

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

MEGAKOL PASTE

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2014/00258/AUT

R4BP asset number: IT-0008704-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	MEGAKOL PASTE
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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	IT/2014/00258/AUT	
<i>R4BP asset number</i>	IT-0008704-0000	
Date of the authorisation	09/03/2016	
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.rl
Address of manufacturer	via Feltre 32 20132 milano Italy
Location of manufacturing sites	Tezza S.r.l-via Tre Ponti 22 37050 S. Maria di Zevio 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

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure Use restricted to professional use..
Precautionary statements	P102: Keep out of reach of children. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P264: Wash your hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P405: Store locked up. P501: Dispose of contents to according to the national rules.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice – professional – 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 mouse Development stage: juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: 40 g pasta bait per bait point. Dilution (%): 0,005 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	From 1,5 Kg up to 25 Kg (containing rodenticide baits of 10 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester

4.1.1. 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.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

4.2. Use description

Table 2. Rats – professional – 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>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: 60-100 g per bait station. Dilution (%): 0,005 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	From 1,5 Kg up to 25Kg (containing rodenticide baits of 10 g in sachets of pasta bait). Packaging material: PE/Aluminium/Polyester.

4.2.1. 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.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

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

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

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

4.3. Use description

Table 3. House mice and Rats – professionals – 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)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles to adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	Other Around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use pasta bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: House mice: 40 g pasta bait per bait point Brown rat: 60-100 g pasta bait per bait point Dilution (%): 0,005 Number and timing of application: 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.

Category(ies) of users	professional
Pack sizes and packaging material	Number of packed bags per packaging: Grams/kg of bait per packed bag: from 1,5 Kg up to 25Kg (containing rodenticide baits of 10 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.

4.3.1. Use-specific instructions

- 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.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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 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.

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

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

4.4. Use description

Table 4. Mice and rats-trained professionals-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)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	outdoor use

	outdoor open areas outdoor waste dumps
Application method(s)	Method: bait application Detailed description: 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
Application rate(s) and frequency	Application rate: Bait products: - High infestation: (100) g of bait per baiting point. - Low infestation: (60) g of bait per baiting point. Dilution (%): 0.005 Number and timing of application: Bait products: - High infestation: (100) g of bait per baiting point. - Low infestation: (60) g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	Number of packed bags per packaging: Grams/kg of bait per packed bag: from 1,5 Kg up to 25Kg (containing rodenticide baits of 10 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.

4.4.1. Use-specific instructions

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.

for application in covered and protected bait points:

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.- Follow any additional instructions provided by the relevant code of best practice.

for direct application in burrows:

Baits must be placed to minimise the exposure to non-target species and children.

- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

4.4.2. Use-specific risk mitigation measures

4.4.3. 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 in pulsed baiting treatments.

in case of direct application in burrows:

Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign

4.4.4. 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 (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

shelf life 24 months.

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.

4.5. Use description

Table 5. Rats-trained professionals-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)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to Adults
Field(s) of use	Other sewers
Application method(s)	Method: bait application Detailed description: - 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.
Application rate(s) and frequency	Application rate: Bait products: - High infestation: (100) grams per manhole. - Low infestation: (60) grams per manhole. Dilution (%): 0.005 Number and timing of application: Bait products: - High infestation: (100) grams per manhole. - Low infestation: (60) grams per manhole.
Category(ies) of users	trained professional
Pack sizes and packaging material	Number of packed bags per packaging: Grams/kg of bait per packed bag: from 1,5 Kg up to 25Kg (containing rodenticide baits of 10 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.

4.5.1. Use-specific instructions

- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.

4.5.2. Use-specific risk mitigation measures

4.5.3. Use-specific risk mitigation measures

- Place baits only in sewer systems which are connected to the sewage treatment plant.

- Do not use this product in pulsed baiting treatments.

4.5.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

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

4.6. Use description

Table 6. Mice and 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: <i>Mus musculus</i> Common name: house mouse Development stage: Juveniles to Adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Juveniles to adults
Field(s) of use	indoor use
Application method(s)	Method: bait application Detailed description: 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.
Application rate(s) and frequency	Application rate: House mice: 40 g pasta bait per bait point Brown rat: 60-100 g pasta bait per bait point Dilution (%): 0.005 Number and timing of application: House mice: 40 g pasta bait per bait point Brown rat: 60-100 g pasta bait per bait point
Category(ies) of users	trained professional
Pack sizes and packaging material	Number of packed bags per packaging: Grams/kg of bait per packed bag: from 1,5 Kg up to 25Kg (containing rodenticide baits of 10 g in sachets of pasta bait) Packaging material: PE/Aluminium/Polyester.

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4.6.1. Use-specific instructions

Remove the remaining product at the end of treatment period.

4.6.2. Use-specific risk mitigation measures

4.6.3. 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 in pulsed baiting treatments.

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

4.6.4. 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.

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

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

shelf life 24 months.

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.

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.
- 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.
- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (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.
- 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.
- Wear protective chemical resistant gloves during product handling phase (PPE).
- 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.
- 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. 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]".
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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

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

- 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.
- Do not wash the bait stations 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:
 - Dermal exposure, wash skin with water and then with water and soap.
 - Eye exposure, always check for and remove contact lenses, rinse eyes with eyes-rinse liquid or water, keep eye 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: 2 years

6. OTHER INFORMATION

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after 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.