

# SAFETY DATA SHEET

[In accordance with the criteria of Regulation No 1907/2006 (REACH) with further changes]

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

### 1.1. Product identifier.

Trade name: **Lichid smokemanía Fresco 12mg**

Description: A solution of Pharmaceutical Vegetable Glycerine with Pharmaceutical Propylene Glycol, nicotine (12 mg/ml) and flavour.

UFI: PJ10-20XD-T00V-R547

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

Relevant identified uses: e-liquids for electronic cigarettes

Uses advised against: not determined

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

Supplier: **SC SUBSTITUTE SRL**

Address: Sibiu, strandului, 4, ROMANIA

Phone: +40730670221

E-mail address of the person responsible for the information card: office@substitute.ro

### 1.4. Emergency telephone number

112 (general emergency phone number)

## Section 2: Hazards Identification

### 2.1. Classification of the substance or mixture.

Classification according to 1272/2008/EC

Acute Tox. 4 (oral) - Acute toxicity, category 4; H302

### 2.2. Label elements

Hazard symbols and signal words



#### Warning

Hazard statements

H302 Harmful if swallowed.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

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

P501 Dispose of contents/container to container for waste.

### 2.3. Other hazards

This mixture does not meet criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation. Product does not have endocrine disrupting properties. No other hazards to determine. This mixture does not contain "Substances of Very High Concern" on the list published by the European Chemicals Agency (ECHA) pursuant to Art. 57 of the REACH regulation.

**EUH 208 Contains furaneol. May produce an allergic reaction.**

# SAFETY DATA SHEET

## Section 3: Composition/Information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

Composition:

No.	Chemical name	Percentage	CAS	EC (EINECS)	Index No./ REACH Registration No.	Classification according to 1272/2008/EC
1.	Glycerol	73,9 %	56-81-5	200-289-5	none/exempt from registration	Not classified
2.	Propylene glycol	24,85 %	57-55-6	200-338-0	none/ 01-2119456809-23-XXXX	Not classified
3.	Nicotine	1,01 %	29790-52-1	249-852-7	614-001-00-4/ 01-2120066934-47-0004, 01-2120066934-47-0011	Acute Tox. 2 H310; Acute Tox. 2 H300; Acute Tox. 2 H330; Aquatic Chronic 2 H411; inhalation: ATE = 0,19 mg/L (dusts or mists); skin: ATE = 70 mg/kg; oral: ATE = 5 mg/kg
4.	Furaneol	0,08 %	3658-77-3	222-908-8	None/ not applicable	Skin Sens. 1A; H317 Eye Irrit.2; H319

Full text H - phrases in section 16. The other ingredients of the flavour are in small, irrelevant quantities and remain a trade secret.

## Section 4: First aid measures

### 4.1. Description of first aid measures.

Skin contact: immediately take off contaminated clothing. Wash out skin with plenty of water with soap. Consult a doctor immediately.

Eye contact: wash out with plenty of water with the eyelid hold wide open, for 10-15 min. Remove any contact lenses. Avoid strong stream of water-risk of cornea damage. Seek medical advice if necessary.

Ingestion: do not induce vomiting. Rinse mouth with water. Do not give anything to drink to an unconscious person. Consult a doctor - show the container or label.

Inhalation: remove to fresh air. Keep warm and calm. Consult a doctor, if symptoms persist.

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

Eye contact: redness, tearing, mild irritation.

Skin contact: can cause irritation, breathing problems, dizziness, cramps, nausea, vomiting. It can be absorbed through the skin. At sensitive individuals may experience an allergic reaction.

Ingestion: nausea, vomiting. In extreme cases, after swallowing very large quantities of product, may appear breathing problems, dizziness, disorders of the respiratory tract.

Inhalation: following exposure to doses above permissible limits include: stimulation of breath, nausea, vomiting, headache, dizziness, diarrhea, tachycardia, increased blood pressure, sweating, salivation, burning sensation in the mouth, throat and stomach.

# SAFETY DATA SHEET

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

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured.

## Section 5: Firefighting measures

### 5.1. Extinguishing media.

Suitable extinguishing media: adjust the extinguishing agent to the material collected in the environment.

Unsuitable extinguishing media: water jet - risk of the propagation of the flame.

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

May produce toxic fumes of carbon and nitrogen oxides, if burning. Do not inhale combustion products.

### 5.3. Advice for firefighters.

Personal protection typical in case of fire. Wear suitable respiratory equipment. Cool down containers with water from safe distance to prevent bursting.

## Section 6: Accidental release measures

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

Limit the access for the outsiders into the breakdown area, until the suitable cleaning operations are completed. In case of large spills, isolate the exposed area. Ensure adequate ventilation. Avoid contact with skin and eyes. Avoid contact with spilled material. Danger of slipping, do not passed through spilled material. Wear adequate personal protective equipment. Do not allow the product to get into mouth.

### 6.2. Environmental precautions.

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Notify relevant emergency services.

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

Soak up with liquid-binding material (e.g. sand, universal binding agent, diatomaceous earth). Collect spilled material in containers. Disposal in accordance with the local legislation. Clean the contamination place.

### 6.4. References to other sections.

Appropriate conduct with waste product - see section 13. Personal protective equipment - see section 8.

## Section 7: Handling and storage

### 7.1. Precautions for safe handling.

Handle in accordance with good occupational hygiene and safety practices. Avoid contact with skin and eyes. Do not inhale vapours. Ensure adequate ventilation. Before break and after work wash carefully hands. Keep not used containers tightly closed. Do not allow the product to get into mouth. Shake before use.

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

Keep containers tightly closed in cool and well-ventilated area. Keep away from food, beverages or feed for animals. After opening seal the container and store in an upright position to prevent leakage. Avoid heat and ignition sources. Store at 10-25°C.

### 7.3. Specific end use(s).

No information about the applications other than those listed in subsection 1.2.

# SAFETY DATA SHEET

## Section 8: Exposure control/personal protection

### 8.1. Control parameters.

Please check any national occupational exposure limit values in your country for substance contained in this product.

Specification	STEL 15 min	TWA 8 hour
propylene glycol [CAS 57-55-6]	-	10 mg/m <sup>3</sup>
nicotine [CAS 54-11-5]	-	0,5 mg/m <sup>3</sup> (skin)
glycerol [CAS 56-81-5]	-	10 mg/m <sup>3</sup> (aerosol)

### 8.2. Exposure controls.

Use the product in accordance with good occupational hygiene and safety practices. Ensure adequate ventilation. When handlings do not eat, drink or smoke. Before break and after work carefully wash hands. In the vicinity of the work should be installed safety showers and separate washer eyewash. At the exit of the room in which you are working with toxic materials should be at least one sink with brought to the warm water - for every twenty employees.

#### Hand and body protection

Wear the protective gloves (long-term exposure - butyl rubber, thickness: 0,3 mm, penetration time: >480 min., short-term exposure: nitrile rubber, thickness: 0,4 mm, penetration time: >30 min.) and protective clothing.

The material that the gloves are made of must be impenetrable and resistant to the product's effects. The selection of material must be performed with consideration of breakthrough time, penetration speed and degradation. Moreover, the selection of proper gloves depends not only on the material, but also on other quality features and changes depending on the manufacturer. The producer should provide detailed information regarding the exact breakthrough time. This information should be followed.



#### Eye/face protection

Wear tight safety glasses when there is a danger of possible eye contamination.

#### Respiratory protection

In case of normal and as intended use, no respirator is needed. If exposure limits are exceeded, apply face mask with appropriate organic vapour cartridge.

#### Environmental exposure controls

Do not allow the mixture to contaminate surface water/ground water.

## Section 9: Physical and chemical properties

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

a) physical state:	liquid
b) colour:	light yellow
c) odour:	no data available
d) melting point/freezing point:	no data available
e) boiling point or initial boiling point and boiling range:	no data available
f) flammability:	no data available
g) lower and upper explosion limit:	17,4 % /2,4 % (for propylene glycol) 11,3%/2,6% (for glycerine)
h) flash point:	no data available
i) auto-ignition temperature:	no data available
j) decomposition temperature:	no data available
k) pH:	7,40 ± 0,09

# SAFETY DATA SHEET

l) kinematic viscosity:	no data available
m) solubility:	no data available
n) partition coefficient n-octanol/water (log value):	no data available
o) vapour pressure:	20 Pa (for propylene glycol) 3,18 Pa (for glycerine)
p) density and/or relative density:	1,19 g/cm <sup>3</sup>
q) relative vapour density:	no data available
r) particle characteristics:	no data available

## 9.2. Other information.

No additional test results.

## Section 10: Stability and reactivity

### 10.1. Reactivity.

Product reactive. See subsection 10.3-10.5.

### 10.2. Chemical stability.

The product is stable under normal conditions.

### 10.3. Possibility of hazardous reactions.

The product can react exothermically with strong oxidizing agents.

### 10.4. Conditions to avoid.

Avoid direct sunlight and sources of ignition.

### 10.5. Incompatible materials.

Strong oxidizers.

### 10.6. Hazardous decomposition products.

Unknown.

## Section 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008.

#### a) Acute toxicity

ATEmix (skin): > 2000 mg/kg bw (No classification)

ATEmix (oral): 497,3 mg/kg (Acute toxicity, category 4)

ATEmix (inhalation): > 5 mg/l (No classification)

Based on available data, the classification criteria are met.

#### b) Skin corrosion/irritation

Based on available data, the classification criteria are not met.

#### c) Serious eye damage/irritation

Based on available data, the classification criteria are not met.

#### d) Respiratory or skin sensitization

Based on available data, the classification criteria are not met. Contains furaneol. May produce an allergic reaction.

#### e) Germ cell mutagenicity

Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

## f) Carcinogenicity

Based on available data, the classification criteria are not met.

## g) Reproductive toxicity

Based on available data, the classification criteria are not met.

## h) STOT-single exposure

Based on available data, the classification criteria are not met.

## i) STOT-repeated exposure

Based on available data, the classification criteria are not met.

## j) Aspiration hazard

Based on available data, the classification criteria are not met.

### **11.2. Information on other hazards.**

No data available.

## Section 12: Ecological Information

### **12.1. Toxicity.**

According to CLP and the calculation method the concentration of nicotine salicylate is below 25%. The criteria for environmental toxicity are not met.

### **12.2. Persistence and degradability.**

Propylene glycol: 81% after 28 days of the OECD 301F test

96% after 64 days of the OECD 301F test

Biodegradation may proceed slowly in anaerobic conditions.

Biodegradation in water - screening tests: Readily biodegradable (100 %).

Glycerine:

Biodegradation: > 60% after 28 days, closed bottle test.

Biodegradation in water - screening tests: Readily biodegradable (100 %).

Nicotine:

Biodegradation in freshwater - screening tests: Readily biodegradable (100 %).

### **12.3. Bioaccumulative potential.**

Propylene Glycol:

Possibility of bioconcentration is low (BCF <100 or log Pow <3) breakdown factor, n-octanol/water (log Pow):

-1.07 @ 20.5 °C and pH 6.2 - 6.4 method EU A.8 Bioconcentration factor: 0,09.

Bioaccumulation potential: No bioaccumulation potential.

Glycerine:

Log Pow breakdown factor: -2.66 -bioaccumulation should not be expected.

Log Pow: -1.75 @ 25 °C and pH 7.4

Nicotine: Log Pow = 1,17 @ 18 °C

### **12.4. Mobility in soil.**

Product mobile in soil and in water. Mobility of components in the mixture depends on the hydrophilic and hydrophobic properties and conditions of biotic and abiotic soil, including its structure, climatic conditions, seasons and soil organisms.

### **12.5. Results of PBT and vPvB assessment.**

The product does not meet the criteria for PBT or vPvB in accordance with the criteria in Annex XIII of Regulation 1907/2006.

# SAFETY DATA SHEET

## 12.6. Endocrine disrupting properties.

Product does not have endocrine disrupting properties.

## 12.7. Other adverse effects.

This product has no influence on the global warming or the ozone layer depletion. Consider other harmful effects of the individual components of the mixture on the environment (eg impact on the growth of global warming).

## Section 13: Disposal considerations

### 13.1. Waste treatment methods.

Disposal methods for the product: disposal in accordance with the local legislation. Store remainders in original containers. Do not dispose of the product in drains or open water systems or on soil. Submit to neutralization by a licensed waste processing company.

Disposal methods for used packing: reuse/recycling/liquidation of packaging and empty containers, dispose in accordance with the local legislation. Do not dispose empty packaging with regular household waste. Do not mix with other waste. Submit to neutralization by a licensed waste processing company.

Proper waste management of the mixture and / or container should be determined in accordance with the provisions of Directive 2008/98 / EC.

## Section 14: Transport Information

### 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

The mixture is not classified as dangerous for the environment.

### 14.6 Special precautions for user

Use protective measures according to section 8.

### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

## Section 15: Regulatory Information.

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

**Regulation (EC) No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

# SAFETY DATA SHEET

**Regulation (EC) No 1272/2008** of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

**COMMISSION REGULATION (EU) 2020/878** of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

## 15.2. Chemical safety assessment.

There is requirement for safety assessment for this mixture.

## Section 16: Other Information.

### a) revised safety data sheet- changes

First version.

### b) legend to abbreviations and acronyms used in the safety data sheet

TWA	Time Weighted Average
PEL	Permissible exposure limit
TLV-C	Threshold limit value- Ceiling Limit
STEL	Short-term exposure limit
PBT	Persistent, Bioaccumulative and Toxic substance
vPvB	very Persistent, very Bioaccumulative substance
CAS	Chemical Abstract Service
EC No.	is a unique seven-digit identifier that is assigned to chemical substances for regulatory purposes within the European Union by the regulatory authorities.
LD50	lethal dose, the point where 50% of test subjects exposed would die
LC50	lethal concentration, the point where 50% of test subjects exposed would die
EC50	half maximal effective concentration
UN number	is four-digit number that identify hazardous substances
ATEmix	Acute Toxicity Estimates for mixture
PEB	permitted exposure for a biological material

### c) list of relevant H phrases, hazard statements, safety phrases and/or precautionary statements- full text

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H411 Toxic to aquatic life with long lasting effects.

### d) trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training.

### e) other data

Classification was made on the basis of data on hazardous substances calculation method based on the guidelines of Regulation 1272/2008/EC (CLP).

The above information is prepared on the basis of current state of knowledge and relates to the product in the form in which it is used. Data relating to the product are presented in order to include safety requirements, and not to guarantee their particular properties.



# SAFETY DATA SHEET

In the event when conditions of application of the product are beyond control of the manufacturer, responsibility for safe use of the product is borne by the user.

The Employer is obligated to inform all employees who have contact with the product, about hazards and personal protection equipment specified in this material safety data sheet.

This material safety data sheet has been prepared on the basis of MSDS provided by the manufacturer and/or web databases and the binding regulations regarding hazardous substances and chemical agents.

The product is classified as hazardous. EXPOSURE SCENARIOS are not required.