

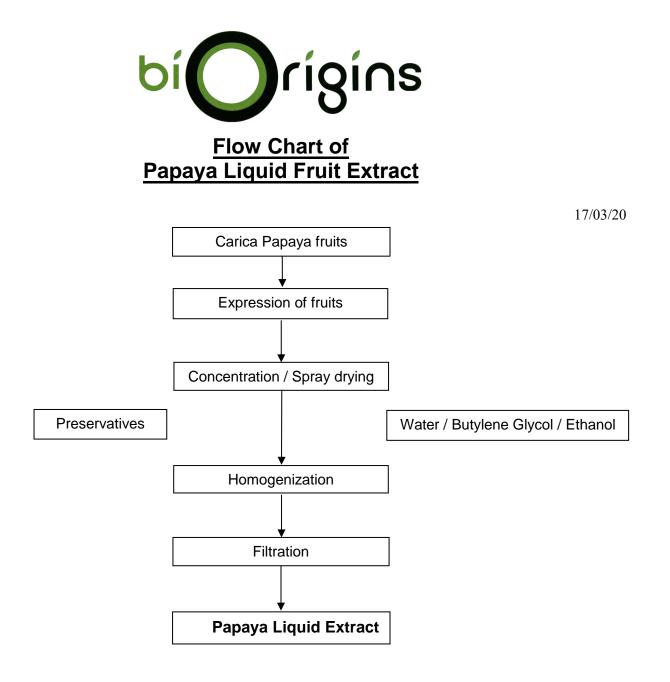
# Certificate of Analysis Papaya Liquid Fruit Extract

Batch Number: 4450202 Best Before End: November 2023

# **Quality Control Results**

st			Malua	11.2	Otatura
Characteristic	Lower	Upper	value	Unit	Status
Addendum 00 REVISION NUMBER	PASS OR FAIL 2.0		Pass Pass		P P
ASPECT	CLEAR LIQUID		Pass		Р
COLOUR	COLOURLESS YELLOW	TO PALE	Pass		Р
ODOUR	CHARACTERIS	TIC	Pass		Р
SPECIFIC GRAVITY (20°C)	1.120	1.150	1.136		Р
REFRACTIVE INDEX (20°C)	1.385	1.415	1.402		Р
WATER CONTENT KARL FISCHER	48.0	52.5	48.9 %		Р
pH VALUE (20°C) TOTAL GERMS MOULDS/YEASTS			5.4 Pass Pass		P P P
	Characteristic Addendum 00 REVISION NUMBER ASPECT COLOUR ODOUR SPECIFIC GRAVITY (20°C) REFRACTIVE INDEX (20°C) WATER CONTENT KARL FISCHER pH VALUE (20°C) TOTAL GERMS	CharacteristicLowerAddendum 00PASS OR FAIL 2.0REVISION NUMBER2.0ASPECTCLEAR LIQUID COLOURCOLOURCOLOURLESS YELLOWODOURCHARACTERIS SPECIFIC GRAVITY1.120 (20°C)1.385 (20°C)REFRACTIVE INDEX1.385 (20°C)WATER CONTENT48.0KARL FISCHER PH VALUE (20°C)4.5TOTAL GERMS100 MAX CFU/M	CharacteristicLowerUpperAddendum 00PASS OR FAIL 2.02.0ASPECTCLEAR LIQUID COLOURCOLOURLESS TO PALE YELLOWODOURCOLOURLESS TO PALE YELLOWODOURCHARACTERISTIC 1.120SPECIFIC GRAVITY1.120(20°C)1.385REFRACTIVE INDEX1.385(20°C)4.5WATER CONTENT48.0KARL FISCHER PH VALUE (20°C)4.56.5100 MAX CFU/ML	CharacteristicLowerUpperValueAddendum 00PASS OR FAILPassREVISION NUMBER2.0PassASPECTCLEAR LIQUIDPassCOLOURCOLOURLESS TO PALEPassCOLOURCOLOURLESS TO PALEPassYELLOWCODOURCHARACTERISTICPassODOURCHARACTERISTICPassSPECIFIC GRAVITY1.1201.1501.136(20°C)1.3851.4151.402WATER CONTENT48.052.548.9 %KARL FISCHERPH VALUE (20°C)4.56.55.4PH VALUE (20°C)4.56.55.4TOTAL GERMS100 MAX CFU/MLPass	CharacteristicLowerUpperValueUnitAddendum 00PASS OR FAILPassREVISION NUMBER2.0PassASPECTCLEAR LIQUIDPassCOLOURCOLOURLESS TO PALEPassCOLOURCHARACTERISTICPassSPECIFIC GRAVITY1.1201.150(20°C)1.3851.415REFRACTIVE INDEX1.3851.415(20°C)4.56.5WATER CONTENT48.052.5KARL FISCHER100 MAX CFU/MLPass

Long term storage, recommended at room temperature The performed analysis are guaranteed on original packaging When stored accordingly, stable for 24 months





# **Composition Information**

# **Product Name: Papaya Liquid Fruit Extract**

INCI Name :	Glycerin, Water, Carica Papaya (Papaya) Fruit Extract		
INCI Name EU :	to follow Cosing, the European Commission database on <a href="http://ec.europa.eu/consumers/cosmetics/cosing/">http://ec.europa.eu/consumers/cosmetics/cosing/</a>		
Composition :			
	Glycerin Water Carica Papaya (Papaya) Fruit Ext	ract*	48 – 52% 45 – 48% 2 – 4%
* Carica Papaya (Papaya) Fruit Extract is expressed as <b>fresh</b> fruit			
Preservatives :	Potassium Sorbate Sorbic Acid	approx. 0. approx. 0.	
Antioxidant :	None		

03/16 This composition replaces the earlier one dated 09/08

Non-warranty

The information in this publication is believed to be accurate and is given in good faith but no representation or warranty as to its completeness or accuracy is made. Suggestions for uses or applications are only opinions. Users are responsible for determining the suitability of these products for their own particular purpose. No representation or warranty, express or implied, is made with respect to information or products including without limitation warranties of merchantability or fitness for a particular purpose or non-infringement of any third party patent or other intellectual property rights including without limit copyright, trademark and designs. Any trademarks identified herein are trademarks of the MADAR Corproation group of companies.



Date: 30/08/2018

# **REACH STATEMENT**

MADAR Corporation is committed to meet the requirements set out in the REACH (Registration Evaluation and Authorization of Chemicals) regulations and we are working with our suppliers to ensure a continued supply of the below mentioned product.

Below listed product is so called preparation composed of ingredients (named under REACH as substances).

# Papaya Liquid Fruit Extract

INCI	CAS	EINECS	REACH status	Comment
Glycerin	56-81-5	200-289-5	Exempt	Annex V
Water	7732-18-5	231-791-2	/	1
Carica Papaya (Papaya) Fruit Extract	84012-30-6	281-675-0	Exempt	Production <1T/yr
Potassium Sorbate	24634-61-5	246-376-1	Registered	01-2119950315-41
Sorbic Acid	110-44-1	203-768-7	Registered	01-2119950330-49

If in the future the amount of a substance produced by our supplier would exceed the 1T/year limit, they will ensure its registration.

Substances of Very High Concern (SVHC; in REACH's Appendix XIV substances' list subjected to authorization) have not been added in the above mentioned product and are not expected to be impurities of the raw materials used in this product

This information is given in good faith and is based on our knowledge to date.

## Non-warranty

The information in this publication is believed to be accurate and is given in good faith but no representation or warranty as to its completeness or accuracy is made. Suggestions for uses or applications are only opinions. Users are responsible for determining the suitability of these products for their own particular purpose. No representation or warranty, express or implied, is made with respect to information or products including without limitation warranties of merchantability or fitness for a particular purpose or non-infringement of any third party patent or other intellectual property rights including without limit copyright, trademark and designs.



# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0

Revision Date 19.11.2015

Print Date 18.03.2020

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	: PAPAYA LIQUID FRUIT EXTRACT
1.2 Relevant identified uses of t	he substance or mixture and uses advised against
Use of the Sub- stance/Mixture	: Manufacture of soap and detergents, cleaning and polishing mixtures Cosmetic additive
1.3 Details of the supplier of the	safety data sheet
Company	: MADAR Corporation Limited 19-20 Sandleheath Industrial Estate Fordingbridge Hampshire SP6 1PA
Telephone	: +44 (0) 1425 655555

E-mail address

: sales@madarcorporation.co.uk

## 1.4 Emergency telephone number

USA: 24 Hour Emergency Response Information CHEMTREC toll free: 1-800-424-9300; direct/international: 1-703-527-3887. CANADA: CANUTEC 1-888-CAN-UTEC (226-8832), 613-996-6666 or \*666. EUROPE: 00 32 3575 5555. ASIA PACIFIC - excl. China: +65 6542-9595. CHINA: +86 816-635 2206. AUSTRALIA: +61 2 7808 3390. SOUTH AFRICA: +32 3 575 55 55. BRASIL:Suatrans 0800 707 7022 / 0800 707 1767. LATAM: Suatrans (+55) 11 98149-0850 / (+55) 19 3833-5300. INDIA: +91 22 30948601/2. JAPAN: +65 6542 9595 (24 時間 日本語対応無料通話, シンガポール). TÜRKIYE: Sağlik Bakanlıği Ulusal Zehir Merkezi - 114

# **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0

Revision Date 19.11.2015

Print Date 18.03.2020

### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

# Hazardous components

Remarks

: No hazardous ingredients

## **SECTION 4: First aid measures**

4.1 Description of first aid measured	res
If inhaled	: If breathed in, move person into fresh air. If symptoms persist, call a physician.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>If symptoms persist, call a physician.</li> </ul>
In case of eye contact	: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If swallowed	: If large quantities of this material are swallowed, call a physician immediately.
4.2 Most important symptoms and	effects, both acute and delayed
Symptoms	: None known.
4.3 Indication of any immediate m	edical attention and special treatment needed
Treatment	: None known.
SECTION 5: Firefighting measure	ures

#### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or car-BiOrigins, 19-20 Sandleh AN IRIOXING Estate, Fordingbridge, Hampshire, SP6 1PA, UK Tel: 01425 655555 Email: technical@madarcorporation.co.uk Page 6 of 21

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0	Revision Date 19.11.2015	Print Date 18.03.2020
Unsuitable extinguishing media	: High volume water jet	
5.2 Special hazards arising from t	the substance or mixture	
Specific hazards during fire- fighting	<ul> <li>In case of fire hazardous decomposition products may be produced such as: Carbon oxides</li> </ul>	
	Do not use a solid water stream a fire.	s it may scatter and spread
5.3 Advice for firefighters		
Special protective equipment for firefighters	: In the event of fire, wear self-conta	ained breathing apparatus.
Further information	: Prevent fire extinguishing water from water or the ground water system Fire residues and contaminated fin be disposed of in accordance with	re extinguishing water must

# **SECTION 6: Accidental release measures**

6.1 Personal precautions, protectiv	ve equipment and emergency procedures		
Personal precautions	: Ensure adequate ventilation. Use personal protective equipment.		
6.2 Environmental precautions			
Environmental precautions	: Prevent product from entering drains.		
6.3 Methods and material for conta	ainment and cleaning up		
Methods for cleaning up	: Soak up with inert absorbent material. Sweep up and shovel into suitable containers for disposal.		
6.4 Reference to other sections None.			
SECTION 7: Handling and stora	nge		
7.1 Precautions for safe handling			
•	: Handle in accordance with good industrial hygiene and safety practice.		

Advice on protection against	: Normal measures for preventive fire protection.
fire and explosion	

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0		Revision Date 19.11.2015	Print Date 18.03.2020
7.2 Conditions for safe storage, i	nc	luding any incompatibilities	
Requirements for storage areas and containers	:	Store in original container. Keep conta dry and well-ventilated place.	iner tightly closed in a
Advice on common storage	:	No special restrictions on storage with	other products.
Recommended storage tem- perature	:	15 - 25 °C	
Other data	:	Recommended storage temperature	
		Stable under recommended storage co	unditions.
7.3 Specific end use(s) Specific use(s)	:	Manufacture of chemical products	

# **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

# **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	GB EH40
Further information	Where no specific short-term exposure limit is listed, a figure three times the			
	long-term exp	osure should be use	d	

#### 8.2 Exposure controls

Personal protective equipment					
Eye protection	: Safety glasses with side-shields				
Hand protection Remarks	: For prolonged or repeated contact use protective gloves.				
Skin and body protection	: Impervious clothing				
Respiratory protection	: No personal respiratory protective equipment normally re- quired.				

# **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Appearance	:	clear, liquid
Colour	:	light yellow
Odour	:	characteristic

Odour Thresheid rigins, 19-20 Sandlehenth Industrial Entering Fordingbridge, Hampshire, SP6 1PA, UK Tel: 01425 655555 Email: technical@madarcorporation.co.uk

# PAPAYA FRUIT LIQUID EXTRACT

sion 1.0	Revision Date 19.11.2015	Print Date 18.03.2020
рН	: 4.5 - 6.5, (20 °C)	
Melting point	: No data available	
Boiling point	: No data available	
Decomposition temperature	No data available	
Flash point	: No data available	
Evaporation rate	: No data available	
Flammability (solid, gas)	: No data available	
Upper explosion limit	: No data available	
Lower explosion limit	: No data available	
Vapour pressure	: No data available	
Relative vapour density	: No data available	
Density	: 1.120 - 1.150 g/cm3 (20 °C)	
Solubility(ies)		
Water solubility	: soluble	
Solubility in other solvents	: not determined	
Partition coefficient: n- octanol/water	: No data available	
Thermal decomposition	: No data available	
Viscosity Viscosity, dynamic	: No data available	
Viscosity, kinematic	: No data available	
Explosive properties	: Classification Code: No data avail	lable
Oxidizing properties	: No data available	

## 9.2 Other information

No data available

PAPAYA FRUIT LIQUID EXTRACT

Version 1.0

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Print Date 18.03.2020

# **SECTION 10: Stability and reactivity**

<b>10.1 Reactivity</b> No data available	
<b>10.2 Chemical stability</b> No data available	
10.3 Possibility of hazardous reaction	ons
Hazardous reactions :	: Stable under recommended storage conditions.
<b>10.4 Conditions to avoid</b> Conditions to avoid	: None known.
<b>10.5 Incompatible materials</b> Materials to avoid :	: Strong oxidizing agents
10.6 Hazardous decomposition proc	ducts
Hazardous decomposition : products	<ul> <li>No data available</li> <li>In case of fire hazardous decomposition products may be produced such as:</li> <li>Carbon oxides</li> </ul>

# **SECTION 11: Toxicological information**

11.1 Information on toxicological effective	cts
---	-----

### Acute toxicity

Product:		
Acute oral toxicity	:	No data available :
Acute inhalation toxicity	:	No data available :
Acute dermal toxicity	:	No data available :
Skin corrosion/irritation		
Due du et		

## Product:

Remarks: No data available

### Serious eye damage/eye irritation

### Product:

Remarks: No data available

PAPAYA FRUIT LIQUID EXTRACT Version 1.0 Revision Date 19.11.2015 Print Date 18.03.2020 Respiratory or skin sensitisation **Product:** Remarks: No data available Germ cell mutagenicity Product: Genotoxicity in vitro : Remarks: No data available Carcinogenicity **Product:** Carcinogenicity - Assess-: No data available ment **Reproductive toxicity** Product: Effects on fertility Test substance: No data available STOT - single exposure Product: Assessment: No data available STOT - repeated exposure Product: Assessment: No data available Aspiration toxicity **Product:** No data available **SECTION 12: Ecological information** 

# 12.1 Toxicity

#### Product:

Toxicity to fish

: Remarks: No data available

#### 12.2 Persistence and degradability

#### Product:

BiodegradabilityOrigins, 19-20 Sandleh ReinharkeriaNEsteat Faveritybyte, Hampshire, SP6 1PA, UK Tel: 01425 655555 Email: technical@madarcorporation.co.uk Page 11 of 21

# PAPAYA FRUIT LIQUID EXTRACT

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#### 12.3 Bioaccumulative potential

|--|

Bioaccumulation : Remarks: No data available

### 12.4 Mobility in soil

### Product:

Distribution among environ-	:	Remarks: No data available
mental compartments		

### 12.5 Results of PBT and vPvB assessment

### Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

### 12.6 Other adverse effects

### Product:

Additional ecological informa- : Remarks: No data available tion

# **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	: Dispose of in accordance with local regulations.
Contaminated packaging	<ul> <li>Empty remaining contents.</li> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> </ul>

# **SECTION 14: Transport information**

## 14.1 UN number

Not regulated as a dangerous good

#### 14.2 Proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class

Not regulated as a dangerous good

## 14.4 Packing group

BiOrigins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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according to Regulation (EC) No. 1907/2006

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Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

# 14.6 Special precautions for user

Not applicable

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable for product as supplied.

# **SECTION 15: Regulatory information**

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this	product are reported in the following inventories:
CH INV	: On the inventory, or in compliance with the inventory
DSL	: All components of this product are on the Canadian DSL
AICS	: On the inventory, or in compliance with the inventory
PICCS	: On the inventory, or in compliance with the inventory
IECSC	: On the inventory, or in compliance with the inventory

For explanation of abbreviations see section 16.

## **15.2 Chemical Safety Assessment**

# **SECTION 16: Other information**

## Key or legend to abbreviations and acronyms used in the safety data sheet

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIOC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.



# **Specification**

Date: 18.03.2020

Product Name:PAPAYA LIQUID FRUIT EXTRACTSpecification:14/11/2006

Period of validity of Certificate of Analysis for material stored in unopened containers and stored in cool dry conditions (unless otherwise specified): 730 days.

Analy. Test Method No.	Characteristic	Specification Limit Lower	s Upper	Units
	REVISION NUMBER	2.0		
AC018000	ASPECT		2	
AC018000	COLOUR	COLOURLESS YELLOW	S TO PALE	
AC018000	ODOUR	CHARACTERI	STIC	
FC0031A0	SPECIFIC GRAVITY (20°C)	1.120	1.150	
FC0032A0	REFRACTIVE INDEX (20°C)	1.385	1.415	
EC003000	WATÉR CONTENT KARL FISCHER	48.0	52.5	%
FC0064A0 JC0054A0 JC0054A0	pH VALUE (20°C) TOTAL GERMS MOULDS/YEASTS	4.5 100 MAX CFU/ 10 MAX CFU/N		

Long term storage, recommended at room temperature The performed analysis are guaranteed on original packaging When stored accordingly, stable for 24 months



# **Toxicological dossier**

# **Product Name: Papaya Liquid Fruit Extract**

INCI Name :	Glycerin, Water, Carica Papaya (Papaya) Fruit Extract
INCI Name EU:	to follow Cosing, the European Commission database on <a href="http://ec.europa.eu/consumers/cosmetics/cosing/">http://ec.europa.eu/consumers/cosmetics/cosing/</a>

#### **Composition :** (A: > 50 %; B: 25 - 50 %; C: 10 - 25 %; D: 5 - 10 %; E: 1 - 5 %; F: 0.1 - 1 %; G: < 0.1 %) В Glycerin Water В Е Carica Papaya (Papaya) Fruit Extract

# Origin of raw materials :

•	Plant origin : - from organic culture : - free of GMO :	Glycerin No Yes	
•	Plant origin : - plant part : - from organic culture : - free of GMO :	Carica Papaya Fruit No Yes	
•	Synthetic origin :	Preservatives	
•	Animal origin :	No	
Prese	rvatives :	Potassium Sorbate	approx 0.4 %
		Sorbic Acid	approx 0.1 %
Antiox	idant :		

# Microbiological Data :

$\Rightarrow$	Bacteria	< 100 cfu / ml
$\Rightarrow$	Moulds and yeasts	< < 10 cfu / ml
$\Rightarrow$	Pathogenic Micro-organisms	Not tested

# Contamination by trace elements :

⇒	Heavy metals :	Total heavy metals expressed as Pb < 10 ppm according to Ph. Eur. 2.4.8 method C or USP <231> method II. Conclusion by analogy
⇒	Pesticides:	Pesticides are expected to pass DFG S 19 (according to "Rückstandshöchstmengenverordnung") Conclusion by analogy
$\Rightarrow$	Impurities :	
Calcium Phosphate Citric Acid		Max. 50 ppm (conclusion by analogy) Max. 70 ppm (conclusion by analogy)
⇒	Residual solvents:	Not expected – not tested
⇒	Papain content :	Because of the dehydration step in the manufacturing process, papain is expected to be inactivated and not

detectable.

# Total volatile components / Allergens content :

We herewith confirm that **Papaya Liquid Fruit Extract**, meets the following properties:

CAS-No.	Allergen	Content expected
122-40-7	Amyl cinnamic aldehyde	< 1ppm*
101-85-9	Amyl cinnamic alcohol	< 1ppm*
105-13-5	, ,	
100-51-6		
120-51-4		
103-41-3 Benzyl cinnamate		< 1ppm* < 1ppm*
118-58-1	Benzyl salicylate	< 1ppm*
104-55-2	Cinnamic aldehyde	< 1ppm*
104-54-1	Cinnamic alcohol	< 1ppm*
5392-40-5	Citral	< 1ppm*
106-22-9	Citronellol	< 1ppm*
91-64-5	Coumarin	< 1ppm*
97-53-0	Eugenol	< 1ppm*
4602-84-0	Farnesol	< 1ppm*
106-24-1	Geraniol	< 1ppm*
101-86-0	Hexyl cinnamaldehyde	< 1ppm*
107-75-5	Hydroxycitronellal	< 1ppm*
97-54-1 Isoeugenol		< 1ppm*
80-54-6	Lilial	< 1ppm*
5989-27-5	d-Limonene	< 1ppm*
78-70-6	Linalool	< 1ppm*
31906-04-4 Lyral		< 1ppm*
111-12-6 Methyl heptine carbonate		< 1ppm*
127-51-5 Methyl ionone alpha iso		< 1ppm*
90028-68-5 Oakmoss		< 1ppm*
90028-67-4	Tree Moss	< 1ppm*

\*not expected as a component of the fruit of Carica Papaya

None of the 26 identified allergen perfume compounds (Directive 2003/15 EC) have been added to the product.

The absence of any of these 26 allergens can not be confirmed, but we attest that they cannot technically occur due to the extraction process used.

The single contents are based on risk estimation which is based on botanical and phytomedicinal reference literature and conclusions by analogy.

## Hazardous & CMR Substances

We herewith confirm that, with reference to the confirmation of our raw materials suppliers, we do not add any CMR (Carcinogenic, Mutagenic, Toxic for reproduction) substances graded 1A, 1B or 2 in accordance with the Annex VI of the European Regulation 1272/2008 and its amendments to our product listed below.

Papaya Liquid Fruit Extract

The product fulfils the requirement of Article 15 of the European Regulation 1223/2009 and its amendments.

Botanical preparations which contain technically unavoidable traces or impurities of plant constituents listed as CMR in the European Regulation 1272/2008.are not affected by the exclusion listed in Article 15 of the European Regulation 1223/2009.

# Animal testing

Our supplier confirms that since 1990, our products have not been tested on animals in order to meet the requirements of the Cosmetic Directive and we will not carry out animal tests in the future to meet the requirements of the Cosmetic Regulation.

We are aware that the individual substances that comprise our products may have been tested on animals in the past, but these tests were not carried out either by or on the request of our supplier.

Our supplier therefore confirms the compliance of our products with the Cosmetic Regulation 1223/2009 concerning the ban on testing in animals in order to meet the requirements of the Cosmetic Regulation.

## Main actives in the plant :

- $\Rightarrow$  Carbohydrates
- $\Rightarrow$  Minerals
- $\Rightarrow$  Vitamins (B-group, C)
- $\Rightarrow$  Fruit acids

### Main actives in the extract :

### Not determined

## Toxicological Data :

We do not see any danger in using Papaya Liquid Fruit Extract in cosmetic agents taking into account the application form, the concentration, the amount used and the frequency of use.

We haven't carried out clinical studies on Papaya Liquid Fruit Extract, but according to literature, Glycerin and Carica papaya don't contain potentially toxic compounds and they are safe when used appropriately.

Ripe Papayas are eaten since hundreds of years and no adverse effects are reported. There is no other data on the side effects and toxicology of these ripe fruits. It can be noted that some people are allergic to the pollen, the fruit and the latex of Carica Papaya.<sup>(5)(6)</sup>

 $\Rightarrow$  Human skin irritation :

Glycerin : Skin irritation studies on albino rabbit showed that no skin irritation appeared after 90 days of application.<sup>(2)</sup>

- Carica Papaya : In Jamaica, users of papaya suggested that topical application of the unripe fruit promoted granulation and healing and reduced odour in chronic skin ulcers. Papaya was considered to be more effective than other topical applications in the treatment of chronic ulcers.<sup>(7)</sup>
- $\Rightarrow$  Mucous membrane irritation :
  - Glycerin : Eye irritation studies on albino rabbit showed that there was no measurable eye irritation.<sup>(2)</sup>
- $\Rightarrow$  Sensitisation potential :
  - Glycerin : Sensitization tests on guinea pigs showed that no sensitization occurred.<sup>(2)</sup>

$\Rightarrow$	Cytotoxicity :		No data available		
$\Rightarrow$	Phototoxicity :		No data available		
$\Rightarrow$	Mutagenicity (	e.g. Ames Test) :	No data available		
$\Rightarrow$	Carcinogenicity	y:	No data available		
$\Rightarrow$	Acute toxicity :	Acute toxicity :			
	Glycerin : LD <sub>50</sub> (mice, oral) = 23 g/kg LD <sub>50</sub> (rats, oral) = 27.2 g/kg LD <sub>50</sub> (guinea pigs, oral) = 10 g/kg <sup>(2)</sup>				
	Carica Papaya (aqueous extract of the unripe fruit) :				
	$LD_{50}$ (rats, oral) = 2520 mg/kg The aqueous extract of unripe papaya is safe, confirming that the belief of the users that the extract has no adverse effect since none has been observed in the past. <sup>(3)</sup>				
	Carica Papaya juice: LD <sub>50</sub> (rats, oral) > 1500 mg/kg – considered non toxic $^{(4)}$				
⇒	Inhalation toxic	bity :	No data available		
$\Rightarrow$	Chronic toxicity :				
	Carica Papaya (aqueous extract of the unripe fruit) : The intake of the extract did not affect the functions of the liver, kidney and bone narrow in rats. <sup>(3)</sup>				
$\Rightarrow$	Reproduction t	oxicity :	No data available		
Ecological Data :					
Our product contains mainly Glycorin/Water extraction vehicle :					
Our product contains mainly Glycerin/Water extraction vehicle :					

 $\Rightarrow$  The ecological information about Glycerin is <sup>(2)</sup>:

Environmental toxicity :

 $LC_{50}$  (fish – 96 hours ) > 1000 mg/l  $EC_{50}$  (Daphnia magna– 24 hours ) > 10 g/l  $EC_{50}$  (Pseudomonias putida – 16 hours ) > 10 g/l

Biodegradability : Totally biodegradable

 $\Rightarrow$  Water hazard class:

1 (self classification)

Phytopharmaceutical Data :						
⇒	External uses :	used in regenerating, conditioning and moisturising skin and hair care, showers gels, anti-ageing care				
$\Rightarrow$	Contraindications :	None known				
$\Rightarrow$	Side effects :	None known				
$\Rightarrow$	Interactions:	None known				

#### **References :**

- (1) Martindale, The Extra Pharmacopoea, 30<sup>th</sup> Edition for toxicological information regarding Glycerin.
- (2) Comparative study of synthetic and natural Glycerin.
- (3) T. Oduola, F Adeniyi, E. Ogunyemi, I. Bello, T. Idowu and H. Subair; Toxicity studies on an unripe Caria papaya aqueous extract: biochemical and haematological effects in wistar albino rats; Journal of Medicinal Plants Research Vol 1 (1), pages 001-004; August 2007
- (4) Mehdipour S., Yasa N, Dehghan G, Khorasani R, Mohammadirad A, Rahimi R, Abdollahi M; Antioxidant potentials of Iranian Carica papaya juice in vitro and in vivo are comparable to alpha-tocopherol.; Phytotherapy Reseach PTR (2006). (Abstract available)
- (5) http://www.hort.purdue.edu/newcrop/duke\_energy/Carica\_papaya.html
- (6) Blanco C, Ortega N, Castillo R, Alvarez M, Dumpierrez AG, Carillo T; Carica papaya pollen allergy; Ann Allergy Asthma Immunol., 1998 Aug; 81(2):171-5.
- (7) Hewitt H, Whittle S, Lopez S, Bailey E, Weaver S; Topical use of papaya in chronic skin ulcer therapy in Jamaica; West Indian Med J; 2000 Mar; 49(1):32-3.

09/19 This toxicological dossier replaces the earlier one dated 09/08, 11/11, 03/15

#### Non-warranty

The information in this publication is believed to be accurate and is given in good faith but no representation or warranty as to its completeness or accuracy is made. Suggestions for uses or applications are only opinions. Users are responsible for determining the suitability of these products for their own particular purpose. No representation or warranty, express or implied, is made with respect to information or products including without limitation warranties of merchantability or finess for a particular purpose or non-infringement of any third party patent or other intellectual property rights including without limit copyright, trademark and designs.



Date : 06.06.2019

To whom it may concern :

# **STATEMENT**

We hereby confirm that the below mentioned product is derived from non-animal sources nor animal by-products. We further confirms that since 1990, this product has not been tested on animals in order to meet the requirements of the Cosmetic Regulation and we will not carry out animal tests in the future to meet the requirements of the Cosmetic Regulation.

# Papaya Extract WI, Art. Code NA22484

Cross-contamination cannot be excluded considering that some of the raw materials used in our production site are from animals' origins, but the risk is expected to be very low as adequate quality measures are implemented to limit the occurrence of contamination.

This information is given in good faith with our actual knowledge. This correspondence will not be automatically updated in the future.