Safety evaluation of the food enzyme cyclomaltodextrin glucanotransferase from the genetically modified Escherichia coli K12 strain DSM 34230

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00434
Adopted 09-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme cyclomaltodextrin glucanotransferase from E. coli K12 DSM 34230. Additional information, requested from the applicant during the assessment process on 23 September 2025 and were received on 20 July 2026.

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 centrifugation followed by filtration. The filtrate containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 1.5 %
Average activity/TOS 54.7 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. DNA was detected in one of the three batches tested. The applicant also provided data demonstrating the absence of DNA from the production strain in three

batches of γ-cyclodextrins. This study is considered not appropriate for the safety assessment of the food enzyme and was therefore not evaluated.

Allergenicity 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 /

Pathogens

Microbiological quality indicators

Metals

Coments Pb: LoQ = 0.01 mg/kg.