

	Dossier technique et réglementaire / <i>technical and regularoty document</i> HUILE DE SOJA RAFFINEE	Février 2019 / <i>February 2019</i>
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INCI: **Glycine soja oil**
N°CAS: 8001-22-7
N°EINECS/ELINCS: 232-274-4

DESCRIPTION / DESCRIPTION:

Liquide limpide, jaune pâle / *Pale yellow, clear liquid*

Produit d'origine végétale / *raw material of vegetable origin*

Produit conforme à la Pharmacopée Européenne en vigueur (monographie : huile de soja raffinée) / *product in accordance with the current European Pharmacopoeia (monograph: refined soy oil)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Densité à 20°C / <i>Density at 20°C</i>	Environ / <i>about</i> 0.922 g/cm ³	Ph.Eur.2.2.5
Indice de refraction / <i>Refractive index at 20°C</i>	Environ / <i>about</i> 1.475	Ph. Eur.2.2.6
Indice d'acide / <i>Acid value</i>	≤ 0.5 mg KOH/g	Ph. Eur.2.5.1
Indice de peroxyde / <i>Peroxide value</i>	≤ 10 meq O ₂ /kg	Ph.Eur.2.2.5
Insaponifiable / <i>Unsaponifiable</i>	≤ 1.5 % (m/m)	Ph. Eur.2.5.7
Impuretés à réaction alcaline / <i>Impurities to alkaline reaction</i>	Conforme / <i>compliant</i>	Ph. Eur.2.4.19
Composition en acides gras / <i>Fatty acid composition</i>		
< C 14 : 0	≤ 0.1 %	Ph. Eur. 2.4.22A
< C 14 : 0 Acide myristique / <i>Myristic acid</i>	≤ 0.2 %	
C 16: 0 Acide palmitique / <i>Palmitic acid</i>	9 – 13 %	
C 16: 1 Acide palmitoléique / <i>Palmitoleic acid</i>	≤ 0.3 %	
C 18: 0 Acide stéarique / <i>Stearic acid</i>	2.5 – 5 %	
C 18: 1 Acide oléique / <i>Oleic acid</i>	17 – 30 %	
C 18: 2 Acide linoléique / <i>Linoleic acid</i>	48 – 58 %	
C 18: 3 Acide linolénique / <i>Linolenic acid</i>	5 – 11 %	
C 20: 0 Acide arachidique / <i>Arachidic acid</i>	≤ 1 %	
C 20: 1 Acide eicosénoïque / <i>Eicosenoic acid</i>	≤ 1 %	
C 22: 0 Acide béhénique / <i>Behenic acid</i>	≤ 1 %	Ph. Eur. 2.4.23
Brassicastérol / <i>Brassicasterol</i>	≤ 0.3 %	

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

Ces caractéristiques sont conformes aux précédentes spécifications datées d'Octobre 2008 / *These features are in accordance with previous specifications dated on October 2008*

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CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Eau / *water* : ≤ 0.1 % (Ph. Eur. 2.5.32)

Miscible à l'éther de pétrole, pratiquement insoluble dans l'éthanol / *Miscible in petroleum ether, practically insoluble in ethanol*

Point de goutte : -5 à -16°C / *Drop point* : -5 to -16°C

Point éclair / *Flash point* : > 300°C (DGF C – IV 8)

Ce produit est végétalien / *This product is vegan*

APPLICATIONS:

Usage industriel, utilisation alimentaire (hors fritures) / *Industrial use, food use (excluding fried foods)*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Container de 900 kg – fût de 190kg – tonnelet de 50 kg / *900 kg container – 190 kg drum – 50 kg keg*

Matière première non dangereuse / *Non hazardous raw material*

A conserver dans des emballages hermétiquement clos / *Store in tightly closed containers*

Additives	This product doesn't contain additives
Allergen	This product doesn't contain food allergen (regulation EU No1169/2011 Annex II) and cosmetic allergen (regulation 1223/2009)
Animal Testing	This product has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk of BSE
California Prop 65	This product (CAS: 8001-22-7) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product doesn't contain CMR (directive 1272/2008/CE)
Composition	100% soy oil. The seeds contain from 17 to 27 % oil
Cosmetic	This product complies with Cosmetic regulation 1223/2009/CEE
Cosmos / Ecocert	This product is not accepted by Cosmos/ Ecocert
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	This product doesn't contain dioxane
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product complies with the European Pharmacopoeia
Food	Is a food grade product
Genetically Modified Organisms (GMO)	This product contain GMO
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Philippines PICCS , Taiwan TCSI, Korea KECI , Australia AICS , Canada DSL
Geographic origin (for plant)	North and South America. Plant (fam. Fabaceae) originating from China
Glycol ether	This product doesn't contain glycol ether
Halal	This product is not Halal certified
Heavy Metals	This product doesn't contain heavy metals
HS code	15079010
Irradiation / ionization	There is no ionization / irradiation during the manufacturing process
Kosher	This product is not Kosher certified
Latex	This product doesn't contain latex
Manufacturing location	Europe

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Microbiological data	This refined oil is deodorized (180 - 205°C) during the refining process, effectively eliminating microbiological activity. The water content (typically less than 0.5%) is low and provides an environment that is not suitable for microorganisms. Therefore this product is not an environment conducive to microbiological development Total aerobic: < 1000 cfu/g Absence of pathogenic germs in 1 g
Nanomaterials	This product doesn't contain nanomaterials (commission recommendation, 2011/696 and cosmetic regulation 1223/2009)
Nutritional data	Nutritional information (for 100g): Caloric value: 3700 KJ (900Kcal), proteins:0g, glucides:0g, lipids (fatty acids): 100g, saturated: 15g, Mono-saturated: 26g, polyunsaturated: 59g, salt: 0g
Origin	100% vegetable
Pesticide	This product doesn't contain pesticides
Phthalate	This product doesn't contain phthalate
Preservative	This product doesn't contain preservative (cosmetic regulation 1223/2009/CEE and 2003/15/CE)
Process	This oil is obtained partly by pressure, partly by solvent extraction, then by chemical refining
REACH	Exempted from the 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	This product doesn't contain residual solvents (note CPMP/ICH/283/95)
RSPO	This product doesn't contain palm – not concerned
Shelf Life before re-check	18 months
Substances of Very High Concern (SVHC)	This product doesn't contain SVHC
Volatiles organic compounds (VOC)	This product doesn't contain VOC (directive N°2010/79/UE)

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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.*