ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

MUSKIL WAX BLOCK

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70607

R4BP asset number: IE-0000337-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	MUSKIL WAX BLOCK
	DIAVLON BLOCK
	MUSKIL BLOCK

1.2. Authorisation holder

Name and address of the authorisation holder	Name	ZAPI S.p.A.
	Address	via Terza Strada 12 35026 Conselve Italy
Authorisation number		IE/BPA 70607
R4BP asset number		IE-0000337-0000
Date of the authorisation		02/05/2013
Expiry date of the authorisation		31/12/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	ZAPI S.p.A.
Address of manufacturer	Via Terza Strada 12 35026 Conselve (PD) Italy
Location of manufacturing sites	Via Terza Strada 12 35026 Conselve (PD) Italy

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

Active substance	Difenacoum
Name of manufacturer	PM TEZZA S.r.l.
Address of manufacturer	Via del Lavoro 326 37050 Angiari Italy
Location of manufacturing sites	Via Tre Ponti 22 37050 S. Maria di Zevio (VR) Italy

Active substance	Bromadiolone
Name of manufacturer	PM TEZZA S.r.l.
Address of manufacturer	Via del Lavoro 326 37050 Angiari Italy
Location of manufacturing sites	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 (%)
Difenacoum	3-(3-biphenyl-4- yl-1,2,3,4- tetrahydro-1- naphthyl)-4- hydroxycoumarin	active substance	56073-07-5	259-978-4	0,0025
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:}. H360D: May damage the unborn child. EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May
	produce an allergic reaction.
Precautionary statements	P201: Obtain special instructions before use.
	P202: Do not handle until all safety precautions have been read and understood.
	P280: Wear protective gloves.
	P314: Get medical advice if you feel unwell.
	P314: Get medical attention if you feel unwell.
	P405: Store locked up.
	P501: Dispose of contents to local regulations.
	P501: Dispose of container to local regulations.
	P260: Do not breathe dust.
	P308+P313: IF exposed or concerned: Get medical advice.
	P308+P313: IF exposed or concerned: Get medical attention.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1# - House mice and/or rats - Professional users with demonstrated competence (equivalent to 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: Mus musculus Common name: house mouse Development stage: all Scientific name: Rattus norvegicus Common name: brown rat Development stage: all
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations- Covered and protected baiting points
Application rate(s) and frequency	Application rate: Rats - Up to 100 g of bait per baiting point. Mice - Up to 50 g of bait per baiting point. Dilution (%): Ready-to-use Number and timing of application: Rats: High infestation: Up to 100 g of bait per baiting point spaced 5m apart. Low infestation: Up to 100 g of bait per baiting point spaced 10m apart. Mice: High infestation: Up to 50 g of bait per baiting point spaced 2m apart. Low infestation: Up to 50 g of bait per baiting point spaced 5m apart. Low infestation: Up to 50 g of bait per baiting point spaced 5m apart.
Category(ies) of users	trained professional
Pack sizes and packaging material	Labelled plastic (PP) bucket with/without inner neutral plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 15kg

Labelled plastic (PP) bucket with product in inner plastic (PE) bags or in single dose plastic (COEX) bags (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 10kg
Labelled fibre-board carton with inner plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks), loose, or in printed plastic (PE) bags or in single dose plastic (COEX) bags – 2.5 kg to 15kg

4.1.1. Use-specific instructions

- Remove the remaining product at the end of treatment period.
- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- 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

- 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.
- Do not use the product in pulsed baiting treatments.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting statergy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

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

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

See Section 5.4 Trained Professionals

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

See Section 5.5

4.2. Use description

Table 2. Use 2# - House mice and/or rats - Professional users with demonstrated competence (equivalent to 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)	Common name: house mouse Development stage: all Scientific name: Rattus norvegicus
	Common name: brown rat Development stage: all
Field(s) of use	outdoor use
	Outdoor around buildings
Application method(s)	Method: bait application
	Detailed description: - Ready-to-use bait to be used in tamper- resistant bait stations- Covered and protected baiting points
Application rate(s) and frequency	Application rate: Rats - Up to 100 g of bait per baiting point. Mice - Up to 50 g of bait per baiting point.
	Dilution (%): Ready-to-use
	Number and timing of application:
	Rats: High infestation: Up to 100 g of bait per baiting point spaced 5m apart. Low infestation: Up to 100 g of bait per baiting point spaced 10m apart.
	Mice: High infestation: Up to 50 g of bait per baiting point spaced 2m apart. Low infestation: Up to 50 g of bait per baiting point spaced 5m apart.
Category(ies) of users	trained professional
Pack sizes and packaging material	Labelled plastic (PP) bucket with/without inner neutral plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 15kg

Labelled plastic (PP) bucket with product in inner plastic (PE) bags or in single dose plastic (COEX) bags (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 10kg
Labelled fibre-board carton with inner plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks), loose, or in printed plastic (PE) bags or in single dose plastic (COEX) bags – 2.5 kg to 15kg

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Where possible, it is recommended that the treated area is revisted every 4 weeks at the latest in order to avoid any selection of a resistant population.
- Remove the remaining product at the end of treatment period.
- 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.

4.2.2. Use-specific risk mitigation measures

4.2.3. 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.
- 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.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly to burrows.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- 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.

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

See Section 5.4 Trained professionals

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

See section 5.5

4.3. Use description

Table 3. Use 3# - House mice and/or rats - professional users - 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: Mus musculus Common name: house mouse Development stage: all Scientific name: Rattus norvegicus Common name: brown rat Development stage: all	
Field(s) of use	indoor use Indoor	
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: Rats - Up to 100 g of bait per baiting point. Mice - Up to 50 g of bait per baiting point. Dilution (%): Ready-to-use Number and timing of application: Rats - Up to 100 g of bait per baiting station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters. Mice - Up to 50 g of bait per baiting station. If more than one bait station is needed, the minimum distance between bait stations should be 2 meters.	

Category(ies) of users	professional
Pack sizes and packaging material	Labelled plastic (PP) bucket with/without inner neutral plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 15kg Labelled plastic (PP) bucket with product in inner plastic (PE) bags or in single dose plastic (COEX) bags (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 10kg Labelled fibre-board carton with inner plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks), loose, or in printed plastic (PE) bags or in single dose plastic (COEX) bags – 2.5 kg to 15kg

4.3.1. Use-specific instructions

- For mice: The baiting 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.
- 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.
- Follow any additional instructions provided by the relevant code of best practice.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

See Section 5.2 Professional users

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 points close to 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

See section 5.4 Professional users

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

See Section 5.5

4.4. Use description

Table 4. Use 4# - House mice and/or rats - professional users - 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: Mus musculus Common name: house mouse Development stage: all Scientific name: Rattus norvegicus Common name: brown rat Development stage: all	
Field(s) of use	outdoor use Outdoor around buildings.	
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: Rats - Up to 100 g of bait per baiting point. Mice - Up to 50 g of bait per baiting point. Dilution (%): Ready-to-use Number and timing of application: Rats - Up to 100 g of bait per baiting station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters. Mice - Up to 50 g of bait per baiting station. If more than one bait station is needed, the minimum distance between bait stations should be 2 meters.	
Category(ies) of users	professional	
Pack sizes and packaging material	Labelled plastic (PP) bucket with/without inner neutral plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 15kg	

Labelled plastic (PP) bucket with product in inner plastic (PE) bags or in single dose plastic (COEX) bags (5, 10, 20, 25, 50, 75, 80 and 100g blocks) – 2.5 kg to 10kg
Labelled fibre-board carton with inner plastic (PE) liner (5, 10, 20, 25, 50, 75, 80 and 100g blocks), loose, or in printed plastic (PE) bags or in single dose plastic (COEX) bags – 2.5 kg to 15kg

4.4.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-liable to flooding.
- For mice: The baiting 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.
- 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.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

See Section 5.4 Professional users.

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

See Section 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Trained professionals:

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).
- 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 (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 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.

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.

Professional Users:

- 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.

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

- 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 (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 (glove material to be specified by the authorisation holder within the product information).
- 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 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

Trained Professionals:

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- 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 permanent baiting).
- 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.
- 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").

Professional Users:

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 at frequent intervals during treatment (e.g. at least twice a week).
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- 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").

- 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, 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 accident, call a poison centre".

- Hazardous to wildlife.
- Poison Information: For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166) retain the label for reference

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 If required, consult a professional waste operator or local authority.

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.
- Use Biocides Safely and Sustainably
- It is illegal to use this product for uses or in a manner other than that prescribed on this label.
- Poison Information: For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference.
- Please note IRELAND applies a minimum Professional pack size of 2.5 Kg instead of 3.0 kg.