



Safety evaluation of the food enzyme sucrose:sucrose fructosyltransferase from the genetically modified Yarrowia lipolytica strain E4772

1 Report

Status Finished

EFSA question number EFSA-Q-2024-00010

Adopted 21-05-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme fructosyltransferase from a genetically modified Yarrowia lipolytica strain E4772. Additional information was requested from the applicant during the assessment process on 14 November 2024 and on 20 March 2025, and received on 20 February 2025 and on 10 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 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 centrifugation. The supernatant 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) 1.2 % Average activity/TOS 606.2 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. The presence of recombinant DNA in the food enzyme was assessed (...). As the production strain does not carry any genes of concern,

the presence of traces of recombinant DNA in this food enzyme is not considered a safety concern

Allergenicity the Panel considered that, under the 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 /
Antifoam agents /
Other /
Pathogens
Microbiological quality indicators
Metals

400d enzyme Datab

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg; Cd = 0.01 mg/kg; Hg = 0.005 mg/kg.