

AUTHORISATION NUMBER: IE/BPA 70762

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 Family Name:	Biocel Sodium Hypochlorite Family	
Name and address of the	Name	BIOCEL LTD
authorisation holder	Address	Rockgrove Industrial Estate, 00000 Little Island, Ireland
Authorisation number	IE/BPA 70762	
Authorisation type	Mutual Recognition in Parallel Authorisation	
Date of the authorisation	17 th June 2024	
Expiry date of the authorisation	05 th June 2034	

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

Lowse Pierce

Pesticide Control Division (PCD)

Official Stamp:

Version: 1.0

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

Biocidal Product Name	Biocel Sodium Hypochlorite Family IE	E/BPA 70762				
Additional Trade names	Sodium Hypochlorite 10-11% (not	IE/BPA 70762-01-001				
(with suffixes to the	marketed)					
Authorisation number)	Gold Assure Chloras (not marketed)	IE/BPA 70762-01-002				
	Coop Source Chloros (not marketed)	IE/BPA 70762-01-003				
	Supercleen Rocklor (not marketed)	IE/BPA 70762-01-004				
	Top Hygiene Hypochlorite (not marketed)	IE/BPA 70762-01-005				
	Chlorisan (not marketed)	IE/BPA 70762-01-006				
	Chlor-Kleen Extra (not marketed)	IE/BPA 70762-01-007				
	Coop Source Klor-cleen (not marketed)	IE/BPA 70762-01-008				
	Gold Assure Chlor Clean (not marketed)	IE/BPA 70762-01-009				
	Benz lightening Cleanze (not marketed)	IE/BPA 70762-01-010				
	Stontex All in One Outdoor Cleaner (not marketed)	IE/BPA 70762-01-011				
	Concept Cleaning Blackwash (not marketed)	IE/BPA 70762-01-012				
	Benz Tornado Cleanze (not marketed)	IE/BPA 70762-01-013				
	Biocel Thick Bleach (not marketed)	IE/BPA 70762-01-014				
	Sodium Hypochlorite 5-6% (not marketed)	IE/BPA 70762-01-015				
	BFS Hotwash (not marketed)	IE/BPA 70762-01-016				
	Kortol (not marketed)	IE/BPA 70762-02-001				
	Tech 100 Beerline Cleaner (not marketed)	IE/BPA 70762-03-001				
	Cerelex N (not marketed)	IE/BPA 70762-03-002				
	Biocel Beerline Cleaner (not marketed)	IE/BPA 70762-03-003				
	Tech100B (not marketed)	IE/BPA 70762-03-004				
	Aquasan (not marketed)	IE/BPA 70762-04-001				
	Agri-san (not marketed)	IE/BPA 70762-04-002				
	Rezult (not marketed)	IE/BPA 70762-04-003				
	Supersan Extra (not marketed)	IE/BPA 70762-04-004				
	Parlorsan Plus (not marketed)	IE/BPA 70762-04-005				
	Coop Source Turbosan (not marketed)	IE/BPA 70762-04-006				
	BFS Xtreme Clean All Temperature Liquid Detergent (not marketed)	IE/BPA 70762-04-007				
	Circo-san (not marketed)	IE/BPA 70762-04-008				
	Gold Assure Hotwash XT (not marketed)	IE/BPA 70762-04-009				
	Magenta Liquid Detergent (not marketed)	IE/BPA 70762-04-010				
	Top Hygiene Circulation Cleaner (not marketed)	IE/BPA 70762-04-011				
	Parlorsan (not marketed)	IE/BPA 70762-04-012				
	Unisan (not marketed)	IE/BPA 70762-04-013				
	Southern Dairies Liquid Line & Tank Cleaner (not marketed)	IE/BPA 70762-04-014				
	Cipsan Liquid (not marketed)	IE/BPA 70762-04-015				
	Multisan (not marketed)	IE/BPA 70762-04-016				
	Gold Assure Universan (not marketed)	IE/BPA 70762-04-017				
R4BP asset number	IE-0032722-0000					
Marketing Company, Address	To be confirmed					

Active Substance(s) (% w/w):	Active chlorine released from sodium hypochlorite (1.9-10.5% w/w)		
Product-Type:	PT02 Disinfectants and algaecides not intended for direct application to humans or animals PT04 Food and feed area		
Product Composition:	See Confidential PAR on R4BP3		
Substance(s) of Concern:	Yes – See Confidential PAR on R4BP3		
Comparative Assessment	NO		
Formulation Type:	SL - Soluble concentrate		
Area of Use:	Indoor Outdoor		
Statement of use:	Biocel Sodium Hypochlorite Family is a product family for PT2 and 4, containing 1.9-10.5% w/w of the active substance Active chlorine released from sodium hypochlorite for indoor and outdoor use by professional users only.		
User Category:	Professional		
Special labelling provisions for Ireland:	In addition to the details recorded on the SPC, the following details shall be recorded on the product label(s).		
	Use Biocides Safely and Sustainably It is illegal to use this product for uses or in a manner other than 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 70762.
- 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 70762. 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 family:

Issue	Re-issue	Version	Modifications applied ²
17/06/2024	-	1.0	National Authorisation - Mutual Recognition in Parallel

Authorisation No.: IE/BPA 70762

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
17/06/2024	-	1.0	bc391ae1-e10d-4ae3-9288-869a0cfca94b