

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code: Flapper Juice Tobacco - Tropic
Product name: Aroma Concentrato - Tropicali dei Caraibi

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

Intended use: not available

1.3. Details of the supplier of the safety data sheet

Name: L ERBORISTERIA SRL
Full address: Via Frattamaggiore 22
District and Country: 00132 Roma (Rm) Italia
Tel.: +39 3934560139
Fax: +39 0662209809

e-mail address of the competent person responsible for the Safety Data Sheet: info@latabaccheria.net

Supplier: Orlando D'Alessandro

1.4. Emergency telephone number

For urgent inquiries refer to: For urgent information contact the Poison Center of Rome +39 06 3054343 (CAV Policlinico Gemelli - Rome)

Telephone numbers of the main Italian Poison Centers (active 24/24 hours)
Poison Center of Pavia +39 0382 24444 (CAV IRCCS Fondazione Maugeri Pavia)
Poison Center of Milan +39 02 66101029 (CAV Niguarda Ca' Granda Milano)
Poison center of Bergamo +39 800 883300 (CAV Ospedali Riuniti - Bergamo)
Poison center of Florence + 39 055 7947819 (CAV Hospital Careggi - Florence)
Poison center of Rome +39 06 49978000 (CAV Policlinico Umberto I - Rome)

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 2020/878.

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.
EUH208 Contains: 4-Hydroxy-2,5-dimethyl-3(2H)-furanone
May produce an allergic reaction.

Precautionary statements: --

SECTION 2. Hazards identification ... / >>

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Propylene Glycol USP-EP-E1520		
INDEX	$96 \leq x < 100$	
EC	200-338-0	
CAS	57-55-6	
REACH Reg.	01-2119456809-23	
Tobacco Extract		
INDEX	$1 \leq x < 1,5$	Acute Tox. 4 H302, Acute Tox. 4 H312, Aquatic Chronic 3 H412
EC	284-656-5	LD50 Oral: 500 mg/kg, LD50 Dermal: 1100 mg/kg
CAS	84961-66-0	
4-Hydroxy-2,5-dimethyl-3(2H)-furanone		
INDEX	$0 \leq x < 0,05$	Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1A H317
EC	222-908-8	STA Oral: 500 mg/kg
CAS	3658-77-3	

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

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. 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

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Propylene Glycol USP-EP-E1520

Predicted no-effect concentration - 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-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation			10 mg/m3	50 mg/m3			10 mg/m3	168 mg/m3

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

SECTION 8. Exposure controls/personal protection ... / >>

; MED = medium hazard ; HIGH = high hazard.

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.

HAND PROTECTION

Protect hands with category III work gloves.

The following should be considered when choosing work glove material (see standard EN 374): 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 Regulation 2016/425 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

Properties	Value	Information
Appearance	not available	
Colour	not available	
Odour	not available	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	not available	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

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 propionaldehyde 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 hazard classes as defined in Regulation (EC) No 1272/2008

Metabolism, toxicokinetics, mechanism of action and other 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

ATE (Inhalation) of the mixture:

Not classified (no significant component)

ATE (Oral) of the mixture:

>2000 mg/kg

ATE (Dermal) of the mixture:

>2000 mg/kg

SECTION 11. Toxicological information ... / >>

Tobacco Extract
LD50 (Dermal): 1100 mg/kg ratto
LD50 (Oral): 500 mg/kg ratto

Propylene Glycol USP-EP-E1520
LD50 (Dermal): > 2000 mg/kg ratto
LD50 (Oral): 22000 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

May produce an allergic reaction.
Contains:
4-Hydroxy-2,5-dimethyl-3(2H)-furanone

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

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

SECTION 11. Toxicological information ... / >>

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

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

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

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 \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. 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 or ID 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. Maritime transport in bulk according to IMO instruments

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/EU: None

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

Product

Point 40

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

SECTION 15. Regulatory information ... / >>

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

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

Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Skin Sens. 1A	Skin sensitization, category 1A
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
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
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 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: 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: Regulation (EC) 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: Time-weighted average exposure limit
- TWA STEL: Short-term 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) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) 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
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

SECTION 16. Other information ... / >>

12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII 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.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.