

Summary of the dossier: Beta-galactosidase from *Aspergillus oryzae*

Applicant: Takabio, Parc d'activités Angers-Beaucouzé 4, rue Joseph Fourier, 49070-France

The applicant requests an authorisation for a food enzyme preparation of Lactase (β -D-galactosidase) produced with a non-genetically modified *Aspergillus oryzae* (strain GL 470) as a novel food. The lactase food enzyme is manufactured in compliance with the principles of HACCP. The food enzyme is produced using food-grade materials and using quality-controlled solid-state fermentation and purification/recovery processes (extraction, solid/liquid separation, concentration and filtration).

The β -D-galactosidase obtained from *Aspergillus oryzae* is then mixed with maltodextrin, calcium hydrogenphosphate or glycerine, depending on the formulation used, under the trade name "Sumizyme" (GLL-SD, GLL-L, GLL(50,000) or GLL(100,000) depending on the formulation).

According to the Article 3, paragraph 2 of Regulation (EU) 2015/2283, it falls under the following categories:

- vi) Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae;
- x) Food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.

The target population is the general adult population. The NF is intended to be consumed just before, during or directly after a meal/snack containing lactose. For examples: a fruit juice containing the NF lactase in addition to the bowl of cereals+milk at the breakfast; a piece of chocolate containing the NF lactase after a lactose-based dessert...

Intended food categories and use levels are described hereafter as FCC/g of food:

- 1) Chocolate: 480 FCC/g
- 2) Biscuits with lactase inclusions: 800 FCC/g
- 3) Tree nuts with a lactase coating: 300 FCC/g
- 4) Dried fruits with a lactase coating: 300 FCC/g
- 5) Soft candies: 1450 FCC/g
- 6) Fruit juices: 17 FCC/ml

The information provided on the identity, composition, specifications, contaminants and lack of batch-to-batch variability of β -D-galactosidase from *Aspergillus oryzae* demonstrates control of manufacturing process and does not raise safety concerns. The shelf-life was set at 12 months (storage at 20-25°C under dry conditions).

The applicant conducted several toxicity studies on this β -D-galactosidase obtained from *Aspergillus oryzae*: an Ames test, a Chromosomal aberration test and two 90-day studies. These studies allowed to determine a No-Observed -Adverse-Effect-Level to this β -D-galactosidase.

According to this toxicological information and the anticipated daily intakes, the proposed uses and use levels are considered as safe for the target population (adults). As a precaution, pregnant and lactating women, as well as people with galactosemia should not consume the product.

The applicant has applied for confidentiality and data protection in accordance with Article 23 and 26 of the novel food regulation, respectively.