

Summary of the application: Inulin-Propionate Ester

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The novel ingredient is inulin-propionate ester, chemically synthesised from food-grade inulin and propionic anhydride. The ingredient is a short chain fatty acid moiety, propionate, chemically bound by an ester bond to inulin, a natural polymer composed mainly of fructose. The ingredient is produced by a chemical reaction between propionic acid (propionate) and food-grade inulin.

The novel food ingredient, inulin-propionate ester, is proposed for use in specific foods targeting the general population. It is not intended for use in infant or baby foods.

Inulin-propionate ester is proposed for use in the EU in specific food categories, intended to provide 5 g of inulin-propionate ester per serving, including breads and rolls, breakfast cereals, and fruit juice (maximum use level of 139, 167, and 31.3 g/kg, respectively). Its inclusion in these foods is intended to provide a dietary source of propionate and inulin.

The safety of the novel food ingredient is largely substantiated by the history of safe consumption of its 2 components, inulin and propionic acid. Both are widely consumed in the regular diet and have a well-established safety profile. Data on the safe consumption of inulin and propionic acid is complemented by the results of ingredient-specific animal and human studies on inulin-propionate ester – animal studies have shown that no toxicological relevant or adverse effects in gut morphology is observed in rats provided 20% inulin-propionate ester in the diet for 21 days (equivalent to approximately 6,000 mg/kg body weight/day), nor in mice provided 10% inulin-propionate ester in the diet for 21 days (equivalent to approximately 20,000 mg/kg body weight/day). Furthermore, the ingredient is well tolerated and safe when consumed by human subjects at bolus doses of up to 20 g/day for 6 weeks or at 10 g/day for up to 24 weeks. The results of a tier 2 dietary exposure assessment (using the UK NDNS) indicate that mean and heavy-level consumption (at the 95th percentile of consumption) is not expected to exceed total daily estimates of 10.3 and 21.5 g/day, respectively, in the consumer-only population based on the maximum intended uses of this novel food ingredient in breads and rolls, breakfast cereals, and fruit juice at 5 g per serving.

Taken together, the body of available scientific data on inulin-propionate ester and its components, inulin and propionic acid, supports the safe use of this novel food ingredient in specific food products at its intended use levels.