AUTHORISATION NUMBER: **IE/BPA 70320**

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:	Jungle Formula Maximum Roll-On	
Name and address of the authorisation holder	**Name**	Perrigo Supply Chain International DAC
	Address	The Sharp Building, Hogan Place, Dublin, D02 TY74, Ireland.
Authorisation number	IE/BPA 70320	
Date of the authorisation	12th July 2016	
Expiry date of the authorisation	31st January 2025	

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

Pesticide Control Division (PCD)

Official Stamp:

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Dept. of Agriculture, Food and the Marine
IRELAND

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ANNEX I

Product Summary and Conditions of Authorisation

Trade name	Jungle Formula Maximum Roll-On IE/BPA 70320
Other Trade Names	N/A

Active Substance(s) (% w/w):	DEET (N,N-diethyl-meta-toluamide) (50% w/w)
Product-Type:	PT 19 – Repellents and attractants (Pest Control)
Product Composition:	See R4BP3 for Confidential PAR
Substance of Concern:	Ethanol (38.31 % w/w)
Formulation Type:	Any other liquid
Where relevant, an exact description of the authorised use	This product can only be used to repel mosquitoes to protect people.
Target organism (including development stage)	*Mosquitoes (Culicidae)* *Ticks (Ixodidae)*
Area of Use:	Indoor use on skin
Application method(s)	Roll sparingly and evenly over the skin that needs to be protected. Do not apply on the face. Avoid contact with eyes, mucous membranes and damaged skin Use ca. 1 ml per 600 cm^2 of skin (corresponds with 1 ml per adult male arm)
Application rate(s) and frequency	Do not use more than once a day. Do not use on children under 18 years old.
User Category:	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 70320.

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 70320. 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 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:

Issue	Re-issue	Version	Modifications applied[2]
12/07/2016	-	1.0	Original certificate
-	17/04/2019	1.1	Change to Authorisation holder address and addition of manufacturing sites
-	25/05/2020	1.2	Addition of Ticks to target species
-	24/08/2021	1.3	Change to the classification and labelling
-	30/04/2024	1.4	NA-TRS (BC-AV089112-26)
-	18/07/2024	1.5	NA-AAT Extension of Authorisation in line with RMS

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 Product may **not** be made available on the market or used in the Republic of Ireland unless it complies with the requirements of the SPC.

The relevant SPC file is referenced below:

Issue	Re-issue	Version	File Name
12/07/2016	-	1.0	spcJungleFormulaMaximumRollOn50DEET_20160715_20160715 1400.xml
-	17/04/2019	1.1	spc_Jungle Formula Maximum Roll On_IE_en_201904171231
-	25/05/2020	1.2	spc_Jungle Formula Maximum Roll-On_IE_en_202005251635
-	24/08/2021	1.3	spc_Jungle Formula Maximum Roll-on IE_en_202007131714
-	30/04/2024	1.4	cf860a3b-a634-4785-97f0-3a85d5718c74
-	18/07/2024	1.5	cf860a3b-a634-4785-97f0-3a85d5718c74