Safety evaluation of the food enzyme endo-1,4-β-xylanase from the genetically modified Trichoderma reesei strain DP-Nzd72

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00085
Adopted 21-05-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme endo-1,4-β-xylanase from Trichoderma reesei DP-Nzd72. Additional information, requested from the applicant during the assessment process on 04 October 2024 and 11 April 2025, was received on 09 January 2025 and 17 April 2025, respectively

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 enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded
Average TOS (w/w) 17.1 %
Average activity/TOS 664.8 NGXU/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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg