Safety evaluation of the food enzyme mannan endo-1,4-β-mannosidase from the non-genetically modified Aspergillus niger strain AE-HCM

1 Report

Status Finished
EFSA question number EFSA-Q-2022-00576
Adopted 21-05-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme mannan endo-1,4-β-mannosidase from Aspergillus niger (strain AE-HCM). Additional information was requested from the applicant during the assessment process on 10 November 2023 and received on 13 February 2014

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 solid biomass is removed from the fermentation broth 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 filtration membrane and is discarded
Average TOS (w/w) 31.8 %
Average activity/TOS 93.8 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 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 aflatoxins (B1, B2, G1, G2), fumonisins (B1, B2), ochratoxin A, sterigmatocystin, HT-2 toxin, T-2 toxin and zearalenone was examined in all food enzyme preparation batches. All were below the LoQ of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg; As, Hg = 0.005 mg/kg each; Cd = 0.001 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2) = 0.2 µg/kg each; sterigmatocystin = 10 µg/kg; ochratoxin A = 0.5 µg/kg; T2-toxin and HT-2 toxin = 10 µg/kg each; fumonisin B1, B2 = 5 µg/ kg; zearalenone = 2 µg/kg.