

RAW MATERIAL INFORMATION

NATURA-TEC PLANTSOFT™ L
Product identification

Manufacturer :	Natura-Tec
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	> 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 **Natura-Tec Plantsoft L** is exempted of Alcohol, Paraben, Perfume, Preservatives, Antioxidants and Colorants.

Impurities:

Impurities	Nature	Specification, ppm
Residual solvents		None
Monomers		None
Heavy metals	Pb	<LOQ (LOQ = 0.04ppm)
	As	<LOQ (LOQ = 0.03ppm)
	Cd	<LOQ (LOQ = 0.01ppm)
	Hg	<LOQ (LOQ = 0.005ppm)
	Cr	<LOQ (LOQ = 0.02ppm)
	Ni	<LOQ (LOQ = 0.15ppm)
	Others	$\Sigma < 3$ ppm
Pesticides		<LOQ (LOQ = 0.01 ppm)
Mycotoxins :	Aflatoxins total (B1, B2, G1, G2)	< LOQ (LOQ = 8 ppb)
	Aflatoxin B1	< LOQ (LOQ = 2 ppb)
Dioxins		Conform to regulation (EC) 1881/2006
PAH	Benzo(a)pyrene	Conform to regulation (EC) 1881/2006

Decontamination by radioactivity

We hereby certify that the product **Natura-Tec Plantsoft L** has not been treated with ionizing 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

Natura-Tec Plantsoft L 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 Or Genus : Elaeis Species : Guineensis Family : Palmaceae	Genus : Olea Species : Europaea Family : Oleaceae
Part used	Fruit	Resin/Fruit	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 **Natura-Tec Plantsoft L** contains no material of animal origin and thus is not concerned by BSE regulation.

Storage conditions

Standard packaging	Plastic pails, 25 kg net.
Storage	Store in a cool dry place in original unopened containers
Shelf Life	24 months in original unopened packaging

Toxicological data

From information available, **Natura-Tec Plantsoft L** is non-toxic under normal conditions of use.

a/ In-vivo test

A human patch test has been performed with the product Natura-Tec Plantsoft L 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</p> <p>“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.

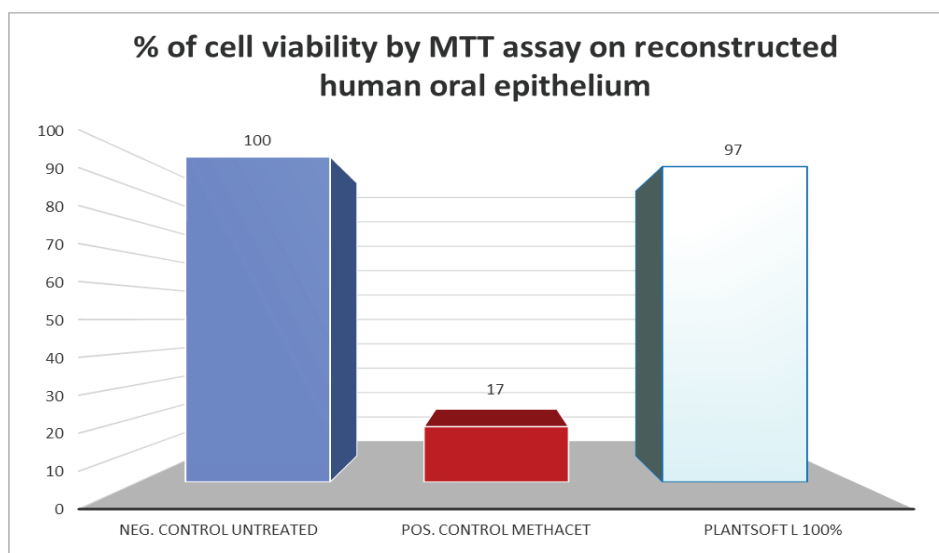
Test items that produce cell viabilities above 60 %, can be considered non-irritants.

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 **Natura-Tec Plantsoft L** 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 Natura-Tec Plantsoft L 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 Regulation compliance

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

Non-GMO origin

We hereby confirm that the product **Natura-Tec Plantsoft L** 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 **Natura-Tec Plantsoft L** of our manufacture, has not been tested on animals.

Absence CMR

It is certified that the product **Natura-Tec Plantsoft L** 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 (EU) N° 790/2009, N°286/2011 and N°2023/1490.

Absence of allergens certificate

It is hereby certified that the product **Natura-Tec Plantsoft L** of our manufacture, does not contain any of the allergens listed in the Regulation (EC) No 1223/2009 (Annex III), as well as in the Regulation (EU) 2023/1545.

Absence SVHC

It is certified that the product **Natura-Tec Plantsoft L** 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

Natura-Tec Plantsoft L 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 **Natura-Tec Plantsoft L** has been identified non-toxic under normal condition of use.

BSE/TSE statement

We, the undersigned, certify that during the manufacturing process of our **Natura-Tec Plantsoft L**:

- 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
- **Natura-Tec Plantsoft L** is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

Gluten free

We certify that the product **Natura-Tec Plantsoft L** that we manufacture is Gluten free.

Nanomaterial free

We hereby confirm that our **Natura-Tec Plantsoft L** does not contain nanomaterial in accordance with Cosmetic Regulation (EC) No. 1223/2009, French Decree 2012-232 and COMMISSION RECOMMENDATION of 10 June 2022 on the definition of nanomaterial (2022/C 229/01).

Microplastics free

We hereby confirm that our **Natura-Tec Plantsoft L** is free from microplastics in accordance with Microplastics Regulation (EU) 2023/2055 of 09/27/2023.

Vegan statement

We hereby confirm that our **Natura-Tec Plantsoft L**, complies with vegan requirements.

Our **Natura-Tec Plantsoft L** is not produced from any animal derived ingredients and has not been tested on animals.

Proposition 65

We hereby certify that our **Natura-Tec Plantsoft L** does not contain any substances listed in the proposition 65.

Microbiological specification

Natura-Tec Plantsoft L 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*

Free from nuts derivatives

We hereby confirm that the substances that composed our **Natura-Tec Plantsoft L** does not contain residues of nuts. We hereby confirm that the refining operations (bleaching and deodorisation and filtration) guarantee the absence of nuts residues in the *Butyrospermum Parkii* Shea Butter substance.

All the allergenic proteins, potentially present, are removed during the refining process.

Free from Soy derivatives

We hereby confirm that the substances that composed our **Natura-Tec Plantsoft L** does not contain soy derivatives.

1,4-dioxane statement

We hereby certify that our **Natura-Tec Plantsoft L** is 1,4-dioxane free.

Absence VOC

We certify that the product **Natura-Tec Plantsoft L** that we manufacture does not contain VOC.

PFAs statement

We hereby certify that our **Natura-Tec Plantsoft L** is free from PFAs (Polyfluoroalkyl and Polyfluoroalkyl Substances).

Siloxanes statement

We hereby certify that our **Natura-Tec Plantsoft L** is free from Cyclotetrasiloxanes (D4), Cyclopentasiloxanes (D5) and Cyclohexasiloxanes (D6).

Global restriction

Europe	No restriction
USA	No restriction
Canada	No restriction, DSL : Butyrospermum Parkii (Shea) Butter -listed; Olea Europaea (Olive) Oil Unsaponifiables – not listed; Glyceryl Rosinate – listed.
Japan	No restriction
China	No restriction
Korea	No restriction
Australia	No restriction AICIS : Butyrospermum Parkii (Shea) Butter – not listed; Olea Europaea (Olive) Oil Unsaponifiables – not listed; Glyceryl Rosinate – listed.

Efficacy tests

PROPERTIES

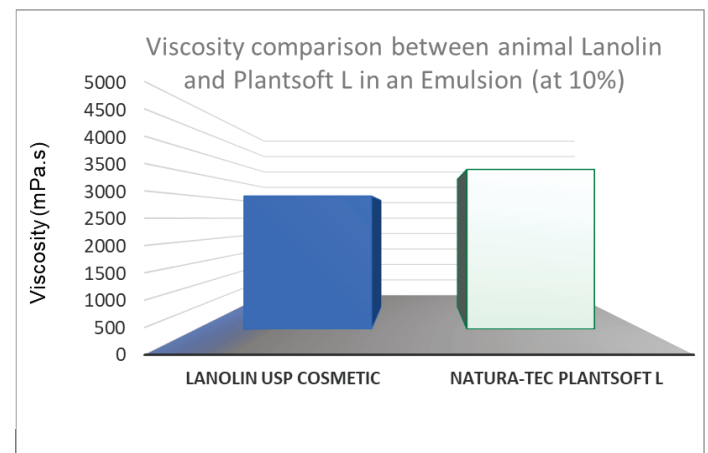
- ❖ Vegetable base alternative to lanolin
- ❖ Manufactured from renewable ingredients
- ❖ Mimic perfectly the original animal derivatives
- ❖ Excellent moisturizers
- ❖ Water binding capacity (4 times its weight in water)
- ❖ Semi-occlusive capability, create a protective barrier
- ❖ Restores skin suppleness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

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

VISCOSITY

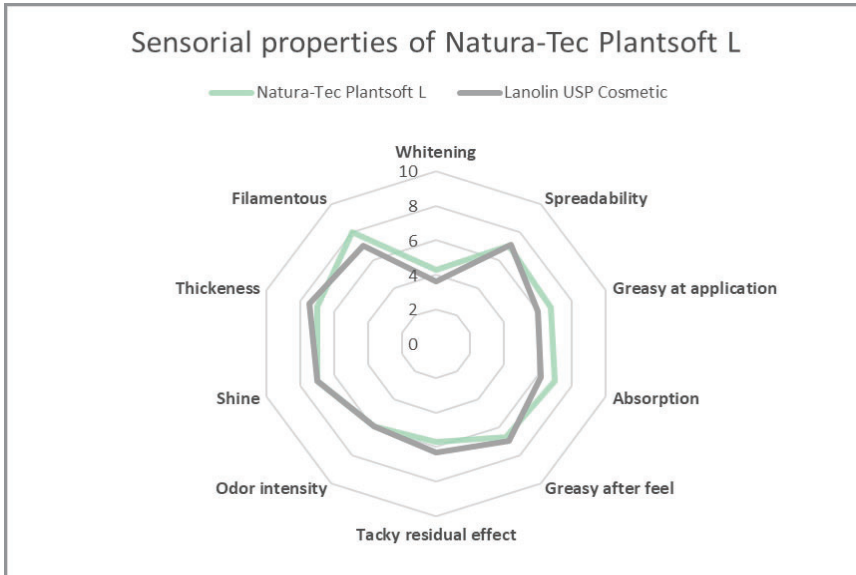
Viscosity comparison between Natura-Tec Plantsoft L and Lanolin (USP Cosmetic).

	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, Natura-Tec Plantsoft L gives a **similar range of viscosity**.

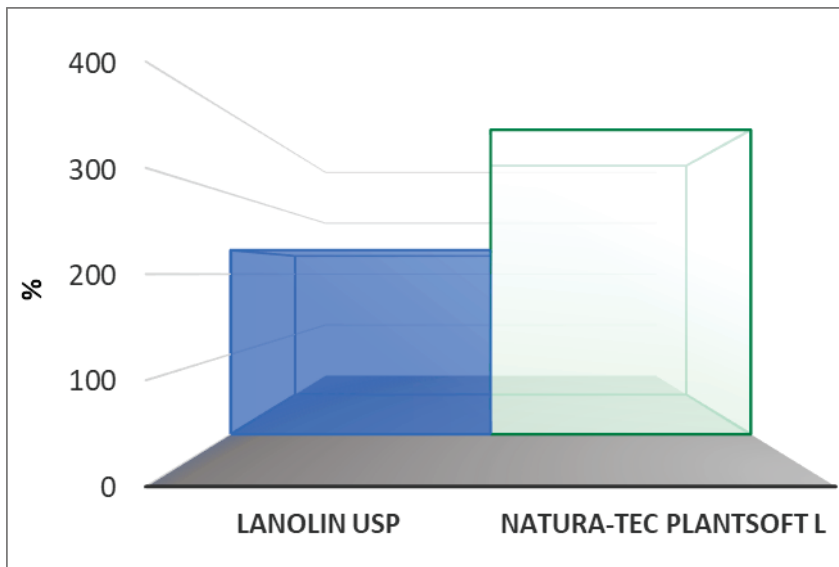
SENSORIAL PROFILE



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

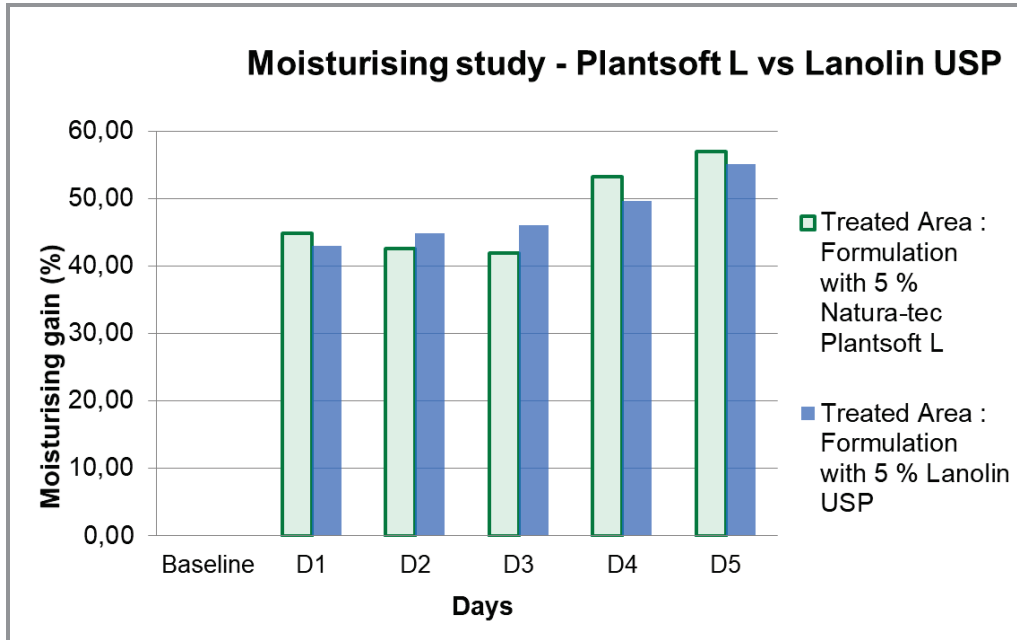
In addition, our product leaves a **slightly less greasy after feel** and is **less tacky**

WATER ABSORPTION STUDY



When compare to Lanolin USP, Natura-Tec Plantsoft L **absorbs 4 times its weight in water** when the Lanolin absorbs 2 times its weight in water.

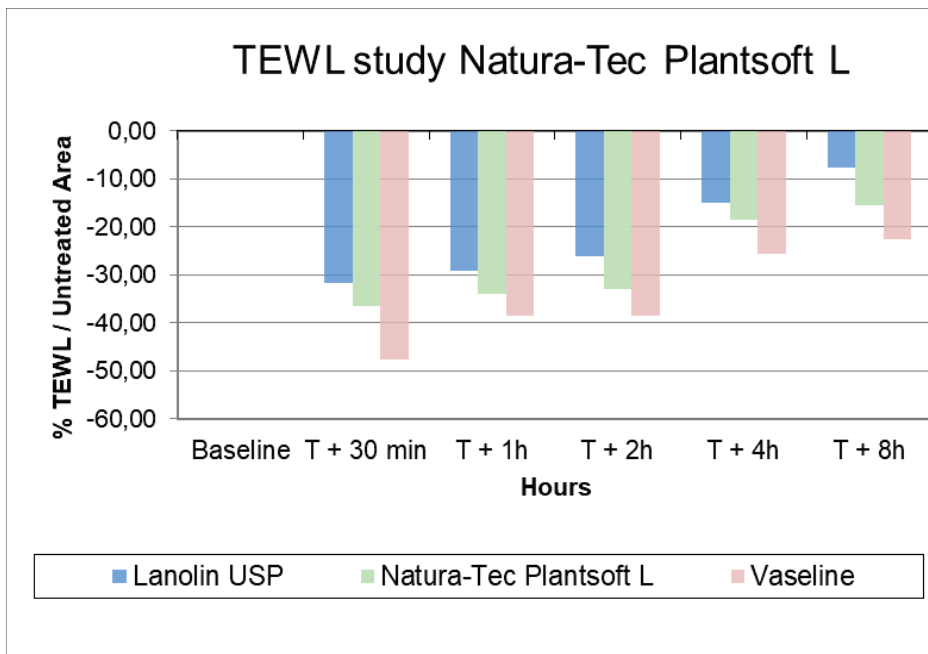
MOISTURIZING STUDY



Moisturizing properties of Natura-Tec Plantsoft L and Lanolin USP are comparable.

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

TEWL STUDIES



The TEWL decrease is related to the repair of the skin barrier function.

The results demonstrate that Natura-Tec Plantsoft L reduces TEWL more than Lanolin (but less than Vaseline which is known to be occlusive).

Reinforced and protected the skin retains water for optimal hydration

Mrs. Pascale Goyat; Sales, Marketing, Regulatory Director
M. Ivan Shersheniuk; Regulatory Officer
Fréjus, May 2025



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