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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Klerat® Pellets XT

Product type(s)

PT14: Rodenticides

Authorisation number:

R4BP asset number: DK-0029074-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Klerat® Pellets XT
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Syngenta Nordics A/S
	Address	Strandlodsvej 44 2300 København S Denmark
Authorisation number		
<i>R4BP asset number</i>		DK-0029074-0000
Date of the authorisation		05/08/2022
Expiry date of the authorisation		05/08/2027

1.3. Manufacturer(s) of the product

Name of manufacturer	Syngenta Hellas SA
Address of manufacturer	2nd Km Kinotiki odos 32011 Enofyta Viotias Greece
Location of manufacturing sites	2nd Km Kinotiki odos 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., Halebank WA8 8NS Widnes United Kingdom of Great Britain and Northern Ireland (the)

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 (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0024

2.2. Type(s) of formulation

RB: Ready-for-use pellet bait

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs blood through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P260: Do not breathe dust. P314: Get medical attention if you feel unwell. P501: Dispose of contents to in accordance with local/regional/national/international regulations. P501: Dispose of container to in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Trained Professionals - Indoor - House mice and Brown rats

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: Adults and Juveniles Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and Juveniles
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application Detailed description: Ready-to-use pellet bait to be used only in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: Mice: 30-50g per bait station or bait point; Rats: 50-75g per bait station or bait point Dilution (%): 0.0 Number and timing of application: Mice: 30-50g per bait station. If more than one bait station/point is needed, the minimum distance between bait stations should be 2m for high infestations and a 5m for low infestations. Rats: 50-75g per bait station. If more than one bait station/point is needed, the minimum distance between bait stations should be 5m for high infestations and 10m for low infestations.
Category(ies) of users	trained professional
Pack sizes and packaging material	Pack size: 3kg, 5kg, 8kg, 10kg Loose bait packed in: Box/Tub/Pouch/ Packaging material: Box: Cardboard; Tub/Pouch: PP (opaque)

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4.1.1. Use-specific instructions

For use only in tamper-resistant bait stations.

The bait stations should be visited at least every 2 to 3 days for mice, and 5 to 7 days for rats at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Remove the remaining product at the end of treatment period.

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

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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

Do not use the product in pulsed baiting treatments.

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 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

See general directions for use.

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

See general directions for use.

4.2. Use description

Table 2. Trained Professionals - Outdoor around buildings - House mice and Brown rats

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and Juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and Juveniles</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait application Ready-to-use pellet bait to be used only in tamper-resistant bait stations.</p>
Application rate(s) and frequency	<p>Application rate: Mice: 30-50g per bait station or bait point; Rats: 50-75g per bait station or bait point, 50 g per burrow</p> <p>Dilution (%): 0.0</p> <p>Number and timing of application:</p> <p>Mice:</p> <p>30-50g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations 5m for low infestations.</p> <p>Rats:</p> <p>50-75g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestations 10m for low infestations.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	Pack size: 3kg, 5kg, 8kg, 10kg

	Loose bait packed in: Box/Tub/Pouch/ Packaging material: Box: Cardboard; Tub/Pouch: PP (opaque)
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4.2.1. Use-specific instructions

For use only in tamper-resistant bait stations.

Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.

Remove the remaining product at the end of treatment period.

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

4.2.2. 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 [in accordance with the applicable code of good practice, if any].

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

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

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

Do not use the product in pulsed baiting treatments.

To protect the environment do not place bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems to prevent flushing away of bait due to high rainfall events and flooding.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Trained Professionals:

- 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.
- The product 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.
- [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.
- 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.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Place the loose pellets in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

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.

5.2. Risk mitigation measures

Trained professionals:

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

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- Where possible, prior to the treatment inform any possible bystanders 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 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

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.

Note to Physician: Antidote - Vitamin K1 administered by medical/veterinary personnel only.

General: Have the product container, label or Safety Data Sheet with you when calling the emergency number, a poison control centre or physician, or going for treatment.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Contact a veterinary surgeon in case of ingestion by a pet.

Hazardous to wildlife

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]

National Poison Centre: [Insert organisation name and contact information]

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

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

Oplysninger til etiket og brugsanvisning for Klerat Pellets XT, BPR-reg. nr. 732-242

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen .

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

”Gnavermiddel

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*) og husmus (*Mus musculus*) i og omkring bygninger og kun i en afstand op til 10 meter. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fra bygninger fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med en R1-autorisation.”

2) I advarselsfeltet:

”ADVARSEL

Kan forårsage organskader (blod) ved længerevarende eller gentagen eksponering (H373).

Indånd ikke pulver.

Vask huden grundigt efter brug.

Brug kemisk resistente beskyttelseshandsker ved brug af produktet.” (Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet).

”Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*) og husmus (*Mus musculus*) i og omkring bygninger og kun i en afstand op til 10 meter. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fra bygninger fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med en R1-autorisation.

Ved kildebekæmpelse skal betingelserne i Miljøstyrelsens vejledning om vurdering og godkendelse af kemiske bekæmpelsesmidler til rotter og mus være opfyldt.

Doseringen af det biocidholdige produkt skal afpasses bekæmpelsen af rotter og mus på den pågældende lokalitet, dog må der mod mus højst anvendes 50 g per udlægningssted med minimum 2 meters afstand, og for rotter højst 75 g per udlægningssted med minimum 5 meters afstand af hensyn til faren for forgiftning af mennesker, pattedyr og fugle.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Det biocidholdige produkt skal anbringes i aflåste foderstationer, så mennesker og dyr uden for målgruppen ikke kan komme i kontakt med giften.

Døde mus og rotter skal eftersøges to gange ugentligt eller efter behov og bortskaffes som dagrenovation af hensyn til faren for sekundær forgiftning af rovfugle og rovdyr.

Produktet må ikke bruges mere end 35 dage uden en evaluering af angrebets status og effekten af behandlingen.

Giftrester og emballage skal afleveres til den kommunale affaldsordning for farligt affald efter endt bekæmpelse.

Foderstationer skal påføres en tekst, hvoraf det fremgår, at der foregår bekæmpelse af mus og rotter i området, og hvorledes man forholder sig i tilfælde af forgiftning. Foderstationer skal være forsynet med kontaktinformation på dem, som udfører bekæmpelsen.

Må ikke benyttes til permanent bekæmpelse af mus og rotter, såsom forebyggende brug i sikringsordninger.

Ved anbringelse af foderstationer tæt på overfladevand eller afløbssystemer skal det sikres, at det biocidholdige produkt ikke kommer i kontakt med vand.

Må ikke tømmes i kloakfløb.

Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Emballagen må ikke genanvendes”

Farepiktogrammet GHS08 for sundhedsfare.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

”Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

Søg lægehjælp ved ubehag.

Dette produkt indeholder et antikoagulerende stof.

Ved indtagelse kan der forekomme forsinkede symptomer, såsom næseblod og blødende tandkød.

I svære tilfælde kan der forekomme blå mærker og blod i afføring eller urin.

Modgift: K1-vitamin; må kun administreres af medicinsk/veterinært personale.

Hvis produktet:

- kommer på huden, vaskes huden med vand og sæbe.
- kommer i øjnene, skylles øjnene med øjenrensevæske eller vand; hold øjnene åbne i mindst 10 minutter.
- kommer i munden, skylles munden grundigt med vand.

Giv aldrig en bevidstløs person noget gennem munden.

Fremkald ikke opkastning.

Hvis produktet synkes, søges der straks lægehjælp. Vis produktets beholder eller etiketten til lægen.

Kontakt en dyrlæge, hvis produktet indtages af et kæledyr ”

3) I deklarationsfeltet:

- a) Teksten ”Gnavermiddel BPR-reg. nr. 732-242. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.
- b) Oplysning om præparattype: ”pellets” for dette præparat.
- c) Indholdet af aktivstof i [vægtprocent (% w/w) og g/kg.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller – betegnelse skal anføres.
- f) Pakningsstørrelse.
- g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: ”Rester og emballage bortskaffes som farligt affald.”

Følgende sætning skal anføres under sikkerhedssætning P501: ”Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl.”