Safety evaluation of the food enzyme containing cellulase and endo-1,3(4)-β-glucanase activities from the non-genetically modified Trichoderma reesei strain 480KY

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00263
Adopted 12-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing cellulase and glucanase (endo-1,3(4)-β-glucanase) activities from T. reesei strain 480KY. Additional information, requested from the applicant during the assessment phase on 2 May 2024, were received on 26 July 2024. Spontaneous data submission was received on 24 January 2024

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a [. . .] 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 membrane and is discarded.
Average TOS (w/w) 18.8 %
Average activity/TOS 11.9 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 alcohol, 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 The presence of aflatoxins (B1, B2, G1, G2), deoxynivalenol, ochratoxin A and zearalenone was examined in three food enzyme batches; the presence of fumonisin B1, fumonisin B2 was examined in two food enzyme batches, and the presence of HT-2, T-2 toxin was examined in one food enzyme batch and all were below the limit of quantification (LoQ) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQ: Pb = 0.1 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 0.5 or 1 µg/kg each; deoxynivalenol = 20 or 100 µg/kg; ochratoxin A = 1 µg/kg; zearalenone =10 or 5 µg/kg; fumonisin B1 = 20 or 5 µg/ kg; fumonisin B2 = 20 or 5 µg/kg; HT-2 = 10 µg/kg; T-2 toxin = 10 µg/kg.