

Summary of product characteristics for a biocidal product

Product name: ACTIPELLET-DIFE

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

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Authorisation number: IT/2012/00004/aUT

R4BP 3 asset reference number: IT-0000232-0000

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Administrative information

1.1. Trade names of the product

ACTIPELLET-DIFE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Activa s.r.l.
	Address	via Feltre, 32 20132 Milano Italy
Authorisation number	IT/2012/00004/aUT	
R4BP 3 asset reference number	IT-0000232-0000	
Date of the authorisation	05/05/2010	
Expiry date of the authorisation	01/07/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Activa S.r.l.
Address of the manufacturer	Via Feltre, 32 20132 Milano Italy
Location of manufacturing sites	Kollant S.r.l. Via C. Colombo, 7A, 30030 Vigonovo VE Italy

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

Active substance	26 - Difenacoum
Name of the manufacturer	ACTIVA SRL
Address of the manufacturer	Via Feltre 32 20132 Milan Italy
Location of manufacturing sites	Tezza S.r.l.-via Tre Ponti 22 37050 S. Maria di Zevio 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	0,005

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	<p>May damage the unborn child.</p> <p>May cause damage to organs to BLOOD through prolonged or repeated exposure .</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Do not handle until all safety precautions have been read and understood.</p> <p>Wear protective gloves.</p> <p>IF exposed or concerned: Get medical advice.</p> <p>Dispose of contents to in accordance with national and international regulations.</p> <p>Do not breathe dust.</p>

4. Authorised use(s)

4.1 Use description

Use 1 - House mice - professionals - 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: juveniles to adult
Field(s) of use	Indoor 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 frequencies	Application Rate: 40g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Minimum pack size of 1,5 kg. Packaging material: Plastic Composite

4.1.1 Use-specific instructions for use

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.

4.1.2 Use-specific risk mitigation measures

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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

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

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

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

Shelf life: 24 months

4.2 Use description

Use 2 - Rats - professionals - 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: juvenile to adult Scientific name: Rattus rattus Common name: Roof rat Development stage: other: juvenile to adult
Field(s) of use	Indoor Indoor
Application method(s)	Method: Bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
	Application Rate: 60-100g of bait per bait point. If more than one bait station is needed,

Application rate(s) and frequencies

the minimum distance between bait stations should be of 5 meters.
Dilution (%): 0
Number and timing of application:
If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.

Category(ies) of users

Industrial
Professional

Pack sizes and packaging material

Minimum pack size of 1,5 kg.
Packaging material: Plastic Composite

4.2.1 Use-specific instructions for use

The bait stations 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

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

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

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

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

Shelf life: 24 months

4.3 Use description

Use 3 - House mice and rats - professionals -outdoor 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: juvenile to adult Scientific name: Rattus rattus Common name: Roof rat Development stage: other: juvenile to adult Scientific name: Mus musculus Common name: House mouse Development stage: other: juvenile to adult
Field(s) of use	Outdoor 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 frequencies	Application Rate: House mouse: 40g of bait per bait point. Rattus: 60-100g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. Dilution (%): 0 Number and timing of application: If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Minimum pack size of 1,5 kg. Packaging material: Plastic Composite

4.3.1 Use-specific instructions for use

- 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.

4.3.2 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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 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.

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

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

Shelf life: 24 months

4.4 Use description

Use 4 - House mice and rats - trained professionals - 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: juvenile to adult Scientific name: Rattus rattus Common name: Roof rat Development stage: other: juvenile to adult Scientific name: Mus musculus Common name: House mouse Development stage: other: juvenile to adult
Field(s) of use	Indoor indoor
Application method(s)	Method: Bait application Detailed description: Bait formulations:

	<p>- Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.</p>
<p>Application rate(s) and frequencies</p>	<p>Application Rate: Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point. Dilution (%): 0 Number and timing of application: Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.</p>
<p>Category(ies) of users</p>	<p>Trained professional</p>
<p>Pack sizes and packaging material</p>	<p>Minimum pack size of 1,5 kg. Bait formulations: Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Packaging material: Plastic Composite</p>

4.4.1 Use-specific instructions for use

<p>Remove the remaining product at the end of treatment period. For permanent baiting : - Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population. - Follow any additional instructions provided by the relevant code of best practice.</p>
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4.4.2 Use-specific risk mitigation measures

<p>- 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 practice. - Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient. - Do not use the product in pulsed baiting treatments.</p> <p>In case of permanent baiting: - Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient. - The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.</p>
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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 points close to water drainage system, 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

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

Shelf life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

4.5 Use description

Use 5 - Mice and rats - trained professionals - outdoor 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: juvenile to adult

Scientific name: *Rattus rattus*
Common name: Roof rat
Development stage: other: juvenile to adult

Scientific name: *Mus musculus*
Common name: House mouse
Development stage: other: juvenile to adult

Field(s) of use

Outdoor

outdoor around buildings

Application method(s)

Method: Bait application

Detailed description:

Bait formulations:

- Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations
- Direct application of ready-to-use bait into the burrow.

Application rate(s) and frequencies

Application Rate: Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per

	bait point. Dilution (%): 0 Number and timing of application: Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Minimum pack size of 1,5 kg. Bait formulations: Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Packaging material: Plastic Composite

4.5.1 Use-specific instructions for use

<p>Remove the remaining product at the end of treatment period.</p> <p>For permanent baiting :</p> <ul style="list-style-type: none"> - Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population. - Follow any additional instructions provided by the relevant code of best practice. <p>For application in covered and protected bait points:</p> <ul style="list-style-type: none"> - For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species. - Follow any additional instructions provided by the relevant code of best practice. <p>For direct application in burrows:</p> <ul style="list-style-type: none"> - Baits must be placed to minimise the exposure to non-target species and children. - Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled. - Follow any additional instructions provided by the relevant code of best practice.

4.5.2 Use-specific risk mitigation measures

<ul style="list-style-type: none"> - 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 practice. - Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient. - Do not use the product in pulsed baiting treatments. <p>In case of permanent baiting:</p> <ul style="list-style-type: none"> - Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient. - The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation. <p>In case of direct applications in burrows:</p> <ul style="list-style-type: none"> - Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
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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 points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

Shelf life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

4.6 Use description

Use 6 - Rats - trained professionals - Outdoor open areas & 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)	Scientific name: Rattus norvegicus Common name: Brown rat Development stage: juvenile to adult Scientific name: Rattus rattus Common name: Roof rat Development stage: other: juvenile to adult
Field(s) of use	Outdoor outdoor open areas & waste dumps
Application method(s)	Method: Bait application Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations - Direct application of ready-to-use bait into the burrow.

Application rate(s) and frequencies

Application Rate: Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.
Dilution (%): 0
Number and timing of application:
Bait products: - High infestation: 60-100g of bait per baiting point. - Low infestation: 40-60g of bait per baiting point. Permanent baiting 60-100 gr of bait per bait point.

Category(ies) of users

Trained professional

Pack sizes and packaging material

Minimum pack size of 1,5 kg.
Bait formulations:
Package is restricted to separately packed bags with a maximum of 10 kg per packed bag.
Packaging material: Plastic Composite

4.6.1 Use-specific instructions for use

- 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 period
- Follow any additional instructions provided by the relevant code of best practice.

For permanent baiting :

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- Follow any additional instructions provided by the relevant code of best practice.

For application in covered and protected bait points:

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

For direct application in burrows:

- Baits must be placed to minimise the exposure to non-target species and children.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Follow any additional instructions provided by the relevant code of best practice.

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 practice.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.

In case of permanent baiting:

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

In case of direct applications in burrows:
- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign

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 waters (e.g. rivers, ponds, water channels, 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

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

Shelf life: 24 months.

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section "General directions for use (trained professionals)", are implemented.

5. General directions for use

5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 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.).
- 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.
- Wear protective chemical resistant 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Instructions for use that are "bait-specific":
- Bait in sachets: Do not open the sachets containing the bait.

5.2. Risk mitigation measures

- 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 (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment unless authorised for permanent baiting treatments.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements.

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

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

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: 24 months

6. Other information

- 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.