

Safety Data Sheet dated 18/10/2021, version 4

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

1.1. Product identifier

Mixture identification

Trade name: DERMAGEL PLUS

UFI: 13G3-50JA-W008-GMHR

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

Recommended use:

Hand disinfectant gel.

Uses advised against:

Different uses than recommended. Do not use in combination with other products.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

SUTTER INDUSTRIES s.p.a. - Società con Unico Socio

15060 Borghetto Borbera (AL) Italia

Tel. +39 0143 631.1

Competent person responsible for the safety data sheet:

regulatory.affairs@sutter.it

1.4. Emergency telephone number

+39 0143 631.1 mon-fri 9.00/17.00

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)



Danger, Flam. Liq. 2, Highly flammable liquid and vapour.



Warning, Eye Irrit. 2, Causes serious eye irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements:

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

P233 Keep container tightly closed.

P235 Keep cool.

P280 Wear eye protection.

P337+P313 If eye irritation persists: Get medical advice/attention.

Special Provisions:

None

Product contents:

polycarboxylates

< 5 %

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The product also contains: Disinfectants
Special provisions according to Annex XVII of REACH and subsequent amendments:
None


2.3. Other hazards
No PBT, vPvB or endocrine disruptor substances present in concentration $\geq 0.1\%$
Other Hazards:
No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances
Not Applicable, the product is a mixture.

3.2. Mixtures
Hazardous components within the meaning of the CLP regulation and related classification:
 $\geq 70\%$ - $< 80\%$ ETHANOL
REACH No.: 01-2119457610-43, Index number: 603-002-00-5, CAS: 64-17-5, EC:
200-578-6

 2.6/2 Flam. Liq. 2 H225

 3.3/2 Eye Irrit. 2 H319

Specific Concentration Limits:
C $\geq 50\%$: Eye Irrit. 2 H319

SECTION 4: First aid measures

4.1. Description of first aid measures
In case of skin contact:
Immediately take off all contaminated clothing.
Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap. Wash thoroughly the body (shower or bath).
Remove contaminated clothing immediately and dispose off safely.
After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:
After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.
Protect uninjured eye.

In case of Ingestion:
Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:
Remove casualty to fresh air and keep warm and at rest.

4.2. Most important symptoms and effects, both acute and delayed
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.
Until revision date of this document, are unknown chronic effects from the mixture contact with skin, eyes, inhalation, ingestion.

4.3. Indication of any immediate medical attention and special treatment needed
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
Treatment:
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.

SECTION 5: Firefighting measures

- 5.1. Extinguishing media
 - Suitable extinguishing media:
CO2 or Dry chemical fire extinguisher.
 - Extinguishing media which must not be used for safety reasons:
None in particular.
- 5.2. Special hazards arising from the substance or mixture
 - The mixture does not contain ingredients classified as explosive according to EC Regulation 1272/2008 (CLP).
 - Do not inhale explosion and combustion gases.
 - Burning produces heavy smoke.
- 5.3. Advice for firefighters
 - Use suitable breathing apparatus .
 - Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
 - Move undamaged containers from immediate hazard area if it can be done safely.
 - The mixture does not contain ingredients classified as explosive according to EC Regulation 1272/2008 (CLP).

SECTION 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
 - For non emergency personnel:
Wear personal protection equipment.
Remove all sources of ignition.
Remove persons to safety.
See protective measures under point 7 and 8.
 - For emergency responders:
Wear personal protection equipment.
- 6.2. Environmental precautions
 - Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
 - Retain contaminated washing water and dispose it.
 - In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
 - Suitable material for taking up: absorbing material, organic, sand
- 6.3. Methods and material for containment and cleaning up
 - Wash with plenty of water. To converge the product in containment tanks.
- 6.4. Reference to other sections
 - See also section 8 and 13

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling
 - Avoid contact with skin and eyes, inhalation of vapours and mists.
 - Don't use empty container before they have been cleaned.
 - Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
 - See also section 8 for recommended protective equipment.
 - Advice on general occupational hygiene:
Contaminated clothing should be changed before entering eating areas.
 - Do not eat or drink while working.
- 7.2. Conditions for safe storage, including any incompatibilities
 - Store away from sunlight.
 - Store in a cool and well ventilated place.
 - Do not store in open or unlabeled containers.
 - Store away from heat sources.

Keep away from unguarded flame and heat sources. Avoid direct exposure to sunlight.
Keep away from unguarded flame, sparks, and heat sources. Avoid direct exposure to sunlight.

Keep away from food, drink and feed.

Incompatible materials:

Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability. see also 1.2 and 7.2.

None in particular.

Instructions as regards storage premises:

Cool and adequately ventilated.

7.3. Specific end use(s)

None in particular, see paragraph 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Until the revision date of this document, no experimental data are available for the mixture. Below, listed occupational exposure limits, if available, for the components listed in paragraph 3.2.

ETHANOL - CAS: 64-17-5

EU - TWA(8h): 1920 mg/m³, 1000 ppm - Notes: WEL

ACGIH - STEL: 1000 ppm - Notes: A3 - URT irr

DNEL Exposure Limit Values

Until the revision date of this document, no experimental data are available for the mixture. Below, listed the DNEL exposure limits, if available, for the components listed in paragraph 3.2.

ETHANOL - CAS: 64-17-5

Worker Industry: 1900 mg/m³ - Consumer: 950 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, local effects

Worker Industry: 950 mg/m³ - Consumer: 114 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Industry: 343 mg/kg - Consumer: 206 mg/kg - Exposure: Human Dermal - Frequency: Long Term, systemic effects - Notes: bw/day

Consumer: 87 mg/kg - Exposure: Human Oral - Frequency: Long Term, systemic effects

PNEC Exposure Limit Values

Until the revision date of this document, no experimental data are available for the mixture. Below, listed the PNEC exposure limits, if available, for the components listed in paragraph 3.2.

ETHANOL - CAS: 64-17-5

Target: Marine water - Value: 0.79 mg/l

Target: Fresh Water - Value: 0.96 mg/l

Target: Marine water sediments - Value: 2.9 mg/kg

Target: Soil (agricultural) - Value: 0.63 mg/kg

Target: Freshwater sediments - Value: 3.6 mg/kg

8.2. Exposure controls

Eye protection:

Use close fitting safety goggles, don't use eye lens.(EN 166)

Protection for skin:

Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or viton (EN 14605 in case of splashes or EN 13982 in case of dust)

Protection for hands:

Not needed for normal use.

Respiratory protection:

Not needed for normal use.

Thermal Hazards:

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The product is flammable.

The product is not explosive - see paragraph 2.1. The product contains no explosive components.

Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.

Environmental exposure controls:

Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.

See also section 6.2.

Appropriate engineering controls:

No further technical checks suitable for your product under normal conditions.

See also section 1.2, section 7 and Exposure Scenario - Annex I of this document.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes:
Physical state:	Liquid	Visual	--
Colour:	colourless	Visual	--
Odour:	Technical	Olfactory	Absence of fragrances
Odour threshold:	Evident	Olfactory	--
Melting point/freezing point:	Not Relevant	--	Parameter not relevant for the type of product
Boiling point or initial boiling point and boiling range:	>78°C	--	Estimated value on chemical / physical properties of components
Flammability:	flammable	--	Estimated parameter on chemical / physical properties of components.
Lower and upper explosion limit:	Not Relevant	--	Parameter not relevant for the type of product
Flash point:	< 23 ° C	--	Estimated value on chemical / physical properties of components
Auto-ignition temperature:	Not Relevant	--	Parameter not relevant for the type of product
Decomposition temperature:	Not Relevant	--	Parameter not relevant for the type of product
pH:	6,5 +/- 0,5	Instrumental control	--
Kinematic viscosity:	12500 +/- 2500 cP	Instrumental control	--
Solubility in water:	Completa	--	Estimated value on chemical / physical properties of components
Solubility in oil:	Partial	--	Estimated value on chemical / physical properties of components
Partition coefficient n-octanol/water (log value):	< 1000	--	Value estimated based on the solubility of the mixture.
Vapour pressure:	Not Relevant	--	Parameter not relevant for the type of product
Density and/or relative density:	0.86 +/- 0.01 g/ml	Instrumental control	--
Relative vapour density:	Not Relevant	--	Parameter not relevant for the

			type of product
Particle characteristics:			
Particle size (average and range)	Not Relevant	--	Parameter not relevant for the type of product

9.2. Other information
No other relevant information

SECTION 10: Stability and reactivity

- 10.1. Reactivity
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.
Do not use in combination with other products.
- 10.2. Chemical stability
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.
- 10.3. Possibility of hazardous reactions
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.
See also section 7.2.
- 10.4. Conditions to avoid
Avoid direct sunlight and exposure to heat sources.
Different uses than recommended. Do not use in combination with other products. See also 1.2 and 7.2
- 10.5. Incompatible materials
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability. see also 1.2 and 7.2.
- 10.6. Hazardous decomposition products
Until the revision date of this document, no adverse effects and symptoms to exposure of the product are known, including chemical reactivity and instability.
Do not use in combination with other products.

SECTION 11: Toxicological information

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

Toxicological information of the product:

DERMAGEL PLUS

- a) acute toxicity
Not classified
Based on available data, the classification criteria are not met
- b) skin corrosion/irritation
Not classified
Based on available data, the classification criteria are not met
- c) serious eye damage/irritation
The product is classified: Eye Irrit. 2 H319
- d) respiratory or skin sensitisation
Not classified
Based on available data, the classification criteria are not met
- e) germ cell mutagenicity
Not classified
Based on available data, the classification criteria are not met
- f) carcinogenicity
Not classified
Based on available data, the classification criteria are not met
- g) reproductive toxicity

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- Not classified
Based on available data, the classification criteria are not met
- h) STOT-single exposure
Not classified
Based on available data, the classification criteria are not met
- i) STOT-repeated exposure
Not classified
Based on available data, the classification criteria are not met
- j) aspiration hazard
Not classified
Based on available data, the classification criteria are not met
- Toxicological information of the main substances found in the product:
Below are reported, if available, the toxicological information of the components listed in paragraph 3.2.
- ETHANOL - CAS: 64-17-5
- a) acute toxicity:
Test: LD50 - Route: Oral - Species: Rat > 6200 mg/kg - Source: OECD401
Test: LC50 - Route: Inhalation - Species: Rat > 50 mg/m³ - Source: OCSE 403
Test: LD50 - Route: Skin - Species: Rabbit = 20 g/kg
- c) serious eye damage/irritation:
Test: Eye Irritant Positive - Source: OECD405 - Notes: Conc. >=50%
- ETHANOL - CAS: 64-17-5
LD50 (RABBIT) ORAL: 6300 MG/KG
LD50 (RAT) ORAL SINGLE DOSE: 7060 MG/KG

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

Until the revision date of this document, are not available experimental data on the mixture.

Below are reported, if available, the eco-toxicological information of the components listed in paragraph 3.2.

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Not classified for environmental hazards

Based on available data, the classification criteria are not met

ETHANOL - CAS: 64-17-5

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Algae = 275 mg/l - Duration h: 72 - Notes: Chlorella vulgaris

Endpoint: LC50 - Species: Fish = 13000 mg/l - Duration h: 96 - Notes: Salmo gairdneri

Endpoint: EC50 - Species: Daphnia = 12340 mg/l - Duration h: 48 - Notes: Daphnia magna

b) Aquatic chronic toxicity:

Endpoint: NOEC - Species: Algae = 3240 mg/l - Duration h: 120 - Notes: Skeletonema costatum

12.2. Persistence and degradability

Until the revision date of this document, are not available experimental data on the mixture.

Below are reported, if available, the eco-toxicological information of the components listed in paragraph 3.2.

ETHANOL - CAS: 64-17-5

Biodegradability: Readily biodegradable

The surfactant(s) contained in this preparation complies with the biodegradability criteria laid down in Regulation (EC) No 648/2004 on detergents. All supporting data are kept available to the competent authorities of the Member States and will be provided to those authorities if they so request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

Until the revision date of this document, are not available experimental data on the mixture. Below are reported, if available, the eco-toxicological information of the components listed in paragraph 3.2.

ETHANOL - CAS: 64-17-5

Bioaccumulation: Slightly bioaccumulative - Test: Kow - Partition coefficient -0.31

12.4. Mobility in soil

Until the revision date of this document, are not available experimental data on the mixture. Below are reported, if available, the eco-toxicological information of the components listed in paragraph 3.2.

Not applicable

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration $\geq 0.1\%$

12.7. Other adverse effects

Until the revision date of this document, unknown adverse effects and symptoms towards the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force. Do not discharge into the ground or into drains.

See also section 6

SECTION 14: Transport information



14.1. UN number or ID number

ADR-UN Number: 1993

IATA-UN Number: 1993

IMDG-UN Number: 1993

14.2. UN proper shipping name

ADR-Shipping Name: FLAMMABLE LIQUID, N.O.S.(Viscous liquid containing ETHANOL)

IATA-Shipping Name: FLAMMABLE LIQUID, N.O.S.(Viscous liquid containing ETHANOL)

IMDG-Shipping Name: FLAMMABLE LIQUID, N.O.S.(Viscous liquid containing ETHANOL)

14.3. Transport hazard class(es)

ADR-Class: 3

ADR - Hazard identification number: -

IATA-Class: 3

IATA-Label: 3

IMDG-Class: 3

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- 14.4. Packing group
ADR-Packing Group: III
IATA-Packing group: III
IMDG-Packing group: III
- 14.5. Environmental hazards
ADR-Environmental Pollutant: No
IMDG-Marine pollutant: No
IMDG-EmS: F-E , S-E
- 14.6. Special precautions for user
ADR-Subsidiary hazards: -
ADR-S.P.: 274 601
ADR-Transport category (Tunnel restriction code): E
IATA-Passenger Aircraft: 355
IATA-Subsidiary hazards: -
IATA-Cargo Aircraft: 366
IATA-S.P.: A3
IATA-ERG: 3L
IMDG-SP 223 274 955
IMDG-Subsidiary hazards: -
IMDG-Stowage and handling: Category A
IMDG-Segregation: -
- 14.7. Maritime transport in bulk according to IMO instruments
Not applicable

SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:
None
Where applicable, refer to the following regulatory provisions :
Directive 2012/18/EU (Seveso III)
Regulation (EC) nr 648/2004 (detergents).
Dir. 2004/42/EC (VOC directive)
- Provisions related to directive EU 2012/18 (Seveso III):
Seveso III category according to Annex 1, part 1
Product belongs to category: P5c

15.2. Chemical safety assessment

No, for instructions on safe mangling you see Sections 7 and 8 and the exposure scenario - Annex I of this document.

A Chemical Safety Assessment has been carried out for the mixture.

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

None

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Hazard class and hazard category	Code	Description
Flam. Liq. 2	2.6/2	Flammable liquid, Category 2
Eye Irrit. 2	3.3/2	Eye irritation, Category 2

This safety data sheet has been completely updated in compliance to Regulation 2020/878.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Flam. Liq. 2, H225	On basis of test data
Eye Irrit. 2, H319	Calculation method

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

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

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EC0/10/20/50/100: Effective concentration, for 0/10/20/50/100 percent of test population.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IATA: International Air Transport Association.



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IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC0/10/20/50/100:	Lethal concentration, for 0/10/20/50/100 percent of test population.
LD0/10/20/50/100:	Lethal dose, for 0/10/20/50/100 percent of test population.
NOEC:	No Observed Effect Concentration
NOAEL(R)/N	No Observed Adverse Effect Level(Repeated)/Concentration
OAEC:	
OECD:	Organisation for Economic Co-operation and Development
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.