

**TECHNICAL DATASHEET****Part 1: General Information**

<b>Product:</b>	SEDOX® fluid extract
<b>Code:</b>	A0247630.EPO
<b>Botanic name:</b>	Plantago lanceolata L.
<b>INCI name:</b>	PLANTAGO LANCEOLATA LEAF EXTRACT
<b>CAS number:</b>	85085-64-9
<b>EINECS/ELINCS number:</b>	285-388-1
<b>Extraction solvent:</b>	ethanol/water
<b>Botanic family:</b>	Plantaginaceae
<b>Product origin:</b>	Italy
<b>Origin of the raw material used for this product:</b>	Italy, Poland, Balkans (Albania)
<b>Growing condition:</b>	cultivated, wild
<b>Vegetable period:</b>	before, after flowering
<b>Collection period:</b>	from May to July
<b>Part of plant used:</b>	leaves
<b>Preparation type:</b>	fluid extract
<b>Intended use:</b>	as raw material (ingredient) intended for manufacturing of food and a wide range of final products

**Active substances of the plant:**

iridoid glucosides (aucubin, catalpol, asperuloside), mucilage, flavonoids, tannins not determined in the extract

**Biologic marker:**

Verbascoside

**Physiologic and healthcare applications:**

Anti-inflammatory, emollient and soothing for the respiratory system (used as a demulcent for oral or pharyngeal irritations, dry cough). Tone of voice. Digestive. Topical use: antimicrobial. Also used in wound healing.

**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

**Radioactivity:**

< 600 Bq/kg

**Contra-indications; warnings:**

none known

**Eventual particular notes:**

A slight sediment may occur; shake the product before use. The possible variation of colour from batch to batch does not affect the final quality of the extract, indeed, it demonstrates its naturalness.

**Nutritional values:**

Not applicable - Energy value given by ethanol content

**Preservatives:**

absent

**Antioxidants:**

absent

**Storage conditions:**

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

**Retest Date:**

three years

1	07/06/2024	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)

<b>Product:</b>	<b>SEDOX® fluid extract</b>
<b>Code:</b>	A0247630.EPO
<b>Definition:</b>	the extract is produced from the dried leaf and scape of <i>Plantago lanceolata</i> L. by a suitable procedure
<b>Description:</b>	clear liquid
<b>Colour:</b>	brown
<b>Odor:</b>	characteristic
<b>Taste:</b>	characteristic
<b>TLC:</b> complies with the analysis performed on the raw material	complies*
<b>Assay:</b> Verbascoside (HPLC met.)	$\geq 0,007$ % w/w
<b>Ethanol content:</b>	26,0 - 30,0 % v/v
<b>Density:</b>	0,900 - 1,010 g/ml
<b>Total solids:</b>	2,5 - 6,5 % w/v
<b>pH:</b>	5,0 - 7,0
<b>Heavy metals:</b>	< 20 ppm (method C Ph. Eur. current edition)
<b>Lead</b> (Reg. No (EU) 2023/915 and subs. amendments and updates):	< = 3.0 ppm*
<b>Cadmium</b> (Reg. No (EU) 2023/915 and subs. amendments and updates):	< = 1.0 ppm*
<b>Mercury</b> (Reg. No (EU) 2023/915 and subs. amendments and updates):	< = 0.10 ppm*
<b>Pesticides:</b>	complies to Ph. Eur. current edition and Reg. 2005/396/EC and amendments concerning pesticides residues searched*
<b>Aflatoxins:</b>	Aflatoxin B1: < 2 ppb* Aflatoxin B1,B2,G1,G2: < 4 ppb*
<b>Benzo(a)pyrene</b> (Reg. No (EU) 2023/915 and subs. amendments and updates)	< = 10,0 ppb*
<b>Sum of 4 PAHs:</b> Reg. No (EU) 2023/915 and subs. amendments and updates	< = 50,0 ppb*
<b>Microbiological quality</b> (Ref. Ph. Eur. current edition depending on the intended use)	
<b>Bacterial count</b> (TAMC: ref. 5.1.4, oral use):	< = 2 x 10.000 cfu/g
<b>Yeasts and Moulds</b> (TYMC: ref. 5.1.4, oral use):	< = 2 x 100 cfu/g
<b>Pathogens</b> (ref. 5.1.4, oral use):	Salmonella: absent in 10 g* Escherichia coli, Staphylococcus aureus: absent in 1 g*
<b>Bile-tolerant gram-negative bacteria</b> (ref. 5.1.4, oral use):	< = 100 cfu/g*
<b>Note:</b>	<b>DNA CERTIFIED RAW MATERIAL</b>
	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.

2	20/11/2023	Dott.ssa A.Colace	Dott.ssa L.Colombo	Dott.ssa S. Vicentini
REV.	DATE	WRITTEN CQ	VERIFIED QA	APPROVED DT

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