Safety evaluation of the food enzyme α-amylase from the non-genetically modified Aspergillus sp. strain AR-SHFA-109

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00451
Adopted 10-12-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme alpha amylase from Aspergillus oryzae strain AR-SHFA-109. Additional information, requested from the applicant during the assessment process on 9 April 2025 and on 10 September 2025, and were received on 26 May 2025 and on 9 October 2025, respectively. Following the reception of additional data by EFSA on 26 May 2025, EFSA requested a clarification teleconference on 27 October 2025, after which the applicant provided additional data on 4 November 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, fed-batch 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) 92.5 %
Average activity/TOS 119.0 /

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 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), fumonisins (B1, B2), ochratoxin A, sterigmatocystin, T-2 toxin and zearalenone was examined in all food enzyme batches and all were below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.005 mg/kg; Cd = 0.009 mg/kg; Hg = 0.005 mg/kg. LoDs: aflatoxins (B1, G1) = 0.1 µg/kg each, (B2, G2) = 0.03µg/kg each; ochratoxin A = 0.2 µg/kg; sterigmatocystin = 10 µg/kg; fumonisins (B1, B2) = 20 µg/kg each; deoxynivalenol = 20 µg/kg; zearalenone = 10 µg/kg; HT-2 Toxin = 10 µg/kg; T-2 Toxin = 10 µg/kg.