#### **ANNEX**

#### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Sakarat D Wax Bait

**Product type(s)** 

PT14: Rodenticides

**Authorisation number:** PL/2014/0152/MR

**R4BP asset number:** PL-0003413-0000

#### 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Sakarat D Wax Bait
---------------	--------------------

#### 1.2. Authorisation holder

	Name	Killgerm GmbH
Name and address of the authorisation holder	Address	Bussardweg 16 41468 Neuss Dusseldorf Germany
Authorisation number		PL/2014/0152/MR
R4BP asset number		PL-0003413-0000
Date of the authorisation		01/07/2014
Expiry date of the authorisation		31/12/2025

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

Name of manufacturer	Killgerm Chemicals Ltd
Address of manufacturer	115 Wakefield Rd WF5 9AR Ossett, West Yorkshire United Kingdom of Great Britain and Northern Irelan d (the)
Location of manufacturing sites	Killgerm Chemicals Ltd site 1 115 Wakefield Rd WF5 9AR Ossett, West Yorkshire United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Difenacoum
Name of manufacturer	Activa S.r.1
Address of manufacturer	ACTIVA S.r.l., Via Feltre, – Milano 3220132 Milano Italy
Location of manufacturing sites	Activa S.r.l site 1 Dr. TEZZA S.r.l Via Tre Ponti, 2237050 S. Maria di Zevio Italy

### 2. PRODUCT COMPOSITION AND FORMULATION

### 2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4- tetrah ydro-1-naphthyl )-4- hydroxycou marin	active substance	56073-07-5	259-978-4	0,005 % (w/w)

### 2.2. Type(s) of formulation

przynęta gotowa do użycia: pasta

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.
	H373: May cause damage to organs (blood) through pr olonged or repeated exposure
Precautionary statements	P201: Obtain special instructions before use.
	P202: Do not handle until all safety precautions have b een read and understood.
	P202: Do not handle until all safety precautions have b een read and understood.
	P280: Wear protective gloves.
	P308+P313: IF exposed or concerned: Get medical protective gloves.
	P308+P313: IF exposed or concerned: Get medical ad vice.
	P314: Get medical attention if you feel unwell.
	P314: Get medical advice if you feel unwell.
	P405: Store locked up.
	P501: Dispose of contents to in accordance with loc al/regional/national/international regulations
	P501: Dispose of contents to in accordance with loc al/regional/national/international regulations

### 4. AUTHORISED USE(S)

### 4.1. Use description

Table 1. Indoor mouse control by professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Mus musculus Common name: house mouse
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use bait for use in tamper-resistant bait stations
Application rate(s) and frequency	Number and timing of application: a) 1-2 sachets (15 g or 30 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m. b) 1 tray (80 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 12-20 m. c) Caulking gun: a portion 2-5 cm long and 1 cm in diameter (equivalent to 2-5 g of bait) per bait station. If more than one bait station is required, the minimum distance between stations should be 2-5 m.
Category(ies) of users	professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg  1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
	<ul> <li>a bucket (PP, PE) with a closure, weighing up to 5 kg,</li> <li>container (cardboard) with a lid, weighing up to 5 kg.</li> </ul>
	1. Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.
	2. Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.

#### 4.1.1. Use-specific instructions

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

• [When available] Follow any additional instructions provided by the relevant code of best practice.

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

See section 5.2

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

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

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

See section 5.4

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

See section 5.5

#### 4.2. Use description

Table 2. Indoor rat control by the professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Scientific name: Rattus norvegicus
stage)	Common name: brown rat
	Scientific name: Rattus rattus
	Common name: roof rat
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use bait for use in tamper-resistant
	bait stations
Application rate(s) and frequency	Application rate: -
	N. alamatica de la Caralina
	Number and timing of application:

	<ul> <li>a) 4-12 sachets (60 g - 180 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m.</li> <li>b) 1-2 trays (80 g -160 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 5-10 m.</li> <li>c) Caulking gun: 4-8 portions of 15 cm long and 1 cm in diameter (equivalent to 50-100 g of bait) per bait station.</li> </ul>
Category(ies) of users	professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg
	1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
	• a bucket (PP, PE) with a closure, weighing up to 5 kg,
	• container (cardboard) with a lid, weighing up to 5 kg.
	<ol> <li>Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.</li> <li>Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.</li> </ol>

#### **4.2.1.** Use-specific instructions

The bait stations 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 stations are intact and to remove rodent bodies. Re-fill bait when necessary.

• [When available] Follow any additional instructions provided by the relevant code of best practice.

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

See section 5.2

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

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

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

See section 5.4

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

See section 5.5

### 4.3. Use description

Table 3. Control of mice and/or rats around buildings by the professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Mus musculus Common name: house mouse Scientific name: Rattus rattus
	Common name: roof rat
	Scientific name: Rattus norvegicus Common name: brown rat
Field(s) of use	outdoor use
	Outdoors – around buildings
Application method(s)	Method:
	Detailed description: Ready-to-use bait for use in tamper-resistant bait stations
Application rate(s) and frequency	Number and timing of application: Mice:  a) 1-2 sachets (15 g - 30 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m.  b) 1 tray (80 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 12 - 20 m.  c) Caulking gun: a portion 2-5 cm long and 1 cm in diameter (equivalent to 2-5 g of bait) per bait station. If more than one bait station is required, the minimum distance between stations should be 2-5 m.  Rats: a) 4-12 sachets (60 g - 180 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m. b) 1-2 trays (80 g -160 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 5-10 m. c) Caulking gun: 4-8 portions of 15 cm long and 1 cm in diameter (equivalent to 50-100 g of bait) per bait station.

Category(ies) of users	professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg
	1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
	<ul> <li>a bucket (PP, PE) with a closure, weighing up to 5 kg,</li> <li>container (cardboard) with a lid, weighing up to 5 kg.</li> </ul>
	1. Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.
	2. Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.

#### 4.3.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice at least every 2 to 3 days at] [for rats only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

• Do not apply this product directly in the burrows.

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

• When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See section 5.4

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

See setion 5.5

### 4.4. Use description

Table 4. Control of mice and/or rats indoors by a trained professional

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	
stage)	Common name: house mouse
	Scientific name: Rattus rattus
	Common name: roof rat
	Scientific name: Rattus norvegicus
	Common name: brown rat
Field(s) of use	indoor use
Application method(s)	Method:
	Detailed description: Indoor Ready-to-use bait for use: • in tamper-resistant bait stations • for use at bait stations (in case a bait station cannot be used, the bait should be placed so that non-target organisms cannot reach it). The product can be used in continuous bait treatments.
Application rate(s) and frequency	Number and timing of application: Mice:  a) 1-2 sachets (15 g - 30 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m.  b) 1 tray (80 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 12 - 20 m.  c) Caulking gun: a portion 2-5 cm long and 1 cm in diameter (equivalent to 2-5 g of bait) per bait station. If more than one bait station is required, the minimum distance between stations should be 2-5 m.  Rats:  a) 4-12 sachets (60 g - 180 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m.  b) 1-2 trays (80 g -160 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 5-10 m.  c) Caulking gun: 4-8 portions of 15 cm long and 1 cm in diameter (equivalent to 50-100 g of bait) per bait station.
Category(ies) of users	trained professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg

- 1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
- a bucket (PP, PE) with a closure, weighing up to 5 kg,
- container (cardboard) with a lid, weighing up to 5 kg.
- 1. Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.
- 2. Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.

#### 4.4.1. Use-specific instructions

- Remove the remaining product at the end of treatment period.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

Additional instructions for use of the product in continuous bait applications:

• If possible, regular inspections of baiting sites should be carried out (at least every 4 weeks) to avoid the development of rodent resistance.

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- 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 at frequent intervals during treatment (e.g. at least twice a week).
- Do not use the product using the pulse method.
- Additional risk mitigation measures for permanent baiting:
- Use of the product in permanent baiting procedures:
- 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.

## 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 stations 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

See section 5.4

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

See section 5.5

#### 4.5. Use description

Table 5. Control of mice and/or rats around buildings by a trained professional

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Mus musculus Common name: house mouse
	Scientific name: Rattus norvegicus Common name: brown rat
	Scientific name: Rattus rattus Common name: roof rat
Field(s) of use	outdoor use Outdoors – around buildings
Application method(s)	Method:
	Detailed description: Ready-to-use bait for use: • in tamper-resistant bait stations • in tamper-resistant bait stations for use at bait stations (in case a bait station cannot be used, the bait should be placed so that non-target organisms cannot reach it). Around buildings.
Application rate(s) and frequency	Number and timing of application: Mice:  a) 1-2 sachets (15 g - 30 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m.  b) 1 tray (80 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 12 - 20 m.  c) Caulking gun: a portion 2-5 cm long and 1 cm in diameter (equivalent to 2-5 g of bait) per bait station. If more than one bait station is required, the minimum distance between stations should be 2-5 m.  Rats: a) 4-12 sachets (60 g - 180 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m. b) 1-2 trays (80 g -160 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 5-10 m.

	c) Caulking gun: 4-8 portions of 15 cm long and 1 cm in diameter (equivalent to 50-100 g of bait) per bait station.
Category(ies) of users	trained professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg
	1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
	<ul> <li>a bucket (PP, PE) with a closure, weighing up to 5 kg,</li> <li>container (cardboard) with a lid, weighing up to 5 kg.</li> </ul>
	1. Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.
	2. Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.

#### **4.5.1.** Use-specific instructions

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.
- Remove the remaining product at the end of treatment period.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- 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 at frequent intervals during treatment (e.g. at least twice a week).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

## 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 stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See section 5.4

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

See section 5.5

#### 4.6. Use description

Table 6. Control of rats in open areas and waste dumps by a trained professional

Product type	PT14: Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat
	Scientific name: Rattus rattus Common name: roof rat
Field(s) of use	Open areas and landfills
Application method(s)	Method:
	Detailed description: Ready-to-use bait for use: • in tamper-resistant bait stations • in tamper-resistant bait stations for use at bait stations (in case a bait station cannot be used, the bait should be placed so that non-target organisms cannot reach it).
Application rate(s) and frequency	Number and timing of application: a) 4-12 sachets (60 g - 180 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 1-2 m. b) 1-2 trays (80 g -160 g of bait) per bait point. If more than one deratization station is required, the minimum distance between stations should be 5-10 m. c) Caulking gun: 4-8 portions of 15 cm long and 1 cm in diameter (equivalent to 50-100 g of bait) per bait station.
Category(ies) of users	trained professional
Pack sizes and packaging material	The minimum size of a collective package - 3 kg
	1. Sachets (PE, PP, paper/PE) weighing 15 g or 30 g packed in sealed or tied inner bags (PE) and then packed in collective packaging:
	<ul> <li>a bucket (PP, PE) with a closure, weighing up to 5 kg,</li> <li>container (cardboard) with a lid, weighing up to 5 kg.</li> </ul>

	1. Packing container (PE, PS, PVC) weighing 80 g with a welded lid (PE, PS, PVC, paper) packed in a box (cardboard) weighing up to 4 kg. For batch containers with a paper lid, they are only available in cardboard boxes with a plastic liner.
	2. Cartridge (HDPE) weighing 0.3 kg for squeezing with a gun. Collective packaging weighing 3 kg.

#### 4.6.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- · Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period .
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

• When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

see section 5.4

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

See section 5.5

#### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### **5.1.** Instructions for use

#### Professional user:

- 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 5.3 for the information to be shown on the label).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Use appropriate chemical resistant gloves (made according to EN374).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Do not open the sachets containing the bait.
- In order to reduce the contact of the product with hands, apply the paste with a spatula, do not touch the contents of the package with your hands.

#### Trained professional user:

- 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.

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

- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Use appropriate chemical resistant gloves (made according to EN374).
- 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 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.
- Do not open the sachets containing the bait.
- Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure avoid reaching into the bucket.

#### **5.2.** Risk mitigation measures

#### Professional user:

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

- 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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

#### Trained professional user:

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment [unless authorised for permanent baiting treatments].
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

Side Effects/Adverse Reactions:

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.

First aid:

In case of:

- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes. .
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"

#### Environmental measures:

- In case of unintentional release of the product into the environment, it should be collected (mechanically) avoiding direct contact with the skin and handed over to a company authorized to recover and dispose of hazardous waste (e.g. in an incineration plant).
- · Hazardous to wildlife.

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

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

• 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 at room temperature.

#### 6. OTHER INFORMATION

- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.