ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Klerat Pellets

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70602

R4BP asset number: IE-0002370-0000

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
	Address	Rosentalstrasse 67 4058 Basel Switzerland
Authorisation number		IE/BPA 70602
R4BP asset number		IE-0002370-0000
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	Vertellus Specialties UK Ltd
Address of manufacturer	Hale Bank WA8 8NS Widnes United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Hale Bank 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-napthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,005

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.
	P308+P313: IF exposed or concerned: Get medical advice.
	P405: Store locked up.
	P501: Dispose of contents to in accordance with local regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Trained Professional - Mice and Rats - Indoors

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
	Ready-to-use bait to be used indoors.
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. Rats 20-50g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 5m for high infestations and 10m for low infestations Mice 5-15g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 2m for high infestations and 5m for low infestations
Application rate(s) and frequency	Application rate: Rats: 20-50g of bait per bait station; Mice: 5-15g of bait per bait station
	Dilution (%): None. Number and timing of application: Initial inspections of bait points after 3 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	Pack size 2.5kg, 3kg, 5kg, 10kg.
	Loose bait within a HDPE tub or pail

4.1.1. Use-specific instructions

Remove the remaining product at the end of treatment period Collect any spilled bait and dead rodents Follow any additional instructions provided by 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.

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.

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 points 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 Section 5.4

4.1.6. 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. Trained Professionals - Mice and Rats - Outdoors 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	outdoor use
	Ready-to-use bait to be used outdoors 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. Rats 20-50g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 5m for high infestations and 10m for low infestations Mice 5-15g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 2m for high infestations and 5m for low infestations Direct application of ready-to-use bait into the burrow Rats 20-50g of bait per burrow
Application rate(s) and frequency	Application rate: Rats: 20-50g of bait per bait station; Mice: 5-15g of bait per bait station
	Dilution (%): None.
	Number and timing of application: Initial inspections of bait points after 3 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	Pack size 2.5kg, 3kg, 5kg, 10kg.
	Loose bait within a HDPE tub or pail

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 (except when applied directly into burrows). For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

Baits must be placed to minimise the exposure to non-target species and children Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled. 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.

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.

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 surface waters (e.g. rivers, ponds, drainage channels, dykes, irrigation ditches) or 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

See Section 5.4

4.2.6. 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. Professionals - Mice and Rats - Indoors

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
	Ready-to-use bait to be used in tamper-resistant bait stations indoors.
Application method(s)	Method: bait application
	Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations. Rats 20-50g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 5m for high infestations and 10m for low infestations Mice 5-15g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 2m for high infestations and 5m for low infestations
Application rate(s) and frequency	Application rate: Rats: 20-50g of bait per bait station; Mice: 5-15g of bait per bait station
	Dilution (%): None.
	Number and timing of application: Initial inspections of bait points after 3 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	Pack size 2.5kg, 3kg, 5kg, 10kg.
	Loose bait within a HDPE tub or pail

4.3.1. Use-specific instructions

The baiting stations should be visited at least every 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.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

See Section 5.2

4.3.4. 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.

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

See Section 5.4

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

See Section 5.5

4.4. Use description

Table 4. Professionals - Mice and Rats - Outdoor 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	outdoor use Ready-to-use bait to be used in tamper-resistant bait stations outdoors around buildings.
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations. Rats 20-50g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 5m for high infestations and 10m for low infestations Mice 5-15g of bait per bait point. If more than one bait point is needed, the distance between bait stations should be of 2m for high infestations and 5m for low infestations
Application rate(s) and frequency	Application rate: Rats: 20-50g of bait per bait station; Mice: 5-15g of bait per bait station Dilution (%): None.

	Number and timing of application: Initial inspections of bait points after 3 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	Pack size 2.5kg, 3kg, 5kg, 10kg.
	Loose bait within a HDPE tub or pail

4.4.1. Use-specific instructions

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-liable to flooding.

For mice: The baiting 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.

For rats: 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.

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.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

4.4.4. 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.

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

See Section 5.4

4.4.6. 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 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.

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 x 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.

Wear protective chemical resistant gloves during product handling phase (specified under Standard 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 light of the survey conducted at the outset of the treatment. Sites where burrow baiting is used should be visited more frequently than those where secure bait boxes are employed. The frequency should be consistent with the recommendations provided by the relevant code of practice.

If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.

If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

Place loose bait in the baiting station by using a dosage devise. Minimise dust during dosing (e.g. wet wiping). 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 aid measures to be taken in case of poisoning must be made alongside the bait stations.

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

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 preventative control measures (e.g. plug holes) 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 x 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.

Wear protective chemical resistant gloves during product handling phase (specified under Standard 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 points to further places and the possibility to change to another bait formulation.

If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

Remove remaining bait or bait stations at the end of the treatment period.

Place loose bait in the baiting station by using a dosage devise. Minimise dust during dosing (e.g. wet wiping).

5.2. Risk mitigation measures

Trained Professionals

Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign. Do not use in areas where resistance to the active substance can be suspected.

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

Do not rotate the use of different anticoagulants with comparable or weaker potency for resistant management purposes. For rotational use consider using a non-anticoagulant rodenticide, if available or a more potent anticoagulant rodenticide.

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 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 ("For Trained Professionals Only)

Professionals

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

To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

The product information (i.e. label and/or leaflet) shall clearly show that: The product shall not be supplied to the general public (e.g. "For Professionals Only".

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. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific info].

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 country relevant 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. Use of gloves is recommended

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.

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.

Minimum pack size in Ireland: 2.5kg