## 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: OlivelLAX® dry extract - DNA Certified

**Code:** 3551200

Botanic name: Hippophae rhamnoides L. (Elaeagnus rhamnoides (L.) A.Nelson)

INCI name: HIPPOPHAE RHAMNOIDES FRUIT EXTRACT

**CAS number:** 90106-68-6 **EINECS/ELINCS number:** 290-292-8

**Extraction solvent:** ethanol / water

Carrier and/or auxiliary substances: Maltodextrin (derived from maize) added until stated assay; silica

(added only if necessary)

Botanic family: Elaeagnaceae

Product origin: Italy
Origin of the raw material used for Ukraine

this product:

Growing condition: cultivated; wild Vegetable period: at maturity Collection period: summer; autumn

Part of plant used: fruit
Preparation type: dry extract

Particle size: not less than 90% through 300 microns

**Intended use:** As raw material (ingredient) intended for manufacturing of food and a wider range of final

products.

Active substances of the plant:

isorhamnetin >= 0.10%; flavonols, ellagitannins, polysaccharides not determined in the extract

Biologic marker:

isorhamnetin

Physiologic and healthcare applications:

Regularity of bowel movement. Digestive function. Supporting and restorative action. Skin trophism and functionality. External 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

#### **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:**

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

2	10/07/2025	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)

OlivelLAX® dry extract - DNA Certified **Product:** 

3551200 Code:

E/D Ratio: up to stated assay hygroscopic powder Description:

Colour: brown Odor: characteristic

Taste: characteristic Assay:isorhamnetin (HPLC method, ref. Eur. Ph) >= 0.10 % w/w

450 - 850 g/l Bulk density: <= 7.0 % w/wLoss on drying: 2.5 - 5.5pH:

Hydrosolubility Solubility in cold or hot water partially watersoluble

< 20 ppm (method C Ph. Eur. current edition) Heavy metals:

Lead (Reg. No (EU) 2023/915 and subs. amendments and < = 3.0 ppm\*

updates):

Cadmium (Reg. No (EU) 2023/915 and subs. amendments and

updates):

Mercury (Reg. No (EU) 2023/915 and subs. amendments and

updates):

Residual solvents: Pesticides:

complies to Ph. Eur. current edition and Reg. 2005/396/EC and amendments concerning pesticides residues searched (with reference

to E/D ratio)\*

< = 1,0 ppm\*

< = 0.1 ppm\*

Aflatoxins: Aflatoxin B1: < 2 ppb\*

Aflatoxin B1,B2,G1,G2:  $< 4 \text{ ppb}^*$ 

Benzo(a)pyrene (Reg. No (EU) 2023/915 and subs. amendments <= 10,0 ppb\*

and updates)

Sum of 4 PAHs: Reg. No (EU) 2023/915 and subs. amendments  $\leq 50.0$  ppb\*

and updates

< = 400 ppb\*Pyrrolizzidine alkaloids: Reg. No (EU) 2023/915 and subs.

amendments and updates

Microbiological quality (Ref. Ph. Eur. current edition depending on the intended use) Bacterial count (TAMC: ref. 5.1.8, cat. B oral use):  $< = 5 \times 10.000 \text{ ufc/g}$ Yeasts and Moulds (TYMC: ref. 5.1.8, cat. B oral use):  $< = 5 \times 100 \text{ ufc/g}$ 

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\*

DNA CERTIFIED RAW MATERIAL Note:

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

complies to Ph. Eur. current edition and Directive 2009/32/EC\*

**BSE/TSE 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	25/03/2025	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

TECHNICAL DATASHEET 3551200