

Safety evaluation of the food enzyme ribonuclease P from the non-genetically modified *Penicillium citrinum* strain AE-RPE

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00877](#)

Adopted 04-02-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Ribonuclease P from a non-genetically modified *P. citrinum* strain AE-RPE. Additional information was requested from the applicant during the assessment phase on 21 October 2024 and on 10 June 2025, and they were received on 30 May 2025 and on 16 June 2025, respectively.

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 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) 50.5 %

Average activity/TOS 223.7 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.



Allergenicity In conclusion, the Panel considered that under the intended 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 *P. citrinum* is known to produce the toxin citrinin, which was analysed in the three commercial batches and was below LoQ of the applied method. In addition, the presence of aflatoxins (B1, B2, G1, G2), HT-2 toxin, T-2 toxin, zearalenone, ochratoxin A and sterigmatocystin was examined in the three food enzyme batches and all were below the limits of quantification (LoQs) of the applied analytical methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQ: Pb = 0.01 mg/kg. LoQ: citrinin = 100 µg/kg. LoQs: aflatoxins (B1, B2, G1 and G2) = 0.2 µg/kg each; HT-2 toxin = 10 µg/kg; T-2 toxin = 10 µg/kg; zearalenone = 10 µg/kg; ochratoxin A = 0.5 µg/kg; sterigmatocystin = 10 µg/kg.