ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Klerat Wax Blocks

Product type(s)

PT14: Rodenticides

Authorisation number: 2009-11-26-B01b

R4BP asset number: MT-0002650-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Klerat Wax Blocks
---------------	-------------------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Syngenta Crop Protection AG
	Address	Rosentalstrasse 67 4058 Basel Switzerland
Authorisation number		2009-11-26-B01b
R4BP asset number		MT-0002650-0000
Date of the authorisation		22/07/2013
Expiry date of the authorisation		31/12/2025

1.3. Manufacturer(s) of the product

Name of manufacturer	Bábolna Bioenvironmental Centre Ltd
Address of manufacturer	Dr. Köves János u. 3 H-2943 Bábolna Hungary
Location of manufacturing sites	Dr. Köves János u. 3 H-2943 Bábolna Hungary

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

Active substance	Brodifacoum
Name of manufacturer	Vertellus Specialties UK Ltd
	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.
	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 national legislation.
	P308+P313: IF exposed or concerned: Get medical attention.

4. AUTHORISED USE(S)

4.1. Use description

 $Table \ 1. \ Use \ \#1 - House \ mice \ and/or \ rats - Professional \ users \ with \ demonstrated \ competence \ (equivalent \ to \ trained \ professionals - indoor$

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant to rodenticides.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles Scientific name: Mus musculus Common name: house mouse Development stage: Adults and Juveniles Scientific name: Rattus rattus Common name: Black or roof rat
Field(s) of use	Development stage: Adults and Juveniles indoor use 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
Application rate(s) and frequency	Application rate: Rats - 20-60g of bait per bait point. Mice - 20g of bait per bait point. Dilution (%): Ready-for-use. Number and timing of application: Rats High infestation: 20–60g of bait per baiting point every 5 metres. Low infestation: 20–60g of bait per baiting point every 10 metres. Mice High infestation: 20g of bait per baiting point every 2 metres. Low infestation: 20g of bait per baiting point every 5 metres.
Category(ies) of users	trained professional
Pack sizes and packaging material	Loose 20g wax blocks within a PP/PE tub or pail. 3kg, 5kg and 10kg.

4.1.1. Use-specific instructions

- Remove the remaining product at the end of treatment period.
- Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

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 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 this 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 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 Directions for use.

4.2. Use description

Table 2. Use #2 - Mice and/or rats - Professional users with demonstrated competence (equivalent to trained professionals) - outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant to rodenticides.

Target organism(s) (including development	Scientific name: Rattus norvegicus
stage)	Common name: brown rat
	Development stage: All
	Scientific name: Mus musculus
	Common name: house mouse
	Development stage: All
	Scientific name: Rattus rattus
	Common name: Black or roof rat
	Development stage: Adult and Juveniles
Field(s) of use	outdoor use
	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.
	Direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	Application rate: Rats - 20-60g of bait per bait point. Mice - 20g of bait per bait point.
	of bart per bart point.
	Dilution (%): Ready-for-use.
	Number and timing of application:
	Rats
	High infestation: 20–60g of bait per baiting point every 5 metres. Low infestation: 20–60g of bait per baiting point every 10 metres.
	Mice
	High infestation: 20g of bait per baiting point every 2 metres.
	Low infestation: 20g of bait per baiting point every 2 metres.
Category(ies) of users	trained professional
Pack sizes and packaging material	Loose 20g wax blocks within a PP/PE tub or pail.
	3kg, 5kg and 10kg.

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Remove the remaining product at the end of treatment period (except when directly applied into burrows).
- 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 CRRU UK Code of Best Practice (or equivalent).
- Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

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 (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 this 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, water 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 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 Directions for use.

4.3. Use description

 $\begin{tabular}{ll} \textbf{Table 3. Use \#3 - Rats - Professional users with demonstrated competence (equivalent to trained professionals) - sewers \end{tabular}$

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant to rodenticides.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and Juveniles
	Scientific name: Rattus rattus Common name: roof rat Development stage: Adults and Juveniles.

Field(s) of use	outdoor use
	Sewers.
Application method(s)	Method: bait application
	Detailed description: Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. Covered and protected baiting points.
Application rate(s) and frequency	Application rate: 20-200g per manhole.
	Dilution (%): Ready-to-use.
	Number and timing of application:
	20-200g per manhole.
Category(ies) of users	trained professional
Pack sizes and packaging material	Loose 20g wax blocks within a PP/PE tub or pail.
	3kg, 5kg and 10kg.

4.3.1. Use-specific instructions

- Baits must be applied in a way so that they do not come into contact with water and are not washed away.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

- Do not use this product in pulsed baiting treatments.

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

See Directions for use.

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

See Directions for use.

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

See Directions for use.

5. GENERAL DIRECTIONS FOR USE¹

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.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- 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).
- 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.
- 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. Sites where burrow baiting is used should be visited more frequently than those where secure bait boxes are employed. That frequency should be consistent with the recommendations provided by the CRRU UK Code of Best Practice (or equivalent).
- Sites where burrow baiting is used should be visited more frequently than those where secure bait boxes are employed.
- 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.

5.2. Risk mitigation measures

- 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 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.

UK only: In the UK poisoned rodents may be disposed of by the waste producer at an incinerator or landfill permitted to accept that type of waste, or collected by a registered waste carrier and taken for disposal

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

at a suitably permitted site. For further information on disposal contact the Environment Agency (http://www.environment-agency.gov.uk) or SEPA (http://www.sepa.org.uk).

UK only: To be used only by professional users holding certification demonstrating compliance with UK rodenticide stewardship regime requirements.

UK only: Read the label before use. Using this product in a manner that is inconsistent with the label may be an offence. Refer to the CRRU UK Code of Best Practice (or equivalent) for guidance.

UK only: When this product is supplied to a user for the control of rodents, it shall only be supplied to a professional user holding certification demonstrating compliance with UK rodenticide stewardship regime 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 accident, call a poison centre" [insert national phone number].

UK only: UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice.

- Hazardous to wildlife.

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. UK only: For information on disposal in the UK contact the Environment Agency (http://www.environmentagency.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.