

TECHNICAL DATASHEET**Part 1: General Information**

Product:	PLANoràl® dry extract - DNA Certified
Code:	3500400.EPO
Botanic name:	Scutellaria lateriflora L.; Cistus x incanus L.
INCI name:	CISTUS INCANUS FLOWER/LEAF/STEM EXTRACT (and) SCUTELLARIA LATERIFLORA EXTRACT
CAS number:	--
EINECS/ELINCS number:	--
Extraction solvent:	water/ethanol
Carrier and/or auxiliary substances:	maltodextrin (derived from maize); arabic gum (E414)
Product origin:	Italy
Origin of the raw material used for this product:	Europe and Eastern Europe
Part of plant used:	aerial parts; 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:

Synergistic association of scutellaria dry extract 10% baicalin and cistus dry extract 18% total polyphenols

Biologic marker:

baicalin; polyphenols

Physiologic and healthcare applications:

For oral hygiene. Antioxidant.

Toxicological data:

in vitro studies performed on the extracts did not show cytotoxic effects on cells of the gingival epithelium up to the concentration of 50 mg / ml

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

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:

three years from manufacturing date

2	03/11/2023	Dott.ssa L.Colombo
REV.	DATE	WRITTEN QA

TECHNICAL DATASHEET**PART 2: Technical Specification**

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

Product:	PLANoràl® dry extract - DNA Certified
Code:	3500400.EPO
Description:	hygroscopic powder
Colour:	brown
Odor:	characteristic
Taste:	characteristic
Assay: total polyphenols expressed as pyrogallol (spectrophotometric met. ref Ph. Eur.)	10,0 - 15,0 % w/w
Bulk density:	500 - 800 g/l
Loss on drying:	≤ 7,0 % w/w
pH:	4,0 - 6,0
Hydrosolubility Solubility in cold or hot water	sparingly soluble
Heavy metals:	< 20 ppm (method C Ph. Eur. current edition)
Lead (Reg. No (EU) 2023/915 and subs. amendments and updates):	≤ 3,0 ppm*
Cadmium (Reg. No (EU) 2023/915 and subs. amendments and updates):	≤ 1,0 ppm*
Mercury (Reg. No (EU) 2023/915 and subs. amendments and updates):	≤ 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)	≤ 10.0 ppb*
Sum of 4 PAHs: Reg. No (EU) 2023/915 and subs. amendments and updates	≤ 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):	≤ 5 x 10.000 cfu/g
Yeasts and Moulds (TYMC: ref. 5.1.8, cat. B oral use):	≤ 5 x 100 cfu/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 cfu/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.

3	17/10/2023	Dott.ssa A.Colace	Dott.ssa L.Colombo	Dott.ssa S. Vicentini
REV.	DATE	WRITTEN CQ	VERIFIED QA	APPROVED DT

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