

Summary of the dossier: Requests to add sachets as an allowed form of lactitol to be used in foods supplements

Applicant: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark.

Lactitol is an approved Novel Food (Decision 2017/450) and listed in the Union List (Regulation 2017/2470). The entry in the Union List allows lactitol to be marketed as a food supplement with a maximum of 20 g/day. However, the conditions of use limits the vehicle for the marketing of the lactitol as food supplement to capsules and tablets. This creates a problem, as there is a practical limit for a tablet or capsule to 1 g, a bigger tablet or capsule is virtually impossible to swallow.

Hence, we would request a change in the conditions of use to, in addition to tablets and capsules, also include sachets as an allowed vehicle. A sachet would allow the customer to open the sachet and add the 20 g lactitol to a beverage.

All the rest in the Novel Food submission and approval stays the same. Hence, there is no changes in production, specification, safety aspects or any other scientific data.