

### **AUTHORISATION NUMBER: IE/BPA 70613**

# 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>Biocidal Product Name:</b>	Calcium Dihydroxide Family		
Name and address of the	Name	Clogrennane Lime Ltd	
authorisation holder	Address	Clogrennane, Carlow, Ireland. R93 EV26	
Authorisation number	IE/BPA 7	70613	
Authorisation type	National	National Authorisation (NA-APP)	
Date of the authorisation	12/09/2023		
Expiry date of the authorisation	12/09/2033		

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

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

Louise Pierce Merryn Pa

Pesticide Control Division (PCD)

Official Stamp:

Ver: 1.1



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

Trade name	Calcium Dihydroxide Family IE/BPA 70613			
Other Trade				
Names	White Rhino Agri Hydrated Lime	IE/BPA 70613-01-001		
	Bennettsbridge Limestone Hydrated Cubicle Lime 15%	IE/BPA 70613-01-002		
	Bennettsbridge Limestone Hydrated Cubicle Lime 20%	IE/BPA 70613-01-003		
	Bennettsbridge Limestone Hydrated Cubicle Lime 30%	IE/BPA 70613-01-004		
	Bennettsbridge Limestone Hydrated Cubicle Lime 40%	IE/BPA 70613-01-005		
	Bennettsbridge Limestone Hydrated Cubicle Lime 50%	IE/BPA 70613-01-006		
	MasterCAL	IE/BPA 70613-01-007		
	MasterCAL PLUS	IE/BPA 70613-01-008		
	MasterCAL PRO IE/BPA 70613-01-009			
	Agrichoice 15% Hydrated Lime Blend	IE/BPA 70613-01-010		
	Agrichoice 30% Hydrated Lime Blend	IE/BPA 70613-01-011		
	Cubisan 15% Hydrated Lime Blend	IE/BPA 70613-01-012		
	Cubisan 20% Hydrated Lime Blend	IE/BPA 70613-01-013		
	Cubisan 30% Hydrated Lime Blend	IE/BPA 70613-01-014		
	Farmcal 15% Hydrated Lime Blend IE/BPA 70613-01-0			
	Farmcal 20% Hydrated Lime Blend	IE/BPA 70613-01-016		
	Farmcal 30% Hydrated Lime Blend	IE/BPA 70613-01-017		
	Farmcal 50% Hydrated Lime Blend	IE/BPA 70613-01-018		
	HyCal 15	IE/BPA 70613-01-019		
	HyCal 30	IE/BPA 70613-01-020		
	Cubicle Lime 15% Hy-Blend	IE/BPA 70613-01-021		
	Cubicle Lime 30% Hy-Blend	IE/BPA 70613-01-022		
	Cubicle Lime 50% Hy-Blend	IE/BPA 70613-01-023		
R4BP asset	IE-0031562-0000			
number				

Active Substance(s) (% w/w):	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime 15-65% (w/w) Calcium Carbonate 35-85% (w/w)		
Product-Type:	PT 3 Veterinary Hygiene (Disinfectants)		
<b>Product Composition:</b>	See Confidential PAR on R4BP3		
Substance(s) of Concern:	N/A		
Formulation Type:	DP – Dustable Powder		
Area of use:	Indoor		
Statement of use:	Calcium Dihydroxide is a PT3 product containing the active substances Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime 15-65% (w/w), and Calcium Carbonate 35-85% (w/w).		
	Calcium Dihydroxide is for the disinfection of indoor floor surfaces of animal accommodations by trained professional and professionals only.		
User Category:	Professional		

	Trained Professional
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 70613.
- 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 70613. The SDS must be submitted to the Irish Competent Authority for Biocides and the National Poisons Information Centre of Ireland

<u>http://www.poisons.ie/manufacturers.asp</u> 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.

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# (b) Amendments to Authorisation

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

Issue	Re-issue	Version	Modifications applied <sup>2</sup>
12/09/2023	-	1.0	Original certificate NA-APP (BC-RQ038593-12)
-	07/03/2024	1.1	NA-AAT Additional Trade Names on request of Applicant

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## 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
12/09/2023	-	1.0	spfbc_Calcium dihydroxide family_IE_en_202309081058
-	07/03/2024	1.1	spfbc_Calcium dihydroxide family_IE_en_202402021613