AUTHORISATION NUMBER: **IE/BPA 70830**

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 Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, as amended by Regulation (EU) No 334/2014, and European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013), grants authorisation to make available on the market in Ireland, the biocidal product:

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| **Product name:** | BRODITOP GEL | |
| **Name and address of the authorisation holder** | **Name** | ZAPI S.p.A. |
| | **Address** | via Terza Strada 12<br>35026<br>Conselve<br>Padova<br>Italy |
| **Authorisation number** | IE/BPA 70830 | |
| **Authorisation type** | National Authorisation (mutual recognition) | |
| **Date of the authorisation** | 10th December 2021 | |
| **Expiry date of the authorisation** | 27th January 2026 | |

subject to the conditions detailed in the Annexes to this certificate.

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

Donal Lynch

Pesticide Control Division (PCD)

Official Stamp:

Version: 1.0

AN ROINN TALMHAÍOCHTA BIA AGUS MARA
ÉIRE ÉIRE
Dept. of Agriculture, Food and the Marine
IRELAND

# ANNEX I

## Product Summary and Conditions of Authorisation

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| **Trade name** | BRODITOP GEL IE/BPA 70830 |
| **Other Trade Names** | BRODITEC GEL-50 IE/BPA 70830-001<br>SAKARAT BRODIFACOUM GEL IE/BPA 70830-002 |
| **R4BP asset number** | IE-0027662-0000 |
| **Name of Marketing Company, Address** | To be confirmed |

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| **Active Substance(s) (% w/w):** | Brodifacoum [0.005% w/w] |
| **Product-Type:** | PT14 Rodenticides |
| **Product Composition:** | See Confidential PAR on R4BP3 |
| **Substance(s) of Concern:** | Silicon dioxide |
| **Comparative Assessment Required:** | No |
| **Formulation Type:** | RB – Bait (ready-to-use) |
| **Area of Use:** | Indoor use<br>Outdoor use (around buildings) |
| **Statement of Use:** | A ready-to-use gel bait containing Brodifacoum [0.005% w/w] for use as a rodenticide by Professionals & Trained Professionals for the control of rats and mice indoors and outdoors around buildings for the protection of public health, stored products and materials. |
| **User Category:** | Professionals<br>Trained Professionals |
| **Special labelling provisions for Ireland:** | In addition to the details recorded on the SPC, the following details shall be recorded on the product label(s).<br><br>**All users:**<br>**Use Biocides Safely and Sustainably.**<br>**It is illegal to use this product for uses or in a manner other than that prescribed on this label.**<br><br>**Bait stations:**<br>Must be labelled with the following information: "Product name or authorisation number"; "Active substance(s)" "Contains a rodenticide"; "Do not move or open"; and "In case of incident, call the National Poisons Information Centre on (01) 809 2166".<br><br>**Poison Information**: |

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| | 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.<br><br>**First Aid:**<br>In case of: 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.<br>Contact a veterinary surgeon in case of ingestion by a pet.<br><br>**Disposal of uneaten bait:**<br>At the end of the treatment, dispose of uneaten bait and the packaging in accordance with EPA requirements for the disposal of hazardous waste. Use of gloves is recommended.<br><br>**Professional and Trained Professional users:**<br>Not for sale to the general public<br>This product should only be used in accordance with a code of best practice such as the CRRU Ireland Best Practice Requirements for Rodent Control and Safe Use of Rodenticides. Follow any additional instructions in that code of best practice.<br>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 code of best practice.<br>Wear protective chemical resistant gloves during product handling phase (EN374).<br><br>**Proof of competence**<br>Trained professional users must register with DAFM as a 'Trained Professional - Pest Management Professional' (PMU) and must present their PMU No at point of sale to purchase this product for use only as specified on the label.<br>Professional users must present their professional number such as herd/flock number at point of sale to purchase this product for use only as specified on this label.<br><br>**Disposal of dead rodents:**<br>Dispose of dead rodents in accordance with local requirements, using one of the following methods of disposal (in order of preference): via an on-site or on-farm small carcass incinerator; with the site's or farm's domestic waste; in the site's or farm's normal non-hazardous waste; or by burial on-site, but away from sensitive areas.<br><br>**Trained Professionals only:**<br>Not for sale to the general public or any person other than trained professionals.<br>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 CRRU Ireland Best |

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| | Practice Requirements for Rodent Control and Safe Use of Rodenticides.<br>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 code of best practice. When the product is being used in public areas and tamper resistant bait stations are not used, 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. |

This authorisation may be subject to review in accordance with Regulation (EU) No 528/2012, as amended by Regulation (EU) No 334/2014, or the European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013). The outcome of such a review may lead to amendments to or the revocation of this authorisation.

The following conditions and restrictions apply:

1. Product may **not** be made available on the market or used in the Republic of Ireland unless it complies with the Annexes of this authorisation.

2. 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.

3. 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.

4. All product made available on the market in Ireland must comply with the classification, labelling and packaging requirements established in: Article 69 of Regulation (EU) No 528/2012; the Chemicals Act 2008 (as amended) giving further effect to Regulation (EC) No 1272/2008; and the classification, labelling and Safety Data Sheet information detailed in the Annex II to this certificate.

5. All biocidal products advertised must comply with Article 72 of Regulation (EU) No 528/2012.

6. A printed copy of the Irish label(s) in accordance with the Annexes of this authorisation must be submitted to the Irish Competent Authority for Biocides prior to any product being made available on the market in Ireland. All product labels must carry the authorisation number in the form: IE/BPA 70830.

7. Safety Data Sheets (SDS) for the biocidal product(s) shall be prepared and made available in accordance with Article 70 of the Biocidal Products Regulation 528/2012 (as amended). Relevant sections of the SDS must be updated post-authorisation in accordance with Annex II of the authorisation certificate. In particular, Section 15 of the SDS should be updated to contain the authorisation number IE/BPA 70830. The SDS 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 the product is made available 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. Details of the distributors name and address must also be submitted at this time.

9. Authorisation holders and marketing companies must inform distributors, wholesalers and retailers of their requirements to keep records of goods in and goods out which can be requested by DAFM for inspection.

10. 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.

11. **The Irish Competent Authority for Biocides requires Irish specific resistance data to be generated for the active substance contained in this product and submitted at renewal.**

## (b) Amendments to Authorisation

The following amendments apply to the conditions of authorisation for the biocidal product:

| Issue | Re-issue | Version | Modifications applied[2] |
|---|---|---|---|
| 10/12/2021 | - | 1.0 | Original certificate |
| | | | |

# ANNEX II

## Summary of Product Characteristics (SPC) for a biocidal product

The following conditions, outlined in the summary of product characteristics (SPC), apply to the authorisation for the biocidal product as provided for in Article 22 of Regulation (EU) No 528/2012 as amended. The authorised biocidal product SPC file is referenced below:

| Issue | Re-issue | Version | File Name |
|---|---|---|---|
| 10/12/2021 | - | 1.0 | spc_BRODITOP GEL_IE_en_202112091319 |
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