MANUKA OIL EXTRACT LEPTOSPERMUM SCOPARIUM

NOVEL FUNCTIONAL INGREDIENTS FOR MULTI-PURPOSE FORMULATIONS

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CAMPO® Multi-Purpose Cosmetic Base Chemicals & Active Ingredients

CAMPO® Novel Functional Active Cosmetic Ingredient & Raw Materials

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Manuka Extract

Leptospermum scoparium

Commonly referred to as Tea-tree, *Leptospermum* is distributed in Australia, South East Asia (i.e. the malay Peninsula, Sumatra, Borneo, Java, Philippines, Sulawesi, Thailand, Flores, Moluccas, southern Burma and New Guinea) and New Zealand. Whilst *Leptospermum* occupies a variety of habitats from coastal dunes to high mountain peaks, it is most commonly found in wet or periodically wet substrates that are acidic and low in nutrient content.

Leptospermum. A rather small genus of shrubs or small trees of the family Myrtaceae, sub-family Leptospermoideae. It currently comprises 85 recognized species. The genus Leptospermum was first recognized by Johann Reinhold Forster and his son Johann Georg Adam Forster whenthey published the name *L. scoparium* Forst. & G. Forst in 1776.

To possess hard wood is a characteristic of the genus, and in those species which attain sufficient size it is useful for small objects. It is related that the aborigines of Australia use the wood of one for spears. Most of them are called 'Tea Tree' because their leaves can be made into a beverage like tea.

ETHNOBOTANY:

A very refreshing tea is made from the leaves, used for fever and lassitude. In the Moluccas, the mountaineers distil a little volatile aromatic oil from the plant, which they inhale for bronchitis and use as an embrocation for rheumatism. The oil was obtained from its leaves and twigs containing terpenes, particularly pinene, and citral. It extract has also been noted to ameliorate skin problems such as itchiness, rashes as well as accelerate healing of skin wounds and cuts. **Campo Manuka Extracts** are available in 3 types; an essential oil, an oil extract with ceramide and an aqueous extract. Both types exhibit anti-microbial properties, which is bacteriostatic. The oil extract is also applied in cosmetic formulations as colourings. It is ideal for body oils and emulsions made especially for sensitive skin.

Technical Specification:

PRODUCT NAME: CAMPO MANUKA OIL EXTRACT

OTHER NAME: Leptospermum scoparium oil

PRODUCT NUMBER: 97.129/63

SPECIES: Leptospermum scoparium

INCI NAME: (Proposed) Leptospermum scoparium Extract and Ceramide 3 oil

PLANT PARTS USED: flowers (90%) and berries (10%)

APPEARANCE: Clear, red, oil

ODOUR: Characteristics

SPECIFIC GRAVITY: 0.910 – 0.980

REFRACTIVE INDEX: 1.430 – 1.465

VISCOSITY: 25 – 35 (Mpa.s)

WATER CONTENT: 010 max.

RECOMMENDED LEVEL OF USE: 2-5%

Technical Specification:

PRODUCT NAME:	CAMPO MANUKA AQUEOUS EXTRACT
OTHER NAME:	Leptospermum scoparium aqueous Extract
PRODUCT NUMBER:	97.129/67
SPECIES:	Leptospermum scoparium
INCI NAME: (Proposed)	Leptospermum scoparium Extract
PLANT PARTS USED:	flowers, leaves and berries
APPEARANCE:	Clear, dark red liquid
ODOUR:	woody aromatic
pH:	3.4 – 6.8
SPECIFIC GRAVITY:	1.010 – 1.090
REFRACTIVE INDEX:	1.370 – 1.445
SOLUBILITY:	Complete in water

Technical Specification:

PRODUCT NAME:	CAMPO MANUKA ESSENTIAL OIL
OTHER NAME:	Leptospermum Scoparium Floral Essence
PRODUCT NUMBER:	97.129/637
SPECIES:	Leptospermum scoparium
INCI NAME: (Proposed)	Leptospermum Scoparium Branch/Leaf Oil
PLANT PARTS USED:	Leaves, Branches, Flowers
APPEARANCE:	Clear, dark red, oil
ODOUR:	Characteristics
SPECIFIC GRAVITY:	0.900 – 0.990
REFRACTIVE INDEX:	1.320 – 1.455

"(SAFETY DATA SHEET – compliant to GHS)" CONFIRMS TO EC DIRECTIVE 91/155/EEC, EC REGULATION NO#1272/2008, AMENDED EC REGULATION NO#790/2009 and Complies to The EU Cosmetic Products Regulation (Regulation (EC) No 1223/2009) effective on July 2013., and to EU Commission Regulation No.358/2014/9 of 9th April 2014 amending Annexes II and V, to EU Regulation No No.1223/2009 of The European Parliament and of The Council on Cosmetic products, (Effective Date 31st October 2014) AND to US DEPT.OF LABOR-Occupational Safety & Health Admin directives and compliant to Globally Harmonized System of Classification and Labeling of Chemicals (hereinafter referred to as "the GHS")., and Complies and Confirms to the Requirements of State of California Proposition 65.

A Quality Management System, compliant to the International Standard ISO 9001, was used to manufacture and test this material.

http://www.osha.gov/dsg/hazcom/ghs.html

http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

http://www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/index-eng.php

	DATE OF FIRST ISSUE	February 18th 1992-Reviewer - Dr Balasubramaniam PhD
	DATE OF LATEST REVISION	Dec. 12th 1997- Rev'wer- Dr Fergus Jes .G.Velasquez Bsc. Med Tech, MD **February 10th 2012 – Reviewer=Joshua Teo** **February 5th 2013 – Reviewer –** **Dr Balasubramaniam M, PhD** **23rd March 2014 - Joshua Teo Balasubramaniam M PhD & Oksana Nemchenko MD** **12th February 2015 - Joshua Teo BSc. Chem, Balasubramaniam M PhD & Oksana Nemchenko MD** **15th May 2016 - Joshua Teo BSc. Chem, Balasubramaniam M PhD & Oksana Nemchenko MD**
1	PRODUCT AND COMPANY IDENTIFICATION	
	COMMERCIAL NAME: OTHER TRADE NAME:	**CAMPO MANUKA ESSENTIAL OIL** **Leptospermum scoparium floral oil essence**
	LATIN NAME:	**Leptospermum scoparium**
	INCI NAME: **China Translation**	**Leptospermum Scoparium Branch / Leaf Oil** 扫帚叶澳洲茶（LEPTOSPERMUM SCOPARIUM）枝 / 叶油
	INTERNATIONAL CHEMICAL IDENTIFICATION ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)and Compliant to the GHS***:	**LEPTOSPERMUM SCOPARIUM BRANCH / LEAF OIL**
	MANUFACTURER : (cGMP MFG. FACILITIES) :	**CAMPO RESEARCH Pte Ltd** **Husdon Industrial Bldg., #05-02,** **14, New Industrial Road, Singapore 536203**
	EMERGENCY TELEPHONE NUMBERS:	(65)-3833631/(65)-3228503 (Singapore)
2	HAZARDS INDENTIFICATION	
	NOT CLASSIFIED AS DANGEROUS ACCORDING TO DIRECTIVE 67/548/EEC OR ITS AMENDMENTS.	DIVISION 1.6; NON-HAZARDOUS NO HAZARD STATEMENT
	HAZARD CLASS and CATEGORY CODE(s)	PICTOGRAM : NONE

	HAZARD STATEMENT CODE(s) ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)*** **and compliant to the GHS**	No GHS Pictogram (Totally Non-Hazardous Division 1.6; NO HAZARD STATEMENT
	GHS CLASSIFICATION : This material is Non-hazardous according To UN-GHS Criteria.	PICTOGRAM : NONE No GHS Pictogram (Totally Non-Hazardous Division 1.6: No Hazard Statement.
	GHS LABEL ELEMENTS:	No GHS Pictogram (Totally Non-Hazardous Division 1.6: No Hazard Statement.
3	COMPOSITION / INFORMATION ON INGREDIENTS	
	100 PERCENT CARBON-DIOXIDE GAS EXTRACTED LEPTOSPERMUM SCOPARIUM -PLANT PARTS OIL SOLUBLE COMPONENTS	**Leptospermum Scoparium Branch / Leaf Oil**
	CTFA Monograph ID:	10572 – Leptospermum Scoparium Branch / Leaf Oil
	CAS# CAS# EU	N/A – Leptospermum Scoparium Branch / Leaf Oil 223749-44-8 (EU) – Leptospermum Scoparium Branch / Leaf Oil
	CAS NO# (CAS Name) ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)and compliant to the GHS***	**223749-44-8 – Leptospermum Scoparium Branch / Leaf Oil**
	EINECS Name and Number EINECS# EU	N/A – Leptospermum Scoparium Branch / Leaf Oil N/A (EU) – Leptospermum Scoparium Branch / Leaf Oil
	EINECS# (EINECS Name) ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009) and compliant to the GHS***	**N/A (EU) – Leptospermum Scoparium Branch / Leaf Oil**
	EINECS Name and Number EINECS# EU European Commission–Health & Consumer Cosmetics–Cosing	Leptospermum Scoparium Branch / Leaf Oil http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=82214 Leptospermum Scoparium Branch / Leaf Oil – N/A (EU)
	RISK PHRASES SAFETY PHRASES 25-26	None Not Mandatory
	GHS CLASSIFICATION : This material is Non-hazardous according To UN-GHS Criteria.	**PICTOGRAM : NONE**
	GHS LABEL ELEMENTS:	**No GHS Pictogram (Totally Non-Hazardous Division 1.6: No Hazard Statement.**
4	FIRST AID MEASURES	
	EYE CONTACT:	Wash with water or standard eye wash solution. Seek medical advice, if irritation occur and persist.
	ORAL INGESTATION:	Edible in small quantities
	SKIN CONTACT:	Wash with water or shower.
5	FIRE FIGHTING MEASURERS	
	COMBUSTIBLE AND PRESENTS NO SPECIAL FIRE HAZARD.	
	EXTINGUISHING MEDIA:	Treat as oil fire when store in HDPE drums with CO2, dry foam or dry chemical.
	PROTECTIVE EQUIPMENTS FOR	Standard Equipments.

	FIGHTERS:	
6	ACCIDENTAL RELEASE MEASURES	
	ABSORB ONTO AN INERT MATERIAL AND SCRAPE UP. REMOVE RESIDUE BY SCRUBBING WITH HOT WATER OR DETERGENT SOLUTION.	
7	HANDLING AND STORAGE	
	STORE IN SEALED CONTAINERS UNDER NORMAL COOL, DRY WAREHOUSING CONDITIONS.	
8	EXPOSURE AND PERSONAL PROTECTION	
	IN ACCORDANCE WITH GOOD INDUSTRIAL PRACTICE AND HANDLING USING STANDARD EYE PROTECTION.	
9	PHYSICAL AND CHEMICAL PROPERTIES	
	PHYSICAL FORM:	Oil liquid
	COLOUR:	Clear, Light to Dark Red
	ODOUR:	Characteristic
	BOILING POINT:	90 deg. Cent.
	MELTING POINT:	-
	VISCOSITY:	-
	FLASH POINT:	-
	FLAMMABILITY SOLID/GAS:	N/A
	AUTO FLAMMABILITY:	N/A
	SPECIFIC REFRACTIVE:	1.320 - 1.455
	EXPLOSIVE PROPERTIES:	N/A
	pH: (1% in Oil Solution)	5.0 – 6.0
	(pH for Campo Internal QA Purpose Only)	**(Campo Internal Use Only)**
	Manuka Oil Constituents:	un-standardized sesquiterpenes, un-standardized Trichetones, and un-standardized Flavesone
	PROPERTIES:	Anti-Bacterial, Perfumeries, antimicrobial, Chapped dry lips, Foot Care
	VAPOUR PRESSURE:	N/A
	DENSITY:	0.9000 -0.9800
	WATER SOLUBILITY:	Insoluble
	OTHER SOLUBILITY:	In Most Cosmetic Solvents
	BULK DENSITY:	-
	PARTITION COEFFICIENT: (OCTANOL/WATER)	-
	EXPLOSIVE LIMITS:	-
10	STABILITY AND REACTIVITY	
	THERMAL DECOMPOSITION:	Stable under normal conditions of use.
11	TOXICOLOGICAL DATA	Animal Tests Last Done 1992, as requirements of the then **EC DIRECTIVE 91/155/EEC**
	ORAL:	LD50 > 9,000 MG/KG (Body Wt.) Rat Essentially Non-Toxic and Edible in Small Quantity.
	DERMAL:	Expected To Be Essentially Non Toxic.
	INHALATION:	N/A
	SPECIFIC CONCENTRATION LIMITS M-FACTORS ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)*** **compliant to the GHS.**	9,000 MG/KG (Body Wt.); CATEGORY 5 Essentially Non-Toxic and Edible in Small Quantity.
	TOXIC EFFECTS:	
	SKIN:	Primarily Irritation Index (PII) = 0.0 (Non- Irritating - Skintex), Not A Primarily Irritant. Non-irritant / Non-sensitizer as per Repeated Patch Insult Test on 50 Human volunteers. Human Repeated Patch Test 48 hours:

	EYE:	50/50 completely non-irritating / non-erythema causing **ingredient at 10% concentrate in water** on 50 human volunteers Very Mild/Minimal-not A Transient Conjunctival Irritant at 10% concentrate in water(Eyetex Classification). *Summarized toxicological data as shown here are formation bounded under Non-Disclosure Agreement with various clients as when these Toxicological Data were established or their exclusive uses.*
12	ECOLOGICAL INFORMATION	
	BIODEGRATION:	Expected To Be Ultimately Biodegradable.
	FISH TOXICITY:	No Data
	BACTERIAL & VIRAL TOXICITY:	No Data
	WGK CLASS:	WGK (Self Classification)
13	DISPOSAL CONDITIONS	
	DISPOSE OFF ACCORDING TO A RECOGNISED METHOD OF CHEMICAL WASTE DISPOSAL.	
14	TRANSPORT INFORMATION	
	UN NUMBER# :	N/A
	UN NAME:	Not Assigned
	IMDG CODE/CLASS:	Not Hazardous
	IMDG CODE PAGE NO.	N/A
	ICAO/IATA AIR CLASS:	Non-Hazardous
	ICAO/IATA AIR CLASS PACKING GROUP:	N/A
	RID/ADR CLASS:	Non-Hazardous
	ADNR CLASS:	Non-Hazardous
	LABELLING: ***(EC REGULATION NO#1272/2008 AMENDED NO#790/2009) and compliant to the GHS.***	
	PICTOGRAM SIGNAL WORD CODE(s):	No GHS Pictograms (Totally Non-Hazardous)
	HAZARD STATEMENT CODE(s):	Division 1.6; No Hazard Statement
	SUPPLEMENTARY HAZARD STATEMENT CODE(s):	Similar Division 1.6; No Hazard Statement
15	REGULATORY INFORMATION	
	OCCUPATIONAL EXPOSURE LIMITS:	N/A
	U.S. State of California Proposition 65 INGREDIENTS Presence	**None (Exempted from CA Prop 65 Register)**
	EU Commission Regulation No.358/2014/9 of 9th April 2014 amending Annexes II and V, to EU Regulation No No.1223/2009 of The European Parliament and of The Council on Cosmetic products	**"Contains No Parabens and nor contains any Branched Chain Parabens".**(EU Regulation No.358/2014/9 of 9th April 2014)
16	OTHER INFORMATION	
	USES AS A COSMETIC ADDITIVE	0.5 - 5.0 %
	This format and information is compiled by Kampoyaki Novel Natural Product Chemistry/ Novel Drug Discovery cGMP Labs Kobe, Japan; for Campo Research, Kyoto and Singapore.	***Please take note that all specifications are liable to changes without prior notice.**

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CAMPO MANUKA OIL EXTRACT
THE ACTIVE NOVEL DRUG FOR THE COSMETIC FORMULATION

TOXICOLOGICAL & ECOTOXICOLOGICAL DATA

TOLERANCE
As to ensure a good level of innocuity Campo Manuka Oil Extract was tested in in-vitro as follows:

***Irritation potential of the chorio-allantoic membrane of an egg.**
When tested on the chorio-allantoic membrane of a chicken egg, according to the technique developed by LUEPKE** in a 10% lipophilic soluble solution, Campo Manuka Oil is classified as non irritant.
**LUEPKE, N.P., Hen's egg chorio-allantoic membrane test for irritation potentiation. Fd. Chem. 1986, 24, 6-7, 495-496.

*** Cytotoxicity on human fibroblasts.**
When tested on human fibroblasts using a method patented by BIOGIR (which can be applied to both hydrosoluble as well as aqueous products). Campo Manuka Oil Extract in a 10% active aqueous phase or oily phase, does not show any signs of toxicity towards fibroblasts in culture.

*** Eyetex**
According to this technique, in a 10% active solution, Campo Manuka Oil Extract is classified non-irritant.

*** Skintex**
According to this technique, in a 10% active solution, Campo Manuka Oil Extract is non irritant. This tolerance data is confirmed by the tests carried out in vivo on health humans.

*** Test on healthy humans**
When patch tests were carried out at increasing concentrations (0.5%, 1.1%, 2.2%, 4.7%, 10% & 100%) on 50 subjects, Campo Manuka Oil Extract did not show any significant irritant reaction at all. Its tolerance is total satisfactory.

COMEDOGENESIS

Campo Manuka Oil Extract was tested in a 10% active solution on human volunteers, according to the usual protocols has proven to be free of comedogenic effect.
Because of its good level of innocuity. Campo Manuka Oil Extract has proved to be first class natural bacteriostatic agent and skin moisturizer for various cosmetic formulae where tolerance is imperative (creams, lotions, moisturizer, etc.)

BIODEGRADABILITY

The ultimate aerobic biodegradability of Campo Manuka Oil Extract is measured according to STRUM TEST (OCDE 301 B, guideline EEC 84/449, Annex V. Method C5).
Under these conditions, a level of biodegradability of Campo Manuka Oil Extract is 100% in 28 days at 50 mg/ml.

The level of biodegradability of Campo Manuka Oil Extract is considered to be excellent.

Campo Research Singapore
Dec. 12th 1997

MATERIAL SAFETY AND CONSUMER PRODUCT SAFETY TESTING LABS.

(DIVISION OF JTC KAMPOYAKI, SINGAPORE)
P.O. BOX 2105, SINGAPORE 9041
REPUBLIC OF SINGAPORE

F I N A L R E P O R T

DIVISION / COMPANY / GROUP: PROCTOR & Gamble
8700 Mason Montgomery Road
Box 1107, Mason, Ohio 45040
USA

ATTENTION: Lynn Mahony

TEST: The MATREX *In Vitro* Toxicity testing system
Salmonella Typhimurium Reverse Assay

TEST ARTICLE: * MANUKA OIL

EXPERIMENT REFERENCE NO: * 1997-12-13 A

Dr. Fergus Jes Velasquez, M.D.*.
Director of Microbiology

Dr. Balasubramaniam M, Ph.D.*
Laboratory Director

Date: Dec. 12th, 1997

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***Computer generated requires no signature**

OBJECTIVE:

To evaluate the test article for irritancy potential utilizing the MATREX *in vitro* toxicity testing system.

INTRODUCTION

TESTSKIN and MATREX are sophisticated *in vitro* systems. Developed in Organogenesis Inc. of Cambridge, Massachusetts, they closely mimic human skin in structure and function. The Living Dermal Matrex (LDM) consist of a three-dimensional construct comprised of living cells in a collagen matrix. Nutrition is provided through the base via a permeable membrane, leaving the surface open to the atmosphere. This makes an ideal system for applying a variety of material, including liquids, powders, oils, gels and creams.

The Living Skin Equivalent (LSE) has all the features previously described, plus the formation of an actual epidermis complete with stratum corneum.

TESTSKIN and MATREX, when used with the recommended cell metabolism assay can quickly provide toxicological profiles. The procedure involves a solubilized, reactive tetrazolium salt (MTT), which is metabolized by the mitochondria of living cells and converted to purple formazan dye. The color intensity if the skin replica extract, measured photometrically, correlates directly with its viability. When measured against controls, values ranging from 0% to 100% (plus or minus approximately 20%) can be calculated for each dose of an applied substance.

Test Article:	**CAMPO MANUKA OIL EXTRACT** **P# 97.129/63 B# 1997-12-13**
Reference Articles:	**PROPYLENE GLYCOL & MORPHOLINE**

METHOD:

The appropriate dilutions of test sample and control articles were applied to MATREX. After the appropriate exposure period, the articles were rinsed from the MATREX surfaces. MTT (tetrazolium salt) assay medium was utilized in order to quantify cell metabolism. At the end of the staining period, excised portion s of each MATREX were immersed in acidified isopropanol which extracted the converted MTT from tissue samples. A Dynatech MR 4000 Automatic Microplate Reader was used to determine the absorbance of each extract at 570 nm. With the absorbance of a negative control defined as 100%, the percent absorbencies of the test and control articles were determined. The percentages listed below directly correlate with the cell metabolism in the MATREX samples.

RESULTS:

Test Article (%& Exposure)	System	Percent Viability	Percent Inhibition
Campo Manuka Oil Extract			
(100% - 1 hr.)	LDM	99.4%	0.6 %
(10% - 1 hr.)	LDM	100%	0 %
(1% - 1 hr.)	LDM	100%	0 %
Propylene glycol			
(100% - 1 hr.)	LDM	73%	27 %
(10% - 1 hr.)	LDM	99%	1 %
(1% - 1 hr.)	LDM	96%	4 %
Morpholine			
(100% - 1 hr.)	LDM	6%	94 %
(10% - 1 hr.)	LDM	4%	96 %
(1% - 1 hr.)	LDM	100%	0 %

HISTORICAL *IN VITRO* RESULTS:
Propylene glycol has historically been categorized as virtually non-irritating when tested using the Draize irritation methodologies. Morpholine has been categorized as moderately irritating when in the same manner.

DISCUSSIONS:
The sponsor-submitted sample elicited in vitro results comparable to those recorded for propylene glycol.

CONCLUSION:
The results indicate that the sponsor-submitted product has virtually no irritation potential, under the conditions of this test.

CCR-Cytotest Cell Research

CCR PROJECT 95

SALMONELLA TYPHIMURIUM

REVERSE MUTATION ASSAY

REPORT ON
MANUKA OIL EXTRACT

Study Completion Date :
December. 12, 1997

CONCLUSIONS

The test article **Campo Manuka Oil Extract** was assessed for its potential to induce gene mutations according to the incorporation test (experiment I) and the preincubation test (experiment II) using Salmonella typhimurium strains TA 1553, TA 1537, TA 100 and TA 102.

The assay was performed in two independent experiments both with and without liver microsomal activation. Each concentration, including the controls, was tested in triplicate. The **Campo Manuka Oil Extract** was tested at the following concentrations:

33.3; 100.0; 333.3; 1000.0; 2500.0; and 5000.0 up/plate

No toxic effects occurred in the test groups with and without metabolic activation in experiment I and II in all strains used.

The plates incubated with the test article showed normal background growth up to 5000.0 up/plate with and without S9 mix in all strains used.

No substantial increases in revertant colony numbers of any of the five tester strains were observed following treatment with **Campo Manuka Oil Extracts** at any does level, either in the presence or absence of metabolic activation (S9 mix). There was also no tendency of higher mutation rates with increasing concentration in the range below the generally acknowledged border of significance.

A slight decrease (0.001%) in revertant colony numbers was observed in strain. TA 102 at 333.3 and 1000.0 up/plate in experiment I in the presence of metabolic activation. However, this effect is considered not to be relevant since it could not be reproduced in normally more sensitive pre-incubation assay.

Appropriate reference mutagens were used as positive controls and showed a distinct increase in induced revertant colonies.

In conclusion, it can be stated that during the described mutagenicity test and under the experimental conditions reported, the test article did not induce point mutations by base pair change of frameshifts in the genome of the strains used.

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