	Dossier technique et réglementaire / <i>technical and regularoty document</i> <b>VASELINE CODEX A</b>	Mai 2020 / May 2020
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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	15-25%
PARAFFINUM LIQUIDUM	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	55-70%
PARAFFIN	64742-51-4 / 8002-74-2	265-154-5 / 232-315-6	5-15%

**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 / METHODS
Aspect à 20 °C	Pâte onctueuse	Visuelle
Couleur	Blanche	Visuelle
Odeur	Néant	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**

**Ces caractéristiques sont conformes aux précédentes spécifications datées de octobre 2005 / These features are in accordance with previous specifications dated on October 2005**

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

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

Point éclair / *Flash point*: > 182°C (ASTM D-92)

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

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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<b>Additives</b>	Doesn't contain additive
<b>Allergen</b>	Doesn't contain cosmetic allergen (regulation 1223/2009) and food allergen (regulation 1169/2011 annex II)
<b>Animal Testing</b>	Has not been tested on animals
<b>BSE - Bovine Spongiform Encephalopathy</b>	No risk for BSE
<b>California Prop 65</b>	<i>No data available</i>
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	Doesn't contain CMR according to Annex VI of Directive CE 1272/2008
<b>Composition</b>	See first page
<b>Cosmetic</b>	Complies with regulation CE 1223/2009
<b>Cosmos / Ecocert</b>	<i>No data available</i>
<b>Danger</b>	This product is not classified as dangerous in accordance with CLP and ADR
<b>Dioxane</b>	Doesn't contain dioxane
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopeia</b>	Compliant with the European Pharmacopoeia
<b>Food</b>	Is not a food grade product
<b>Genetically Modified Organisms (GMO)</b>	Doesn't contain GMO
<b>Inventories</b>	<i>No data available</i>
<b>Geographic origin (for plant)</b>	Not concerned
<b>Glycol ether</b>	Doesn't contain Glycol ether
<b>Halal</b>	Contains no animal products and/or ethyl alcohol (residual extraction solvent or natural). The source of the product is from mineral. 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
<b>Heavy Metals</b>	<p>These raw materials, highly refined by hydrogenation, do not contain any (intentionally added) heavy metals or metal reagents as listed in Classes 1 - 4 of Guideline for Elemental Impurities. Metals Ni (Class 2A) and Mo (Class 3) are employed as catalyst substances for hydrogenation. These metals could not be detected in the product (concentration below detection limit of &lt; 1 ppm).</p> <p>Based on the well known manufacturing, refining process and regularly quality controls the appearance of metal catalysts or metal reagents in the finished product can be excluded; respectively metal concentrations will be considerably below the maximum allowed values as pointed out in above</p>
<b>HS code</b>	<i>No data available</i>
<b>Irradiation / ionization</b>	Has not been irradiated or ionized
<b>Kosher</b>	Contains no animal products and/or ethyl alcohol (residual extraction solvent or natural). The source of the product is from mineral. 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

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<b>Latex</b>	Doesn't contain latex
<b>Manufacturing location</b>	France
<b>Microbiological data</b>	<i>No data available</i>
<b>Nanomaterials</b>	Doesn't contain nanomaterials (commission recommendation 2011/696 and cosmetic regulation 1223/2009)
<b>Nutritional data</b>	Not concerned
<b>Origin</b>	100% mineral
<b>Pesticide</b>	Doesn't contain pesticides
<b>Phthalate</b>	Doesn't contain phthalates
<b>Preservative</b>	Doesn't contain preservative
<b>Process</b>	Mixture of wax and mineral oil highly purified and refined
<b>REACH</b>	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
<b>Residual Solvents</b>	<p>The raw materials, highly refined by hydrogenated, do not contain any (intentionally added) solvents listed in class 1, class 2 or class 3 of ICH-Guideline „Residual Solvents“(implemented under General Chapter 5.4 of European Pharmacopoeia 9.0 (2017)) and USP &lt;467&gt; Residual Solvents.</p> <p>Based on the well-known manufacturing and refining process and regularly quality controls the appearance of solvents in the finished product can be excluded, respectively solvent concentrations will be considerably below the maximum allowed values as pointed out in ICH-Guideline; refer to ICH Guideline „IMPURITIES: GUIDELINE FOR RESIDUAL SOLVENTS“Q3C (R6) dated October 20, 2016.</p>
<b>RSPO</b>	This product doesn't contain palm oil – Not concerned
<b>Shelf Life</b>	4 years
<b>Substances of Very High Concern (SVHC)</b>	Doesn't contain SVHC
<b>Volatiles organic compounds (VOC)</b>	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.*