

## TECHNICAL DATA SHEET

### Product

**Bitter Orange PE 6% – Food grade**

### Characteristics

Botanical and supply-chain information

|                                          |                                                               |
|------------------------------------------|---------------------------------------------------------------|
| <b>Botanical name</b>                    | Citrus Aurantium var. amara L.                                |
| <b>Synonym</b>                           | Citrus x aurantium ssp. amara (Link) Engl                     |
| <b>Family</b>                            | Rutaceae                                                      |
| <b>Plant part used</b>                   | Unripe fruit                                                  |
| <b>CAS number</b>                        | 72968-50-4                                                    |
| <b>Growth conditions</b>                 | Cultivated                                                    |
| <b>Harvest period</b>                    | Novembre-febbraio                                             |
| <b>Harvest conditions</b>                | Manual                                                        |
| <b>Primary processing</b>                | Harvesting, washing, drying                                   |
| <b>Novel food</b>                        | Out of the scope of Reg. (EU) 2015/2283                       |
| <b>Use permitted in food supplements</b> | Compliant with Italian Ministerial Decree 10/08/2018, Annex I |
| <b>Plant origin</b>                      | China                                                         |
| <b>Raw material provenance</b>           | China                                                         |

### Chemical and physical properties

Main technical specifications

|                           |                                |
|---------------------------|--------------------------------|
| <b>TLC identification</b> | Positive                       |
| <b>Preparation type</b>   | Dry extract                    |
| <b>Extraction solvent</b> | Alcohol and water              |
| <b>Active constituent</b> | Sinefrina (HPLC) (6.00 % min.) |
| <b>Carriers</b>           | Maltodextrin max. 5.00%        |
| <b>Appearance</b>         | Fine light-brown powder        |
| <b>Particle size</b>      | 95.0% through 80-mesh sieve    |
| <b>Moisture</b>           | 5.0 % max                      |
| <b>Ashes</b>              | 5.0 % max                      |
| <b>Bulk density</b>       | 30-70 g/100ml                  |

## Contaminants

Main compliance (EU regulations)

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

## Indications

Intended use and general information

|                                                  |                                                                                                                                                                                                                                                         |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Physiological and health-related purposes</b> | Equilibrio del peso corporeo. Stimolo metabolico e metabolismo dei lipidi. Funzione digestiva. Regolare motilità gastrointestinale ed eliminazione dei gas. (Ministero Salute)                                                                          |
| <b>Contraindications, warnings, interactions</b> | 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                                                                                                           |
| <b>Toxicological data</b>                        | Nessuno                                                                                                                                                                                                                                                 |
| <b>Additional notes</b>                          | 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. |
| <b>Usage indications</b>                         | Exclusively plant-based origin; suitable for vegetarian and vegan use                                                                                                                                                                                   |
| <b>Storage</b>                                   | Store in a cool, dry place in original sealed packaging                                                                                                                                                                                                 |
| <b>Shelf life</b>                                | 3 years from production if properly stored                                                                                                                                                                                                              |

Revision: 2026-09-19