

**PROTON VASELINE MEDICAL GRADE VASELINE
SD-58**

SECTION 1: IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE COMPANY OR FIRM

- 1.1 Product identifier:** PROTON VASELINE MEDICAL GRADE
VASELINE SD-58
- Other means of identification:**
Not relevant
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Raw material for cosmetic, pharmaceutical and food industries. Exclusive use for professional user/industrial user.
Uses not recommended: Any use not specified in this section or in section 7.3.
- Safety Data Sheet supplier data:**
- 1.3 TATTOO PROTON SL**
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EUROPE@TATTOOPROTON.COM
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- 1.4**

SECTION 2: HAZARD IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Regulation 1272/2008 (CLP):
According to Regulation 1272/2008 (CLP), the product is not classified as hazardous.
- 2.2 Label elements: Regulation No.**
1272/2008 (CLP):
None
- 2.3 Other hazards:**
The product does not meet PBT/vPvB criteria.
The product does not meet the criteria for endocrine disrupting properties.

SECTION 3: COMPOSITION/INFORMATION ON COMPONENTS

- 3.1 Substance:**
Not applicable
- 3.2 Blends:**
Chemical description: Mixture of white oils, waxes and kerosene waxes.
Components:
None of the substances in the mixture exceeds the values set out in Annex II of Regulation (EC) No 1907/2006.

SECTION 4: FIRST AID

- 4.1 Description of first aid:**
Seek medical advice if you feel unwell with this Safety Data Sheet.
- By inhalation:**
In case of symptoms, move the affected person to air.
- By contact:**
In case of contact it is recommended to clean the affected area with water and neutral soap. In case of skin alterations (itching, redness, rashes, blisters...), seek medical advice with this Safety Data Sheet.
- By eye contact:**
Rinse with water until the product is eliminated. In case of discomfort, seek medical advice with the SDS of this product.
- By ingestion/aspiration:**

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SECTION 4: FIRST AID (continued)

In case of ingestion of large , it is recommended to seek medical assistance.

4.2 Main symptoms and effects, acute and delayed:

Acute and delayed effects are as indicated in sections 2 and 11.

4.3 Indication of any medical attention and special treatment to be given immediately:

Not relevant

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Preferably use multi-purpose powder extinguishers (ABC powder), alternatively use physical foam or carbon dioxide extinguishers (CO₂), according to the Fire Protection Installations Regulation (R.D. 513/2017 and subsequent) modifications).

Unsuitable extinguishing media:

It is NOT RECOMMENDED to use water jet as an extinguishing agent.

5.2 Specific hazards arising from the substance or mixture:

Due to its flammability characteristics, the product does not present a fire hazard under normal conditions of storage, handling and use.

5.3 Recommendations for personnel:

Depending on the magnitude of the fire, it may be necessary to wear full protective clothing and self-contained breathing apparatus. To a minimum of emergency facilities or action elements (fire blankets, portable first aid kit,...) according to R.D.486/1997 and later modifications.

Additional provisions:

Act in accordance with the Indoor Emergency Plan and the Information Sheets on action to be taken in case of accidents and other emergencies. Suppress any source of ignition. In case of fire, cool containers and storage tanks of products susceptible to ignition, explosion or BLEVE due to high temperatures. Avoid spilling the products used to extinguish the fire into the aquatic environment.

SECTION 6: MEASURES IN CASE OF ACCIDENTAL SPILLAGE

6.1 Personal precautions, protective equipment and emergency procedures: For non-emergency services personnel:

Isolate leaks as long as it does not pose a risk to the people performing this function.

For emergency personnel:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 precautions:

Product not classified as hazardous to the environment. Keep the product away from drains and surface and ground water.

6.3 Methods and material for containment and cleaning:

Recommended:

Sweep up and collect the product with shovels or other means and place it in a container for reuse (preferably) or disposal.

6.4 References to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A. - General precautions

Comply with current legislation on occupational risk prevention in terms of manual handling of loads. Maintain order, cleanliness and disposal by safe methods (section 6).

B. - Technical recommendations for fire and explosion prevention.

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SECTION 7: HANDLING AND STORAGE (continued)

It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that could affect flammable products. See section 10 for conditions and materials to be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks.

Do not eat, drink or smoke in work areas; wash hands after each use, and remove contaminated clothing and protective equipment before entering eating areas.

D.- Technical recommendations to prevent environmental risks

No special measures are necessary to prevent environmental hazards. For further information see section 6.2.

7.2 Conditions for safe storage, including possible incompatibilities:

A. - Technical storage measures

ITC (R.D.656/2017): Not relevant

Classification: Not Relevant

Minimum temperature: 5 °C

Maximum temperature: 30 °C

B. - General storage conditions.

Avoid sources of heat, radiation, static electricity and contact with foodstuffs. For additional information see section 10.5.

7.3 Specific end uses:

Except for the indications already specified, no special recommendations regarding the use of this product are necessary.

SECTION 8: EXPOSURE CONTROLS/INDIVIDUAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limit values must be monitored in the environment: INSST 2022:

Identification	Environmental limit values		
Kerosene waxes and hydrocarbon waxes	VLA-ED		2 mg/m ³
Particulates not specified: Inhalable fraction VLA-ED= 10 mg/m ³ // Respirable fraction VLA-ED= 5 mg/m ³	VLA-EC		

DNEL (Workers):

Not relevant

DNEL (Population):

Not relevant

PNEC:

Not relevant

8.2 Exposure controls:

A. - Individual protection measures, such as personal protective equipment

As a preventive measure, the use of basic personal protective equipment is recommended, with the corresponding CE marking in accordance with R.D.1407/1992 and subsequent modifications. For more information on personal protective equipment (storage, use, cleaning, maintenance, protection class,...) consult the information leaflet provided by the PPE manufacturer. The indications contained in this point refer to the pure product. The protection measures for diluted product may vary depending on the degree of dilution, use, method of application, etc. To determine the obligation to install emergency showers and/or eye showers in the storage facilities, the applicable regulations for the storage of chemical products should be taken into account. For more information see sections 7.1 and 7.2.

All the information included here is a recommendation and needs to be specified by the occupational risk prevention services as it is not known what additional prevention measures the company may have in place or if they have been included in the relevant risk assessment.

B. - Respiratory protection.

The use of protective equipment will be necessary in the case of mist formation or in the case of exceeding the occupational exposure limits if they exist (See Section 8.1).

C. - Specific hand protection.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	EPI	Marking	CEN Standards	Remarks
 Mandatory hand	Protective gloves against minor hazards			Replace gloves at any sign of deterioration. For prolonged periods of exposure to the product for professional/industrial users it is recommended to use CE III gloves, according to EN 420:2004+A1:2010 and EN ISO 374-1:2016+A1:2018.

Since the product is a mixture of different materials, the strength of the glove material cannot be calculated in advance. with total reliability and therefore has to be checked prior to application.

D.- Eye and face protection

Pictogram	EPI	Marking	CEN Standards	Remarks
 Mandatory protection of the face	Panoramic goggles against splashes and/or projections		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to manufacturer's instructions. Recommended for use in case of risk of splashing.

E.- Body protection

Pictogram	EPI	Marking	CEN Standards	Remarks
	Work clothes			Replace at any sign of deterioration. For prolonged periods of exposure to the product for professional/industrial users, CE III is recommended, according to EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Slip-resistant work shoes		EN ISO 20347:2012	Replace at any sign of deterioration. For prolonged periods of exposure to the product for professional/industrial users, CE III is recommended, according to EN ISO 20345:2012 and EN 13832-1:2007.

F.- Complementary emergency measures

No additional emergency measures are required.

Environmental exposure controls:

Under EU environmental protection legislation it is recommended to avoid discharge of both the product and its container into the environment. For additional information see section 7.1.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see product data sheet/specification sheet.

Physical appearance:

Physical state at 20:	Semi-solid
Appearance:	Pasty
Color:	Not determined
Odor:	Not determined
Olfactory threshold:	Not relevant *

Volatility:

Boiling temperature at atmospheric pressure:	Not relevant *
Vapor pressure at 20 °C:	Not relevant *
Vapor pressure at 50 °C:	Not relevant *
Evaporation rate at 20 °C:	Not relevant *
Product characterization:	Not relevant *
Density at 20 °C:	Not relevant *
Relative density at 20:	Not relevant *

*Not relevant due to the nature of the product, not providing characteristic information of its hazardousness.

Not relevant *

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Not relevant *

Not relevant *

Not relevant *

Not relevant *

Not relevant *

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Dynamic viscosity at 20:	Not relevant *
Kinematic viscosity at 20:	Not relevant *
Kinematic viscosity at 40:	>20.5 mm ² /s
Concentration:	Not relevant *
pH:	Not relevant *
Vapour density at 20:	Not relevant *
Partition coefficient n-octanol/water at 20 °C:	Not relevant *
Solubility in water at 20:	Not relevant *
Solubility property:	Not relevant *
Decomposition temperature:	Not relevant *
Melting point/freezing point:	Not relevant *

Flammability:

Flash point:	Not applicable
Flammability (solid, gas):	Not relevant *
Auto-ignition temperature:	Not relevant *
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *

Explosiveness (Solid):

Lower explosive limit:	Not relevant *
Upper explosive limit:	Not relevant *

Particle characteristics:

Equivalent mean diameter:	Not relevant *
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9.2 Other data:

Information regarding physical hazard classes:

Explosive properties:	Not relevant *
Oxidizing properties:	Not relevant *
Corrosive to metals:	Not relevant * Not relevant * Not relevant * Not relevant * Not relevant * Not relevant *
* Not relevant * Not relevant * Not relevant	
Heat of combustion:	Not relevant *
Aerosols-total percentage (by mass) of flammable components:	Not relevant * Not relevant * Not relevant * Not relevant * Not relevant * Not relevant * Not relevant * Not relevant *

Other security features:

Surface tension at 20 °C:	Not relevant *
Refractive index:	Not relevant *

*Not relevant due to the nature of the product, not providing characteristic information of its hazard class.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected if the technical instructions for chemical storage are followed. See section 7.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of dangerous reactions:

Under the conditions indicated, no dangerous reactions are expected that could result in excessive pressure or temperatures.

10.4 Conditions to be avoided:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Heating	Solar Light	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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SECTION 10: STABILITY AND REACTIVITY (continued)

10.5 Incompatible materials:

Acids	Water	Oxidizing substances	Fuel materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid strong alkalis or bases

10.6 Hazardous decomposition products:

See sections 10.3, 10.4 and 10.5 for specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemicals may be released as a result of decomposition: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Oral LD50 > 2000 mg/kg (rat).

Hazardous health effects:

In case of repeated, prolonged exposure or at concentrations above the occupational exposure limits, adverse health effects may occur depending on the route of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met. For further information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. For further information see section 3.

B- Inhalation (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met. For further information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. For further information see section 3.

C- Contact with skin and eyes (acute effect):

- contact: Based on available data, the classification criteria are not met. For further information see section 3.
- Eye contact: Based on available data, the classification criteria are not met. For further information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met. For further information see section 3. IARC: White mineral oil, >=20.5mm²/s (40°C) (3); Distillates (petroleum), solvent dewaxed heavy paraffinic fraction, < 3%. DMSO (3)
- Mutagenicity: Based on available data, the classification criteria are not met. For further information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met. For further information see section 3.

E- Sensitization effects:

- Respiratory: Based on available data, the classification criteria are not met. For further information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met. For further information see section 3.

F- Specific target organ toxicity (STOT)-single exposure:

Based on available data, the classification criteria are not met. For further information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met. For further information see section 3.
- Skin: Based on available data, the classification criteria are not met. For further information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met. For further information see section 3.

Additional information:

Not relevant

Substance-specific toxicological information:

Not determined

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

11.2 Information on other hazards:

Endocrine disrupting properties

The product does not meet the criteria for endocrine disrupting properties.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

No experimental data are available for the mixture itself concerning ecotoxicological properties.

12.1 Toxicity:

Not determined

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not determined

12.4 Mobility on the ground:

Not determined

12.5 Results of PBT and vPvBm assessment:

The product does not meet PBT/vPvB criteria.

12.6 Endocrine disrupting properties:

The product does not meet the criteria for endocrine disrupting properties.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Methods for waste treatment:

Code	Description	Type of waste (Regulation (EU) No. 1357/2014).
	It is not possible to assign a specific code, as it depends on the user's intended use.	Non-hazardous

Type of waste (Regulation (EU) No. 1357/2014):

Not relevant

Waste management (disposal and recovery):

Consult the authorized waste manager for recovery and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, Law 7/2022). According to the codes 15 01 (2014/955/EU) in case the packaging has been in direct contact with the product it will be managed in the same way as the product itself, otherwise it will be managed as non-hazardous waste. Discharge into is not recommended. See section 6.2.

Legislative provisions related to waste management:

Annex II of Regulation (EC) No 1907/2006 (REACH) lists the Community or State provisions related to waste management.

EU legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No. 1357/2014.

National legislation: Law 7/2022, of April 8, on waste and contaminated soils for a circular economy.

SECTION 14: TRANSPORT INFORMATION

Land transportation of dangerous goods:

In application to ADR 2021 and RID 2021:

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SECTION 14: TRANSPORTATION INFORMATION (continued)

14.1	UN number or ID number:	Not relevant
14.2	United Nations official transport designation:	Not relevant
14.3	Transport hazard class(es):	Not relevant
	Tags:	Not relevant
14.4	Packaging group:	Not relevant
14.5	hazards:	No
14.6	Special precautions for users	Special provisions:
		Not relevant
	Code of restriction in tunnels:	Not relevant
	Physico-chemical properties:	See section 9
	Limited quantities:	Not relevant
14.7	Bulk shipping under IMO instruments:	Not relevant

Maritime transport of dangerous goods:

In application to IMDG 40-20:

14.1	UN number or ID number:	Not relevant
14.2	United Nations official transport designation:	Not relevant
14.3	Transport hazard class(es):	Not relevant
	Tags:	Not relevant
14.4	Packaging group:	Not relevant
14.5	Marine pollutant:	No
14.6	Special precautions for users	Special provisions:
		Not relevant
	FEm codes:	
	Physicochemical properties:	See section 9
	Limited quantities:	Not relevant
	Segregation group:	Not relevant
14.7	Bulk shipping under IMO instruments:	Not relevant

Air transport of dangerous goods:

In application to IATA/ICAO 2022:

14.1	UN number or ID number:	Not relevant
14.2	United Nations official transport designation:	Not relevant
14.3	Transport hazard class(es):	Not relevant
	Tags:	Not relevant
14.4	Packaging group:	Not relevant
14.5	hazards:	No
14.6	Special precautions for users	
	Physical-chemical properties:	See section 9
14.7	Bulk shipping under IMO instruments:	Not relevant

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations and legislation specific to the substance or mixture:

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SECTION 15: REGULATORY INFORMATION (continued)

Candidate substances for authorization in Regulation (EC) 1907/2006 (REACH): Not relevant Substances

included in Annex XIV of REACH (authorization list) and expiration date: Not relevant Regulation (EC)

1005/2009, on substances that deplete the ozone layer: Not relevant

Active substances which have been included in Article 95 of Regulation (EU) No. 528/2012: Not relevant REGULATION (EU)

No. 649/2012, concerning the export and import of dangerous chemicals: Not relevant **Seveso III**:

Not relevant

Restrictions on the marketing and use of certain hazardous substances and mixtures (Annex XVII of the REACH Regulation, etc ...):

Not relevant

Special provisions for the protection of persons or the environment:

It is recommended to use the information collected in this safety data sheet as input data in a risk assessment of the local circumstances in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 and all subsequent amendments.

HACCP: Hazard analysis and critical control points, ISO: 22000

15.2 Chemical safety assessment:

The supplier has not conducted a chemical safety assessment.

SECTION 16: OTHER INFORMATION

Legislation applicable to safety data sheets:

This safety data sheet has been developed in accordance with ANNEX II-Guidance for the preparation of Safety Data Sheets of Regulation (EC) No. 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications with respect to the previous safety data sheet affecting risk management measures:

COMMISSION REGULATION (EU) 2020/878

Texts of the legislative sentences referred to in section 3:

The phrases listed do not refer to the product, they are for information purposes only and refer to the individual components listed in section 3.

Regulation n°1272/2008 (CLP):

Not relevant

Classification procedure:

Not relevant

Advice on training:

Minimum training in occupational risk prevention is recommended for personnel who will handle this product, in order to facilitate the understanding and interpretation of this safety data sheet, as well as the product labeling.

Main bibliographic sources:

<http://echa.europa.eu> [http://eur-](http://eur-lex.europa.eu)

[lex.europa.eu](http://eur-lex.europa.eu) **Abbreviations and**

acronyms:



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SECTION 16: OTHER INFORMATION (continued)

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road IMDG:
International Maritime Dangerous Goods Code
IATA: International Air Transport Association ICAO:
International Civil Aviation Organization COD:
Chemical Oxygen Demand
BOD5: Biological Oxygen Demand 5 days BCF:
Bioconcentration Factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective Concentration 50
Log POW: Logarithm Partition Coefficient Octanol-
Water Koc: Partition Coefficient Organic Carbon SDS:
Material Safety Data Sheet
UFI: unique formula identifier
IARC: International Agency for Research on Cancer

The information contained in this Safety Data Sheet is based on sources, technical knowledge and legislation in force at European and national level, and the accuracy of this cannot be guaranteed. This information cannot be considered as a guarantee of the properties of the product, it is simply a description of the requirements. The methodology and working conditions of the users of this product are beyond our knowledge and control, and it is always the ultimate responsibility of the user to take the necessary measures to comply with the legislative requirements regarding handling, storage, use and disposal of chemicals. The information in this safety data sheet refers only to this product, which should not be used for purposes other than those specified.

- END OF THE SAFETY DATA SHEET
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