Safety evaluation of the food enzyme glucan 1,4-α-maltotetraohydrolase from the genetically modified Bacillus licheniformis strain DP-Dzf95

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00068
Adopted 12-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Glucan 1,4-α-maltotetraohydrolase from Bacillus licheniformis strain DP-Dzf95. 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, 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 filtration. The filtrate 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 membrane and is discarded
Average TOS (w/w) 13.1 %
Average activity/TOS 2895.0 BMU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production strain in the concentrated food enzyme was demonstrated. The absence of recombinant DNA in the food enzyme was tested by polymerase chain reaction analysis of three batches

in triplicate. DNA was detected in one batch with primers that amplify a [...] with a limit of detection of 10 ng spiked DNA/mL food enzyme.

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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.01 mg/kg.