



AUTHORISATION NUMBER: IE/BPA 70333

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:

<b>Trade name:</b>	DEET 100	
<b>Name and address of the authorisation holder</b>	<b>Name</b>	Scotmas Group Ltd
	<b>Address</b>	Spylaw Road, Kelso, TD5 8DL, Scotland, UK
<b>Authorisation number</b>	IE/BPA 70333	
<b>Authorisation type</b>	Mutual recognition in sequence (NA-MRS)	
<b>Date of the authorisation</b>	26/07/2016	
<b>Expiry date of the authorisation</b>	19/05/2021	

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

Pesticide Control Division (PCD)

Official Stamp:



**ANNEX I****Product Summary and Conditions of Authorisation**

<b>Trade name</b>	DEET 100
<b>Other Trade Names</b>	IE/BPA 70333-001 Trek Ultra IE/BPA 70333-002 TMB Extreme Insect Repellent IE/BPA 70333-003 Protect Once
<b>R4BP asset number</b>	IE-0010713-0000

<b>Active Substance(s) (% w/w):</b>	DEET (N,N-diethyl-meta-toluamide) (30% w/w)
<b>Product-Type:</b>	19
<b>Product Composition:</b>	See Confidential section of the PAR.
<b>Substance(s) of Concern:</b>	
<b>Formulation Type:</b>	Ready to use, solvent based liquid
<b>Area of Use:</b>	Use on skin Indoor use Outdoor use
<b>User Category:</b>	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 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 70333.
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 70333. 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.
9. Fees are payable for the maintenance of the product on the Register of Biocidal Products and shall be paid by the 31<sup>st</sup> December of the following year and each year thereafter.
10. Risk Mitigation Measures:

**(b) Amendments to Authorisation**

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

<b>Issue</b>	<b>Re-issue</b>	<b>Version</b>	<b>Modifications applied<sup>2</sup></b>
26/07/2016	-	1.0	Original certificate
26/07/2016	11/04/2017	1.1	<ol style="list-style-type: none"> <li>1. Additional trade name added certificate "TMB Extreme - Insect Repellent"</li> <li>2. Additional active substance supplier Vertelus SA added.</li> <li>3. R4BP3Asset number added</li> </ol>
11/04/2017	22/06/2018	2.0	Additional trade names.

**ANNEX II****Summary of Product Characteristics (SPC) for a biocidal product**

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

<b>Issue</b>	<b>Re-issue</b>	<b>Version</b>	<b>File Name</b>
26/07/2016	-	1.0	spc_DEET_100_IE_v1.xml
26/07/2016	11/04/2017	1.1	20170411 70333 v1_1 spc_DEET 100_I.xml
11/04/2017	22/06/2018	2.0	spc_DEET 100_IE_en_201806242326

