Safety evaluation of the food enzyme α-amylase from the non-genetically modified Bacillus licheniformis strain TTME 6280 KY

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00216
Adopted 07-10-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme alpha-amylase from B. licheniformis strain TTME 6280 KY. Additional information, requested from the applicant during the assessment phase on 12 February 2025 and 23 September 2025, was received on 9 May 2025 and 24 September 2025, respectively

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) 6.0 %
Average activity/TOS 4967.0 MWU/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 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 Panel considered that a 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoQ: Pb = 3.44 mg/kg