

TECHNICAL DATA SHEET

Product

Red rice yeast PE 3% – Food grade

Characteristics

Botanical and supply-chain information

Botanical name	Monascus purpureus L.
Family	Momascaceae
Plant part used	Microfungus
Growth conditions	Controlled fermentation
Harvest period	Continuo
Harvest conditions	Mechanical
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	Monakolin (HPLC) (3.00 % min.)
Carriers	Maltodextrin max. 5.00%
Appearance	Fine red-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	Azione ipocolesterolemizzante. (Ministero Salute)
Contraindications, warnings, interactions	Nessuno
Toxicological data	Nessuno
Additional notes	L'etichetta deve includere le avvertenze seguenti: non consumare un quantitativo giornaliero pari o superiore a 3 mg di monacoline da riso rosso fermentato. Non deve essere consumato dalle donne in gravidanza o in allattamento, dai bambini di età inferiore ai 18 anni e dagli adulti di età superiore ai 70 anni. Consultare un medico sul consumo di questo prodotto se si manifestano problemi di salute. Non deve essere consumato se si assumono medicinali per abbassare il colesterolo. Non deve essere consumato se già si consumano altri prodotti contenenti riso rosso fermentato. L'etichetta deve specificare il tenore di monacoline per dose di prodotto e deve recare il numero di singole dosi di prodotto per l'assunzione massima giornaliera.
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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Revision: 2026-09-19