

Safety evaluation of the food enzyme glucan 1,4- α -maltohydrolase from the genetically modified Escherichia coli strain MLAVSC

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00034](#)

Adopted 20-05-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme maltogenic amylase from Escherichia Coli strain MLAVSC. Additional information, requested from the applicant during the assessment process on 14 November 2024 and 11 April 2025, was received on 17 March and 16 April 2025, respectively

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 and release of the intracellular enzyme by homogenisation, the solid biomass is removed from the fermentation broth by filtration followed by centrifugation. The supernatant 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. Finally, the food enzyme is spray-dried in the presence of a stabiliser prior to analysis.

Average TOS (w/w) 82.5 %

Average activity/TOS 83.6 MANU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production



strain in the food enzyme preparation was demonstrated. The absence of recombinant DNA in the food enzyme preparation was demonstrated

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 No antimicrobial activity was detected in any of the tested batches.

Antifoam agents /

Other The presence of aflatoxins B1, B2, G1 and G2, and ochratoxin A was examined in all food enzyme preparation batches and was below the LoQ of the applied method

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.1 mg/kg; As = 0.1 mg/kg; Cd = 0.1 mg/kg; Hg = 0.025 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 1 µg/kg each; ochratoxin A = 1 µg/kg.