

90737-HYDROPHOBIC GEL BASE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1. Identification of the substance or preparation.

Name: Hydrophobic gel base

Bulk code: 90737

Internal code: 41023

1.2. Synonyms.

Basis hydrophobic gel; base gel hydrophobique

2. DESCRIPTION.

Appearance: Gel.

Colour: White / colourless.

Odour: Characteristic.

Origin: Hamburg, Germany.

Ingredient	Chemical description	Origin of raw material
Paraffinum liquidum	Oil	Petrochemical
Polyethylene	Polymer	Synthetic

At most, 20 ppm of tocopherol is added during the manufacturing process

Method of production: After preparing the source material, the tank is filled with oil and this is heated overnight. Then the polymer is added and dispersed until it swells (via mixing and heat). After undergoing a control process, it is filtered, cooled and sampled, before finally being packaged.

3. COMPOSITION/INFORMATION ON COMPONENTS.


Mixture of liquid paraffin and polyethylene (ologel).

INCI	INCI (EU)	%	CAS No.	EG No.
Mineral oil	Paraffinum liquidum	95	8042-47-5	232-455-8
Polyethylene	Polyethylene	5	9002-88-4	Polymer

4. PHYSICO-CHEMICAL DATA.

For more information, see the analysis report.

Solubility: The product is insoluble in water.

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	TECHNICAL DATA SHEET	
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5. PROPERTIES/USES.

Excipient for pharmaceutical use.
Cosmetic use.

Given the gel's structure it does not have an elasticity limit, meaning the product can be applied without pressure. It presents good stability to temperature and the product can be cold processed.

The product can be used as a base gel for essential oils and other problematic substances, such as additives that fight rheumatism.

In combination with the right emulsifiers, it can enable the manufacture of W/O emulsions and highly stable lotions.

The product does not irritate the mucous membranes.

6. DOSAGE.

No information available.

7. REMARKS.

STORAGE

During transport and storage, the paraffin oil phase may become separated. It will recover its original appearance after mixing, with the product's quality remaining unaffected.

Store at room temperature $25\pm 2^{\circ}\text{C}$ in a cool, dry, well-ventilated place away from sunlight.

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

BSE/TSE:

The product is made from mineral oil and polyethylene and, therefore, it is not of plant or animal origin. The guidelines for minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicines (EMA 410/01 Rev. 3) do not apply to this product.

GMOs:

The product is made from mineral oil and polyethylene and, therefore, it is not of plant or animal origin. The guidelines of Regulation (EC) No. 1829/2003 on genetically modified food and feed and Regulation (EC) No. 1831/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms do not apply to this product.

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CMR:

In accordance with Regulation (EC) No. 1223/2009 of the European Parliament and of the Council, of 30 November 2009, on cosmetic products, the product does not contain any substances classed as carcinogenic, mutagenic and/or reprotoxic (CMR) categories 1A, 1B and 2 in accordance with Regulation (EC) 1272/2008.

The product is not classed as a CMR substance, nor does it appear as prohibited in Appendix II of Regulation (EC) 1223/2009 L342/112.

The product may contain some HAPs listed in Appendix II under numbers 38, 612, 637, 638, 639, 640, 641, 642, 643 and 1167 that may be detected in very low concentrations (ppb range) using GC-MS (according to DIN EN 16143). These products are present given the product's origin and they have been reduced to traces during the manufacturing process thanks to several purification phases. Bear in mind that the manufacturer does not perform tests on this parameter during quality control on the end product.

SVHC:

The substances in the mixture do not meet PBT or vPvB criteria according to REACH appendix XIII.

The product does not contain substances on the SVHC list > 0.1% in accordance with Regulation (EC) No. 1907/2006 (REACH).

VOCs:

The product is not subject to VOCs guidelines (Directive (EU) No. 2010/75 and Directive (EC) No. 2004/42 of the European Parliament and of the Council, and Swiss Ordinance article I) and it has a VOCs content of <3 %.

NANOMATERIALS:

The product does not contain nanomaterials according to the definitions of Regulation (EC) No. 1223/2009.

The definition of microplastic does not apply to the product.

COLOURINGS/PRESERVATIVES/ADDITIVES:

The hydrophobic gel base contains a maximum of 20 ppm of vitamin E.

RESIDUAL SOLVENTS:

During the manufacturing process no solvent listed in EMA/CHMP/ICH/82260/2006 is added intentionally to the hydrophobic gel base. The starting raw materials comply with the requirements set out in the aforementioned guide. Bear in mind that no tests are performed on these parameters during quality control on the end product.

IMPURITIES/CONTAMINANTS:

The raw materials comply with the Eur. Ph.

- Nitrosamines: No nitrites or nitrosating agents, amines, amides or ammonium salts are added during the manufacturing process, therefore none are expected to be present in the end product. The formation of nitrosamines during the manufacturing process is not likely. Nitrosamine control does

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not form a part of quality control and no risk assessment has been performed for the risk of contamination by nitrosamines.

- Elemental impurities: No metal component listed in the ICH Q3D guide is added intentionally during the manufacturing process. The starting raw materials comply with the requirements set out in the aforementioned guide. For these reasons, metal impurities are unlikely to be present, although it is important to consider that no tests are performed on these parameters during the quality control stage.
- RoHS: The relevant substances for electrical and electronic devices (Pb, Hg, Cd, Cr (VI), PBBs, PBDEs and DEHP, BBP, DBP and DIBP phthalates) are not added intentionally to the product in accordance with Appendix II of Regulation 2011/65/EU.

The following substances are related to the process and product. They are not expected to be present, nor are they added intentionally during the manufacturing process (determination of these substances is not a part of the quality control phase):

- Dioxins
- Latex
- Silicones

CALIFORNIA PROPOSITION 65

The following information is based on the supplier's disclosure. Based on its knowledge, the source materials may contain traces of impurities related to the processing of several substances listed under California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act (issue date: January 2020) in the ppm range. The product may present traces of PAHs (ppb range). Compliance with the exposure limit values listed in California Proposition 65 can only be confirmed by the user.

ALLERGENS:

- **Food allergens:** In accordance with EU regulations, mineral oil products do not have food status, with very few exceptions. However, note that the product does not contain any allergens, such as gluten, nuts, crustaceans, eggs, milk, soya, mustard, sesame, celery, fish, seeds, flavourings, lupins, sulphur dioxide and sulphites through analogy with Regulation (EC) No. 1169/2011, Appendix II on the provision of food information to consumers. Given the production process, these allergens are not present in our products and are not added intentionally. These parameters are not monitored.
- **Cosmetic allergens:** None of the allergens listed in Appendix III of Regulation (EC) No. 1223/2009 (entries 67 to 92) are added and the raw materials used are free from these substances in accordance with the information provided by suppliers.

HALAL:

The product is Halal certified.

KOSHER:

The product is Kosher certified.

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VEGAN/VEGETARIAN:

The product's raw materials are not animal products and no animal product or derivative is added intentionally during the manufacturing process. The product has not come into contact with animal derivatives.

The product does not hold vegan or vegetarian certification.

TESTED ON ANIMALS:

The product has not been tested on animals since March 2009, meaning it can be considered "in place to comply with the Cosmetic Products Directive".

RSPO:

Palm oil is not expected to be present as it is not added intentionally during the manufacturing process.

ISO 16128

The ISO 16128 Standard provides guidelines on definitions and criteria for natural and organic cosmetic products. In accordance with the definition given in ISO 16128-1, this standard cannot be applied to components made exclusively from fossil and synthetic raw materials. These substances are always classified as non-natural. The hydrophobic gel base is made from medicinal white oil and polyethylene and it does not contain components of natural or biological origin, meaning that, pursuant to ISO 16128-1, this is a non-natural material.

REACH:

The product complies with Regulation (EC) No. 1907/2006 (REACH), as all the substances it contains have been registered by the supplier or are exempt from registration as per Regulation (EC) No.1907/2006.

INVENTORIES:

All of the product's components are registered/listed in the following inventories:

Country	Inventory	Status
European Union	EINECS / ELINCS / NLP	listed
USA	TSCA	listed
Canada	DSL	listed
	NDSL	not listed
Australia	AICS	listed
Japan	ENCS	listed
Korea	KECI	listed
The Phillippines	PICCS	listed
New Zealand	NZIoC	listed
China	IECSC	listed
Taiwan	TCSI	not listed
REACH Registration		completed



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