

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Murin Dife Pasta

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70720

R4BP asset number: IE-0021699-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Murin Dife Pasta
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Vebi Istituto Biochimico s.r.l.
	Address	via Desman, 43 35010 Borgoricco Italy
Authorisation number	IE/BPA 70720	
<i>R4BP asset number</i>	IE-0021699-0000	
Date of the authorisation	20/12/2012	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	Vebi Istituto Biochimico s.r.l.
Address of manufacturer	via Desman, 43 35010 Borgoricco (PD) Italy
Location of manufacturing sites	via Desman, 43 35010 Borgoricco (PD) Italy

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

Active substance	Difenacoum
Name of manufacturer	Dr Tezza s.r.l.
Address of manufacturer	via Tre Ponti, 22 37050 Santa Maria di Zevio (VR) Italy
Location of manufacturing sites	via Tre Ponti, 22 37050 Santa 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	0,005

2.2. Type(s) of formulation

PA Paste

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }. H360D: May damage the unborn child.
Precautionary statements	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P501: Dispose of contents to in accordance to national law.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles 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 use outdoor use In and around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: rat 200 g, mice 20-40 g Dilution (%): 0 Number and timing of application: <u>Mice Bait products:</u> 20-40 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. In case of high infestation level, applications sites are located 2 meters apart. 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. <u>Rats Bait products:</u>

	<p>200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 10 meters. In case of high infestation level, applications sites are located 5 meters apart.</p> <p>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.</p>
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>MURIN DIFE PASTA is furnished in two different type:</p> <ol style="list-style-type: none"> 1. heat sealed food paper or PE coated bags: 10 g, 12,5 g, 15, g, 20g 2. single dose plastic containers: 25- 30- 40- 50- 75 -80 -100- 150 g <p>Pack size: <i>from 1,5 kg to 25 kg</i></p> <p><i>In case of packaging higher than 10 kg Package is restricted to separately packed bags with a maximum bag size of 5 or 10 kg</i></p> <p>Packaging material:</p> <ul style="list-style-type: none"> - envelope, Plastic: coextruded/ HDPE/polethylene - Can /Tin, Paper, cardboard , - Box, Paper, cardboard with envelope inside coextruded/ HDPE/ polethylene - envelope plastic: PP MAT20 + PET MET 12 + PE45 - envelope plastic: PP MAT20 + PET MET 12 + PE60 - bucket: HDPE

4.1.1. Use-specific instructions

- 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.

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- 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*).
 - *[If national policy or legislation require it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
 - Bait should be secured so that it cannot be dragged away from the bait station.
 - Place the product out of the reach of children, birds, pets 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 (UNI EN 374) during product handling phase*

 - 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.

 - *Do not open the sachets containing the bait*
 - When the product is used in single-dose plastic trays, once positioned cut the upper protective film.

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

- 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

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

- 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"; "Murin dife pasta or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre".
- Hazardous to wildlife.

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

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

4.1.6. Where specific to the use, the 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

4.2. Use description

Table 2. Trained Professional

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

Target organism(s) (including development stage)	<p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles</p>
Field(s) of use	<p>indoor use outdoor use</p> <p>Mice and rats: indoor and outdoor around buildings Rats: Outdoor open areas Rats: Outdoor waste dumps</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 Direct application of ready-to-use bait into the burrow</p>
Application rate(s) and frequency	<p>Application rate: rat 200 g, mice 20-40g, Permanent baiting 100g</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Mice Bait products: - 20-40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. In case of high infestation level, applications sites are located 2 meters apart</p> <p>Mice - 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.</p> <p>Rats: Bait products: - 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 10 meters. In case of high infestation level, applications sites are located 5 meters apart</p> <p>Rats - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in</p>

	<p>order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.</p> <ul style="list-style-type: none"> - Permanent baiting 100g
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>MURIN DIFE PASTA is furnished in two different type:</p> <ol style="list-style-type: none"> 1. heat sealed food paper or PE coated bags: 10 g, 12,5 g, 15, g, 20g 2. single dose plastic containers: 25- 30- 40- 50- 75 -80 -100- 150 g <p>Pack size: <i>from 1,5 kg to 25 kg</i></p> <p><i>In case of packaging higher than 10 kg Package is restricted to separately packed bags with a maximum bag size of 5 or 10 kg</i></p> <p>Packaging material:</p> <ul style="list-style-type: none"> - envelope, Plastic:coextruded/ HDPE/polethylene - Can /Tin, Paper, cardboard , - Box, Paper, cardboard with envelope inside coextruded/ HDPE/ polethylene - envelope plastic: PP MAT20 + PET MET 12 + PE45 - envelope plastic: PP MAT20 + PET MET 12 + PE60 - bucket: HDPE

4.2.1. Use-specific instructions

- 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.

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- 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.
 - 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 labelled with the following information: "do not move or open"; "contains a rodenticide"; "Murin dife pasta or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre".

 - 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.
 - Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
 - Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

 - Wear protective chemical resistant gloves ((UNI EN 374)during product handling phase.

 - Remove the remaining product at the end of treatment period.
 - 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.
 - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided
 - Baits must be placed to minimise the exposure to non-target species and children.
 - *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.*
 - Bait should be secured so that it cannot be dragged away from the bait station.
 - 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.
 - 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 product at the end of treatment period (if the product are not used in a permanent bait system)*
 - *In case of use in a permanent bait system* - 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.

 - Do not open the sachets containing the bait
 - *When the product is used in single-dose plastic trays, once positioned cut the upper protective film.*

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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- 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.
 - Do not use the product in pulsed baiting treatments.
 - 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.
 - 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.
 - 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.

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 water drainage systems, ensure that bait contact with water is avoided.
- 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
- Hazardous to wildlife.

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

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

- Use of gloves is recommended.

4.2.6. Where specific to the use, the 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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

please refer to specific authorised uses

5.2. Risk mitigation measures

please refer to specific authorised uses

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"; "Murin pasta defend 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 uneaten bait and the packaging in accordance with local requirements

- Use of gloves (*UNI EN 374*) is recommended.

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

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

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- 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

- 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.
- Use Biocides Safely and Sustainably
- It is illegal to use this product for uses or in a manner other than that prescribed on this label.
- Poison Information: For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference.
- Please note IRELAND applies a minimum Professional pack size of 2.5 Kg instead of 3.0 kg.