

	Dossier technique et réglementaire / <i>technical and regulatory document</i> VASELINE CODEX A	Mars 2025 / March 2025
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Nom INCI / <i>INCI name</i>	N° CAS	N° EINECS/ELINCS	Composition
CERA MICROCRISTALLINA	64742-60-5 / 63231-60-7	265-163-4 / 264-038-1	9-25%
PARAFFINUM LIQUIDUM	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	60-66%
PARAFFIN	64742-51-4 / 8002-74-2	265-154-5 / 232-315-6	10-30%

DESCRIPTION / *DESCRIPTION* :

Mélange de cires et d'huiles minérales hautement purifiées et raffinées / *Mixture of wax and mineral oil highly purified and refined*

Matière Première conforme à la Pharmacopée Européenne en vigueur (monographie 1799 : Vaseline blanche), à la Pharmacopée Française, à la Pharmacopée Britannique / *Raw material according to the European Pharmacopoeia in force (monograph: **White Vaseline**), French pharmacopia and british pharmacopia.*

CARACTERISTIQUES GARANTIES / *GUARANTEED SPECIFICATIONS:*

CARACTERISTIQUES	SPECIFICATIONS	METHODES / <i>METHODS</i>
Aspect à 20 °C	Pâte onctueuse	Visuelle
Couleur	Blanche	Visuelle
Odeur	Caractéristique	Olfactive
Pénétration au cône à 25°C : 1/10 m	175 – 195	Ph eur
Point de goutte	46 – 52 °C	Ph eur

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

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

Pratiquement insoluble dans l'eau / *Practically insoluble in water*

Densité à 20°C / Density at 20°C: about 0.840

Vegan product

Natural Index (ISO 16128) :

natural : 0 / natural origin : 0 / organic : 0 / organic origin : 0

APPLICATIONS :

Pharmaceutique / cosmétique : crème et lait cosmétiques tels que les soins hydratants du corps et du visage et des mains. Son côté « glissant » et son excellente facilité d'application en font une base très intéressante pour les crèmes de massage. / *Pharmaceutique / cosmetics : creams and lotions such as body, hand and face hydrating products. Its lubricity and ease of application make it a very interesting base for massage creams.*

CONDITIONNEMENT STANDARD / *STANDARD PACKAGING* :

Fut 175 kg, tonnelet de 45kg / *175 kg drum, 45kg keg*

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

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Additives	Contain additive: max 10 ppm BHT
Allergen	Doesn't contain cosmetic allergen (regulation 1223/2009 & 2023/1545) and food allergen (regulation 1169/2011 annex II)
Animal Testing	Has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk for BSE
California Prop 65	<i>No data available</i>
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Doesn't contain CMR according to 1272/2008 & 2023/1490
Composition	CERA MICROCRISTALLINA + PARAFFINUM LIQUIDUM + PARAFFIN
Cosmetic	Compliant with regulation CE 1223/2009 and its amendments
Cosmos / Ecocert	This product is not accepted by cosmos standards
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	Doesn't contain dioxane
Ecolabel	<i>No data available</i>
European Pharmacopeia	Compliant with the European Pharmacopoeia
Food	Is not a food grade product
Genetically Modified Organisms (GMO)	Doesn't contain GMO
Inventories	<i>No data available</i>
Geographic origin (for plant)	Not concerned
Glycol ether	Doesn't contain Glycol ether
Halal	Contains no animal products and/or ethyl alcohol (residual extraction solvent or natural). The source of the product is from petrochemical origin. The equipment used for manufacturing these products is not used for the manufacture of other products of animal origin or products containing ingredients of animal origin. The product is stored in area dedicated to pharmaceutical product
Heavy Metals	Doesn't contain
HS code	2712109000
Irradiation / ionization	Has not been irradiated or ionized
Kosher	Contains no animal products and/or ethyl alcohol (residual extraction solvent or natural). The source of the product is from petrochemical origin. The equipment used for manufacturing these products is not used for the manufacture of other products of animal origin or products containing ingredients of animal origin. The product is stored in area dedicated to pharmaceutical product
Latex	Doesn't contain latex
Manufacturing location	France
Microbiological data	This product is free of any trace of water and it is manufactured at temperature of 90°C, we believe that under these conditions there is no risk of microbiological proliferation

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Microplastics	Doesn't contain (2023/2055)
Nanomaterials	Doesn't contain nanomaterials (commission recommendation 2011/696 and cosmetic regulation 1223/2009)
Nitrosamine	Doesn't contain
Nutritional data	Not concerned
Origin	100% petrochemical
PAH/ PFAS	Doesn't contain
Pesticide	Doesn't contain pesticides
Phthalate	Doesn't contain phthalates
Preservative	Contain BHT 10ppm max
Process	Blending, Heating and stirring of wax + mineral oil + paraffin wax
REACH	Component are Registered : cas n° 8042-47-5 = reach n°01-2119487078-27 cas n° 63231-60-7 = reach n°01-2119495561-32 cas n° 8002-74-2 = reach n°01-2119488076-30
Residual Solvents	Doesn't contain residual solvent (note CPMP/ICH/283/95)
RSPO	This product doesn't contain palm oil – Not concerned
Shelf Life	4 years
Substances of Very High Concern (SVHC)	Doesn't contain SVHC
Volatiles organic compounds (VOC)	Doesn't contain VOC (directive n°2010/79/UE)

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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.*