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### ANNEX

### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

**Klerat Pellets** 

### **Product type(s)**

PT14: Rodenticides

Authorisation number: BPR-reg.nr. 732-2

**R4BP asset number:** DK-0009899-0000

### 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Klerat Pellets

### **1.2.** Authorisation holder

Name and address of the authorisation holder	Name	Syngenta Crop Protection AG
Name and address of the authorisation holder	Address	Rosentalstrasse 67 4058 Basel Switzerland
Authorisation number		BPR-reg.nr. 732-2
R4BP asset number		DK-0009899-0000
Date of the authorisation		22/07/2013
Expiry date of the authorisation		31/12/2026

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

Name of manufacturer	Syngenta Hellas SA
Address of manufacturer	2nd Km Kirotiki odos 32011 Enofyta Viotias Greece
Location of manufacturing sites	Syngenta Hellas SA 32011 Enofyta Viotias Greece

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

Active substance	Brodifacoum
Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Rosentalstrasse 67 4058 Basel Switzerland
Location of manufacturing sites	Aurorium UK Ltd., Hale Bank WA8 8NS Widnes United Kingdom of Great Britain and Northern Ireland (the)

### 2. PRODUCT COMPOSITION AND FORMULATION

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'- bromobiphenyl- 4-yl)-1,2,3,4- tetrahydro -1- napthyl]-4- hydroxycoumarin	active substance	56073-10-0	259-980-5	0,005

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

### **2.2.** Type(s) of formulation

RB Bait (ready for use)

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.
	H373: May cause damage to organs blood through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.
Precautionary statements	P201: Obtain special instructions before use.
	P202: Do not handle until all safety precautions have been read and understood.
	P260: Do not breathe dust.
	P280: Wear protective gloves.
	P314: Get medical attention if you feel unwell.
	P308+P313: IF exposed or concerned: Get medical advice.
	P405: Store locked up.
	P501: Dispose of contents to in accordance with national legislation.

### 4. AUTHORISED USE(S)

### 4.1. Use description

### Table 1. Use 1 - Professionals – House mice and/or rats in and around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not applicable.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: All
	Scientific name: Rattus rattus Common name: roof rat Development stage: All
	Scientific name: Mus musculus Common name: house mouse Development stage: All
Field(s) of use	indoor use outdoor use
	Ready-to-use bait to be used in tamper-resistant bait stations in and around buildings.
Application method(s)	Method: bait application
	Detailed description: Rats20-50 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 5-10 metre.Mice5-15 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 2-5-metre (move periodically).
Application rate(s) and frequency	Application rate: See above.
	Dilution (%): None.
	Number and timing of application: Initial inspections of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed. Repeat approximately 4 days later and then weekly. Replace contaminated or spoiled bait.
Category(ies) of users	professional
Pack sizes and packaging material	Min packaging size 3kg
	Maximum 10 kg.
	Loose bait within a HDPE tub

### 4.1.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- Initial inspections of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed. Repeat approximately 4 days later and then weekly. Replace contaminated or spoiled bait.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

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

**4.1.3.** Use-specific risk mitigation measures Not applicable.

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

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.

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

Not applicable.

# **4.1.6.** Where specific to the use, the conditions of storage and shelf-life of the product **under normal conditions of storage** Not applicable.

#### 4.2. Use description

## Table 2. Use 2 - Trained Professional Use House mice and/or rats in and around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not applicable.
Target organism(s) (including development	C C
stage)	Common name: brown rat
	Development stage: All
	Scientific name: Rattus rattus
	Common name: roof rat
	Development stage: All
	Scientific name: Mus musculus
	Common name: house mouse
	Development stage: All
Field(s) of use	indoor use
	outdoor use

	Ready-to-use bait to be used in and around buildings.
Application method(s)	Method: bait application
	Detailed description: - Ready-to-use bait to be used in tamper- resistant bait stations Covered and protected baiting points including use in burrows.Rats20-50 g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 5-10 metre.Mice5-15 g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 2-5-metre (move periodically).
Application rate(s) and frequency	Application rate: See above.
	Dilution (%): None.
	Number and timing of application: Initial inspections of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed. Repeat approximately 4 days later and then weekly. Replace contaminated or spoiled bait.
Category(ies) of users	trained professional
Pack sizes and packaging material	Min packaging size 3kg
	Maximum 10 kg.
	Loose bait within a HDPE tub.

### 4.2.1. 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 - not applicable to burrow baiting.

### 4.2.2. Use-specific risk mitigation measures

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of re-invasion.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- 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.

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

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

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

Not applicable.

**4.2.6.** Where specific to the use, the conditions of storage and shelf-life of the product **under normal conditions of storage** Not applicable.

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

#### 5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- 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 re-invasion.

- 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.

- 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.

- Loose pellets-granules, grains: Place the bait in the bait station by using a dosage device.

#### 5.2. 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:

<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.

The product shall not be supplied to the general public.

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

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

• This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

• Antidote: Vitamin K1 administered by medical/veterinary personnel only.

- In case of:-
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]

• Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]".

• 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. In the UK, poisoned rodents should be disposed of at a suitably permitted incinerator, landfill or burial site by the waste producer or a registered waste carrier. For further information on disposal contact the Environment Agency (http://www.environment-agency.gov.uk) or SEPA (http://www.sepa.org.uk).

### 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

### 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.