AUTHORISATION NUMBER: **IE/BPA 70431**

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:

Biocidal Product Name:	MecDEET Solution	
Name and address of the authorisation holder	**Name**	Beaphar BV
	Address	BeapharBV Drostenkamp 3, 8101 Raalte Nederland
Authorisation number	IE/BPA 70431	
Authorisation type	Mutual recognition in sequence (NA-MRP)	
Date of the authorisation	04/02/2019	
Expiry date of the authorisation	24/04/2028	

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

==========

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

Donal Lynch

Pesticide Control Division (PCD)

Official Stamp:

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

Ver 1.2

ANNEX I

Product Summary and Conditions of Authorisation

Biocidal Product	MecDEET Solution
Biocidal Product Trade names (with suffixes to the Authorisation number)	None.
R4BP asset number	IE-0014753-0000

Active Substance(s) (% w/w):	N,N-diethyl-meta-toluamide (19.0% w/w)
Product-Type:	PT19 - Repellents and attractants (Pest control)
Product Composition:	Confidential (see Confidential PAR)
Substance(s) of Concern:	None.
Formulation Type:	ME - Micro-emulsion
Area of Use:	Repellent for use against: Ixodes ricinus castor bean tick Indoor Outdoor Spraying on skin 1,67 µL/cm² Adults and children (between 6-11 years old): apply once per day.
User Category:	General public (non-professional)
Irish Distributer:	To be confirmed.
Special labelling provisions for Ireland:	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.

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.

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.

2. 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.

3. 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.

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

5. 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 70431.

6. 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 70431. 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.

7. 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.

8. 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.

(b) Amendments to Authorisation

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

Issue	Re-issue	Version	Modifications applied[2]
04/02/2019	-	1.0	Original certificate
	08/02/2019	1.1	Correction of Expiry date
	18/10/2021	1.2	Addition of phrase to RMM in line with eCA decision

ANNEX II

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

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

Issue	Re-issue	Version	File Name
04/02/2019	-	1.0	spc_MECDEET Solution_IE_en_201902041739
	08/02/2019	1.1	spc_MECDEET_Solution_IE_en_201902041739
	18/10/2021	1.2	spc_MECDEET Solution_IE_en_202110181025