

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE DE VASELINE CODEX FLUIDE	Août 2019 / <i>August 2019</i>
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INCI: **Paraffinum liquidum**

N°CAS: 8042-47-5

N°EINECS/ELINCS: 232-455-8

DESCRIPTION / DESCRIPTION:

L'huile de vaseline codex fluide ou huile de paraffine liquide légère est un mélange purifié d'hydrocarbures saturés liquides obtenus à partir du pétrole / *Vaseline liquid codex fluid or light liquid paraffin oil is a purified mixture of liquid saturated hydrocarbons obtained from petroleum.*

Produit conforme aux exigences de la Pharmacopée Européenne en vigueur (monographie : Paraffinum perliquidum) USP et FDA / *Product in compliance with the requirements of the European Pharmacopoeia in force (monograph : Paraffinum perliquidum) USP and FDA.*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Acidité ou alcalinité / <i>Alcidity or alkalinity</i>	Conforme / <i>Compliant</i>	Ph Eur en vigueur / <i>Ph Eur in force</i>
Densité relative à 20°C / <i>Relative density at 20°C</i>	0.810 – 0.875	
Viscosité dynamique à 20°C / <i>Dynamic viscosity at 20°C</i>	25 – 80 mPa.s	
Hydrocarbures arom.Polycyl / <i>Hydrocarbons arom.polycyl</i>	Conforme / <i>Compliant</i>	
Substances carbonisables / <i>Carbonizable substances</i>	Conforme / <i>Compliant</i>	
Paraffines solides / <i>Solid paraffins</i>	Conforme / <i>Compliant</i>	ISO 3104 / ASTMD 445
Viscosité cinématique à 40°C / <i>Cinematic viscosity at 40°C</i>	13 - 19 mm ² /s	

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Septembre 2017 / *These features are in accordance with previous specifications dated on September 2017*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Point éclair COC / *Flash point COC* : > 180°C

Apparence/aspect : incolore / transparent / *Appearance/ aspect : Colourless / Transparent*

Ce produit est végétalien / *this product is vegan*

Ce produit ne respecte pas les recommandations du COLIPA 14 / *This product is not complying to the COLIPA 14 recommendation*

APPLICATIONS:

Médecine, applications alimentaires et cosmétiques / *Medecine, food and cosmetic applications*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Fût plastique de 175 kg, IBC de 850 kg, tonnelet de 25 ou 50kg / *175 kg plastic drum, 850 kg IBC, 25 ou 50kg keg*

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: 8042-47-5) is not listed

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Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product is not classified as CMR
Composition	100% white mineral oil
Cosmetic	This product can be used in cosmetics industries, and is not listed as forbidden in annex II of EC 1223/2009
Cosmos / Ecocert	This product contains mineral derivatives – Not accepted by Cosmos
Danger	This product is classified as dangerous in accordance with CLP but not with ADR
Dioxane	This product doesn't contain dioxane
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product complies with the current European Pharmacopoeia
Food	This product is conform to FDA 21 CFR 172.878 & 178.3620(a)
Genetically Modified Organisms (GMO)	This product doesn't contain GMO (decree n°2012-128)
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Korea KECI, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	Not concerned
Glycol ether	This product doesn't contain glycol ether
Halal	This product complies to the halal requirement
Heavy Metals	Catalytic hydrogenation is used in the production process. The test results are below the detection limit (0.02ppm) for the elements used in the catalyst systems: Pt, Pd, Ni, Mo & Zn. The other in the ICH Q3D listed heavy metal could be excluded by process understanding.
HS code	27101985
Irradiation / ionization	There is no ionization / irradiation during the manufacturing process
Kosher	This product complies to the kosher requirement
Latex	This product doesn't contain latex
Manufacturing location	Europe (Netherlands & Germany)
Microbiological data	Formation of microbiological organisms is not expected due to its water content <1 00ppm
Nanomaterials	This product doesn't contain nanomaterials (cosmetic regulation 1223/2009)
Nutritional data	<i>No data available</i>
Origin	100% mineral
Pesticide	This product doesn't contain pesticides
Phthalate	This product doesn't contain phthalates
Preservative	This product doesn't contain preservative (cosmetic regulation 1223/2009/CEE and 2003/15/CE)
Process	Distillation, solvent extraction, dewaxing and high pressure hydrogenation (two-stage) batch-processing
REACH	This product is registered 01-2119487078-27
Residual Solvents	During the manufacturing process the solvents: 1,2-Dichloroethane (Class 1), Dichloromethane (class 2), N-Methylpyrrolidone (class 2) & Furfural (not listed) are used. In the hydration step a residual solvent content of max mg/kg, the following high-pressure hydrogenation reduces the content further. This product complies with the limits according to the ICH guideline EMA/CHMP/ICH/82260/2006.
RSPO	The product doesn't contain palm derivatives – Not concerned
Shelf Life before re-check	2 years
Substances of Very High Concern (SVHC)	This product doesn't contain SVHC
Volatiles organic compounds (VOC)	This product is not subject to VOC guidelines (directive 1999/13/EC & directive 2004/42/CE & Swiss VOC article 1) and has a VOC content of < 3%.

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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.*