

Safety data sheet
complying with Regulation 1907/2006/EC (REACH
Regulation), EU 2020/878 and Regulation No 1272/2008/EC
(CLP)

Printing date 13.07.2021

Version number 1

Revision: 13.07.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **NOSODERM GEL 80**

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

No further relevant information available.

Application of the substance / the mixture: Antiseptic hydroalcoholic hand gel

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

MEDALKAN

Michalakopoulou 102, P.C. 11528, Athens, Greece

Tel.. 2107484847, Fax. 210 7772009

e-mail: contact@medalkan.gr

website: www.medalkan.com

1.4 Emergency telephone number:



European Emergency Tel.: 112

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation EC No 1272/2008 CLP:



GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

2.2 Label elements

Labelling according to Regulation EC No 1272/2008 CLP:

The product is classified and labelled according to the CLP regulation.

Hazard pictograms:



GHS02

Signal word: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

Precautionary statements

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

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P102 Keep out of reach of children.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P370+P378 In case of fire: Use CO₂, powder or water spray to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture: consisting of the following components.

Ingredients according Regulation (EU) 2020/878:

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5 Reg.nr.: 01-2119457610-43-XXXX	ethanol ☠ Flam. Liq. 2, H225	≥75-≤80%
CAS: 112-72-1 EINECS: 204-000-3 Reg.nr.: 01-2119485910-33-XXXX	1-Tetradecanol ☠ Aquatic Chronic 1, H410; ☠ Eye Irrit. 2, H319	≥0.025-<0.25%

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Take affected persons out into the fresh air.

In case of unconsciousness place patient stably in side position for transportation.

In all cases call a doctor.

After inhalation:

Seek medical treatment in case of complaints.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Generally the product does not irritate the skin.

After eye contact:

Rinse opened eye for at least 15 minutes under running water.

Remove contact lenses and continue rinsing for several minutes

If persistent irritation occurs, seek medical advice.

Avoid strong water jet-risk of cornea damage, consult a doctor.

After swallowing:

Drink plenty of water and provide fresh air. Call for a doctor immediately.

Seek immediate medical advice.

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4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, foam, extinguishing powder, water spray

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

Self contained breathing apparatus and full protective clothing must be worn in case of fire.

Additional information

Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Wear protective equipment. Keep unprotected persons away.

Keep away from ignition sources.

Ensure adequate ventilation.

Keep people at a distance and upwind.

Avoid contact with oxidising agents.

Avoid inhalation of vapors.

Goggles and/ or face shield, if contact with eyes or splashes are anticipated.

Avoid contact with eyes.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust, silica gel).

Dispose contaminated material as waste according to item 13.

Send for recovery or disposal in suitable receptacles.

6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Open and handle receptacle with care.

Do not eat, drink or smoke during the usage of the product.

Avoid contact with eyes.

Handle with care. Avoid jolting, friction and impact.

Store in cool, dry place in tightly closed receptacles.

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Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

Flammable gas-air mixtures may form in empty receptacles.

Keep it in a dry, cool, well ventilated, fixed in advance place, away from sources of heat, flames, ignition and direct sunlight.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

Store in a cool location.

Provide ventilation for receptacles.

Information about storage in one common storage facility:

Store away from flammable substances.

Store away from oxidising materials.

Further information about storage conditions:

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 64-17-5 ethanol

WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm

CAS: 57-55-6 Propane-1,2-diol

WEL (Great Britain) Long-term value: 474* 10** mg/m³, 150* ppm
*total vapour and particulates **particulates

DNELs

(CAS: 64-17-5) ethanol

Workers

Systemic effects, acute and chronic:

Inhalation - 950 mg/m³

Dermal - 343 mg/kg bw/d

Local effects, acute and chronic:

Inhalation - 1900 mg/m³

Consumers

Systemic effects, acute and chronic:

Inhalation - 114 mg/m³

Dermal - 206 mg/kg bw/d

Oral - 87 mg/kg bw/d

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Local effects, acute and chronic:

Inhalation - 950 mg/m³

112-72-1: Tetradecanol

worker:

Short-term exposure - systemic effects, dermal: 125 mg/kg

Short-term exposure - systemic effects, Inhalation: 220 mg/m³

Long-term exposure- systemic effects, dermal: 125 mg/kg

Long-term exposure- systemic effects, Inhalation: 220 mg/m³

consumer:

Short-term exposure - systemic effects, dermal: 75 mg/kg

Short-term exposure - systemic effects, Inhalation: 65 mg/m³

Short-term exposure - systemic effects, oral: 75 mg/kg

Long-term exposure- systemic effects, dermal: 75 mg/kg

Long-term exposure- systemic effects, Inhalation: 65 mg/m³

Long-term exposure- systemic effects, oral: 75 mg/kg

PNECs

(CAS: 64-17-5) ethanol

Freshwater: 0.96 mg/l

Marine water: 0.79 mg/l

STP (Sewage Treatment Plant): 580 mg/l

Sediment (freshwater): 3.6 mg/kg sediment dw

Sediment (marine water): 2.9 mg/kg sediment dw

Soil: 0.63 mg/kg soil dw

Secondary poisoning: 0.38 g/kg food

112-72-1: Tetradecanol

freshwater: 0.00032 mg/l

marine water: 0.000032 mg/l

intermittent release: No PNEC value available.

STP: 0.0019 mg/l

sediment (freshwater): 0.36 mg/kg

sediment (marine water): 0.036 mg/kg

soil: 0.28 mg/kg

oral (secondary poisoning): No PNEC value available.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes.

Do not eat, drink or smoke while using the product.

Do not breathe vapours or mists.

Respiratory protection: Not required.

Hand protection Not required under normal conditions of use.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance and has therefore

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to be checked prior to the application.

Penetration time of glove material

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

Eye/face protection



Goggles recommended during refilling

Body protection:



Protective work clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Gel
Colour:	Transparent
Odour:	Product specific
Odour threshold:	Not determined
Melting point/freezing point:	Not determined
Boiling point or initial boiling point and boiling range	78 °C (CAS: 64-17-5 ethanol)
Flammability	Not applicable
Lower and upper explosion limit	
Lower:	3.5 Vol % (CAS: 64-17-5 ethanol)
Upper:	15 Vol % (CAS: 64-17-5 ethanol)
Flash point:	13 °C (CAS: 64-17-5 ethanol)
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined
pH at 20 °C	5.5-7
Viscosity:	
Kinematic viscosity	Not determined
Kinematic viscosity	
Dynamic:	Not determined
Solubility	
water:	Fully miscible
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure at 20 °C:	20,000-50,000 hPa
Density and/or relative density	
Density at 20 °C:	0.8-0.86 g/cm ³

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Relative density Not determined
Vapour density Not determined

9.2 Other information

Appearance:

Form: gel

Important information on protection of health and environment, and on safety.

Auto-ignition temperature: Not determined

Explosive properties: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

Cloud point / clarification point:

Oxidising properties Not oxidising

Evaporation rate Not determined

Information with regard to physical hazard classes

Explosives Void

Flammable gases Void

Aerosols Void

Oxidising gases Void

Gases under pressure Void

Flammable liquids Highly flammable liquid and vapour.

Flammable solids Void

Self-reactive substances and mixtures Void

Pyrophoric liquids Void

Pyrophoric solids Void

Self-heating substances and mixtures Void

Substances and mixtures, which emit flammable gases in contact with water Void

Oxidising liquids Void

Oxidising solids Void

Organic peroxides Void

Corrosive to metals Void

Desensitised explosives Void

Desensitised explosives Void

SECTION 10: Stability and reactivity

10.1 Reactivity Stable under normal conditions

10.2 Chemical stability

Thermal decomposition / conditions to be avoided

To avoid thermal decomposition do not overheat.

Stable at environment temperature.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid

The product should not be exposed to high temperatures, sparks, flame and electrostatic charges.

10.5 Incompatible materials Oxidizing agents

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10.6 Hazardous decomposition products No dangerous decomposition products known.

SECTION 11: Toxicological information

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

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

LD/LC50 values relevant for classification:

(CAS: 56-81-5) Glycerol
 LD50, oral, 27 mg/kg bw (rat)
 LD50, oral, 23 000 mg/kg bw (mouse)
 LD50, oral, 10 000 mg/kg bw (guinea pig)
 LC50 (1h), inhalation, rat: >11 mg/L
 LD50, dermal, guinea pig: 56.750 mg/kg
 Propan-1,2-diol CAS number: 57-55-6
 LD50, oral, rat: 22 000 mg/kg bw
 LD50, dermal, rabbit: 20 800 mg/kg bw

CAS: 64-17-5 ethanol

Oral	LD50	7,060 mg/kg (rat)
Inhalative	LC50/4 h (vapour)	20,000 mg/l (rat)

CAS: 112-72-1 1-Tetradecanol

Oral	LD50	>5,000 mg/kg (rat) (Acute Oral Toxicity)
Dermal	LD50	>5,000 mg/kg (rabbit) (Acute Dermal Toxicity)

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Potentially irritant

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

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

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

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

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

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

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

Additional toxicological information:

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

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Propane-1,2-diol cas number: 57-55-6
 LC50 Oncorhynchus mykiss, 96 h: 40.613 mg/l
 LC50 Ceriodaphnia dubia, 48 h: 18.340 mg/l

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LC50 Mysidopsis bahia, 96 h: 18.800 mg/l
ErC50 Selenastrum capricornutum, 96 h: 19.000 mg/l
ErC50 Skeletonema costatum, 96 h: 19.100 mg/l

Long-term toxicity to aquatic invertebrates
NOEC (7 days) 13.02 - 29 g/L

Toxicity to microorganisms
EC10 or NOEC for microorganisms 20 g/L
(CAS: 81-13-0) Dexpanthenol
NOEC (96h) for rainbow trout (Iridescent trout) \geq 1000 mg/l
EbCGO (72h) > 100 mg/l algae (OECD 202)
NOEbC (72h) 100 mg/l algae (OECD 202)
(CAS: 56-81-5) Glycerol
LC50 (96h), fish: 54.000 mg/L
EC50 (48h), daphnia magna: 1.955 mg/L

Toxicity to aquatic algae and cyanobacteria
EC50 for freshwater algae 2.9 g/L

Toxicity to microorganisms
EC50 for microorganisms 10 g/L
EC10 or NOEC for microorganisms 10 g/L
CAS: 64-17-5 Ethanol
EC50 5012 mg/l (Ceriodaphnia sp.)
LC50 11200 mg/l (Fresh water fish)
857 mg/l (Artemisia salina)
275 mg/l (algae)
9,6 mg/l (daphnia magna)

CAS: 112-72-1 1-Tetradecanol

EC50 (72h) >10-100 mg/l (ssu) (Freshwater Alga and Cyanobacteria, Grow Inhibition)
EC50 (48h) 1-10 mg/l (Daphnia magna) (Daphnia sp. Acute Immobilisation Test)
LC50 (96h) >100 mg/l (Brachydanio rerio)

12.2 Persistence and degradability

(CAS: 64-17-5) Ethanol
Biodegradability: 94%
readily biodegradable
Method: OECD Guideline 301 B
CAS 57-55-6 Propylene Glycol
Oxygen consumption 106.80% 28 d
CO2 Evolution 81.70% 28 d
(CAS: 56-81-5) Glycerol
readily biodegradable
Biodegradation: 82% - 20 days

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12.3 Bioaccumulative potential

Ethanol CasNo 64-17-5:

It has a low bioaccumulation potential.

(CAS: 57-55-6) Propan-1,2-diol

BCF: 1

Pow Log: -0.92

Low potential

(CAS: 56-81-5) glycerol

Log Pow -1.76

12.4 Mobility in soil

(CAS: 64-17-5) ethanol

It is volatile and is not absorbed in soil: Log Pow = -0,32

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

12.7 Other adverse effects No further relevant information available.

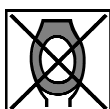
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation



Dispose according to National Regulations.



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Empty containers may contain hazardous waste.

Do not remove the label on the packaging until it is cleaned.

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

Packaging may be reused or recycled after cleaning.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA

UN1170

14.2 UN proper shipping name

ADR

1170 ETHANOL (ETHYL ALCOHOL) mixture

IMDG

ETHANOL (ETHYL ALCOHOL) mixture

IATA

ETHANOL mixture

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14.3 Transport hazard class(es)

ADR, IMDG, IATA



Class	3 Flammable liquids.
Label	3
14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	33
EMS Number:	F-E,S-D
Stowage Category	A
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.

Transport/Additional information:

ADR

Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E

IMDG

Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL) MIXTURE, 3, II

SECTION 15: Regulatory information

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

REACH Regulation 1907/2006/EC
Regulation (EU) 2020/878
CLP Regulation 1272/2008/EC
Directive 98/24/EC on the protection of health and safety of workers from the risks related to chemicals agents at work.

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Council Directive 94/33/EC on the protection of young people at work, as amended.
Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Directive 2012/18/EU**Named dangerous substances - ANNEX I** None of the ingredients is listed.**Seveso category** P5c FLAMMABLE LIQUIDS**Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t**Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t**REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3**National regulations:****Other regulations, limitations and prohibitive regulations****Substances of very high concern (SVHC) according to REACH, Article 57**

It doesn't contain substances of very high concern (SVHC).

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. "This document has been drawn up in English and will be translated into other languages. The English text will prevail in case of conflict between the two versions."

Relevant phrases

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

Training hints

Suitable training on safety in handling, storing and converting the product should be given to the employees based on all the existing information.

Department issuing SDS:

SUSTCHEM S.A.

REACH & Chemical Services Department

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

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PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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