EPO Istituto Farmochimico Fitoterapico S.r.l.
Via Stadera 19 - 20141 Milano - Tel.: +39-02-89557.1 Fax +39-02-89557.390

TECHNICAL DATASHEET

Part 1: General Information

Product:	**Mallow fluid extract**
Code:	D0120530
Botanic name:	Malva sylvestris L.
INCI name:	MALVA SYLVESTRIS LEAF EXTRACT
CAS number:	84082-57-5
EINECS/ELINCS number:	282-003-9
Extraction solvent:	ethanol/water
Carrier and/or auxiliary substances:	caramel (E150d), sorbitol E420 (ii)
Botanic family:	Malvaceae
Product origin:	Italy
Origin of the raw material used for this product:	France, Italy, Albania
Growing condition:	cultivated
Vegetable period:	at flowering, before flowering
Collection period:	June-October
Part of plant used:	leaves
Preparation type:	fluid extract
Intended use:	As raw material (ingredient) intended for manufacturing of food and a wider range of final products.

Active substances of the plant:
mucilage (containing glucuronic acid, galacturonic acid, rhamnose and galactose), flavonoids, anthocyanins and tannins not determined in the extract

Biologic marker:
flavonoids

Physiologic and healthcare applications:
Laxative. Expectorant. Anti-inflammatory, emollient and soothing for the digestive, urinary and respiratory systems. Tone of voice (used for dysphonia). Topical use: skin conditioning.

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

REV.	DATE	WRITTEN QA
1	17/09/2024	Dott.ssa L.Colombo

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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:	**Mallow fluid extract**
Code:	D0120530
Description:	clear liquid
Colour:	brown
Odor:	characteristic
Taste:	characteristic
TLC:complies with the analysis performed on the raw material	complies *
Ethanol content:	28,0 - 32,0 % v/v
Density:	0,990 - 1,020 g/ml
Total solids:	8,0 - 13,5 % w/v
pH:	5,0 - 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*
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*
Microbiological quality (Ref. Ph. Eur. current edition depending on the intended use)	
Bacterial count (TAMC: ref. 5.1.4, oral use):	< = 2 x 10.000 ufc/g
Yeasts and Moulds (TYMC: ref. 5.1.4, oral use):	< = 2 x 100 ufc/g
Pathogens (ref. 5.1.4, oral use):	Salmonella: absent in 10 g* Escherichia coli, Staphylococcus aureus: absent in 1 g*
Bile-tolerant gram-negative bacteria (ref. 5.1.4, 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 token from literature, among which (if applicable) Italian minesterial 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 completly 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 manufatturing process. MRL (Maximum Residue Levels) are not applied to extract, but it is applied to vegetal raw material.

1	19/12/2023	Dott.ssa A.Colace	Dott.ssa L.Colombo	Dott.ssa S. Vicentini
REV.	DATE	WRITTEN CQ	VERIFIED QA	APPROVED DT

COPY OF ORIGINAL DOCUMENT,ALTHOUGH NOT SIGNED