

Safety Data Sheet

Compliant with Annex II of REACH - Regulation 2015/830

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

1.1. Identification of the product

Code: STERIMAN GEL 70
Name: STERIMAN GEL 70

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

Description/Use: COSMETIC HAND SANITIZER

1.3. Details of the supplier of the safety data sheet

Business name: PROMOPHARMA
Address: VIA BIAGIO DI SANTOLINO,156
Location and state: 47892 ACQUAVIVA REP SAN MARINO
ufficiocq@promopharma.it
tel. +390549911338 (9.00-12.00 / 15.00-17.00).

1.4. Emergency telephone number

For urgent information contact

CAV "Osp. Pediatrico Bambino Gesù" –
Roma. Tel. 06-68593726
Az. Osp. Univ. Foggia–
Foggia. Tel. 0881-732326
Az. Osp. “
A. Cardarelli”
–
Napoli. Tel. 081-7472870
CAV Policlinico “
Umberto I”
–
Roma. Tel. 06-49978000
CAV Policlinico “
A.Gemelli”
–
Roma. Tel. 06-3054343
Az. Osp. “
Careggi”
U.O. Tossicologia Medica –
Firenze. Tel. 055-7947819
CAV Centro Nazionale di Informazione Tossicologica –
Pavia. Tel. 0382-24444
Osp. Niguarda Ca' Granda –
Milano. Tel. 02-66101029
Azienda Ospedaliera Papa Giovanni XXII –
Bergamo. Tel. 800883300

SECTION 2. Hazards identification

2.1. Substance or mixture classification

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and adjustments). The product therefore requires a safety data sheet in compliance with the provisions of Regulation (EU) 2015/830. Any additional information regarding risks to health and / or the environment are given in sect. 11 and 12 of this sheet.

Hazard classification and indications:

Flammable liquid, category 2

H225

Highly flammable liquid and vapor.

2.2. Label elements

Hazard labeling pursuant to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and adjustments.

Hazard pictograms



Warnings:

Danger

Hazard statements::

H225

Highly flammable liquid and vapor.

Precautionary statements::

P210

Keep away from heat, hot surfaces, sparks, open flames or other sources of ignition. Do not smoke.

P280

Wear protective gloves / clothing and protect eyes / face..

P370+P378

In case of fire: use. . . to extinguish.

P233

Keep container tightly closed.

2.3. Other dangers

Based on the available data, the product does not contain PBT or vPvB substances in a percentage higher than 0.1%.

SECTION 3. Composition / information on ingredients

3.2. Mixtures

It contains:

Identification

x = Conc. %

Classification 1272/2008 (CLP)

ETHANOL

CAS 64-17-5

$70 \leq x < 74$

Flam. Liq. 2 H225

CE 200-578-6

INDEX 603-002-00-5

The full text of the hazard statements (H) is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

There are no known episodes of damage to personnel assigned to use of the product. In case of need, the following general measures are adopted:

INHALATION: Take the subject to fresh air. If breathing stops, give artificial respiration. See a doctor immediately.

INGESTION: Get medical attention immediately. Induce vomiting only if directed by your doctor. Do not give anything by mouth if the person is unconscious.

EYES and SKIN: Wash with plenty of water. In case of persistent irritation, consult a doctor.

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

No specific information is known about the symptoms and effects caused by the product.

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 MEDIA

The extinguishing media are: carbon dioxide, foam, chemical powder. For leaks and spills of the product that have not ignited, the water spray can be used to disperse flammable vapors and protect people committed to stopping the leak.

UNSUITABLE EXTINGUISHING MEDIA

Do not use water jets. Water is not effective in extinguishing the fire, however it can be used to cool closed containers exposed to flame, preventing bursts and explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF A FIRE

Overpressure may occur in containers exposed to fire with risk of explosion. Avoid breathing combustion products.

5.3. Recommendations for firefighters

GENERAL INFORMATION

Cool the containers with jets of water to avoid product decomposition and the development of substances potentially hazardous for health. Always wear equipment complete with fire protection. Collect extinguishing water which must not be discharged into the sewer. Dispose of the contaminated water used for extinguishing and the residue of the fire according to current regulations

EQUIPMENT

Normal fire fighting clothing, such as an open circuit compressed air breathing apparatus (EN 137), flame retardant suit (EN469), flame retardant gloves (EN 659) and boots for the Fire Brigade (HO A29 or A30).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Stop the leak if there is no danger.

Wear appropriate protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent contamination of the skin, eyes and personal clothing. These indications are valid both for workers and for emergency interventions.

Keep unprotected persons away. Use explosion-proof equipment. Eliminate any source of ignition (cigarettes, flames, sparks, etc.) or heat from the area where the leak occurred.

6.2. Environmental precautions

Prevent the product from entering drains, surface waters, groundwater.

6.3. Methods and materials for containment and cleaning up

Aspirate the spilled product in a suitable container. Assess the compatibility of the container to be used with the product, checking section 10. Absorb the remainder with inert absorbent material.

Provide sufficient ventilation of the place affected by the leak. The disposal of contaminated material must be carried out in accordance with the provisions of point 13.

6.4. Reference to other sections

Any information regarding personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for Safe Handling

Keep away from heat, sparks and open flames, do not smoke or use matches or lighters. Vapours may ignite with explosion, therefore accumulation must be avoided by keeping doors and windows open and ensuring cross ventilation. Without adequate ventilation, the vapours can accumulate on the ground and ignite even at a distance, if ignited, with the risk of backfire. Avoid the accumulation of electrostatic charges. Connect to an earth socket in the case of large packaging during transfer operations and wear antistatic shoes. The strong agitation and the vigorous flow of the liquid in the pipes and equipment can cause the formation and accumulation of electrostatic charges. To avoid the risk of fire and explosion, never use compressed air when handling. Open the containers carefully, because they can be under pressure. Do not eat, drink or smoke during use. Avoid dispersal of the product in the environment.

7.2. Conditions for safe storage, including any incompatibilities

Keep only in the original container. Keep containers closed, in a well-ventilated place, away from direct sunlight. Store in a cool, well-ventilated place, away from heat, open flames, sparks and other sources of ignition. Keep containers away from any incompatible materials, checking section 10.

7.3 Specific end uses

Information non available

SECTION 8. Exposure controls / personal protection

8.1. Control parameters

Normative requirements:

TLV-ACGIH

ACGIH 2019

ETHANOL

Threshold limit value

Type	State	TWA/8h	STEL/15min	Note / Remarks
		mg/m3	ppm	mg/m3
			ppm	
TLV-ACGIH			1884	1000

SODIUM HYDROXIDE

Threshold limit value

Type	State	TWA/8h	STEL/15min	Note / Remarks
		mg/m3	ppm	mg/m3
			ppm	
TLV-ACGIH			2 (C)	

LINALOOL

Health - Derived no-effect level - DNEL / DMEL

Routes of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				0,20 mg/kg/d				
Dermic				1,25 mg/kg/d				2,5 mg/kg/d

Legend:

(C) = CEILING ; INALAB = Inhalable fraction ; RESPIR = Breathable fraction ; TORAC = Thoracic fraction

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

8.2. Exposure controls

Considering that the use of adequate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace through effective local extraction.

HAND PROTECTION

Protect your hands with category III work gloves (ref. standard EN 374).

For the final choice of the material of the work gloves, the following must be considered: compatibility, degradation, breaking time and permeation.

In the case of preparations, the resistance of work gloves to chemical agents must be checked before use as it cannot be foreseen. The gloves have a wear time that depends on the duration and mode of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (ref. Regulation 2016/425 and EN ISO 20344). Wash with soap and water after removing protective clothing.

Evaluate the advisability of providing antistatic clothing in case the work environment presents a risk of explosiveness.

EYE PROTECTION

It is recommended to wear airtight protective glasses (ref. Standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) of the substance or one or more of the substances present in the product is exceeded, it is advisable to wear an AX filter mask whose use limit will be defined by the manufacturer (ref EN 14387 standard). If gases or vapors of a different nature and / or gases or vapors with particles (aerosols, fumes, mists, etc.) were present, combined filters should be provided.

The use of respiratory protection means is necessary if the technical measures adopted are not sufficient to limit the worker exposure to the threshold values taken into consideration. The protection offered by the masks is however limited.

In case the substance considered is odorless or its olfactory threshold is higher than the relative TLV-TWA, and in case of emergency, wear an open circuit compressed air breathing apparatus (ref. Standard EN 137) or a plug-in respirator outdoor air (ref. standard EN 138). For the correct choice of the respiratory protection device, refer to EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

Emissions from production processes, including those from ventilation equipment, should be checked for compliance with environmental protection legislation.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Color	Light blue
Odor	Characteristic odor of alcohol
Odor threshold	Not available
pH	7
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	< 23 °C
Evaporation rate	Not available
Flammability of solids and gases	Not available
Lower flammability limit	Not available
Upper flammability limit	Not available
Lower explosion limit	Not available
Upper explosion limit	Not available
Vapor pressure	Not available
Vapor density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient: n-octanol / water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidizing properties	Not available

9.2. Other information

VOC (Directive 2010/75/CE) : 77,20 % - 702,47 g/liter

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular dangers of reaction with other substances under normal conditions of use.

PROPYLENE GLYCOL

Hygroscopic. Stable under normal conditions of use and storage.

At high temperatures it tends to oxidize to give propionaldehyde and lactic and acetic acid

10.2. Chemical stability

The product is stable under normal conditions of use and storage.

10.3. Possibility of dangerous reactions

Vapours can form explosive mixtures with air.

ETHANOL

Explosion hazard in contact with: alkali metals, alkaline oxides, calcium hypochlorite, sulfur monofluoride, acetic anhydride, acids, concentrated hydrogen peroxide, perchlorates, perchloric acid, perchloronitrile, mercury nitrate, nitric acid, silver, silver nitrate, ammonia, silver oxide, ammonia, strong oxidizing agents, nitrogen dioxide. May react dangerously with: bromine acetylene, chlorine acetylene, bromine trifluoride, chromium trioxide, chromyl chloride, fluorine, potassium tert-butoxide, lithium hydride, phosphorus trioxide, black platinum, zirconium chloride (IV), zirconium iodide (IV). Form explosive mixtures with: air.

PROPYLENE GLYCOL

It can react dangerously with: acid chlorides, acid anhydrides, oxidizing agents.

10.4. Conditions to avoid

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any source of ignition.

ETHANOL

Avoid exposure to: heat sources, open flames.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

By thermal decomposition or in case of fire, gases and vapors potentially harmful to health can be released.

PROPYLENE GLYCOL

May develop: carbon oxides.

SECTION 11. Toxicological information

There are no known episodes of damage to health due to exposure to the product. In any case, it is recommended to operate in compliance with the rules of good industrial hygiene.

11.1. Information on toxicological effects

Metabolism, kinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed, immediate and chronic effects from short and long term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:
Not classified (no relevant component)
LD50 (Oral) of the mix:
Not classified (no relevant component)
LD50 (Dermal) of the mixture:
Not classified (no relevant component)

PROPYLENE GLYCOL

LD50 (Oral) 20800 mg/kg Rat

LD50 (Dermal) 20800 mg/kg Rat

ETHANOL

LD50 (Oral) > 5000 mg/kg Rat

LC50 (Inhalation) 120 mg/l/4h Pimephales promelas

SKIN CORROSION / SKIN IRRITATION

It does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / EYE IRRITATION

It does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN AWARENESS

It does not meet the classification criteria for this hazard class

MUTAGENICITY ON GERMINAL CELLS

It does not meet the classification criteria for this hazard class

CARCINOGENICITY

It does not meet the classification criteria for this hazard class

REPRODUCTION TOXICITY

It does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY FOR TARGET ORGANS (STOT) - SINGLE EXPOSURE

It does not meet the classification criteria for this hazard class

SPECIFIC TOXICITY FOR TARGET ORGANS (STOT) - REPEATED EXPOSURE

It does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

It does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use according to good working practices, avoiding to disperse the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability**PROPYLEN GLYCOL**

Solubility in water

1000 - 10000 mg/l

Rapidly degradable

ETHANOL

Solubility in water 1000 - 10000 mg/l

Rapidly degradable

12.3. Bioaccumulative potential

PROPYLEN GLYCOL

Partition coefficient: n-octanol / water -1,07

BCF 0,09

ETHANOL

Partition coefficient: n-octanol / water -0,35

12.4. Mobility in the soil

PROPYLEN GLYCOL

Partition coefficient: soil / water 0,46

12.5. Results of PBT and vPvB assessment

Based on the available data, the product does not contain PBT or vPvB substances in a percentage higher than 0.1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse if possible. Product residues are to be considered special hazardous waste. The hazardous nature of the waste which partially contains this product must be assessed on the basis of the laws in force.

Disposal must be entrusted to a company authorized to manage waste, in compliance with national and possibly local regulations.

The transport of waste can be subject to ADR.

CONTAMINATED PACKAGING

Contaminated packaging must be sent for recovery or disposal in compliance with national waste management regulations.

SECTION 14. Transport information

14.1. UN Number

ADR / RID, IMDG, 1170
IATA:

PROMOPHARMA

Revision n. 1

Revision date 30/04/2020

New emission

STERIMAN GEL 70

Printed on 30/04/2020

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14.2. UN proper shipping name

ADR / RID: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL IN SOLUTION)
IMDG: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
IATA: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class (es)

ADR / RID: Class: 3 Sticker: 3



IMDG: Class: 3 Sticker: 3



IATA: Class: 3 Sticker: 3

**14.4. Packing group**

ADR / RID, IMDG, II
IATA:

14.5. Environmental hazards

ADR / RID: NO
IMDG: NO
IATA: NO

14.6. Special precautions for users

ADR / RID: HIN - Kemler: 33

Limited
quantities: 1L

Tunnel
restriction
code: (D/E)

IMDG: Special provision: -
EMS: F-E, S-D

Limited
quantities: 1L
Maximum
quantity: 60 L

IATA: Cargo:

Maximum
quantity: 5 L

Packaging
instructions:
364
Packaging
instructions:
353

Pass.:

Special instructions:

A3, A58,
A180

14.7. Transport in bulk according to Annex II of MARPOL and the IBC code

Not relevant information

SECTION 15. Regulatory information

15.1. Health and safety and environmental laws and regulations specific for the substance or mixture

Seveso category - Directive 2012/18 / EC: P5c

Restrictions relating to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006

Product
Point 3 - 40

Substances in Candidate List (Art. 59 REACH)

Based on available data, the product does not contain SVHC substances in a percentage higher than 0.1%

Substances subject to authorization (Annex XIV REACH)

None

Substances subject to export notification obligation Reg. (EC) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Sanitary checks

Information not available

15.2. Chemical safety assessment

A chemical safety assessment has not been developed for the mixture / substances listed in section 3.

SECTION 16. Other information

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

Flam. Liq. 2	Flammable liquid, category 2
H225	Highly flammable liquid and vapor.

LEGEND:

- ADR: European agreement for the transport of dangerous goods by road
- CAS NUMBER: Number of Chemical Abstract Service
- EC50: Concentration that gives effect to 50% of the test population
- CE NUMBER: Identification number in ESIS (European archive of existing substances)
- CLP: Regulation CE 1272/2008
- DNEL: Derived no effect level
- EmS: Emergency Schedule
- GHS: Global harmonized system for the classification and labeling of chemical products
- IATA DGR: Regulations for the transport of dangerous goods by the International Air Transport Association
- IC50: Immobilization concentration of 50% of the test population
- IMDG: International maritime code for the transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in Annex VI of the CLP
- LC50: Letal concentration 50%
- LD50: Letal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulating and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable level of exposure
- PNEC: Predictable concentration without effects
- REACH: Regulation CE 1907/2006
- RID: Regulations for the international transport of dangerous goods by train
- TLV: Threshold limit value
- TLV CEILING: Concentration that must not be exceeded during any time of the work exposure
- TWA STEL: Short term exposure limit
- TWA: Weighted average exposure limit
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulating according to REACH
- WGK: Aquatic hazard class (Germany)

GENERAL BIBLIOGRAPHY:

1. Regulation (EC) 1907/2006 of the European Parliament (REACH)
 2. Regulation (EC) 1272/2008 of the European Parliament (CLP)
 3. Regulation (EU) 790/2009 of the European Parliament (I Atp. CLP)
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 of the European Parliament (II Atp. CLP)
 6. Regulation (EU) 618/2012 of the European Parliament (III Atp. CLP)
 7. Regulation (EU) 487/2013 of the European Parliament (IV Atp. CLP)
 8. Regulation (EU) 944/2013 of the European Parliament (V Atp. CLP)
 9. Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)
 10. Regulation (EU) 2015/1221 of the European Parliament (VII Atp. CLP)
 11. Regulation (EU) 2016/918 of the European Parliament (VIII Atp. CLP)
 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) 2018/1480 (XIII Atp. CLP)
 16. Regulation (EU) 2019/521 (XII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Toxicological sheet
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - Website IFA GESTIS
 - Website agency ECHA
 - SDS database of chemical substances - Ministry of Health and Higher Institute of Health

Note for the user:

The information contained in this sheet is based on the knowledge available from us at the date of the latest version. The user must ensure the suitability and completeness of the information in relation to the specific use of the product.

This document must not be interpreted as a guarantee of any specific property of the product.

Since the use of the product does not fall under our direct control, it is the user's obligation to observe the laws and regulations in force on hygiene and safety under his own responsibility. No liability is assumed for improper use.

Provide adequate training to personnel involved in the use of chemicals.

The classification of the product is based on the calculation methods referred to in Annex I of the CLP, unless otherwise indicated in sections 11 and 12.

The methods of evaluation of the chemical-physical properties are reported in section 9.