Safety Data Sheet

5.2. Risk mitigation measures

The rodenticide bait is placed in an appropriate bait box, protected from the atmospheric agents, the ingestion of non-target species and of dispersal 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. Avoid touching the product 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 haemorragies 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

Remove as soon as possible dead animals and discarded according to local rules.

At the end of treatment eliminate bait boxes containing the bait remained, according to current rules. Read carefully the Safety Data Sheet

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

Keep in a cool, dry, well ventilated area Shelf 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