	Dossier technique et réglementaire / <i>technical and regularoty document</i> HUILE DE VASELINE CODEX FLUIDE	Mai 2025 / May 2025
---	--	------------------------

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
Aspect		Visuel
Densité relative à 15°C / <i>Relative density at 15°C</i>	0.84 – 0.865	ISO 12185 / ASTM D4052
Viscosité dynamique à 20°C / <i>Dynamic viscosity at 20°C</i>	25 – 80 mPa.s	Ph Eur / ASTM D445
Viscosité cinématique à 40°C / <i>Cinematic viscosity at 40°C</i>	13 - 19 mm²/s	ISO 3104 / ASTMD445
Acidité ou alcalinité / <i>Alcidity or alkalinity</i>	Conforme / <i>Compliant</i>	Ph Eur
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 COC / *Flash point COC* : > 180°C

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

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

Iso 16128 : 0/0/0/0


APPLICATIONS:

Applications pharmaceutique et cosmétiques / *pharmaceutical & 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 & 2023/1545)
Animal Testing	This product has not been tested on animals since March 11, 2009
BSE - Bovine Spongiform Encephalopathy	No risk of BSE
California Prop 65	This product (CAS: 8042-47-5) is not listed

	Dossier technique et réglementaire / <i>technical and regularoty document</i> HUILE DE VASELINE CODEX FLUIDE	Mai 2025 / May 2025
---	--	------------------------

Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product is not classified as CMR (directive 1272/2008/CE & 2023/1490)	
Composition	100% white mineral oil INCI : 100% Paraffinum liquidum	
Cosmetic	This product can be used in cosmetics industries, complying with 1223/2009 & its amendments	
Cosmos / Ecocert	This product contains mineral derivates – Not accepted by Cosmos	
Danger	This product is classified as dangerous in accordance with CLP, see our MSDS	
Dioxane	This product doesn't contain dioxane or 1.4 dioxine	
Ecolabel	No data available	
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	Listed in China IECSC, USA TSCA, New Zealand NZIoC, Korea KECL, Philippines PICCS,	Australia AIIIC, Canada DSL, Taiwan TCSI, Thailand TECL
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. Our test results support this statement, as the values of our investigations (ICP-OES for white oils, ICP-MS for paraffins and waxes) are below the detection limit of 0.02 ppm. The presence of other in the ICH Q3D listed elements, which are not used in the catalysts, could be excluded by product and 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	Various UE & non-UE	
Microbiological data	Formation of microbiological organisms in not expected due to its water content <100ppm	
Microplastics	Not expected (2023/2055). note that a content determination of microplastics is not part of our quality control.	
Nanomaterials	This product doesn't contain nanomaterials (2011/696 & cosmetic regulation 1223/2009)	
Nutritional data	No data available	
Origin	100% mineral	
PAH/PFAS	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	
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	

	Dossier technique et réglementaire / <i>technical and regulatory document</i> HUILE DE VASELINE CODEX FLUIDE	Mai 2025 / May 2025
---	--	------------------------

Residual Solvents	<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>
RSPO	The product doesn't contain palm derivatives – Not concerned
Shelf Life before re-check	24 months
Substances of Very High Concern (SVHC)	This product doesn't contain SVHC
Volatiles organic compounds (VOC)	This product 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.*