Safety evaluation of the food enzyme glucan 1,4-α-glucosidase from the non-genetically modified Aspergillus niger strain AE-GN

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00223
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucan 1,4-α-glucosidase from a non-genetically modified Aspergillus niger AE-GN. Additional information, requested from the applicant during the assessment process on 25 March 2024 and 21 April 2026, was received on 23 April 2024 and 24 April 2026, respectively

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 To facilitate glucan 1,4-α-glucosidase production, an α-amylase (EFSA FEZ Panel, 2024) is added during fermentation to liquefy starch present in the fermentation medium. After completion of the fermentation, the solid biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 94.6 %
Average activity/TOS 453.0 Unit/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 In conclusion, when used for the production of distilled alcohol, 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 cannot be excluded, but the likelihood is low

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

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1, G2), ochratoxin A, fumonisins (B1, B2), T2-toxin, HT2-toxin, zearalenone and sterigmatocystin was examined in the three food enzyme batches intended for commercialisation. All were below the limits of quantification (LoQs) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb: 0.01 mg/kg. LoQs: aflatoxins: B1, B2, G1 and G2 = 0.2 µg/kg each; ochratoxin A = 0.5 µg/kg; fumonisins B1 and B2 = 5.0 µg/kg each; T2-toxin, HT2-toxin, zearalenone, sterigmatocystin = 10.0 µg/kg each.