

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE D'ONAGRE RAFFINEE	Juillet 2018 / <i>July 2018</i>
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INCI: **Oenothera biennis oil**
N° CAS: 90028-66-33
N°EINECS/ELINCS: 289-859-2

DESCRIPTION / DESCRIPTION:

Liquide clair, de couleur jaune claire à jaune. Une des huiles riches en acide gamma linoléique (ou vitamine F) / *Clear liquid, light yellow to yellow. One of the oils rich in gamma linoleic acid (or vitamin F)*
Produit d'origine végétale / *Product of vegetable origin*
Produit conforme à la Pharmacopée Européenne en vigueur / *Product in accordance with the European Pharmacopoeia in force*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Identifications	Conforme / <i>Compliant</i>	Ph. Eur
Indice de réfraction à 20°C / <i>Refractive index at 20°C</i>	Environ / <i>about 1.478</i>	Ph. Eur 2.2.6
Densité à 20°C / <i>Density at 20°C</i>	Environ / <i>about 0.923 g/cm³</i>	Ph. Eur 2.2.5
Indice d'acide / <i>Acid value</i>	≤ 0.5 mg KOH / g	Ph. Eur 2.5.1
Indice de peroxyde / <i>Peroxide index</i>	≤ 10 meq O ₂ / kg	Ph. Eur 2.5.5
Insaponifiable / <i>Unsaponifiable</i>	≤ 2,5 % (m/m)	Ph. Eur 2.5.7
Impuretés alcalines / <i>Alkaline Impurities</i>	Conforme / <i>Compliant</i>	Ph. Eur 2.4.19
Teneur en eau / <i>Water content</i>	≤ 0.1 %	Ph. Eur 2.5.32
Composition en acides gras / <i>Fatty acid composition</i>		
≤ C 16: 0	≤ 0.3 %	Ph. Eur 2.4.22a
C 16: 0 Acide palmitique / <i>Palmitic acid</i>	4 – 10 %	Ph. Eur 2.4.22a
C 18: 0 Acide stéarique / <i>stearic acid</i>	1 – 4 %	Ph. Eur 2.4.22a
C 18: 1 Acide oléique / <i>Oleic acid</i>	5 – 12 %	Ph. Eur 2.4.22a
C 18: 2 Acide linoléique / <i>linoleic acid</i>	65 – 85 %	Ph. Eur 2.4.22a
C 18: 3 Acide g.linoléique / <i>g.linolenic acid</i>	9 – 14 %	Ph. Eur 2.4.22a
C18 : 3 Acide a.linoléique / <i>a.linolenic acid</i>	≤ 0.5 %	Ph. Eur 2.4.22a
Brassicastérol / <i>Brassicasterol</i>	≤ 0.3 %	Ph. Eur 2.4.23

Ces éléments seront repris sur nos BA / *these elements will be on our CoA*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Pratiquement insoluble dans l'eau et l'éthanol (96%), miscible à l'éther de pétrole (40 – 60°C) et les solvants organiques / *Practically insoluble in water and ethanol (96%), miscible with petroleum ether (40 – 60°C) and organic solvents*
Point d'ébullition / *Boiling point*: > 250°C

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APPLICATIONS :

Alimentaire, Cosmétique, Pharma / *Food, Cosmetic, Pharma*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Fût de 190 kg, tonnelet de 50 kg / *Drum of 190 kg - Keg of 50 kg*

Matière première non classifiée comme substance dangereuse / *Raw material not calssified as dangerous substance*

Eviter le stockage à proximité de flammes ou d'étincelles / *Avoid storage near flames or sparks*

Additives	Doesn't contain additives, antioxidants. The presence of formol, formol releasers, sulfates is not expected but not analyzed
Allergen	This product does not contain substances classified as sensitizers according to cosmetic regulation 1223/2009/ EEC, annex II and VI as an ingredient.
Animal Testing	Has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk for BSE
California Prop 65	This product (CAS: 90028-66-33) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Doesn't contain substances or traces of substances CMR according to Annex VI of Directive CE 1272/2008
Composition	100 % Oenothera biennis oil
Cosmetic	This product does not contain substances classified as sensitizers according to cosmetic regulation 1223/2009/CEE, annex II and IV as ingredient
Cosmos / Ecocert	<i>No data available</i>
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	<i>No data available</i>
Ecolabel	<i>No data available</i>
European Pharmacopeia	Compliant with the European Pharmacopoeia
Food	Is a food grade product. Complies with European regulation 1881/2006 on the fixing of maximum levels on foodstuffs
Genetically Modified Organisms (GMO)	Doesn't contain GMO
Inventories	Not compliant with inventories
Geographic origin (for plant)	Flower (fam. Onagraceae) originating from North America. The seeds contain about 25% of oil
Glycol ether	The presence of Glycol ether is not expected but not analyzed
Halal	<i>No data available</i>
Heavy Metals	Complies with European regulation 1881/2006 on the fixing of maximum levels
HS code	15159060
Irradiation / ionization	Has not been irradiated or ionized
Kosher	<i>No data available</i>
Latex	Doesn't contain latex
Manufacturing location	<i>No data available</i>
Microbiological data	Are not favorable to microbiological development. The oils are deodorized (180-250°C) during the refining process, which effectively eliminates microbiological activity. The water content (typically less than 0.5%) is low and provides an environment that is not suitable for microorganisms (total aerobic: < 1000 cfu/g, absence of pathogens germs in 1 g)

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Nanomaterials	Doesn't contain nanomaterials as ingredient
Nutritional data	Nutritional information (for 100g): Caloric value: 3700 KJ (900Kcal), Proteins:0g, Glucides:0g, Lipids (fatty acids): 100g, saturated:9g, Mono-saturated: 8g, polyunsaturated: 83g, salt:0g
Origin	100% vegetable
Pesticide	Complies with European Regulation EC 396/2005 on the presence of pesticides in products of plant and animal origin
Phthalate	The presence of phthalates ether is not expected but not analyzed
Preservative	Doesn't contain preservatives
Process	Oil obtained by pressing then refining
REACH	Exempt of obligation according to Annex II, n° 9 of EC Regulation n° 987/2008 of the Commission amending REACH Regulation EC No 1907/2006, annexes IV and V
Residual Solvents	Doesn't contain residual solvents
RSPO	Doesn't contain palm oil – Not concerned
Shelf Life	18 months
Substances of Very High Concern (SVHC)	Doesn't contain SVHC according to Annex XIV of the regulation REACH as ingredient
Volatiles organic compounds (VOC)	Doesn't contain VOC beyond the authorized limits (because of the ambient pollution, it is impossible to exclude a possible contamination at the level of traces)

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Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancel and replace all technical and regulatory previous documents.*