

Safety evaluation of the food enzyme papain from the latex of *Carica papaya* L.

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00226](#)

Adopted 09-12-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme papain from the latex of the unripe fruit of *C. papaya* L. Additional information was spontaneously submitted on 15 February 2024. Additional information, requested from the applicant during the assessment process on 1 March 2024 and 22 September 2025, was received on 5 April 2024 and on 25 September 2025, respectively.

2 Production method

Manufacturing The food enzyme is obtained by [...] from the papaya latex.

Formulation Unknown

Downstream processing After a flocculation step, the liquid containing the enzyme is centrifuged and filtrated. The filtrate containing the enzyme is further purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded. Finally, the food enzyme is dried. Around [...] kg of fresh latex is needed to produce 1 kg of papain, corresponding to a yield factor of [..].

Average TOS (w/w) 89.6 %

Average activity/TOS 1182.0 TU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA /

Allergenicity The Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly for papaya, ananas, kiwi, soy, fig and pollen allergic individuals, cannot be excluded. However, the likelihood



of such reactions will not exceed the risk of reactions after consumption of papaya, ananas, kiwi, soy and fig.

Antimicrobial resistance /

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1 and G2), fumonisin B1 and B2, deoxynivalenol, T-2 toxin, zearalenone and ochratoxin A was examined in three food enzyme batches and were below the LoQ.

Pathogens

Microbiological quality indicators

Metals

Comments LoDs/LoQs: Pb = 1 mg/kg; As = 1 mg/kg; Cd = 10 µg/kg; Hg = 10 µg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 1.0 µg/kg each; fumonisin B1 and B2 = 50 µg/kg each; deoxynivalenol = 50 µg/kg; T-2 toxin = 10 µg/kg; zearalenone = 50 µg/kg; ochratoxin A = 5 µg/kg.