Safety evaluation of the food enzyme containing β-fructofuranosidase and β-glucosidase activities from the non-genetically modified Aspergillus tubingensis strain IN 319

1 Report

Status Finished
EFSA question number EFSA-Q-2016-00577
Adopted 12-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzymes Invertase and Exo-β-glucosidase from Aspergillus tubingensis (strain IN 319). Additional information, requested from the applicant during the assessment process on 14 October 2022 and 27 April 2013, was received on 17 January 2023 and 28 July 2023, respectively. Following the reception of additional data by EFSA on 28 July 2023, EFSA requested a clarification teleconference on 23 July 2025, after which the applicant provided additional data on 7 August 2025

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a [. . .] fermentation system with conventional process controls in place.
Formulation Unknown
Downstream processing After completion of the fermentation, the enzyme is extracted with water and the biomass is removed from the suspension by centrifugation, followed by microfiltration. The filtrate containing the enzyme is concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded
Average TOS (w/w) 8.3 %
Average activity/TOS 846.2 U/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production strain in the food enzyme was demonstrated.

Allergenicity when used for the production of distilled alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining intended uses, the risk of allergic reactions upon dietary exposure to this food enzyme, particularly for tomato allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after tomato consumption

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches

Antifoam agents /

Other The presence of fumonisin B1 and B2, aflatoxins B1, B2, G1 and G2, ochratoxin A, T2-toxin, zearalenone, sterigmatocystin, cyclopiazonic acid, kojic acid and 3-nitropropionic acid was examined in three food enzyme batches, and all were below the limit of detection/quantification (LoD/LoQ) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 0.5 µg/kg each; zearalenone = 50 µg/kg; sterigmatocystin = 20 µg/kg; T2-toxin = 0.1 mg/kg; fumonisin B1 and B2 = 0.5 mg/kg; kojic acid = 1 mg/kg; 3-nitropropionic acid = 1 mg/kg. LoDs: ochratoxin A = 0.5 µg/kg; cyclopiazonic acid = 1 mg/kg.