

### Certificate of Analysis

Batch Details

Product Name: APPLELIQUIDFRUITEXTRACT

Batch No: 439043
Best Before End: MARCH 2022

### Quality Control Results

Analytical Te	est	Specificatio	n Limit		
Method No.	Characteristic	Lower	Upper	Value Unit	Status
	Addendum 00	PASS OR FAIL		Pass	р
	REVISION NUMBER	1.0		Pass	p
AC018000	ASPECT	LIQUID		Pass	p
AC018000	ASPECT	CLEAR TO SLIGH	ITLY	Pass	р
		OPALESCENT			
AC018000	ASPECT	SLIGHT SEDIMEN POSSIBLE	NTATION	Pass	p
. <b></b>	COLOUR	PALE YELLOW TO	)	Pass	р
		YELLOW			
AC018000	ODOUR	CHARACTERISTI	С	Pass	p
FC0031AO	SPECIFIC GRAVITY	0.995	1.025	1.024	p
	(20°C)				
FC0032AO	REFRACTIVE INDEX (20°C)	1.320	1.350	1.342	p
FC0064AO	pH VALUE (20°C)	4.5	6.5	4.7	p
JC0054B0	MOULDS/YEASTS	10 MAX CFU/G		Pass	p

Long term storage between 15 - 25°C, dark in closed containers. The performed analysis are guaranteed on original packaging

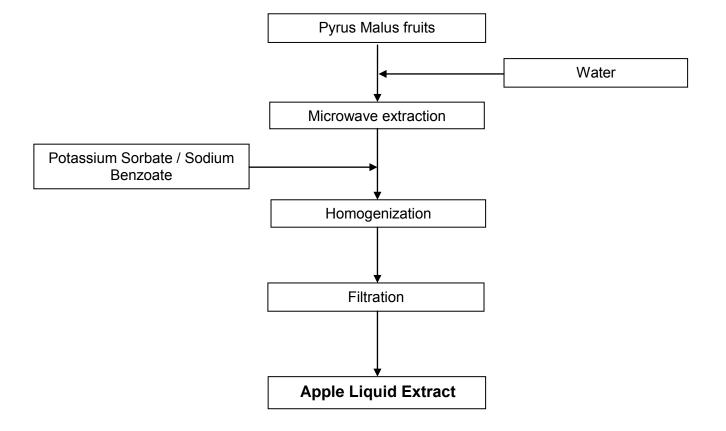
### Batch Status: Pass

The quality tests on this batch are reported above. The tests carried out are those necessary to demonstrate compliance with our product specification and are not intended to guarantee the product as suitable for any application beyond those contained in the specification. We recommend you perform your own quality and or identification checks on receipt



# Flow Chart of Apple Liquid Fruit Extract

17/03/2020





Date: 31.05.2017

To whom it may concern:

### **ORIGIN STATEMENT**

We herewith confirm that the product Fruit liquid Apple EC, is produced from synthetic and plants from organically cultivated origin raw materials, with reference to the confirmation of our raw materials suppliers.

This product is derived from non animal sources and does not contain material of bovine, ovine, caprine origin with reference to the confirmation of our raw materials suppliers.

According our knowledge and the confirmation of our suppliers, this product:

- Does not contain any genetically modified organism
- □ Is not produced with help of genetic engineering techniques

However, this confirmation does not permit any claims such as "produced without genetically modified organism" for products manufactures from our delivered product, according the EC regulations N° 1829/2003 and 1830/2003 because this law is not applicable to non-food products.

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.



# Composition Information

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

INCI Name: Water, Pyrus Malus (Apple) Fruit Extract

**INCI Name EU:** to follow Cosing, the European Commission database on

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

Composition:

Water 58 - 61 %

Pyrus Malus (Apple) Fruit Extract\* 38 – 42%

\*Pyrus Malus (Apple) Fruit Extract is expressed as fresh fruits.

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

Sodium Benzoate approx. 0.1%

Antioxidant: None

03/20



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).

### **Apple Liquid Fruit Extract**

INCI	CAS	EINECS	REACH status	Comment
Water	7732-18-5	231-791-2	/	1
Pyrus Malus (Apple) Fruit Extract	85251-63-4	286-475-7	Exempt	Production <1T/yr
Potassium sorbate	24634-61-5	246-376-1	Registered	01-2119950315-41
Sodium Benzoate	532-32-1	208-534-8	Registered	01-2119460683-35

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

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 Print Date 18.03.2020

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

1.1 Product identifier

Trade name : APPLE LIQUID FRUIT EXCTRACT

Substance name : BOTANICAL 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 UK

Telephone : +44 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

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 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-

bon dioxide.

according to Regulation (EC) No. 1907/2006

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 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

for firefighters

Special protective equipment : 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

: Ensure adequate ventilation. Personal precautions

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

### **APPLE LIQUID FRUIT EXTRACT**

Version 1.0 Revision Date 13.01.2016 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

Contains no substances with occupational exposure limit values.

#### 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, opalescent

Colour : 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

according to Regulation (EC) No. 1907/2006

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 Print Date 18.03.2020

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 : 0.995 - 1.025 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

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

### 10.1 Reactivity

No data available

#### 10.2 Chemical stability

No data available

### 10.3 Possibility of hazardous reactions

according to Regulation (EC) No. 1907/2006

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Print Date 18.03.2020 Revision Date 13.01.2016

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 :

: No data available : Acute dermal toxicity

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

according to Regulation (EC) No. 1907/2006

## **APPLE LIQUID FRUIT EXTRACT**

Version 1.0 Revision Date 13.01.2016 Print Date 18.03.2020

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:

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

**Product:** 

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

**Product:** 

Distribution among environ-

mental compartments

: Remarks: No data available

BiOrigins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK
Tel: 01425 655555 Email: technical@madarcorporation.co.uk
Page 12

according to Regulation (EC) No. 1907/2006

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 Print Date 18.03.2020

#### 12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

> to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher...

12.6 Other adverse effects

**Product:** 

Additional ecological informa: Remarks: No data available

### **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

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.

according to Regulation (EC) No. 1907/2006

### APPLE LIQUID FRUIT EXTRACT

Version 1.0 Revision Date 13.01.2016 Print Date 18.03.2020

### **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

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: APPLE LIQUID FRUIT EXTRACT

**Product Code:** FEAPPL **Specification:** 22/05/2014

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	1.0		
AC018000	ASPECT	LIQUID		
AC018000	ASPECT	CLEAR TO S	SLIGHTLY	
		OPALESCE		
AC018000	ASPECT	SLIGHT SEDIMENTATION		
		POSSIBLE		
AC018000	COLOUR	PALE YELLOW TO		
		YELLOW		
AC018000	ODOUR	CHARACTERISTIC		
FC0031A0	SPECIFIC GRAVITY	0.995	1.025	
	(20°C)			
FC0032A0	REFRACTIVE INDEX	1.320	1.350	
	(20°C)			
FC0064A0	pH VALUE (20°C)	4.5	6.5	
JC0054B0	MOULDS/YEASTS	10 MAX CFU/G		
JC0054B0	TOTAL GERMS	100 MAX CFU/G		

Long term storage between 15 - 25°C, dark in closed containers The performed analysis are guaranteed on original packaging When stored accordingly, stable for 24 months



# **Apple Liquid Fruit Extract**



### PLANT INFORMATION

<u>Latin name</u> Pyrus malus <u>Family</u> Rosaceae

### Common names

English: Apple Portuguese: Maçã French: Pomme リンゴ Japanese: German: Chinese: 蘋果 Apfel Spanish: Manzana Russian: яблоко

### **History / Uses**

Wild Apple (*Pyrus malus*), is native to Britain and is the wild ancestor of all the cultivated varieties of apple trees. It is known since the Genesis. In the Antiquity, doctors already prescribed apple wine as a cure-all. They are a traditional remedy for joint pain and stiffness due to rheumatism.

Apple contains proteins, starch, sugars, acids, vitamins and salts. The sugar content of a fresh apple varies from 6 to 10 per cent., according to the variety. All apples contain a varying amount of the organic acids, malic acid and gallic acid, and an abundance of as magnesium and iron.

In cosmetics, apples are claimed for emollient, hydrating, stimulating and tonifying properties.

#### Active molecules / Related properties

Carbohydrates (mainly fructose, glucose, sucrose)

Moisturising, smoothing, conditioning

Fruit acids

Mild keratolytic / bleaching, antibacterial

Vitamins, minerals Regenerating

### **Used plant characteristics**

Plant part	Certified geographic origin	Organic certified	Fair trade	FSC
Fruit	The Italian Alps	No	No	No



## PRODUCT INFORMATION

INCI Name Glycerin, Water, Pyrus Malus (Apple) Fruit Extract

**CAS Number** 56-81-5, 7732-18-5, 85251-63-4 **EINECS Number** 200-289-5, 231-791-2, 286-475-7

<u>Preservative</u> Sodium benzoate, potassium sorbate

Manufacturing process Maceration

Appearance Pale yellow, clear liquid (has to be confirmed on industrial batch)

Guarantee / Certification

Organic certified	Natural validated	Certifiable	Chinese regulation	Active level	Proven effect
No	No	No	SFDA 2003 SFDA 2007	No	No

## Application / Concept

### **Cosmetic application**

Everyday-nourishing-care
After-sun care
After-shave products
Shampoos for dry hair and scalp
Mild facial cleansers
Shower gels

### **Concept / Trends**

Refreshing concepts Modesty trend (Earthly)

## Formulation Advices

Recommended level of use Max. 10%

Solubility Water: soluble / Alcohol: soluble / Oil: insoluble (at T0)

Stability pH3: not tested / pH10: not tested (at 2% in unpreserved water)

**Precaution** Add to the formula at 40°C max.

#### Non-warranty

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# Toxicological dossier

Product Name:	Fruitliqu	id Apple l	EC
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Water, Pyrus Malus (Apple) Fruit Extract INCI Name :

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 %)

Water A

Pyrus Malus (Apple) Fruit Extract\* B

### Origin of raw materials:

Plant origin : Pyrus Malus

plant part : Fruit
from organic culture : Yes
free of GMO : Yes

Synthetic origin : Preservatives

Animal origin : No

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

Sodium Benzoate approx. 0.1%

Antioxidant: None

Manufacturing process: Microwaves extraction of organically

cultivated, dried, peeled apples in water followed by preservation, filtration,

conditioning and filling

<sup>\*</sup> Pyrus Malus (Apple) Fruit Extract is expressed as **fresh** fruits.

### Microbiological Data:

⇒ Bacteria
 ⇒ Moulds and yeasts
 ⇒ Pathogenic Micro-organisms
 < 100 cfu / g</li>
 < 10 cfu / g</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 : Not expected – not tested

Impurities are residual monomer, dioxane, chloroacetic acid, 3-Chloropropanol, nitrosamines, amine, polychloro biphenyls, benzene, nuts, polychloro dibenzo dioxins and dibenzo furans and dimethyl aminopropylamine

⇒ Residual solvents: Not expected – not tested

The plants used for Apple Liquid Fruit Extract have been organically cultivated. Therefore pesticides, heavy metals or impurities are not expected.

### Total volatile components / Allergens content :

We herewith confirm that **Apple Liquid Fruit Extract**, 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**

<sup>\*!</sup>They are synthetic substances that do not occur in botanicals.

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 cannot 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.

Apple 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.

<sup>\*\*</sup> The substances are not expected to be part of the fruits of Pyrus malus

### **Animal testing**

Our manufacturer 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 the request of MADAR Corporation.

MADAR Corporation 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: (1)(2)(3)

Apples contain mainly water, proteins, fats, fibers and :

- ⇒ Carbohydrates (mainly Glucose, Fructose, Saccharose, Sorbitol, Polysaccharides as Cellulose, Hemicellulose, Fucogalactosyloglucan, Pentosane and Pectin)
- ⇒ Fruit acids (mainly Malic Acid)
- ⇒ Provitamin A, Vitamin B types, C, H
- ⇒ Phenolics (mainly Hydroxycinnamic acids and Hydroxybenzoic acids, P-cumaric Acid, Caffeic Acid, Ferulic Acid, Catechin, Epicatechin, Gallocatechin)

Total phenol content in dried apples : approx 1000mg/100g according to literature

Main actives in the extract: Not determined

### **Toxicological Data:**

We do not see any danger in using Apple 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 Apple Liquid Fruit Extract, but according to literature, Water and Pyrus malus don't contain potentially toxic compounds and they are safe when used appropriately.

Apples, fruits of Pyrus malus are eaten since hundreds of years. No adverse effects are reported. There is no data on the side effects and toxicology of the fruits.

Human skin irritation: No data available Mucous membrane irritation: No data available  $\Rightarrow$ Sensitisation potential: No data available  $\Rightarrow$ Cytotoxicity: No data available Phototoxicity: No data available  $\Rightarrow$ Mutagenicity (e.g. Ames Test): No data available  $\Rightarrow$ Carcinogenicity: No data available No data available Acute toxicity:  $\Rightarrow$ 

⇒ Inhalation toxicity: No data available
 ⇒ Chronic toxicity: No data available
 ⇒ Reproduction toxicity: No data available

### Toxicological information about main actives of the plant:

⇒ Carbohydrates Toxic effects aren't reported.

⇒ Malic Acid (4):

Dermal irritation on animals: Moderately irritant to rabbit skin and strong irritant to

guinea pig.

Eye irritation : Severe ocular irritation in rabbit eyes.

Mutagenicity (e.g. Ames Test): Ames test: not mutagenic

Acute toxicity:  $LD_{50}$  (rat) = 1.60 – 3.5 g/kg bw by oral route

 $LD_{50}$  (mice) = 2.66 – 3.2 g/kg bw by oral route  $LD_{50}$  (rabbit) = 3 – 5 g/kg bw by oral route

LD<sub>50</sub> (rabbit) = 2.4 g/kg bw by intravenous injection

Chronic toxicity: No significant changes or lesions were observed

when dogs were fed malic acid.

Reproduction toxicity: It did not cause reproductive toxicity in mice, rats

and rabbits.

 $\Rightarrow$  Apple polyphenols (2):

Apple polyphenol extracts are listed in the FDA's approved additive/GRAS (Generally Recognized as Safe) database.

Acute toxicity: LD50 (rat, subcutaneous) = 2000mg/kg

Sensitisation potential: Tests using rabbits indicated that procyanidin B-2

containing preparations shows no primary irritation. Tests on guinea pigs shows no evidence of

sensitization to this polyphenol.

Topically, procyanidin B-2 is concluded as safe and

acceptable.

Mutagenicity (e.g. Ames Test): Procyanidin B-2 is non mutagenic.

Applephenon is safe and no toxic at average dietary level.

### **Ecological Data:**

Our product contains mainly water.

⇒ Environmental toxicity: Not expected to be toxic
 ⇒ Biodegradability: Easily biodegradable
 ⇒ Water hazard class: 1 (self classification)

#### **Phytopharmaceutical Data:**

⇒ External uses: used in everyday-nourishing-care, after-sun care,

after-shave products, shampoos for dry hair and

scalp, mild facial cleansers, shower gels

⇒ Contraindications : None known
 ⇒ Side effects : None known
 ⇒ Interactions: None known

### References:

- 1. Hager CDRom 2010 ; Springer Medizin Verlag Heidelberg; information regarding Pyrus malus
- 2. <a href="http://www.mdidea.com/products/proper/proper00714.html">http://www.mdidea.com/products/proper/proper00714.html</a>
- 3. Constituents of apple, parsley and lentil edible plants and their therapy treatments for blood picture as well as liver and kidneys functions against lipidemic disease, El-Beltagi, H.S et al. EJEAFChe, 9 (6), 2010. [1117-1127]
- 4. CIR Report, CTFA 2006 for toxicological information regarding Malic Acid

02/20

This toxicological dossier replaces the earlier one dated 08/11, 02/16



Date: 17.03.2020

To whom it may concern:

## **STATEMENT**

We hereby confirm that the below mentioned product is derived from non-animal sources. We further confirm 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.

### **Apple Liquid Fruit Extract**

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