

TECHNICAL DATA SHEET

Product

Bitter Orange PE 10% – Food grade

Characteristics

Botanical and supply-chain information

Botanical name	Citrus aurantium var. amara L.
Synonym	Citrus x aurantium ssp. amara (Link) Engl
Family	Rutaceae
Plant part used	Unripe fruit
Primary processing	Harvesting, washing, drying
Novel food	Out of the scope of Reg. (EU) 2015/2283
Use permitted in food supplements	Compliant with Italian Ministerial Decree 10/08/2018, Annex I
Plant origin	China
Raw material provenance	China

Chemical and physical properties

Main technical specifications

TLC identification	Positive
Preparation type	Dry extract
Extraction solvent	Alcohol and water
Active constituent	Sinefrina (HPLC) (10.00 % min.)
Carriers	Maltodextrin max. 5.00%
Appearance	Fine yellow-brown powder
Particle size	100.0% through 80-mesh sieve
Moisture	5.0 % max
Ashes	5.0 % max
Bulk density	40-60 g/100ml

Contaminants

Main compliance (EU regulations)

Pesticide residues	Compliant with Reg. (EC) No. 396/2005
Solvent residues	Compliant with Dir. 2009/32/EC
Allergens	Reg. (EU) No. 1169/2011, Annex II — Not present as intentional ingredients
GMO	Absent — Reg. (EC) No. 1829/2003 and No. 1830/2003
Nickel	Compliant with Reg. (EU) 2024/1987
Ethylene oxide (EtO)	Not used; EtO + 2-chloroethanol residues compliant with Reg. (EC) No. 396/2005
Irradiation	Not irradiated — Dir. 1999/2/EC and 1999/3/EC
Radioactivity	Within natural limits
BSE, TSE	Product of plant origin; TSE/BSE risk not applicable (no ingredients of animal origin)
WADA list	Does not contain substances on the current WADA list
Nanomaterials	No 'engineered nanomaterials' as per Reg. (EU) 2015/2283
Total aerobic microbial count (TAMC)	$\leq 1.0 \times 10^4$ CFU/g. Salmonella: absent in 25 g; E. coli and S. aureus: absent in 1 g
Total yeasts and moulds (TYMC)	$\leq 1.0 \times 10^3$ CFU/g
Other contaminants	Compliant with Reg. (EU) 2023/915 (heavy metals, PAHs, mycotoxins, pyrrolizidine alkaloids, etc.)

Indications

Intended use and general information

Physiological and health-related purposes	Equilibrio del peso corporeo. Stimolo metabolico e metabolismo dei lipidi. Funzione digestiva. Regolare motilità gastrointestinale ed eliminazione dei gas. (Ministero Salute)
Contraindications, warnings, interactions	L'apporto massimo di sinefrina non deve superare i 30 mg/die. L'apporto massimo di octopamina non deve superare 1/8 di quello della sinefrina
Toxicological data	Nessuno
Additional notes	Occorre indicare in etichetta la titolazione in sinefrina. Si sconsiglia l'uso del prodotto in gravidanza, durante l'allattamento e al di sotto dei 12 anni. Consultare il medico prima dell'uso se le condizioni cardiovascolari non sono nella norma.
Usage indications	Exclusively plant-based origin; suitable for vegetarian and vegan use
Storage	Store in a cool, dry place in original sealed packaging
Shelf life	3 years from production if properly stored

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