

FDA USE ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**GENERALLY RECOGNIZED AS SAFE
(GRAS) NOTICE** (Subpart E of Part 170)

GRN NUMBER <i>000716</i>	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway (*see Instructions*); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835.

SECTION A – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission (*Check one*)

New Amendment to GRN No. _____ Supplement to GRN No. _____

2. All electronic files included in this submission have been checked and found to be virus free. (*Check box to verify*)

3. Most recent presubmission meeting (*if any*) with FDA on the subject substance (*yyyy/mm/dd*): 2015/02/24

4. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? (*Check one*)
 Yes If yes, enter the date of communication (*yyyy/mm/dd*): _____
 No

SECTION B – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person See Agent	Position or Title See Agent
Organization (<i>if applicable</i>) Arla Foods Ingredients Group P/S	
Mailing Address (<i>number and street</i>) Soenderhoej 10-12	

City VibyJ	State or Province	Zip Code/Postal Code DK-8260	Country Denmark
Telephone Number +1 4849195759	Fax Number	E-Mail Address kal.ramanujam@arlafoods.com	

**1b. Agent or Attorney
(if applicable)**

Name of Contact Person Ray A. Matulka, Ph.D.	Position or Title Director of Toxicology
Organization (<i>if applicable</i>) Burdock Group Consultants	
Mailing Address (<i>number and street</i>) 859 Outer Road	

Orlando	State or Province Florida	Zip Code/Postal Code 32814	Country United States of America
Telephone Number 407.802.1400	Fax Number 407.802.1405	E-Mail Address rmatulka@burdockgroup.com	

SECTION E – PARTS 2 -7 OF YOUR GRAS NOTICE

(check list to help ensure your submission is complete – PART 1 is addressed in other sections of this form)

- PART 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect (170.230).
- PART 3 of a GRAS notice: Dietary exposure (170.235).
- PART 4 of a GRAS notice: Self-limiting levels of use (170.240).
- PART 5 of a GRAS notice: Experience based on common use in foods before 1958 (170.245).
- PART 6 of a GRAS notice: Narrative (170.250).
- PART 7 of a GRAS notice: List of supporting data and information in your GRAS notice (170.255)

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

Yes No

Did you include this other information in the list of attachments?

Yes No

SECTION F – SIGNATURE AND CERTIFICATION STATEMENTS

1. The undersigned is informing FDA that Arla Foods Ingredients Group P/S
(name of notifier)

has concluded that the intended use(s) of Lacprodan® OPN-10
(name of notified substance)

described on this form, as discussed in the attached notice, is (are) not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is generally recognized as safe under the conditions of its intended use in accordance with § 170.30.

2. See Agent *(name of notifier)* agrees to make the data and information that are the basis for the conclusion of GRAS status available to FDA if FDA asks to see them; agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so; agrees to send these data and information to FDA if FDA asks to do so.

859 Outer Road, Orlando, FL 32814
(address of notifier or other location)

The notifying party certifies that this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, pertinent to the evaluation of the safety and GRAS status of the use of the substance. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

3. Signature of Responsible Official, Agent or Attorney <i>(b) (6)</i>	Printed Name and Title Ray A. Matulka, Ph.D., Director of Toxicology	Date (mm/dd/yyyy) 07/06/2017
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