Safety evaluation of the food enzyme glucan 1,4-α-maltohydrolase from the genetically modified Trichoderma reesei strain DP-Nyn90

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00014
Adopted 12-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Glucan 1,4-α-maltohydrolase from a genetically modified strain of Trichoderma reesei (strain DP-Nyn90). Additional information, requested from the applicant during the assessment process on 4 November 2024, was received on 13 February 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 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 filtration membrane and is discarded.
Average TOS (w/w) 27.1 %
Average activity/TOS 179.0 SSU/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

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches.

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1 and G2), fumonisins (B1 and B2), ochratoxin A, sterigmatocystin, T-2 toxin and zearalenone was examined in all food enzyme batches, and all were below the limit of detection/quantification (LoD/LoQ) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments Pb: LoD = 0.01 mg/kg. LoDs: aflatoxins B1, B2, G1 and G2 = < 2 µg/kg each; fumonisins B1 and B2 = < 0.2 mg/kg; ochratoxin A = < 2 µg/kg; sterigmatocystin = < 10 µg/kg; T-2 toxin = < 10 µg/kg; zearalenone = < 5 µg/kg.