

Executive Summary

Martek Biosciences Corporation (now DSM Nutritional Products) has commercially manufactured and sold algal oil containing approximately 40% docosahexaenoic acid (DHA), a n-3 long-chain polyunsaturated fatty acid (n-3 LCPUFA), produced via fermentation using *Cryptocodinium cohnii* microalgae since 1994 (DHASCO[®]). DHA Algal Oil (tradename: DHASCO[®]) has been added to infant formula sold in Australia and New Zealand since 1998. According to Standard 2.9.1 of the Food Standards Code, n-3 LCPUFA may be present in an infant formula or follow-on formula at a maximum 1% of the total fatty acid content.

DSM has now developed a strain of *Schizochytrium* species to produce oil which is rich in DHA and is primarily being targeted as a replacement/alternative/addition to existing sources of DHA in infant formula products [including infant (term or preterm) and follow-on formula]. This new production strain produces Algal Oil which contains approximately 40% DHA, and is referred to as DHA Algal Oil (DHASCO[®]-B).

This application contains information pertaining to DHASCO[®]-B's method of manufacture, product specification, analytical data, intended use levels in infant formula products (including preterm and term infant formula, as well as follow on formula), consumption estimates for all intended uses, safety studies conducted on DHA Algal Oil (DHASCO[®]-B) produced with this new production strain including a bioequivalence (DHASCO[®]-B compared to DHASCO[®]) study in piglets, a 90-day rat study with an *in utero* phase and a suite of mutagenicity studies. All other relevant data on safety and tolerance-related information is also provided including a summary of published clinical studies reporting growth and health outcomes in infants (preterm and full term) receiving DHA from various sources.

This application has been prepared in accordance with the *Application Handbook* prepared by Food Standards Australia New Zealand (FSANZ) (1 September 2013 and amended 18 September 2013). Under these guidelines, DHASCO[®]-B would be classified as a nutritive substance being added to special purpose food (infant formula products). Consistent with the recommendations, we have included Sections "General Requirements", "Nutritive Substances - Standards related to substances added to food", and "Special purpose food - Infant formula products - Standards related to special purposed foods and standardized foods".