18 September 2020

Ad hoc meeting with industry representatives – Joint dossiers on food enzymes produced from animal and plant sources

Papain: data gaps and proposals

EFSA FIP Unit – food enzyme team

Trusted science for safe food

efsa
European Food Safety Authority

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

SOURCE MATERIAL

Available data	Product specific data
▪ Fruit of the papaya plant ▪ Papaya latex	▪ Documented evidence of human consumption ▪ Documented history of safe use ▪ Quantity of consumption

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	CHARACTERISTICS OF THE FOOD ENZYME	
Food enzyme	**Available data**	**Product specific data**
	Reported chromatographic protein profile of the food enzyme papain (Wüthrich, 1996): ▪ 73% Glycyl endopeptidase/chymopapain ▪ 22% Caricain ▪ 5% Papain	Activities of the distinct proteases
	Mention of known side activities: ▪ Lipase ▪ Chitinase	▪ Side activities ▪ Methods for their quantification ▪ LoD

Enzyme activities

2015-00559	Activity (4 distinct proteases)				
Interested parties (applicant: AMFEP)	**Papain *sensu stricto***	**Chymopapain**	**Glycyl endopeptidase**	**Caricain**	**Value***
	Preference for an amino acid bearing a hydrophobic side chain at the P2 position.	Similar to that of papain	Preferential cleavage: Gly, in proteins and small molecule substrates	Similar to those of papain and chymopapain	
A	**X**	**X**	**X**	**X**	**859 TU/mg**
B	**X**	**X**	**X**	**X**	**833 TU/mg**
C	**X**	**X**	**X**	**X**	**1,059,633 U/g**

*Enzyme activity was measured with different methods

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	CHARACTERISTICS OF THE FOOD ENZYME **Properties of the food enzyme**	
Food enzyme	**Available data**	**Product specific data**
	Optimum pH 6-8 Optimum temperature 60-75°C	▪ Temperature and pH during measurements ▪ Data on thermostability of the FE

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

MANUFACTURING PROCESS, RAW MATERIAL

	Available data	Product specific data
	▪ One general list substances used	▪ List all specific raw materials ▪ Step of the manufacturing where used ▪ Functions and identity of individual raw material
	▪ Five different primary solid liquid separation and 3 different concentration techniques are indicated in the dossier	▪ Detailed description of each concrete manufacturing process ▪ Flowchart for each production process

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	PURITY **Pesticides**	
	**Available data**	**Product specific data**
	max 100 ppb	▪ Information on the MRLs of pesticides used for the treatment of the source ▪ CoA MRL in compliance with Reg. (EC) No 396/2005

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	PURITY **Mycotoxins**	
	**Available data**	**Product specific data**
	Mycotoxins: no significant levels	▪ Presence of mycotoxins ▪ Analytical methods ▪ LoD, LoQ

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	TOXICOLOGICAL DATA Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes. OJ L 168/21, 28.06.2012, p. 21-23).	
FOOD ENZYME	**Available data**	**Product specific data**
	No toxicological data provided The enzyme is extracted from papaya latex	A documented history on the safety of the source of the food enzyme **Are latex and skin of the fruit consumed as food?**

Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	ALLERGENICITY	
FOOD ENZYME	**Available data**	**Product specific data**
	Amino-acid sequence for proteins of the papain enzyme complex (Moutim et al., 1999)	**Allergenicity assessment** – a comprehensive literature search for possible adverse reactions, allergy after consumption of source material, published in the last 10 years. Preferably via oral route

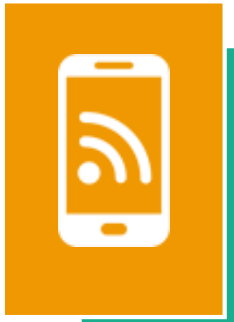
Scientific requirements

EFSA-Q-2015-00559 Papain from *Carica papaya*

	INTENDED USES AND EXPOSURE CALCULATION	
FOOD ENZYME	**Available data**	**Product specific data**
	brewing, flavour production, animal protein hydrolysis - fish, animal protein hydrolysis - meat, vegetal protein hydrolysis - soy, baking, rice hydrolysis/cooking	**Intended uses** aligned with the 'EC working document describing the food processes in which food enzymes are intended to be used'
		Use levels to be expressed as **mg TOS/kg raw material**
	Budget method	Estimation of dietary exposure, if deemed necessary, will be carried out by EFSA

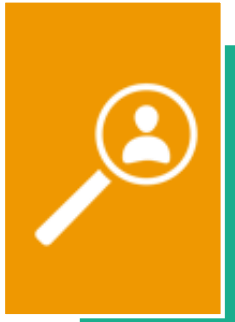
Stay connected

European Food Safety Authority



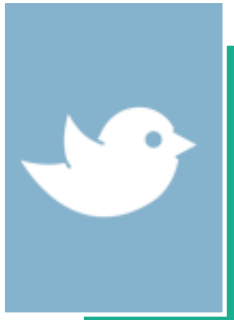
Subscribe to

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss



Receive job alerts

careers.efsa.europa.eu – job alerts

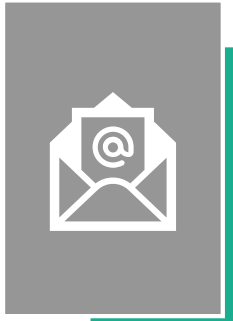


Follow us on Twitter

@efsa_eu
@plants_efsa
@methods_efsa
@animals_efsa

Follow us Linked in

Linkedin.com/company/efsa



Contact us

efsa.europa.eu/en/contact/askefsa