

RAW MATERIAL INFORMATION

**NATURAL VASELIN TYPE B**

**Product identification**

**Manufacturer :** Natura-tec  
**Country of origin :** France  
**Custom Tariff :** 15180099

**Manufacturing process and chemical composition**

**Manufacturing process:**

The manufacturing process consists of the blending of Castor Oil, Hydrogenated Castor Oil, Carnauba Wax and Beeswax. This is carried out at 80°C under nitrogen atmosphere. After QC control, the blend is cooled following a programmed cooling process, filtered on a paper filter of 100µm and packaged directly at 70°C.

**Chemical composition:**

INCI/USA	INCI/EEC	CAS No.	EINECS / ELINCS No.	Function	%
Ricinus Communis (Castor) Seed Oil	Ricinus Communis Seed Oil	8001-79-4	232-293-8	Emollient	> 50 %
Hydrogenated Castor Oil	Hydrogenated Castor Oil	8001-78-3	232-292-2	Consistency agent	5 - 9,99 %
Copernicia Cerifera (Carnauba) Wax	Copernicia Cerifera Cera	8015-86-9	232-399-4	Natural wax	1 – 4,99 %
Beeswax	Cera Alba	8012-89-3	232-383-7	Natural wax	1 – 4,99 %

**Impurities:**

Impurities	Nature	Specification, ppm
Residual solvents		None
Monomers		None
Heavy metals	Pb	< 10
	As	< 3
	Cd	< 1
	Hg	< 1
	Cr	< 10
	Cu	< 5
	Ni	< 10
	Se	< 5
	Zn	< 5
	Ba	< 10
	Sb	< 5
	Co	< 10
Pesticides		None
Other impurities		Absence

**Decontamination by radioactivity**

We hereby certify that the product **Natural Vaseline Type B** has not been treated with ionising radiation.

**Reach compliance / CLP classification**
**Reach (CE regulation n°1907/2006)**

INCI/USA	CAS No.	EINECS / ELINCS No.	Pre-registration	Registration dateline
Ricinus Communis (Castor) Seed Oil	8001-79-4	232-293-8	Exempted Annex V	
Hydrogenated Castor Oil	8001-78-3	232-292-2	05-2118364429-36-0000	2013
Copernicia Cerifera (Carnauba) Wax	8015-86-9	232-399-4	Exempted annex V	
Beeswax	8012-89-3	232-383-7	Exempted	

**CLP classification**

**Natural Vaseline Type B** is not classified under regulation CE 1272/2008



## Ingredient of vegetable origin

General description of the vegetal		
INCI name of the ingredient of vegetal origin	Ricinus Communis (Castor) Seed Oil	Copernicia Cerifera (Carnauba) Wax
Name of the vegetal (genus – species – Family))	Genus : Ricinus Species : R. Communis Family : Euphorbiaceae	Genus : Copernicia Species : Cerifera Family : Palmae
Part used	Seeds	leaves
Geographical origin	Tropical region, mainly Eastern Africa	Brazilian tropical palm tree
Is the plant cultivated or natural?	cultivated	Cultivated
Is it a regulated vegetal species (CITES, IUCN red list...)? If yes, please enclose a duplicate of the authorization certificate	No	No

We the undersigned, certify that our **Natural Vaseline Type B** contains no material of animal origin and thus is not concerned by BSE regulation

## Storage conditions

Packaging	Plastic pails 25 kg net
Storage	Store in original unopened containers in a cool dry place
Shelf life	24 months in original unopened containers

## Toxicological data

From information available, **Natural Vaseline Type B** is non-toxic under normal conditions of use.

**Bibliographic data - Source : [www.cosmeticsinfo.org](http://www.cosmeticsinfo.org) + Cosmetic Ingredient Review – “Final report Plant Fatty Acid Oils as used in Cosmetics”**

### Castor Oil & Hydrogenated Castor Oil

The safety of Ricinus Communis (Castor) Seed Oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and noted the overall pattern of use of these ingredients in different product categories. The CIR Expert Panel concluded that Castor Oil and its derivatives were safe for use as cosmetic ingredients

CIR Safety Review: The CIR Expert Panel considered that the available data on Ricinus Communis (Castor) Seed Oil and Hydrogenated Castor Oil were sufficient for evaluating the safety of these ingredients. The available data demonstrated few toxic effects in acute, subchronic, or chronic toxicity tests. Additionally, there were no genotoxic effects of Castor Oil in in vitro or in vivo tests.

UV absorption spectra on Ricinus Communis (Castor) Seed Oil indicated maximum absorbance at 270 nm, suggesting there would be no photosensitization potential of Ricinus Communis (Castor) Seed Oil in human subjects exposed to the sun.

#### Carnauba Wax

CIR Safety Review: The CIR Expert Panel reviewed the safety data on Carnauba Wax and noted that this ingredient produced no toxicity in acute or subchronic studies and were not mutagenic when tested with and without metabolic activation on microorganisms. In skin irritation tests, this ingredient at high concentrations resulted in mild irritation while products containing this ingredient caused no irritation. When tested alone Carnauba wax was not irritating to the eyes. In clinical studies, products containing Carnauba wax was practically nonirritating in 21-day cumulative patch tests, and repeat insult patch tests.

#### Beeswax

The safety of Beeswax has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Beeswax was safe for use in cosmetics and personal care products. In 2003, the CIR Expert Panel considered available new data on this ingredient and reaffirmed the above conclusion.

**CIR Safety Review:** The CIR Expert Panel reviewed the safety data on Beeswax and noted that this ingredient produced no toxicity in acute or subchronic studies and was not mutagenic when tested with and without metabolic activation on microorganisms. In skin irritation tests, Beeswax at high concentrations resulted in mild irritation while products containing it caused no irritation. When tested alone Beeswax was not irritating to the eyes. In clinical studies, products containing Beeswax were practically nonirritating in 21-day cumulative patch tests, and repeat insult patch tests. No phototoxicity of a product containing 10% Beeswax was seen. Additionally, a product containing 4% Beeswax was not sensitizing to the skin.

## Regulatory information - Certificates

### **Cosmetic directive compliance**

In conformance to the EC Directive n° 1223/2009 in respect to the use in cosmetic products, **Natural Vaseline Type B** is exempt of prohibited substances (Annex II) and restricted substances (Annex III). **Natural Vaseline Type B** is exempt of Phtalates, nonylphenol, alkylphenols, phenol, nitrosamines, glycol ethers.

### **Non GMO origin**

We hereby confirm that the product **Natural Vaseline Type B** does not contain GMO's or GMO derived components; no GMO derived materials or processing aids are employed in the manufacture of this product.

### **Non animal testing**

We hereby confirm that **Natural Vaseline Type B** of our manufacture, has not been tested on animals.

### **Absence CMR**

It is certified that the product **Natural Vaseline Type B** does not contain carcinogenic, mutagenic or reprotoxic (CMR) substances of categories 1, 2, 3 or 1A, 1B or 2 listed in regulation 1272/2008 and amendments: commission regulation (CE) n° 790/2009 and n°286/2011.

### **Absence of allergens certificate**

It is hereby certified that the product **Natural Vaseline Type B** of our manufacture, does not contain any of the 26 allergens listed in the Cosmetic Directive CEE / 76 / 768 and amendments

### **Absence SVHC**

It is certified that the product **Natural Vaseline Type B** of our manufacture does not contain substances identified as SVHC featuring in the "REACH candidate list" published.

The "REACH candidate list" is present on ECHA web site and has been updated in in June, 18 2012

Link: [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

### **NOAEL**

**Natural Vaseline Type B** meets the Cosmetic European Directive and no-observed-adverse-effect-level (NOAEL) have been reported after a wide use in the cosmetic.

Based on in-vivo uses our **Natural Vaseline Type B** has been identified non toxic under normal condition of use.

### **BSE statement**

We, the undersigned, certify that during the manufacturing process of our **Natural Vaseline Type B**:

- No material derived from animal has been used during the manufacture, processing or packing / re-packing.
- There is no risk of cross contamination from products derived from animal during the manufacture, processing or packing / re-packing

### **Gluten free**

We certify that the product **Natural Vaseline Type B** that we manufacture is Gluten free.

### **Absence of Petrochemical**

We certify that the product **Natural Vaseline Type B** of our manufacture does not contain Petrochemical substances.

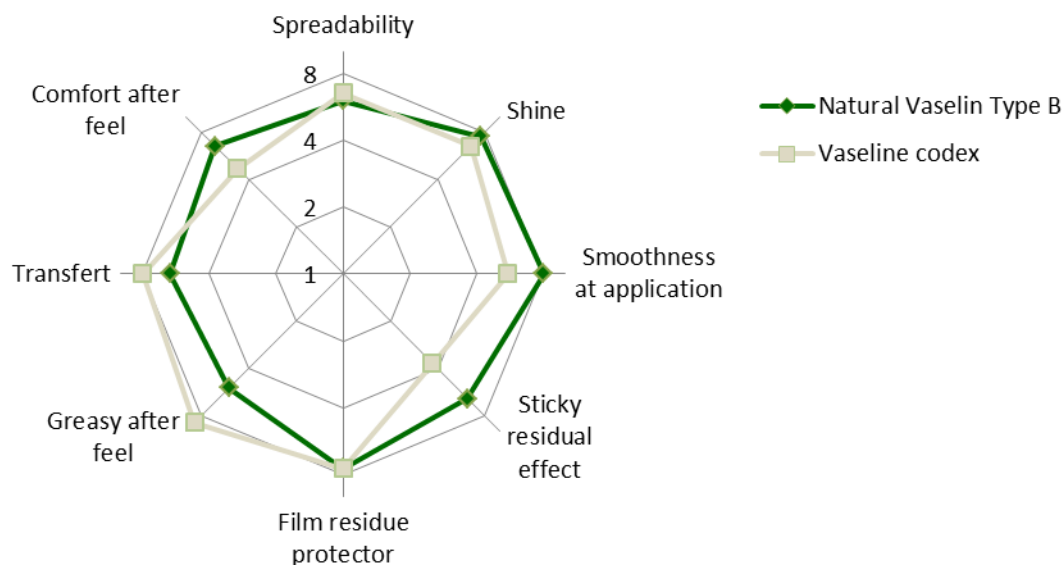
## **Global restriction**

Europe	No restriction
USA	No restriction
Canada	No restriction
Japan	No restriction
China	No restriction
Korea	No restriction

Efficacy tests

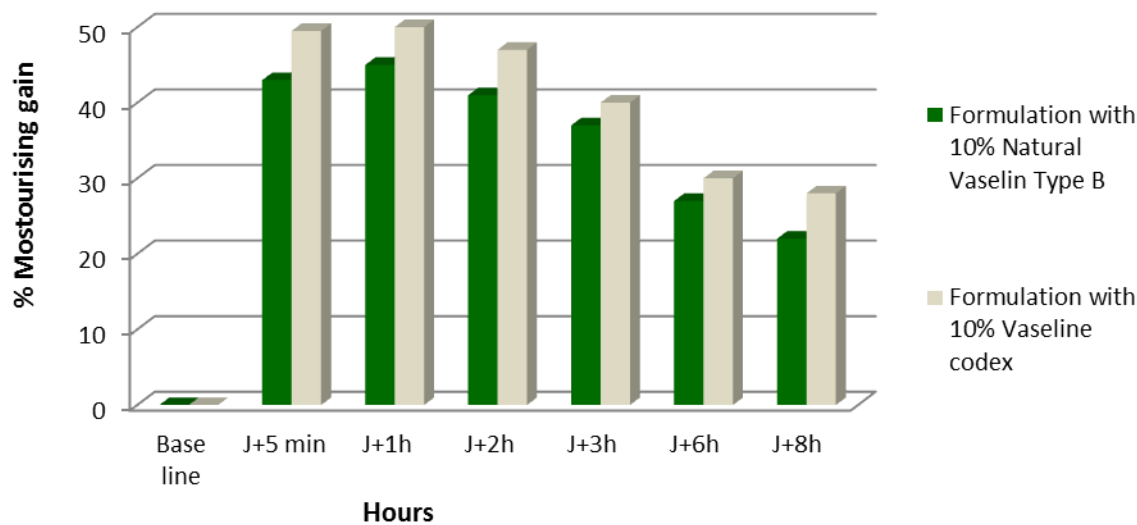
## SENSORIAL PROFILE

### Sensorial Properties of Natural Vaseline Type B

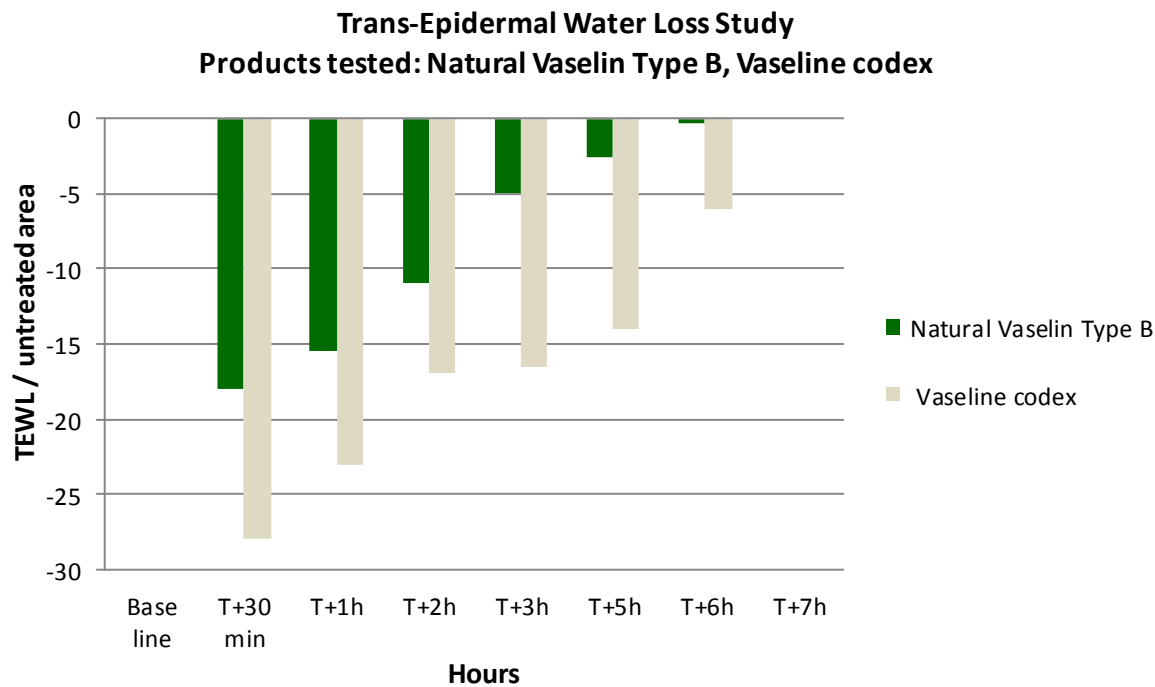


## MOISTURIZING STUDY

### Moisturising effect of cosmetic formulations containing Natural Vaseline Type B, Vaseline codex



## TRANS EPIDERMAL WATER LOSS STUDY



Regulatory Affairs Manager : Pascale Goyat p.o. Lucie Brun

Fréjus, February 2016



*This document completes the product technical and safety data sheet. Information contained in this notice are based on our current knowledge and relate to the product in the state in which it is delivered*  
*This certificate does not exempt or prevent the user to test under its own responsibility the material described in the document*