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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

TITANIUM B

Product type(s)

PT14: Rodenticides

Authorisation number: FR-2016-1026

R4BP asset number: FR-0014978-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Titanium B
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	EDIALUX
	Address	ZA MACON EST 01750 REPLONGES France
Authorisation number	FR-2016-1026	
<i>R4BP asset number</i>	FR-0014978-0000	
Date of the authorisation	05/07/2017	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	EDIALUX
Address of manufacturer	ZA Mâcon Est 01750 REPLONGES France
Location of manufacturing sites	ZA Mâcon Est 01750 REPLONGES France

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

Active substance	Difenacoum
Name of manufacturer	PELGAR INTERNATIONAL LTD
Address of manufacturer	UNIT 13 Newman Lane GU34 2QR ALTON United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	UNIT 13 Newman Lane GU34 2QR ALTON United Kingdom of Great Britain and Northern Ireland (the)

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	active substance	56073-07-5	259-978-4	0,0026

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure ..
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P314: Get medical advice/attention if you feel unwell. P501: Dispose of to [in accordance with local/regional/national/international regulation]..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice and/or rats – trained professionals – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles and adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	indoor use Indoor.
Application method(s)	Method: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations - [Covered and protected baiting points] Detailed description: Bait formulations:- Ready-to-use bait to be used in tamper-resistant bait stations - [Covered and protected baiting points]
Application rate(s) and frequency	Application rate: Bait products: - Rats: 100-200 g of bait per baiting point. - Mice: 30 g of bait per baiting point. Dilution (%): - Number and timing of application: Bait products: - Rats: 100-200 g of bait per baiting point. - Mice: 30 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (In France only : minimum pack size of 5 kg) Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. TITANIUM B is supplied in sachet or loose. PP sachets (20-200 g for rats and 25-30 g for mice) are packed in:

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| | <ul style="list-style-type: none">- PP, PE or HDPE bucket (3-10 kg),- Cardboard box (3-10 kg),- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (3-25 kg),- Prefilled bait station in cardboard box (3-10 kg). |
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Loose baits are packed in:

- PP bucket (3-10 kg),
- Cardboard box with one PP bag inside (3-10 kg),
- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) with one PP bag inside (3-10 kg).

4.1.1. 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.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.

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

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

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

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

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4.2. Use description

Table 2. 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>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	outdoor use Outdoor around buildings.
Application method(s)	Method: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - [Covered and protected baiting points] Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - [Covered and protected baiting points]
Application rate(s) and frequency	Application rate: Bait products : - Rats: 100-200 g of bait per baiting point. Dilution (%): 0 Number and timing of application: Bait products: - Rats: 100-200 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (In France only : minimum pack size of 5 kg) - Bait formulations: Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.

TITANIUM B is supplied in sachet or loose.

PP sachets (20-200 g for rats) are packed in:

- PP, PE or HDPE bucket (3-10 kg),
- Cardboard box (3-10 kg),
- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (3-25 kg),
- Prefilled bait station in cardboard box (3-10 kg).

Loose baits are packed in:

- PP bucket (3-10 kg),
- Cardboard box with one PP bag inside (3-10 kg),
- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) with one PP bag inside (3-10 kg).

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- [When available] Follow any additional instructions provided by the relevant code of best practice.
- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

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4.3. Use description

Table 3. (not relevant in France) – 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: juveniles and adults
Field(s) of use	indoor use Indoor.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: Bait products: - Mice: 30 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters. Dilution (%): 0 Number and timing of application: Bait products: - Mice: 30 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. - Bait formulations:

	<p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>TITANIUM B is supplied in sachet or loose.</p> <p>PP sachets (25-30 g for mice) are packed in:</p> <ul style="list-style-type: none"> - PP, PE or HDPE bucket (3-10 kg), - Cardboard box (3-10 kg), - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (3-25 kg), - Prefilled bait station in cardboard box (3-10 kg). <p>Loose baits are packed in:</p> <ul style="list-style-type: none"> - PP bucket (3-10 kg), - Cardboard box with one PP bag inside (3-10 kg), - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) with one PP bag inside (3-10 kg).
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4.3.1. Use-specific instructions

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

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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

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

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4.4. Use description

Table 4. (not relevant in France) – 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: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	indoor use Indoor.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: - Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters. Dilution (%): 0 Number and timing of application: Bait products: - Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters.

Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>- Bait formulations:</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>TITANIUM B is supplied in sachet or loose.</p> <p>PP sachets (20-200 g for rats) are packed in:</p> <ul style="list-style-type: none"> - PP, PE or HDPE bucket (3-10 kg), - Cardboard box (3-10 kg), - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (3-25 kg), - Prefilled bait station in cardboard box (3-10 kg). <p>Loose baits are packed in:</p> <ul style="list-style-type: none"> - PP bucket (3-10 kg), - Cardboard box with one PP bag inside (3-10 kg), - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) with one PP bag inside (3-10 kg).

4.4.1. Use-specific instructions

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [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

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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

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

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4.5. Use description

Table 5. (not relevant in France) – 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>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	outdoor use Outdoor around buildings
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: - Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters. Dilution (%): 0 Number and timing of application: Bait products: - Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. - Bait formulations:

	<p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>TITANIUM B is supplied in sachet or loose.</p> <p>PP sachets (20-200 g for rats) are packed in:</p> <ul style="list-style-type: none">- PP, PE or HDPE bucket (3-10 kg),- Cardboard box (3-10 kg),- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (3-25 kg),- Prefilled bait station in cardboard box (3-10 kg). <p>Loose baits are packed in:</p> <ul style="list-style-type: none">- PP bucket (3-10 kg),- Cardboard box with one PP bag inside (3-10 kg),- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) with one PP bag inside (3-10 kg).
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4.5.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [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 apply this product directly in the burrows.

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

- When placing bait stations close to 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

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

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4.6. Use description

Table 6. House mice – general public – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles and adults
Field(s) of use	indoor use Indoor.
Application method(s)	Method: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: - 30 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters. Dilution (%): 0 Number and timing of application: Bait products: - 30 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum pack size of 150 g TITANIUM B is supplied only in sachet. PP sachets (20-150 g for rats and 25-30 g for mice) are packed in: - PP or HDPE bucket (Rats and mice: up to 150 g; Mice: up to 50 g) - Cardboard box (Rats and mice: up to 150 g; Mice: up to 50 g) - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (Rats and mice: up to 150 g; Mice: up to 50 g) - Prefilled bait station in cardboard box (Rats and mice: up to 150 g; Mice: up to 50 g)

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4.6.1. Use-specific instructions

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

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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

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

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

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4.7. Use description

Table 7. Rats – general public – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	indoor use

	Indoor.
Application method(s)	Method: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: - 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters. Dilution (%): 0 Number and timing of application: Bait products: - 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum pack size of 150 g. TITANIUM B is supplied only in sachet. PP sachets (20-150 g for rat) are packed in: - PP or HDPE bucket (up to 150 g), - Cardboard box (up to 150 g), - Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (up to 150 g), - Prefilled bait station in cardboard box (up to 150 g).

4.7.1. Use-specific instructions

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.7.2. Use-specific risk mitigation measures

4.7.3. Use-specific risk mitigation measures

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

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

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

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4.8. Use description

Table 8. Rats – general public – outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles and adults
Field(s) of use	outdoor use Outdoor around buildings.
Application method(s)	Method: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: Bait products: - 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters. Dilution (%): 0 Number and timing of application: Bait products: - 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 15 meters.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum pack size of 150 g. TITANIUM B is supplied only in sachet.

	PP sachets (20-150 g for rat) are packed in: <ul style="list-style-type: none">- PP or HDPE bucket (up to 150 g),- Cardboard box (up to 150 g),- Multilayered kraft paper bag (alternative OPET/LDPE alternative PE) (up to 150 g),- Prefilled bait station in cardboard box (up to 150 g).
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4.8.1. Use-specific instructions

- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.8.2. Use-specific risk mitigation measures

4.8.3. Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- [Where required by the risk assessment:
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

FOR TRAINED PROFESSIONAL ONLY- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.

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

FOR PROFESSIONALS ONLY Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

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

- Bait in sachets: - Do not open the sachets containing the bait.
- Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).
- Decanting is to be avoided. In case decanting cannot be avoided, an RPE of APF 10 has to be used.

FOR NON PROFESSIONAL USERS

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

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

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- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
 - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
 - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
 - Where possible, bait stations must be fixed to the ground or other structures.
 - [Do not open the sachets containing the bait - where relevant for the bait formulation in the product].
 - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
 - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
 - Do not place bait stations near water drainage systems where they can come into contact with water.
 - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
 - Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [in accordance with the applicable code of good practice, if any]".
- 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").
- FOR TRAINED PROFESSIONAL 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.
- FOR TRAINED PROFESSIONAL ONLY Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- FOR PROFESSIONAL ONLY 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].
- FOR PROFESSIONAL ONLY Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- FOR PROFESSIONAL ONLY. 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").
- FOR PROFESSIONAL ONLY Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

FOR NON PROFESSIONAL USERS

- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

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- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
 - The product information (i.e. label and/or leaflet) shall clearly show that:
 - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").
 - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
 - Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
 - Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
 - Dermal exposure, wash skin with water and then with water and soap.
 - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
 - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
- Hazardous to wildlife.

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

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Do not store at temperatures above 40°C.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 24 month.

6. OTHER INFORMATION

- (In France only: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance difenacoum. Results of the resistance monitoring must be submitted at the renewal of the product.)
- The authorisation holder must provide the results of the long-term (2 years) storage study with the new formulation within 24 months in post-authorization.
- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective 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.