Safety evaluation of the food enzyme protein-glutamine glutaminase from the non-genetically modified Chryseobacterium proteolyticum strain AE-PG

1 Report

Status Finished
EFSA question number EFSA-Q-2015-00695
Adopted 13-11-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme protein-glutamine glutaminase from the non-genetically modified C. proteolyticum (strain AE-PG). Additional information, requested from the applicant during the assessment phase on 27 March 2023 and 10 February 2025, were received on 7 November 2024 and 28 August 2025. Following the request for additional data sent by EFSA on 27 March 2023, the applicant requested a clarification teleconference on 17 November 2023, after which the applicant provided additional data on 7 November 2024.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged 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 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 filtration membrane and is discarded
Average TOS (w/w) 1.7 %
Average activity/TOS 65.3 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 absence of recombinant DNA in the food enzyme was demonstrated.

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 LoQ: Pb = 0.01 mg/kg.