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***ANNEX***

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

Endorats Original Rat & Mouse Killer

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** IE/BPA 70554

**R4BP asset number:** IE-0001553-0000

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## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	Endorats Original Rat & Mouse Killer
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	Detia Degesch GmbH
	Address	Dr.-Werner-Freyberg-Straße 11 69514 Laudenbach Germany
Authorisation number	IE/BPA 70554	
<i>R4BP asset number</i>	IE-0001553-0000	
Date of the authorisation	29/03/2012	
Expiry date of the authorisation	31/12/2025	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	Detia Freyberg GmbH
Address of manufacturer	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
Location of manufacturing sites	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany

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

Active substance	Difenacoum
Name of manufacturer	PelGar international Limited
Address of manufacturer	Unit 13, Newman Lane GU34 2QR Alton, Hampshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Praszka 54 280 02 Kolin Czechia

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## 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

RB Bait (ready for use)

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H360D: May damage the unborn child.</p> <p>H373: May cause damage to organs &lt;blood&gt; through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.</p>
Precautionary statements	<p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P260: Do not breathe dust.</p> <p>P260: Do not breathe vapours.</p> <p>P260: Do not breathe fume.</p> <p>P260: Do not breathe gas.</p> <p>P260: Do not breathe mist.</p> <p>P260: Do not breathe spray.</p> <p>P280: Wear protective gloves.</p> <p>P280: Wear protective clothing.</p> <p>P280: Wear eye protection.</p> <p>P280: Wear face protection.</p> <p>P308+P313: IF exposed or concerned: Get medical advice.</p> <p>P308+P313: IF exposed or concerned: Get medical attention.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to ....</p> <p>P501: Dispose of container to ....</p>

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Use 1 Brown rats- trained professionals - indoor**

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: Juveniles, Adults
Field(s) of use	indoor use  Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations  Detailed description: Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequency	Application Rate: Max. 200 g per bait station Permanent baiting (please see use specific instruction for use)  Dilution (%): 100  Number and timing of application: see instructions for use
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. PE-bag or paper bag ( PE coated paper): 50g, 100g, 200g, 400g, 500g, 1000g in carton or plastic bucket (PE) up to 10kg plastic bucket (PP): up to 10kg loose baits carton (10kg): 100 PE-bag with each 100g product paper sack (sack paper-PE-sack paper): 14kg divided in bags with a maximum of 10 kg, 25kg divided in bags with a maximum of 10 kg

#### 4.1.1. Use-specific instructions for use

- 1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning. (Derogation in Germany)
- 2) Additional elements to be considered for permanent baiting (Derogation in Germany):  
Strategic permanent baiting (Strategic permanent baiting independent of infestation is to be distinguished from large scale permanent baiting as defined by the DIN 10523 (permanent- or perimeter baiting).) independent of infestation is permitted for professional user with competence according to German Hazardous Substances Ordinance (Gefährstoffverordnung), Annex 1, No. 3, provided that all of the following conditions are met:  
Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the professional user with

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competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewhere protected (e.g. cable lines, sub-construction of electric appliances).

An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 during an on-site assessment.

This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e.g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i.e. they need to be necessary in order to protect constitutional rights.

A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

In these cases the use of permanent baits containing the active substances difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 in each individual case. In each case, the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can for instance be made for operations that produce, process, market or store food- or feeding stuff; operations that produce, process or store pharmaceutical or medical products or for waste disposal companies or storage businesses or warehouses.

Permanent baiting with rodenticides containing difenacoum may only be implemented by or under the supervision of a professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures. It is at the discretion of the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, additional control measures have to be taken due to an actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks.

Additional inspections of the permanent bait points in consultation with the pest control company in charge may be carried out also by other trained professional users according to the definition under point 6. (Other information) No. 1 a) and b), if not different required by Annex I No. 3 of the German Ordinance on Hazardous Substances (Version 29.03.2017). 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.

#### **4.1.2. Use-specific risk mitigation measures**

- 1) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
- 2) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed (Derogation in Germany).
- 3) Take the following measures to avoid re-infestation after a successful control (Derogation in Germany):
  - a) Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.

c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

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

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

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

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

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### **4.2. Use description**

**Table 2. Use 2 Brown rat - trained professionals - outdoor around buildings**

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: Juveniles, Adults
Field(s) of use	indoor use  Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations  Detailed description: Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequency	Application Rate: Max. 200 g per bait station Permanent baiting (please see use specific instruction for use)  Dilution (%): 100  Number and timing of application: see instructions for use
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. PE-bag or paper bag ( PE coated paper): 50g, 100g, 200g, 400g, 500g, 1000g in carton or plastic bucket (PE) up to 10kg plastic bucket (PP): up to 10kg loose baits carton (10kg): 100 PE-bag with each 100g product



paper sack (sack paper-PE-sack paper): 14kg divided in bags with a maximum of 10 kg, 25kg divided in bags with a maximum of 10 kg
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#### 4.2.1. Use-specific instructions for use

1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning. (Derogation in Germany)

2) Additional elements to be considered for permanent baiting (Derogation in Germany):

Strategic permanent baiting (Strategic permanent baiting independent of infestation is to be distinguished from large scale permanent baiting as defined by the DIN 10523 (permanent- or perimeter baiting).) independent of infestation is permitted for professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, provided that all of the following conditions are met:

Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewhere protected (e.g. cable lines, sub-construction of electric appliances).

An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 during an on-site assessment.

This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e.g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i.e. they need to be necessary in order to protect constitutional rights.

A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

In these cases the use of permanent baits containing the active substances difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 in each individual case. In each case, the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can for instance be made for operations that produce, process, market or store food- or feeding stuff; operations that produce, process or store pharmaceutical or medical products or for waste disposal companies or storage businesses or warehouses.

Permanent baiting with rodenticides containing difenacoum may only be implemented by or under the supervision of a professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures. It is at the discretion of the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, additional control measures have to be taken due to an actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks.

Additional inspections of the permanent bait points in consultation with the pest control company in charge may be carried out also by other trained professional users according to the definition under point 6. (Other information) No. 1 a) and b), if not different required by Annex I No. 3 of the German Ordinance on Hazardous

Substances (Version 29.03.2017).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.

#### **4.2.2. Use-specific risk mitigation measures**

- 1) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
- 2) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed (Derogation in Germany).
- 3) Take the following measures to avoid re-infestation after a successful control (Derogation in Germany):
  - a) Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
  - c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

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

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

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

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

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### **4.3. Use description**

**Table 3. Use 3 – Brown rat – trained professionals - outdoor open areas & waste dumps**

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: Juveniles, Adults
Field(s) of use	indoor use  Ready-to-use bait to be used in tamper-resistant bait stations. Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species. Direct application of ready-to-use bait into the burrow
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations  Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations. Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure

	to non-target species. Direct application of ready-to-use bait into the burrow
Application rate(s) and frequency	Application Rate: Max. 200 g per bait station/baiting point  Dilution (%): 100  Number and timing of application: see instructions for use
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. PE-bag or paper bag ( PE coated paper): 50g, 100g, 200g, 400g, 500g, 1000g in carton or plastic bucket (PE) up to 10kg plastic bucket (PP): up to 10kg loose baits carton (10kg): 100 PE-bag with each 100g product paper sack (sack paper-PE-sack paper): 14kg divided in bags with a maximum of 10 kg, 25kg divided in bags with a maximum of 10 kg

#### 4.3.1. Use-specific instructions for use

- 1) Protect bait from the weathering (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding (Derogation in Germany).
- 2) Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- 3) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning (Derogation in Germany).

For direct application of ready-to-use bait into the burrow:

- 4) Baits must be placed to minimise the exposure to non-target species and children.
- 5) Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- 6) Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
- 7) The authorisation holder shall recommend how spilled bait shall be remediated.
- 8) The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
- 9) No use of the biocidal product during times of rainfall.

#### 4.3.2. Use-specific risk mitigation measures

- 1) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days (Derogation in Germany).
- 2) Bait stations have to be used. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed (Derogation in Germany).
- 3) -Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

Outdoor open areas:

- 4) Take the following measures to avoid re-infestation after a successful control (Derogation in Germany):
  - a) Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
  - c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

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

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

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

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

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### 4.4. Use description

**Table 4. Use 4 House mice – trained professionals - indoor**

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>Mus musculus</i> Common name: house mouse Development stage: Juveniles, Adults
Field(s) of use	indoor use  Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations  Detailed description: Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequency	Application Rate: Max. 200 g per bait station Permanent baiting (please see use specific instruction for use)  Dilution (%): 100  Number and timing of application: see instructions for use
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. PE-bag or paper bag ( PE coated paper): 50g, 100g, 200g, 400g, 500g, 1000g in carton or plastic bucket (PE) up to 10kg plastic bucket (PP): up to 10kg loose baits carton (10kg): 100 PE-bag with each 100g product paper sack (sack paper-PE-sack paper): 14kg divided in bags with a maximum of 10 kg, 25kg divided in bags with a maximum of 10 kg

#### 4.4.1. Use-specific instructions for use

- 1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning. (Derogation in Germany)
- 2) Additional elements to be considered for permanent baiting (Derogation in Germany):

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Strategic permanent baiting (Strategic permanent baiting independent of infestation is to be distinguished from large scale permanent baiting as defined by the DIN 10523 (permanent- or perimeter baiting).) independent of infestation is permitted for professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, provided that all of the following conditions are met: Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewhere protected (e.g. cable lines, sub-construction of electric appliances).

An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 during an on-site assessment.

This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e.g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i.e. they need to be necessary in order to protect constitutional rights.

A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

In these cases the use of permanent baits containing the active substances difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 in each individual case. In each case, the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can for instance be made for operations that produce, process, market or store food- or feeding stuff; operations that produce, process or store pharmaceutical or medical products or for waste disposal companies or storage businesses or warehouses.

Permanent baiting with rodenticides containing difenacoum may only be implemented by or under the supervision of a professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures. It is at the discretion of the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, additional control measures have to be taken due to an actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks.

Additional inspections of the permanent bait points in consultation with the pest control company in charge may be carried out also by other trained professional users according to the definition under point 6. (Other information) No. 1 a) and b), if not different required by Annex I No. 3 of the German Ordinance on Hazardous Substances (Version 29.03.2017). 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.

#### **4.4.2. Use-specific risk mitigation measures**

1) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.

- 2) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed (Derogation in Germany).
- 3) Take the following measures to avoid re-infestation after a successful control (Derogation in Germany):
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
  - As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

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

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

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

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

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### **4.5. Use description**

**Table 5. Use 5 House mouse (outdoor around buildings)**

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>Mus musculus</i> Common name: house mouse Development stage: Juveniles, Adults
Field(s) of use	indoor use  Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application method(s)	Method: Ready-to-use bait to be used in tamper-resistant bait stations  Detailed description: Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequency	Application Rate: Max. 200 g per bait station Permanent baiting (please see use specific instruction for use)  Dilution (%): 100  Number and timing of application: see instructions for use

Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Minimum pack size of 2.5 kg. PE-bag or paper bag ( PE coated paper): 50g, 100g, 200g, 400g, 500g, 1000g in carton or plastic bucket (PE) up to 10kg plastic bucket (PP): up to 10kg loose baits carton (10kg): 100 PE-bag with each 100g product paper sack (sack paper-PE-sack paper): 14kg divided in bags with a maximum of 10 kg, 25kg divided in bags with a maximum of 10 kg

#### 4.5.1. Use-specific instructions for use

1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning. (Derogation in Germany)

2) Additional elements to be considered for permanent baiting (Derogation in Germany):

Strategic permanent baiting (Strategic permanent baiting independent of infestation is to be distinguished from large scale permanent baiting as defined by the DIN 10523 (permanent- or perimeter baiting).) independent of infestation is permitted for professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, provided that all of the following conditions are met: Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewhere protected (e.g. cable lines, sub-construction of electric appliances).

An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 during an on-site assessment.

This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e.g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i.e. they need to be necessary in order to protect constitutional rights.

A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

In these cases the use of permanent baits containing the active substances difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 in each individual case. In each case, the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can for instance be made for operations that produce, process, market or store food- or feeding stuff; operations that produce, process or store pharmaceutical or medical products or for waste disposal companies or storage businesses or warehouses.

Permanent baiting with rodenticides containing difenacoum may only be implemented by or under the supervision of a professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures. It is at the discretion of the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, additional control measures have to be taken due to an

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actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks.

Additional inspections of the permanent bait points in consultation with the pest control company in charge may be carried out also by other trained professional users according to the definition under point 6. (Other information) No. 1 a) and b), if not different required by Annex I No. 3 of the German Ordinance on Hazardous Substances (Version 29.03.2017). 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.

#### **4.5.2. Use-specific risk mitigation measures**

- 1) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
- 2) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed (Derogation in Germany).
- 3) Take the following measures to avoid re-infestation after a successful control (Derogation in Germany):
  - a) Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
  - c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

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

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

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

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#### **4.5.5. 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 USE<sup>1</sup>

### 5.1. Instructions for use

- 1) Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 2) 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.
- 3) Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
- 4) The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
- 5) Remove water sources and 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.
- 6) 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.
- 7) 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.).
- 8) Where possible, bait stations must be fixed to the ground or other structures.
- 9) Bait stations have to be mechanically stable and tamper-resistant.
- 10) Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- 11) 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).
- 12) Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures. The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings. The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
  - a) First measures to be taken in case of poisoning,
  - b) Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
  - c) Name of the product and the active substance(s) incl. concentration,
  - d) Contact information of the person in charge of the rodent control,
  - e) Telephone number of a poison information centre and the name of the antidote,
  - f) Date of the beginning of the campaign, i.e. when the baits were deployed first.
- 13) Bait should be secured so that it cannot be dragged away from the bait station.
- 14) Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- 15) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 16) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 17) When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 18) Replace consumed baits at each visit; the uptake of baits has to be documented.
- 19) 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.
- 20) 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.

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

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- 21) For the label and / or the leaflet, the authorisation holder has to specify how the equipment (e.g. bait boxes) shall be cleaned and how residues of baits have to be collected. The recommended methods shall lead to minimized exposure.
  - 22) Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (suitable methods shall be moist or wet processes in accordance with the state of the art e.g. wet wiping or suction processes using suitable vacuum cleaners or dust removers).

## **5.2. Risk mitigation measures**

- 1) 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").
- 2) Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- 3) Do not use in areas where resistance to the active substance can be suspected.
- 4) Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment [unless authorised for permanent baiting treatments].
- 5) 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.
- 6) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 7) Undamaged bait stations and untouched baits may be reused.
- 8) The success of the control measure has to be documented and proven.
- 9) The client has to be informed of possible preventive measures against re-infestation.
- 10) All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
- 11) Do not use the product in pulsed baiting treatments.

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

- 1) 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.
- 2) Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- 3) In case of:
  - a) Dermal exposure, wash skin with water and then with water and soap.
  - b) Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
  - c) 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]
- 4) Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
- 5) Hazardous to wildlife.

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

- 1) At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

- 1) Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- 2) Store in places prevented from the access of children, birds, pets and farm animals.
- 3) Shelf-life: 24 month

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## **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.