

Safety Data Sheet
complying with Regulation 1907/2006/EC (REACH
Regulation), EU 2015/830 and Regulation No 1272/2008/EC
(CLP)

Printing date 24.03.2016

Version number 1

Revision: 23.03.2016

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

1.1 Product identifier

Trade name: MEDASEPT 100

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: Disinfectant for medical devices

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.gr

1.4 Emergency telephone number:



Emergency telephone number: 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.



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

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 GHS07

Signal word: Danger

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Hazard-determining components of labelling:

propan-2-ol

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements

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

P102 Keep out of reach of children.

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Regulation (EC) No 648/2004 on detergents / Labelling for contents

disinfectants

2.3 Other hazards**Results of PBT and vPvB assessment**

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients**3.2 Chemical characterisation: Mixtures****Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous Ingredients:**

CAS: 67-63-0 EINECS: 200-661-7 Index number: 603-117-00-0	propan-2-ol ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336	≤75%
CAS: 111-76-2 EINECS: 203-905-0 Index number: 603-014-00-0	2-butoxyethanol ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.1-≤2.5%
CAS: 2372-82-9 EINECS: 219-145-8	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine ⚠ Acute Tox. 3, H301; ⚠ STOT RE 2, H373; ⚠ Skin Corr. 1A, H314; ⚠ Aquatic Acute 1, H400 (M=10)	0.1-<1%
CAS: 7173-51-5 EINECS: 230-525-2 Index number: 612-131-00-6	didecyldimethylammonium chloride ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400	0.1-<1%

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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Take affected persons out into the fresh air.
Seek immediate medical advice.

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.
Immediately wash with water and soap and rinse thoroughly.
Wash contaminated clothing before use.
If skin irritation continues, consult a doctor.

After eye contact:

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

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.

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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 skin and 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

Avoid contact with skin, eyes and clothing.
Open and handle receptacle with care.
Handle with care. Avoid jolting, friction and impact.
Store in cool, dry place in tightly closed receptacles.
Keep receptacles tightly sealed.
Keep away from heat and direct sunlight.
Ensure good ventilation/exhaustion at the workplace.
Avoid prolonged exposure with skin

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.

Further information about storage conditions:

Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.

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Protect from heat and direct sunlight.

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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:

67-63-0 propan-2-ol

WEL (Great Britain)	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm
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111-76-2 2-butoxyethanol

WEL (Great Britain)	Short-term value: 246 mg/m ³ , 50 ppm Long-term value: 123 mg/m ³ , 25 ppm Sk, BMGV
IOELV (EU)	Short-term value: 246 mg/m ³ , 50 ppm Long-term value: 98 mg/m ³ , 20 ppm Skin

Ingredients with biological limit values:

111-76-2 2-butoxyethanol

BMGV (Great Britain)	240 mmol/mol creatinine Medium: urine Sampling time: post shift Parameter: butoxyacetic acid
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Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.
 Wash hands before breaks and at the end of work.
 Avoid contact with the eyes.
 Do not eat, drink or smoke while using the product.
 Avoid close or long term contact with the skin.

Respiratory protection: Not required.

Protection of hands:



Protective gloves

Penetration time of glove material

The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

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Eye protection:



Tightly sealed goggles

Body protection:



Protective work clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Liquid
Colour:	According to product specification
Odour:	alcohol
Odour threshold:	Not determined

pH value:	9.0-9.6
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined

Flash point: 35 °C

Flammability (solid, gaseous): Not applicable

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Self-igniting: Product is not selfigniting.

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

Explosion limits:

Lower:	Not determined
Upper:	Not determined

Oxidising properties Not considered as oxidising.

Vapour pressure: Not determined

Density:	Not determined
Relative density at 20 °C	0.968 g/cm ³
Vapour density	Not determined
Evaporation rate	Not determined

Solubility in / Miscibility with water: Fully miscible

Partition coefficient (n-octanol/water): Not determined

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Viscosity:

Dynamic:

Not determined

Kinematic:

Not determined

9.2 Other information

No further relevant information available.

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 Strong oxidising agents

10.6 Hazardous decomposition products No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

LD/LC50 values relevant for classification:

Oral	LD50	9547 mg/kg
Dermal	LD50	35556 mg/kg (rab)
Inhalative	LC50/4 h (vapour)	978 mg/l

67-63-0 propan-2-ol

Oral	LD50	5045 mg/kg (rat)
Dermal	LD50	12800 mg/kg (rabbit)
Inhalative	LC50/4 h (vapour)	30 mg/l (rat)

111-76-2 2-butoxyethanol

Oral	LD50	1746 mg/kg (rat)
Dermal	LD50	400 mg/kg (rab)

2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

Oral	LD50	871 mg/kg (rat)
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7173-51-5 didecyldimethylammonium chloride

Oral	LD50	84 mg/kg (rat)
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Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Potentially irritant

Causes serious eye irritation.

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

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

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

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

STOT-single exposure

The product is classified as Specific Target Organ Toxicity after single exposure Category 3
May cause drowsiness or dizziness.

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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes: Toxic for aquatic organisms

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 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.

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
ADR, IMDG, IATA

UN1993

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14.2 UN proper shipping name

ADR

1993 FLAMMABLE LIQUID, N.O.S.
 (ISOPROPANOL (ISOPROPYL ALCOHOL))

IMDG, IATA

FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL
 (ISOPROPYL ALCOHOL))

14.3 Transport hazard class(es)

ADR, IMDG, IATA



**Class
 Label**

3 Flammable liquids.
 3

14.4 Packing group

ADR, IMDG, IATA

III

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Danger code (Kemler):

Warning: Flammable liquids.

EMS Number:

33

F-E,S-E

**14.7 Transport in bulk according to Annex II
 of Marpol and the IBC Code**

Not applicable.

Transport/Additional information:

ADR

Limited quantities (LQ)

5L

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 1000
 ml

Transport category

3

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 1993 FLAMMABLE LIQUID, N.O.S.
 (ISOPROPANOL (ISOPROPYL ALCOHOL)), 3, III

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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) 2015/830

CLP Regulation 1272/2008/EC

Constituents of the mixture that fall within the scope of REACH Regulation 1907/2006/EC, have been (pre)-registered from their suppliers.

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

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.

Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H336 May cause drowsiness or dizziness.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

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 MSDS:



SUSTCHEM Engineering Ltd
REACH & Chemical Services Department
144, 3rd Septemvriou, GR 112 51, Athens, Greece
Tel.: +30 210 8252510 Fax: +30 210 8252575
E-mail: info@suschem.gr
Website: www.sustchem.gr

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Abbreviations and acronyms:

ADR: Accord européen sur le transport 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)

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, Hazard Category 2

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1