AUTHORISATION NUMBER: **IE/BPA 70437**

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:	**Iobac pre/post**	
Name and address of the authorisation holder	**Name**	DeLaval NV
	Address	Industriepark-Drongen 10, 9031 Gent Belgium
Authorisation number	IE/BPA 70437	
Authorisation type	National Authorisation (NA-APP)	
Date of the authorisation	10/01/2019	
Expiry date of the authorisation	02/10/2028	

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

Pesticide Control Division (PCD)

Official Stamp:

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

ANNEX I

Product Summary and Conditions of Authorisation

Biocidal Product Name	**Iobac pre/post** 70437
Biocidal Product Trade names (with suffixes to the Authorisation number)	Iobac pre/post 70437
R4BP asset number	IE-0016073-0000
Marketing Company, Address	To be confirmed.

Active Substance(s) (% w/w):	Iodine (0.15% w/w)
Product-Type:	PT 3 (Veterinary Hygiene)
Product Composition:	See Confidential PAR on R4BP3
Substance(s) of Concern:	None.
Comparative Assessment:	Not relevant
Formulation Type:	AL (no dilution)
Statement of use:	Iobac pre/post is only intended for teat disinfection of lactating animals. The product can be applied before and/or directly after milking on the teats. No dilution. To be applied before and/or after each milking (usually 2 times per day). The product should be used all year during the lactation period. For virucidal targeting the product can only be used post-milking Disinfection of udder teats by dipping or spraying - ready-to-use product Disinfection of udder teats by dipping or spraying pre- and post-milking for bactericidal and yeasticidal and just post-milking for virucidal effect: Dip method: Dip 3/4 of each teat seperately in a cup filled with the product. Allow for a minimum contact time of 30 seconds for bactericidal or yeasticidal targeting and 5 minutes/no wiping off for virucidal targeting. Spray method: Spray the disinfectant onto 3/4 of each teat from below. Allow for a minimum contact time of 30 seconds for bactericidal or yeasticidal targeting and a minimum contact time of 5 minutes/no wiping off for virucidal targeting. Spraying can be done manually, using a spray container. Alternatively, milking machines with integrated automated spraying may be

	used.
Area of Use:	Indoor Teats of lactating animals.
User Category:	Professional Users
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 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 70437.

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 70437. 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]
10/01/2019	-	1.0	Original certificate
	22/08/2022	1.1	Change to the classification and labelling requirements

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
06/06/2018	-	1.0	spc_Iobac pre_post_IE_en_201901101754
	22/08/2022	1.1	spc_Iobac_pre_post_IE_en_202111301250