

AUTHORISATION NUMBER: IE/BPA 70331

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:

Trade name:	TMB Classic Insect Repellent	
Name and address of the	Name	Scotmas Group Ltd
authorisation holder	Address	Spylaw Road, Kelso, TD5 8DL, Scotland, UK
Authorisation number	IE/BPA 70331	
Authorisation type	Mutual recognition in sequence (NA-MRS)	
Date of the authorisation	26/07/2016	
Expiry date of the authorisation	31/01/2025	

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

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

Merrya Pa

Pesticide Control Division (PCD)

Official Stamp:

Version: 1.2

ANNEXI

Product Summary and Conditions of Authorisation

Trade name	TMB Classic Insect Repellent
Other Trade Names	IE/BPA 70331-001 Repel 55
R4BP asset number	IE-0010533-0000

Active Substance(s) (% w/w):	DEET (N, N-diethyl-meta-toluamide) (55% w/w)	
Product-Type:	19	
Product Composition:	Confidental (see Appendix III)	
Formulation Type:	Ready to use, solvent based liquid	
Area of Use:	Use on skin Indoor use Outdoor use	
User Category:	Non Professional/General Public	

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(s) 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; S.I. 624 (2001) transposing Directive 99/45/EC; the Chemicals Act 2008 (as amended) transposing Regulation (EC) No 1272/2008; and the Labelling and Safety Data Sheet Annex detailed in 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 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 of the form: IE/BPA 70330.
- 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 SOS must be updated post-authorisation in accordance with Annex II of the authorisation certificate. In particular, Section 15 of the SOS should be updated to contain the authorisation number IE/BPA 70330. The SOS 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.
- 9. Fees are payable for the maintenance of the product on the Register of Biocidal Products and shall be paid by the 31st of December of the following year and each year thereafter.
- 10. Risk Mitigation Measures:

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(b) Amendments to Authorisation

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

Issue	Re-issue	Version	Modifications applied ²	
26/07/2016	-	1.0	Original certificate	
26/07/2016	22/06/2018	1.1	Additional trade names.	
	04/07/2022	1.2	Extension of authorisation	

ANNEX II

Summary of Product Characteristics (SPC) for a biocidal product

The SPC generated using the SPC Editor (.xmJ) detail the authori sed biocidal product information provided for in Article 22 of Regulation (EU) No 528/2012 as amended. The relevant SPC file is referenced below:

Issue	Re-issue	Version	File Name
26/07/2016	-	1.0	spc_DEET_50_IE_v I .xml
26/07/2016	22/06/2018	1.1	spc_DEET50_IE_en_201806242309