

	Dossier technique et réglementaire / <i>technical and regularoty document</i> HUILE DE SESAME RAFFINEE	Mars 2020 / March 2020
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INCI: **Sesamum indicum seed oil**
N° CAS: 8008-74-0
N°EINECS/ELINCS: 232-370-6

DESCRIPTION / DESCRIPTION:

Huile raffinée extraite des graines de sésame (*sesamum indicum L*) / *Refined oil extracted from sesame seeds (sesamum indicum L)*

Liquide clair, jaune pâle, presque inodore obtenu par extraction ou pression des graines mûres de *sesamum indicum L*, puis raffinée / *Clear, pale yellow, almost odorless liquid obtained by extraction or pressing of mature sesamum indicum seeds L, then refined*

Produit conforme à la Pharmacopée Européenne / *Product in accordance with the European Pharmacopoeia in force*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS :

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Densité à 20°C / <i>Density at 20°C</i>	Environ / about 0.919 g/cm ³	Ph. Eur 2.2.5
Indice de réfraction à 20°C / <i>Refractive index at 20°C</i>	1.470 – 1.476	Ph. Eur 2.2.6
Impuretés alcalines / <i>Alkaline Impurities</i>	Conforme / <i>Compliant</i>	Ph. Eur 2.4.19
Indice d'acide / <i>Acid value</i>	≤ 0.6 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 % (m/m)	Ph. Eur 2.5.7
Teneur en eau / <i>Water content</i>	≤ 0.1 %	Ph. Eur 2.5.32
Test huile de coton / <i>Cotton oil test</i>	Conforme / <i>Compliant</i>	Ph. Eur 6.7
Composition en triglycérides / <i>Triglycerides composition</i>		
LLL	7 – 19 %	Ph. Eur 2.2.29
OLL	13 – 30 %	Ph. Eur 2.2.29
PLL	5 – 9 %	Ph. Eur 2.2.29
OOL	12 – 23 %	Ph. Eur 2.2.29
POL	6 – 14 %	Ph. Eur 2.2.29
OOO	5 – 16 %	Ph. Eur 2.2.29
SOL	2 – 8 %	Ph. Eur 2.2.29
POO	2 – 10 %	Ph. Eur 2.2.29

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, miscible à l'éther et à l'éther de pétrole / *Practically insoluble in water and ethanol, miscible with ether and petroleum ether*

Point de solidification / *Solidification point*: ± 3 ou ± 6°C

Point de fumée / *Smoke point*: > 230°C

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Viscosité à 25°C / *Viscosity at 25°C*: 57 mPas

APPLICATIONS :

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

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

IBC de 900 kg, Fût de 190 ou 195 kg, tonnelet de 50 kg / *IBC of 900 kg, drum of 190 kg or 195 kg, keg of 50 kg*
Matière première non classifiée comme substance dangereuse (voir fiche de données de sécurité) / *Raw material not classified as dangerous substance (see safety data sheet)*

A conserver dans un récipient bien rempli, bien fermé, à l'abri de la lumière et de la chaleur / *Store in a well-filled container, well-closed, protected from light and heat*

Additives	Doesn't contain additives, antioxidants, the presence of formol, formol releasers, sulfates are 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. This product is derived from sesame seeds classified as allergen according to Directive 2003/89 / EC
Animal Testing	Has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk for BSE
California Prop 65	This product (CAS: 8008-47-0) 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% Sesamum indicum seed 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	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Korea KECL, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	Plant (fam. Pedaliaceae) originally from Africa. Its cultivation is very extensive (west and north-east Africa, India, China, Central America, USA...). The seed contains from 50 to 57.4% 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	1515091
Irradiation / ionization	Has not been irradiated or ionized
Kosher	<i>No data available</i>

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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)
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:16g, Mono-saturated: 39g, polyunsaturated: 45g, salt:0g
Origin	100% vegetable (matures seed of sesame). The seed contains from 50 to 57.4% of oil
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	The oil is obtained by extraction or pressing of mature sesamum indicum seeds L, then refined
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 cancels and replaces all technical and regulatory previous documents.*