STEVIA OIL

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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IMPORTANT NOTICE

Specifications may change without prior notice. Information contained in this technical literature is believed to be accurate and is offered in good faith for the benefit of the customer. The company, however, cannot assume any liability or risk involved in the use of its natural products or their derivatives, since the conditions of use are beyond our control. Statements concerning the possible use are not intended as recommendations to use our products in the infringement of any patent. We make no warranty of any kind; expressed or implied, other than that the material conforms to the applicable standard specifications.

Ask about our Herbal Natural Products Chemistry Consultancy Services – Product Registration EEC/UK New Drug Development (NDA-US); Quasi-Drug Topicals (MOHW_Japan); Development of Standards, Analysis & Profiles of Phytochemicals; Literature searches, Cultivation of Medicinal Plants, Clinical-Trials, Development of new uses for Phytochemicals and Extracts; Contract Research and Development Work in Natural Products for Novel Drugs, New Cosmetic Active Ingredients for Active Topica/OTC Cosmetic with functionality and Consumer-perceivable immediate-results, New Food Ingredients for Nutraceuticals & Functional Foods.

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Stevia oil produced from processing of Stevia Sugar crystals .
Stevia oil contains the highest quality C-6 to C-12 Esters.

Stevia oil is an essentially odorless liquid. Stevia Oil is destined in the future to be one of the most popular cosmetic esteric additive, conferring excellent spreading and emollient properties to preparations at a very low cost. Stevia oil is also an effective vehicle and solvent or co-solvent.

Stevia oil is found to be a suitable alternative as a diluent for mineral and vegetable oils to increase solvency promote spreading or lighten these mineral or vegetable oils' texture.

It is particularly useful in bath oils, aerosols, antiperspirants, deodorants, hygiene sprays, sunscreens, skin care creams and lotions, make up foundations and bases, and hair care products.

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KAMPOYAKI RESEARCH & EXPORTS Sys.

P R O D U C T D A T A S H E E T

STEVIA OIL (STEVIOSIDE)

The Stevia oil (oil of stevioside) cosmetic grade is produced through the solvent and CO_2 extraction process of Stevia rebaudiana leaves into stevia sugar (stevioside).

It is a high quality, unrefined grade and would normally meet the following specifications and properties. It may be used as an additive in skin and hair care preparations, as an additive in 'Caffee Oil de Cosmetique (L'oreal)', or as an effective vehicle and solvent or co-solvent of mineral oil or other vegetable oils.etc

PARAMETERS	UNIT	TYPICAL	MAXIMUM
Moisture	%	0.05	1.00
Specific Gravity	g/ml	.840	.890
Refraction Index	--	1.300	1.470
Viscosity 40°C.(Brookfield)	cps	47.5	70.0
Viscosity 100°C.(Brookfield)	cps	15.0	57.5
Flash Point (cc)	°C	180	235
Heavy Metals	ppm	0.005	1
Hexane Insoluble	%	0.1	0.25
Insoluble Impurities	%	0.2	0.25
ASH @ 800°C	%	0.1	0.10
Iodine Value	--	1	5
Saponification Value	mg KOH/g	200	230
Unsaponifiable Matter	%	3.5	5.0
Peroxide Index	meq/K	1.8	2.0
Free Fatty Acid	%	1.0	3.0
Neutralization Index	mg KOH/g	2.5	3.0
Titer	°C	29.0	30.0
Color (lovibond)	Red	0.05	0.09
Color (lovibond)	Yellow	0.01	0.07
FATTY ACIDS C6 - C12 Esters COMPOSITON:			
Myristic Acid	%	0.2	10.3
Palmitic Acid	%	6.3	28.5
Stearic Acid	%	6.7	17.2
Oleic Acid	%	9.4	19.7
Linoleic Acid	%	2.2	13.3
Linolenic Acid	%	0.8	11.**0**

All of the above specifications are based on Kampoyaki Novel Drug Discovery & Standardization Lab's modification of American Oil Chemists Society. Because of natural occurring variations in Stevia crops, from time to time the chemical and physical parameters shown above may slightly deviate. This specification do not constitute as a specification for sales.

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Technical Specification:

Product name:	**Campo Stevia Oil**
Product number:	**98.563-02**
INCI name (Proposed):	**Stevia rebaudiana extract**
INCI name (Existing):	**Stevioside**
Plant parts used:	**Whole plant**
Appearance:	**Oily liquid**
Colour:	**Almost Colorless**
Acid Value:	**0.05 max.**
Iodine Value:	**1.00 max.**
Saponification Value:	**200-230**
Cloud Point/melting Pt :	**+2 to -2°C °C (approx.)**
Specific gravity:	**0.840 - 0.890**

Application:

Stevia oil can be used in formulations for velvety emolliency.
It is an emollient and a natural oil solvent to be used in cosmetic and topical preparations where good absorption through the skin is desired.

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CAMPO STEVIA OIL
THE ACTIVE NOVEL DRUG FOR THE COSMETIC FORMULATION

TOXICOLOGICAL & ECOTOXICOLOGICAL DATA

TOLERANCE

As to ensure a good level of innocuity *Campo Stevia Oil* 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 30% liposoluble solution, *Campo Stevia 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 Stevia Oil* in a 30% 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 Stevia Oil is classified non-irritant.***

*** Skintex**
According to this technique, in a 10% active solution, ***Campo Stevia Oil 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 10 subjects, ***Campo Stevia Oil*** did not show any significant irritant reaction at all. Its tolerance is total satisfactory.

COMEDOGENESIS

Campo Stevia Oil 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 Stevia Oil* has proved to be first class emollient and natural oil solvent for cosmetic and topical preparation where good absorption through the skin is imperative. (skin moisturizing cream, moisturizing lotion, etc.).

BIODEGRADABILITY

The ultimate aerobic biodegradability of *Campo Stevia Oil* 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 Stevia Oil* is 100% in 28 days at 50 mg/ml.

The level of biodegradability of *Campo Stevia Oil* is considered to be excellent.

Campo Research Pte Ltd (Singapore)

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Campo Stevia Oil was safety tested using a variety of in vivo and vitro protocols . The CAMVA was used to determine irritancy. This in vitro assay determines the irritancy of a test compound based on its ability to induce hemorrhage on the chorioallantoic membrane of a chicken egg. Two other in vitro tests were run on Campo Stevia Oil - EpiDerm and Epi-Ocular. EpiDerm is a three - dimensional system composed of human epithelial cells to which the test compound is applied. After incubation, the number of viable cells is measured using the MTT conversion assay.

An ET_{50} is determined, which gives an idea of potential skin toxicity. EpiOcular is a three- dimensional system composed of stratified human keratinocytes to which the test material is applied. After incubation , the number of viable cells is measured using the MTT conversion assay. An ET_{50} is determined, which gives idea of possible ocular irritation . Results are shown in Figure I.

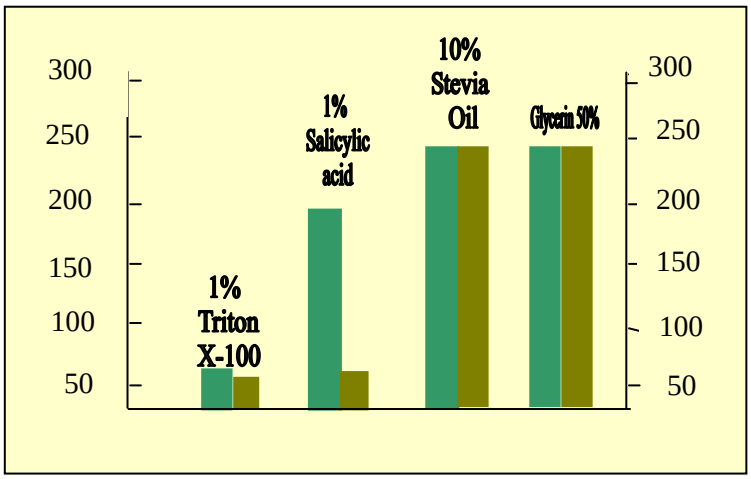

Figure 4. in vitro Toxicology

A sixty -person RIPT was run on Campo Stevia Oil to assess its ability to induce skin irritation and sensitization. The method is modified from the 200 person methodology cited in the reference Appraisal of the Safety of Chemicals in Food, Drugs, and Cosmetics. The material was tested at 100% concentration and underwent nine inductive patchings.

Results

The CAMVA gave an RC_{50} value of 27%. This value is indicative of a material that is not a primary irritant. The results for EpiDerm and EpiOcular are detailed in Figure I. For Campo Stevia Oil, the ET_{50} for the EpiDerm was >24 hours and for the EpiOcular it was >240 minutes. In comparison, salicylic acid yielded ET_{50} values of 19.3 hours for EpiDerm and 14.8 minutes for EpiOcular . Campo Stevia Oil gave scores similar to the scores of glycerine, whereas salicylic acid scored more closely to Triton X-100 , the positive control for the system.

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Discussion

Campo Stevia Oil has less irritation potential than salicylic acid. The safety testings done on Campo Stevia Oil clearly shows this. The EpiDerm and The EpiOcular Assays made actual comparisons between Campo Stevia Oil and salicylic acid , and the Campo natural extract proved to be much less irritating.

Conclusion

Campo Stevia Oil is safe, efficacious natural extracts for use in a variety of cosmetic formulations.

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CAMPO RESEARCH Pte Ltd
TECHNICAL SPECIFICATION

Product Name (Campo Research) Other Trade Names (Campo Research) Existing CTFA / INCI Name Chinese Translation CAMPO PRODUCT # HS Code CTFA Monograph ID CAS# CAS# EU EINECS Numbers and Name EINECS# EU EINECS Number and Name EINECS# EU European Commission–Health & Consumer Cosmetics–Cosing	**CAMPO STEVIA OIL** Stevia Rebaudiana extract / Stevioside Stevioside 甜叶菊苷 **98.563-02** 1302.19.0000 7261 – Stevioside 57817-89-7 – Stevioside 57817-89-7 (EU) – Stevioside 260-975-5(1) – Stevioside 260-975-5 (EU) – Stevioside Stevioside http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=79199 Stevioside – 260-975-5 (EU)
BATCH / LOT	**See COA Batch Lot**
SPECIES	Stevia rebaudiana Syn: *Stevioside*
PARTS USED	Whole plant
RAW MATERIAL – ORIGIN	South America
CONCENTRATION	-
COMMENTS	A Quality Management System, compliant to the International Standard ISO 9001,was used to manufacture and test this material *Please take note that all specifications are liable to changes without prior notice.

Specification Parameter Analysis	**Specification Range**	**Results**	**Methods**
Physical Form	Oily Liquid	Conforms	Visual
Color	Almost colorless	Conforms	Visual
Odor	Odorless	Conforms	Olfactory
Specific Gravity (20°C)	0.840 – 0.890	See COA	USP XXIX/Paar,DMA35
Refractive Index (20°C)	1.4340 – 1.4380	See COA	USP XXIX/DGF IV C (52)
pH (20°C) (100% Concentrate) (pH for Campo Internal QA Purpose Only)	4.5 – 6.5	See COA	USP XXIX/DGF H III (92)
Water Solubility	-	Insoluble	-
Saponification Value	185.0 – 191.0	See COA	-
Acid Value	0.00 – 0.50	See COA	-
Iodine Value	0.00 – 1.00	See COA	
Water Content	0.00 – 0.10	See COA	
Assay	90.0 – 999.0	See COA	
Dry Residue (160°C / 2hrs)	1 – 15%	See COA	Mettler 16J
Preservation	None	Conforms	-

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Pesticide Content	None	Conforms	Pflanzaniaschuttal 1989
Total Germs	<100 Cfu/ml – Non-Pathogenic	Conforms	USP XXIX/Ph.Eur.2.6.12(97)
Total Yeast/Mold	<100 Cfu/ml	Conforms	USP XXIX/Ph.Eur.2.6.12(97)
Heavy Metals(Total)As,Pb,Hg	<0.05 ppm	Conforms	USP XXIX/Ph.Eur.2.6.12(97)

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CAMPO RESEARCH Pvt. Ltd, CHENNAI , INDIA
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"(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	May 5th 1996-Reviewer - Dr Balasubramaniam PhD
DATE OF LATEST REVISION	Jan. 20th 1997- Reviewer- Dr Fergus Jes .G.Velasquez Bsc. Med Tech, MD **Mr Jimmy Kee, 30th June 2003** **Mr Teo SH 5th Jan 2004** **Balasubramaniam M,PhD 21st August 2007** **Mr Joshua Teo, 21st Jan 2011** **Februrary 5th 2013 – Reviewer –** **Dr Balasubramaniam M PhD** **12th February 2015 - Joshua Teo BSc. Chem,** **Dr Balasubramaniam M. PhD & Oksana Nemchenko MD** **15th May 2016 - Joshua Teo BSc. Chem,** **Dr Balasubramaniam M. PhD & Oksana Nemchenko MD**
1 PRODUCT AND COMPANY IDENTIFICATION	
COMMERCIAL NAME: OTHER TRADE NAME:	CAMPO STEVIA OIL Stevia Rebaudiana Extract / Stevioside
LATIN NAME:	Stevia rebaudiana
CTFA ADOPTED NAME / INCI NAME:	Stevioside
CHINESE TRANSLATION:	甜叶菊苷
INTERNATIONAL CHEMICAL IDENTIFICATION *(EC REGULATION NO#1272/2008 AMENDED NO#790/2009) and Compliant to the GHS*:	Stevioside
EPA (USA) GENERIC NAME:	-
MANUFACTURER: (cGMP MFG. FACILITIES)	CAMPO RESEARCH Pte Ltd Level 30, 6 Battery Road Singapore 049909

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	EMERGENCY TELEPHONE NUMBERS:	(+65) 6383 3631 / (+65) 6322 8503 (Singapore)
2	HAZARDS IDENTIFICATION	
	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 STEVIA REBAUDIANA WHOLE PLANT OIL SOLUBLE COMPONENTS	Stevia Extract / Stevioside
	CTFA Monograph ID:	7261 – Stevioside
	CAS# CAS# EU	57817-89-7 – Stevioside 57817-89-7 (EU) – Stevioside
	CAS NO# (CAS Name) *(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)and compliant to the GHS*	57817-89-7 – Stevioside
	EINECS Numbers and Name EINECS# EU	260-975-5(1) – Stevioside 260-975-5 (EU) – Stevioside
	EINECS# (EINECS Name) *(EC REGULATION NO#1272/2008 AMENDED NO#790/2009) and compliant to the GHS*	260-975-5 – Stevioside
	EINECS Name and Number EINECS# EU European Commission–Health & Consumer Cosmetics–Cosing	Stevioside http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=79199 Stevioside – 260-975-5 (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.

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	ORAL INGESTATION:	Essentially edible in small quantity with bland to bitter sweet after taste.
	SKIN CONTACT:	Wash with water or shower
5	FIRE FIGHTING MEASURES	
	COMBUSTIBLE BUT PRESENTS NO SPECIAL FIRE HAZARD.	
	EXTINGUISHING MEDIA:	Treat as oil fire when store in HDPE drums with CO_2, dry foam or dry chemical.
	PROTECTIVE EQUIPMENTS FOR FIGHTERS:	Standard Equipments.
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:	Oily Liquid
	COLOUR:	Almost colorless
	ODOUR:	Odorless
	BOILING POINT:	N/A
	MELTING POINT:	+2 to –2
	VISCOSITY @ 20^{o}C (mPa.S):	-
	FLASH POINT:	N/A
	FLAMMABILITY SOLID/GAS:	N/A
	AUTO FLAMMABILITY:	-
	SPECIFIC REFRACTIVE:	1.434 – 1.438
	EXPLOSIVE PROPERTIES:	N/A
	pH: (100% Concentrate) (pH for Campo Internal QA Purpose Only)	4.5 – 6.5
	OXIDIZING PROPERTIES:	N/A
	VAPOUR PRESSURE:	N/A
	DENSITY:	0.840 – 0.890
	WATER SOLUBILITY:	Insoluble
	OTHER SOLUBILITY:	In Most Cosmetic Solvent
	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:	LD_{50} > 36,000 MG/KG (Body Wt.) Rat Essentially Non-Toxic and Edible in Small Quantity.
	DERMAL:	Expected To Be Essentially Non Toxic.
	INHALATION:	Slight Ethanolic Sting – irritation
	SPECIFIC CONCENTRATION LIMITS M-FACTORS *(EC REGULATION NO#1272/2008 AMENDED NO#790/2009)* compliant to the GHS.	36,000 MG/KG (Body Wt.); CATEGORY 5 Essentially Non-Toxic and Edible in Small Quantity.

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	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: 50/50 completely non-irritating / non-erythema causing ingredient at 10% concentrate in water with Tween 20 on 50 human volunteers
	EYE:	Very Mild/Minimal-not A Transient Conjunctival Irritant at 10% concentrate in water with Tween 20 (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	1.0 – 10.0 %
	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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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

DIVISIONAL / COMPANY/ GROUP:

ONES CO. LTD.
Shin-Hwa Building, 805
34-1 Mapo-Dong, Mapo-gu
Seoul, Korea

ATTENTION:

MR D.H Lee

TEST:

The MATREX *In Vitro* Toxicity testing System

TEST ARTICLE:

CAMPO STEVIA OIL

EXPERIMENT REFERENCE NO.: 98.563-02

_____

Ms. Nupar., MSc.Director of Laboratories Services
Computer generated forms requires no signature
Date: Feb.10 , 1998

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OBJECTIVE:

To evaluate the test article for irritancey 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) con sist
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 materials, 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.

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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 a purple formazan dye. The color intensity of 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 STEVIA OIL

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 portions 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 absorbancies 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 STEVIA OIL			
(100% - 1 hr.)	LDM	90%	10%
(10% - 1 hr.)	LDM	96%	4%
(1% - hr.)	LDM	99.5%	0.5%
Propylene glycol			
(100% - 1 hr.)	LDM	73%	27%
(10% - 1 hr.)	LDM	99%	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 tested 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.

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Stevia Leaf - Too Good To Be Legal?
by Rob McCaleb, Herb Research Foundation

For hundreds of years, people in Paraguay and Brazil have used a sweet leaf to sweeten bitter herbal teas including mate. For nearly 20 years, **Japanese consumers by the millions have used extracts of the same plant as a safe, natural, non-caloric sweetener.** The plant is stevia, formally known as Stevia rebaudiana, and today it is under wholesale attack by the U.S. Food and Drug Administration.

Stevia is a fairly unassuming perennial shrub of the aster family (Asteraceae), native to the northern regions of South America. It has now been grown commercially in Brazil, Paraguay, Uruguay, Central America, the United States, srael, Thailand and China. The leaves contain several chemicals called glycosides, which taste sweet, but do not provide calories. **The major glycoside is called stevioside, and is one of the major sweeteners in use in Japan and Korea**. Stevia and its extracts have captured over 40% of the Japanese market. Major multinational food companies like Coca Cola and Beatrice foods, convinced of its safety, use stevia extracts to sweeten foods for sale in Japan, Brazil, and other countries where it is approved. Europeans first learned of stevia when the Spanish Conquistadors of the Sixteenth Century sent word to Spain that the natives of South America had used the plant to sweeten herbal tea since "ancient times".

The saga of American interest in stevia began around the turn of the Twentieth Century when researchers in Brazil started hearing about "a plant with leaves so sweet that a part of one would sweeten a whole gourd full of mate." The plant had been described in 1899 by Dr. M. S. Bertoni. In 1921 the American Trade Commissioner to Paraguay commented in a letter "Although known to science for thirty years and used by the Indians for a much longer period nothing has been done commercially with the plant. This has been due to a lack of interest on the part of capital and to the difficulty of cultivation."

Dr. Bertoni wrote some of the earliest articles on the plant in 1905 and 1918. In he latter article he notes: "The principal importance of Ka he'e (stevia) is due to the possibility of substituting it for saccharine. It presents these great advantages over saccharine:

1. It is not toxic but, on the contrary, it is healthful, as shown by long experience and according to the studies of Dr. Rebaudi.
2. It is a sweetening agent of great power.
3. It can be employed directly in its natural state, (pulverized leaves).
4. It is much cheaper than saccharine."

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` Unfortunately, this last point may have been the undoing of stevia. **Noncaloric sweeteners are a big business in the U.S.,** as are caloric sweeteners like sugar and the sugar-alcohols, sorbitol, mannitol and xylitol. It is small wonder that the powerful sweetener BUSINESS interests here, do not want the natural, inexpensive, and non-patentable stevia approved in the U.S.

In the 1970s, the **Japanese government approved the Stevia plant,** and food manufacturers began using stevia extracts to sweeten everything from sweet soy sauce and pickles to diet Coke. Researchers found the extract interesting, resulting in dozens of well-designed studies of its safety, chemistry and stability for use in different food products. Various writers have praised the taste of the extracts, which has much less of the bitter aftertaste prevalent in most noncaloric sweeteners**. In addition to Japan, other governments have approved stevia and stevioside, including those of Brazil, China and South Korea, among others.**

Unfortunately, the US was destined to be a different story. Stevia has been safely used in this country for over ten years, but a few years ago, the trouble began.

FDA ATTACK ON STEVIA Around 1987, FDA inspectors began visiting herb companies who were selling stevia, telling them to stop using it because it is an "unapproved food additive". By mid 1990 several companies had been visited. Inone case FDA's inspector reportedly told a company president they were trying to get people to stop using stevia "because Nutra Sweet complained to FDA." The Herb Research Foundation(HRF), which has extensive scientific files on stevia, became concerned and filed a Freedom of Information Act request with FDA for information about contacts between Nutra Sweet and FDA about stevia. It took over a year to get any information from the FDA, but the identity of the company who prompted the FDA action was masked by the agency.

In May, 1991 FDA acted by imposing an import alert on stevia to prevent it from being imported into the US. They also began formally warning companies to stop using the "illegal" herb. By the beginning of 1991, the American Herbal Products Association (AHPA) was working to defend stevia. At their general meeting at Natural Products Expo West, members of the industry pledged most of the needed funds to support work to convince FDA of the safety of stevia. AHPA contracted HRF to produce a professional review of the stevia literature. The review was conducted by Doug Kinghorn, Ph.D., one of the world's leading authorities on stevia and other natural non-nutritive sweeteners. Dr. Kinghorn's report was peer-reviewed by several other plant safety experts and concluded that historical and current common use of stevia, and the scientific evidence all support the safety of this plant for use in foods. Based on this report, and other evidence, AHPA filed a petition with FDA in late October asking FDA's "acquiescence and concurrence" that stevia leaf is exempt from food additive regulations and can be used in foods.

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FDA, apparently attempting to regulate this herb as they would a new food additive, contends that there is inadequate evidence to approve stevia. However, because of its use in Japan, there is much more scientific evidence of stevia's safety than for most foods and additives. The extent of evidence FDA is demanding for the approval of stevia, far exceeds that which has been required to approve even new synthetic food chemicals like aspartame (Nutra Sweet).

AHPA's petition points out that FDA's food additive laws were meant to protect consumers from synthetic chemicals added to food. FDA is trying, in the case of stevia to claim that stevia is the same as a chemical food additive. But as the AHPA petition points out, Congress did not intend food additive legislation to regulate natural constituents of food itself. In fact, Congressman Delaney said in 1956, "There is hardly a food sold in the market today which has not had some chemicals used on or in it at some stage in its production, processing, packaging, transportation or storage." He stressed that his proposed bill was to assure the safety of "new chemicals that are being used in our daily food supply," and when asked if the regulations would apply to whole foods, he replied "No, to Food chemicals only." AHPA contends that stevia is a food, which is already recognized as safe because of its long history of food use. Foods which have a long history of safe use are exempted by law from the extensive laboratory tests required of new food chemicals. The AHPA petition, however, supports the safe use of stevia with both the historical record, and references to the numerous toxicology studies conducted during the approval process in Japan, and studies by interested researchers in other countries.

To date, the FDA still refuses to allow stevia to be sold in the U.S. but the recently-enacted Dietary Supplement Health and Education Act of 1994 may prevent the FDA from treating stevia and other natural herbs as "food additives."

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