

LEPIVITS Belgium
 4 Avenue Franklin – Unité 16
 1300 Wavre
 BELGIQUE



Fiche technique – Huile d'onagre 500mg

Code EAN : 5430002936017 (60 capsules)
 : 5430002936116 (120 capsules)
 : 5430002936024 (200 capsules)
 *NUT : 3760/34

(Certificat analyse - Onagre (plante))

Product name : Evening Primrose Oil GLA 10.0% Cold Pressed, Refined

Items	Limit	Result
Identification [Ph. Eur. (2.3.2)]	Complies	Complies
Acid Value [Ph. Eur. (2.5.1)]	0.5 mg KOH/g Max.	0.46
Peroxide Value [Ph. Eur. (2.5.5)]	5.0 meq/kg Max.	1.00
Relative Density [Ph. Eur. (2.2.5)]	About 0.923 g/ml	0.925
Refractive Index [Ph. Eur. (2.2.6)]	About 1.478	1.4765
Alkaline Impurities [Ph. Eur. (2.4.19)]	Complies	Complies
Unsaponification	2.5% Max.	Conforms
Cold Test (5.5h at 0°C)	Blank	Blank
Color (Gartner)	< 5	4.5
Water [Ph. Eur. (2.5.32)]	0.1% Max.	< 0.1%
Fatty Acid Composition:		
< C16	0.3% Max.	< 0.1%
C16:0 Palmitic	4.0 - 10.0%	7.1%
C18:0 Stearic	1.0 - 4.0%	2.0%
C18:1 Oleic	5.0 - 12.0%	7.1%
C18:2 Linoleic	65.0 - 85.0%	72.2%
C18:3 γ-Linolenic	10.0% Min. (EP 7.0 - 14.0%)	10.0%
C18:3 α-Linolenic	0.5% Max.	0.5%
Brassicasterol	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).

Product description : Glycamed® 99,7%

Feature / Inspection Methode	Target Value	LTL/USP/FCC/EP*	UTL/USP/FCC/EP*	Actual Value	Unit
Glycerin		98,00	101,00	99,96	%
Identification by IR	PASS			pass	
Refractive index(nD20)		1,470	1,474	1,472	
Appearance of solution	clear, colourless			clear, colourless	
Solubility	PASS			pass	
Acidity or Alkalinity			0,20	0,04	MLNAOH,1N
Aldehydes	<=10 ppm			< 10	PPM
Esters		8,00		9,45	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	1,262	
Density at 25°C		1,257		1,260	
APHA-Colour ASTM 1209			10	2	
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 Pharmacopoeia (EP), the United States Pharmacopoeia (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.

CERTIFICATE OF ANALYSIS *Producto / Product: Aceite de Onagra 10%GLA 500mg / Evening primrose 10%GLA 500mg*

FÓRMULA / FORMULA

Código / Code	Ingredientes / Ingredients	mg/cápsula / mg/capsule
100324	Aceite de Onagra 10%GLA Cold press (extraído de las semillas de <i>Oenothera biennis</i> L.) <i>Evening primrose oil 10%GLA Cold press (extracted from the seeds of Oenothera biennis L.)</i>	500,0 mg
100161	Vitamina E Natural 67% (D-alfa tocoferol) <i>Natural Vitamin E 67% (D-alpha tocopherol)</i>	5,0 mg
	Envolvente / Shell	
	Gelatina bovina / <i>Bovine Gelatin</i>	162,879 mg
	Glicerina / <i>Glycerin</i>	53,030 mg
	Peso total de la cápsula / Total capsule weight	720,909 mg

ANÁLISIS FÍSICO / PHYSICO SPECIFICATIONS

Test	Especificacion / Specification	Resultado / Result
Formato <i>Size and shape</i>	Cápsula gelatina blanda 10 mín. oval <i>10 min. oval softgel</i>	CUMPLE / COMPLIES
Color <i>Colour</i>	AP00_01 Natural	CUMPLE / COMPLIES
Peso medio de la cápsula <i>Average capsule</i>	721,0 mg ± 15% (612,8 – 829,0 mg)	CUMPLE / COMPLIES
Uniformidad de masa (contenido) <i>Average content</i>	(18/20) 505 mg ± 7,5% (467,1 – 542,9 mg) (20/20) 505 mg ± 15% (429,3 – 580,8 mg)	CUMPLE / COMPLIES
Espesor de soldadura <i>Thickness of the join</i>	≥50%	CUMPLE / COMPLIES
Test de desintegración <i>Disintegration test</i>	≤ 30 min	CUMPLE / COMPLIES

ANÁLISIS QUÍMICO / CHEMICAL SPECIFICATIONS

Test	Especificacion / Specification	Resultado / Result
Gluten/ <i>Gluten</i>	Cuantificación/ <i>Quantification</i>	<5 ppm
Lactosa/ <i>Lactose</i>	Cuantificación/ <i>Quantification</i>	<0,01%

ANÁLISIS MICROBIOLÓGICOS/ MICROBIOLOGICAL ANALYSIS*

Descripción / Description	Especificación / Specification	Resultado / Result
Aerobios mesófilos a 30°C, recuento / Total Aerobic count	$\leq 10^4$ ufc/g	$< 10^4$ ufc/g
Mohos y Levaduras / Yeast and Moulds	$\leq 10^2$ ufc/g	$< 10^2$ ufc/g
Enterobacterias / Enterobacteriaceae	$\leq 10^2$ ufc/g	$< 10^2$ ufc/g
<i>Escherichia coli</i>	Ausencia 1g / Absence 1g	Ausencia 1g / Absence 1g
<i>Salmonella</i>	Ausencia 10g / Absence 10g	Ausencia 10g / Absence 10g
<i>Staphylococcus aureus</i>	Ausencia 1g / Absence 1g	Ausencia 1g / Absence 1g
<i>Listeria monocytogenes</i>	Ausencia 25g / Absence 25g	Ausencia 25g / Absence 25g

* Análisis microbiológico realizado según lotes programados / Microbiological analysis realized according scheduled batches.

INFORMACIÓN ADICIONAL / ADDITIONAL INFORMATION

METALES PESADOS / HEAVY METALS:

Plomo / Plumb	$\leq 3,0$ mg/Kg
Cadmio / Cadmium	$\leq 1,0$ mg/Kg
Mercurio / Mercury	$\leq 0,1$ mg/Kg

Acorde al Reglamento (CE) N° 629/2008 de la Comisión de 2 de Julio de 2008 que modifica al Reglamento (CE) n° 1881/2006 por el que se fija el contenido máximo de algunos contaminantes en los productos alimenticios. HC Clover no realiza controles de metales pesados por lote fabricado. Estos controles son exigidos a nuestros proveedores de materias primas.

According to Regulation (EC) N° 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

HC Clover does not perform any control of heavy metals by batch manufactured. These controls are required of our suppliers of raw materials.

ALÉRGENOS / ALLERGENS:

La gelatina usada en la fabricación del producto contiene Sulfitos en cantidad inferior a 10 ppm.
The gelatin used in the manufacture of the product contains Sulphites in quantities not exceeding 10 ppm.

El producto no contiene alérgenos indicados en el anexo II del Reglamento (UE) N° 1169/2011.
The product does not contain allergens indicated in the attachment II of the Regulation (UE) N° 1169/2011.

GMO / GMO:

Este producto es no GMO.

This product is non OGM.

BSE - TSE / BSE -TSE:

Este producto está libre de BSE y TSE.

This product is BSE&TSE free.

CONSERVACIÓN / CONSERVATION:

Conservar en lugar fresco y seco. Entre temperaturas 15-25°C y HR <60%.

Keep in cold and dry places. Temperatures between 15-25°C y HR <60%.

Specifications-vitamine-e-acetate-500ui-naturelle

PRODUCT INFORMATION : NATURAL VITAMIN E 500 UI/g ACETATE

Natural/synthetic?	Natural from soybeans	CAS N°	58-95-7
Country of origin	China	Composition	D-alpha tocopheryl acetate : NLT 51,50% Silicon dioxide SiO ₂ : 0,5% Sodium octenylsuccinate starch: 47-48%
Shelf life	3 years	Version	02
ACTIVE INGREDIENTS / SUBSTANCES TO CONTROL			
Assay		NLT 500UI/g	EP

Analytical data

Appearance	Off-white to beige granular powder
Sieve analysis	40 mesh
Loss on drying	NMT 5%
Specific gravity / Density (25°C)	0,35-0,60 g/cm ³
Acidity (as d-α-tocopheryl acetate)	< 0,35 mL KOH 0,1N / g

Heavy metals/purity

Heavy metals	NMT 10ppm
Lead (Pb)	NMT 3ppm
Arsenic (As)	NMT 2ppm
Cadmium(Cd)	NMT 1ppm
Mercury (Hg)	NMT 0,1ppm
Pesticides	In compliance with Regulation (EC) N°396/2005
PAH	NMT 50 ppb
Benzo (a) pyrene	NMT 10ppb
- Sum of dioxins	0,75pg/g fat
- Sum of dioxins and dioxin-like PCBs	1,25 pg/g fat
- Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180	40ng/g fat

MICROBIOLOGY	
Total aerobic microbial	20 000cfu/g Max
Tot. yeast and mould	200cfu/g Max
Salmonella	Negative/g
E.Coli	Negative/g
ATTESTATION	
Allergens	Allergen free
GMO	Non OGM
Irradiation	Non Irradiation
PACKAGING AND STORAGE	
Packing	Must be suitable for food industry
Storage	Ambient temperature. Protection from light, moisture and air. Store in tightly closed bags

Product Specification

Evening Primrose Oil EP

(Cold Pressed, Refined, GLA 10.0% min.)

Description: Evening Primrose Oil obtained from seeds of *Oenothera biennis* 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 (bp: 40-60 °C). A suitable antioxidant may be added. Extract Ratio is 7:1.

Physical & Chemical Property:

Relative Density [Ph. Eur. (2.2.5)]	About 0.923 g/ml
Refractive Index [Ph. Eur. (2.2.6)]	About 1.478
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.
Unsaturation [Ph. Eur. (2.5.7)]	2.5% Max.
Alkaline Impurities [Ph. Eur. (2.4.19)]	Complies
Water [Ph. Eur. (2.5.32)]	0.1% Max.
Color (Gardner)	< 5
Cold Test (5.5h at 0°C)	Blank
Fatty Acid Composition: [Ph. Eur. (2.4.22)]	
< C16	0.3% Max.
C16:0 Palmitic	4.0 - 10.0%
C18:0 Stearic	1.0 - 4.0%
C18:1 Oleic	5.0 - 12.0%
C18:2 Linoleic	65.0 - 85.0%
C18:3 γ -Linolenic	10.0% Min. (EP 7.0 - 14.0%)
C18:3 α -Linolenic	0.5% 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).

Vitahees E

VITAHEESS E

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 – Tocoferol	%	68,0 – 69,0
	β + γ – Tocoferol	%	13,0 – 14,0
	δ – Tocoferol	%	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

Gelatine Helm Ibérica

Product: GELATIN 180 BLOOM 6 MESH

Origin: Bovine

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-26	< 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.		
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.		