ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

RUBY PASTE

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70530

R4BP asset number: IE-0000686-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	RUBY PASTE
	RODED PASTE

1.2. Authorisation holder

	Name	LODI S.A.S.
Name and address of the authorisation holder	Address	Parc d'Activités des Quatre Routes 35390 Grand Fougeray France
Authorisation number		IE/BPA 70530
R4BP asset number		IE-0000686-0000
Date of the authorisation		01/07/2011
Expiry date of the authorisation		01/07/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	LODI
Address of manufacturer	Parc d'activites des 4 routes 35390 Grand Fougeray France
Location of manufacturing sites	Parc d'activités des 4 routes 35390 Grand Fougeray France
	Parc d'activités du Pays du Grand Fougeray Espace Nord 24 et 26 rue des Pionniers 35390 GRAND FOUGERAY France

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

Active substance	Difenacoum
Name of manufacturer	Pelgar
Address of manufacturer	Unit 13, Newman Lane GU34 2QR ALTON HANTS United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Prazska 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 (%)
Difenacoum	3-(3-biphenyl-4- yl-1,2,3,4- tetrahydro-1- naphthyl)-4- hydroxycoumarin	active substance	56073-07-5	259-978-4	0,005
ВНТ		Non-active substance	128-37-0		0,15

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.
	H373: May cause damage to organs (blood) through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.
Precautionary statements	P201: Obtain special instructions before use.
	P202: Do not handle until all safety precautions have been read and understood.
	P260: Do not breathe dust.
	P280: Wear protective gloves.
	P308+P313: IF exposed or concerned: Get medical advice.
	P314: Get medical attention if you feel unwell.
	P405: Store locked up.
	P501: Dispose of container to in accordance with applicable regulations.

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: Mus musculus Common name: house mouse Development stage: Adults and Juveniles
Field(s) of use	indoor use
	Indoors
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: 20-30 g of bait per bait station.
	Dilution (%): 0
	Number and timing of application: 20-30 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 3 meters (high infestation). If there is a low infestation the distance between bait stations should be 5 meters.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size 2.5 kg Grams of bait in individual sachet: 10 Packaging material and size: Bucket: (PP,PE) 10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cardboard box with inner PE liner 10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g Outer packaging - cardboard box with pack sizes of: 50 cartridges of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15

cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g, 18 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12 cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500g.

Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.1.1. Use-specific instructions

- For mice use 20-30 g securely in tamper-resistant bait stations spaced 5m apart (3m apart in high infestation areas) in areas where mice are active.
- 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.).
 - 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.
- · Do not use this product for permanent or pulse-baiting.
- · 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

- 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.

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: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles Scientific name: Rattus rattus Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	indoor use Indoors
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: 90-100 g of bait per bait station
	Dilution (%): 0
	Number and timing of application:
	00 100 a of hait non-hait station. If more than one hait station is
	90-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters (high infestation) and 10 meters (low infestation).
Category(ies) of users	professional
Pack sizes and packaging material	
	Minimum pack size 2.5 kg
	Grams of bait in individual sachet: 10 Packaging material and size:
	Bucket: (PP,PE)
	10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg
	(400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg
	(600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10),
	8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10)
	Cardboard box with inner PE liner
	10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg
	(400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg
	(850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10)
	Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g
	Outer packaging - cardboard box with pack sizes of: 50 cartridges
	of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15 cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g,
	18 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 260g,
	260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges
	of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12
	cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500c
	500g. Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box
	of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.2.1. Use-specific instructions

- For rat infestations use 90-100 g of bait securely in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
- 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.).
- 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.
 - · Do not use this product for permanent or pulse-baiting.
 - 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

- \cdot 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.

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

Non

4.3. Use description

Table 3. House mice and/or rats - Professionnals - 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: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles Scientific name: Mus musculus Common name: house mouse Development stage: Adults and Juveniles Scientific name: Rattus rattus Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	outdoor use Other Outdoor and 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: 20-30 g/ Rats 90-100 g of bait per bait station Dilution (%): 0 Number and timing of application: Mice: 20-30 g / Rats 90-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 3 meters for mice and 5 meters for rats (high infestation). If there is a low infestation the distance between bait stations should be 5 meters for mice and 10 meters for rat.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size 2.5 kg Grams of bait in individual sachet: 10

Packaging material and size:

Bucket: (PP,PE)

10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10).

6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10)

Cardboard box with inner PE liner

10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg

(850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g

Outer packaging - cardboard box with pack sizes of: 50 cartridges of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15 cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g, 18 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12 cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500g.

Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.3.1. Use-specific instructions

- · For mice use 20-30 g in tamper-resistant bait stations.
- Secure 20-30 g of bait in tamper resistant baiting stations spaced 5m apart (3m 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.
- · For rats up to 90-100 g in tamper-resistant bait stations.
- Secure 90-100 g 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. 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. 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.
- 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.).
 - 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.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- 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.

- · Do not use this product for permanent or pulse-baiting.
- · 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.
- 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.

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: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles
	Scientific name: Mus musculus Common name: house mouse Development stage: Adults and Juveniles
	Scientific name: Rattus rattus Common name: roof rat Development stage: Adults & Juveniles
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: 20-30 g/ Rats 90-100 g of bait per bait station.
	Dilution (%): 0
	Number and timing of application:
	Mice: 20-30 g / Rats: 90-100 g of bait per bait station
	Bait products:
	Mice
	- High infestation: (20-30) g of bait per baiting point every 3 meters
	- Low infestation: (20-30) g of bait per baiting point every 5 meters
	Rats
	- High infestation: (90-100) g of bait per baiting point every 5 meters

	- Low infestation: (90-100) g of bait per baiting point every 10 meters
	Permanent baiting -
	Mice
	- High infestation: (20-30) g of bait per baiting point every 3 meters
	- Low infestation: (20-30) g of bait per baiting point every 5 meters
	Rats
	- High infestation: (90-100) g of bait per baiting point every 5 meters
	- Low infestation: (90-100) g of bait per baiting point every 10 meters
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size 2.5 kg Grams of bait in individual sachet: 10 Packaging material and size: Bucket: (PP,PE) 10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cardboard box with inner PE liner 10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g Outer packaging - cardboard box with pack sizes of: 50 cartridges of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15 cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g,

260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12 cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500g.

Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.4.1. Use-specific instructions

- For mice use 20-30 g in tamper-resistant bait stations or covered bait points.
- Secure 20-30g of bait in covered tamper resistant baiting stations or covered bait points spaced 5m apart (3m 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.
- For rats up to 90-100 g in tamper-resistant bait stations or covered bait points.
- Secure 90-100 g of bait in covered tamper resistant baiting stations or covered bait points 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. 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. 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.
- The product 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.).
- 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). Make frequent inspections of the bait points during the first 10-14 days.
- 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.
- 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 product at the end of treatment period.
- For Permanent Baiting: Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population. [When available] 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

- 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 [unless authorised for permanent baiting treatments].
- 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.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation

4.4.4. 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

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: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles Scientific name: Mus musculus Common name: house mouse Development stage: Adults and Juveniles Scientific name: Rattus rattus Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	outdoor use Other Outdoors 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 in direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	Application rate: Mice: 20-30 g/ Rats 90-100 g of bait per bait station. Dilution (%): 0 Number and timing of application:
	Mice: 20-30 g / Rats: 90-100 g of bait per bait station Bait products:
	Mice - High infestation: (20-30) g of bait per baiting point every 3 meters

	- Low infestation: (20-30) g of bait per baiting point every 5 meters
	Rats
	- High infestation: (90-100) g of bait per baiting point every 5 meters
	- Low infestation: (90-100) g of bait per baiting point every 10 meters
	- In burrows: 90-100g of bait per burrow.
	Permanent baiting -
	Mice
	- High infestation: (20-30) g of bait per baiting point every 3 meters
	- Low infestation: (20-30) g of bait per baiting point every 5 meters
	Rats
	- High infestation: (90-100) g of bait per baiting point every 5 meters
	- Low infestation: (90-100) g of bait per baiting point every 10 meters
Category(ies) of users	trained professional
Pack sizes and packaging material	
	Minimum pack size 2.5 kg

Grams of bait in individual sachet: 10

Packaging material and size:

Bucket: (PP,PE)

10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10),

6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10)

Cardboard box with inner PE liner

10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg

(850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g

Outer packaging - cardboard box with pack sizes of: 50 cartridges of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15 cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g, 18 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12 cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500g.

Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.5.1. Use-specific instructions

- For mice use 20-30 g in tamper-resistant bait stations or covered bait points.
- Secure 20-30g of bait in covered tamper resistant baiting stations or covered bait points spaced 5m apart (3m 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.
- For rats up to 90-100 g in tamper-resistant bait stations or covered bait points, or directly into the burrow.
- Secure 90-100 g of bait in covered tamper resistant baiting stations or covered bait points 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. 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. 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.
- The product 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.).
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

- 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). Make frequent inspections of the bait points during the first 10-14 days.
- 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 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.
- 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.
- 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.
- 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.
- For Permanent Baiting: Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population. [When available] 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

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

4.5.4. 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 - Outdoor open areas & waste dumps

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles Scientific name: Rattus rattus Common name: roof rat Development stage: Adults & Juveniles
Field(s) of use	outdoor use Other Outdoor open areas & waste dumps
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: Rats 90-100 g of bait per bait station.

	Dilution (%): 0
	Number and timing of application:
	Rats 90-100 g of bait per bait station
	- High infestation: (90-100) g of bait per baiting point every 5 meters
	- Low infestation: (90-100) g of bait per baiting point every 10 meters
	- In burrows: 90-100g of bait per burrow.
	Permanent baiting -
	Rats
	- High infestation: (90-100) g of bait per baiting point every 5 meters
	- Low infestation: (90-100) g of bait per baiting point every 10 meters
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size 2.5 kg
	Grams of bait in individual sachet: 10 Packaging material and size:
	Bucket: (PP,PE)
	10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10),
	6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg (850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cardboard box with inner PE liner

10 g: 2.5 kg (250*10), 3 kg (300*10), 3.5 kg (350*10), 4 kg (400*10), 4.5 kg (450*10), 5 kg (500*10), 5.5 kg (550*10), 6 kg (600*10), 6.5 kg (650*10), 7 kg (700*10), 7.5 kg (750*10), 8 kg (800*10), 8.5 kg

(850*10), 9 kg (900*10), 9.5 kg (950*10), 10 kg (1000*10) Cartridge in PP: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500g

Outer packaging - cardboard box with pack sizes of: 50 cartridges of 50g, 25 cartridges of 100g, 20 cartridges of 150g, 15 cartridges of 200g, 10 cartridges of 250g, 12 cartridges of 250g, 18 cartridges of 250g, 10 cartridges of 260g, 12 cartridges of 260g, 18 cartridges of 260g, 10 cartridges of 270g, 12 cartridges of 270g, 18 cartridges of 270g, 10 cartridges of 280g, 12 cartridges of 280g, 18 cartridges of 280g, 10 cartridges of 310g, 12 cartridges of 310g, 18 cartridges of 310g or 5 cartridges of 500g.

Pre-baited station (PP,PS,PVC): 2*10g or 3*10g in cardboard box of 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg

4.6.1. Use-specific instructions

- For rats use 90-100 g of bait in tamper-resistant bait stations or covered bait points, or directly into the burrow.
- Secure 90-100 g of bait in covered tamper resistant baiting stations or covered bait points 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.
- The product 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.).
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- 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). Make frequent inspections of the bait points during the first 10-14 days.
- 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 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.
- 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.
- 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.
- 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.
- For permanent baiting - Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

[When available] 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 use the product 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 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 [unless authorised for permanent baiting treatments].
- 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.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.

The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

4.6.4. 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.
- 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.
- 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.
- Bait in sachets: Do not open the sachets containing the bait].

Wear protective chemical resistant gloves during product handling phase (nitrile gloves EN 374-2)

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 Difenacoum-containing products for pulse baiting.
- 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].

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

• 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.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine. Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.

Eye exposure, always check for and remove contact lenses, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. [insert country specific information].

Contact a veterinary surgeon in case of ingestion by a pet <u>[insert country specific information].</u>

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 them.

This product contains a bittering agent and a dye.