	Dossier technique et réglementaire / <i>technical and regularoty document</i> <b>HUILE DE VASELINE CODEX FLUIDE</b>	Novembre 2020 / <i>November 2020</i>
---	--	--------------------------------------

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>	
Viscosité cinématique à 40°C / <i>Cinematic viscosity at 40°C</i>	13 - 19 mm <sup>2</sup> /s	ISO 3104 / ASTMD 445

**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*

<b>Additives</b>	This product doesn't contain additives
<b>Allergen</b>	This product doesn't contain food allergen (regulation EU No1169/2011 Annex II) and cosmetic allergen (regulation 1223/2009)
<b>Animal Testing</b>	This product has not been tested on animals
<b>BSE - Bovine Spongiform Encephalopathy</b>	No risk of BSE
<b>California Prop 65</b>	This product (CAS: 8042-47-5) is not listed

	Dossier technique et réglementaire / <i>technical and regulatory document</i> <b>HUILE DE VASELINE CODEX FLUIDE</b>	Novembre 2020 / November 2020
---	--	----------------------------------

<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	This product is not classified as CMR
<b>Composition</b>	100% white mineral oil
<b>Cosmetic</b>	This product can be used in cosmetics industries, and is not listed as forbidden in annex II of EC 1223/2009
<b>Cosmos / Ecocert</b>	This product contains mineral derivatives – Not accepted by Cosmos
<b>Danger</b>	This product is classified as dangerous in accordance with CLP but not with ADR
<b>Dioxane</b>	This product doesn't contain dioxane
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopoeia</b>	This product complies with the current European Pharmacopoeia
<b>Food</b>	This product is conform to FDA 21 CFR 172.878 & 178.3620(a)
<b>Genetically Modified Organisms (GMO)</b>	This product doesn't contain GMO (decree n°2012-128)
<b>Inventories</b>	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Korea KECI, Philippines PICCS, Australia AICS, Canada DSL
<b>Geographic origin (for plant)</b>	Not concerned
<b>Glycol ether</b>	This product doesn't contain glycol ether
<b>Halal</b>	This product complies to the halal requirement
<b>Heavy Metals</b>	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.
<b>HS code</b>	27101985
<b>Irradiation / ionization</b>	There is no ionization / irradiation during the manufacturing process
<b>Kosher</b>	This product complies to the kosher requirement
<b>Latex</b>	This product doesn't contain latex
<b>Manufacturing location</b>	Europe (Netherland & Germany)
<b>Microbiological data</b>	Formation of microbiological organisms is not expected due to its water content <1 00ppm
<b>Nanomaterials</b>	This product doesn't contain nanomaterials (cosmetic regulation 1223/2009)
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	100% mineral
<b>Pesticide</b>	This product doesn't contain pesticides
<b>Phthalate</b>	This product doesn't contain phthalates
<b>Preservative</b>	This product doesn't contain preservative (cosmetic regulation 1223/2009/CEE and 2003/15/CE)
<b>Process</b>	Distillation, solvent extraction, dewaxing and high pressure hydrogenation (two-stage) batch-processing
<b>REACH</b>	This product is registered 01-2119487078-27
<b>Residual Solvents</b>	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 5 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.
<b>RSPO</b>	The product doesn't contain palm derivatives – Not concerned
<b>Shelf Life before re-check</b>	2 years
<b>Substances of Very High Concern (SVHC)</b>	This product doesn't contain SVHC
<b>Volatiles organic compounds (VOC)</b>	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%.

----- END

Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*