Safety evaluation of the food enzyme chymosin from the genetically modified Trichoderma reesei strain DP-Nyj88

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00907
Adopted 11-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme chymosin from the genetically modified Trichoderma reesei strain DP-Nyj88. Additional information, requested from the applicant during the assessment process on 05 December 2024, was received on 04 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 centrifugation and filtration. The supernatant or filtrate containing the enzyme is 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) 3.9 %
Average activity/TOS 76.2 IMCU/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 intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly in pollen-allergic individuals, cannot be excluded

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches
Antifoam agents /
Other /
Pathogens
Microbiological quality indicators
Metals
Coments LoDs: Pb = 0.01 mg/kg.