

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE D'OLIVE RAFFINEE	Juillet 2018 / <i>July 2018</i>
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INCI: **Olea europaea fruit oil**
N° CAS: 8001-25-0
N°EINECS/ELINCS: 232-277-0

DESCRIPTION / DESCRIPTION :

Huile grasse obtenue par raffinage de l'huile d'olive brute préparée à partir des drupes mûres d'Olea europaea L, par pression à froid / *Fatty oil obtained by refining raw olive oil prepared from Olea europaea L ripe drupes, by cold pressing*

Son apparence devient trouble à partir de 10°C et se solidifie en masse butyreuse vers 0°C / *Its appearance becomes cloudy from 10°C and solidifies in greasy mass towards 0°C*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie: Huile d'olive raffinée) / *Raw material according to the European Pharmacopoeia in force (monograph: Refined olive oil)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS :

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect à 20°C / <i>Aspect at 20°C</i>	Liquide limpide, transparent, incolore à jaune vert / <i>Clear, transparent, colorless to green yellow-green liquid</i>	Visuelle / <i>Visual</i>
Densité à 20°C / <i>Density at 20°C</i>	~ 0.193 g.cm ⁻³	Ph. Eur 2.2.5
Impuretés à la réaction alcaline / <i>Impurities to alkaline reaction</i>	Conforme / <i>Compliant</i>	Ph. Eur 2.4.19
Absorbance à 270 nm / <i>Absorbance at 270 nm</i>	≤ 1.20	Ph. Eur 2.2.25
Indice d'acide / <i>Acid value</i>	≤ 0.3 mg KOH / g	Ph. Eur 2.5.1
Indice de peroxyde / <i>Peroxide value</i>	≤ 10 meq O ₂ / kg	Ph. Eur 2.5.5
Insaponifiable / <i>Insaponifiable</i>	≤ 1.5 %	Ph. Eur 2.5.7
Test huile de sésame / <i>Sesame oil test</i>	Conforme / <i>Compliant</i>	Ph. Eur
Eau / <i>Water</i>	≤ 0.1 %	Ph. Eur 2.5.32
Composition en acides gras / <i>Fatty acid composition</i>		
C 14 : 0 Acide myristique / <i>Myristic acid</i>	≤ 0.1 %	Ph. Eur. 2.4.22
C 16 : 0 Acide palmitique / <i>Palmitic acid</i>	7.5 – 20 %	Ph. Eur. 2.4.22
C 16 : 1 Acide palmitoléique / <i>Palmitoleic acid</i>	≤ 3.5 %	Ph. Eur. 2.4.22
C 18 : 0 Acide stéarique / <i>Stearic acid</i>	0.5 – 5 %	Ph. Eur. 2.4.22
C 18 : 1 Acide oléique / <i>Oleic acid</i>	56 – 85 %	Ph. Eur. 2.4.22
C 18 : 2 Acide linoléique / <i>Linoleic acid</i>	3.5 – 20 %	Ph. Eur. 2.4.22
C 18 : 3 Acide linolénique / <i>Linolenic acid</i>	≤ 1.2 %	Ph. Eur. 2.4.22
C 20 : 0 Acide arachidique / <i>Arachidic acid</i>	≤ 0.7 %	Ph. Eur. 2.4.22

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C 20 : 1 Acide eicosénoïque / <i>Eicosenoic acid</i>	≤ 0.4 %	Ph. Eur. 2.4.22
C 22 : 0 Acide béhénique / <i>Behenic acid</i>	≤ 0.2 %	Ph. Eur. 2.4.22
C 24 : 0 Acide lignocérique / <i>Lignoceric acid</i>	≤ 0.2 %	Ph. Eur. 2.4.22
Cholestérol / <i>Cholesterol</i>	≤ 0.5 %	DGF F-III 1 / Ph. Eur. 2.4.23
Campestérol / <i>Campesterol</i>	≤ 4 %	DGF F-III 1 / Ph. Eur. 2.4.23
Stigmastérol / <i>Stigmasterol</i>	≤ <i>Campesterol</i>	DGF F-III 1 / Ph. Eur. 2.4.23
Delta 7 Stigmastérol / <i>Delta 7 Stigmasterol</i>	≤ 0.5 %	DGF F-III 1 / Ph. Eur. 2.4.23
Beta sitostérine (somme) / <i>Beta sitosterine (sum)</i>	≥ 93%	DGF F-III 1 / Ph. Eur. 2.4.23

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

Ces caractéristiques sont conformes aux précédentes spécifications datées d'Avril 2011 / *These features are in accordance with previous specifications dated on April 2011*

CARACTERISTIQUES A TITRE D'INFORMATION / *ADDITIONAL INFORMATION:*

Pratiquement insoluble dans l'éthanol (96 %), miscible à l'éther de pétrole (50 – 70 °C) / *Practically insoluble in ethanol (96%), miscible with petroleum ether (50 - 70 °C)*

Point éclair / *Flash point* : > 260 °C

Point de fusion : env 0 à 9 °C / *Melting point* : ~ 0 to 9 °C

Pression de vapeur : < 1 mbar à 20 °C / *Steam pressure* : < 1 mbar to 20 °C

APPLICATIONS :

Alimentaire, Cosmétique, Pharma / *Food, Cosmetics, Pharma*

CONDITIONNEMENT STANDARD / *STANDARD PACKAGING :*

Tonnelet de 50 kg – 25 kg, Fut 190 kg – Container de 900 kg / *Keg of 50 kg-25 kg - Barrel 190 kg - Container of 900 kg*

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

A conserver en emballage soigneusement fermé dans un endroit sec, frais. Eviter tout contact avec la lumière et l'air / *Store in a tightly closed container in a dry, cool place. Avoid contact with light and air*

Additives	The presence of additives, antioxidants, formol and formol releasers, sulfates is not expected but not analyzed
Allergen	<i>No data available</i>
Animal Testing	Has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk for BSE
California Prop 65	This product (CAS: 8001-25-0) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Doesn't contain CMR according to Annex XIV of Directive CE 1272/2008
Composition	100% Olea europaea fruit oil
Cosmetic	This product does not contain substances classified as sensitizers according to cosmetic regulation 1223/2009/EEC, annex II and VI as an ingredient
Cosmos / Ecocert	This product is manufactured by chemical refining – Not accepted by cosmos
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	<i>No data available</i>

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Ecolabel	<i>No data available</i>
European Pharmacopeia	Compliant with the European Pharmacopoeia
Food	Is a food grade product
Genetically Modified Organisms (GMO)	Doesn't contain GMO
Inventories	China IECSC, USA TSCA, New Zealand NZIoC, Korea KECI, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	<i>No data available</i>
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	15099000
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 (total aerobic: < 1000 cfu/g, absence of pathogens germs in 1 g)
Nanomaterials	Doesn't contain nanomaterials as ingredient
Nutritional data	Proteins:0g, Glucides:0g, Lipids (fatty acids): 100g, saturated:15g, Mono-saturated:79g, polysaturated: 6g, salt:0g
Origin	100% vegetable (oliv)
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	By chemical refining
REACH	Exempted from obligations according to Annex II, n° 9 of EC Regulation n° 987/2008 of the Commission amending the REACH Regulation EC No 1907/2006, annexes IV and V
Residual Solvents	Doesn't contain residual solvents
RSPO	This product is not derived from palm – 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.*