

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

NYNA 3 CEREALES 25

Product type(s)

PT14: Rodenticides

Authorisation number: FR-2016-0032

R4BP asset number: FR-0013429-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	NYNA 3 CEREALES 25 RATICIDE DIF 25 MULTIFAR 25
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	TRIPLAN SA
	Address	BP 258 LA POSTE FRANCAISE AD500 ANDORRA LA VELLA France
Authorisation number		FR-2016-0032
<i>R4BP asset number</i>		FR-0013429-0000
Date of the authorisation		11/04/2016
Expiry date of the authorisation		31/12/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	SOFAR France
Address of manufacturer	ZA DU DREVERS BP 02 29190 PLEYBEN France
Location of manufacturing sites	ZA DU DREVERS BP 02 29190 PLEYBEN France

Name of manufacturer	AEDES PROTECTA
Address of manufacturer	75 Rue D'Orgemont 95210 SAINT-GRATIEN France
Location of manufacturing sites	Lieu-dit DOUILLAC 81310 PARISOT France

Name of manufacturer	RATOUCY SAS
Address of manufacturer	29 Rue de la forêt - LOOZE - BP145 89303 JOIGNY Cedex France
Location of manufacturing sites	29 Rue de la forêt - LOOZE - BP145 89303 JOIGNY Cedex France

Name of manufacturer	IRIS
Address of manufacturer	1126A Avenue Du Moulinas - Route De Saint Privat 30340 SALINDRES France
Location of manufacturing sites	1126A Avenue Du Moulinas - Route De Saint Privat 30340 SALINDRES France

Name of manufacturer	NOXIMA
Address of manufacturer	Carrefour jean monnet - LACROIX SAINT OUEN 60201 COMPIEGNE France
Location of manufacturing sites	Carrefour jean monnet - LACROIX SAINT OUEN 60201 COMPIEGNE France

Name of manufacturer	INDUSTRIAL CHIMICA SRL
Address of manufacturer	VIA SORGAGLIA 40 35020 Arre (PD) Italy
Location of manufacturing sites	VIA SORGAGLIA 40 35020 Arre (PD) Italy

Name of manufacturer	FHS
Address of manufacturer	2 RUE DE LA TETE A LOUP - ZAC DE GRANDCHAMP 77440 OCQUERRE France
Location of manufacturing sites	2 RUE DE LA TETE A LOUP - ZAC DE GRANDCHAMP 77440 OCQUERRE France

Name of manufacturer	FARMAVIT OOD
Address of manufacturer	BUL. TSAR BORIS III, N°63, OFFICE 1 1612 SOFIA Bulgaria
Location of manufacturing sites	INDUSTRIALNA 2 STR - PLEVEN DISTRICT 5960 GULIANTSI Bulgaria

Name of manufacturer	HDA
Address of manufacturer	ZA LA CHARME MENETROL 63200 RIOM France
Location of manufacturing sites	ZA LA CHARME MENETROL 63200 RIOM France

Name of manufacturer	SALOMEZ
Address of manufacturer	ZI - Avenue du General de Gaulle 89130 TOUCY France
Location of manufacturing sites	ZI - Avenue du General de Gaulle 89130 TOUCY France

Name of manufacturer	FARMA-CHEM S.A.
Address of manufacturer	Industrial Area of Sindos P.O BOX 1026 Block 53 Zone C 57022 THESSALONIKI Greece
Location of manufacturing sites	Industrial Area of Sindos P.O BOX 1026 Block 53 Zone C 57022 THESSALONIKI Greece

Name of manufacturer	AGROZA AGROTECHNICAL LTD
Address of manufacturer	AITOLIAS 2 & EL. VENIZELOU 158 16341 ATHENS Greece
Location of manufacturing sites	AITOLIAS 2 & EL. VENIZELOU 158 16341 ATHENS Greece

Name of manufacturer	AGROLOGY SA
Address of manufacturer	P.O.BOX 1089 Industrial of Thessaloniki 57022 THESSALONIKI Greece
Location of manufacturing sites	P.O.BOX 1089 Industrial of Thessaloniki 57022 THESSALONIKI Greece

Name of manufacturer	LABORATOIRE LOGISSAIN
Address of manufacturer	Zone Industrielle Argiésans 90800 ARGIESANS France
Location of manufacturing sites	Zone Industrielle Argiésans 90800 ARGIESANS France

Name of manufacturer	DALTA SA
Address of manufacturer	Zone Industrielle – RN20 BP6 82270 MONTPEZAT DE QUERCY France
Location of manufacturing sites	Zone Industrielle – RN20 BP6 82270 MONTPEZAT DE QUERCY France

Name of manufacturer	LARC
Address of manufacturer	Z.A DE KERAMPAOU 29940 MELGVEN France
Location of manufacturing sites	Z.A DE KERAMPAOU 29940 MELGVEN France

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

Active substance	Difenacoum
Name of manufacturer	ACTIVA
Address of manufacturer	Via Feltre, 32 20132 MILAN Italy
Location of manufacturing sites	Via Tre Ponti, 22 37050 MS. MARIA DI ZEVIO (VR) Italy

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	active substance	56073-07-5	259-978-4	0,0025

2.2. Type(s) of formulation

Ready-to-use bait: grain

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs {0:or state all organs affected, if known:} 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	P260: Do not breathe dust/fume/gas/mist/vapours/spray. P314: Get medical advice/attention if you feel unwell. P501: Dispose of {0:....:contents container} to {1:....:}.

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 Indoor
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application 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: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point. Dilution (%): 0 Number and timing of application: Bait products: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg.

	<p>(In France only : minimum pack size of 5 kg)</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk.</p> <p>Secondary packaging Sachets are then packed in:</p> <ul style="list-style-type: none"> - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg. <p>The product is also supplied in loose in:</p> <ul style="list-style-type: none"> - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).
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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. 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 Outdoor around buildings
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: adults</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait formulations:- Ready-to-use bait to be used in tamper-resistant bait stations.- [Covered and protected baiting points]</p>
Application rate(s) and frequency	Application rate: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point.

	<p>Dilution (%): 0</p> <p>Number and timing of application: Bait products: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg. (In France only : minimum pack size of 5 kg)</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk.</p> <p>Secondary packaging Sachets are then packed in: - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg.</p> <p>The product is also supplied in loose in: - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).</p>

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. Mice and/or 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 Outdoor open areas x Outdoor waste dumps x
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat</p>

	<p>Development stage: adults</p> <p>Scientific name: Rattus rattus Common name: Black or roof rat Development stage: juveniles</p> <p>Scientific name: Rattus rattus Common name: Black or roof rat Development stage: adults</p>
Field(s) of use	<p>outdoor use Other</p> <p>Outdoor open areas x Outdoor waste dumps x</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations.- [Covered and protected baiting points]</p>
Application rate(s) and frequency	<p>Application rate: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Bait products: Rats: 100 g of bait per baiting point. Mice: 40 g of bait per baiting point.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg. (In France only : minimum pack size of 5 kg)</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk.</p> <p>Secondary packaging Sachets are then packed in:</p> <ul style="list-style-type: none"> - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg. <p>The product is also supplied in loose in:</p> <ul style="list-style-type: none"> - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).

4.3.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the bait stations 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.
- [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].

4.3.2. Use-specific risk mitigation measures

4.3.3. 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].
- 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 apply this product directly in the burrows.

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

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or 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) – House mice – professionals – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides Indoor
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mice

	<p>Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i></p> <p>Common name: House mice</p> <p>Development stage: adults</p>
Field(s) of use	<p>indoor use</p> <p>Indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: 40 g of bait per bait station</p> <p>Dilution (%): 0</p> <p>Number and timing of application: - 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.</p> <p>Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk.</p> <p>Secondary packaging Sachets are then packed in: - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg.</p> <p>The product is also supplied in loose in: - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).</p>

4.4.1. Use-specific instructions

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

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

Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: 100 g of bait per bait station Dilution (%): 0 Number and timing of application: - 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.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk. Secondary packaging Sachets are then packed in: - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg. The product is also supplied in loose in: - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).

4.5.1. Use-specific instructions

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

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

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

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

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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. (not relevant in France) – 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 Outdoor around buildings
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: adults</p>
Field(s) of use	outdoor use

	Outdoor around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Rats - 100 g of bait per bait station. Mice - 40 g of bait per bait station. Dilution (%): 0 Number and timing of application: Rats - 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. Mice - 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 200 g) and in bulk. Secondary packaging Sachets are then packed in: - Bag (paper bags several layers with one or without plastic film in LDPE) -5-10-15-20-25 kg, - Bucket (HDPE/PP) - 5-10-15-18-20-25 kg, - Carton box with a polypropylene or polyethylene bag inside - 5-10-12-15-20-25-30-50 kg. The product is also supplied in loose in: - LDPE/PP sachets (100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000 g) and packed in cardboard box (5-10 kg), - Paper bags with or without LDPE film (5-10 kg), - HDPE or PP bucket (5-10 kg), - Cardboard box with LDPE or PP bag inside (5-10 kg).

4.6.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [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 apply this product directly in the burrows.

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

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

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

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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. House mice – general public – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides Indoor
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: juveniles Scientific name: <i>Mus musculus</i> Common name: House mice Development stage: adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application

	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: 40 g of bait per bait station Dilution (%): 0 Number and timing of application: Bait products: - 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 150g). Secondary packaging Sachets are then packed in: - Bucket (HDPE/PP), cardboard box, metal box without lacquer and Flacon (HDPE) up to 150g, - Bait box (plastic PET/PP/HDPE/PVC) containing up to 150g , dimensions o 230 mm x 135 mm x 85 mm.

4.7.1. 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.

4.7.2. 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 – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides Indoor
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults Scientific name: Rattus rattus Common name: Black or roof rat Development stage: juveniles Scientific name: Rattus rattus Common name: Black or roof rat Development stage: adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application 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: 100 g of bait per bait station Dilution (%): 0 Number and timing of application: Bait products: 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.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 150g).

	<p>Secondary packaging Sachets are then packed in:</p> <ul style="list-style-type: none"> - Bucket (HDPE/PP), cardboard box, metal box without lacquer and Flacon (HDPE) up to 150g, - Bait box (plastic PET/PP/HDPE/PVC) containing up to 150g , dimensions <ul style="list-style-type: none"> o 230 mm x 135 mm x 85 mm.
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4.8.1. 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.

4.8.2. Use-specific risk mitigation measures

4.8.3. Use-specific risk mitigation measures

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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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4.9. Use description

Table 9. Rats – general public – outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides Outdoor around buildings

Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles</p> <p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults</p> <p>Scientific name: Rattus rattus Common name: Black or roof rat Development stage: juveniles</p> <p>Scientific name: Rattus rattus Common name: Black or roof rat Development stage: adults</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: 100 g of bait per bait station</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Bait products: 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.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Primary packaging NYNA 3 CEREALES 25 is supplied in LDPE/ PP sachets (10, 20, 25, 30, 40, 45, 50, 60, 90, 100 or 150g).</p> <p>Secondary packaging Sachets are then packed in:</p> <ul style="list-style-type: none"> - Bucket (HDPE/PP), cardboard box, metal box without lacquer and Flacon (HDPE) up to 150g, - Bait box (plastic PET/PP/HDPE/PVC) containing up to 150g , dimensions <ul style="list-style-type: none"> o 230 mm x 135 mm x 85 mm.

4.9.1. 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.

4.9.2. Use-specific risk mitigation measures

4.9.3. Use-specific risk mitigation measures

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

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

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4.9.6. 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.
- 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.
- 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 devise. Specify the methods to minimise dust (e.g. wet wiping).
- Loose pellets-granules, grains: Decanting is to be avoided. In case decanting cannot be avoided, gloves and 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.
- 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.

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

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- 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.
- 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").

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- 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:
 - o Dermal exposure, wash skin with water and then with water and soap.
 - o Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
 - o 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.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years

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.
- 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.
- Results of the long-term stability study (2 years) must be provided to eCA within 24 months in post-authorisation.