Safety evaluation of the food enzyme triacylglycerol lipase from the genetically modified Komagatella phaffii strain LALL-LI2

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00201
Adopted 21-05-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme triacylglycerol lipase from Komagataella phaffii strain LALL-LI2. Additional information was requested to the applicant during the assessment process on 18 October 2024 and received on 17 December 2024

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch or fed-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 or filtration. The supernatant or 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) 2.7 %
Average activity/TOS 310.0 LBLU/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 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 /
Pathogens
Microbiological quality indicators
Metals
Coments LoD Pb = 0.017 mg/kg