

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

AVOINE DECORTIQUEE

Product type(s)

PT14: Rodenticides

Authorisation number: FR-2015-0015

R4BP asset number: FR-0009983-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	AVOINE DECORTIQUEE GRAINS BROMA RATY PLUS 25 GRAIN BM 25 DUAL GRAIN BROMA KILL
---------------	---

1.2. Authorisation holder

Name and address of the authorisation holder	Name	LODI S.A.S.
	Address	Parc d'activités des Quatre Routes 35390 Grand Fougeray France
Authorisation number	FR-2015-0015	
<i>R4BP asset number</i>	FR-0009983-0000	
Date of the authorisation	30/09/2012	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	CGB (Compagnie Générale des biocides)
Address of manufacturer	Parc d'activité des quatre routes 35390 Grand Fougeray France
Location of manufacturing sites	Parc d'activité des quatre routes 35390 Grand Fougeray France

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

Active substance	Bromadiolone
Name of manufacturer	PelGar International Ltd
Address of manufacturer	Unit 13 Newman Lane Industrial Estate GU34 2 QR Alton. Hants United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Unit 13 Newman Lane Industrial Estate GU34 2 QR Alton. Hants United Kingdom of Great Britain and Northern Ireland (the)

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	0,0025

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause 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	P260: Do not breathe dust. P314: Get medical advice if you feel unwell. P501: Dispose of container to in accordance with local regulation.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice – general public – 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: Adults & Juveniles
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. 25 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2 to 5 meters.
Application rate(s) and frequency	Application rate: 25 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2 to 5 meters. Dilution (%): 0 Number and timing of application: 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.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	PP or PE individual sachet (25-50 g) are packed in: - Pre-baited station in PP, PS or PVC packed carton sleeve (up to 50 g) - Cardboard box (up to 50 g) - Plastic can in PP or PE (up to 50 g) - Metal box (up to 50 g)

	<p>Tea paper sachet (10 g) are packed in:</p> <p>- Pouch in PE/MET-PET/PET, PET/PE, PE, OPP or PET/PE with zip (20-30-40-50 g)</p> <p>Maximum pack size: 50 g</p>
--	---

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. Field mice – general public – 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>Apodemus sylvaticus</i> Common name: Field mice Development stage: Adults & Juveniles
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
Application rate(s) and frequency	Application rate: 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2 to 5 meters. Dilution (%): 0 Number and timing of application: 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.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	PP or PE individual sachet (25-50 g) are packed in: - Pre-baited station in PP, PS or PVC packed carton sleeve (up to 150 g) - Cardboard box (up to 150 g) - Plastic can in PP or PE (up to 150 g) - Metal box (up to 150 g) Tea paper sachet (10 g) are packed in: - Pouch in PE/MET-PET/PET, PET/PE, PE, OPP or PET/PE with zip (20-30-40-50-90-100-110-120-130-140-150 g) Maximum pack size: 150 g

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

/

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. Rats – general public – 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: Adults & Juveniles Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	indoor use
Application method(s)	Method: bait application

	Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations.
Application rate(s) and frequency	<p>Application rate: 50-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: 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>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>PP or PE individual sachet (25-50-100 g) are packed in:</p> <ul style="list-style-type: none"> - Pre-baited station in PP, PS or PVC packed carton sleeve (up to 150 g) - Cardboard box (up to 150 g) - Plastic can in PP or PE (up to 150 g) - Metal box (up to 150 g) <p>Tea paper sachet (10 g) are packed in:</p> <ul style="list-style-type: none"> - Pouch in PE/MET-PET/PET, PET/PE, PE, OPP or PET/PE with zip (20-30-40-50-90-100-110-120-130-140-150 g) <p>Maximum pack size: 150 g</p>

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.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

/

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

/

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. Rats – general public – 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: Adults & Juveniles Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	outdoor use Other outdoor around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: 50-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. Dilution (%): 0

	<p>Number and timing of application:</p> <ul style="list-style-type: none"> - Place the bait stations in areas not liable to flooding. - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. - 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.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>PP or PE individual sachet (25-50-100 g) are packed in:</p> <ul style="list-style-type: none"> - Pre-baited station in PP, PS or PVC packed carton sleeve (up to 150 g) - Cardboard box (up to 150 g) - Plastic can in PP or PE (up to 150 g) - Metal box (up to 150 g) <p>Tea paper sachet (10 g) are packed in:</p> <ul style="list-style-type: none"> - Pouch in PE/MET-PET/PET, PET/PE, PE, OPP or PET/PE with zip (20-30-40-50-90-100-110-120-130-140-150 g) <p>Maximum pack size: 150 g</p>

4.4.1. Use-specific instructions

- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- 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.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

/

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

/

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

/

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.

- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

- 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.

- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

- Where possible, bait stations must be fixed to the ground or other structures.

- Do not open the sachets containing the bait.

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- Do not place bait stations near water drainage systems where they can come into contact with water.

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

- Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

- 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.

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

- The product information (i.e. label and/or leaflet) shall clearly show that:

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

- 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.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

5.3. 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 [insert national phone number]".

- Hazardous to wildlife.

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

- At the end of the treatment, dispose 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].
Use of gloves is recommended.

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.

[Where relevant under Annex III to the CLP Regulation] The package of the product has been tested for child resistance.