Safety evaluation of the food enzyme α-amylase from the genetically modified Bacillus licheniformis strain CCTCC M 2023118

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00524
Adopted 07-10-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme α-amylase from Bacillus licheniformis CCTCC M 2023118. Additional information, requested from the applicant during the assessment process on 12 February 2025, were received on 25 March 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 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) 18.4 %
Average activity/TOS 80.5 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. The absence of recombinant DNA 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 zearalenone, deoxynivalenol and ochratoxin A was examined in three food enzyme preparation batches, and all were below the LoQs of the applied analytical methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg; As = 0.01 mg/kg; Hg = 0.002 mg/kg; Cd = 0.002 mg/kg. LoQs: ochratoxin A = 8.3 µg/kg; zearalenone = 50 µg/kg; deoxynivalenol = 200 µg/kg; fumonisin B1 + B2 + B3 = not determined; citrinin = not determined. LoDs: aflatoxins = 1.8 µg/kg; fumonisin B1 + B2 + B3 = 25 µg/kg; citrinin = 15 µg/kg.