

Summary of product characteristics for a biocidal product

Product name: RATISTOP FARM PLUS

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: RO/2018/0166/MRA/ES/APP(NA)-2018-14-00059

R4BP 3 asset reference number: RO-0016308-0000

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Administrative information

1.1. Trade names of the product

RATISTOP FARM PLUS

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Pasteur Filiala Filipesti SA
	Address	Principala 944 107245 Comuna Filipestii de Padure Romania
Authorisation number	RO/2018/0166/MRA/ES/APP(NA)-2018-14-00059	
R4BP 3 asset reference number	RO-0016308-0000	
Date of the authorisation	27/11/2012	
Expiry date of the authorisation	01/07/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	S.C. PASTEUR FILIALA FILIPESTI S.R.L.
Address of the manufacturer	Principala Street, No. 944 107245 Filipestii de Padure Romania
Location of manufacturing sites	Principala Street, No. 944 107245 Filipestii de Padure Romania

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

Active substance	26 - Difenacoum
Name of the manufacturer	Activa s.r.l. / Dr. Tezza s.r.l.
Address of the manufacturer	Via Feltre, 32 20132 Milano Italy
Location of manufacturing sites	Dr. Tezza s.r.l.: Via Tre Ponti, 22 37050 S. Maria di Zevio (VR) Italy

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal 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	0,0029

2.2. Type of formulation

Ready-to-use bait: grain

3. Hazard and precautionary statements

Hazard statements	May cause damage to organs through prolonged or repeated exposure .
Precautionary statements	<p>Keep out of reach of children.</p> <p>Read carefully and follow all instructions.</p> <p>Wear protective clothing.</p> <p>IF SWALLOWED:Immediately call a POISON CENTER.</p>

4. Authorised use(s)

4.1 Use description

Use 1 - Use #1 - Mice - General Public - In and around buildings

Product type	PT14 - Rodenticides (Pest control)
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: Adults Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Juveniles
Field(s) of use	Indoor Other In and around homes and outbuilding for private use.
Application method(s)	Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.
Application rate(s) and frequencies	Application Rate: Mice: bait boxes with 50-100 g of product for each 10m ² Dilution (%): 0 Number and timing of application: 50-100 g of bait per bait station depending on the infestation grade. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g. These sachets are supplied inside the following secondary packaging: <u>Bag or sack (Sachet):</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE.

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Plastic bucket/tub

Description: Rectangular or conical bucket sealed

Material: HDPE or PE or PP

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Bottle

Description: Conical bottle sealed

Material: HDPE or PE or PP or PET or PVC

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded

Material: Tektura (kind of carton) + PET or LDPE

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

* PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.

* PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.

* PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.

* PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE).

4.1.1 Use-specific instructions for use

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

4.1.2 Use-specific risk mitigation measures

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.2 Use description

Use 2 - Use #2 - Rats - General Public - In and around buildings

Product type	PT14 - Rodenticides (Pest control)
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 Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles
Field(s) of use	Indoor Other In and around homes and outbuilding for private use.
Application method(s)	Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.
Application rate(s) and frequencies	Application Rate: Rat: bait boxes with 100-200 g of product for each 10m2 Dilution (%): 0 Number and timing of application: 50-100 g of bait per bait station depending on the infestation grade. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.

These sachets are supplied inside the following secondary packaging:

Bag or sack (Sachet):

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE.

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Plastic bucket/tub

Description: Rectangular or conical bucket sealed

Material: HDPE or PE or PP

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Bottle

Description: Conical bottle sealed

Material: HDPE or PE or PP or PET or PVC

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded

Material: Tektura (kind of carton) + PET or LDPE

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

* PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.

* PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.

* PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.

* PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE).

4.2.1 Use-specific instructions for use

The bait station should be visited at least every 5 to 7 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.

4.2.2 Use-specific risk mitigation measures

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.3 Use description

Use 3 - Use #3 - Mice - Professional - Indoor

Product type	PT14 - Rodenticides (Pest control)
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: Adults Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Juveniles
Field(s) of use	Indoor Indoor use.-
Application method(s)	Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.

Application rate(s) and frequencies

Application Rate: Mice: bait boxes with 50-100 g of product for each 10m²
Dilution (%): 0
Number and timing of application:
50-100 g of bait per bait station depending on the infestation grade. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Category(ies) of users

Professional

Pack sizes and packaging material

The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.

These sachets are supplied inside the following secondary packaging:

Bag or sack (Sachet):

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE.

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Plastic bucket/tub

Description: Rectangular or conical bucket sealed

Material: HDPE or PE or PP

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Bottle

Description: Conical bottle sealed

Material: HDPE or PE or PP or PET or PVC

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded

Material: Tektura (kind of carton) + PET or LDPE

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

* PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.

* PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.

* PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.

* PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE)

4.3.1 Use-specific instructions for use

The bait station 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 station are intact and to remove rodent bodies. Re-fill bait when necessary.

4.3.2 Use-specific risk mitigation measures

See this point in section 5, directions for use.

4.3.3 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 station closing to water drainage systems, ensure that bait contact with water is avoided.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.4 Use description

Use 4 - Use #4 - Rats - Professional - Indoor

Product type

PT14 - Rodenticides (Pest control)

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

Scientific name: Rattus norvegicus
Common name: Brown rat
Development stage: Juveniles

Field(s) of use

Indoor

Indoor use.

Application method(s)

Method: Bait application
Detailed description:
The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.

Application rate(s) and frequencies

Application Rate: Rat: bait boxes with 100-200 g of product for each 10m²
Dilution (%): 0
Number and timing of application:
50-100 g of bait per bait station depending on the infestation grade. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Category(ies) of users

Professional

Pack sizes and packaging material

The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.

These sachets are supplied inside the following secondary packaging:

Bag or sack (Sachet):

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE.

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Plastic bucket/tub

Description: Rectangular or conical bucket sealed
Material: HDPE or PE or PP

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Bottle

Description: Conical bottle sealed
Material: HDPE or PE or PP or PET or PVC

Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: Tektura (kind of carton) + PET or LDPE
Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

- * PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.
- * PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.
- * PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.
- * PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE).

4.4.1 Use-specific instructions for use

The bait station should be visited at least every 5 to 7 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.

4.4.2 Use-specific risk mitigation measures

See this point in section 5, directions for use.

4.4.3 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.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.5 Use description

Use 5 - Use #5 - Rats and/or Mice - Professional - Around buildings

Product type	PT14 - Rodenticides (Pest control)
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 Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles Scientific name: Mus musculus Common name: House mouse Development stage: Adults

Scientific name: Mus musculus
Common name: House mouse
Development stage: Juveniles

Field(s) of use

Other

Around buildings and by using fixed or mobile installations closely related to farm operations.

Application method(s)

Method: Bait application
Detailed description:
The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.

Application rate(s) and frequencies

Application Rate: Rat: bait boxes with 100-200 g of product for each 10m² / Mice: bait boxes with 50-100 g of product for each 10m²
Dilution (%): 0
Number and timing of application:
50-100 g of bait per bait station depending on the infestation grade. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Category(ies) of users

Professional

Pack sizes and packaging material

The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.

These sachets are supplied inside the following secondary packaging:

Bag or sack (Sachet):
Description: Prefabricated bags or serial production bags, both thermal-welded
Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE.
Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Plastic bucket/tub
Description: Rectangular or conical bucket sealed
Material: HDPE or PE or PP
Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Bottle
Description: Conical bottle sealed
Material: HDPE or PE or PP or PET or PVC
Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg

Carton Sachet:
Description: Prefabricated bags or serial production bags, both thermal-welded
Material: Tektura (kind of carton) + PET or LDPE
Contents (Net weight): from 50 g to 5 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5 kg
Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

- * PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.
- * PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.
- * PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.
- * PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE).

4.5.1 Use-specific instructions for use

The bait station 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 station are intact and to remove rodent bodies. Re-fill bait when necessary. The bait station should be visited at least 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 station are intact and to remove rodent bodies. Re-fill bait when necessary. Protect bait for 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.

4.5.2 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

4.5.3 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 station close to surface waters or water drainage systems, ensure that bait contact with water is avoided.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.6 Use description

Use 6 - Use #6 - Rats and Mice - Trained Professional - In and around buildings

Product type	PT14 - Rodenticides (Pest control)
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 Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles Scientific name: Mus musculus Common name: House mouse Development stage: Adults Scientific name: Mus musculus Common name: House mouse Development stage: Juveniles
Field(s) of use	Indoor Outdoor Other In and around buildings
Application method(s)	Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.
Application rate(s) and frequencies	Application Rate: Rats: bait boxes with 100-200 g of product for each 10m ² / Mice: bait boxes with 50-100 g of product for each 10m ² Dilution (%): 0 Number and timing of application: Rats: bait boxes with 100-200 g of product for each 10m ² depending on infestation grade. Mice: bait boxes with 50-100 g of product for each 10m ² depending on infestation grade.
Category(ies) of users	Trained professional
Pack sizes and packaging material	The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.

These sachets are supplied inside the following secondary packaging:

Bag or sack (Sachet):

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE.
Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Plastic bucket/tub

Description: Rectangular or conical bucket sealed
Material: HDPE or PE or PP
Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Bottle

Description: Conical bottle sealed
Material: HDPE or PE or PP or PET or PVC
Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded
Material: Tektura (kind of carton) + PET or LDPE
Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

- * PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.
 - * PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.
 - * PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.
 - * PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE)
- Avoid touching the product with bare hands

4.6.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Protect bait from 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.

4.6.2 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.
- 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 practise.
- 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.
- Do not apply this product directly in the burrows.

4.6.3 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 water (e.g. rivers, ponds, waterchannels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.7 Use description

Use 7 - Use #7 - Rats -Trained Professional - Open areas and waste dumps

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults</p> <p>Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles</p>
Field(s) of use	<p>Outdoor</p> <p>Other</p>

<p>Application method(s)</p>	<p>Open areas and waste dumps.</p> <p>Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.</p>
<p>Application rate(s) and frequencies</p>	<p>Application Rate: Rats: bait boxes with 100-200 g of product for each 10m2 Dilution (%): 0 Number and timing of application: Rats: bait boxes with 100-200 g of product for each 10m2 depending on infestation grade.</p>
<p>Category(ies) of users</p>	<p>Trained professional</p>
<p>Pack sizes and packaging material</p>	<p>The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g.</p> <p>These sachets are supplied inside the following secondary packaging:</p> <p><u>Bag or sack (Sachet):</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg</p> <p><u>Plastic bucket/tub</u> Description: Rectangular or conical bucket sealed Material: HDPE or PE or PP Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg</p> <p><u>Bottle</u> Description: Conical bottle sealed Material: HDPE or PE or PP or PET or PVC Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg</p> <p><u>Carton Sachet:</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: Tektura (kind of carton) + PET or LDPE Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg</p> <p>Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.</p> <p>NOTE: * PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and</p>

metalizedpolyethylene terephthalate and polyethylene.
* PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.
* PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.
* PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE)
Avoid touching the product with bare hands

4.7.1 Use-specific instructions for use

- Protect bait from 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.

4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

4.7.3 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 water (e.g. rivers, ponds, waterchannels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

4.8 Use description

Use 8 - Use #8 - Rats - Trained Professional - Sewers

Product type	PT14 - Rodenticides (Pest control)
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 Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles
Field(s) of use	Outdoor Sewers
Application method(s)	Method: Bait application Detailed description: The product can be supplied in sachets or as loose grain, but always should be applied inside bait boxes correctly labelled. Furthermore, the product could be supplied in sealed non-refillable bait stations.
Application rate(s) and frequencies	Application Rate: Rats: bait boxes with 100-200 g of product for each 10m2 Dilution (%): 0 Number and timing of application: Rats: bait boxes with 100-200 g of product for each 10m2 depending on infestation grade.
Category(ies) of users	Trained professional
Pack sizes and packaging material	The product can be placed on the market in individual plastic sachets each containing 10, 20, 25, 50, 100, 200 and 400 g. These sachets are supplied inside the following secondary packaging: <u>Bag or sack (Sachet):</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg <u>Plastic bucket/tub</u> Description: Rectangular or conical bucket sealed Material: HDPE or PE or PP Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25

and 30 kg

Bottle

Description: Conical bottle sealed

Material: HDPE or PE or PP or PET or PVC

Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Carton Sachet:

Description: Prefabricated bags or serial production bags, both thermal-welded

Material: Tektura (kind of carton) + PET or LDPE

Contents (Net weight): from 50 g to 25 kg. In case of a detailed content, then it would be 50, 90, 100, 150, 200, 250, 300, 400, 450, 500 g and 1,2, 2.5, 3, 5, 10, 15, 20, 25 and 30 kg

Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

NOTE:

* PET/PETMET/PE is a triplex foil consisting of Polyethylene terephthalate and metalized polyethylene terephthalate and polyethylene.

* PET/ALU/PE is a triplex foil consisting of Polyethylene terephthalate and aluminium foil and Polyethylene.

* PET/PE is a duplex foil consisting of Polyethylene terephthalate and polyethylene.

* PA/PE is a duplex foil consisting of polyamide and polyethylene. In all cases the material in contact with the product is Polyethylene (PE)

Avoid touching the product with bare hands

4.8.1 Use-specific instructions for use

Baits must be applied in a way so that they do not come into contact with water and are not washed away.

4.8.2 Use-specific risk mitigation measures

- Place baits only in sewer systems which are connected to the sewage treatment plant.

- Do not use the product in pulsed baiting treatments.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

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

See this point in section 5, directions for use.

5. General directions for use

5.1. Instructions for use

General Public

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not open the sachets containing the bait except for loose grain formulation (only authorised for trained professionals)
- 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.
- Do not use in areas where resistances to the active substance can be suspected.

- The treatment has to be alternated with other kind of active substances in order to avoid resistance and cross-resistances occurrence to rodenticides.
- Anticoagulant rodenticides authorised for use by the general public users shall be used in tamper-resistant bait stations of category 1, for products to be authorised for use in and around buildings, Category 2, for products to be authorised for indoor use only, provided that the bait stations are kept dry and intact.

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.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (*see section 5.3 for the information to be shown on the label*).
- 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.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

- If the grain bait is supplied as a loose grain, use a dosage device and minimize the dust (e.g. wet wiping).

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

- The treatment has to be alternated with other kind of active substances in order to avoid resistance and cross-resistances occurrence to rodenticides.
- Anticoagulant rodenticides authorised for use by professional users shall be used in tamper-resistant bait stations of category 1, for products to be authorised for use in and around buildings, Category 2, for products to be authorised for indoor use only, provided that the bait stations are kept dry and intact.

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*).
- 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 plastic gloves during product handling phase.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- If the grain bait is supplied as a loose grain, use a dosage device and minimize the dust (e.g. wet wiping).
- Do not use in areas where resistances to the active substance can be suspected.
- The treatment has to be alternated with other kind of active substances in order to avoid resistance and cross-resistances occurrence to rodenticides.

5.2. Risk mitigation measures

General Public

- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- The product information (i.e. label and/or leaflet) shall clearly show that:
 - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- 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 authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.
- The product shall contain an aversive or bittering agent.

Professional users

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign..
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:
 - the product shall not be supplied to the general public (e.g. "for professionals only").
 - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not wash the bait stations with water between applications.
- Dispose dead rodents in accordance with local requirements.
- The authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.
- The product shall contain an aversive or bittering agent.

Trained professional users

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- 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.
- 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 or permanent baiting treatments] in certain conditions.
- 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 authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.
- The product shall contain an aversive or bittering agent.

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 eyelids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. Contact a veterinary surgeon in case of ingestion by a pet.

DO NOT LEAVE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CENTER

- Clinical symptoms: Bleeding diathesis, derived from antiprothrombin effect – prolonged prothrombin time – that may become evident at minimum 24 – maximum 72 hours (A normal prothrombin time when the patient is admitted in the hospital, does not exclude the diagnosis).

- To report human poisoning incidents call the relevant national poison information centre. Include information on the product authorisation number, product trade name and active substance. Where possible provide a copy of the label or safety data sheet.

- 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 +4 021/318606, 021/3183620 (Toxicological information office).

- Hazardous to wildlife

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

General public

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

Professional users

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.

Trained professional users

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.

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: The biocidal product is stable for 24 months.

6. Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.

- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

- This product contains a bittering agent and a dye.

