

Summary of product characteristics for a biocidal product

Product name: BRODITOP GEL

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: IE/BPA 70830

R4BP 3 asset reference number: IE-0027662-0000

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Administrative information

1.1. Trade names of the product

BRODITOP GEL
BRODITEC GEL-50
SAKARAT BRODIFACOUM GEL

1.2. Authorisation holder

Name and address of the authorisation holder	Name	ZAPI S.p.A.
	Address	via Terza Strada 12 35026 Conselve Italy
Authorisation number	IE/BPA 70830	
R4BP 3 asset reference number	IE-0027662-0000	
Date of the authorisation	10/12/2021	
Expiry date of the authorisation	27/01/2026	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Zapi S.p.A.
Address of the manufacturer	Via Terza Strada 12 35026 Conselve (PD) Italy
Location of manufacturing sites	Via Terza Strada 12 35026 Conselve (PD) Italy

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

Active substance	11 - Brodifacoum
Name of the manufacturer	Activa S.r.l.
Address of the manufacturer	Via Feltre 32 20132 Milano Italy
Location of manufacturing sites	Dr. Tezza S.r.l., Via Tre Ponti 22 37050 S. Maria di Zevio (VR) Italy

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal 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	0,005
Silicon dioxide	Silicon dioxide	Non-active substance	7631-86-9	231-545-4	4,5

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	<p>May damage the unborn child.</p> <p>May cause damage to organs (blood) through prolonged or repeated exposure ..</p>
Precautionary statements	<p>Obtain special instructions before use.</p> <p>Do not handle until all safety precautions have been read and understood.</p> <p>Wear protective gloves.</p> <p>IF exposed or concerned: Get medical advice.</p> <p>IF exposed or concerned: Get medical attention.</p> <p>Get medical advice if you feel unwell.</p>

Get medical attention if you feel unwell.

Store locked up.

Dispose of contents to in accordance with local regulation.

Dispose of container to in accordance with local regulation.

4. Authorised use(s)

4.1 Use description

Use 1 - House mice and rats – Trained professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
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>Indoor</p> <p>Indoor</p>
Application method(s)	<p>Method: Bait formulations: Detailed description:</p> <ul style="list-style-type: none"> - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequencies	<p>Application Rate: Bait products: Dilution (%): Number and timing of application:</p> <p>Rats:</p> <ul style="list-style-type: none"> - High infestation: 100 g of bait per baiting point spaced 5m apart. - Low infestation: 100 g of bait per baiting point spaced 10m apart. <p>Mice:</p> <ul style="list-style-type: none"> - High infestation: 50 g of bait per baiting point spaced 2m apart. - Low infestation: 50 g of bait per baiting point spaced 5m apart.

Category(ies) of users

Trained professional

Pack sizes and packaging material

Cardboard box containing labelled plastic (PET) trays of 50 g with peel-off covering for mice and rats – from 2.5 to 15kg

Cardboard box containing labelled plastic (PET) trays of 100 g with peel-off covering for rats - from 2.5 to 15kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 50 g with peel-off covering for mice - from 2.5 to 15kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 100 g with peel-off covering for rats - from 2.5 to 15kg

Labelled/printed plastic (HDPE) tubes (for use with caulking gun) each up to 600 g in labelled cardboard box or in labelled plastic (PP) bucket for mice and rats – from 2.5 to 15kg

Labelled/printed plastic bucket (PP) for mice and rats - from 2.5 to 15kg

4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

4.1.2 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.
- Do not use this product in pulsed baiting treatments.

4.1.3 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.

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

See Section 5.4

4.1.5 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

Use 2 - House mice and rats – Trained professionals - outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)
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	Outdoor Outdoor around buildings
Application method(s)	Method: Bait formulations: Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequencies	Application Rate: Bait products: Dilution (%): Number and timing of application: Rats: - High infestation: 100 g of bait per baiting point spaced 5m apart. - Low infestation: 100 g of bait per baiting point spaced 10m apart. Mice: - High infestation: 50 g of bait per baiting point spaced 2m apart. - Low infestation: 50 g of bait per baiting point spaced 5m apart.

Category(ies) of users

Trained professional

Pack sizes and packaging material

Cardboard box containing labelled plastic (PET) trays of 50 g with peel-off covering for mice and rats – from 2.5 to 15 kg

Cardboard box containing labelled plastic (PET) trays of 100 g with peel-off covering for rats - from 2.5 to 15 kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 50 g with peel-off covering for mice - from 2.5 to 15 kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 100 g with peel-off covering for rats - from 2.5 to 15 kg

Labelled/printed plastic (HDPE) tubes (for use with caulking gun) each up to 600 g in labelled cardboard box or in labelled plastic (PP) bucket for mice and rats – from 2.5 to 15 kg

Labelled/printed plastic bucket (PP) for mice and rats from 2.5 to 15 kg

4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-labile 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.
- Follow any additional instructions provided by the relevant code of best practice.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.2.2 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.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

See Section 5.4

4.2.5 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

Use 3 - House mice and rats - Professional users - indoor

Product type	PT14 - Rodenticides (Pest control)
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>Indoor</p> <p>Indoor</p>

Application method(s)

Method: Bait formulations:
Detailed description:
- Ready-to-use bait to be used in tamper-resistant bait stations

Application rate(s) and frequencies

Application Rate: Bait products:
Dilution (%):
Number and timing of application:
Rats:
- High infestation: 100 g of bait per baiting point spaced 5m apart.
- Low infestation: 100 g of bait per baiting point spaced 10m apart.

Mice:
- High infestation: 50 g of bait per baiting point spaced 2m apart.
- Low infestation: 50 g of bait per baiting point spaced 5m apart.

Category(ies) of users

Professional

Pack sizes and packaging material

Cardboard box containing labelled plastic (PET) trays of 50 g with peel-off covering for mice and rats - from 2.5kg to 15kg

Cardboard box containing labelled plastic (PET) trays of 100 g with peel-off covering for rats - from 2.5kg to 15kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 50 g with peel-off covering for mice - from 2.5kg to 15kg

Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 100 g with peel-off covering for rats - from 2.5kg to 15kg

Labelled/printed plastic (HDPE) tubes (for use with caulking gun) each up to 600 g in labelled cardboard box or in labelled plastic (PP) bucket for mice and rats – from 2.5kg to 15kg

Labelled/printed plastic bucket (PP) for mice and rats - from 2.5kg to 15kg

4.3.1 Use-specific instructions for use

- For mice: The bait 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.
- Follow any additional instructions provided by the relevant code of best practice.

4.3.2 Use-specific risk mitigation measures

See section 5.2

4.3.3 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.

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

See section 5.4 Professional users

4.3.5 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

Use 4 - House mice and rats – Professional users – outdoor around buildings

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

Not relevant for rodenticides

Target organism(s) (including development stage)

Scientific name: *Mus musculus*
Common name: House mouse
Development stage: Adults and Juveniles

Scientific name: *Rattus norvegicus*
Common name: Brown rat
Development stage: Adults and Juveniles

Field(s) of use	<p>Outdoor</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: Bait formulations: Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequencies	<p>Application Rate: Bait products: Dilution (%): Number and timing of application: Rats: - High infestation: 100 g of bait per baiting point spaced 5m apart. - Low infestation: 100 g of bait per baiting point spaced 10m apart.</p> <p>Mice: - High infestation: 50 g of bait per baiting point spaced 2m apart. - Low infestation: 50 g of bait per baiting point spaced 5m apart.</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>Cardboard box containing labelled plastic (PET) trays of 50 g with peel-off covering for mice and rats – from 2.5 kg to 15 kg</p> <p>Cardboard box containing labelled plastic (PET) trays of 100 g with peel-off covering for rats - from 2.5 kg to 15 kg</p> <p>Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 50 g with peel-off covering for mice - from 2.5 kg to 15 kg</p> <p>Printed cardboard box containing labelled pre-dosed tamper resistant bait stations (PP) with inner plastic (PET) tray of 100 g with peel-off covering for rats - from 2.5 kg to 15 kg</p> <p>Labelled/printed plastic (HDPE) tubes (for use with caulking gun) each up to 600 g in labelled cardboard box or in labelled plastic (PP) bucket for mice and rats – from 2.5 kg to 15 kg</p> <p>Labelled/printed plastic bucket (PP) for mice and rats - from 2.5 kg to 15 kg</p>

4.4.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-labile 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.
- Follow any additional instructions provided by the relevant code of best practice.

4.4.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

See section 5.4

4.4.5 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 use

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.
- 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).
- 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 inaccessible to children, companion animals and non-target animals
- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 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. That frequency should be consistent with the recommendations provided by the relevant code of best 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 the bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket (buckets only).
- Use a spatula for post-application (cleaning/disposal) of bait (for buckets and tubes for use with caulking gun).
- Clean the spatula with a wipe and dispose of it in accordance with local requirements.

Professional users

- 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 reinvasion.
- The product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- 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 inaccessible to children, companion animals and non-target animals.
- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
- 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 the remaining bait or the bait stations at the end of the treatment period.

only).

- Use a spatula for post-application (cleaning/disposal) of bait (for buckets and tubes for use with caulking gun).
- Clean the spatula with a wipe and dispose of it in accordance with local requirements.

5.2. Risk mitigation measures

Trained professionals

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

Professional users

- 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.
- 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 the National Poisons Information Centre on (01) 809 2166"
- Hazardous to wildlife.
- Poison Information: For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-809 2166), retain the label for reference.

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.

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.
- Protect from frost.
- Do not store at temperature >35°C.
- 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.
- 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.

