



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **VASELINA BIANCA BP-USP**

NOME INCI	Petrolatum
NOME INCI USA	Petrolatum
CAS	8009-03-8
EINECS / ELINCS	232-373-2

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Identificazione IR		Conforme allo standard	
Punto Congelamento	ASTM D 938	50,0 - 56,0	° C
Punto Goccia	Ph.Eur.	35,0 - 70,0	° C
Penetrazione Conica a 25 °C	ASTM D 937	60 - 300	1/10 mm
* Colore Lovibond	IP 17 mod.	<=0,5	
Viscosità Cinematica a 100 °C	ASTM D 7042	5,0 - 9,0	mm ² /s
Idrocarburi Policiclici Aromatici	Ph.Eur.	Passa	
Identificazione	Ph.Eur.	Passa	
Aspetto	Ph.Eur.	Passa	
Acidità o alcalinità	Ph.Eur.	Passa	
Ceneri solforiche	Ph.Eur.	<=0,05	%
Revisione Capitolato		1	
Data Approvazione		28/11/2014	

* saggi non obbligatori

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



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Allergens according to EC 1169/2011

In accordance with EU regulations mineral oil products have no food status with very few exceptions.

However, we can confirm that they do not contain any allergens such as nuts, crustaceans, eggs, milk, soybeans, mustard, sesame, celery, fish, seeds, flavours, lupins, sulphur dioxide, and sulfites by analogy with EC Regulation No. 1169/2011, Ann. II to the provision of food information to consumers.

Because of the production process these allergens are not present in our products and are not intentionally added. A monitoring of these parameters is not carried out.

Risk of Transmitting BSE/TSE (CPMP/BWP/1230) and EMEA 410/01 Rev.3, GMO (Note for Guidance EMEA 410/01 Rev.3), Residual solvents EMA/CHMP/ICH/82260/2006, former CPMP/ICH/283/95 and Guideline „Note for Guidance on Impurities“) and Aflatoxin-Verbotsverordnung

We wish to confirm that our product White Vaseline Ph.Eur. WHITE SOFT PARAFFIN BP-USP is a petroleum derivative. The problems caused by BSE/TSE and GMO do not concern mineral oil products. The origin of these materials is not animal but petroleum. No animal or animal-derived products are utilised in the manufacture, nor is this material at any time in contact with such products.

Due to the conditions of manufacture, involving high temperature, pressure and aggressive chemical conditions with the destruction of any reactive organic material, micro organisms including Aflatoxin are not present. As long as they are kept dry, white mineral oils and petroleum jellies are unsuitable media for micro organism growth, and also reduce the adhesion of micro organisms on surfaces.

We hereby confirm that these products are free of residual solvents as per the Guideline „Note of Guidance on Impurities: Residual Solvents (EMA/CHMP/ICH/82260/2006)“ and the European Pharmacopeia, addendum 1999, chapt. 5.4 Residual solvents. Any traces originating from previous production steps are completely eliminated.

Risk of Transmitting BSE/TSE (CPMP/BWP/1230) and EMEA 410/01 Rev.3, GMO (Note for Guidance EMEA 410/01 Rev.3), Residual solvents EMA/CHMP/ICH/82260/2006, former CPMP/ICH/283/95 and Guideline „Note for Guidance on Impurities“) and Aflatoxin-Verbotsverordnung

Vaseline White Ph.Eur./USP WHITE SOFT PARAFFIN BP-USP is a petroleum derivative and is hydrogenated by catalyst at very high temperatures and pressure.

This process destroys all organic substances except for saturated hydrocarbons. A contamination with materials of biological origin during the production is not possible. The growth of micro-organisms is unlikely if the product is stored non-sterile, since the water content is lower than 100 ppm and the necessary components for the metabolism are not present.

Therefore the problems relating to Aflatoxin-Verbotsverordnung (Regulation of the Prohibition of Aflatoxin), GMO and BSE/TSE according to CPMP/BWP/1230 and EMEA/410/01 Rev.1 are not applicable for this substance.

We hereby confirm that this product is free of residual solvents as per the Guideline „Note for Guidance on Impurities: EMA/CHMP/ICH/82260/2006. Any traces originating from previous production steps are completely eliminated. Tests for these parameters are not carried out.

Nanomaterial

We can confirm herewith that the classification as nanomaterial of our product: White Vaseline Ph.Eur. WHITE SOFT PARAFFIN BP-USP is unknown to us.

Animal testing

This is to confirm that our product: White Petroleum Jelly BP/USP/Ph.Eur. WHITE SOFT PARAFFIN BP-USP has not been tested on animals.



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Prodotto **VASELINA BIANCA BP-USP**

We herewith confirm that our product: White vaseline Ph.Eur./USP WHITE SOFT PARAFFIN BP-USP does not contain neither palm oil nor latex.

According to the Regulation (EC) No 1223/2009, (§32) of the European Parliament and of the Council of 30.11.2009 on cosmetic products, substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2 pursuant to Regulation (EC) No 1272/2008 are not allowed for use in cosmetic products.

We guarantee for our petrolatum that the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. Therefore petrolatum is not restricted or prohibited in the use of cosmetics according to Annex II of EC 1223/2009 L 342/112 (Ref 904)

The purity of our product: White vaseline Ph.Eur. WHITE SOFT PARAFFIN BP-USP complies with Pharmacopoeia Eur.

Please notice that there are a few PAH listed on Annex II under number 38, 612, 637, 638, 639, 640, 641, 642, 643 and 1167 which can be detected in very small concentrations (ppb range) in this material.

SVHC

In order to establish a meaningful communication within the supply chain, Cefic (European Chemical Industry Council) has worked out a paper "Messages to communicate in the supply chain". It includes information about how to handle enquiries, which the downstream users initiate at their suppliers. This paper highlights the SVHC issue : "The presence of SVHCs in chemical mixtures will be communicated by suppliers of those mixtures via the SDS, following the usual rule for the communication of hazardous substances. There is no additional obligation for suppliers of mixtures containing SVHCs besides the usual obligations regarding SDS." and "There is no need for downstream users to request statements from suppliers about the "absence of SVHCs".

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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