

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE DE SOJA RAFFINEE	Mai 2025 / May 2025
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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
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
Indice de refraction / <i>Refractive index at 20°C</i>	Environ / <i>about</i> 1.475	Ph. Eur.2.2.6
Densité à 20°C / <i>Density at 20°C</i>	Environ / <i>about</i> 0.922 g/cm ³	Ph.Eur.2.2.5
Impuretés à réaction alcaline / <i>Impurities to alkaline reaction</i>	Conforme / <i>compliant</i>	Ph. Eur.2.4.19
Insaponifiable / <i>Unsaponifiable</i>	≤ 1.5 % (m/m)	Ph. Eur.2.5.7
Teneur en eau / <i>water content</i>	≤ 0.1 %	Ph. Eur.2.5.32
Composition en acides gras / Fatty acid composition		
< C 14 : 0	≤ 0.1 %	Ph. Eur. 2.4.22
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 – 5.4 %	
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>	4.5 – 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 %	

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

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

Ce produit est végétalien / *This product is vegan*

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ISO 16128 :

NI = 1 NOI = 1

OI = 0 OOI = 0

APPLICATIONS:

Usage industriel, cosmétique, pharmaceutique, alimentaire / *Industrial, cosmetic, pharmaceutic, food use*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Container de 900 kg – fût de 190kg – tonnelet de 27 kg / *900 kg container – 190 kg drum – 27 kg keg*

A conserver dans des emballages hermétiquement clos à l'abris de la chaleur et la lumière / *To be kept in hermetically sealed packaging away from heat and light*

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 & 2023/1545)	
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 & 2023/1490)	
Composition	100% soy oil. The seeds contain from 17 to 27 % oil INCI: 100 % Glycine soja oil	
Cosmetic	This product complies with Cosmetic regulation 1223/2009/CEE and tis amendments	
Cosmos / Ecocert	This product is not accepted by Cosmos because of solvent extraction	
Danger	This product is not classified as dangerous in accordance with CLP and ADR	
Dioxane	Complying to regulation 2023/915	
Ecolabel	No data available	
European Pharmacopeia	This product complies with the European Pharmacopoeia	
Food	Is a food grade product	
Genetically Modified Organisms (GMO)	This product doesn't contain GMO	
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Philippines PICCS ,	Taiwan TCSI, Korea KECL , Australia AIIC , Canada DSL; Thailand TECI
Geographic origin (for plant)	Europe, Africa, Brasil	
Glycol ether	Not expected but not analyzed	
Halal	This product is not Halal certified but complying with halal requirements	
Heavy Metals	Complying to regulation 2023/915	
HS code	15079010	
Irradiation / ionization	There is no ionization / irradiation during the manufacturing process	
Kosher	This product is not Kosher certified but complying with kosher requirements	
Latex	This product doesn't contain latex	
Manufacturing location	Europe	
Microbiological data	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	

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	conducive to microbiological development	
Microplastic	Not expected (2023/2055)	
Nanomaterials	This product doesn't contain nanomaterials (commission recommendation 2011/696 and cosmetic regulation 1223/2009)	
Nitrosamine	Not expected but not analyzed	
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 (soy)	
PAH/PFAS	Doesn't contain PAH or PFAS	
Pesticide	Complying to regulation 396/2005	
Phthalate	Not expected but not analyzed	
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 (hexane), then by chemical refining	
REACH	Exempted	
Residual Solvents	This product doesn't contain residual solvents (note CPMP/ICH/283/95) Residual Hexane content = 0 mg/kg	
RSPO	This product doesn't contain palm – not concerned	
Shelf Life before re-check	12 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 cancels and replaces all technical and regulatory previous documents.*