Certificate of Analysis

Papaya Liquid Fruit Extract

Batch Number: 4520101
Best Before End: October 2025

Quality Control Results

Analytical Test Method No.	Characteristic	Specification Limit Lower	Upper	Value	Unit	Status
	Addendum 00	PASS OR FAIL		Pass		P
	REVISION NUMBER	.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	1.120		P
. C0032A0	REFRACTIVE INDEX (20°C)	1.385	1.415	1.385		P
EC003000	WATER CONTENT KARL FISCHER	48.0	52.5	46.5	%	P
FC0064A0	pH VALUE (20°C)	4.5	6.5	4.5		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

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

Product Information File – cosmetic ingredient

Product Name: Fruitliquid Brazilian Papaya
Article No: NA22119

PCPC INCI Name: Glycerin, Water, Carica Papaya (Papaya) Fruit Extract

EU INCI Name: to follow Cosing, the European Commission database on http://ec.europa.eu/consumers/cosmetics/cosing/

Certifications

Our suppiler is certified ISO 14001, ISO 9001, ISO 45001, EFfCI Guide for Good Manufacturing Practices (2012) and AEO.

Brazilian Papaya is Halal certified by HCS (Halal Certifying Services)

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, expressed or implied, is made with respect to information or products including, without limitation, warranties of merchantability, fitness for a particular purpose, 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 CRODAROM.

I.PRODUCT INFORMATION

Composition

Ingredient PCPC INCI Name	**CAS**	**EINECS**	**Function**	**Origin***	**Free of GMO** (yes/no)	**Concentration (%)** *based on theoretical composition*
Glycerin	56-81-5	200-289-5	Solvent	V	Yes	45 – 55 %
Water	7732-18-5	231-791-2	Solvent	N	N/A	43 – 53 %
Carica Papaya (Papaya) Fruit Extract	84012-30-6	281-675-0	Botanical extract	V	Yes	1 – 5 %
Potassium Sorbate	24634-61-5	246-376-1	Preservative	S	N/A	Approx 0.4%
Sorbic Acid	110-44-1	203-768-7	Preservative	S	N/A	Approx 0.1%

**V: vegetable; S: synthetic, B: biotechnological; N: natural*

*** Carica Papaya is expressed as **fresh** Fruits*

The value of the water content in the final selling specification (SAP specification) per batch will be slightly higher due to the water entry by the plant material. The definition of "water content" in selling spec is the total water composed of process and plant water. The "water content" in the PIF is the process water only.

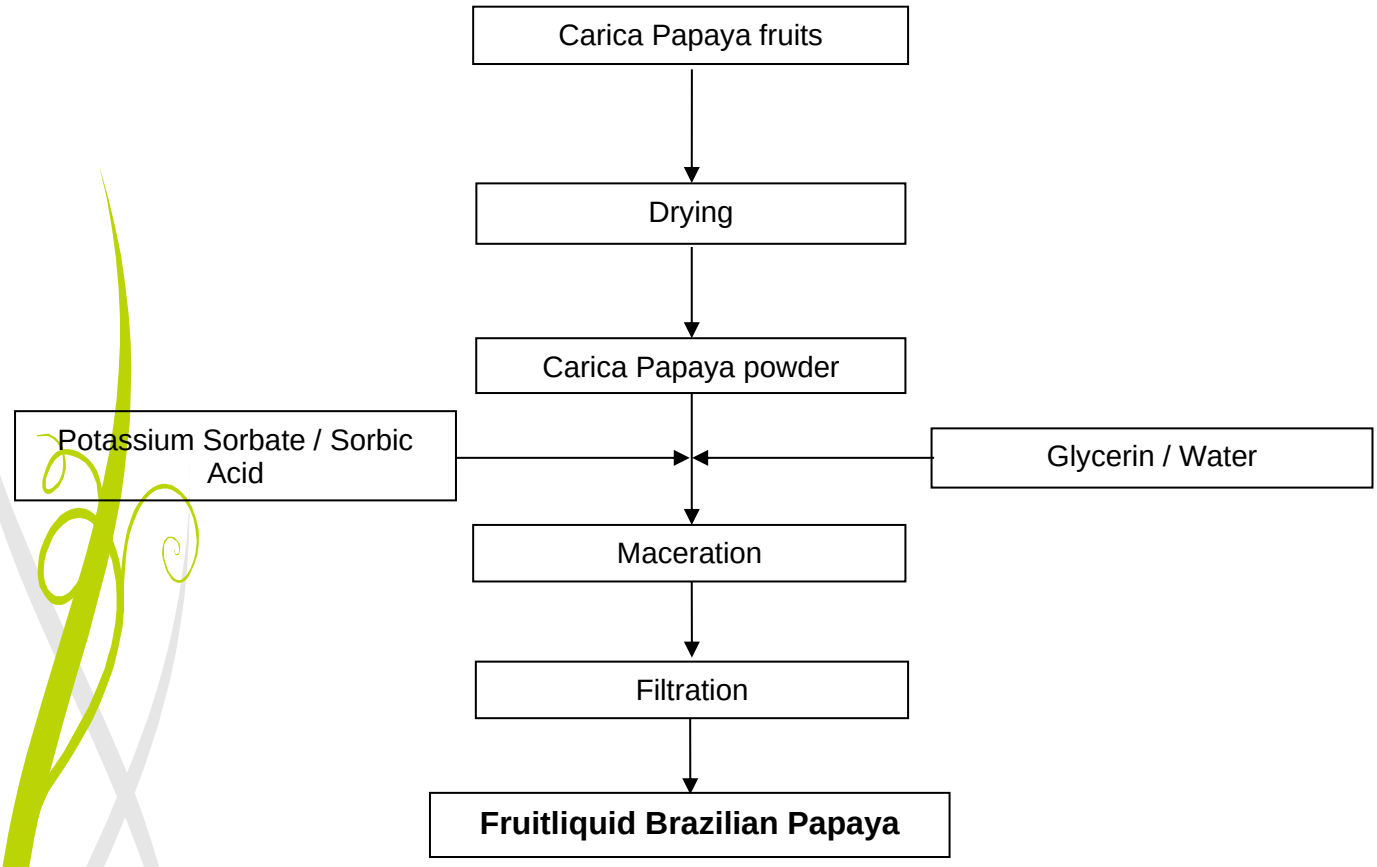
Microbiological data

Bacteria	< 100 cfu / g
Moulds and yeasts	< 10 cfu / g
Pathogenic Micro-organisms	Not tested

Uses

Cosmetic application:

Regenerating, conditioning and moisturising skin and hair care
Anti-ageing care
Sensitive skin
Shower gels & tonics
Cleansing lotion
Baby care creams


Carica Papaya fruits
Drying
Carica Papaya powder
Potassium Sorbate / Sorbic Acid
Glycerin / Water
Maceration
Filtration
Fruitliquid Brazilian Papaya

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
Conclusion by analogy

Residual solvents: Not expected

Other impurities:

*These substances are not used as raw material and are not intentionally added to the product. Based on the manufacturing process, the above-mentioned substances are not expected to be present.
However, these substances are not a part of our routine analytical procedures and quality control system; therefore, they are not measured on a regular basis.

- Papain content : Because of the dehydration step in the manufacturing process, papain is expected to be inactivated and not detectable.
- Calcium Phosphate: Maximum expected 50 ppm (conclusion by analogy)
- Citric Acid: Maximum expected 70 ppm (conclusion by analogy)
- Ethylene/Diethylene Glycol: Diethylene Glycol: Glycerin used to produce Fruitliquid Brazilian Papaya Art. N°NA22119 is compliant with the USP monograph (DEG: < 0.10%).
- Formaldehyde: Not added- not expected – not tested*
- Nitrosamines: Not added- not expected – not tested*
- Nonylphenol, alkylphenol, phenol, nonoxynol components: Not added- not expected – not tested*
- Dioxanes: Not added- not expected – not tested*
- Phthalates: Not added- not expected – not tested*

Substance	CAS N°
Dibutyl phthalate (DBP)	84-74-2
Diethylhexyl phthalate (DEHP)	117-81-7
Benzyl butyl phthalate (BBP)	85-68-7
Di-n-pentyl phthalate (DnPP)	131-18-0
bis(2-Methoxyethyl) phthalate (DMEP)	117-82-8
Diisopentylphthalate (DiPP)	605-50-5
n-pentyl isopentyl phthalate (DPP)	84777-06-0
Diisobutyl phthalate (DiBP)	84-69-5

- Glycol ethers: Not added- not expected – not tested*

Substance	CAS N°
2-methoxyethanol / ethylene glycol monomethyl ether (EGME)	109-86-4
2-methoxyethyl acetate / methylglycol acetate (EGMEA)	110-49-6

2-ethoxyethanol (EGEE)	110-80-5
2-ethoxyethyl acetate (EGEEA)	111-15-9
1,2-dimethoxyethane / ethylene glycol dimethyl ether (EGDME)	110-71-4
Oxybis(2-methoxyethyl) / dimethoxydiglycol (DEGDME)	111-96-6
1,2-bis(2-methoxyethoxy)ethane / triethylene glycol dimethyl ether (TEGDME)	112-49-2
2-butoxyethanol (EGBE)	111-76-2
2-(2-butoxyethoxy)ethanol (DEGBE)	112-34-5
2-(2-ethoxyethoxy)ethanol (DEGEE)	111-90-0

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.

Brazilian Papaya 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.

VOC:

Brazilian Papaya does not contain one or more Volatile Organic Compounds (VOC) in compliance with the Swiss ordinance and the definition of California.

However, VOC content is not a part of our routine analytical procedures and quality control system; therefore, they are not measured on a regular basis.

Proposition 65:

The ingredients constituting Brazilian Papaya are not known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act of which we regularly follow the updates.

Palm Oil:

We herewith confirm that palm oil and palm kernel oil are not used as raw materials and are not intentionally added in Brazilian Papaya and that it is not produced from palm oil or palm kernel oil derived ingredients, with reference to the confirmation of our raw materials suppliers.

Petrochemicals derivatives:

We herewith confirm that our product is not derived from petrochemicals raw materials.
However, according to our raw materials suppliers Potassium Sorbate (approx. 0.4 %) is used as raw material and is derived from petrochemicals.

Irradiation:

We herewith confirm that Brazilian Papaya has not been irradiated radioactively.

Allergens – EU Cosmetic Regulation:

We herewith confirm that Brazilian Papaya, meets the following properties:

CAS-No.	Allergen	Content expected
122-40-7	Amyl cinnamic aldehyde	not expected
101-85-9	Amyl cinnamic alcohol	not expected
105-13-5	Anisyl alcohol	not expected
100-51-6	Benzyl alcohol	not expected
120-51-4	Benzyl benzoate	not expected
103-41-3	Benzyl cinnamate	not expected
118-58-1	Benzyl salicylate	not expected
104-55-2	Cinnamic aldehyde	not expected
104-54-1	Cinnamic alcohol	not expected
5392-40-5	Citral	not expected
106-22-9	Citronellol	not expected
91-64-5	Coumarin	not expected
97-53-0	Eugenol	not expected
4602-84-0	Farnesol	not expected
106-24-1	Geraniol	not expected
101-86-0	Hexyl cinnamaldehyde	not expected
107-75-5	Hydroxycitronellal	not expected
97-54-1	Isoeugenol	not expected
80-54-6	Lilial	not expected*
5989-27-5	d-Limonene	not expected
78-70-6	Linalool	not expected
31906-04-4	Lyral	not expected*
111-12-6	Methyl heptine carbonate	not expected
127-51-5	Methyl ionone alpha iso	not expected
90028-68-5	Oakmoss	not expected
90028-67-4	Tree Moss	not expected

* They are synthetic substances that do not occur in botanicals.

None of the 26 identified allergen perfume compounds have been added to the product.
The absence of any of these 26 allergens cannot be confirmed, but we attest that they cannot technically occur due to the extraction process used.
This information is based on risk estimation which is based on botanical and phytomedicinal reference literature and conclusions by analogy.

Allergens – Food :

We herewith confirm that Brazilian Papaya., meets the following properties:

Allergens	Presence expected	Used in production site
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybrids) and products thereof	No	Yes
Crustaceans and products thereof	No	No
Eggs and products thereof	No	Yes
Fish and products thereof	No	Yes
Peanuts and products thereof	No	Yes
Soybeans and products thereof	No	Yes
Milk and products thereof (including lactose)	No	Yes
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan, Brazil nut, pistachio nut, macadamia nut, Queensland nut) and products thereof	No	Yes
Celery and products thereof	No	No
Mustard and products thereof	No	No
Sesame seeds and products thereof	No	Yes
Lupin and products thereof	No	Yes
Molluscs and products thereof	No	Yes
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg expressed or 10 mg/litre as SO2	No	Yes

*Most common food allergens according to EU Directive 2007/68/EC modifying Annex III bis of directive 2000/13/EC

None of the food allergens above listed is used as raw materials in the above mentioned products. With reference to the confirmation of our raw materials suppliers, no other ingredient used in the composition of this product derives from any of the a.m. allergens.

Cross-contamination cannot be excluded considering that some of the raw materials used in our production site may derive from food allergens or contain them as impurities, but the risk is expected to be very low as adequate quality measures are implemented to limit the occurrence of contamination.

However, these allergens are not a part of our routine analytical procedures and quality control system (except the manufacturing protocol when used as ingredients). Therefore, their presence or absence are not measured on a regular basis.

We herewith confirm below the contents according to the ISO 16128-1 and ISO 16128-2 standards (including formulation water) of Brazilian Papaya is:

Natural content (%)	Derived natural content (%)*	Organic content (%)	Derived organic content (%)
49.1	99.5	0,0	0,0

** : based on an index of natural origin = 1 for the ingredient Glycerin (Carbon 14 method).*

These values are provided according to our interpretation of the standard ISO 16128, theoretical composition and information communicated by our suppliers.

However, this information is calculated according to our interpretation of the standard ISO 16128, theoretical composition and information communicated by our suppliers.

It is likely to evolve along the way of discussions with professional federations of cosmetic industry.

II. REGULATORY INFORMATION

REACH:

Our supplier 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.

Brazilian Papaya is so called preparation composed of ingredients (named under REACh as substances).

INCI	CAS	EINECS	REACH status	Comment
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 Crodarom would exceed the 1T/year limit, we ensure its registration.

We do not anticipate any disruptions of this Crodarom product supplied to our customers. However changes to the product portfolio may become necessary also for reasons not connected with REACh.

EU Cosmetic Regulation:

We herewith confirm that, Brazilian Papaya complies with the European Cosmetic Regulation EC 1223/2009.

- substances listed in Annexes II, III, IV and VI of the European Cosmetic Regulation 1223/2009 EC are not used as raw material and are not intentionally added.

Botanical preparations which contain technically unavoidable traces or impurities of plant constituents listed in Annexes II or III are not affected by the exclusion or restriction of the European Regulation 1223/2009.

- Preservatives used are listed in Annex V of the European Cosmetic Regulation 1223/2009 EC:
  Potassium sorbate: approx. 0.4%
  Sorbic acid: approx. 0.1 %

Nanomaterial:

Brazilian Papaya is not a nanomaterial and does not contain any nanomaterial, according to the Cosmetic Regulation (EC) No 1223/2009 and French Decree n° 2012-232 from 17th of February 2012.

BSE/TSE:

Brazilian Papaya Art. is originated from synthetic and plant raw material with reference to the confirmation of our raw materials suppliers.
None of the ingredients used to produce this product are of bovine, ovine, equine or porcine origin. Therefore, Bovine Spongiform Encephalopathy (BSE) / Transmitting Spongiform Encephalopathy (TSE) risk, as defined in the European Commission Decision 97/534/EC and EMEA/410/10, does not concern this product.

CITES:

Brazilian Papaya does not contain endangered species (source CITES list) and is not subject to the Convention of Washington to our knowledge to date.
The plants raw materials used are not parts of Annexes I, II and III of the Convention of Washington.

Information about the packaging:

According to information provided by our suppliers, we can confirm that packaging used for Brazilian Papaya is conform with the following requirements:

- The packaging is made from HDPE (High Density PolyEthylene)
- is compliant with European REACH regulation CE 1907/2006
- is compliant with European Directive 94/62/CE on packaging and packaging waste
- is compliant to European regulation CE 10/2011 and conform for food use
- is free from animal products and derivatives, free of silicones, free of bisphenol A and phthalates and not concerned by nanotechnologies

III. INFORMATION ON 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 Regulation 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 request
We therefore confirm 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.

IV. ACTIVES and EFFECTS

Main actives in the plant:

- ⇒ Carbohydrates
- ⇒ Minerals
- ⇒ Vitamins (B-group, C)
- ⇒ Fruit acids

Main actives in the extract: Not determined

V. TOXICOLOGICAL DATA

Toxicity tests on the product

.We herewith confirm that no NOAEL measure has been made on this product.

We haven't carried out clinical studies on Brazilian Papaya 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_{50} (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

Our product contains mainly Glycerin / Water vehicle:

⇒ The ecological information about Glycerin is:

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

⇒ Water hazard class: 1 (self-classification)

VI. CONCLUSION AND RECOMMENDATIONS

According to available information from test results or bibliography, we recommend to use the product at a maximum level of: 5.0% in leave on / rinse off products.

Contraindications: none known

Remarks: none

VII. REFERENCES

This information is given in good faith and is based on our knowledge to date. This correspondence will not be automatically updated in the future.

(1) Martindale, The Extra Pharmacopoea, 30th 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.

Version: 1
Date: 12/2020
This version replaces the earlier one dated 07/2020

Version	Revision Date:	Date of last issue:	Print Date :
2.0	29.05.2020	-	03.10.2023
		Date of first issue: 29.05.2020	

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

1.1 Product identifier

Product name : FRUITLIQUID BRAZILIAN PAPAYA

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/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
SP6 1PA
GB

Telephone **: +441425 655 555**

E-mail address **: technical@madarcorporation.co.uk**

1.4 Emergency telephone number

Emergency telephone number : USA: 24 Hour Emergency Response Information CHEMTREC toll free: 1-800-424-9300; direct/international: 1-703-527-3887. CANADA: GFL 1-877-898-7222. 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: Ambipar 0800 117 2020. LATAM: Suatrans (+55) 11 98149-0850 / (+55) 19 3833-5300. COLOMBIA: +312 586 2890 / 310 588 1555. 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 Bakanliği 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.

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

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 car-

bon dioxide.

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.

Specific extinguishing methods : Standard procedure for chemical fires.

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.

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

Further information on storage stability : 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/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 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
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 / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability 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
Decomposition temperature	:	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

Self-ignition : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

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

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

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

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

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 : 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 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

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 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

15.2 Chemical safety assessment

SECTION 16: Other information

Full text of other abbreviations

GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical

Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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.

GB / EN

Specification
Manufacturing site is certified according to ISO9001, EFfCl, ISO14001 and ISO45001 standards.

Date: 11.07.2023

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

Specification: 28/11/2022

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 Lower	Upper	Units
	REVISION NUMBER	3.0		
AC018000	APPEARANCE FORM	LIQUID		
AC018000	APPEARANCE CLARITY	CLEAR		
AC018000	APPEARANCE COLOUR	COLOURLESS TO PALE YELLOW		
AC018000	ODOUR	CHARACTERISTIC		
AC027000	PLANT GEOGRAPHIC ORIGIN	CERTIFIED		
FC0031A0	SPECIFIC GRAVITY (20°C)	1.120	1.150	
FC0032A0	REFRACTIVE INDEX (20°C)	1.385	1.415	
EC003000	WATER CONTENT KARL FISCHER	46.5	53.0	%
FC0064A0	pH VALUE (20°C)	4.5	6.5	
JC0054B0	MOULDS/YEASTS	10 MAX CFU/G		
JC0054B0	TOTAL GERMS	100 MAX CFU/G		

The PLANT GEOGRAPHIC ORIGIN For this product is certified BRAZIL.

Long term storage between 15 - 25°C, dark in closed containers.
The performed analysis are guaranteed on original packaging.
When stored accordingly, stable during period of validity.

Future deliveries will be tested to this specification and the results reported on Certificate of Analysis

If you agree to accept this specification please complete the following section and return to the person named below. If we do not receive a reply from you within 14 days we will take this to indicate you have accepted the specification.

Product Information File – cosmetic ingredient

Product Name: Fruitliquid Brazilian Papaya

PCPC INCI Name: Glycerin, Water, Carica Papaya (Papaya) Fruit Extract

EU INCI Name: to follow Cosing, the European Commission database on http://ec.europa.eu/consumers/cosmetics/cosing/

Certifications

Our supplier is certified ISO 14001, ISO 9001, ISO 45001, EFfCI Guide for Good Manufacturing Practices (2012) and AEO.

Fruitliquid Brazilian Papaya is Halal certified by HCS (Halal Certifying Services)

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, expressed or implied, is made with respect to information or products including, without limitation, warranties of merchantability, fitness for a particular purpose, non-infringement of any third-party patent or other intellectual property rights including, without limit, copyright, trademark and designs.

I.PRODUCT INFORMATION

Composition

Ingredient PCPC INCI Name	**CAS**	**EINECS**	**Function**	**Origin***	**Free of GMO** (yes/no)	**Concentration (%)** *based on theoretical composition*
Glycerin	56-81-5	200-289-5	Solvent	V	Yes	45 – 55 %
Water	7732-18-5	231-791-2	Solvent	N	N/A	43 – 53 %
Carica Papaya (Papaya) Fruit Extract	84012-30-6	281-675-0	Botanical extract	V	Yes	1 – 5 %
Potassium Sorbate	24634-61-5	246-376-1	Preservative	S	N/A	Approx 0.4%
Sorbic Acid	110-44-1	203-768-7	Preservative	S	N/A	Approx 0.1%

**V: vegetable; S: synthetic, B: biotechnological; N: natural*

*** Carica Papaya is expressed as **fresh** Fruits*

The value of the water content in the final selling specification (SAP specification) per batch will be slightly higher due to the water entry by the plant material. The definition of "water content" in selling spec is the total water composed of process and plant water. The "water content" in the PIF is the process water only.

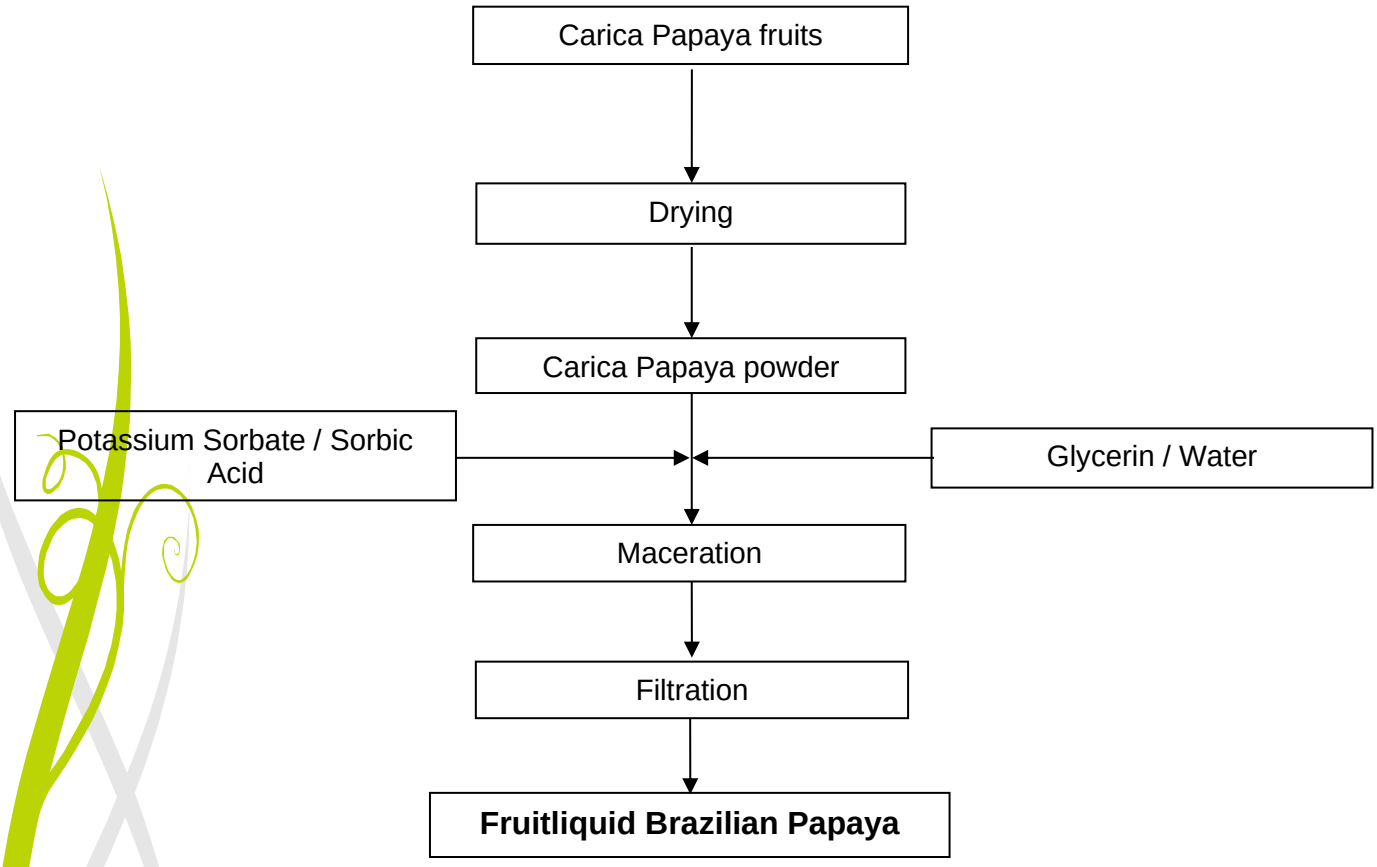
Microbiological data

Bacteria	< 100 cfu / g
Moulds and yeasts	< 10 cfu / g
Pathogenic Micro-organisms	Not tested

Uses

Cosmetic application:

Regenerating, conditioning and moisturising skin and hair care
Anti-ageing care
Sensitive skin
Shower gels & tonics
Cleansing lotion
Baby care creams


Carica Papaya fruits
Drying
Carica Papaya powder
Potassium Sorbate / Sorbic Acid
Glycerin / Water
Maceration
Filtration
Fruitliquid Brazilian Papaya

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
Conclusion by analogy

Residual solvents: Not expected

Other impurities:

*These substances are not used as raw material and are not intentionally added to the product. Based on the manufacturing process, the above-mentioned substances are not expected to be present.
However, these substances are not a part of our routine analytical procedures and quality control system; therefore, they are not measured on a regular basis.

- Papain content : Because of the dehydration step in the manufacturing process, papain is expected to be inactivated and not detectable.
- Calcium Phosphate: Maximum expected 50 ppm (conclusion by analogy)
- Citric Acid: Maximum expected 70 ppm (conclusion by analogy)
- Ethylene/Diethylene Glycol: Diethylene Glycol: Glycerin used to produce Fruitliquid Brazilian Papaya is compliant with the USP monograph (DEG: < 0.10%).
- Formaldehyde: Not added- not expected – not tested*
- Nitrosamines: Not added- not expected – not tested*
- Nonylphenol, alkylphenol, phenol, nonoxynol components: Not added- not expected – not tested*
- Dioxanes: Not added- not expected – not tested*
- Phthalates: Not added- not expected – not tested*

Substance	CAS N°
Dibutyl phthalate (DBP)	84-74-2
Diethylhexyl phthalate (DEHP)	117-81-7
Benzyl butyl phthalate (BBP)	85-68-7
Di-n-pentyl phthalate (DnPP)	131-18-0
bis(2-Methoxyethyl) phthalate (DMEP)	117-82-8
Diisopentylphthalate (DiPP)	605-50-5
n-pentyl isopentyl phthalate (DPP)	84777-06-0
Diisobutyl phthalate (DiBP)	84-69-5

- Glycol ethers: Not added- not expected – not tested*

Substance	CAS N°
2-methoxyethanol / ethylene glycol monomethyl ether (EGME)	109-86-4
2-methoxyethyl acetate / methylglycol acetate (EGMEA)	110-49-6

2-ethoxyethanol (EGEE)	110-80-5
2-ethoxyethyl acetate (EGEEA)	111-15-9
1,2-dimethoxyethane / ethylene glycol dimethyl ether (EGDME)	110-71-4
Oxybis(2-methoxyethyl) / dimethoxydiglycol (DEGDME)	111-96-6
1,2-bis(2-methoxyethoxy)ethane / triethylene glycol dimethyl ether (TEGDME)	112-49-2
2-butoxyethanol (EGBE)	111-76-2
2-(2-butoxyethoxy)ethanol (DEGBE)	112-34-5
2-(2-ethoxyethoxy)ethanol (DEGEE)	111-90-0

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.

Fruitliquid Brazilian Papaya 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.

VOC:

Fruitliquid Brazilian Papaya does not contain one or more Volatile Organic Compounds (VOC) in compliance with the Swiss ordinance and the definition of California.

However, VOC content is not a part of our routine analytical procedures and quality control system; therefore, they are not measured on a regular basis.

Proposition 65:

The ingredients constituting Fruitliquid Brazilian Papaya are not known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act of which we regularly follow the updates.

Palm Oil:

We herewith confirm that palm oil and palm kernel oil are not used as raw materials and are not intentionally added in Fruitliquid Brazilian Papaya, and that it is not produced from palm oil or palm kernel oil derived ingredients, with reference to the confirmation of our raw materials suppliers.

Petrochemicals derivatives:

We herewith confirm that our product is not derived from petrochemicals raw materials.
However, according to our raw materials suppliers Potassium Sorbate (approx. 0.4 %) is used as raw material and is derived from petrochemicals.

Irradiation:

We herewith confirm that Fruitliquid Brazilian Papaya has not been irradiated radioactively.

Allergens – EU Cosmetic Regulation:

We herewith confirm that Fruitliquid Brazilian Papaya, meets the following properties:

CAS-No.	Allergen	Content expected
122-40-7	Amyl cinnamic aldehyde	not expected
101-85-9	Amyl cinnamic alcohol	not expected
105-13-5	Anisyl alcohol	not expected
100-51-6	Benzyl alcohol	not expected
120-51-4	Benzyl benzoate	not expected
103-41-3	Benzyl cinnamate	not expected
118-58-1	Benzyl salicylate	not expected
104-55-2	Cinnamic aldehyde	not expected
104-54-1	Cinnamic alcohol	not expected
5392-40-5	Citral	not expected
106-22-9	Citronellol	not expected
91-64-5	Coumarin	not expected
97-53-0	Eugenol	not expected
4602-84-0	Farnesol	not expected
106-24-1	Geraniol	not expected
101-86-0	Hexyl cinnamaldehyde	not expected
107-75-5	Hydroxycitronellal	not expected
97-54-1	Isoeugenol	not expected
80-54-6	Lilial	not expected*
5989-27-5	d-Limonene	not expected
78-70-6	Linalool	not expected
31906-04-4	Lyral	not expected*
111-12-6	Methyl heptine carbonate	not expected
127-51-5	Methyl ionone alpha iso	not expected
90028-68-5	Oakmoss	not expected
90028-67-4	Tree Moss	not expected

* They are synthetic substances that do not occur in botanicals.

None of the 26 identified allergen perfume compounds have been added to the product.
The absence of any of these 26 allergens cannot be confirmed, but we attest that they cannot technically occur due to the extraction process used.
This information is based on risk estimation which is based on botanical and phytomedicinal reference literature and conclusions by analogy.

Allergens – Food :

We herewith confirm that Fruitliquid Brazilian Papaya, meets the following properties:

Allergens	Presence expected	Used in production site
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybrids) and products thereof	No	Yes
Crustaceans and products thereof	No	No
Eggs and products thereof	No	Yes
Fish and products thereof	No	Yes
Peanuts and products thereof	No	Yes
Soybeans and products thereof	No	Yes
Milk and products thereof (including lactose)	No	Yes
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan, Brazil nut, pistachio nut, macadamia nut, Queensland nut) and products thereof	No	Yes
Celery and products thereof	No	No
Mustard and products thereof	No	No
Sesame seeds and products thereof	No	Yes
Lupin and products thereof	No	Yes
Molluscs and products thereof	No	Yes
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg expressed or 10 mg/litre as SO2	No	Yes

*Most common food allergens according to EU Directive 2007/68/EC modifying Annex III bis of directive 2000/13/EC

None of the food allergens above listed is used as raw materials in the above mentioned products. With reference to the confirmation of our raw materials suppliers, no other ingredient used in the composition of this product derives from any of the a.m. allergens.

Cross-contamination cannot be excluded considering that some of the raw materials used in our production site may derive from food allergens or contain them as impurities, but the risk is expected to be very low as adequate quality measures are implemented to limit the occurrence of contamination.

However, these allergens are not a part of our routine analytical procedures and quality control system (except the manufacturing protocol when used as ingredients). Therefore, their presence or absence are not measured on a regular basis.

We herewith confirm below the contents according to the ISO 16128-1 and ISO 16128-2 standards (including formulation water) of Fruitliquid Brazilian Papaya is:

Natural content (%)	Derived natural content (%)*	Organic content (%)	Derived organic content (%)
49.1	99.5	0,0	0,0

** : based on an index of natural origin = 1 for the ingredient Glycerin (Carbon 14 method).*

These values are provided according to our interpretation of the standard ISO 16128, theoretical composition and information communicated by our suppliers.

However, this information is calculated according to our interpretation of the standard ISO 16128, theoretical composition and information communicated by our suppliers.

It is likely to evolve along the way of discussions with professional federations of cosmetic industry.

II. REGULATORY INFORMATION

REACH:

Crodarom SAS 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.

Fruitliquid Brazilian Papaya is so called preparation composed of ingredients (named under REACh as substances).

INCI	CAS	EINECS	REACH status	Comment
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 would exceed the 1T/year limit, we ensure its registration.

We do not anticipate any disruptions of this product supplied to our customers. However changes to the product portfolio may become necessary also for reasons not connected with REACh.

EU Cosmetic Regulation:

We herewith confirm that, Fruitliquid Brazilian Papaya complies with the European Cosmetic Regulation EC 1223/2009.

- substances listed in Annexes II, III, IV and VI of the European Cosmetic Regulation 1223/2009 EC are not used as raw material and are not intentionally added.

Botanical preparations which contain technically unavoidable traces or impurities of plant constituents listed in Annexes II or III are not affected by the exclusion or restriction of the European Regulation 1223/2009.

- Preservatives used are listed in Annex V of the European Cosmetic Regulation 1223/2009 EC:
  Potassium sorbate: approx. 0.4%
  Sorbic acid: approx. 0.1 %

Nanomaterial:

Fruitliquid Brazilian Papaya is not a nanomaterial and does not contain any nanomaterial, according to the Cosmetic Regulation (EC) No 1223/2009 and French Decree n° 2012-232 from 17th of February 2012.

BSE/TSE:

Fruitliquid Brazilian Papaya is originated from synthetic and plant raw material with reference to the confirmation of our raw materials suppliers.
None of the ingredients used to produce this product are of bovine, ovine, equine or porcine origin. Therefore, Bovine Spongiform Encephalopathy (BSE) / Transmitting Spongiform Encephalopathy (TSE) risk, as defined in the European Commission Decision 97/534/EC and EMEA/410/10, does not concern this product.

CITES:

Fruitliquid Brazilian Papaya does not contain endangered species (source CITES list) and is not subject to the Convention of Washington to our knowledge to date.
The plants raw materials used are not parts of Annexes I, II and III of the Convention of Washington.

Information about the packaging:

According to information provided by our suppliers, we can confirm that packaging used for Fruitliquid Brazilian Papaya is conform with the following requirements:

- The packaging is made from HDPE (High Density PolyEthylene)
- is compliant with European REACH regulation CE 1907/2006
- is compliant with European Directive 94/62/CE on packaging and packaging waste
- is compliant to European regulation CE 10/2011 and conform for food use
- is free from animal products and derivatives, free of silicones, free of bisphenol A and phthalates and not concerned by nanotechnologies

III. INFORMATION ON ANIMAL TESTING

Our supplier confirms that since 1990, their products have 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.

They 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.
They therefore confirm the compliance of their products with the Cosmetic Regulation 1223/2009 concerning the ban on testing in animals in order to meet the requirements of the Cosmetic Regulation.

IV. ACTIVES and EFFECTS

Main actives in the plant:

- ⇒ Carbohydrates
- ⇒ Minerals
- ⇒ Vitamins (B-group, C)
- ⇒ Fruit acids

Main actives in the extract: Not determined

V. TOXICOLOGICAL DATA

Toxicity tests on the product

.We herewith confirm that no NOAEL measure has been made on this product.

We haven't carried out clinical studies on Fruitliquid Brazilian Papaya 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_{50} (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

Our product contains mainly Glycerin / Water vehicle:

⇒ The ecological information about Glycerin is:

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

⇒ Water hazard class: 1 (self-classification)

VI. CONCLUSION AND RECOMMENDATIONS

According to available information from test results or bibliography, we recommend to use the product at a maximum level of: 5.0% in leave on / rinse off products.

Contraindications: none known

Remarks: none

VII. REFERENCES

This information is given in good faith and is based on our knowledge to date. This correspondence will not be automatically updated in the future.

(1) Martindale, The Extra Pharmacopoea, 30th 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.

Version: 1
Date: 12/2020
This version replaces the earlier one dated 07/2020

Date: 12/07/2023

STATEMENT

We hereby confirm that the below mentioned product is derived from non-animal* sources nor animal* by-products (including dairy products, honey, eggs, pearls).

We further confirm that since 1990, this product has not been tested on animals* in order to meet the requirements of the Cosmetic Regulation neither by nor on the request of Crodarom and we will not carry out animal tests in the future to meet the requirements of the Cosmetic Regulation.

Brazilian Papaya Liquid Fruit Extract

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 and with reference to our raw materials suppliers.

** The word 'animal' is understood to refer to the entire Animal Kingdom, that is all vertebrates and all multi-cellular invertebrates.*