

Safety evaluation of the food enzyme mannan endo-1,4- β -mannosidase from the non-genetically modified *Aspergillus niger* HBI-GM01

1 Report

Status Finished

EFSA question number [EFSA-Q-2022-00519](#)

Adopted 18-06-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme mannanase from *A. niger* (strain HBI-GM01). Additional information, requested from the applicant during the assessment process on 23 January 2024 and 18 May 2026 was received on 27 September 2024 and 29 May 2026. Following the reception of additional data by EFSA on 27 September 2024, EFSA requested a clarification teleconference on 27 April 2026, after which the applicant provided additional data on 12 May 2026.

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 [...] and the solid biomass is removed by filtration. The filtrate containing the enzyme is then 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) 40.3 %

Average activity/TOS 26.1 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.



Allergenicity In conclusion, the Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that the likelihood is low.

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

Antifoam agents /

Other The presence of fumonisins (B1, B2) and ochratoxin A was examined in four batches and all were below the limit of quantification (LoQ) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQ: Pb = 0.1 mg/kg. LoQs: fumonisins (B1, B2) = 0.05 mg/kg each; ochratoxin A = 5 µg/kg.