	Dossier technique et réglementaire / <i>Technical and regulatory document</i> <b>HUILE DE VASELINE CODEX EPAISSE</b>	Mai 2025 / May 2025
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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 épaisse ou huile de paraffine liquide est un mélange purifié d'hydrocarbures saturés liquides obtenus à partir du pétrole / *Vaseline thick codex oil 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 liquidum) / *Product in compliance with the requirements of the current European Pharmacopoeia (monograph : Paraffinum liquidum)*

#### CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect		Visuel
Densité relative à 15 ou 20°C / <i>Relative density at 15 or 20°C</i>	0.85 – 0.88	ASTM D4052
Viscosité dynamique à 20°C / <i>Dynamic viscosity at 20°C</i>	110 – 230 mPa.s	ASTM D445
Viscosité cinématique à 40°C / <i>Cinematic viscosity at 40°C</i>	63 – 80 mm²/s	ISO 3104 / ASTM D 7279
Acidité ou alcalinité / <i>Acidity or alkalinity</i>	Conforme / <i>Compliant</i>	Ph Eur en vigueur / <i>Ph Eur in force</i>
Substances carbonisables / <i>Carbonizable substances</i>	Conforme / <i>Compliant</i>	
Paraffines solides / <i>Solid paraffins</i>	Conforme / <i>Compliant</i>	

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

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

Point éclair PM / *Flash point* : > 240°C

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

Insoluble dans l'eau / *Insoluble in water*

Iso 16128 : 0/0/0/0


#### APPLICATIONS:

*Cosmetic, pharmaceutical and general industrial applications*


#### CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Fût plastique de 175kg, IBC DE 850 kg, tonnelet de 25 ou 50kg / *175 kg plastic drum, 850 kg IBC, 25 or 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 & 2023/1545)
<b>Animal Testing</b>	This product has not been tested on animals since March 11, 2013
<b>BSE - Bovine Spongiform Encephalopathy</b>	No risk of BSE
<b>California Prop 65</b>	This product (CAS: 8042-47-5) is not listed
<b>Carcinogenic, Mutagenic</b>	This product is not classified as CMR (directive 1272/2008/CE & 2023/1490)

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<b>and Reprotoxic (CMR)</b>	
<b>Composition</b>	100% white mineral oil INCI : 100% Paraffinum liquidum
<b>Cosmetic</b>	This product can be used in cosmetics industries, complying with 1223/2009 & its amendments
<b>Cosmos / Ecocert</b>	This product contains mineral derivatives – Not accepted by Cosmos
<b>Danger</b>	This product is not classified as dangerous in accordance with CLP & ADR
<b>Dioxane</b>	This product doesn't contain dioxane or 1.4 dioxine
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopeia</b>	This product complies with the current European Pharmacopoeia
<b>Food</b>	Is not a food grade product
<b>Genetically Modified Organisms (GMO)</b>	This product doesn't contain GMO (decree n°2012-128)
<b>Inventories</b>	<div> Listed in China IECSC,  USA TSCA,  New Zealand NZIoC,  Korea KECL,  Philippines PICCS,  </div> <div> Australia AIIIC,  Canada DSL,  Taiwan TCSI,  Thailand TECI </div>
<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. Our test results support this statement, as the values of our investigations are Lead < 10 ppm Arsenic < 3 ppm Mercury < 1 ppm Cadmium < 3 ppm Antimony < 1 ppm
<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>	UE
<b>Microbiological data</b>	Formation of microbiological organisms is not expected due to its water content <100ppm
<b>Microplastics</b>	Not expected (2023/2055). note that a content determination of microplastics is not part of our quality control.
<b>Nanomaterials</b>	This product doesn't contain nanomaterials (2011/696 & cosmetic regulation 1223/2009)
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	100% mineral
<b>PAH/PFAS</b>	The PAH content is at trace levels, well below 0.2 mg/kg. Polycyclic aromatic hydrocarbons are components that occur in mineral oil products because of the petroleum origin and have been reduced to technical unavoidable trace levels by several purification steps during the refining process PFAS are not expected
<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

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<b>REACH</b>	This product is registered 01-2119487078-27
<b>Residual Solvents</b>	<p>During manufacturing of our white mineral oils, solvents are used in the extraction steps, which are listed in ICH guideline EMA/CHMP/ICH/82260/2006. In the process control of these production steps, a residual content of these solvents of max. 5 mg/kg is ensured via a suitable characterization. In addition to this, this product is treated after the extraction steps by high-pressure hydrogenation, which reduces the solvent content further.</p> <p>The final product complies with the limit values of the used solvents according to the ICH guideline EMA/CHMP/ICH/82260/2006. Please note that tests of this parameter are only part of the process control during the extraction steps and not carried out during quality control of the finished products.</p>
<b>RSPO</b>	The product doesn't contain palm derivatives – Not concerned
<b>Shelf Life before re-chck</b>	24 months
<b>Substances of Very High Concern (SVHC)</b>	This product doesn't contain SVHC
<b>Volatiles organic compounds (VOC)</b>	This product 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.*