



Safety evaluation of the food enzyme endo-1,4-β-xylanase from the non-genetically modified Trichoderma citrinoviride strain X31

1 Report

Status Finished

EFSA question number EFSA-Q-2023-00297

Adopted 20-05-2025

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 the non-genetically modified T. citrinoviride strain X31. The data package was submitted on 31 March 2023 and updated on 17 October 2023. Additional information, requested from the applicant during the assessment process on 18 September 2023 and 8 December 2023, were received on 17 October 2023 and 8 April 2024, respectively

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in fermentation system with conventional process controls in place

Formulation Unknown

Downstream processing After completion of the fermentation and (...), the solid biomass is removed from the fermentation broth by (...) and (...). The filtrate containing the enzyme is further purified and concentrated, including (...) 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) 21.4 %

Average activity/TOS 88.8 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

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 fooderzyme cannot be excluded, but the likelihood is low

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

Antifoam agents /

Other The presence of ochratoxin A, aflatoxin B1, B2, G1, and G2, zearalenone, sterigmatocystin, T-2 toxin, fumonisin B1 and B2 was examined in all food enzyme batches and all were below the limits of detection (LoD) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoDs: ochratoxin A = 0.5 µg/kg; aflatoxin (B1, B2, G1, G2) = 0.5 µg/kg each; zearalenone = 100 µg/kg; sterigmatocystin = 100 µg/kg; T-2 toxin = 1 mg/kg; fumonisin (B1, B2) = 0.5 mg/kg each.