

Safety evaluation of the food enzyme cyclomaltodextrin glucanotransferase from the genetically modified *Escherichia coli* K12 strain DSM 34229

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00435](#)

Adopted 25-06-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme α -cyclomaltodextrin glucanotransferase from *Escherichia coli* strain K12 DSM 34229. Additional information was requested during the risk assessment phase.

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 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 filtration membrane and is discarded.

Average TOS (w/w) 1.4 %

Average activity/TOS 127.3 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 by polymerase chain reaction analysis of three batches in triplicate. Using primers that amplify a 566-bp fragment that is specific [...], DNA was detected in two



of the three batches tested.²⁷ As no gene of concern was identified in the production strain, the presence of DNA in the food enzyme is not considered a hazard.

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

Comments LoQ: Pb = 0.01 mg/kg.