

# 2 September 2019

# **PRESS RELEASE**

# Arla Foods Ingredients obtains GRAS approval for alpha-lactalbumin in infant formula

Arla Foods Ingredients has obtained Generally Recognized as Safe (GRAS) approval relating to its use of alpha-lactalbumin in infant formula.

The US Food & Drug Administration (FDA) issued the company with a GRAS Notice known as a 'no objection letter'. It states that it has no questions regarding the safety of fractionated whey protein concentrate containing 41% alpha-lactalbumin – marketed by Arla Foods Ingredients as Lacprodan® ALPHA-10 – when used in infant formula.

The FDA's decision means Lacprodan® ALPHA-10 is permitted as an ingredient in cows' milk-based non-exempt formula for term infants at levels of to 8.3g per liter. It will also allow Arla Foods Ingredients to supply fractionated whey protein concentrate containing 41% alpha-lactalbumin to the US infant formula market.

Alpha-lactalbumin is rich in essential amino acids and the most abundant protein in human milk, comprising about 25% of total protein content. Adding an alpha-lactalbumin ingredient such as Lacprodan® ALPHA-10 to an infant formula means it can emulate human milk more closely in terms of protein concentration and composition.

It also makes it possible to reduce overall protein levels in a formula. This is widely considered desirable because, while more research is needed, reducing the protein concentration of formula has been suggested as a preventive strategy for cutting the risk of overweight and obesity in children. Other benefits associated with alphalactalbumin include a reduction in feeding-related gastrointestinal events, protection against intestinal infections and support for a healthy gut microbiota.

Kal Ramanujam, Senior Scientific Advisor, Pediatric, at Arla Foods Ingredients said: "Lacprodan® ALPHA-10 delivers safe and documented benefits when used in infant formula. This approval is a regulatory milestone in the U.S. It will benefit millions of babies by allowing them to consume clinically documented levels of bovine alpha lactalbumin."

Lacprodan® ALPHA-10 is a whey protein fraction with 41% alpha-lactalbumin and a high content of tryptophan, cysteine and 88% protein concentrate in dry matter.

The GRAS notice (GRN No. 809) is available at: https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=809

Arla Foods Ingredients supports the WHO recommendation for exclusive breastfeeding for the first six months of an infant's life and continued breastfeeding up to the age of two or beyond in combination with nutritionally appropriate complementary foods.

# For more information, please contact:

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# **About Arla Foods Ingredients**

Arla Foods Ingredients is a global leader in value-added whey solutions. We discover and deliver ingredients derived from whey, supporting the food industry with the development and efficient processing of more natural, functional and nutritious foods. We serve global markets within early life nutrition, medical nutrition, sport nutrition, health foods and other foods and beverage products.

#### Five reasons to choose us:

- We have R&D in our DNA
- We offer superior quality
- We are your trusted business partner
- We support sustainability
- We ensure security of supply

Arla Foods Ingredients is a 100% owned subsidiary of Arla Foods. Our head office is in Denmark.

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