# **Macerato - Tobacco Extract**

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# Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

#### 1.1. Product identifier

Tobacco Extract.

This safety data sheet is valid for the commercial name and product code listed in the following table and belong to the "Macerated Tobacco".

List of the commercial names and product codes:

Assolo di Virginia - 81

Assolo di Izmir - 83

Assolo di Kentucky - 84

Assolo di Latakia - 85

Assolo di Black Cavendish - 87.

Code: Macerato
Product name Tobacco Extract

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

Identified relevant uses: Utilize with a dilution of 10-15% to flavor inhalation liquid (Neutral Bases) for electronic cigarettes (ECig), electronic cigar (ECigar) and electronic pipe (EPipe).

Identified non relevant uses: It is not food. Do not swallow. Dot not use as it is. Everything else not stated is identified as non relevant.

Intended use

Tobacco Extract. Utilize with a dilution of 10-15% to flavor inhalation liquid (Neutral Bases) for electronic cigarettes (ECig), electronic cigar (ECigar) and electronic pipe (EPipe).

# 1.3. Details of the supplier of the safety data sheet

Name LA TABACCHERIA DI ORLANDO D ALESSANDRO

Full address Via Frattamaggiore 22

District and Country 00132 Roma (Rm)

Italia
Tel. 3934560139
Fax 0662209809

e-mail address of the competent person

responsible for the Safety Data Sheet info@latabaccheria.net

Product distribution by: Orlando D'Alessandro

## 1.4. Emergency telephone number

For urgent inquiries refer to Per informazioni urgenti rivolgersi al Centro Antiveleni di Roma 06 3054343 (CAV

Policlinico Gemelli - Roma)

Numeri telefonici dei principali Centri Antiveleni Italiani (attivi 24/24 ore)
Centro Antiveleni di Pavia 0382 24444 (CAV IRCCS Fondazione Maugeri Pavia)
Centro Antiveleni di Milano 02 66101029 (CAV Niguarda Ca' Granda Milano)
Centro Antiveleni di Bergamo 800 883300 (CAV Ospedali Riuniti - Bergamo)
Centro Antiveleni di Firenze 055 7947819 (CAV Ospedale Careggi - Firenze)
Centro Antiveleni di Roma 06 49978000 (CAV Policlinico Umberto I - Roma)

# **SECTION 2. Hazards identification**

### 2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2015/830.

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### SECTION 2. Hazards identification .../>>

Hazard classification and indication:

### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

**EUH210** Safety data sheet available on request.

Precautionary statements:

P102 Keep out of reach of children. P103 Read label before use.

P301+P312 IF SWALLOWED: Call a POISON CENTER or a doctor if you feel unwell.

P401 Store between 1°C and 40°C away from sunlight.

**P501** Dispose of product / container in accordance with national regulations.

#### 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

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

#### 3.1. Substances

Information not relevant

### 3.2. Mixtures

It may contain unavoidable traces of nicotine derived from the maceration process.

Contains:

Identification x = Conc. % Classification 1272/2008 (CLP)

Propylene Glycol USP-EP-E1520

CAS 57-55-6  $94 \le x < 98$ 

EC 200-338-0

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Reg. no. 01-2119456809-23

Tobacco Extratc

CAS 84961-66-0 5 ≤ x < 6 Acute Tox. 4 H302, Acute Tox. 4 H312, Aquatic Chronic 3 H412

EC 284-656-5

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The full wording of hazard (H) phrases is given in section 16 of the sheet.

# **SECTION 4. First aid measures**

### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

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Information not available

# **SECTION 5. Firefighting measures**

## 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

### 5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

## 5.3. Advice for firefighters

## **GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## SECTION 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

## 6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

### 6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

### 6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

# **SECTION 7. Handling and storage**

# 7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

## 7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

# 7.3. Specific end use(s)

Information not available

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

### 8.1. Control parameters

|  |                      |            | Propylene Gly | col USP-EP-E | E1520              |          |         |          |
|--|----------------------|------------|---------------|--------------|--------------------|----------|---------|----------|
| Predicted no-effect cor                      | ncentration          | - PNEC     |               |              |                    |          |         |          |
| Normal value in fresh water                  |                      |            |               |              |                    | 260      | mg/l    |          |
| Normal value in marine water                 |                      |            |               |              |                    | 26       | mg/l    |          |
| Normal value for fresh water sediment        |                      |            |               |              |                    | 572      | mg/kg   |          |
| Normal value for marine water sediment       |                      |            |               |              |                    | 57,2     | mg/kg   |          |
| Normal value for water, intermittent release |                      |            |               |              |                    | 183      | mg/l    |          |
| Normal value of STP microorganisms           |                      |            |               |              |                    | 20000    | mg/l    |          |
| Normal value for the terrestrial compartment |                      |            |               |              |                    | 50       | mg/kg   |          |
| Health - Derived no-eff                      | ect level - D        | NEL / DMEL |               |              |                    |          |         |          |
|  | Effects on consumers |            |               |              | Effects on workers |          |         |          |
| Route of exposure                            | Acute                | Acute      | Chronic       | Chronic      | Acute local        | Acute    | Chronic | Chronic  |
|  | local                | systemic   | local         | systemic     |                    | systemic | local   | systemic |
| Inhalation                                   |                      |            | 10            | 50           |                    |          | 10      | 168      |
|  |                      |            | mg/m3         | mg/m3        |                    |          | mg/m3   | mg/m3    |

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

#### 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

# SECTION 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance Colour various Odour characteristic Odour threshold Not available Ηα Not available Melting point / freezing point Not available Initial boiling point Not available Boiling range Not available Flash point Not available Evaporation rate Not available Flammability (solid, gas) Not available

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### SECTION 9. Physical and chemical properties .... / >>

Lower inflammability limit Not available Upper inflammability limit Not available Lower explosive limit Not available Upper explosive limit Not available Not available Vapour pressure Vapour density Not available Relative density Not available Solubility Not available Partition coefficient: n-octanol/water Not available Auto-ignition temperature Not available Decomposition temperature Not available Not available Viscosity Explosive properties Not available Oxidising properties Not available

### 9.2. Other information

Information not available

# SECTION 10. Stability and reactivity

### 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

Propylene Glycol USP-EP-E1520

Hygroscopic. Stable in normal conditions of use and storage.

At high temperatures it tends to oxidate to form propional dehyde and lactic and acetic acid.

## 10.2. Chemical stability

The product is stable in normal conditions of use and storage.

Propylene Glycol USP-EP-E1520

Maintaining a temperature of less than 40 °C.

Stable in normal conditions of use and storage.

### 10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

Propylene Glycol USP-EP-E1520

May react dangerously with: acid chlorides,acid anhydrides,oxidising agents.

## 10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

# 10.5. Incompatible materials

Information not available

# 10.6. Hazardous decomposition products

Propylene Glycol USP-EP-E1520 May develop: carbon oxides.

## **SECTION 11. Toxicological information**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

## 11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

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#### SECTION 11 Toxicological information ..../>>

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

**ACUTE TOXICITY** 

LC50 (Inhalation) of the mixture: Not classified (no significant component)

LD50 (Oral) of the mixture: >2000 mg/kg LD50 (Dermal) of the mixture: >2000 mg/kg

Tobacco Extratc

 LD50 (Oral)
 500 mg/kg ratto

 LD50 (Dermal)
 1100 mg/kg ratto

Propylene Glycol USP-EP-E1520

LD50 (Oral) 22000 mg/kg ratto LD50 (Dermal) > 2000 mg/kg ratto

Propylene Glycol USP-EP-E1520

Tossicità dopo assunzione ripetuta (subacuta, subcronica, cronica)

Tossicità orale subacuta

Parametro: NOAEL(C) (PROPANE-1,2-DIOL; No. CAS: 57-55-6)

Via di esposizione : Per via orale Specie : Ratto (maschio) Dose efficace : 1700 mg/kg Tossicità inalativa subacuta

Parametro: NOAEC (PROPANE-1,2-DIOL; No. CAS: 57-55-6)

Via di esposizione : Inalazione Specie : Ratto (maschio) Dose efficace : 2200 mg/m3.

### SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Propylene Glycol USP-EP-E1520 Potere irritante: non irritante.

## **SERIOUS EYE DAMAGE / IRRITATION**

Does not meet the classification criteria for this hazard class

Propylene Glycol USP-EP-E1520 Potere irritante: non irritante.

## **RESPIRATORY OR SKIN SENSITISATION**

Does not meet the classification criteria for this hazard class

Respiratory sensitization Propylene Glycol USP-EP-E1520 Non si conoscono effetti sensibilizzanti.

Skin sensitization
Propylene Glycol USP-EP-E1520
Non si conoscono effetti sensibilizzanti.

# **GERM CELL MUTAGENICITY**

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#### SECTION 11. Toxicological information .../>

Does not meet the classification criteria for this hazard class

### **CARCINOGENICITY**

Does not meet the classification criteria for this hazard class

Propylene Glycol USP-EP-E1520

Cancerogenicità

Parametro: NOAEL(C) (PROPANE-1,2-DIOL; No. CAS: 57-55-6)

Via di esposizione : Ratto (maschio) Dose efficace : 1700 mg/kg.

# REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on development of the offspring

Propylene Glycol USP-EP-E1520

Possibili effetti nocivi sulla tossicità dello sviluppo

Parametro: NOAEL (Sviluppo fetale) ( PROPANE-1,2-DIOL; No. CAS: 57-55-6)

Via di esposizione : Topo

Dose efficace: 10400 mg/kg bw/day.

### STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

### **STOT - REPEATED EXPOSURE**

Does not meet the classification criteria for this hazard class

### **ASPIRATION HAZARD**

Does not meet the classification criteria for this hazard class

# **SECTION 12. Ecological information**

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

### 12.1. Toxicity

Propylene Glycol USP-EP-E1520

LC50 - for Fish 40613 mg/l/96h Oncorhynchus mykiss EC50 - for Crustacea 18340 mg/l/48h Ceriodaphnia dubia EC50 - for Algae / Aquatic Plants 19000 mg/l/48h Skeletonema costatum

# 12.2. Persistence and degradability

Propylene Glycol USP-EP-E1520

Solubility in water 1000 - 10000 mg/l

Rapidly degradable

### 12.3. Bioaccumulative potential

Propylene Glycol USP-EP-E1520

Partition coefficient: n-octanol/water -1,07 BCF 0,09

# 12.4. Mobility in soil

Propylene Glycol USP-EP-E1520

Partition coefficient: soil/water 0,46

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### SECTION 12. Ecological information .../>>

## 12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

### 12.6. Other adverse effects

Information not available

# **SECTION 13. Disposal considerations**

#### 13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

**CONTAMINATED PACKAGING** 

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## **SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

### 14.1. UN number

Not applicable

### 14.2. UN proper shipping name

Not applicable

### 14.3. Transport hazard class(es)

Not applicable

# 14.4. Packing group

Not applicable

# 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

# 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Information not relevant

# **SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EC:

None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

None

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisarion (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

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### SECTION 15. Regulatory information ..../>>

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

<u>Healthcare controls</u> Information not available

### 15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

### **SECTION 16. Other information**

### Additional Informations:

- Leaflet and safety data sheet on web site www.latabaccheria.net.
- The sale is prohibited under the age of 18.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 4 Acute toxicity, category 4

Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3

H302 Harmful if swallowed.
H312 Harmful in contact with skin.

H412 Harmful to aquatic life with long lasting effects.

EUH210 Safety data sheet available on request.

#### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

### **GENERAL BIBLIOGRAPHY**

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
- 4. Regulation (EU) 2015/830 of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament

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- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

### Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.