Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)

MURIN DIFE BLOCK

Product type(s) [PT14]

Difenacoum

Case Number in R4BP: BC-EY000505-28

Evaluating Competent Authority: [Italy]

 Date: [13/12/2017]

ASSESSMENT REPORT

* 1. Summary of the product assessment
		1. **Administrative information**
			1. **Identifier of the product / product family**

|  |  |
| --- | --- |
| **Identifier** | **Country (if relevant)** |
| Murin Dife Block | Italy |

* + - 1. **Authorisation holder**

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| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Vebi Istituto Biochimico s.r.l. |
| **Address** | Via Desman, 43, 35010 Borgoricco (PD) |
| **Authorisation number** | IT/2012/00043/AUT |
| **Date of the authorisation** | 20/06/2012 |
| **Expiry date of the authorisation** | 31/12/2022 |

* + - 1. **Manufacturer of the product**

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| --- | --- |
| **Name of manufacturer** | Vebi Istituto Biochimico s.r.l. |
| **Address of manufacturer** | Via Desman, 43, 35010 Borgoricco (PD) |
| **Location of manufacturing sites** | Via Desman, 43, 35010 Borgoricco (PD) |

* + - 1. **Manufacturer of the active substance**

|  |  |
| --- | --- |
| **Active substance** | Difenacoum |
| **Name of manufacturer** | Activa S.r.l. |
| **Address of manufacturer** | Via Feltre, 3220132 – Milano Italy |
| **Location of manufacturing sites** | Dr. Tezza s.r.l. - Via Tre Ponti 22 - S. Maria di Zevio (VR) |

* + 1. **Product composition and formulation**

The full composition of the product according to Annex III Title 1 is provided in the confidential annex and is identical to the composition approved for the reference product ACTIBLOCK-DIFE – Authorization N. IT/2012/00006/AUT).

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ¨

No þ

# Identity of the active substance

|  |  |
| --- | --- |
|  | **Main constituent** |
| **ISO name** | Difenacoum |
| **IUPAC name (\*)** | *3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4- hydroxycoumarin* |
| **EC number** | 259-978-49 |
| **CAS number** | 56073-07-5 |
| **Index number in Annex VI of CLP** | 607-157-00-X |
| **Minimum purity** | 96.0% |
| **Structural formula** |  |

(\*) As published for the ISO common name difenacoum. It is considered that the ISO-common name difenacoum covers all possible ratios of the two diastereomers and that it is thus applicable to the substance presented herein.

# Candidate(s) for substitution

Difenacoum is considered to be potentially persistent, potentially bioaccumulative and toxic. However, in spite of the potential persistency of the active substance, no potential for long-range environmental transport is expected, either. Subsequently, it is concluded that difenacoum is not expected to meet the POP criteria.

The alternatives mentioned in all contributions fall into two groups:

1. to be used to kill rodents (e.g. chemical alternatives, mechanical or electrical traps or glue-

/sticky-boards), and

1. measures to be taken to restrict access of rodents to food sources.

Ad 1) As chemical alternatives alphachloralose, hydrogen cyanide, aluminium phosphide, carbon dioxide and powdered corn cob are mentioned but at the same time some limitations in terms of use

(limited to use for – indoor - mouse control or fumigants which can only be used by trained professionals), efficacy and effectiveness of using these substances are listed.

Mechanical and electrical traps are proposed in some contributions as a serious alternative to anticoagulant rodenticides due to technical progress in trap development, for example multi-catch traps and equipping traps with electronic communication devices limiting the frequency of inspection to when a rodent is actually killed by the trap. Traps have been developed for mouse and rats, with dedicated traps for the control of rats in sewers. Limited testing on efficacy and effectiveness for rodent control has been carried out, for example on the control of house mice. Other contributions state that traps cannot be considered as cost-effective and efficient as the use of an efficacious rodenticide. The following disadvantages are mentioned: requirement of a high degree of skill, adverse impacts of non-target wild life and humaneness. It is stated that traps may provide effective control of small infestations, in particular for mice. Some of these disadvantages are particularly relevant for glue-/sticky boards, which are not allowed in some MS.

Ad 2) Measures to restrict access to food sources, are rather considered as complementary techniques. Examples are habitat modification, rodent proofing and the use of repellents. It is stated in a contribution that no chemical repellents for rodent control are approved under Regulation (EU) No 528/2012 and there is no convincing scientific evidence that electromagnetic devices are effective.

# 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 | 259-978-49 | 0.005 |
| Denatonium benzoate | benzyl-[2-(2,6- dimethylanilino)-2- oxoethyl]- diethylazanium benzoate | Human taste deterrent | 3734-33-6 | 223-095-2 | 0.001 |
| Other components | - | Edible substances and coformulants | - | - | Up to 100 |

* + - 1. **Information on technical equivalence**

Activa S.r.l. is one of the approved Active Suppliers on the Article 95 list.

# Information on the substance(s) of concern

Substances of concern are not present in the product.

# Type of formulation

Ready-to-use bait: wax block.

* + 1. **Hazard and precautionary statements**

**Classification and labelling of the product according to the Regulation (EC) 1272/2008**

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| --- |
| **Classification** |
| Hazard category | Repr. 1B; H360D STOT RE 2; H373 |
| Hazard statement | H360D: May damage the unborn childH373: May cause damage to the blood through prolonged or repeated exposure |
| **Labelling** |
| Pictograms | GHS08 |
| Signal words | Danger |
| Hazard statements | H360D: May damage the unborn childH373: May cause damage to the blood through prolonged or repeated exposure |
| 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/attention. P501 Dispose of contents and container in accordance with national and international regulations. |
|  |
| Note | **-** |

* + 1. **Authorised uses**
			1. **Use # 1 – House mice - professionals - indoor**
				1. ***Use description***

Use # 1 – House mice - professionals - indoor

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus*House mouseJuveniles*Mus musculus*House mouseAdults |
| **Field of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - 40 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait point should be of 5 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

* + - * 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.

* + - * 1. ***Use-specific risk mitigation measures***

Use-specific risk mitigation measures are not necessary when risk mitigation measures, as detailed in the section “General directions for use (professionals)”, are implemented.

* + - * 1. ***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.

* + - * 1. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

Use specific instruction for safe disposal of the product and its packaging are not necessary when

instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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 (professionals)”, are implemented.

* + - 1. **Use # 2 – Rats - professionals - indoor**
				1. ***Use description***

Use # 2 – Rats - professionals - indoor

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus*Brown ratJuveniles*Rattus norvegicus*Brown ratAdults*Rattus rattus*Roof ratJuveniles*Rattus rattus*Roof ratAdults |
| **Field of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - 60-100 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait stations should be of 5 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

## 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 is intact and to remove rodent bodies. Re-fill bait when necessary.

* + - * 1. ***Use-specific risk mitigation measures***

Use-specific risk mitigation measures are not necessary when risk mitigation measures, as detailed in the section “General directions for use (professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment***
				2. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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 (professionals)”, are implemented.

* + - 1. **Use # 3 – House mice and rats - professionals - outdoor around buildings**
				1. ***Use description***

Use # 3 – House mice and rats - professionals - outdoor around buildings

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus*Brown ratJuveniles*Rattus norvegicus*Brown ratAdults*Rattus rattus*Roof ratJuveniles*Rattus rattus*Roof ratAdults*Mus musculus*House mouseJuveniles*Mus musculus*House mouseAdults |
| **Field of use** | Outdoor around building |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | * 40 g of bait per bait point for mice.
* 60-100 g of bait per bait point for rats.

If more than one bait point is needed, the minimum distance between bait points should be of 5 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

## 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 station should be visited for mice at least every 2 to 3 days at the beginning of the treatment and for rats only 5 to 7 days after the beginning of the treatment and at least weekly afterwards (for mice and rats), in order to check whether the bait is accepted, the bait station is intact and to remove rodent bodies. Re-fill bait when necessary.
* Replace any bait in bait station in which bait has been damaged by water or contaminated by dirt.
	+ - * 1. ***Use-specific risk mitigation measures***

- Do not apply this product directly in the burrows.

* + - * 1. ***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 water (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or drainage systems, ensure that bait contact with water is avoided.

* + - * 1. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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 (professionals)”, are implemented.

* + - 1. **Use # 4 – House mice and rats - trained professionals - indoor**
				1. ***Use description***

Use # 4 – House mice and rats - trained professionals - indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus*Brown ratJuveniles*Rattus norvegicus*Brown ratAdults*Rattus rattus*Roof ratJuveniles*Rattus rattus*Roof ratAdults*Mus musculus*House mouseJuveniles*Mus musculus*House mouseAdults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait formulations:* ready-to-use bait to be used in tamper-resistant bait stations
* ready-to-use bait may be used in 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 station
* direct application of the ready-to-use bait in the burrow.
 |
| **Application rate(s) and frequency** | Bait products*Rats** High infestation: 100 g of bait per baiting point.
* Low infestation: 60 g of bait per baiting point.

*Mice** 40 g of bait per baiting point.
* Permanent baiting, where applicable.
 |
| **Category(ies) of users** | Trained professionals. |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

## Use-specific instructions for use

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

* + - * 1. ***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 as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- Do not use the product in pulsed baiting treatments.

* + - * 1. ***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.

* + - * 1. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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.

* + - 1. **Use # 5 – Mice and rats - trained professionals - outdoor around buildings**
				1. ***Use description***

Use # 5 – Mice and rats - trained professionals - outdoor around buildings

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus*Brown ratJuveniles*Rattus norvegicus*Brown ratAdults*Rattus rattus*Roof ratJuveniles*Rattus rattus*Roof ratAdults*Mus musculus*House mouseJuveniles*Mus musculus*House mouseAdults |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:* ready-to-use bait to be used in tamper-resistant bait stations
* ready-to-use bait may be used in 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 station
* direct application of the ready-to-use bait in the burrow.
 |
| **Application rate(s) and frequency** | Bait products*Rats** High infestation: 100 g of bait per baiting point.
* Low infestation: 60 g of bait per baiting point.

*Mice** 40 g of bait per baiting point.
* Permanent baiting, where applicable.
 |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

## Use-specific instructions for use

* 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.
* Unless when used in burrows, remove the remaining product at the end of treatment period.
	+ - * 1. ***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.
* 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 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.
	+ - * 1. ***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.

* + - * 1. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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.

* + - 1. **Use # 6 – Rats - trained professionals - Outdoor open areas &**
				1. ***Use description***

Use # 6 – Rats - trained professionals - Outdoor open areas & waste dumps

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus*Brown ratJuveniles*Rattus norvegicus*Brown ratAdults*Rattus rattus*Roof ratJuveniles*Rattus rattus*Roof ratAdults |
| **Field of use** | Outdoor open areas Outdoor waste dumps |
| **Application method(s)** | Bait formulations:* ready-to-use bait to be used in tamper-resistant bait stations or in covered and protected baiting points
* direct application of the ready-to-use bait in the burrow.
 |
| **Application rate(s) and frequency** | Bait products* High infestation: 100 g of bait per baiting point.
* Low infestation: 60 g of bait per baiting point.
* Permanent baiting, where applicable.
 |
| **Category(ies) of users** | Trained professionals only |
| **Pack sizes and packaging material** | Bait product of 10 or 20 gr unitsMinimum pack size of 1.5 kg up to 25 kg.Where applicable package is restricted to separately packed bags with a maximum bag size of 10 kg.Packaging material:- envelope, Plastic:coextruded HDPE/polyethylene- Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene- bucket: HDPE-envelope plastic: PP MAT20 + PET MET 12 + PE45﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 |

## 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.
* Unless for the application in the burrow, remove the remaining product at the end of treatment period.
	+ - * 1. ***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 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.
	+ - * 1. ***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.

* + - * 1. ***Where specific to the use, the instructions for safe disposal of the product and its packaging***

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

* + - * 1. ***Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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.

* + - 1. **Addendum 1.– Additional elements to be considered for permanent baiting**

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| --- | --- |
| Application rate(s) and frequency | Bait products:- 60-100 g of bait per baiting point. |
| Category(ies) of users | Trained professionals only |

Additional specific instructions for use

* 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.

Additional specific risk mitigation measures

* 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.

# Addendum 2.– Additional elements to be considered for application in covered and protected bait points

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| --- | --- |
| Application rate(s) and frequency | Bait products:* High infestation: 100 g of bait per baiting point.
* Low infestation: 60 g of bait per baiting point.
 |
| Category(ies) of users | Trained professionals only |

Additional specific instructions for use

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

Additional specific risk mitigation measures No additional specific risk mitigation measures.

* + - 1. **Addendum 3.– Additional elements to be considered for direct application in burrows**

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| --- | --- |
| Application method(s) | - Direct application of ready-to-use bait into the burrow |
| Application rate(s) and frequency | Bait products:60-100 g of bait per burrow. |

|  |  |
| --- | --- |
| Category(ies) of users | Trained professionals only |

Additional specific instructions for use

* 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.

Additional specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.

* + 1. **General directions for use (professionals)**
			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.).
* 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 *“Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment”* 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 (rubber).
* 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.

# 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.

# 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 or 118.
* Hazardous to wildlife.
	+ - 1. **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.

* + - 1. **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.
	+ 1. **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.
	+ 1. **General directions for use (trained professionals)**
			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.
* 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 “Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment” 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 (rubber) 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.

# 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.
* 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.
	+ - 1. **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 or emergency telephone number (i.e. for Italy 118).
* Hazardous to wildlife.
	+ - 1. **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.

* + - 1. **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.
	+ 1. **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.
	+ 1. **Packaging of the biocidal product**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non- professional)** | **Compatibility of the product with the proposed packaging materials****(Yes/No)** |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | - envelope, Plastic:coextruded HDPE/polyethylene | welded | - Professional- Trained professional | y |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | - Box, Paper, cardboard with envelope inside coextruded HDPE/polyethylene | Envelope : welded, carton Scotch tape | - Professional- Trained professional | y |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | - bucket: HDPE | With seal | - Professional- Trained professional | y |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | -envelope plastic: PP MAT20 + PET MET 12 + PE45 | welded | - Professional- Trained professional | y |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | ﻿﻿-envelope plastic: PP MAT20 + PET MET 12 + PE60 | welded | - Professional- Trained professional | y |
| Bait product of 10 or 20 gr units | Minimum pack size from 1.5 kg up to 25 kg  | Envelope plastic: PP MAT20 + PET MET 12 + PE60 | welded | - Professional- Trained professional | y |

**Decision**

Considering the final Product Assessment Report (PAR) and the final Summary of Product Characteristics of the Reference Biocidal Product ACTIBLOCK-DIFE (asset n. IT-0000218-0000), the IT-CA considers that sufficient information has been provided to adopt the same conclusions, and permits the renewal of the authorisation of the same biocidal product.

**Notes**

The product SPC and labels shall be provided/revised strictly according to this opinion.