Safety evaluation of the food enzyme thermomycolin from the genetically modified Trichoderma reesei strain AR-201

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00367
Adopted 11-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme thermomycolin from T. reesei strain AR-201. Additional information, requested from the applicant during the assessment process on 7 March 2024 and 21 May 2025, was received 16 May 2024 and 11 July 2025, respectively. Following the reception of additional data by EFSA on 16 May 2024, EFSA requested a clarification teleconference on 15 July 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 filtration membrane and is discarded.
Average TOS (w/w) 16.2 %
Average activity/TOS 2395.0 BPU/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 intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly for natto allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after natto consumption

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

Antifoam agents /

Other The presence of T-2 and HT-2 toxins was examined in all food enzyme batches and was below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.5 mg/kg; Hg = 0.05 mg/kg; Cd = 0.05 mg/kg. LoQs: T-2 toxin, HT-2 toxin = 10 µg/kg each.