

TECHNICAL DATASHEET**Part 1: General Information**

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| Product: | Gastalagin® min. 1% castalagine and vescalagine dry extract |
| Code: | 3500300.EPO |
| Botanic name: | Castanea sativa Miller; Cistus x incanus L. |
| INCI name: | CASTANEA SATIVA LEAF EXTRACT (and) CISTUS INCANUS FLOWER/LEAF/STEM EXTRACT |
| CAS number: | 84695-99-8 (and) 93165-04-9 |
| EINECS/ELINCS number: | 283-619-0 (and) 296-887-9 |
| Extraction solvent: | ethanol / water |
| Carrier and/or auxiliary substances: | maltodextrin (derived from maize); arabic gum (E414) |
| Product origin: | Italy |
| Origin of the raw material used for this product: | Southeastern Europe (mainly Italy) |
| Part of plant used: | leaves; herb |
| Preparation type: | Blend of dry extracts |
| Particle size: | not less than 90% through 300 microns |
| Intended use: | as raw material (ingredient) intended for manufacturing of food and a wide range of final products |

Active substances of the plant:

Tot. polyphenols $\geq 10\%$, ellagic tannins (castalagine and vescalagine $\geq 1.0\%$). Flavonoids, proanthocyanidins and phenolic acids not determined in the extract

Biologic marker:

polyphenols

Physiologic and healthcare applications:

Digestive

Toxicological data:

plant extract of natural origin for which no experimental data are available for acute toxicity, by analogy with chemically similar products are assumed a moderate level of acute toxicity

Contra-indications; warnings:

none known

Eventual particular notes:

The possible variation of colour from batch to batch, and presence of small dots (stippling), does not affect the final quality of the extract, indeed, it demonstrates its naturalness. if used during lactation it may give a characteristic odor to the mil

Nutritional values:

available upon request

Preservatives:

absent

Antioxidants:

absent

Storage conditions:

store in a well closed container away from moisture and direct sun light

Retest Date:

two years from manufacturing date

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| 2 | 21/05/2024 | Dott.ssa L.Colombo |
| REV. | DATE | WRITTEN QA |

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PART 2: Technical Specification

(Analytical methods from Ph. Eur current edition, except where otherwise specified; mentioned Regs. include subs. amendments and updates)

Product: **Gastalagin® min. 1% castalagine and vescalagine dry extract**
Code: 3500300.EPO
E/D Ratio: up to stated assay

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| Description: | hygroscopic powder |
| Colour: | brown |
| Odor: | characteristic |
| TLC:complies with the analysis performed on the raw material | complies* |
| Assay:Total Ellagitannins expressed as sum of castalagin and vescalagin (HPLC internal method) | $\geq 1,0$ - % w/w |
| Assay:total polyphenols expressed as pyrogallol (spectrophotometric met. ref Ph. Eur.) | $\geq 10,0$ % w/w |
| Bulk density: | 500 - 750 g/l |
| Loss on drying: | $\leq 6,0$ % w/w |
| pH: | 4,0 - 6,0 |
| Hydrosolubility Solubility in cold or hot water | partially watersoluble |
| Heavy metals: | < 20 ppm (method C Ph. Eur. current edition) |
| Lead (Reg. No (EU) 2023/915 and subs. amendments and updates): | $\leq 3,0$ ppm* |
| Cadmium (Reg. No (EU) 2023/915 and subs. amendments and updates): | $\leq 1,0$ ppm* |
| Mercury (Reg. No (EU) 2023/915 and subs. amendments and updates): | $\leq 0,1$ ppm* |
| Residual solvents: | complies to Ph. Eur. current edition and Directive 2009/32/EC* |
| Pesticides: | complies to Ph. Eur. current edition and Reg. 2005/396/EC and amendments concerning pesticides residues searched (with reference to E/D ratio)* |
| Aflatoxins: | Aflatoxin B1: < 2 ppb* Aflatoxin B1,B2,G1,G2: < 4 ppb* |
| Benzo(a)pyrene (Reg. No (EU) 2023/915 and subs. amendments and updates) | $\leq 10,0$ ppb* |
| Sum of 4 PAHs: Reg. No (EU) 2023/915 and subs. amendments and updates | $\leq 50,0$ ppb* |
| Pyrrolizidine alkaloids: Reg. No (EU) 2023/915 and subs. amendments and updates | ≤ 400 ppb* |
| Microbiological quality (Ref. Ph. Eur. current edition depending on the intended use) | |
| Bacterial count (TAMC: ref. 5.1.8, cat. B oral use): | $\leq 5 \times 10.000$ ufc/g |
| Yeasts and Moulds (TYMC: ref. 5.1.8, cat. B oral use): | $\leq 5 \times 100$ ufc/g |
| Pathogens (ref. 5.1.8, cat. B oral use): | Salmonella: absent in 25 g* Escherichia coli: absent in 1 g* |
| Bile-tolerant gram-negative bacteria (ref. 5.1.8, cat. B oral use): | ≤ 100 ufc/g* |
| Note: | DNA CERTIFIED RAW MATERIAL |

GMO: Free from GMO (Reg. (EC) 1829/2003 and 1830/2003)

BSE/TSE FREE - GLUTEN FREE

ALLERGENS: Free from substances or products causing allergies or intolerances (Reg. (EU) 1169/2011 Annex II)

(*)analysis performed on the basis of the specific self-control plan. TLC is performed on raw material.

The data reported in this Technical Data Sheet (excluding analytical ones) are taken from literature, among which (if applicable) Italian ministerial guidelines for physiological effects and CosIng (European Commission database for information on cosmetic substances).

Our extracts must be considered as raw materials (ingredients), produced in a food manufacturing site and they are non intended to be used by the final Consumer.

EPO srl guarantees that extracts are completely conforming to local and European legal frameworks. If belonging to specific category, otherwise the Customers must check the intended use (including the final formulation) and legal requirements for their final product at local a regional level

-The drug extract ratio (DER) is intended as drug (final) extract ratio, included any excipient, as per Ph. Eur. current edition "Monographs on herbal drug extracts"

- Herbal extracts with assay are intended as standardised extracts, unless otherwise specified

- In standardised extract the excipient is added for adjust the content of constituent(s) (assay) and for guarantee the final DER in extracts based on this parameter

- Concerning the pesticides residues, the stated conformity includes an uncertainty of measurement(according to SANTE') and processing factor coming from manufacturing process. MRL (Maximum Residue Levels) are not applied to extract, but it is applied to vegetal raw material.

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| 2 | 21/05/2024 | Dott.ssa A.Colace | Dott.ssa L.Colombo | Dott.ssa S. Vicentini |
| REV. | DATE | WRITTEN CQ | VERIFIED QA | APPROVED DT |

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