

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

RODILON SOFT BLOCK

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70565

R4BP asset number: IE-0000757-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|---|
| Trade name(s) | Rodilon Soft Block BAYER GARDEN RAT & MOUSE SOFT BLOCK DEADFAST MOUSE AND RAT KILLER PLUS SACHET DEADFAST RAT KILLER PLUS SACHETS |
|---------------|---|

1.2. Authorisation holder

| | | |
|--|-----------------|---|
| Name and address of the authorisation holder | Name | LIPHATECH |
| | Address | Bonnel - CS 10005 47480 Pont Du Casse France |
| Authorisation number | IE/BPA 70565 | |
| <i>R4BP asset number</i> | IE-0000757-0000 | |
| Date of the authorisation | 20/04/2011 | |
| Expiry date of the authorisation | 31/12/2025 | |

1.3. Manufacturer(s) of the product

| | |
|---------------------------------|--|
| Name of manufacturer | LIPHATECH SAS |
| Address of manufacturer | Bonnel - CS 10005 47480 PONT DU CASSE France |
| Location of manufacturing sites | Production centre, avenue Jean Serres, ZA Malère 47480 PONT DU CASSE France |

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

| | |
|---------------------------------|---|
| Active substance | Difethialone |
| Name of manufacturer | LIPHATECH S.A.S |
| Address of manufacturer | Bonnel BP3 47480 PONT DU CASSE France |
| Location of manufacturing sites | CONFIDENTIAL - LIPHATECH S.A.S at AlzChem Trostberg GmbH - Chemie Park Trostberg - Dr Albert Frank strasse 32 83308 Trostberg Germany |

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 (%) |
|--------------|--|------------------|-------------|-----------|-------------|
| Difethialone | 3-[3-(4-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothio-pyran-2-one | active substance | 104653-34-1 | | 0,0025 |

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|--------------------------|---|
| Hazard statements | H373: May cause damage to organs (blood) through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}. H412: Harmful to aquatic life with long lasting effects. |
| Precautionary statements | P273: Avoid release to the environment. P314: Get medical advice if you feel unwell. P501: Dispose of contents to according to local legislation. P501: Dispose of container to according to local legislation. |

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Trained professionals

| | |
|--|--|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: All Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: All Scientific name: <i>Rattus rattus</i> Common name: Black / Roof rat Development stage: All |
| Field(s) of use | indoor use outdoor use Indoors and outdoors around buildings |
| Application method(s) | Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations, covered and protected baiting points. |
| Application rate(s) and frequency | Application rate: see Number and Timing of applications Dilution (%): 0 Number and timing of application: Mice High infestation – Up to 50 g in bait stations or covered bait points every 1 to 1.5 metres Low infestation – Up to 50 g in bait stations or covered bait points every 2 to 3 metres Rats High infestation – Up to 200 g in bait stations every 4 to 5 metres Low infestation – Up to 200 g in bait stations every 8 to 10 metres |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | Minimum pack size of 2.5 kg. Plastic bucket (sachets of 10 to 40 g) - Up to 17 kg Cardboard carton with integral plastic bag (sachets of 10 g to 40 g) - Up to 20 kg Plastic container (sachets of 10 g to 40 g) – Up to 4 kg Lockable plastic pouch (sachets of 10 g to 40g) – Up to 4 kg |

| | |
|--|--|
| | Pre-filled bait stations (sachets of 10 g to 40 g)/ cardboard box – 2 to 60 bait stations Pre-filled bait stations (sachets of 10 g to 40 g)/ plastic bag – 2 to 60 bait stations |
|--|--|

4.1.1. Use-specific instructions

- 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.).
- 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.
- Remove the remaining product at the end of treatment period.

Specific to Outdoor around buildings:

- 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.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species

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.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.
- 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.
- 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").

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

Indoor:

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

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

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

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4.2. Use description

Table 2. Professionals

| | |
|--|--|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: All</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: All</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black/Roof rat Development stage: All</p> |
| Field(s) of use | <p>indoor use outdoor use</p> <p>Indoors and outdoors around buildings</p> |
| Application method(s) | <p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p> |
| Application rate(s) and frequency | <p>Application rate: See number and timing of application</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Mice:</p> |

| | |
|-----------------------------------|---|
| | <p>- up to 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1-1.5 meter.</p> <p>Rats: - up to 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4-5 meters.</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>Minimum pack size of 2.5 kg.</p> <p>Plastic bucket (sachets of 10 to 40 g) - Up to 17 kg</p> <p>Cardboard carton with integral plastic bag (sachets of 10 g to 40 g) - Up to 20 kg</p> <p>Plastic container (sachets of 10 g to 40 g) – Up to 4 kg</p> <p>Lockable plastic pouch (sachets of 10 g to 40g) – Up to 4 kg</p> <p>Pre-filled bait stations (sachets of 10 g to 40 g)/ cardboard box – 2 to 60 bait stations</p> <p>Pre-filled bait stations (sachets of 10 g to 40 g)/ plastic bag – 2 to 60 bait stations</p> |

4.2.1. Use-specific instructions

- 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.).
- Protect bait from the atmospheric conditions. Place the baiting points in areas non-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

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

- Do not apply this product directly in the burrows.
- Do not wash the bait stations with water between applications.
- 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 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").

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

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

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

4.3. Use description

Table 3. General public

| | |
|--|--|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: All</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: All</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Black / Roof rat Development stage: All</p> |
| Field(s) of use | <p>indoor use outdoor use</p> <p>Indoors and outdoors around buildings The use against mice is authorised indoor only.</p> |

| | |
|-----------------------------------|---|
| Application method(s) | <p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.</p> |
| Application rate(s) and frequency | <p>Application rate: see Number and timing of applications</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Mice (indoor only): - up to 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1-1.5 meter.</p> <p>Rats (in and around buildings): - up to 150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4-5 meters.</p> <p>.</p> |
| Category(ies) of users | general public (non-professional) |
| Pack sizes and packaging material | <p>Pre-filled plastic (PP, HDPE or PS) tamper-resistant bait stations (sachets of 10 to 40 g)/ cardboard box – up to 150g for rats/rats and mice or up to 50 g for mice only.</p> <p>Pre-filled plastic (PP, HDPE or PS) tamper-resistant bait stations (sachets of 10 to 40 g)/ plastic bag – up to 150g for rats/rats and mice or up to 50 g for mice only.</p> <p>Lockable plastic (PP, HDPE or PS) tamper resistant bait station (sachets of 10 to 40 g)/cardboard box – up to 150g for rats/rats and mice or up to 50 g for mice only.</p> <p>Lockable plastic (PP, HDPE or PS) tamper resistant bait stations (sachets of 10 to 40 g) /plastic bag - up to 150g for rats/rats and mice or up to 50 g for mice only.</p> <p>Plastic (PP) bucket (sachets of 10 to 40g) – up to 150g for rats/ rats and mice or up to 50 g for mice only</p> <p>Cardboard or PE carton with integral plastic bag (sachets of 10 to 40g) – up to 150g for rats/rats and mice or up to 50 g for mice only</p> |

| | |
|--|---|
| | <p>Plastic (PE or PP) container (sachets of 10 to 40g) – up to 150g for rats/rats and mice or up to 50 g for mice only</p> <p>Lockable plastic (PE or PP) pouch (sachets of 10 to 40g) – up to 150g for rats/rats and mice or up to 50 g for mice only</p> <p>[NB Sachets of 10 to 40 g: paper, PP or PE]</p> |
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4.3.1. Use-specific instructions

- The bait stations should be visited at least every 2 to 3 days (use against mice) / 5 to 7 days (use against rats) 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.
- Place the bait stations in areas non-liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- 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.).
- 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- 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.
- 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").

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

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.

TRAINED PROFESSIONALS / PROFESSIONALS: - 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.

TRAINED PROFESSIONALS / PROFESSIONALS: - 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.

- Where possible, bait stations must be fixed to the ground or other structures.

TRAINED PROFESSIONALS / PROFESSIONALS: - 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).

TRAINED PROFESSIONALS / PROFESSIONALS: - [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

TRAINED PROFESSIONALS / PROFESSIONALS: - Bait should be secured so that it cannot be dragged away from the bait station.

TRAINED PROFESSIONALS / PROFESSIONALS: - Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

TRAINED PROFESSIONALS / PROFESSIONALS: - Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

TRAINED PROFESSIONALS / PROFESSIONALS: - Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

TRAINED PROFESSIONALS / PROFESSIONALS: - 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.

TRAINED PROFESSIONALS / PROFESSIONALS: - 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.

- Do not open the sachets containing the bait

5.2. Risk mitigation measures

TRAINED PROFESSIONALS / PROFESSIONALS: - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

TRAINED PROFESSIONALS / PROFESSIONALS: - Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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

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- 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 [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre"
- 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 is recommended.

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: 4 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.