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|  | Dossier technique et réglementaire <i>Technical and regulatory document</i> VASELINE PHARMACEUTIQUE | Octobre 2024 / <i>October 2024</i> |
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INCI: **Petrolatum**
N° CAS: 8009-03-8
N°EINECS/ELINCS: 232-373-2

DESCRIPTION / DESCRIPTION :

Blend of refined paraffinic hydrocarbons; petroleum jelly; petrolatum; vaseline

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

Le produit contient un agent antioxydant pour la stabilité / *The product contains an antioxidant agent for stability*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie: **1799**) / *Raw material according to the European Pharmacopoeia in force (monograph: 1799)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

| CARACTERISTIQUES | SPECIFICATIONS | METHODES / METHODS |
|--|-----------------------------|--------------------|
| Point de figeage | 50 – 56 °C | ISO 2207 |
| Point de goutte / <i>Drop point</i> | 35 - 70°C | Ph.Eur.2.2.17/B |
| Pénétration au cône / Consistance à 25 °C / <i>Consistency at 25 °C</i> 1/10mm | 140 - 160 | DIN 51580 |
| Couleur Lovibond jaune | 0-0.5 | DGF C-IV 4b, mod |
| Viscosité cin. à 100 °C | 5 – 9 mm ² /s | ASTM D7042 |
| Cendre sulfate | 0 – 0.05% | Ph.Eur. 1799 |
| Acidité ou alcalinité / <i>Acidity or alkalinity</i> | Conforme / <i>compliant</i> | Ph.Eur. 1799 |

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

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*

Produit végétalien / *vegan product*


ISO 16128 :

Natural index :0 Natural origin index :0

Organic index :0 Organic origin index:0

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*

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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 ouverture total 195 kg / 195 kg full opening barrel

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| Additives | The presence of Formaldehyde, Bisphenol A, Bisphenol F is not expected but not analyzed, doesn't contain antioxidants, Contains tocopherol (max 25ppm) |
| Allergen | To the best of our present knowledge, this product does not contain substances listed under Annex II (Substances or products causing allergies or intolerances) of Regulation (EU) No 1169/2011 on the provision of food information to consumers and its amendments. To the best of our present knowledge, this product does not contain allergens listed in Regulation (EU) No 1223/2009 (annex III) and its amendments. |
| Animal Testing | Has not been tested on animals |
| BSE - Bovine Spongiform Encephalopathy | No risk for BSE |
| California Prop 65 | This product does not contain any substances listed on the current version of the California Proposition 65. |
| Carcinogenic, Mutagenic and Reprotoxic (CMR) | This product does not contain any CMR-substances classified as CMR category 1A, 1B and 2 in accordance with Regulation 1272/2008 (EC) and its adaptations. |
| Composition | Blend of refined paraffinic hydrocarbons; petroleum jelly; petrolatum; vaseline |
| Cosmetic | Complies with regulation 1223/2009 and last amendments (2023/1490 & 2023/1545) |
| Cosmos / Ecocert | Not accepted by Cosmos because it's synthetic origin |
| Danger | This product is not classified as dangerous in accordance with CLP and ADR |
| Dioxane | Doesn't contain dioxine |
| Ecolabel | No data available |
| European Pharmacopeia | Compliant with the European Pharmacopoeia monograph 1799 |
| Food | Is not a food grade product |
| Genetically Modified Organisms (GMO) | Doesn't contain GMO |
| Inventories | Listed in: Australian Inventory of Industrial Chemicals - ZAU_AIIC Canadian Domestic Substances List (DSL) - DSL Switzerland. Consolidated Inventory (based on EU-EINECS and EU-NLP) - CH INV China. Inventory of Existing Chemical Substances in China (IECSC) - IECSC Japan. ENCS - Existing and New Chemical Substances Inventory - ENCS (JP) Japan. ISHL - Inventory of Chemical Substances - ISHL (JP) Korea. Korean Existing Chemicals Inventory (KECI) - KECI (KR) Philippines Inventory of Chemicals and Chemical Substances (PICCS) - PICCS (PH) Taiwan Chemical Substance Inventory (TCSI) - ZTW_INV United States TSCA Inventory - TSCA |
| Geographic origin (for plant) | Not concerned (doesn't contain plant) |
| Glycol ether | The presence of Glycol derivated is not expected but not analyzed |
| Halal | Product is made by a process in which only auxiliaries of non-animal origin have been used. Product is made by a process in which only auxiliaries of non-ethanol origin have |

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| | <p>been used. Product is made by a process without the use of any enzymes. Enzymes, material of animal origin and ethyl alcohol is not used at any time at the equipment of each production line, on which the product is produced. Product is produced under muslimic supervision, a Halal Certificate is available.</p> |
| Heavy Metals | <p>Product does not contain any (intentionally added) heavy metals or metal reagents as listed in Classes 1 - 4 of Guideline for Elemental Impurities.</p> <p>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 < 1 ppm).</p> <p>Based on the well known manufacturing and 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 mentioned guideline.</p> |
| HS code | 27121090 |
| Irradiation / ionization | Has not been irradiated or ionized |
| Kosher | Product is produced under rabbinical supervision, a Kosher Certificate is available. |
| Latex | Not expected |
| Manufacturing location | Europe (Germany) |
| Microbiological data | <p>Usually, refined hydrocarbon waxes and petroleum jellies are not the target for microorganisms (e.g. germs, fungi, mould, yeasts, and bacteria) due to the lack of water content, humidity and absence of a suitable inoculum. Thus pure refined hydrocarbon waxes and petroleum jellies will not be the base for or promote microbiological growth if stored properly.</p> <p>Statistical testing of our products for fungi and bacteria (Escherichia coli; Staphylococcus aureus; Enterobacteriaceae; Pseudomonas; Salmonella) according to European Pharmacopoeia, General Chapter 5.1.4. "Microbiological quality of pharmaceutical preparations" gave the following (typical) results:</p> <ul style="list-style-type: none"> - Germ count of bacteria: < 1,0 *10¹ cfu/g - Germ count of fungi: < 1,0 *10¹ cfu/g - Enterobacteriaceae and certain gramnegative bacteria (Escherichia coli; Salmonella): < 10 cfu/g - Staphylococcus aureus: not detectable - Pseudomonas: not detectable |
| Microplastic | <p>In the EU the term 'microplastic' means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where $\geq 1\%$ w/w of particles have (i) all dimensions $1\text{ nm} \leq x \leq 5\text{ mm}$, or (ii), for fibres, a length of $3\text{ nm} \leq x \leq 15\text{ mm}$ and length to diameter ratio of > 3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable.</p> <p>This product does not contain intentionally added microplastics nor synthetic polymer microparticles as mentioned in Regulation (EU) 2023/2055 amending Annex XVII to Regulation (EC) No 1907/2006.</p> |
| Nanomaterials | <p>This product is neither defined as such nor contains nanomaterials intentionally produced or intentionally introduced in terms of:</p> <ul style="list-style-type: none"> - European Cosmetics Regulation (EU) 1223/2009; Article 16; - Medical Devices Regulation (EU) 2017/745; Article 2 (18); - French Decree no. 2012-232. |
| Nitrosamines | <p>Product does not consist of intentionally added nitrosamines, nitrosamine precursors or substances, which may form and/or release nitrosamines. Excipient Nitrosamines Risk Evaluation has been done according to European Medicines Agency (EMA) requirements and International Pharmaceutical Excipients Council Europe (IPEC) Questionnaire. Based on the materials and the manufacturing process there are no nitrites, nitrates, nitrosamines, amines and/or nitrosating agents present in manufacturing process as raw material, intermediate, reagent, catalyst, solvent,</p> |

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| | processing aids. Thus, the presence of nitrosamines in our products can be excluded. |
| Nutritional data | Not concerned |
| Origin | 100% mineral |
| PAH | Not expected but not analyzed |
| Pesticide | Not expected |
| Phthalate | The presence of phthalates is not expected but not analyzed |
| Preservative | This product contains following stabilizer: dl-Alpha-Tocopherol (vitamin E) <u>3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol</u> (Cas n° :10191-41-0 / 233-466-0) Max 25 PPM This product does not contain any preservatives. |
| Process | Slack wax + oil composant + Brightstock-Slackwax/micro wax (mix in tank) ↓ Blending ↓ hydrogenation with high pressure ↓ final tank |
| REACH | Registered 01-211940412-42 |
| Residual Solvents | Product is manufactured without any organic solvent and complies with the requirements on residual solvents from Ph. Eur. (Chapter 5.4) and USP (Chapter 467). Based on raw material and production process no solvents according to "Impurities Guideline for Residual Solvents" (EMA/CHMP/ICH/82260/2006 former CPMP/ICH/283/95) are expected to be present in this product. |
| RSPO | This product doesn't contain palm oil – Not concerned |
| Shelf Life | 3 years |
| Substances of Very High Concern (SVHC) | This product does not contain substances of very high concern (SVHC) as mentioned in the current SVHC-list with >0.1 % (w/w). |
| Volatiles organic compounds (VOC) | <u>Swiss VOC Ordinance 814.018 (Ordinance on the Incentive Tax on Volatile Organic Compounds)</u> As the product has a vapor pressure lower than 0,01 KPa at 20°C it is not considered to be a VOC under this law. The boiling range of the product at atmospheric pressure is higher than 250°C, so it has to be considered as not VOC containing under this law. <u>Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) and its amendments</u> As the product has a vapor pressure lower than 0,01 KPa at 20°C it is not considered to be a VOC under this law. The boiling range of the product at atmospheric pressure is higher than 250°C, so it has to be considered as not VOC containing under this law. |

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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.*