



Safety evaluation of the food enzyme papain, a cysteine endopeptidase complex from the latex of *Carica papaya* L.

1 Report

Status Finished

EFSA question number [EFSA-Q-2021-00173](#)

Adopted 10-12-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme papain from *Carica papaya*. The dossier was updated on 10 June 2021. Additional information was requested from the applicant during the assessment phase on 16 November 2021 and on 1 March 2024 and received on 17 December 2021 and on 11 March 2024

2 Production method

Manufacturing The food enzyme is obtained from the papaya latex.

Formulation Unknown

Downstream processing The latex batches are routinely tested for the presence of pesticides, heavy metals, mycotoxins and enterotoxins. The latex is homogenised, and the insoluble material is separated by centrifugation and filtration. After separation, the liquid containing the enzyme is concentrated by an ultrafiltration step, in which enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded. Around 10 kg of fresh latex is needed to produce 1 kg of papain, corresponding to a yield factor of 0.1.

Average TOS (w/w) 91.5 %

Average activity/TOS 1075.0 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.03 mg/kg; As, Cd, Hg = 0.01 mg/kg each.