

Summary of the dossier

Applicant: SAVANNA Ingredients GmbH, Dürener Straße 67, 50189 Elsdorf, Germany

The present Novel Food application in accordance with Regulation (EU) 2015/2283 concerns the production of a allulose as syrup and in crystalline form.

Allulose is manufactured at high purity by enzymatic conversion from fructose. The product shall be marketed as syrup and as crystalline product.

The identity of the product was unequivocally verified by NMR.

The applicant demonstrated the robustness and consistency of the manufacturing process and proved the compliance with all regulatory requirements based on thorough analysis of five representative batches of allulose syrup and crystalline allulose, respectively.

Product-specific toxicity studies including mutagenicity, genotoxicity and sub-chronic oral toxicity studies in the rat conducted with allulose manufactured by the applicant did not reveal any sign of toxicity.

A human study sponsored by the applicant confirmed the tolerability 0.8 g allulose/kg/day in two daily servings, which confirm recently published data.

The anticipated intake was calculated using the FAIM tool and more refined, using the summary statistics in the Comprehensive European Food Consumption Database. With the refined calculation, the obtained lower bound mean anticipated intake on all days and the 95th percentile on consuming days for consumers elder than 10 years of age are in the range of the tolerable intake established in the human studies. The higher maximum mean intakes and intakes in the 95th percentile on consuming days consumer are not considered critical as allulose is not supposed to completely replace sugars in all food categories and throughout the entire market.

The applicant considers the toxicity studies and the human study proprietary information and therefore requests data protection according to Article 26 of regulation (EU) 2015/2283.

The applicant concluded that allulose is safe and suitable to substitute sugar in a broad variety of food stuffs without compromising appearance or organoleptic properties. The novel food is intended for all age groups except of infants.