

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Vertox Whole Wheat Bait

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70538 1-1

R4BP asset number: IE-0012375-0001

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Vertox Whole Wheat Bait (red)
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	PelGar International Limited
	Address	18 rue des Remparts d'Ainay 69002 Lyon France
Authorisation number	IE/BPA 70538 1-1	
<i>R4BP asset number</i>	IE-0012375-0001	
Date of the authorisation	01/07/2015	
Expiry date of the authorisation	01/07/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	PelGar International Limited GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Prazska 54 280 02 Kolin Czechia

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	0,005
Durazol red 2BN Liquid		Non-active substance	64683-40-5		0,08

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>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: }.</p> <p>H360D: May damage the unborn child.</p> <p>H317: May cause an allergic skin reaction.</p> <p>EUH208: Contains 1,2-benzisothiazolin-3-one and 2-octyl-2H-isothiazol-3-one. May produce an allergic reaction.</p>
Precautionary statements	<p>P280: Wear protective gloves.</p> <p>P404: Store in a closed container.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of container to in accordance with local regulations.</p> <p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P260: Do not breathe dust.</p> <p>P308+P313: IF exposed or concerned: Get medical advice.</p> <p>P314: Get medical advice if you feel unwell.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. 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
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: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Dilution (%): 0 Number and timing of application: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg 15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg Loose bait: in PE/PP packs (tubs, pails or pouches), in PE lined carton Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg

Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers

Pack sizes:

Multiples

10g – 250

15g – 250

20g – 120

25g – 120, 144

30g – 96, 120, 144

40g – 72, 96, 120, 144

50g – 60, 72, 96, 120, 144

60g – 48, 60, 72, 96, 120

Loose bait of up to packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper

Pack sizes:

Multiples

10g – 250

15g – 250

20g – 120

25g – 120, 144

30g – 96, 120, 144

40g – 72, 96, 120, 144

50g – 60, 72, 96, 120, 144

60g – 48, 60, 72, 96, 120

80g – 32, 48, 60, 72, 96

90g – 32, 48, 60, 72, 96

100g – 32, 48, 60, 72, 96

120g – 24, 32, 48, 60, 72

200g – 16, 24, 32, 48, 60

240g – 16, 24, 32, 48, 60

4.1.1. Use-specific instructions

For mice secure 5 to 20 g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active.

Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped.

Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

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.

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

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

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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.

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

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 stations 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

None

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

None

4.2. Use description

Table 2. 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
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: 10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation). Dilution (%): 0 Number and timing of application: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg 15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/AL/PE sachets: in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg Loose bait: in PE/PP packs (tubs, pails or pouches), in PE lined carton Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg Package is restricted to separately packed bags with a maximum bag size of 10 kg.

	<p>Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers</p> <p>Pack sizes:</p> <p>Multiples</p> <p>10g – 250</p> <p>15g – 250</p> <p>20g – 120</p> <p>25g – 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120, 144</p> <p>50g – 60, 72, 96, 120, 144</p> <p>60g – 48, 60, 72, 96, 120</p> <p>Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper</p> <p>Pack sizes:</p> <p>Multiples</p> <p>10g –250</p> <p>15g - 250</p> <p>20g – 120</p> <p>25g – 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120, 144</p> <p>50g – 60, 72, 96, 120, 144</p> <p>60g – 48, 60, 72, 96, 120</p> <p>80g – 32, 48, 60, 72, 96</p> <p>90g – 32, 48, 60, 72, 96</p> <p>100g – 32, 48, 60, 72, 96</p> <p>120g – 24, 32, 48, 60, 72</p> <p>200g – 16, 24, 32, 48, 60</p> <p>240g – 16, 24, 32, 48, 60</p>
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4.2.1. Use-specific instructions

For rat infestations use 10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.

Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.

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.

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

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

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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.

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

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 stations close to 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

None

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

None

4.3. Use description

Table 3. 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> and/or <i>Rattus norvegicus</i> Common name: House mouse and/or 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: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres Dilution (%): 0 Number and timing of application: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.

Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg

15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets:

in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers

Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg

Loose bait:

in PE/PP packs (tubs, pails or pouches), in PE lined carton

Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg

Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers

Pack sizes:

Multiples

10g – 250

15g – 250

20g – 120

25g – 120, 144

30g – 96, 120, 144

40g – 72, 96, 120, 144

50g – 60, 72, 96, 120, 144

60g – 48, 60, 72, 96, 120

	<p>Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper</p> <p>Pack sizes:</p> <p>Multiples</p> <p>10g –250</p> <p>15g - 250</p> <p>20g – 120</p> <p>25g – 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120, 144</p> <p>50g – 60, 72, 96, 120, 144</p> <p>60g – 48, 60, 72, 96, 120</p> <p>80g – 32, 48, 60, 72, 96</p> <p>90g – 32, 48, 60, 72, 96</p> <p>100g – 32, 48, 60, 72, 96</p> <p>120g – 24, 32, 48, 60, 72</p> <p>200g – 16, 24, 32, 48, 60</p> <p>240g – 16, 24, 32, 48, 60</p>
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4.3.1. Use-specific instructions

For mice secure 5 to 20 g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

For rat infestations use 10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

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

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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.

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

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

When placing bait stations close to 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

None

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

None

4.4. Use description

Table 4. 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> and/or <i>Rattus norvegicus</i> Common name: House mouse and/or Brown rat Development stage: All
Field(s) of use	indoor use Indoors
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres Dilution (%): 0 Number and timing of application: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres

Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg</p> <p>15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg</p> <p>Loose bait: in PE/PP packs (tubs, pails or pouches), in PE lined carton Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg</p> <p>Package is restricted to separately packed bags with a maximum bag size of 10 kg.</p> <p>Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers Pack sizes: Multiples 10g – 250 15g – 250 20g – 120 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120</p> <p>Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Pack sizes: Multiples 10g –250 15g - 250 20g – 120 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72</p>

200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60
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4.4.1. Use-specific instructions

Remove the remaining product at the end of treatment period.

[When available] Follow any additional instructions provided by the relevant code of best practice.

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. Follow the specific instructions provided by the applicable code of good practice at national level.

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.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

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.

Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

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

None

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

None

4.5. Use description

Table 5. 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> and/or <i>Rattus norvegicus</i> Common name: House mouse and/or 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 covered bait points or in tamper-resistant bait stations or direct application of ready-to-use bait into the burrow
Application rate(s) and frequency	Application rate: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres Dilution (%): 0 Number and timing of application: Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres

	<p>Low infestation – 10 to 60g bait in bait stations every 10 metres</p> <p>Burrow baiting: 10 to 60 g of bait per burrow</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg</p> <p>15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg</p> <p>Loose bait: in PE/PP packs (tubs, pails or pouches), in PE lined carton Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg</p> <p>Package is restricted to separately packed bags with a maximum bag size of 10 kg.</p> <p>Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers Pack sizes: Multiples 10g – 250 15g – 250 20g – 120 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120</p> <p>Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Pack sizes: Multiples 10g –250 15g - 250 20g – 120</p>

25g – 120, 144
30g – 96, 120, 144
40g – 72, 96, 120, 144
50g – 60, 72, 96, 120, 144
60g – 48, 60, 72, 96, 120
80g – 32, 48, 60, 72, 96
90g – 32, 48, 60, 72, 96
100g – 32, 48, 60, 72, 96
120g – 24, 32, 48, 60, 72
200g – 16, 24, 32, 48, 60
240g – 16, 24, 32, 48, 60

4.5.1. Use-specific instructions

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

When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

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.

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.

[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.

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

Remove the remaining product at the end of treatment period.

Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

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. [When available] Follow the specific instructions provided by the applicable code of good practice at national level

4.5.2. Use-specific risk mitigation measures

4.5.3. 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

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.

When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

Wear protective chemical resistant gloves during product handling phase (EN374).

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 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.

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

None

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

None

4.6. Use description

Table 6. 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.
Application rate(s) and frequency	Application rate: In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole). Dilution (%): 0 Number and timing of application: In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Up to 20kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.
Pack sizes: 2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg

15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets:

in PE/PP packs (tubs, pails or pouches), in PE lined carton, in fibreboard carton/cardboard outers

Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg

Loose bait:

in PE/PP packs (tubs, pails or pouches), in PE lined carton

Pack sizes: 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg, 20kg

Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers

Pack sizes:

Multiples

10g – 250

15g – 250

20g – 120

25g – 120, 144

30g – 96, 120, 144

40g – 72, 96, 120, 144

50g – 60, 72, 96, 120, 144

60g – 48, 60, 72, 96, 120

Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper

Pack sizes:

Multiples

10g –250

15g - 250

20g – 120

25g – 120, 144

30g – 96, 120, 144

40g – 72, 96, 120, 144

50g – 60, 72, 96, 120, 144

60g – 48, 60, 72, 96, 120

80g – 32, 48, 60, 72, 96

90g – 32, 48, 60, 72, 96

100g – 32, 48, 60, 72, 96

120g – 24, 32, 48, 60, 72

200g – 16, 24, 32, 48, 60

240g – 16, 24, 32, 48, 60

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4.6.1. Use-specific instructions

In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole). Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.

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.

Baits must be applied in a way so that they do not come into contact with water and are not washed away. The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

[If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.

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.

Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

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

When placing bait points close to 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

None

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

None

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.

[When available] Follow any additional instructions provided by the relevant code of best practice.

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 drink as far as possible) to improve product intake and reduce the likelihood of reinvasion.

Bait stations/ points 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 2.5.3 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, 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.

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

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.

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

If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents, so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

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

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Instructions for use that are "bait-specific":

Bait in sachets: [For non-emptiable sachets - Do not open the sachets containing the bait].

Loose pellets-granules, grains: Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

5.2. Risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

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

Dispose of 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].

To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week) [Where relevant, specify if more frequent or daily inspection is required], in line with the recommendations provided by the relevant code of best practice.

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

Professionals: Do not wash the bait stations with water between applications.

Trained professionals:

Do not use in areas where resistance to the active substance can be suspected.

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.

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 eye-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 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 of uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

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

Shelf-life: 24 months

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.

Keep only in original container.

6. OTHER INFORMATION

- Because of their delayed mode of action, anticoagulant rodenticides may 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 of them.
- This product contains a bittering agent and a dye.

There are a number of errors in the drop-down menus in the hazard statements section. The correct phrases are:

P220 Keep / Store away from foodstuffs, beverages and animal feeding stuffs.

P262 Do not get on skin.

P280 Wear protective gloves [Professional users only]

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

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