

# Safety evaluation of the food enzyme containing metalloendopeptidase and leucyl aminopeptidase activities from the non-genetically modified *Aspergillus oryzae* strain HBI-POP01

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2022-00861](#)

**Adopted** 14-04-2026

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of a food enzyme containing neutral protease, leucyl amino peptidase, oryzin and aspergillopepsin I from a non-genetically modified *Aspergillus oryzae* HBI-POP01. The dossier was updated in December 2022. Additional information was requested from the applicant during the assessment process on 27 April 2023 and 4 March 2024 and received on 27 October 2023 and 24 March 2025.

## 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 food enzyme is extracted with and 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. Finally, the food enzyme is spray-dried in the presence of a stabiliser.

**Average TOS (w/w)** 39.2 %

**Average activity/TOS** 214.0 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** 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 cannot be excluded, but the likelihood is low

**Antimicrobial resistance** No antimicrobial activity was detected in any of the tested batches.

**Antifoam agents** /

**Other** The presence of aflatoxins (B1, B2, G1, G2), ochratoxin A, sterigmatocystin, T2-toxin and zearalenone was examined in the three food enzyme preparation batches intended for commercialization, and in addition the presence of ochratoxin A was examined in three batches, one of which was used for the toxicological studies; all results were below the limits of quantification (LoQ) of the applied analytical methods

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoQ: Pb = 0.05 mg/kg/0.1 mg/kg. LoDs/LoQs: aflatoxins (B1, B2, G1, G2) = 1 µg/kg each; ochratoxin A = 0.5 µg/kg; sterigmatocystin, T2-toxin = 10 µg/kg each; zearalenone = 0.01 µg/kg.