AUTHORISATION NUMBER: **IE/BPA 70734**

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:

Product name:	Protect Home Express	
Name and address of the authorisation holder	**Name**	SBM Developpement
	Address	60 Chemin des Mouilles, 69130, Ecully, France
Authorisation number	IE/BPA 70734	
Authorisation type	National Authorisation Mutual Recognition in Sequence	
Date of the authorisation	22nd March 2019	
Expiry date of the authorisation	30th June 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

Louise Pierce

Marya Pow

Pesticide Control Division (PCD)

Official Stamp:

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

Version: 1.4

ANNEX I

Product Summary and Conditions of Authorisation

Trade name	Protect Home Express
Other Trade Names	N/A
R4BP asset number	IE-0020399-0000
Name of Marketing Company, Address	To be confirmed

Active Substance(s) (% w/w):	Alphachloralose 4.0%
Product-Type:	PT14 Rodenticides
Product Composition:	See Confidential PAR on R4BP3
Substance(s) of Concern:	None
Comparative Assessment Required:	No
Formulation Type:	Ready-to-use bait: wax block
Area of Use:	Indoor use
Statement of Use:	A ready-to-use [wax block] bait containing alphachloralose (4.0% w/w) for use as a rodenticide by the General Public for the control of mice indoors for the protection of public health, stored products and materials.
User Category:	General Public
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). **All users:** **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.** **Bait stations:** 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". **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.

	First Aid: 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. Contact a veterinary surgeon in case of ingestion by a pet. **Disposal of uneaten bait:** 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. **General Public users only:** Where control of rodents has not been achieved by a contro program after 35 days, the user should seek advice from th product supplier or call a pest control service. Do not use this product for permanent or pulse-baiting. Poisoned rodents should be double-bagged using plastic bags an either disposed of in a household waste bin with a secure lid t prevent access of wildlife or pets, or collected by a specialis waste contractor.

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 70734.

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 70734. 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]
22/03/2019	-	1.0	Original certificate
-	25/02/2020	1.1	National transfer of Authorisation
-	25/05/2021	1.2	Update to manufacturer details
-	23/06/2021	1.3	Expiry date extended
-	21/02/2024	1.4	Extension of authorisation in line with RMS

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
22/03/2019	-	1.0	spc_Protect home express_IE_en_201903131659
-	25/02/2020	1.1	spc_Protect home express_IE_en_202002251502
-	25/05/2021	1.2	spc_Protect_home_express_IE_en_201912131144
-	23/06/2021	1.3	spc_Protect_home_express_IE_en_201912131144
-	21/02/2024	1.4	f4b6a2e0-a354-4a7f-ac67-d44fc25412ec