Safety evaluation of the food enzyme bacillolysin from the non-genetically modified Bacillus amyloliquefaciens strain BP

1 Report

Status Finished
EFSA question number EFSA-Q-2022-00517
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme bacillolysin from the non-genetically modified B. amyloliquefaciens strain BP. Additional information, requested from the applicant during the assessment phase on 27 April 2023, 18 September 2023 and 28 June 2024, was received on 19 July 2023, 18 October 2023 and 8 July 2024, respectively

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a [. . .] 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 membrane and is discarded.
Average TOS (w/w) 5.8 %
Average activity/TOS 1963.0 U/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA /
Allergenicity In conclusion, when used for the production of distilled alcohol, 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, particularly for 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 LoQ: Pb = 0.05 mg/kg.