



Certificate of Analysis  
Papaya Liquid Fruit Extract

Batch Number: 4411908 Best  
Before End: October 2022

Quality Control Results

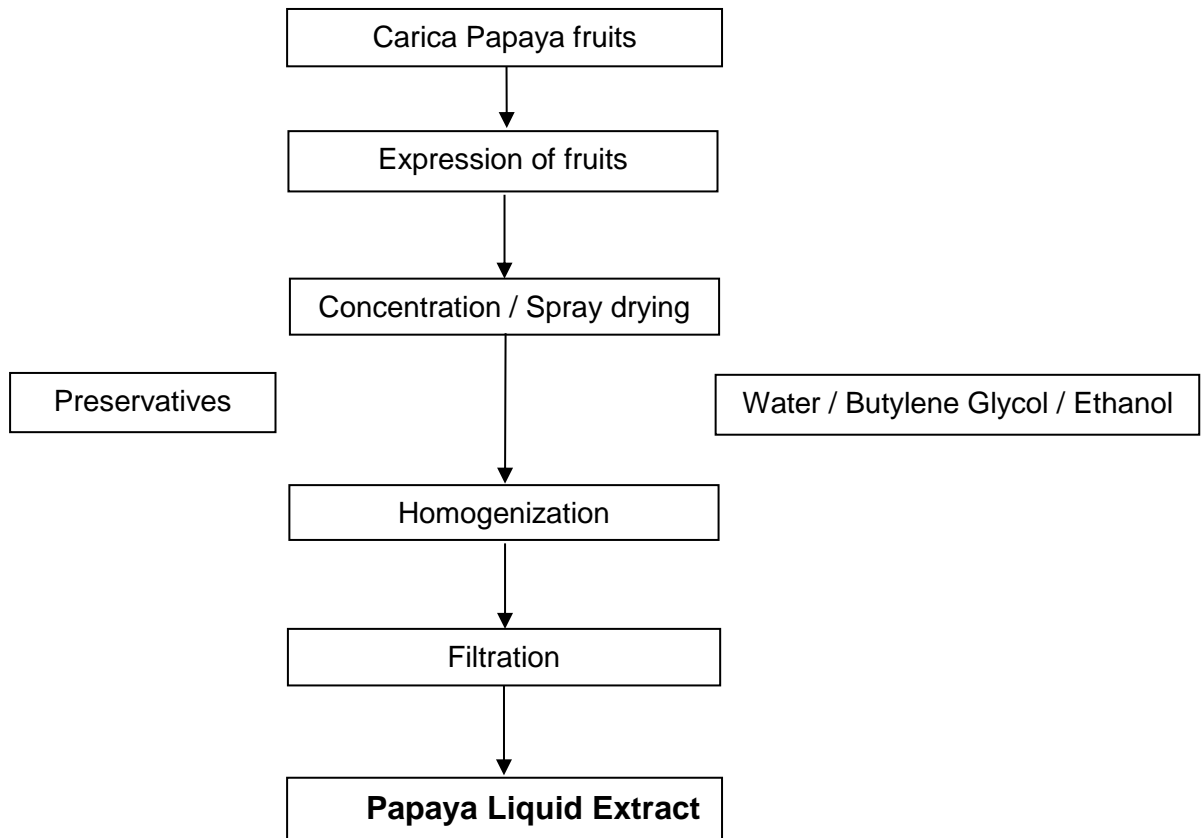
Analytical Test Method No.	Characteristic	Specification Limit		Value	Unit	Status
		Lower	Upper			
	Addendum 00	PASS OR FAIL		Pass		P
	REVISION NUMBER	2.0		Pass		P
AC018000	ASPECT	CLEAR LIQUID		Pass		P
AC018000	COLOUR	COLOURLESS TO PALE YELLOW		Pass		P
AC018000	ODOUR	CHARACTERISTIC		Pass		P
FC0031A0	SPECIFIC GRAVITY (20°C)	1.120	1.150	1.136		P
JC0032A0	REFRACTIVE INDEX (20°C)	1.385	1.415	1.402		P
EC003000	WATER CONTENT KARL FISCHER	48.0	52.5	48.7	%	P
FC0064A0	pH VALUE (20°C)	4.5	6.5	5.4		P
JC0054A0	TOTAL GERMS	100 MAX CFU/ML		Pass		P
JC0054A0	MOULDS/YEASTS	10 MAX CFU/ML		Pass		P

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%

\* Carica Papaya (Papaya) Fruit Extract is expressed as **fresh** fruit

<b>Preservatives :</b>	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 Corporation group of companies.

## **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**

<b>INCI</b>	<b>CAS</b>	<b>EINECS</b>	<b>REACH status</b>	<b>Comment</b>
Glycerin	56-81-5	200-289-5	Exempt	Annex V
Water	7732-18-5	231-791-2	/	/
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.



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

**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: Sağlık 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.

**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

### **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 physician 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 circumstances and the surrounding environment.  
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**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 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.

**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, including any incompatibilities**

Requirements for storage areas and containers : Store in original container. Keep container tightly closed in a dry and well-ventilated place.

Advice on common storage : No special restrictions on storage with other products.

Recommended storage temperature : 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 of exposure)	Control parameters	Basis
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	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 required.

---

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Appearance : clear, liquid

Colour : light yellow

Odour : characteristic

Odour Threshold : No data available

Origins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

Tel: 01425 655555 Email: technical@madarcorporation.co.uk



**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

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/cm <sup>3</sup> (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

**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

---

**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 products : No data available  
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

**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

**Respiratory or skin sensitisation**

**Product:**

Remarks: No data available

**Germ cell mutagenicity**

**Product:**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

**Product:**

Carcinogenicity - Assessment : 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:**

Biodegradability : Remarks: No data available  
Origins, 19-20 Sandley Rd, Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK  
Tel: 01425 655555 Email: technical@madarcorporation.co.uk

**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

---

**12.3 Bioaccumulative potential**

**Product:**

Bioaccumulation : Remarks: No data available

**12.4 Mobility in soil**

**Product:**

Distribution among environmental compartments : Remarks: No data available

**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 information : Remarks: No data available

---

**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 handling 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**

BiOrigins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

Tel: 01425 655555 Email: [technical@madarcorporation.co.uk](mailto:technical@madarcorporation.co.uk)

**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

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 Limits		Units
		Lower	Upper	
AC018000	REVISION NUMBER	2.0		
AC018000	ASPECT	CLEAR LIQUID		
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	WATER 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 <http://ec.europa.eu/consumers/cosmetics/cosing/>

**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 : Fruit
  - from organic culture : No
  - free 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	< 100 cfu / ml
⇒	Moulds and yeasts	< < 10 cfu / ml
⇒	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
⇒	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	Lylal	< 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.<sup>(5)(6)</sup>

### ⇒ 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> |

### ⇒ Mucous membrane irritation :

- |            |                                                                                                            |
|------------|------------------------------------------------------------------------------------------------------------|
| Glycerin : | Eye irritation studies on albino rabbit showed that there was no measurable eye irritation. <sup>(2)</sup> |
|------------|------------------------------------------------------------------------------------------------------------|

### ⇒ Sensitisation potential :

- |            |                                                                                          |
|------------|------------------------------------------------------------------------------------------|
| Glycerin : | Sensitization tests on guinea pigs showed that no sensitization occurred. <sup>(2)</sup> |
|------------|------------------------------------------------------------------------------------------|

- ⇒ Cytotoxicity : No data available
- ⇒ Phototoxicity : No data available
- ⇒ Mutagenicity (e.g. Ames Test) : No data available
- ⇒ Carcinogenicity : No data available

⇒ 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<sub>50</sub> (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 <sup>(4)</sup>

- ⇒ 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 marrow in rats.<sup>(3)</sup>

- ⇒ Reproduction toxicity : No data available

### Ecological Data :

Our product contains mainly Glycerin/Water extraction vehicle :

- ⇒ The ecological information about Glycerin is <sup>(2)</sup> :

Environmental toxicity :

LC<sub>50</sub> (fish – 96 hours ) > 1000 mg/l  
 EC<sub>50</sub> (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 Carica 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 Research PTR (2006). (*Abstract available*)
- (5) [http://www.hort.purdue.edu/newcrop/duke\\_energy/Carica\\_papaya.html](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 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.