

TECHNICAL DATASHEET**Part 1: General Information**

Product:	ENOTProst® 15% Oenothain B (HPLC) dry extract - DNA Certified
Code:	3500200.EPO
Botanic name:	Epilobium angustifolium L.
INCI name:	EPILOBIUM ANGUSTIFOLIUM FLOWER/LEAF/STEM EXTRACT
CAS number:	90028-31-2
EINECS/ELINCS number:	289-821-5
Extraction solvent:	ethanol / water
Carrier and/or auxiliary substances:	maltodextrin added until stated assay (if necessary)
Botanic family:	Onagraceae
Product origin:	Italy
Origin of the raw material used for this product:	Italy and Europe (mainly Eastern Europe)
Growing condition:	wild, cultivated
Vegetable period:	at flowering
Collection period:	spring, summer
Part of plant used:	herb
Preparation type:	dry extract
Intended use:	As raw material (ingredient) intended for manufacturing of food and a wider range of final products.
Particle size:	not less than 90% through 300 microns

Active substances of the plant:

Oenothain B \geq 15.0%. There are also flavonoids (derivatives of kaempferol, quercetin, myricetin), chlorogenic acid, gallic acid derivatives, triterpene acids, mucilages.

Biologic marker:

flavonoids

Physiologic and healthcare applications:

Anti-inflammatory. Antioxidant. Anti-prostatic (also used in BPH).

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.

Nutritional values:

available upon request

Preservatives:

absent

Antioxidants:

absent

Storage conditions:

Store in a well closed containers, away from moisture and direct sun light.

Retest Date:

three years from manufacturing date. The extract tend to absorbing moisture over time, while remaining unchanged in terms of quality and safety. See storage conditions.

2	06/06/2023	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:	ENOTProst® 15% Oenothain B (HPLC) dry extract - DNA Certified
Code:	3500200.EPO
E/D Ratio:	up to stated assay
Description:	hygroscopic powder
Colour:	brown
Odor:	characteristic
Taste:	characteristic
Assay:Oenothain B (HPLC internal method)	>= 15,0 % w/w
Bulk density:	300 - 600 g/l
Loss on drying:	<= 7,0 % 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):	<= 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*
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 ufc/g
Yeasts and Moulds (TYMC: ref. 5.1.8, cat. B oral use):	<= 5 x 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.

4	19/10/2023	Dott.ssa A.Colace	Dott.ssa L.Colombo	Dott.ssa S. Vicentini
REV.	DATE	WRITTEN CQ	VERIFIED QA	APPROVED DT

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