

SECTION1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product code : TRICOVEL VIALS WITH PHYSIOGENINA

Trades code : F4060760

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

Cosmetic (anti-fallen hairline)

Sectors of use: Private households (= general public = consumers)[SU21], Professional use[SU22]

Uses advised against: Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

Giuliani S.p.A.

Via Palagi 2, 20129 Milano - Italy

www.giulianipharma.com

1.4. Emergency telephone number

Centro Antiveleni di Milano: +39 02 66101029 (CAV Ospedale Niguarda Cà Granda, Milano, Italy)

IPCS: http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/index.html

SECTION2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms:

GHS02, GHS07

Hazard Class and Category Code(s):

Flam. Liq. 3, Eye Irrit. 2

Hazard statement Code(s):

H226 - Flammable liquid and vapour.

H319 - Causes serious eye irritation.

The product is a liquid that ignites at temperatures above 21 °C if it exposed to an ignition source.

If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):

GHS02, GHS07 - Warning

Hazard statement Code(s):

H226 - Flammable liquid and vapour.

H319 - Causes serious eye irritation.

Supplemental Hazard statement Code(s):



not applicable

Precautionary statements:

General

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

P102 - Keep out of reach of children.

Prevention

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Response

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P370+P378 - In case of fire: Use CO2 or foam to extinguish.

Disposal

P501 - Dispose of contents/container in accordance with local/regional/national/international regulation.

Content of VOC ready to use condition: 17,73 %

2.3. Other hazards

The substance / mixture NOT contains substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII
No information on other hazards

SECTION3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration	Classification	Identificativi
ETHYL ALCOHOL	> 10 <= 20%	Flam. Liq. 2, H225; Eye Irrit. 2, H319	CE 603-002-00-5 CAS 64-17-5 EINECS 200-578-6 REACH 01-2119457610-43
PROPAN-2-OL	> 1 <= 5%	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	CE 603-117-00-0 CAS 67-63-0 EINECS 200-661-7 REACH 01-2119457558-25

SECTION4. First aid measures

4.1. Description of first aid measures

Inhalation:

Air the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area.
If you feel unwell seek medical advice.

Direct contact with skin (of the pure product):.

Take contaminated clothing Immediately off.

Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately

Ingestion:

Rinse mouth with water of the subject. Consult a physician.

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

No data available.

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

If eye irritation persists: Get medical advice/attention.

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

SECTION5. Firefighting measures

5.1. Extinguishing media

Advised extinguishing agents:

In the case of fire use: water spray or CO₂.

Extinguishing means to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective suit.

The spray water can be used to protect the people involved in the extinction

You may also use selfrespirator, especially when working in confined and poorly ventilated area and if you use halogenated extinguishers (Halon 1211 fluobrene, Solkan 123, NAF, etc...)

Keep containers cool with water spray

SECTION6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Wear mask, gloves and protective clothing.

6.1.2 For emergency responders:

Wear mask, gloves and protective clothing.

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provision of sufficient ventilation.

Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand.

If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify it to the authorities.

Discharge the remains in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 For containment:

Rapidly recover the product, wear a mask and protective clothing

Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material.

Prevent it from entering the sewer system.

6.3.2 For cleaning up:

After wiping up, wash the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage**7.1. Precautions for safe handling**

Avoid contact and inhalation of vapors

Do not smoke at work

At work do not eat or drink.

Wear protective gloves/protective clothing/eye protection/face protection.

See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers.

Keep containers upright and safe by avoiding the possibility of falls or collisions.

Keep away from open flames, sparks and heat sources. Avoid direct sunlight exposure.

7.3. Specific end use(s)

Private households (= general public = consumers):

Handle in a well ventilated area.

Professional use:

Follow the rules of good hygiene in the workplace.

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Related to contained substances:

ETHYL ALCOHOL:

TLV-TWA: 1000 ppm A4 (not classifiable as a human carcinogen); (ACGIH 2004).

TWA: 1920mg/m³, 1000ppm (WEL, GBR)
TWA: 1900mg/m³, 1000ppm (VLEP, FRA)
STEL: 9500mg/m³, 5000ppm (VLEP, FRA)
STEL: 1910mg/m³, 1000ppm (VLA, ESP)
TWA: 260mg/m³ (OEL; NLD, skin)
STEL: 1900mg/m³ (OEL; NLD, skin)
TWA: 1900mg/m³ (NDS, POL)
MAK: 960 ppm 500 mg/m peak limitation Category: II (2); Cancerogenicity class: 5; Risk group for pregnancy: C; Group mutagen to germ cells: 5; (DFG 2004).

PROPAN-2-OL:

TLV-TWA: 200 ppm (ACGIH 2004).
OEL-TWA=400ppm (IRL)
TLV-STEL: 400ppm (not classifiable as a human carcinogen); (ACGIH 2004).
OEL-STEL=500ppm (IRL)
MAK: 200 ppm 500 mg/m peak limitation Category: II (2); Risk group for pregnancy: C; (DFG 2004).

- Substance: ETHYL ALCOHOL

DNEL

Systemic effects Long term Workers inhalation = 950 (mg/m³)
Systemic effects Long term Workers dermal = 343 (mg/kg bw/day)
Systemic effects Long term Consumers inhalation = 114 (mg/m³)
Systemic effects Long term Consumers dermal = 206 (mg/kg bw/day)
Systemic effects Long term Consumers oral = 87 (mg/kg bw/day)
Local effects Short term Workers inhalation = 1900 (mg/m³)
Local effects Short term Consumers inhalation = 950 (mg/m³)
PNEC
Sweet water = 0,96 (mg/l)
sediment Sweet water = 3,6 (mg/kg/sediment)
Sea water = 0,79 (mg/l)
sediment Sea water = 2,9 (mg/kg/sediment)
intermittent emissions = 2,75 (mg/l)
STP = 580 (mg/l)
ground = 0,63 (mg/kg ground)

- Substance: PROPAN-2-OL

DNEL

Systemic effects Long term Workers inhalation = 500 (mg/m³)
Systemic effects Long term Workers dermal = 888 (mg/kg bw/day)
Systemic effects Long term Consumers inhalation = 89 (mg/m³)
Systemic effects Long term Consumers dermal = 319 (mg/kg bw/day)
Systemic effects Long term Consumers oral = 26 (mg/kg bw/day)
PNEC
Sweet water = 140,9 (mg/l)
sediment Sweet water = 552 (mg/kg/sediment)
Sea water = 140,9 (mg/l)
sediment Sea water = 552 (mg/kg/sediment)
intermittent emissions = 140,9 (mg/l)
STP = 2251 (mg/l)
ground = 28 (mg/kg ground)

8.2. Exposure controls

Appropriate engineering controls:
Observe the safety measures used in handling chemicals.



Individual protection measures:

- a) Eye / face protection: When handling the pure product use safety glasses (spectacles cage) (EN 166).
- b) Skin protection
 - i) Hand protection: When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)
 - ii) Other: Wear normal work clothing.
- c) Respiratory protection: Not needed for normal use.
- d) Thermal hazards: No hazard to report

Environmental exposure controls: Use according to good working practices to avoid pollution into the environment.

SECTION9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical and chemical properties	Value
Appearance	Liquid
Odour	Characteristic
Odour threshold	Undefined
pH	6
Melting point/freezing point	Undefined
Initial boiling point and boiling range	85°C
Flash point	39-40°C
Evaporation rate	Undefined
Flammability (solid, gas)	Undefined
Upper/lower flammability or explosive limits	Undefined
Vapour pressure	Undefined
Vapour density	Undefined
Relative density	0,98g/mL
Solubility	Undefined
Water solubility	Water soluble
Partition coefficient: n-octanol/water	Undefined
Auto-ignition temperature	Undefined
Decomposition temperature	Undefined
Viscosity	Undefined
Explosive properties	Undefined
Oxidising properties	Undefined

9.2. Other information

Content of VOC ready to use condition: 17,73 %

SECTION10. Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

Avoid contact with combustible materials. The product could catch fire. heat, open flames, sparks or hot surfaces.

10.5. Incompatible materials

It can generate inflammable gases to contact with elementary metals, nitrides, inorganic sulfide, strong reducing agents.

It can generate toxic gases to contact with inorganic sulfide, strong reducing agents.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11. Toxicological information**11.1. Information on toxicological effects**

ATE(mix) oral = ∞

ATE(mix) dermal = ∞

ATE(mix) inhal = ∞

(a) acute toxicity: ETHYL ALCOHOL: The substance irritates the eyes. Inhalation of high vapour concentrations may cause irritation of the eyes and respiratory tract. The substance may cause effects on the central nervous system.

Acute hazards/symptoms:

Inhalation: Cough. Headaches. Fatigue. Drowsiness.

SKIN: dry scalp.

Eye Redness. Pain. Burning.

Ingestion: burning sensation. Headaches. Confusion. Vertigo. Unconsciousness.

PROPAN-2-OL: Acute hazards/symptoms;

Inhalation: Cough. Vertigo. Drowsiness. Headaches. Sore throat. See If Swallowed.

Skin: dry scalp.

Eye Redness.

Ingestion: abdominal pain. Difficulty in breathing. Nausea. Unconsciousness. Vomiting.

(b) skin corrosion/irritation based on available data, the classification criteria are not met.

(c) serious eye damage/irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.

ETHYL ALCOHOL: Irritating

(d) respiratory or skin sensitization: based on available data, the classification criteria are not met.

(e) germ cell mutagenicity: based on available data, the classification criteria are not met.

(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) specific target organ toxicity (STOT) single exposure: PROPAN-2-OL: The substance irritates the eyes and respiratory tract.

The substance may cause effects on the central nervous system, causing depression.

Much greater exposure to the OEL may lead to unconsciousness.

(i) specific target organ toxicity (STOT) repeated exposure: ETHYL ALCOHOL: The liquid degreasing the skin features. The substance may have an effect on the high central nervous system respiratory tract, causing irritation, headaches, fatigue and lack of concentration.

PROPAN-2-OL: The liquid degreasing the skin features.

(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:

ETHYL ALCOHOL:

ROUTES of EXPOSURE: the substance can be absorbed into the body by inhalation of its fumes and ingestion.

INHALATION RISK: A harmful contamination of the air will be reached quite slowly due to evaporation of the substance at 20°C.

NOTE. The consumption of ethanol during pregnancy can have adverse effects on the unborn child. Chronic ethanol ingestion can cause cirrhosis of the liver.

LD50 (rat) Oral (mg/kg body weight) = 14000

LD50 Dermal (rat or rabbit) (mg/kg body weight) = 20000

CL50 Inhalation (rat) vapour/dust/mist/fume (mg/l/4h) or gas (ppmV/4h) = 20000

PROPAN-2-OL:

The substance can be absorbed into the body by inhalation of its fumes.

A harmful contamination of the air will be reached quite slowly due to evaporation of the substance at 20°C; However, for spraying or scattering, much more quickly.

The use of alcoholic beverages enhances the harmful effect.

LD50 (rat) Oral (mg/kg body weight) = 4710

LD50 Dermal (rat or rabbit) (mg/kg body weight) = 12800

CL50 Inhalation (rat) vapour/dust/mist/fume (mg/l/4h) or gas (ppmV/4h) = 72,6

SECTION12. Ecological information

12.1. Toxicity

Related to contained substances:

ETHYL ALCOHOL:

Practically non-toxic to aquatic organisms.

CE50=275mg/L (algae, *Chlorella vulgaris*, 72h)

CE50=12,34mg/L (invertebrates, *daphnia magna*, 48h)

EC50=13g/L (fish, *salmo gairdneri*, 96h)

NOEC (mg/l) = 9,6

PROPAN-2-OL:

C(E)L50 (mg/l) = 7060

Use according to good working practices to avoid pollution into the environment.

12.2. Persistence and degradability

Related to contained substances:

ETHYL ALCOHOL:

This product is readily biodegradable.

PROPAN-2-OL:

Dispersed by evaporation within a day.

The product is lighter than water and is completely miscible at 20°C.

12.3. Bioaccumulative potential

Related to contained substances:

ETHYL ALCOHOL:

There is no evidence of bioaccumulation of this product at attraverso the food chain.

Log Pow =-0.35

PROPAN-2-OL:

Low bioaccumulation potential.

12.4. Mobility in soil

Related to contained substances:

ETHYL ALCOHOL:

This product quickly evaporates in the air due to the high vapour pressure. The product is poorly absorbed by soils and sediments.

PROPAN-2-OL:

High mobility on the ground. Volatilization from moist surfaces. Not adsorb to sediment and suspended solids. In the atmosphere exists in the vapor phase.

Large volumes may penetrate soil and contaminate groundwater.

12.5. Results of PBT and vPvB assessment

The substance / mixture NOT contains substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

12.6. Other adverse effects

No adverse effects

SECTION13. Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.

Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to local and National rules in force

SECTION14. Transport information

14.1. UN number

ADR/RID/IMDG/ICAO-IATA: 1266

If subject to the following characteristics is ADR exempt:

Combination packagings: per inner packaging 5 L per package 30 Kg

Inner packagings placed in shrink-wrapped or stretch-wrapped trays: per inner packaging 5 L per package 20 Kg



14.2. UN proper shipping name

ADR/RID/IMDG: PERFUMERY PRODUCTS with flammable solvents
ICAO-IATA: PERFUMERY PRODUCTS with flammable solvents

14.3. Transport hazard class(es)

ADR/RID/IMDG/ICAO-IATA: Class : 3
ADR/RID/IMDG/ICAO-IATA: Label : 3
ADR: Tunnel restriction code : D/E
ADR/RID/IMDG/ICAO-IATA: Limited quantities : 5 L
IMDG - EmS : F-E, S-D

14.4. Packing group

ADR/RID/IMDG/ICAO-IATA: III

14.5. Environmental hazards

ADR/RID/ICAO-IATA: Product is not environmentally hazardous
IMDG: Marine polluting agent : Not

14.6. Special precautions for user

The goods must be transported by vehicles authorized to transport of dangerous goods according to the current edition of ADR requirements and applicable national regulations.
The goods must be in original packing, however, in packaging made of materials resistant to their content and not likely to generate with this dangerous reactions. People loading and unloading dangerous goods must be trained on the risks from these substances and that must be taken in case of emergency situations.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

It is not intended to carry bulk

SECTION15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Reg (EC) n. 1907/2006 (REACH), Reg (EC) n. 1272/2008 (CLP), Reg (EC) n. 830/2015 (Requirements for the compilation of safety data sheets), Reg (E) n.790/2009, Dir 96/82/EC as amended.

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION16. Other information**16.1. Other information**

Description of the hazard statements exposed to point 3
H225 = Highly flammable liquid and vapour.
H319 = Causes serious eye irritation.

H336 = May cause drowsiness or dizziness.

Classification based on data of all mixture components

Regulatory information:

Reg 1907/2006 EC

Reg 1272/2008 EC

Reg 830/2015 EC

NOTICE TO USERS

The information contained in this sheet are based on the knowledge available at the date of the preparation of this sheet.

The user must be aware of the possible risks associated with the use of the product, other than that for which the product is supplied. The sheet does not exonerate the user from knowing and applying all the regulations governing its activities. The set of regulations mentioned is simply to help the user to fulfill its obligations regarding the use of hazardous products.

This sheet does not exonerate the user from other legal obligations than those mentioned and from rules regulating possession and use of the product, since the user is the only responsible.

*** This sheet supersedes all previous editions.
