

TECHNICAL DATA SHEET

Product

Ballota PE 4:1 – Food grade

Characteristics

Botanical and supply-chain information

Botanical name	Ballota nigra L.
Family	Lamiaceae
Plant part used	Herb
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 ratio 4:1
Extraction solvent	Alcohol and water
Carriers	Maltodextrin max. 5.00%
Appearance	Fine yellow-brown powder
Particle size	95.0% through 80-mesh sieve
Moisture	5.0 % max
Ashes	5.0 % max
Bulk density	30-70 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	Rilassamento, benessere mentale. Fluidità delle secrezioni bronchiali. Funzione digestiva. (Ministero Salute)
Contraindications, warnings, interactions	Nessuno
Toxicological data	Nessuno
Additional notes	Nessuna
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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