

# Certificate of Analysis Papaya Liquid Fruit Extract

Batch Number: 4471112 Best Before End: May 2024

# **Quality Control Results**

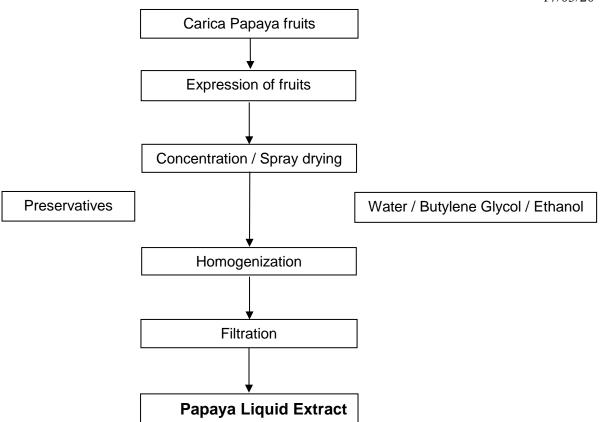
Analytical Tes	st Characteristic	Specificati Lower	on Limit Upper	Value	Unit	Status
			орро.		· · · · ·	0.0
	Addendum 00	PASS OR FAIL		Pass		Р
	REVISION NUMBER	2.0		Pass		Р
AC018000	ASPECT	CLEAR LIQUID		Pass		Р
AC018000	COLOUR	COLOURLESS T	O PALE	Pass		Р
		YELLOW				
AC018000	ODOUR	CHARACTERIST	TC	Pass		Р
FC0031A0	SPECIFIC GRAVITY	1.120	1.150	1.137		Р
	(20°C)					
. J0032A0	REFRACTIVE INDEX	1.385	1.415	1.402		Р
	(20°C)					
EC003000	WATER CONTENT	48.0	52.5	48.2 %		Р
	KARL FISCHER					
FC0064A0	pH VALUE (20°C)	4.5	6.5	5.4		, P
JC0054A0	TOTAL GERMS	100 MAX CFU/M	L	Pass		Р
JC0054A0	MOULDS/YEASTS	10 MAX CFU/ML		Pass		Р

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



# Flow Chart of Papaya Liquid Fruit Extract

17/03/20





# **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

http://ec.europa.eu/consumers/cosmetics/cosing/

**Composition:** 

Glycerin 48 - 52% Water 45 - 48% Carica Papaya (Papaya) Fruit Extract\* 2 - 4%

**Preservatives:** Potassium Sorbate approx. 0.4%

Sorbic Acid approx. 0.1%

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.

<sup>\*</sup> Carica Papaya (Papaya) Fruit Extract is expressed as fresh fruit



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.



according to Regulation (EC) No. 1907/2006

# 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 the substance or mixture and uses advised against

Use of the Sub- : Manufacture of soap and detergents, cleaning and polishing

stance/Mixture 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 Bakanlığı 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.

according to Regulation (EC) No. 1907/2006

# 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 measures

If inhaled : If breathed in, move person into fresh air.

If symptoms persist, call a physician.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

If symptoms persist, call a physician.

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 physi-

cian immediately.

## 4.2 Most important symptoms and effects, both acute and delayed

Symptoms : None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : None known.

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray, alcohol-resistant foam, dry chemical or car-

BiOrigins, 19-20 Sandleh อัลที เคียงที่ผู้ Estate, Fordingbridge, Hampshire, SP6 1PA, UK

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 the substance or mixture

Specific hazards during fire-

fighting

: In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

Do not use a solid water stream as it may scatter and spread

fire.

#### 5.3 Advice for firefighters

Special protective equipment

for firefighters

: In the event of fire, wear self-contained breathing apparatus.

Further information : Prevent fire extinguishing water from contaminating surface

water or the ground water system.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

#### **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective 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 containment 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 storage**

#### 7.1 Precautions for safe handling

Advice on safe handling : Handle in accordance with good industrial hygiene and safety

practice.

Advice on protection against

fire and explosion

: Normal measures for preventive fire protection.

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, including any incompatibilities

Requirements for storage

: Store in original container. Keep container tightly closed in a

areas and containers

dry and well-ventilated place.

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 conditions.

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 exposure should be used			

#### 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

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0 Revision Date 19.11.2015 Print Date 18.03.2020

pH : 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 available

Oxidizing properties : No data available

#### 9.2 Other information

No data available

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0 Revision Date 19.11.2015 Print Date 18.03.2020

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

No data available

#### 10.2 Chemical stability

No data available

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

# 10.6 Hazardous decomposition products

Hazardous decomposition

: No data available

products

In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

# **SECTION 11: Toxicological information**

# 11.1 Information on toxicological effects

#### **Acute toxicity**

#### **Product:**

Acute oral toxicity : No data available :

Acute inhalation toxicity : No data available :

Acute dermal toxicity : No data available :

#### Skin corrosion/irritation

## **Product:**

Remarks: No data available

# Serious eye damage/eye irritation

#### **Product:**

Remarks: No data available

according to Regulation (EC) No. 1907/2006

# 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-

ment

: No data available

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:** 

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0 Revision Date 19.11.2015 Print Date 18.03.2020

#### 12.3 Bioaccumulative potential

**Product:** 

: Remarks: No data available Bioaccumulation

12.4 Mobility in soil

**Product:** 

Distribution among environ-

mental compartments

: Remarks: No data available

#### 12.5 Results of PBT and vPvB assessment

**Product:** 

: This substance/mixture contains no components considered Assessment

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 : Empty remaining contents.

Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

#### **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

according to Regulation (EC) No. 1907/2006

# PAPAYA FRUIT LIQUID EXTRACT

Version 1.0 Revision Date 19.11.2015 Print Date 18.03.2020

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 EXTRACT

Specification: 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	its Upper	Units
-	REVISION NUMBER	2.0		
AC018000	ASPECT	CLEAR LIQUI	D	
AC018000	COLOUR	COLOURLESS TO PALE YELLOW		
AC018000	ODOUR	CHARACTERISTIC		
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	pH VALUE (20°C)	4.5	6.5	
JC0054A0	TOTAL GERMS	100 MAX CFU/ML		
JC0054A0	MOULDS/YEASTS	10 MAX CFU/ML		

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 %)

Glycerin B

Water B

Carica Papaya (Papaya) Fruit Extract E

Origin of raw materials:

Plant origin : Glycerin
- from organic culture : No

- free of GMO : Yes

Plant origin : Carica Papaya

plant part : Fruitfrom organic culture : Nofree of GMO : Yes

Synthetic origin : Preservatives

Animal origin : No

**Preservatives:** Potassium Sorbate approx 0.4 %

Sorbic Acid approx 0.1 %

Antioxidant: None

**Manufacturing process :** Fresh papaya pulp is dehydrated by spray

drying on a maltodextrin carrier. The concentrate is homogenized in a glycerin-aqueous solvent, conditioned,

preserved and filtered.

# Microbiological Data:

⇒ Bacteria
 ⇒ Moulds and yeasts
 ⇒ Pathogenic Micro-organisms
 < 100 cfu / ml</li>
 < < 10 cfu / ml</li>
 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

⇒ Impurities :

Calcium Phosphate Max. 50 ppm (conclusion by analogy)
Citric Acid 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	Anisyl alcohol	< 1ppm*
100-51-6	Benzyl alcohol	< 1ppm*
120-51-4	Benzyl benzoate	< 1ppm*
103-41-3	Benzyl cinnamate	< 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:

- ⇒ Carbohydrates
- ⇒ Minerals
- ⇒ Vitamins (B-group, C)
- ⇒ 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. (5)(6)

#### ⇒ Human skin irritation :

Glycerin: Skin irritation studies on albino rabbit showed that no skin

irritation appeared after 90 days of application. (2)

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.(7)

#### ⇒ Mucous membrane irritation :

Glycerin: Eye irritation studies on albino rabbit showed that there was no

measurable eye irritation.(2)

#### ⇒ Sensitisation potential:

Glycerin: Sensitization tests on guinea pigs showed that no sensitization

occurred.(2)

⇒ Cytotoxicity : No data available

⇒ Phototoxicity : No data available

⇒ Mutagenicity (e.g. Ames Test) : No data available

⇒ Carcinogenicity: No data available

⇒ Acute toxicity:

Glycerin:  $LD_{50}$  (mice, oral) = 23 g/kg

 $LD_{50}$  (rats, oral) = 27.2 g/kg

 $LD_{50}$  (guinea pigs, oral) = 10 g/kg (2)

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.(3)

Carica Papaya juice:

LD<sub>50</sub> (rats, oral) > 1500 mg/kg - considered non toxic (4)

⇒ Inhalation toxicity : No data available

⇒ 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.(3)

⇒ Reproduction toxicity : No data available

# **Ecological Data:**

Our product contains mainly Glycerin/Water extraction vehicle:

⇒ The ecological information about Glycerin is (2):

Environmental toxicity:

 $LC_{50}$  (fish – 96 hours ) > 1000 mg/l

 $EC_{50}$  (Daphnia magna– 24 hours ) > 10 g/l

EC<sub>50</sub> (Pseudomonias putida – 16 hours ) > 10 g/l

Biodegradability: Totally biodegradable

⇒ 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

⇒ Contraindications : None known
 ⇒ Side effects : None known
 ⇒ 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) <a href="http://www.hort.purdue.edu/newcrop/duke\_energy/Carica\_papaya.html">http://www.hort.purdue.edu/newcrop/duke\_energy/Carica\_papaya.html</a>
- (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 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.



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.