

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Ratimor brodifacoum wax blocks

Product type(s)

PT14: Rodenticides

Authorisation number: 2021-08-20-B02

R4BP asset number: MT-0026922-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Ratimor brodifacoum wax blocks
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Unichem d.o.o.
	Address	Sinja Gorica 2 SI 1360 Vrhnika Slovenia
Authorisation number	2021-08-20-B02	
<i>R4BP asset number</i>	MT-0026922-0000	
Date of the authorisation	06/08/2013	
Expiry date of the authorisation	31/12/2025	

1.3. Manufacturer(s) of the product

Name of manufacturer	Unichem d.o.o
Address of manufacturer	Sinja Gorica 2 1360 Vrhnika Slovenia
Location of manufacturing sites	Sinja Gorica 2 1360 Vrhnika Slovenia

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

Active substance	Brodifacoum
Name of manufacturer	Activa Srl
Address of manufacturer	Via Feltre 32 20132 Milan 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 (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0029

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:}. EUH208: Contains octhilinone (ISO); 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
Precautionary statements	P260: Do not breathe dust. P314: Get medical advice if you feel unwell. P501: Dispose of container to in accordance with local regulations. P102: Keep out of reach of children.

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: 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: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. Dilution (%): 0 Number and timing of application: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Loose 5g - 20g blocks (with or without hook/wire): - in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes (fitted with tactile warning) up to 100g - in PE or PP packs (fitted with tactile warning) up to 100g - in PE or PP containers (fitted with tactile warning) up to 100g - in PE or PP buckets (fitted with tactile warning) up to 100g - in cardboard or fibreboard boxes (fitted with tactile warning) up to 100g - in cardboard or fibreboard boxes with PE bag or liner (fitted with tactile warning) up to 100g - Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g - 20g (up to 20 g total bait per mouse bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 100g - Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g - 20g (up to 20 g total bait per mouse bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 100g

	- HDPE or PP rat bait station (refillable or single use) containing one or more 5g – 200g (up to 20 g total bait per mouse bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 100g
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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

See 5.2

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

See 5.3

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

See 5.4

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

See 5.5

4.2. Use description

Table 2. 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: all

	<p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: all</p>
Field(s) of use	<p>indoor use</p> <p>Indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.</p>
Application rate(s) and frequency	<p>Application rate: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p>
Category(ies) of users	<p>general public (non-professional)</p>
Pack sizes and packaging material	<p>Loose 5g - 60g blocks (with or without hook/wire):</p> <ul style="list-style-type: none"> - in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in PE or PP packs (fitted with tactile warning) up to 300g - in PE or PP containers (fitted with tactile warning) up to 300g - in PE or PP buckets (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes with PE bag or liner (fitted with tactile warning) up to 300g - Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g - Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g - HDPE or PP rat bait station (refillable or single use) containing one or more 5g – 60g (up to 60g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g

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

See 5.2

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

See 5.3

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

See 5.4

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

See 5.5

4.3. Use description

Table 3. 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: all Scientific name: <i>Rattus rattus</i> Common name: roof 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	<p>Application rate: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Loose 5g - 60g blocks (with or without hook/wire):</p> <ul style="list-style-type: none"> - in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in PE or PP packs (fitted with tactile warning) up to 300g - in PE or PP containers (fitted with tactile warning) up to 300g - in PE or PP buckets (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes with PE bag or liner (fitted with tactile warning) up to 300g - Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g - Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g - HDPE or PP rat bait station (refillable or single use) containing one or more 5g – 60g (up to 60g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g

4.3.1. 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.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

See 5.2

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

See 5.3

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

See 5.4

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

See 5.5

4.4. Use description

Table 4. House mice - 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: 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: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. Dilution (%): 0 Number and timing of application: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.

Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg</p> <p>Loose 5 g - 20 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg</p> <p>Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 20 g (up to 20 g total bait per mouse bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p> <p>HDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 20 g (up to 20 g total bait per mouse bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p>

4.4.1. 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.

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

See 5.2

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 stations close to 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 5.4

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

See 5.5

4.5. Use description

Table 5. Rats - 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>Rattus norvegicus</i> Common name: brown rat Development stage: all Scientific name: <i>Rattus rattus</i> Common name: roof 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	<p>Application rate: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg</p> <p>Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p>

	HDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg
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4.5.1. 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.

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

See 5.2

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

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

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

See 5.4

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

See 5.5

4.6. Use description

Table 6. House mice and/or rats - 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>Mus musculus</i> Common name: house mouse

	<p>Development stage: all</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: all</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: all</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.</p>
Application rate(s) and frequency	<p>Application rate: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg</p>

	<p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg</p> <p>Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p> <p>HDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p>
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4.6.1. 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.

Follow any additional instructions provided by the relevant code of best practice.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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 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.

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

See 5.4

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

See 5.5

4.7. Use description

Table 7. House mice and/or 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: all Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: all Scientific name: <i>Rattus rattus</i> Common name: roof 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. Ready-to-use bait to be used in covered and protected baiting points.
Application rate(s) and frequency	Application rate: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations. Dilution (%): 0 Number and timing of application: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.
Category(ies) of users	trained professional

<p>Pack sizes and packaging material</p>	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg</p> <p>Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p> <p>HDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p>
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4.7.1. Use-specific instructions

Remove the remaining product at the end of treatment period.

If used for pulsed baiting: Replace eaten bait only after 3 days and than at maximum 7 day intervals. Collect any spilled bait and dead rodents.

Follow any additional instructions provided by the relevant code of best practice.

4.7.2. Use-specific risk mitigation measures

4.7.3. 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 as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

4.7.4. 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.

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

See 5.4

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

See 5.5

4.8. Use description

Table 8. House mice and/or 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>Mus musculus</i> Common name: house mouse Development stage: all Scientific name: <i>Rattus norvegicus</i>

	<p>Common name: brown rat Development stage: all</p> <p>Scientific name: Rattus rattus Common name: roof rat Development stage: all</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations. Ready-to-use bait to be used in covered and protected baiting points. Direct application of ready-to-use bait into the burrow.</p>
Application rate(s) and frequency	<p>Application rate: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg</p>

	<p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg</p> <p>Loose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg</p> <p>Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p> <p>HDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg</p>
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4.8.1. Use-specific instructions

Protect bait from the atmospheric conditions. Place the baiting points 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. If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents. 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. When applied directly into the burrow: 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.

4.8.2. Use-specific risk mitigation measures

4.8.3. 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 as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

4.8.4. 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.

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

See 5.4

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

See 5.5

4.9. Use description

Table 9. Rats - trained professionals - sewers

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: all
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. Ready-to-use bait to be anchored or applied in covered and protected baiting points preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Application rate: For rat infestations in sewers use 10 g up to 200g per manhole. For high rat infestations in sewers use 200g per manhole. Dilution (%): 0 Number and timing of application: For rat infestations in sewers use 10 g up to 200g per manhole. For high rat infestations in sewers use 200g per manhole.

Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Maximum outer pack size up to 25 kg.</p> <ul style="list-style-type: none"> - Loose 10 g - 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg - Loose 10 g - 200 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg - Loose 10 g - 200 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg - Loose 10 g - 200 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg - Loose 10 g - 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg - Loose 10 g - 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg - Loose 10 g - 200 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg - Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 10 g - 200 g (up to 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg - HDPE or PP rat bait station (refillable or single use) containing one or more blocks of 10 g - 200 g (up to 200 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg

4.9.1. 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.

4.9.2. Use-specific risk mitigation measures

4.9.3. 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 or as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

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

See 5.3

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

See 5.4

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

See 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

General public:

- 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 - where relevant for the bait formulation in the product].
- 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.
- Prevent skin contact when disposing remains of baits.

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.
- 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 (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation require it] 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 (EN374).
- 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

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

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.

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).

- [If national policy or legislation requires it] 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 (EN374).

- 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.

5.2. Risk mitigation measures

General public:

- 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:

- 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.

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- 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].

Professionals:

- 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").
 - 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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

Trained professionals:

- Where possible, prior to the treatment inform any possible bystanders about the rodent control.
- 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").
- 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.
- 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 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. For information or to report a poisoning incident contact 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 [tel.: ...]".

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. This material and its container must be disposed of safely. Dispose of packaging, remains of unused product and dead rodents in accordance with local regulations. If required, consult a professional waste operator or local authority.

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.

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

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.

The dye can be either Durazol red 2BN 110 liquid OR Ecozol blue N liquid at a concentration of 0.08% w/w.

In accordance with Commission Implementing Regulation (EU) 2017/1381, the maximum amount of bait (wax blocks) of 300 g per pack is allowed for combined packaging against mice and rats intended for use by the general public

Correct P statements are:

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local regulations.