

RAW MATERIAL INFORMATION

Veg-Lanolin

Product identification

Country of origin :	France
Custom Tariff :	15180099
COSMOS :	Approved
Kosher :	Certified

Manufacturing process and chemical composition

Manufacturing process:

Shea Butter and Olive Oil Unsaponifiables are mixed and heated to 80-85°C under nitrogen atmosphere with steering. Glyceryl Rosinate is added progressively by maintaining the temperature at 80-85°C. After QC control, the blend is cooled to 70°C, filtered and packaged directly

Chemical composition:

INCI/USA	INCI/EEC	CAS No.	EINECS / ELINCS No.	Function	%
Butyrospermum Parkii (Shea) Butter	Butyrospermum Parkii Butter	194043-92-0	293-515-7	Emollient	25 - 50 %
Glyceryl Rosinate	Glyceryl Rosinate	8050-31-5	232-482-5	Skin conditioning agent, Emollient	25 - 50 %
Olea Europaea (Olive) Oil Unsaponifiables	Olea Europaea Oil Unsaponifiables	156798-12-8	232-277-0	Anti-ageing active, emollient	5 - 9,99 %

We hereby declare that our Veg-Lanolin is exempted of Alcohol, Paraben, Perfume and colorants.

Impurities:

Impurities	Nature	Specification, ppm
Residual solvents		None
Monomers		None
Heavy metals	Pb	< 10
	As	<LOQ
	Cd	<LOQ
	Hg	<LOQ
	Cr	<LOQ
	Ni	<LOQ
	Others	$\Sigma < 3$ ppm
Pesticides		< 0,1 ppm
Mycotoxins		Undetected

Dioxins		Conform to Regulation (EC) No 1881/2006
Polycyclic aromatic hydrocarbons		conform to Regulation (EC) No 1881/2006
Phthalate and other plastic materials		conform to Regulation (EC) No 10/2011

Decontamination by radioactivity

We hereby certify that the product **Veg-Lanolin** has not been treated with ionising radiation.

ISO16128 guideline Information

Substance INCI name	Ingredient type	% mass fraction	Natural index	Natural origin index	Organic index	Organic origin index
Butyrospermum Parkii Butter	Natural	25 - 50 %	1	1	0	0
Glyceryl Rosinate	Derived natural	25 - 50 %	0	1	0	0
Olea Europaea Oil Unsaponifiables	Natural	5 - 9,99 %	1	1	0	0
Natural origin content %	100 %					

Natural origin content %*: the mass percentage, between 0% and 100%, of all natural ingredients and natural portions of derived natural ingredients in the product.

Reach compliance / CLP classification

Reach (CE regulation n°1907/2006)

Substance INCI name	CAS No	EINECS	REACH Registration
Butyrospermum Parkii (Shea) Butter	194043-92-0	293-515-7	Exempted annex V
Glyceryl Rosinate	8050-31-5	232-482-5	01-2119488167-27-0000
Olea Europaea (Olive) Oil Unsaponifiables	156798-12-8	232-277-0	Exempted annex V

CLP classification

Veg-Lanolin is not classified under regulation CE 1272/2008

Ingredient of vegetable origin

General description of the vegetable			
INCI name of the ingredient of vegetable origin	Butyrospermum Parkii (Shea) Butter	Glyceryl Rosinate	Olea Europaea (Olive) Oil Unsaponifiables
Name of the vegetable (genus – species – family)	Genus : Vitellaria Species : V. Paradoxa Family : Sapotaceae	Genus : Pinus Species : Pinaster Family : Pinaceae	Genus : Olea Species : Europaea Family : Oleaceae
Part used	Fruit	resin	Fruit
Geographical origin	Burkina Faso	France Spain, Portugal	Spain, Italy, Greece
Is the plant cultivated or natural?	Natural	Cultivated	cultivated
Is it a regulated vegetal species (CITES, IUCN red list...)?	No	No	No

We the undersigned, certify that our **Veg-Lanolin** contains no material of animal origin and thus is not concerned by BSE regulation

Storage conditions

Storage Store in a cool dry place in original unopened containers

Toxicological data

From information available, **Veg-Lanolin** is non-toxic under normal conditions of use.

a/ In-vivo test

A human patch test has been performed with the product Veg-Lanolin by the company Farcoderm in collaboration with the University of Pavia (Laboratory of Pharmacobiochemistry, Pharmacology and Toxicity Division)

	Method	Tested concentration	Results
Patch test	<ul style="list-style-type: none"> - Occlusive application of the test product in the back of 20 volunteers with specific patch (Finn Chamber). - The product is left in contact with the skin surface for 48 hours. - Skin reactions (erythema, edema ...) are evaluated by the dermatologist 15 minutes, one hour and 24 hours after removal of the patch. 	diluted to 10% in corn oil	<p>Clinical score of skin reactions : No oedema and erythema reactions has been observed on the 20 volunteers.</p> <p>Natura-Tec Plantsoft L has been classified NON IRRITATING "Dermatologically tested" according to the amended Draize classification</p>

b/ in vitro oral mucosa irritation test with human cell cultures

Protocol:

Cell type : human buccal epithelial cells reconstructed in vitro, model HOE_{EPIKIN}[™]

Direct application of test item on the surface of HOE (Human Oral Epithelium).

Test concentration : 100 % of Plantsoft L

Contact : 30 min

Measured parameters:

- *Epithelium viability via colorimetric test MTT-positive control : Methyl Acetate (MetAcet)*

MTT, a yellow tetrazolium dye, is reduced to purple formazan in living cells. Reduction of MTT and other tetrazolium dyes depends on the cellular metabolic activity due to NAD(P)H flux. The more MTT is reduced, the higher cell viability is.

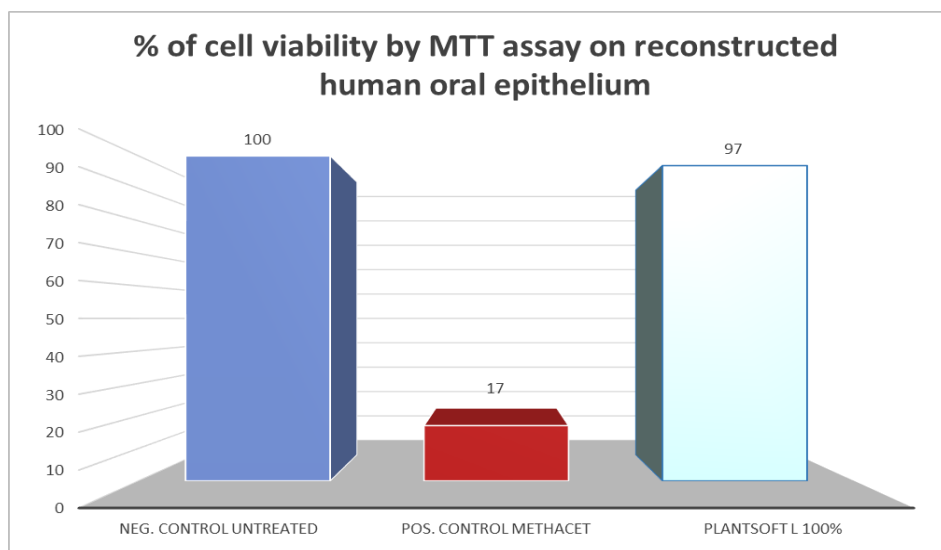
Test items that produce cell viabilities above 60 %, can be considered non-irritants.

Predictability:

Classification of test items : Non-Irritant (NI) / Irritant (I) * based on the results of viability test (MTT)

Results of MTT Assay:

Test item	Viability (%)		classification
Negative control	100%	-	Non-irritant
Natura-Tec Plantsoft L	97%	> 60%	Non-irritant
Positive control(MetAcet)	17%	< 60%	Irritant



Conclusion: The test results demonstrate that our **Veg-Lanolin** is **not-irritant** for oral mucosa.



C/ Bibliographic data - Source : www.cosmeticsinfo.org + Cosmetic Ingredient Review – “Final report Plant Fatty Acid Oils as used in Cosmetics”

Butyrospermum Parkii (Shea) Butter

The safety of Butyrospermum Parkii (Shea) Butter has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that this ingredient was safe for use as ingredients in cosmetics and personal care products. Data indicating these ingredients were not dermal irritants or sensitizers.

Glyceryl Rosinate

The safety of the glyceryl monoesters has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that the following glyceryl monoesters were safe as cosmetic ingredients in the present practices of use (skin conditioning agent, emollient): ..., Glyceryl Rosinate, ...

In addition, the ingredient **Glyceryl Rosinate** used in our Veg-Lanolin has been registered following Reach regulation and a Chemical safety report has been done.

The substance is not classified according to Regulation (EC) No 1272/2008.

The substance is not classified according to Directive 67/548/CEE.

Primary irritant effect:

on the skin:

No irritation effects or slight reversible effects were observed in several irritation studies conducted in rabbits according to the OECD 404 guideline or to comparable methods. Criteria for classification were not met. Similar results were found in human subjects following prolonged (5 days) or repeated (15 applications) exposure.

on the eye:

Only slight signs of irritation were seen in two eye irritation studies conducted in rabbits. Criteria for classification were not met.

Acute toxicity :

LD50 (Oral-rat) (OECD 401) > 2000 mg/kg

LD50 (Dermal – rabbit) > 2000 mg/kg

Sensitization:

No evidence of a sensitization response was observed in human subjects repeatedly exposed to the substance under occlusive patch. Similarly, no signs of sensitization were observed in mice tested in a Local Lymph Node Assay (OECD 429) or when groups of guinea pigs were tested in the Guinea Pig Maximization Test (GPMT - similar to the OECD 406 guideline).

Mutagenicity/genotoxicity:

Studies conducted on structurally related substances clearly show the absence of genotoxic potential: the tested materials were not mutagenic in two Ames tests (OECD 471) and in an in vitro mammalian cell gene mutation assay (OECD 476).



Carcinogenicity:

The substance is not expected to be carcinogenic: absence of genotoxic potential and no evidence from the repeated dose toxicity study that the substance is able to induce hyperplasia or preneoplastic lesions.

Reproductive toxicity:

Results of a reproductive/developmental screen in rats (OECD 421) conducted with a structurally related substance and results of a 90-day repeat dose study in rats with a histological examination of reproductive tissues (OECD 408) have not suggested any evidence of toxicity to reproduction or development.

Specific target organ toxicity - single exposure

No specific target organ toxicity was observed in studies for determining LD50

Specific target organ toxicity - repeated exposure

There are no changes (functional, macros or histopathological) related to treatment in an organ or system in male and female rats exposed to the substance by alimentation to 10,000 ppm for 13 weeks (OECD 408). NOAEL = 10000ppm.

Olea Europaea (Olive) Oil Unsaponifiables

The CIR Expert Panel concluded that the 244 plant-derived fatty acid oils included in this review are safe in the present practices of use and concentration described in this safety assessment. Were the ingredients not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and concentrations comparable to others in these groups. The ingredients found safe are:

... Olea Europaea (Olive) Oil Unsaponifiables ...

Regulatory information - Certificates

Cosmetic directive compliance

In conformance to the Regulation (EC) No 1223/2009 in respect to the use in cosmetic products, **Veg-Lanolin** is exempted of prohibited substances (Annex II) and restricted substances (Annex III). **Veg-Lanolin** is exempted of Phtalates, nonylphenol, alkylphenols, phenol, nitrosamines, glycol ethers.

Non GMO origin

We hereby confirm that the product **Veg-Lanolin** 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 **Veg-Lanolin** of our manufacture, has not been tested on animals.



Absence CMR

It is certified that the product **Veg-Lanolin** 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 **Veg-Lanolin** of our manufacture, does not contain any of the allergens listed in the Regulation (EC) No 1223/2009 (Annex III).

Absence SVHC

It is certified that the product **Veg-Lanolin** 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 on the link below.

Link: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

NOAEL

Veg-Lanolin 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 **Veg-Lanolin** has been identified non-toxic under normal condition of use.

BSE statement

We, the undersigned, certify that during the manufacturing process of our **Veg-Lanolin**:

- 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 **Veg-Lanolin** that we manufacture is Gluten free.

Microbiological specification

Veg-Lanolin respects the below specifications :

- Bacteria specification < 100 cfu/g/ml
- Yeasts and molds specification <10 cfu/g/ml
- Absence of pathogen micro-organisms :
 - Absence of Pseudomonas aeruginosa
 - Absence of Escherichia coli
 - Absence of Staphylococcus aureus
 - Absence of Enterococcus faecium and Enterococcus faecalis
 - Absence of Candida albicans

Global restriction

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

Efficacy tests

PROPERTIES

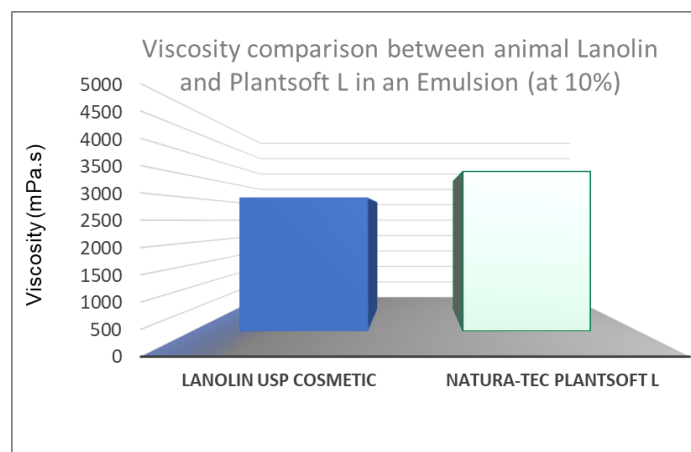
- ❖ Vegetable base alternative to lanolin
- ❖ Manufactured from renewable ingredients
- ❖ Mimic perfectly the original animal derivatives
- ❖ Excellent moisturizers
- ❖ Water binding capacity (4 times its weight in water)
- ❖ Semi-occlusive capability, create a protective barrier
- ❖ Restores skin suppleness and elasticity
- ❖ Enhances the substantivity
- ❖ Helps to control the viscosity of formulations

Four tests were performed to compare characteristics between our Veg-Lanolin and Lanolin (USP Cosmetic): viscosity, sensorial profile, water absorption and moisturizing effect.

VISCOSITY

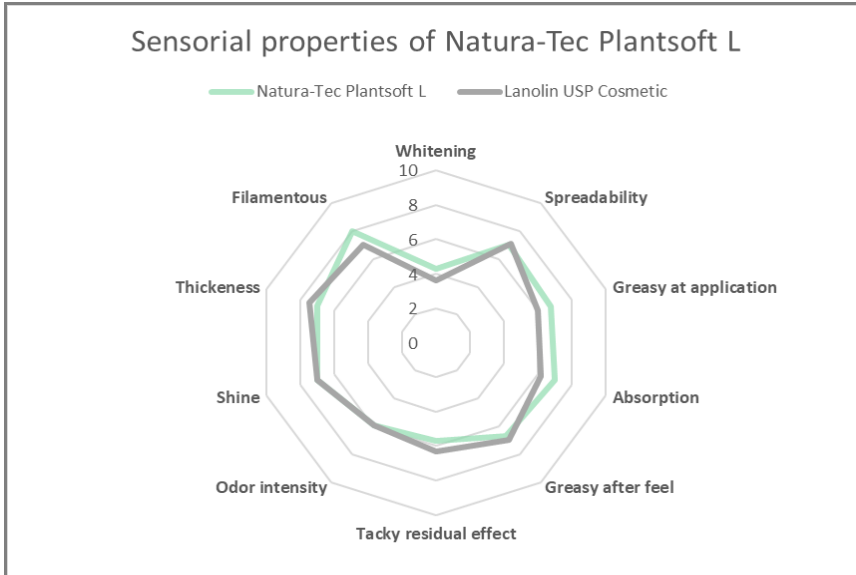
Viscosity comparison between Veg-Lanolin and Lanolin (USP Cosmetic).

	Ingredients	%	%
A	Deionized Water	72,7	72,7
	Xanthan Gum	0,3	0,3
B	Natura-Tec Emulactive W	6,0	6,0
	Lanolin (USP Cosmetic)	10,0	-
	Natura-Tec Plantsoft L	-	10,0
	Natura-Tec Plantsil	10,0	10,0
C	Geogard ECT	1,0	1,0



In comparison with Lanolin USP, Veg-Lanolin gives a **similar range of viscosity**.

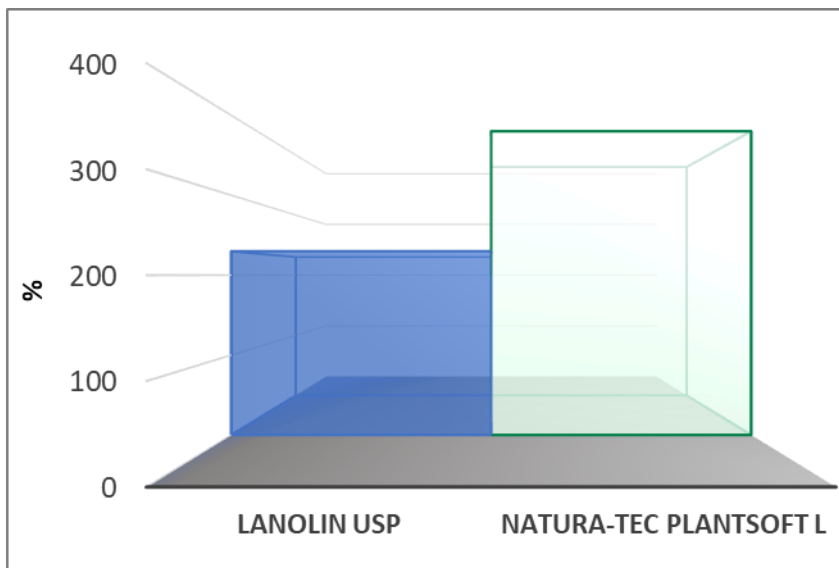
SENSORIAL PROFILE



Lanolin USP and Veg-Lanolin used at 10 % in an emulsion system show very similar sensorial characteristics. Indeed, **spreadability, shine, texture, thickness and odor intensity are equivalent.**

In addition, our product leaves a **slightly less greasy after feel** and is **less tacky**

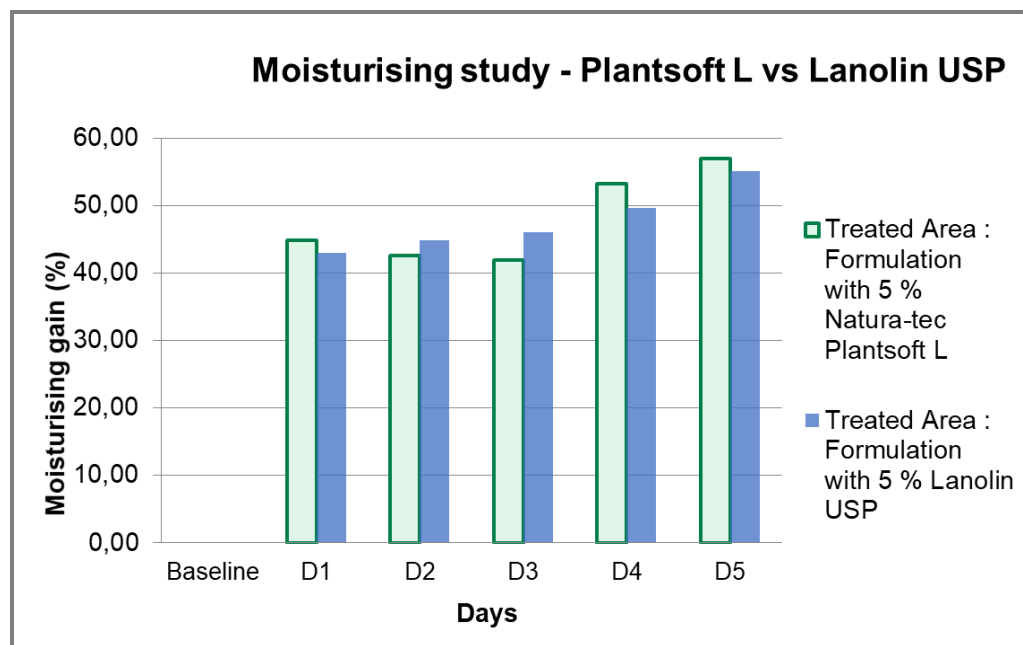
WATER ABSORPTION STUDY



When compare to Lanolin USP, Veg-Lanolin **absorbs 4 times its weight in water** when the Lanolin absorbs 2 times its weight in water.



MOISTURIZING STUDIES



Moisturizing properties of Veg-Lanolin and Lanolin USP are comparable.

Both ingredients present a **cumulated effect of the moisturising gain.**

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