

	Dossier technique et réglementaire / <i>technical and regulatory document</i> VASELINE PHARMACEUTIQUE	Juillet 2018 / July 2018
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INCI: **Petrolatum**
N° CAS: 8009-03-8
N°EINECS/ELINCS: 232-373-2

DESCRIPTION / DESCRIPTION :

Mélange purifié et décoloré d'hydrocarbures semi-solides obtenus à partir du pétrole / *Purified and discolored mixture of semi-solid hydrocarbons obtained from petroleum*

Masse blanche, translucide, de consistance onctueuse, légèrement fluorescente à la lumière du jour / *White, translucent mass, unctuous consistency, slightly fluorescent in daylight*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie: **Vaseline blanche**) / *Raw material according to the European Pharmacopoeia in force (monograph: **White Vaseline**)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect à 20°C / <i>Aspect at 20 °C</i>	Pâte blanche / <i>White paste</i>	Visuelle / <i>Visual</i>
Point de goutte / <i>Drop point</i>	35 - 70°C	Ph.Eur.2.2.17
Cendres sulfuriques / <i>Sulfuric ashes</i>	≤ 0.05 %	Ph.Eur.2.4.14
Consistance à 25 °C / <i>Consistency at 25 °C</i>	60 – 300	Ph.Eur.2.9.9
Hydrocarbures aromatiques polycycliques / <i>Polycyclic aromatic hydrocarbons</i>	Conforme / <i>compliant</i>	Ph.Eur. 6.2
Acidité ou alcalinité / <i>Acidity or alkalinity</i>	Conforme / <i>compliant</i>	Ph.Eur. 6.2

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Mars 2010 / These features are in accordance with previous specifications dated on March 2010

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Non adapté à un usage oral / *Not suitable for oral use*

Pratiquement insoluble dans l'eau, l'alcool et le glycérol / *Practically insoluble in water, alcohol and glycerol*

Soluble dans le chlorure de méthylène / *Soluble in methylene chloride*

Point de fusion / *Melting point*: 48 – 56°C (DIN ISO 2207)

Point éclair / *Flash point*: > 150°C (DIN ISO 2592)

Viscosité systématique à 100°C / *Systematic viscosity at 100°C*: 5 – 10 mm²/s (DIN 51 562)

Densité à 20°C: environ 0.9 g/cm³ / *Density at 20°C: about 0.9 g/cm³*

Couleur: Blanc à jaune / *Color: light to yellow*

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APPLICATIONS :

La vaseline est essentiellement utilisée dans les préparations dermatologiques comme véhicule de principes actifs en raison de sa grande inertie et de son effet occlusif favorisant la pénétration percutanée / *Vaseline is mainly used in dermatological preparations as a vehicle of active ingredients because of its high inertia and its occlusive effect promoting percutaneous penetration*

Moins utilisée dans l'industrie cosmétique en raison de son toucher peu agréable / *Less used in the cosmetics industry because of its unpleasant feel*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Fut 175 kg / 175 kg barrel

A conserver dans un emballage bien rempli, soigneusement fermé, à l'abri de la lumière et de la chaleur / *Store in a well-filled container, tightly closed, protected from light and heat*

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

Additives	The presence of additives, formol or formol releasers are not expected but not analyzed, doesn't contain antioxidants, contain natural tocopherol (25ppm)
Allergen	<i>No data available</i>
Animal Testing	Has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	No risk for BSE
California Prop 65	This product (CAS:8009-03-8) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Doesn't contain CMR according to Annex VI of Directive CE 1272/2008
Composition	Paste mixture of refined hydrocarbons, petrolatum
Cosmetic	Complies with regulation CE 1223/2009 but exempted annex II and can be use as cosmetic ingredient
Cosmos / Ecocert	<i>No data available</i>
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	<i>No data available</i>
Ecolabel	<i>No data available</i>
European Pharmacopeia	Compliant with the European Pharmacopoeia
Food	<i>No data available</i>
Genetically Modified Organisms (GMO)	Doesn't contain GMO
Inventories	IECSC China, TSCA USA, NZIoC New Zealand, KECI Korea, PICCS Philippines, AICS Australia, DSL Canada
Geographic origin (for plant)	<i>No data available</i>
Glycol ether	The presence of Glycol ether is not expected but not analyzed
Halal	<i>No data available</i>
Heavy Metals	Complies with European regulation 1881/2006 on the fixing of maximum levels
HS code	27121090
Irradiation / ionization	Has not been irradiated or ionized
Kosher	<i>No data available</i>
Latex	Doesn't contain latex

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Manufacturing location	Europe
Microbiological data	This product is not favorable to microbiological development (total aerobic: < 1000 cfu/g, absence of pathogens germs in 1 g)
Nanomaterials	Doesn't contain nanomaterials as ingredient
Nutritional data	<i>No data available</i>
Origin	100% mineral
Pesticide	Complies with European Regulation EC 396/2005 on the presence of pesticides in products of plant and animal origin
Phthalate	The presence of phthalates is not expected but not analyzed
Preservative	This product contain natural tocopherol at 25 ppm
Process	Soft wax + oil composant + microcrystalline waxe (mix in tank) -> filtration station -> catalyst (hydrogenation with high pressure) -> final tank: filling in bulk – filling in drums
REACH	Registered 01-211949412-42
Residual Solvents	Doesn't contain residual solvents
RSPO	This product doesn't contain palm oil – Not concerned
Shelf Life	24 months
Substances of Very High Concern (SVHC)	Doesn't contain SVHC according to Annex XIV of the regulation REACH as ingredient
Volatiles organic compounds (VOC)	Doesn't contain VOC beyond the authorized limits (because of the ambient pollution, it is impossible to exclude a possible contamination at the level of traces)

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