Summary of the application: Paramylon

Applicant: Kemin Foods L.C., 2100 Maury Street, Des Moines, IA 50317, USA

Kemin Foods L.C. wishes to market a paramylon, derived from the biomass of proprietary strain of Euglena gracilis, as an ingredient in breakfast, granola and protein bars, yoghurt and yoghurt beverages, fruit juices and flavoured drinks, meal replacement beverages, and food supplements in the European Union (EU).

Paramylon has a characteristically high concentration of beta-1,3-glucan (paramylon) comprising at least 95% of the material. The ingredient contains small quantities of protein (≤3.0%), fats (≤3.0%), ash (≤1.0%) and moisture (≤6%), which originate from the cell biomass as carry-over products from the isolation process. Batch data for paramylon isolate demonstrate a consistent product that aligns with the proposed specification.

Paramylon is generally recognized as safe (GRAS) for use as an ingredient in conventional food and beverage products in the United States. Furthermore, dried *E. gracilis* is an approved novel food in the EU, and there is a history of safe consumption of *E. gracilis* in foods and dietary supplement products in the U.S., China, as well as Japanese and other Asian Marketplaces.

Estimates for the anticipated intake of paramylon by the EU population have been determined using consumption data from the European Food Safety Authority (EFSA) Comprehensive database and the United Kingdom (UK) National Diet and Nutrition Survey (NDNS) 2008-2014. Based on the UK NDNS dataset (which provides more refined estimates of intake overall), adolescents were calculated to have the highest absolute mean and 95th percentile intakes at 228 mg/person/day (4 mg/kg body weight/day) and 550 mg/person/day (11 mg/kg body weight/day), respectively; while toddlers were noted to consume the greatest levels of paramylon on a per body weight basis using this dataset, at 13 mg/kg body weight/day at the mean and 29 mg/kg body weight/day at the 95th percentile, as expected for younger individuals who have intakes on a body weight basis. These values are in the same range as the highest 95th percentile intakes determined for the target consumer group of adolescents and older from the EFSA Comprehensive Database of 17.4 mg/kg bodyweight/day. Exposure to paramylon from food supplements, assuming an individual chronically consumes a food supplement product containing paramylon at the maximum dose, would result in an estimated consumption on a body weight basis ranging from 2.9 to 4.3 mg/kg body weight/day. Furthermore, consumption of meal replacements containing paramylon, based on the worst case of 3 meals being replaced with products containing paramylon, would result in an estimated consumption of 8.6 to 37.5 mg/kg body weight/day.

Paramylon largely consists of beta-1,3-glucan (paramylon), with minor amounts of protein, fat, ash, and moisture. The major constituents of the ingredient are similar to normal components of the diet and therefore will be digested and metabolized in established pathways that are, in principle, similar to digestive processes and metabolism pathways that occur following the ingestion of plant matter (e.g., vegetables). Paramylon is completely insoluble at all physiological conditions throughout the gastrointestinal tract and will not be digested by mammalian pancreatic, salivary, or small intestinal enzymes. Paramylon granules are therefore not absorbed and are transported intact to the large intestine where they are subjected to partial fermentation by the indigenous microbiota.

Paramylon was demonstrated to be neither clastogenic nor aneugenic, which supports a lack of genotoxicity of the NF. In addition, two subchronic studies have been conducted using paramylon to demonstrate safety. In the first study, inclusion of paramylon in the diets of rats for 90 days resulted in a no-observed-adverse-effect level (NOAEL) of 50,000 mg/kg for paramylon, equivalent to 3,450 and 3,877 mg paramylon/kg body weight/day, the highest dose administered, in male and female Sprague-Dawley rats, respectively. In the second study, a NOAEL of 5,000 mg/kg body weight (highest dose administered) was assigned to paramylon after administration in the diet for 90 days, in which paramylon did not significantly impact neurotoxic, immunological, reproductive, and endocrine-related endpoints. Using the most conservative NOAEL and comparing it to the worst-case exposure estimates of up to 34 mg/kg bodyweight/day this would represent at least 100-fold safety factors for this ingredient. Furthermore, Kemin's dried, inactive, proprietary E. gracilis strain consisting of >50% paramylon was well-tolerated and does not present any safety concerns when provided to healthy adults for 90 days at 367 mg/day.

Together, the weight of the available evidence on paramylon support the safe use of the ingredient under the proposed conditions of use.