

AUTHORISATION NUMBER: IE/BPA 70729

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:

Creosote (Maderoil Grade C and B) BPF		
Name	Bilbaina de Alquitranes, S.A.	
Address	Obispo Olaechea 49, 48903, Lutxana- Barakaldo (Vizcaya), Spain	
IE/BPA 70729		
Mutual re	Mutual recognition in sequence (NA-MRS)	
10 th January 2019		
31 ST December 2024		
	Name Address IE/BPA 7 Mutual re 10 th Janua	

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

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

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Pesticide Control Division (PCD)

Official Stamp:



Ver: 1.3

$\underline{\textbf{ANNEX I}}$ Product Family Summary and Conditions of Authorisation

Biocidal Product Family Name	Creosote (Maderoil Grade C and B) BPF IE/BPA 70729
Biocidal Product Family Trade names (with suffixes to the Authorisation number)	(IE/BPA 70729-1-001) Creosote (Maderoil Grade B) (IE/BPA 70729-1-002) Creosote (Maderoil Grade C)
R4BP asset number	IE-0020074-0000

Active Substance(s) (% w/w):	Creosote (100% w/w) Grade B or Grade C creosote as specified in European Standard EN 13991:2003	
Product-Type:	PT8 (wood preservative)	
Product Composition:	Confidential PAR on R4BP	
Substance(s) of Concern:	Not applicable	
Formulation Type:	AL (Any other liquid)	
Area of Use:	Impregnation of timber in an industrial timber treatment facility for preventative purposes In situ surface treatment of creosote impregnated wood (UC 3 and UC 4) after modifications such as sawing, cutting, shaping and machining by professionals only. Treated wood to be used in the following use class areas as defined according to EN Standard 335: Use Class 3 (UC3): The product is for use in situations in which the wood or wood-based product is above ground and exposed to the weather (particularly rain). 3.1 (UC 3.1): In this situation the risk of components becoming and remaining wet is limited. NOTE this may be achieved by, for example, a maintained coating, or by design or orientation of components to shed water or to dry quickly. 3.2 (UC 3.2): In this situation, the time of wetness may be prolonged but not continuous. NOTE components are not designed or orientated to shed water or dry quickly. Treated wood to be used only for: Railway sleepers. Use Class 4 (UC4): The product is for use in situations in which the wood or wood-based product is in contact with the ground or fresh water and thus is permanently exposed to wetting. Treated wood to be used only for: Wood poles for overhead electricity and telecommunication. Does not include indoor use where the interior is dry or the	

	interior is subject to occasional wetting (condensation).	
User Category:	Professional Industrial (For Professional/Industrial Use Only)	
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 70729.
- 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 70729. 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.

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(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
10/01/2019	-	1.0	Original certificate
_	25/02/2021	1.1	Extension to expiry date
-	30/11/2022	1.2	NA-AAT following COMMISSION IMPLEMENTING REGULATION (EU) 2022/1950
-	25/03/2024	1.3	Extension of authorisation in line with RMS

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
10/01/2019	-	1.0	spfbc_Creosote (Maderoil Grade C and B) BPF_IE_en_201901101303
-	25/02/2021	1.1	spfbc_Creosote (Maderoil Grade C and B) BPF_IE_en_202102250944
-	30/11/2022	1.2	spfbc_Creosote (Maderoil Grade C and B) BPF_IE_en_v2
-	25/03/2024	1.3	0c5e5843-5a2b-4cf7-8ce2-66a9a45c6f50