

1088-VASELINE SOFT**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Vaseline soft

Bulk code: 1088

Internal code: 405863

1.2. Synonyms

Paraffinum molle; Albolene; Cosmolene; White petroleum jelly; White soft paraffin; Petrolatum; White petrolatum; Paraffin ointment; Vaseline; White Vaseline; Officinal Vaseline.

2. DESCRIPTION

Appearance: Soft, translucent and unctuous to the touch.

Colour: Colourless to white.

Odour: Odourless.

Origin: Non-animal. The raw materials that make up the petroleum jelly are derived from petroleum.

Geographical origin: Spain.

3. COMPOSITION/INFORMATION ON COMPONENTS

Components: A mixture of hydrogenated raw materials (oils, waxes and paraffins).

INCI substance	CAS No	Weight %
Paraffinum liquidum	8042-47-5	50-80
Hydrogenated Microcrystalline wax	64742-60-5	10-20
Paraffin	64742-51-4/8002-74-2	10-20

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Petroleum jelly is compatible with oils and the different products added in cosmetic and pharmaceutical preparations.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

Food industry use: Vaseline soft is used as a protection and lubrication product in the food and pharmaceutical industries.

1088-VASELINE SOFT**6. DOSAGE**

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container.

Complies with all current pharmacopoeias: Royal Spanish Pharmacopoeia, EuP. BP, USP, CODEX. NSF-H1 (Register No 151580).

The documentation available related to the product's regulatory compliance is included below.

TSE & BSE:

The raw materials in the VASELINE SOFT product are not genetically modified and do not contain products with a risk of transmitting animal spongiform encephalopathy agents (TSE & BSE).

GMOs:

The product and its component raw materials do not contain genetically modified organisms (GMOs). It therefore complies with European Regulation (EC) 1829/2003 and (EC) 1830/2003 and European Directive 2001/18/EC.

CMR substances:

The product does not contain CMR substances (carcinogenic, mutagenic and toxic for reproduction). Following COLIPA recommendation No 15 (arising from order SCO/544/2005 amending Annex II and IX to RD 1599/97) on the safety of medicinal and technical petroleum jelly as a raw material for the cosmetic industry, the manufacturer's technical department guarantees that the petroleum jelly is manufactured from substances that are not carcinogenic in accordance with the Dangerous Substances Directive, and that the full refining history is known.

SVHC:

The product is a mixture of components, so it does not need to be registered under REACH, unlike its components, which are pre-registered and/or registered by the supplier. Does not contain any of the substances listed on the Candidate List of Substances Subject to Authorisation (SVHCs), as last updated on 10/06/22.

NANOMATERIALS:

The product does not contain nanomaterials.

VOCs:

The product does not contain volatile organic compounds.

1088-VASELINE SOFT**PESTICIDES:**

The product does not contain pesticides and is compliant with Regulation (EC) No 396/2005.

RESIDUAL SOLVENTS:

The product complies with Directive 88/344/EC, CPMP/ICH/283/95, CPMP/ICH/1940/00 (Residual Solvents).

ICHQ3D ELEMENTAL IMPURITIES:

The product complies with ICHQ3D.

No metal reagents or products for metal catalysis are used in the manufacturing process, so these substances are not expected to be present.

IMPURITIES:

The product does not contain any of the following substances:

- Polymers
- Preservatives
- Colourants
- PCBs
- Melamine
- Dioxins
- Aflatoxins
- Ethylene oxide
- VOCs
- Latex
- Silicone
- Gluten
- Lactose
- Fructose
- Nitrosamine

METAL REAGENTS/METAL CATALYSTS:

Metal catalysts or reagents listed in EMEA/CHMP/SWP/4446/2000 are not used in the manufacturing of the product.

ALLERGENS:

The product does not contain any of the allergens included in RD 1334/1999 and its amendments, nor in Regulation (EU) 1169/2011 (food allergens), nor those included in Directive 2003/15/EC (cosmetic allergens).

HALAL:

The product is Halal certified.

KOSHER:

The product is Kosher certified.

TESTED ON ANIMALS:

The product has not been tested on animals.