DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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)
   - [X] 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
Organization (if applicable)
Arla Foods Ingredients Group P/S
Mailing Address (number and street)
Soenderhoey 10-12

City
Viby

State or Province
DK-8260

Zip Code/Postal Code

Country
Denmark

Telephone Number
+1 484 919 5759

Fax Number

E-Mail Address
kal.ramanujam@arlafoods.com

Position or Title
Director of Toxicology

1b. Agent or Attorney (if applicable)

Name of Contact Person
Ray A. Matulka, Ph.D.

Organization (if applicable)
Burdock Group Consultants

Mailing Address (number and street)
859 Outer Road

City
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 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 or 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

   Ray A. Matulka, Ph.D., Director of Toxicology

   Date (mm/dd/yyyy) 07/06/2017

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