

Safety evaluation of the food enzyme pullulanase from the genetically modified *Bacillus licheniformis* strain DP-Dzp107

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00088](#)

Adopted 20-05-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme pullulanase from *Bacillus licheniformis* DP-Dzp107. Additional information requested from the applicant during the assessment process on 02 December 2024 were received on 03 March 2025

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 filtration membrane and is discarded

Average TOS (w/w) 24.2 %

Average activity/TOS 137.2 ASPU/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 tested by polymerase chain reaction analysis of three batches in triplicate. DNA



was detected with primers (...), with a limit of detection of 10 ng spiked DNA/mL food enzyme

Allergenicity when used for the production of distilled alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining intended uses, the risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but 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 LoD: Pb = 0.01 mg/kg.