

Reference: Regulation (EC) 1907/2006 878/2020	MATERIAL SAFETY DATA SHEET (MSDS) Product: Gel Derm	Version 15 Date last revision: 12.12.22 SHEET 1 of 10
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1. SECTION 1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND OF THE COMPANY:

1.1. Product identifier: Gel Derm

1.2. Relevant identified uses of the substance or mixture and uses advised against Use of the substance: Hidro-alcoholic solution for hand disinfection.

Spanish Ministry of Health register:

Register num. DGFyPS: 729-DES

1.3. Details of the supplier of the safety data sheet

Manufacturer: Vesimin S.L.U. C/Aribau 230-240, 6th floor, L-O - 08006 Barcelona (Spain) vesimin@vesimin.com

Telephone number: +34 934 095 301

Fax: +34 933 396 628

e-mail: vesimin@vesimin.com

1.4. Emergency number: +34 934 095 301 (working hours)

2. SECTION 2. HAZARD IDENTIFICATION:

2.1. Classification of the substance or mixture

Classification according to EC Regulation num. 1272/2008 [CLP]

LIQUID FLAMMABLE. Category 2 (H225)

EYE IRRITATION. Category 2 (H319)

2.2. Label elements: according to EC Regulation num. 1272/2008 [CLP]

Hazard pictograms:



Signal word: DANGER

Hazard statements:

- Highly flammable liquid and vapour (H225)
- Causes serious eye irritation (H319)

Precautionary Statements

- Keep away from heat/sparks/open flames/hot surfaces. — No smoking. (P210)
- Keep container tightly closed (P233)
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305 + P351 + P338)
- If eye irritation persists: Get medical advice/attention. (P337+P313)
- Store in a well-ventilated place. Keep cool. (P403+P235)
- Dispose of contents and container in accordance with local regulations (P501)

2.3. Other hazards

Flammable (contains ethyl and isopropyl alcohol). Wait until total evaporation.

No significant environmental or health risks if used under standard conditions of commercial and industrial use.

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PBT: This product is not identified as PBT/vPvB

This mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal or greater than 0,1%.

3. SECTION 3. COMPONENT COMPOSITION / INFORMATION

3.2. Substance/Mixture: Mixture

Dangerous components:

Ingredient	N° CAS / N° Registro REACH	Classification* 1272/2008	Concentration
Ethyl alcohol	64-17-5 / 01- 2119457610- 43-xxxx	Flam. liq. 2: H225	60% (v/v)
Isopropyl alcohol	67-63-0	Flam. liq 2: H225 Eye Irrit.2: H319 STOT SE 3: H336	15% (v/v)
Excipients (panthenol, glicerín, perfum) and water		-	qsf 100 %

* Complete text of Hazard statements indicated in this Section are explained in Section 16.

4. SECTION 4. FIRST AID MEASURES:

4.1. Description of first aid measures

First aid measures:

Swallowing: (*) Rinse mouth with water and require immediately medical assistance. If the patient is conscious, give him water.

Inhalation (ethanol): Transfer the victim to a non contaminated atmosphere. In case of breathing interruption, apply artificial respiration. Maintain the victim in repose and seek for medical advice.

Eye contact: Wash with plenty of water for at least for 15 minutes. If irritation persists, consult an ophthalmologist.

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

Effects and symptoms: No specific effects and/or symptoms are known. Hazards derived from ethanol and isopropyl alcohol: headaches, vertigo, narcosis, drowsiness. The swallowing can cause inebriation, coma. Skin, eye and respiratory tract irritation.

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

See section 4.1.

5. SECTION 5. FIRE-FIGHTING MEASURES

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5.1. Extinguishing media

Suitable extinguishing media: Foam, dry chemical powder, CO₂, sand and water spray fog.

5.2. Special hazards arising from the substance or mixture

Special hazards of fire/explosion: Extremely flammable product with heat, sparks, static electricity or flammes. Vapor/air mixtures are explosive.

Special measures: Cool the bottles pulverizing water to them if they are exposed to fire. Do not use a jet of water. Keep away from sources of ignition – Do not smoke.

5.3. Advice for firefighters

Special protective equipment for fire-fighters: Fire-fighters must be provided with adequate protective equipment.

6. SECTION 6. ACCIDENTAL RELEASE MEASURES:

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Take common precautions. Extinguish the flames. Eliminate ignition sources. Do not smoke. Avoid sparks.

6.2. Environmental precautions

Environmental precautions: Avoid pouring the product into the public drainage. If the product reaches a river course or a sewer, or it has contaminated the soil or vegetation, warn the Authorities. Collect it in plastic containers and eliminate it in appropriate places.

6.3. Methods and material for containment and cleaning up

Cleaning measures: Do not release product into drainpipes or in the environment. Eliminate the spilled product with materials that act as absorbents (sawdust, peat, or chemical chelating agents). Place the collected product in containers that can be closed. Clean floor and all objects with this material using a damp cloth. Collect the cleaning materials and put them inside containers that can be closed.

6.4. Reference to other sections

Refer to sections 8, 12 and 13 of SDS.

7. SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handling: Take measures to avoid splashing in the eyes and on skin.

7.2. Conditions for safe storage, including any incompatibilities Storage: Store in high density polyethylene containers or PET. Store at room temperature and avoid extreme temperatures and direct contact with sunlight. Store only in the original containers.

7.3. Specific end use(s)

Antiseptic for healthy skin. For professional use only.

8. SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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8.1. Control parameters

Threshold Limit Value (TLV) of Isopropyl alcohol: The ACGIH recommends a TWA of 400 ppm (980 mg/m³) and a STEL of 500 ppm (1225 mg/m³).

Threshold Limit Value (TLV) of Ethyl alcohol: The ACGIH recommends a TWA of 1000 ppm (1880 mg/m³).

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006 (workers):

Identification		Short exposure		Long exposure	
		Sistemic	Local	Sistemic	Local
Ethanol	Oral	Non relevant	Non relevant	Non relevant	Non relevant
	Cutaneous	Non relevant	Non relevant	343 mg/kg pc/dia	Non relevant
	Inhalation	Non relevant	1900 mg/m ³	950 mg/m ³	Non relevant

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006 (population):

Identification		Short exposure		Long exposure	
		Sistémica	Local	Sistemic	Local
Ethanol	Oral	Non relevant	Non relevant	87 mg/kg pc/dia	Non relevant
	Cutaneous	Non relevant	Non relevant	206 mg/kg pc/dia	Non relevant
	Inhalation	Non relevant	950 mg/m ³	114 mg/m ³	Non relevant

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Identification				
Ethanol	STP	580 mg/l	Sweet water	0.96 mg/l
	Soil	0.63 mg/kg d.w.	Salted water	0.79 mg/l
	Intermittent	2.75 mg/l	Sediment (Sweet water)	3.6 mg/kg d.w.
	Oral	380 mg/kg	Sediment (Salted water)	2.9 mg/kg d.w.

8.2. Exposure controls

Hygienic measures: Do not eat, drink or smoke during use.

Exposure control: Avoid spilling, contact with eyes and ingestion.

Equipment to provide adequate personal protection: Non specific protection equipment is required.

9. SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect (physical state, color): Transparent liquid gel

Odour: Characteristic (alcohol)

Melting point / freezing point: Not available

Boiling point : Not available

Flammability: Flammable

Upper and lower explosive limit: Not available

Auto-ignition temperature: Closed flash point: 11°C

Decomposition temperature: Not available

pH (100% in water): 5.5 – 7.5 (20 °C)

Viscosity: Not available

Water solubility: 100% soluble

Partition coefficient n-octanol/water (Log Know): Not available

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Vapour pressure: Not available
Density: 0,80 – 1,00 g/cc (20°C)
Relative density: Not available
Relative vapour density at 20°C: Not available
Particle characteristics: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Data for Ethyl Alcohol

Flash Point: 13 °C

Relative density of vapour: 1.59

Octanol-water partition coefficient: $\log P_{ow} = 0.32$

Data for Isopropyl Alcohol

Flash Point: 12 °C

Relative density of vapour: > 1.0

10. SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Ethyl alcohol. Reacts with strong oxidizers, nitric acid, perchlorates, peroxydes and in general with all unstable organic components. Reacts with alcalin metals, liberating hydrogen in a violent reaction.

10.2. Chemical stability

Product is stable in recommended conditions of handling and storage.

Isopropyl alcohol. Reacts with strong oxidizers.

10.3 Possibility of hazardous reactions

It does not present.

10.4. Conditions to avoid

Non applicable

10.5. Incompatible materials

Non applicable

10.6. Hazardous decomposition products

Non applicable.

11. SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:

Oral route: Not harmful by oral ingestion. DL_{50} (oral route) > 2000 mg/kg

Inhalation route:

Isopropyl alcohol: The ACGIH recommends a TLV-TWA of 400 ppm (980 mg/m³) and a STEL of 500 ppm (1225 mg/m³).

Ethyl alcohol: The ACGIH recommends a TWA of 1000 ppm (1880 mg/m³).

These values are not exceeded during the use of the product, according to the expected use of the product.

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Through skin and/or eyes:

- *Skin irritation: It is not irritating.
- *Eye irritation: It is irritating to the eyes.
- *Skin sensitisation: It does not cause hypersensitisation.

Substance data

Etanol	
LD50 (rat), oral	10470 mg/kg
LD50 (rabbit), cutaneous	> 2000 mg/kg
LC50 (rat), inhalation	51 mg/l
Eye irritation	Causes serious eye irritation (rabbit)
Skin irritation	Non irritating for the skin (rabbit)
Sensibilisation	Non sensibilising (guinea pig – maximisation test, rat, inhalation – rat)
Toxicity specific for organs	Unique exposition: not classified Repeated exposition: not classified

Isopropanol	
LD50 (rat), oral	5000 mg/kg
LD50 (rabbit), dermal	12.800 mg/kg
LC50 (rat), inhalation	500 mg/lg
Eye irritation	Irritating
Dermal irritation	Slightly irritating
Mutagenicity	Mutagenicity in germinal cells Genotoxicity in vitro: Negative
Carcinogenicity	Non carcinogenic
Toxicity for reproduction	Not known

Corrosiveness: Not corrosive.

Carcinogenicity: Not carcinogenic

Mutagenicity: Not mutagenic

Toxicity for reproduction: Not toxic for reproduction

11.2. Information on other hazards

11.2.1. Properties on endocrine alteration

No additional information available.

12. SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity:

In order to avoid human and environmental risks, follow the instructions for use.

Substance data

Etanol	
CL50, 96h (Pimephales promelas)	15.300 mg/l
CL50, 24h (Salmo gairdneri)	11.200 mg/l
CL50, 96h (Oncorhynchus mykiss)	13.000 mg/l
CE50, 24h (Artemia salina)	858 mg/l
CE50, 48h (Daphnia magna)	12.340 mg/l
CL50, 48h (Ceriodaphnia dubia)	5.012 mg/l
CE50, 72h (Chlorella vulgaris)	275 mg/l
EC10, 72h (Chlorella vulgaris)	11,5 mg/l
CE50, 4h (Paramecium caudatum)	5800 mg/l

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Persistence	Non significant hydrolysis
Biodegradability	Easily biodegradable
Bioaccumulation	Log Pow -0,35 FBC: 0,66 Should not bioaccumulate
Mobility	This substance has mobility in the aquatic environment
Valoration PBT and mPmB	It is not considered persistent, bioaccumulative nor toxic. It is not considered to be very persistent nor very bioaccumulative.
Biochemical/chemical oxygen demand	DBO: 100 mg/g DQO: 1900 mg/g

Isopropanol	
EC50/LC50, 48h (Daphnia magna)	> 100 mg/l
EC50, 72h (Scenedesmus subspicatus)	> 100 mg/l

12.2. Persistence and degradability

The product has powerful bactericide, virucide and fungicide action, hence it could affect the EDAR microbial flora.

12.3. Bioaccumulative potential

Not available.

Isopropyl alcohol: Octanol-water partition coefficient (log Kow): ≤ 4

Ethyl alcohol: Octanol-water partition coefficient (log Kow): 0,35

12.4. Movility in soil

Not available

12.5. Results of PBT and vPvB assessment

This product is not identified as a PBT/vPvB substance

12.6. Endocrine disrupting properties

No further information available. This substance does not have endocrine disrupting properties on non-target organisms, as it does not meet the criteria established in section B of Regulation (EU) No. 2017/2100.

12.7. Other adverse effects

Not applicable

Isopropyl alcohol

- *Mobility:*
 - The product is soluble in water and it will probably remain in water.
- *Persistence and degradability:*
 - Easily biodegradable, according to OECD standards.
 - Easily eliminated in a sewage treatment.
- *Bioaccumulation:*
 - A low acute toxicity is predicted for aquatic organisms.
 - No long-term effects are predicted for aquatic organisms.

Ethyl alcohol

- *Mobility:*

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- The product is volatile/gaseous and it easily goes into the air. The product dissolves quickly in water. The product is not well absorbed in soils or sediments.
- *Persistence and degradability:*
 - The product is easily biodegradable. DBO5=37-74% of DTO. DBO20=75-84% of DTO.
- *Bioacumulación:*
 - The product does not bioaccumulate.
 - LC₅₀-48h > 8000 mg/l in Fish.
 - LC₅₀-48h > 9000 mg/l in Rats.
 - Limit toxicity concentration in seaweed (test of inhibition of citomultiplication) = 5000 mg/l.
 - Bacterial inhibition test have shown that the product does not inhibit the biomass.

13. SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

It is recommended to package product surplus or waste resulting from normal use. Label it for identification purposes and seal it. Dirty, empty recipients should be handled in the same manner. The product may be taken to a controlled incineration site, always according to local regulations.

14. SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number:

1993

14.2. UN proper shipping name

Flammable liquid, n.e.p. (contains isopropanol and ethanol)

14.3. Transport hazard class(es)

Class 3

14.4. Packaging group

Group II

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

ADR Classification:

- ONU number: 1993
- Class: 3
- Classification code: F1
- Packaging group: II
- Label: 3 (Flammable)
- Risk:30

MDG Classification:

- Class: 3
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Air (IATA/ICAO):

ONU 1993 – Flammable liquid n.e.p.

Label: Flammable liquid

Class 3

Special provisions A3

Packaging group II

Passenger aircraft (PAX)

Packaging instructions Y341 max. quantity 1 L (if LQ)

Packaging instructions 353 max quantity 5L

Cargo aircraft (CAO): Packaging instructions 364 Max. net quantity 60L

15. SECTION 15. REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

The information for safety and health with respect to the label of this product is in accordance with the European Union regulation: n° 1907/2006, 453/2010, 830/2015 and 878/2020.

European legislation: Regulation (EC) n° 1272/2008

15.2. Chemical safety assessment: not required

16. SECTION 16. OTHER INFORMATION

Other information: The text in the SDS which has changed since the last version.

Complete text of hazard statements as referred to in sections 2 and 3:

H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness

Formation advice:

The product must be handled by specialized personnel, following manufacturer instructions.

Changes from last version refer to format and content of EC Regulation 453/2010.

Calculation method determination according to Regulation (EC) 1272/2008 has been used for the classification of the mixture.

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