



AUTHORISATION NUMBER:

IE/BPA 70242

EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET,
USE AND CONTROL OF BIOCIDAL PRODUCTS)
REGULATIONS

CERTIFICATE OF AUTHORISATION

The Competent Authority for Biocides in Ireland, pursuant to the provisions of the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001, (S.I. 625 of 2001, as amended), grants authorisation to:



**PelGar International Ltd,
Unit 13, Newman Lane Industrial Estate,
Newman Lane,
Alton
Hampshire
GU34 2QR, UK**

to place the biocidal product:

Vertox Whole Wheat Bait

on the market in Ireland, subject to the conditions detailed in the Annexes to this certificate.

Authorisation granted on behalf of the Competent Authority for Biocides in Ireland by

Pesticide Registration and Control Division, (PRCD).

Date of authorisation: 18 July 2013

Official Stamp:



ANNEX I

Conditions and Product Summary

This authorisation may be subject to review in accordance with the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001, (S.I. 624 of 2001, as amended). The outcome of such a review may lead to amendments to or the revocation of this authorisation.

The following conditions apply:

1. This product shall **not** be used as a tracking poison, shall be ready-to-use and shall contain an aversive agent and/or dye.
2. Product may **not** be placed on the Irish Market unless it complies with the Annexes of this authorisation.
3. The requirements and conditions, specified in the Annexes, of this authorisation may **not** be altered without prior approval of modifications by the Irish Competent Authority for Biocides in Ireland. Where any amendments are made to the original authorisation in another Member State, the Irish Competent Authority for Biocides in Ireland must be informed by the Authorisation Holder.
4. The holder of this certificate for authorisation must inform or provide the Irish Competent Authority for Biocides with any new or requested information/data, respectively, that shows this biocidal product and/or any of its active substances cause or may cause an adverse effect on human or animal health, ground water or the environment.
5. All product placed on the Irish market must comply with the classification, labelling and packaging requirements established in: S.I. 625 (2001) Regulation 33 (as amended) transposing Article 20 of Directive 98/8/EC; S.I. 624 (2001) transposing Directive 99/45/EC; the Chemicals Act 2008 (as amended) transposing Regulation (EC) No 1272/2008; and the Classification, Labelling and Packaging Annex detailed in this certificate.
6. A printed copy of the Irish label must be submitted to the Irish Competent Authority for Biocides prior to any product being placed on the Irish market. All product labels must carry the authorisation number of the form: IE/BPA 70242.
7. A product safety data sheet (SDS) prepared in compliance with Regulation (EC) No 1907/2006 (as amended), as transposed in Ireland by the Chemicals Act 2008 (as amended), must be submitted to the Irish Competent Authority for Biocides and the National Poisons Information Centre of Ireland <http://www.poisons.ie/manufacturers.asp> before product is placed on the market for sale or use.
8. On an annual basis, details of the quantities of this product (by pack size) manufactured in Ireland, imported into Ireland and/or exported from Ireland must be submitted to the Irish Competent Authority for Biocides by 31 January of the following year.
9. Fees are payable for the maintenance of the product on the Register of Biocidal Products and shall be paid by the 31st December of the following year and each year thereafter.

Product Summary

Product name:	Vertex Whole Wheat Bait
Authorisation type:	Authorisation
Authorisation number:	IE/BPA 70242
	Authorisation suffixes: 001 = Red product, 002 = Purple product
Main Group:	MG03 (Pest Control)
Product-type:	PT14 (Rodenticides)
Frame Formulation (Y/N):	Y
Date of authorisation:	18 July 2013
Date of authorisation expiry:	31 January 2017
IUPAC name of the active substance:	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
Common name of the active substance:	Brodifacoum
CAS number:	56073-10-0
EC number:	259-980-5
Content of active substance:	0.005 % w/w
Information on co-formulants that classify:	Not applicable
Formulation type:	Ready-to-use (RB)
Statement of use:	A ready-to-use whole wheat bait containing brodifacoum (0.005% w/w) for use as a rodenticide by professionals for the control of rats and mice indoors, outdoors around buildings and in sewers for the protection of public health, stored products and materials.
Area of use:	IV.1 Indoor use IV.2 Outdoor use (around buildings only) IV.3 In sewers
Target organism(s):	(I.1) Rodents (I.1.1) Murids (I.1.1.1) Brown rat (<i>Rattus Norvegicus</i>) (I.1.1.2) House rat (<i>Rattus rattus</i>) (I.1.1.3) House mouse (<i>Mus musculus</i> and <i>Mus domesticus</i>)
Development stage:	(II.1) Juveniles (II.2) Adults
Function:	Rodenticide

Mode of action:

III.2 Long-term action
III.2.1 Anticoagulant
III.2.1.1 Ingestion toxin
III.2.1.1.1 Ingestion by eating

Application method:

VI.2 Covered applications
VI.2.1 In bait stations
VI.2.2 Other coverings

Application aim:

Protection of:
VII.1 Stored product protection/food protection
VII.2 Health protection
VII.3 Material protection (e.g. historical buildings, technical objects)

User Category:

V.2 Professional
V.3 Specialised Professional

ANNEX II

Product Classification, Labelling and Packaging

The following conditions apply:

Classification

Classification according to Directive 99/45/EC (valid until 1st June 2017)

The following symbols and indications of danger: N/A

The following risk phrases: N/A

The following safety phrases:

- S1+S2: Keep locked up and out of reach of children ✓
- S13: Keep away from food, drink and animal feeding stuffs. ✓
- S20 + S21: When using do not eat, drink or smoke. ✓
- S24: Avoid contact with skin ✓
- S35: This material and its container must be disposed of in a safe way. ✓
- S37: Wear suitable gloves ✓
- S46: If swallowed, seek medical advice immediately and show this container or label. ✓
- S49: Keep only in the original container ✓
- S61: Avoid release to the environment. Refer to special instructions/safety data sheet ✓

Classification according to Regulation (EC) No 1272/2008

The following pictograms and signal word(s) (if applicable): N/A

The following hazard statements (if applicable): N/A

The following precautionary statements (if applicable):

- P102: Keep out of reach of children.
- P103: Read label before use.
- P220: Keep/Store away from food, drink and animal feedingstuffs.
- P262: Do not get on skin
- P270: Do not eat, drink or smoke when using this product.
- P273: Avoid release to the environment
- P280: Wear protective gloves
- P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician.
- P404+405: Store locked up in a closed container.
- P501: Dispose of contents/container in accordance with national regulations.

Labelling

Please note: The section on labelling below outlines the minimum labelling requirements for the product in addition to the statutory classification requirements indicated in the classification section above. Authorisation holders may place additional label information as they consider necessary, which must be in accordance with relevant labelling legislation.

Product Name:	Brodifacoum ✓
Authorisation No.:	IE/BPA 70242 ✓
Common names and content of each active ingredient:	Brodifacoum (0.005 % w/w) ✓
Name of any additional dangerous substances in the product:	Not applicable
Nature of formulation:	Ready-to-use (RB) ✓
Function:	For Use as a Rodenticide Only ✓
Restriction on category of user:	For Professional Use Only ✓
Batch number and expiry date:	Must be printed or embossed on label or packaging
'e-mark':	Must be printed on label
The name, address of the authorisation holder:	Pelgar International Ltd Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK ✓
Tel:	+44 1420 80744
If different, the name and address of the marketing company:	As above
Addition safety Information:	To avoid risks to human health and the environment, comply with the instructions for use. ✓ Use bait containers clearly marked "poison" at all surface baiting points. ✓ Remove all remains of bait, dead rodents during and after treatment and dispose of safely. ✓ Prevent access to bait by children, domesticated animals and pets, (particularly cats, dogs and pigs). ✓ Harmful to wildlife. ✓

Special labelling provisions for Ireland:

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. ✓
 NOT for Amateur Sale ✓

If a separate leaflet is attached to or supplied with the product, add the following information to the front label:

Read attached instructions before use

Particulars of direct or indirect adverse effects:

Effects result from the inhibition of blood coagulation, through interaction with vitamin K1. Poisoning symptoms may include: bruising easily, nose or gum bleeds, blood in stools or urine, excessive bleeding from minor cuts or abrasions. Note that poisoning symptoms may develop over the course of several days.

First aid information for use in the event of accidental exposure or ingestion.

First Aid: In case of accident, suspected exposure or if you feel unwell, seek medical advice immediately (show the label where possible).
 In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing.
 In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek medical advice immediately. ✓
 In case of ingestion or if swallowed seek medical advice immediately.

Note to Physician: Antidote – Vitamin K1 – under medical supervision. ✓

National Poison Centre information and reporting of incidents

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. ✓

Directions for use (*may be included on separate leaflet - if separate leaflet is used, Trade Name and Authorisation Number must be stated*):

Statement of use

“A ready-to-use whole wheat bait, containing brodifacoum (0.005 % w/w), for use as a rodenticide for the control of rats and mice indoors, outdoors around buildings and in sewers by professionals for the protection of public health, stored products and materials.” ✓

Instructions for safe handling and use

- Always read the label before use and follow the instructions provided. ✓
- Avoid all unnecessary exposure, in particular avoid ingestion. ✓
- Product must be handled in a safe manner. ✓
- Do not decant product into unlabelled containers. ✓

- A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
- Baits must be securely deposited in baiting stations or other coverings so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.
- PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. When the product is being used in public areas, the areas treated must 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. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- For use in sewers where there is no risk to children, companion animals and non-target species blocks should be secured to available structures by wire to ensure the block is not washed away.
- Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- It is illegal to use this product for the intentional poisoning of non-target, beneficial and protected animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.
- For professional users the use of appropriate personal protective equipment (PPE) is advised.

Application Details:

Indoors and outdoors around buildings (in urban and agricultural buildings)

Rats:

Secure 10-60g of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).

Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

Mice:

Secure 5-20g bait in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).

Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait

points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

In sewers

Rats:

Secure 20-200g of bait per station to available structures to ensure the bait is not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.

Resistance Information

The resistance status of the rodent population to brodifacoum should be taken into account when considering the choice of rodenticide to be used. Where resistance to Brodifacoum has been shown or is suspected, resistant management strategies should be employed.

Storage Instructions

Store in a cool, dry, well-ventilated place

Keep only in original container.

Directions for the safe disposal

This material and its container must be disposed of safely.

Dispose of packaging, remains of unused product and dead rodents in accordance with local regulations.

If required, consult a professional waste operator or local authority.

Packaging

IE/BPA 70242

Packaging type/description	Packaging material ¹	Pack Sizes
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N/A Outer Packaging: Paper, PP, PE sack, PP sack	5, 10, 20 or 25kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 8kg, 10kg, 15kg or 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 8kg, 10kg, 15kg or 20 kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets	1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg,

Packaging type/description	Packaging material ¹	Pack Sizes
paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Outer Packaging: fibreboard carton/cardboard	4kg, 5kg, 6kg, 8kg or 10kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N/A Outer Packaging: PE/PP packs (tubs, pails or pouches)	1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 8kg, 10kg, 15kg or 20kg
Loose bait in PE lined carton	Inner packaging: N/A Outer Packaging: PE lined carton	10kg or 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat sealed lid packed in multiples of 2/4/8/12/16/20/24/32 packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 2/4/8/12/16/20/24/32)
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4)

¹ PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride

Bait sizes	10, 15, 20, 25, 30, 50, 60, 100 or 200 g
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