

LEPIVITS Belgium
4 Avenue Franklin – Unité 16
1300 Wavre
BELGIQUE



Fiche technique – Huile de bourrache

Code EAN : 5430002936031 (30 capsules)
: 5430002936048 (90 capsules)
*NUT : 3760/33

Certificate of Analysis : Borage Oil GLA 20% Cold Pressed, Refined

Items	Limit	Result
Identification [Ph. Eur. (2.3.2)]	Complies	Complies
Relative Density [Ph. Eur. (2.2.5)]	About 0.921 g/ml	0.925
Refractive Index [Ph. Eur. (2.2.6)]	1.474 - 1.479	1.4765
Acid Value [Ph. Eur. (2.5.1)]	0.5 mg KOH/g Max.	0.48
Peroxide Value [Ph. Eur. (2.5.5)]	5.0 meq/kg Max.	1.00
Unsaponification [Ph. Eur. (2.5.7)]	2.0% Max.	Complies
Alkaline Impurities [Ph. Eur. (2.4.19)]	Complies	Complies
Water [Ph. Eur. (2.5.32)]	0.1% Max.	< 0.1%
Color [Gardner]	< 5	3.6
Cold Test (5.5h at 0°C)	Blank	Blank
Fatty Acid Composition:		
< C16	0.3% Max.	< 0.1%
C16:0 Palmitic	9.0 - 12.0%	9.2%
C16:1 Palmitoleic	0.6% Max.	0.3%
C18:0 Stearic	2.0 - 6.0%	5.1%
C18:1 Oleic	12.0 - 22.0%	19.3%
C18:2 Linoleic	30.0 - 41.0%	36.1%
C18:3 γ-Linolenic	20.0% Min.	20.0%
C18:3 α -Linolenic	0.5% Max.	0.2%
C20:0 Arachidic	0.5% Max.	0.3%
C20:1 Eicosenoic	2.8 - 4.4%	4.4%
C22:1 Erucic	3.0% Max.	2.5%
C24:1 Nervonic	4.5% Max.	1.6%
Brassicasterol [Ph. Eur. (2.4.23)]	0.3% Max.	< 0.1%

Packaging & Storage

The oil is packed in 190kgs net HDPE drum, purged with nitrogen. It should be stored in cool and drying place, protect from light. Shelf Life is 24 months in original package.

The oil conforms to Ph Eur (European Pharmacopoeia).

Aceite de borraja 20% GLA

Product Specification

Borage Oil EP

(Cold Pressed, Refined, GLA 20.0% min.)

Description: Borage (Starflower) Oil obtained from seeds of *Borago officinalis* L. by extraction and/or expression. It is then refined. It is a clear, light yellow or yellow liquid. Practically insoluble in water and in ethanol (96 per cent), miscible with light petroleum. A suitable antioxidant may be added. Extract Ratio is 4:1.

Physical & Chemical Property:

Relative Density [Ph. Eur. (2.2.5)]	About 0.921 g/ml
Refractive Index [Ph. Eur. (2.2.6)]	About 1.476
Identification [Ph. Eur. (2.3.2)]	Complies
Acid Value [Ph. Eur. (2.5.1)]	0.5 mg KOH/g Max.
Peroxide Value [Ph. Eur. (2.5.5)]	5.0 meq/kg Max.
Unsaponification [Ph. Eur. (2.5.7)]	2.0% Max.
Alkaline Impurities [Ph. Eur. (2.4.19)]	Complies
Water [Ph. Eur. (2.5.32)]	0.1% Max.
Color (Gardner)	< 5
Fatty Acid Composition: [Ph. Eur. (2.4.22)]	
< C16	0.3% Max.
C16:0 Palmitic	9.0 - 12.0%
C16:1 Palmitoleic	0.6% Max.
C18:0 Stearic	2.0 - 6.0%
C18:1 Oleic	12.0 - 22.0%
C18:2 Linoleic	30.0 - 41.0%
C18:3 γ -Linolenic	20.0% Min. (EP 17.0 -27.0%)
C18:3 α -Linolenic	0.5% Max.
C20:0 Arachidic	0.5% Max.
C20:1 Eicosenoic	2.8 - 4.4%
C22:1 Erucic	3.0% Max.
C24:1 Nervonic	4.5% Max.
Brassicasterol [Ph. Eur. (2.4.23)]	0.3% Max.

Packaging & Storage

The oil is packed in 190kgs net HDPE drum, purged with nitrogen. It should be stored in cool and drying place, protect from light. Shelf Life is 24 months in original package.

The oil conforms to Ph Eur (European Pharmacopoeia).

Certificate of Analysis : Glycamed® 99,7%

Origin: Pure vegetable basis. The quality meets the requirements of the European Food Safety Authority concerning the classification as food additive E 422 Glycerin.

Appearance: Clear, colourless, hygroscopic, syrupy liquid with only mild, characteristic odour, is neither strong nor unpleasant.

Feature / Inspection Methode	Target Value	LTL/USP/FFC/EP*	UTL/USP/FCC/EP*	Actual Value	Unit
Glycerin		98,00	101,00	99,94	%
Identification by IR	PASS			pass	
Refractive index(nD20)		1,470	1,474	1,474	
Appearance of solution	clear, colourless			clear, colourless	
Solubility	PASS			pass	
Acidity or Alkalinity			0,20	0,04	MLNAOH0,1N
Aldehydes	<=10 ppm			< 10	PPM
Esters		8,00		8,60	ML HCL0,1N
Impurities related substances (GC)	PASS			pass	
Single impurities before Glycerin peak			0,10	0,01	%
Sum of impurities after Glycerin peak	<= 0,5 %			< 0,5	%
Diethylenglycol	<= 0,1 %			< 0,1	%
Water (guaranteed by Glaconchemie)			0,50	0,02	%
Density at 20°C		1,258	1,268	1,261	
Density at 25°C		1,257		1,260	
APHA-Colour ASTM 1209			10	4	
Fatty Acids and Esters (expressed as butyric acid)	<=0,1 %			< 0,1	%
Halogenated compounds	<=35 ppm			< 35	PPM
Chlorinated compounds (as Cl)	<=30 ppm			< 30	PPM
Sugars	PASS			pass	
Chlorides (as Chlorine)	<=10 ppm			< 10	PPM
Sulfates	<=20 ppm			< 20	PPM
Lead (Pb)	<=2 ppm			< 2	PPM
Arsenic	<=1 ppm			< 1	PPM
Cadmium	<=1 ppm			< 1	PPM
Mercury (Hg)	<=1 ppm			< 1	PPM
Sulphated ash	<=0,01 %			< 0,01	%
Residue on Ignition	<=70 ppm			< 70	PPM
Acrolein, Glucose and NH3 combinations	PASS			pass	
1,2,3-Butantrirole and 1,2,4-Butantrirole	<=0,05 %			< 0,05	%
free 3-MCPD	< 0,05 mg/kg			< 0,05	MG/KG
Aerobic Plate count	<=100 cfu/g			< 100	CFU/G
Coliforms	<=10 cfu/g			< 10	CFU/G
Yeast and Mould	<=10 cfu/g			< 10	CFU/G

*Conforming to the standards of the European Pharmacopeia (EP), the United States Pharmacopeia (USP) and the Food Chemicals Codex (FCC).

Storage Information: Approx 1 year when stored in refined steel or aluminium at temperature of max. 40°C and kept under nitrogen blanket. The shelf life may decrease at higher temperature.

MANUFACTURER'S DECLARATION Borage Oil Cold Pressed Refined (Declaration of pyrrolizidine alkaloids)

To Whom It May Concern JAN 1ST 2018

We confirm that our Borage Oil Cold Pressed Refined is processed by pure Borage Seed only, no Borage flower/leaf contaminated, therefore there is no Pyrrolizidine Alkaloids founded in our oil. After testing, we confirm that total 28 kinds of PAs -

Echimidine Echimidine-N-oxide Erucifoline Erucifoline-N-oxide Europine Europine-N-oxide Heliotrine Heliotrine-N-oxide Intermedine Intermedine-N-oxide Jacobine Jacobine-N-oxide Lasiocarpine Lasiocarpine-N-oxide Lycopsamine Lycopsamine-N-oxide Monocrotaline Monocrotaline-N-oxide Retrorsine Retrorsine-N-oxide Senecionine Senecionine-N-oxide Seneciphylline Seneciphylline-N-oxide Senecivernine Senecivernine-N-oxide Senkirkine Trichodesmine

Content is less than 1 mcg/kg.

Vitaheess E - Natural Tocopherols

Natural antioxidant made up of mixed Natural Tocopherols from sunflower oil, Ascorbyl Palmitate and Propyl Gallate, especially appropriate for foodstuffs.

Dosage: 0.02 to 0.03% regarding the fat contents.

Product No.: 8506

No.	Composition	Unit	Value	
1.1.	Tocopherol rich extract, E-306 *	%	20,0	
1.2.	Ascorbyl Palmitate, E-304i	%	5,0	
1.3.	Propyl gallate, E-310	%	20,0	
1.4.	Carriers:	GPAC E-472c	%	20,0
		Propylene glycol E-1520	%	35,0
(*E-306)	Tocopherols (mixture of isomers)	%	Max. 20,0	
	α – Tocopherol	%	68,0 – 69,0	
	β + γ – Tocopherol	%	13,0 – 14,0	
	δ – Tocopherol	%	17,0 – 18,0	
	Sterols	%	Max. 10,0	
	Squalene	%	Max. 5,0	
	Monoglycerides	%	Max. 20,0	
	REST: Sunflower Oil			

2. Technical Characteristics

2.1.	Appearance	Oily paste liquid
2.2.	Color	Amber
2.3.	Olor – Sabor	Characteristic
2.4.	Dispersability	100% in fats and oils.

Storage : Keep in original packaging well-closed or under inert gas, and protect from light. Once opened, the immediate use is recommended

TDS (ENG) - Gelatine Helm Ibérica (6)

TECHNICAL SPECIFICATIONS

Date: January 03, 2018

Product: GELATIN 180 BLOOM 6 MESH

Customer: HELM IBERICA S.A.

Origin: Bovine

Address: SPAIN

Definition: Gelatin is the result of partial hidrolisis of collagen contained in bovine hides.

CHARACTERISTICS	PARAMETERS	USED METHOD	LIMITS
PHYSICAL-CHEMICAL	Bloom	LB-PR-08	180 - 220 g
	Viscosity	LB-PR-05	30 - 40 mp
	Ph	LB-PR-03	5,0 - 6,20
	Grain Size	LB-PR-12	6 mesh
RESIDUES	As (Detection limit = 0,0000001 ppm)	LB-PR-50	1 ppm
	Pb (Detection limit = 0,005 ppm)	LB-PR-48	3 ppm
	Hg (Detection limit = 0,003 ppm)	AOAC (Cold Steam)	0,10 ppm
	Cr (Detection limit = 0,02 ppm)	LB-PR-37	2 ppm
	Cu (Detection limit = 0,1 ppm)	LB-PR-45	30 ppm
	Cd (Detection limit = 0,02 ppm)	LB-PR-47	0,5 ppm
	Zn (Detection limit = 0,2 ppm)	LB-PR-46	30 ppm
	Heavy metals (Detection limit = 0,0005 ppm)	LB-PR-48	30 ppm
	Iron (Detection limit = 0,02 ppm)	LB-PR-17	30 ppm
	Moisture (105°C)	LB-PR-15	15%
	Ash (550°C)	LB-PR-11	2%
	SO ₂	LB-PR-49	10 ppm
	H ₂ O ₂	LB-PR-78	10 ppm
	Conductivity	LB-PR-28	< 500 µS/cm
MICROBIOLOGICAL	Total aerobic bacteria	BC-PR-009	10 ³ /g
	Coliforms (30°C)	BC-PR-011	0/g
	Coliforms (44,5°C)	BC-PR-010	0/10g
	Anaerobic Sulphite-reducing	BC-PR-007	10/g
	Clostridium Perfringens	BC-PR-016	0/g
	Sthapylococcus SP	BC-PR-012	0/g
	Salmonella	BC-PR-020	0/25g
	Total Moulds and Yeasts	BC-PR-013	< 10 CFU/g
	E. Coli	BC-PR-010	Absent/10 g
INGREDIENTS	100 % GELATIN		
APPEARANCE	Granulated Powder.		
INGREDIENTS	100 % GELATIN		
APPEARANCE	Granulated Powder.		
COLOR	Light Yellow		
FLAVOR	Neutral		
ODOR	Neutral		
USE	PHARMA		
PACKAGING	25 kg Paper bag with polyethylene inner bag.		
VALIDITY PERIOD	5 Years in the original packing.		
STORAGE	Must be stored over platforms, in ventilated store-rooms, at ambient temperatures. Must not be stored or transported near excessive heat sources or in contact with water, chemical products, poisons or plague control products.		