

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE DE BOURRACHE RAFFINEE	Juillet 2018 / July 2018
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INCI: **Borago officinalis seed oil**
N° CAS: 225234-12-8
N°EINECS/ELINCS: –

DESCRIPTION / DESCRIPTION:

Huile provenant des sommités fleuries du Borago Officinalis, obtenue par extraction et raffinage. De couleur jaune pale presque *inodore* / Oil from the flowering tops of Borago Officinalis, obtained by extraction and refining. Pale yellow and almost odorless

Matière première d'origine végétale / Raw material of vegetable origin

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Densité à 20°C / <i>Density at 20°C</i>	Environ / about 0.923 g/cm ³	Ph. Eur 2.2.5
Indice de réfraction à 20°C / <i>Refractive index at 20°C</i>	Environ / about 1.477	Ph. Eur 2.2.6
Indice d'acide / <i>Acid value</i>	≤ 1 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
Impuretés à réaction alcaline / <i>Impurities to alkaline reaction</i>	Conforme / <i>Compliant</i>	Ph. Eur 2.4.19
Insaponifiable / <i>Unsaponifiable</i>	≤ 2 % (m/m)	Ph. Eur 2.5.7
Composition en acides gras / Fatty acid composition		
C 16: 0 Acide palmitique / <i>Palmitic acid</i>	9 – 13 %	Ph. Eur 2.4.22A
C 16: 1 Acide palmitoléique / <i>Palmitoleic acid</i>	≤ 0.5 %	Ph. Eur 2.4.22A
C 18: 0 Acide stéarique / <i>stearic acid</i>	2 – 6 %	Ph. Eur 2.4.22A
C 18: 1 Acide oléique / <i>Oleic acid</i>	14 – 20 %	Ph. Eur 2.4.22A
C 18: 2 Acide linoléique / <i>linoleic acid</i>	34 – 45 %	Ph. Eur 2.4.22A
C 18: 3 Acide linolénique (alpha) / <i>linolenic acid (alpha)</i>	≤ 1.5 %	Ph. Eur 2.4.22A
C 18: 3 Acide linolénique (gamma) / <i>linolenic acid (gamma)</i>	20 – 25 %	Ph. Eur 2.4.22A
C20 : 0 Acide arachidique / <i>Arachidic acid</i>	≤ 1 %	Ph. Eur 2.4.22A
C20: 1 Acide gadoléique / <i>Gadoleic acid</i>	3 – 5 %	Ph. Eur 2.4.22A
C 22: 0 Acide behénique / <i>Behenic acid</i>	≤ 0.5 %	Ph. Eur 2.4.22A
C 22: 0 Acide érucique / <i>Erucic acid</i>	1 – 4 %	Ph. Eur 2.4.22A
C 22: 0 Acide nervonique / <i>Nervonic acid</i>	1 – 3 %	Ph. Eur 2.4.22A
Autres acides gras / <i>Others fatty acids</i>	≤ 2 %	Ph. Eur 2.4.22A

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Septembre 2007 / *These features are in accordance with previous specifications dated on September 2007*

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

Insoluble dans l'eau et l'alcool, soluble dans les solutions lipophiles et miscible à l'éther de pétrole / *Insoluble in water and alcohol, soluble in lipophilic solutions and miscible with petroleum ether*

Point d'ébullition / *Boiling point:* > 250°C

Point d'éclair / *Flash point:* > 290°C

APPLICATIONS :

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

Diététique, cosmétologie / *Dietetics, Cosmetology*

CONDITIONNEMENT STANDARD / *STANDARD PACKAGING :*

Tonnelet de 5 à 50 kg – fût 190 kg / *Keg of 5 to 50 kg – drum 190 kg*

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

A conserver en emballage soigneusement fermé, sous atmosphère inerte à l'abri de la lumière et de la chaleur / *Store in a well-filled, well-closed container, protected from light and heat*

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: 225234-12-8) 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% Borago officinalis 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	<i>No data available</i>
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	This product is not compliant with inventories
Geographic origin (for plant)	Flower (fam. Boraginaceae). The seeds contain 29,8 to 38 % 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	15159099

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Irradiation / ionization	Has not been irradiated or ionized
Kosher	<i>No data available</i>
Latex	Doesn't contain latex
Manufacturing location	Europe
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 informations (for 100g): Caloric value: 3700 KJ (900Kcal), Proteins:0g, Glucides:0g, Lipids (fatty acids): 100g, saturated:16g, Mono-saturated: 28g, polyunsaturated: 56g, 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	The oil is obtained by mechanic extraction 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.*