Safety evaluation of the food enzyme amidase from the genetically modified Escherichia coli strain SP-a

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00307
Adopted 14-04-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme amidase from E. coli strain SP-a. Additional information was requested during the risk assessment phase. Following the request for additional data sent by EFSA on 05 May 2025, the applicant requested a clarification teleconference on 20 June 2025, after which the applicant provided additional data on 30 July 2025. Following the request for additional data sent by EFSA on 13 October 2025, the applicant requested another clarification teleconference on 4 November 2025, after which the applicant provided additional data on 13 January 2026.

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, cells are harvested by centrifugation and then mechanically disrupted to release the intracellular enzyme. Afterwards, the cell homogenate is treated with nuclease to degrade DNA, and the solid biomass is removed from the fermentation broth by centrifugation followed by filtration. The filtrate containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 8.3 %
Average activity/TOS 102.1 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 the Panel considered that under the 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg; As = 0.01 mg/kg; Cd = 0.002 mg/kg; Hg = 0.002 mg/kg.