AUTHORISATION NUMBER: **IE/BPA 70380**

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:	K-Othrine WG 250	
Name and address of the authorisation holder	**Name**	2022 ENVIRONMENTAL SCIENCE FR SAS
	Address	3, place Giovanni Da Verrazzano, 69009, Lyon, France
Authorisation number	IE/BPA 70380	
Authorisation type	Mutual Recognition in Parallel (NA-MRP)	
Date of the authorisation	07/07/2017	
Expiry date of the authorisation	26/01/2027	

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:

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

Version: 1.3

ANNEX I

Product Summary and Conditions of Authorisation

Trade name	K-Othrine WG 250, IE/BPA 70380
Other Trade Names	-
R4BP asset number	IE-0010436-0000

Active Substance(s) (% w/w):	Deltamethrin (25% w/w)
Product-Type:	PT 18 (Insecticides, acaricides and other products to control arthropods).
Product Composition:	See Confidential PAR on R4BP3
Substance(s) of Concern:	Deltamethrin
Formulation Type:	Water Dispersible Granule (WG)
Statement of use:	It is a Water Dispersible Granule, not ready-to-use containing Deltramethrin (25 % w/w) for use as an insecticide sprayed indoors by professionals and trained professionals for the preventative control of crawling insects, bed bugs and flying insects when at rest. 1. Spray indoors for control of chronic infestations of crawling insects (including cockroach) in domestic, commercial and industrial buildings, at an application rate of 12.5 mg/m2 (5g of product in 5L of water for 100 m2). 2. Spray indoors for control of localised infestations of crawling insects (including cockroach) in domestic, commercial and industrial buildings at an application rate of 6.25 mg/m2 (2.5g of product in 5L of water for 100 m2). 3. Spray indoors for control of bed bugs in domestic, commercial and industrial buildings at a dose of 25 mg/m2 (10g of product in 5L of water for 100m2). 4. Spray indoors for control of flies when at rest, in domestic, commercial and industrial buildings at a dose of 12.5 mg/m2 (5g of product in 5L of water for 100 m2).
Area of Use:	IV 1.3.2. Indoor use in/at household/private areas
User Category:	Professional Users Trained Professional Users
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.

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) transposing 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 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 70380.**

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 70380**. 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]
07/07/2017	-	1.0	Original certificate
	08/06/2018	1.1	Certificate amended to correct the IE/BPA number in the header from IE/BPA 70249 to IE/BPA 70380. Removal of the Confidential Annex and the additional of "Product Composition: See Confidential PAR on R4BP3" in Annex 1.
	11/02/2019	1.2	Transfer of National Authorisation
	07/02/2023	1.3	Transfer of authorisation holder - BC-MF075830-40

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
07/07/2017	-	1.0	2017_06_28 70380 spc_K-Othrine WG 250_IE_en_201706280927.xml
	11/02/2019	1.2	spc_K-Othrine_WG_250_IE_en_201901151555
	07/02/2023	1.3	spc_K-Othrine_WG_250_IE_en_201901151555