EPO Istituto Farmochimico Fitoterapico S.r.l.

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TECHNICAL DATASHEET

Part 1: General Information

Product: Arnica liposoluble extract

Code: 5003300

Botanical name: Arnica montana L. aut Arnica spp.

INCI name: ARNICA MONTANA FLOWER EXTRACT

CAS number: 68990-11-4

EINECS/ELINCS number: 273-579-2

Extraction solvent: corn oil

E/D Ratio: 2/1

Botanical family: Asteraceae

Country of origin: Europe

Origin of the raw material used for Europe, Mexico

this product:

Part of plant used: flowers

Preparation type: liposoluble extract

Intended Use: cosmetic.

Active substances of the plant:

sesquiterpene lactones (helenaline and its esters), essential oil, triterpenes, flavonoids (isoquercetin, astragalin, luteolin-7-glucoside), coumarins not determined in the extract

Biological marker:

flavonoids

Physiologic and healthcare applications:

inflammatory, antimicrobial, antineuralgic, anti-ecchymotic, vulnerary for EXTERNAL USE

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:

the presence of sesquiterpene lactones can lead to contact dermatitis

Eventual particular notes:

none

Preservatives:

absent

Antioxidants:

absent

Storage conditions:

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

Shelf life:

three years

Bibliography:

Dizionario di fitoterapia e piante medicinali - Campanini - Tecniche Nuove Piante officinali per infusi e tisane - OEMF

3	27.11.2012	Dott.ssa R.Gatti
REV.	DATE	WRITTEN QA

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TECHNICAL DATASHEET

Part 2: Technical Specifications

(Analytical methods from Ph. Eur. current edition, except where otherwise specified)

Product: Arnica liposoluble extract

Code:5003300Description:clear liquidColour:golden yellowOdor:characteristic

Density: 0,900 - 0,940 g/ml

Acid value: 0,50 - 1,00

Refractive index: 1,460 - 1,480

Saponification value: 160 - 200

Benzo(a)pirene: <= 2 ppb

Liposolubility: totally liposoluble

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

Lead (ref. Reg. (EC) 1881/2006): <=3,0 ppm*Cadmium (ref. Reg. (EC) 1881/2006): <=1,0 ppm*Mercury (rif. Reg. (EC) 1881/2006): <=0,1 ppm*

Pesticides: complies to Ph. Eur. current edition*

Aflatoxins: Aflatoxin B1: < 2 ppb*

Aflatoxin B1,B2,G1,G2: < 4 ppb*

Microbiological quality (Ref. Ph. Eur. current edition

EXTERNAL USE)

- Bacterial count (TAMC): $<=5 \times 10000 \text{ ufc/g}$ - Yeasts and Moulds (TYMC): $<=5 \times 100 \text{ ufc/g}$

- Pathogens: Salmonella: absent in 10 g*

Escherichia coli, Staphylococcus aureus: absent in 1 g*

Bile-tolerant gram-negative bacteria: <=100 ufc/gFlashing point: $>254^{\circ} \text{ C}$ Boiling point: $>350^{\circ} \text{ C}$

Note: The corn oil used complies to Reg. (EC) n. 1881/2006 and amendments

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

BSE/TSE FREE - GLUTEN FREE

(*) analysis performed on basis of specific self-control plan

4	24.07.2015	Dott.ssa A.Colace	Dott.ssa R.Gatti	Dott.ssa S.Vicentini
REV.	DATE	WRITTEN QC	VERIFIED QA	APPROVED TD

The data reported in this Technical Data Sheet (excluding analytical ones) are taken from the texts listed in the Bibliography. In any case this information will not discharge you from duty to identify and to monitor the product according to the use to which it is intended and the current legislation in the Country of use.

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