

# APPLICATION TO PERMIT THE OPTIONAL USE OF MILKFAT GLOBULE MEMBRANE ENRICHED WHEY PROTEIN CONCENTRATE IN INFANT FORMULA PRODUCTS

**Applicant:**

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## Executive Summary

Arla Foods Ingredients P/S (AFI) is a Danish food ingredient manufacturer supplying dairy-based ingredients, using standard whey processing techniques, for a wide variety of food applications including infant and medical nutrition formulations. Arla Foods Ingredients P/S has developed a dairy-derived whey protein concentrate (WPC) known under the tradename Lacprodan® MFGM-10. The unique feature of Lacprodan® MFGM-10, compared to typical WPC, is the enrichment of membrane components including phospholipids, glycolipids, membrane proteins, and sphingolipids. These stem from the three-layer milk fat globule membrane (MFGM) and single layer membrane of extracellular vesicles (EV) enriched in this product. MFGM is a component of all mammalian milks and is the primary delivery mechanism of fats in mammalian milk to offspring. For simplicity the MFGM and EV membrane materials are collectively referred to as MFGM as per the body of existing literature. All infants, breast-fed and formula-fed, therefore consume MFGM and its lipid and protein components, albeit at different levels. The components of MFGM are typically present at low levels in infant formula products that are milk-based or that contain milk-based ingredients. Vegetable oils, increasingly used over the last several decades as a fat source in infant formula products, typically lack the complex phospholipids present in MFGM, including sphingomyelin and gangliosides.

The addition of Lacprodan® MFGM-10 to infant formula products will ensure these products contain levels of phospholipids, sphingolipids, gangliosides and membrane proteins, that better align to the levels in human milk. The milk fat globule components represent only a fraction of the total whey protein concentrate, Lacprodan® MFGM-10. Due to complexity of assaying the total milk fat globule components present in Lacprodan® MFGM-10, sphingomyelin is used as the marker phospholipid to determine the level of addition of Lacprodan® MFGM-10. Clinical studies involving infants fed formula supplemented with Lacprodan® MFGM-10 demonstrate that Lacprodan® MFGM-10 is safe for consumption. These studies also show that infants consuming infant formula with added Lacprodan® MFGM-10 experience benefits in neurodevelopment and cognition endpoints compared to infants fed conventional infant formula products and approaching levels observed in breastfed infants.

The use of Lacprodan® MFGM-10 in infant formula products at 4 – 7 g/L is safe. This equates to a final proposed sphingomyelin (SM) range (1.8 – 7.5 mg/100 kJ) which also accounts for naturally occurring levels of SM in the dairy ingredients in infant formula products (IFP). Clinical studies on infants demonstrate the safety of the intended addition of Lacprodan® MFGM-10 to infant formula products at this level. The safe use of Lacprodan® MFGM-10 is also demonstrated by the history of safe consumption of infant formula products containing Lacprodan® MFGM-10 in over 20 countries, including countries in Europe, Asia and Central and South America. In the European Union, Lacprodan® MFGM-10 is not considered a novel food because it was supplied as a food ingredient prior to May 1997. In the Australia New Zealand context, Lacprodan® MFGM-10 is likely to be considered a nutritive substance when added to infant formula products and therefore requires permission in the Australia New Zealand Food Standards Code (the Code) before it can be added to these foods.

Arla Foods Ingredients P/S is requesting amendment to the Code to permit the addition of Lacprodan® MFGM-10 to infant formula and follow-on formula products in Australia and New Zealand at a level of 4 - 7 grams per litre (g/L). Arla Foods Ingredients P/S is requesting permission only for addition of

Lacprodan® MFGM-10 to infant formula products, including infant formula products for special dietary use, for infants up to 12 months of age. Permission is not sought, in this application, for the addition of Lacprodan® MFGM-10 to toddler milks or other foods that are formulated for young children.

Permission to add Lacprodan® MFGM-10 to infant formula products will provide the Australian and New Zealand market with infant formula products that more closely resemble the composition and the benefits provided by breastmilk. The optional addition of Lacprodan® MFGM-10 to infant formula products will increase the range of beneficial ingredients that can be used in IFP, providing additional benefits and increase consumer choice of products for formula-fed infants.