Safety evaluation of the food enzyme dextransucrase from the genetically modified Bacillus subtilis strain DP-Eyp97

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00208
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme dextransucrase from Bacillus subtilis strain DP-Eyp97. 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, cells are lysed mechanically by means of homogenisation to release the intracellular enzyme and the solid biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is then 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 2.9 GTFU/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 In conclusion, 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.