Safety evaluation of the food enzyme α-amylase from the genetically modified Bacillus licheniformis strain DP-Dzb105

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00087
Adopted 25-06-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme alpha amylase from Bacillus licheniformis DP-Dzb105. Additional information, requested from the applicant during the assessment phase on 30 September and 18 November 2024, were received on 29 October 2024 and 17 March 2025, respectively. Following the request for additional data sent by EFSA on 18 November 2024, the applicant requested a clarification teleconference on 17 January 2025 and provided additional data on 17 March 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch or 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) 4.7 %
Average activity/TOS 952.3 LPAU/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 presence of recombinant DNA in the food enzyme was tested by polymerase chain reaction analysis of three batches in triplicate. DNA was detected in one batch with primers with a limit of detection below 10 ng spiked DNA/mL food enzyme

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 use, 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 LoD: Pb = 0.01 mg/kg.