

# Safety evaluation of the food enzyme glucan 1,4- $\alpha$ -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- $\alpha$ -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- $\alpha$ -glucosidase production, an  $\alpha$ -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**

**Comments** 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.