Safety evaluation of the food enzyme triacylglycerol lipase from the genetically modified Trichoderma reseei strain AR-822

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00529
Adopted 09-12-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme triacylglycerol lipase from a genetically modified T. reseei (strain AR-822). Additional information was requested from the applicant during the assessment phase on 30 January 2024 and received on 12 June 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, [...] 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 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) 19.4 %
Average activity/TOS 148.4 ALU/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. In conclusion, the Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that the likelihood is low.

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 method.

Pathogens

Microbiological quality indicators

Metals

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