

Safety evaluation of the food enzyme triacylglycerol lipase from the genetically modified *Komagataella phaffii* strain DSM 34125

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00083](#)

Adopted 25-06-2025

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 DSM 34125). Additional information, requested from the applicant during the assessment phase on 4 October 2024, was received on 6 February 2025

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, 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 filtration. The filtrate containing the enzyme is sterile filtered

Average TOS (w/w) 1.2 %

Average activity/TOS 86.1 LVU/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

Comments LoQ: Pb = 0.05 mg/kg.