

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: MEDAPROTECT

Registration number: Not applicable-Mixture of substances

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: Disinfection of 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:



GHS05 corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation EC No 1272/2008 CLP:

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

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Hazard pictograms:

GHS05 GHS07 GHS09

Signal word: Danger**Hazard-determining components of labelling:**

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
 didecyldimethylammonium chloride
 Isotridecanol, ethoxylated

Hazard statements:

H302 Harmful if swallowed.
 H314 Causes severe skin burns and eye damage.
 H400 Very toxic to aquatic life.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.
 P102 Keep out of reach of children.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P264 Wash thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P310 Immediately call a POISON CENTER/doctor.
 P321 Specific treatment (see on this label).
 P363 Wash contaminated clothing before reuse.
 P391 Collect spillage.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

EUH208 Contains Fir, Abies sibirica, ext.. May produce an allergic reaction.

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

non-ionic surfactants	5 - 15%
disinfectants	

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

PBT: Not applicable.

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vPvB: Not applicable.

















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SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous Ingredients:

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)	2.5-<10%
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	2.5-<10%
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	2.5-<10%
CAS: 69011-36-5 NLP: 500-241-6	Isotridecanol, ethoxylated  Eye Dam. 1, H318;  Acute Tox. 4, H302	2.5-<10%
CAS: 91697-89-1 EINECS: 294-351-9	Fir, Abies sibirica, ext.  Flam. Liq. 3, H226;  Asp. Tox. 1, H304;  Aquatic Acute 1, H400;  Aquatic Chronic 1, H410;  Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-<1%

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.
Take affected persons out into the fresh air.

After inhalation:

Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
Seek medical treatment in case of complaints.

After skin contact:

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

After eye contact:

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids.
Check for and remove any contact lenses.
Continue to rinse for at least 10 minutes.
Get medical attention if irritation occurs.

After swallowing:

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

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Do not induce vomiting; call for medical help immediately.
Never give anything by mouth to an unconscious person.
Rinse mouth and lips with plenty of water if the subject is conscious, then hospitalize.

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, powder or water spray. Fight larger fires with water spray.

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.

Avoid formation of dust.

Avoid contact with spilled material.

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

Avoid contact with skin and eyes.

Wear protective clothing.

Ensure adequate ventilation.

6.1.1 For non-emergency personnel

Keep away from ignition sources.

Use personal protective equipment.

6.1.2 For emergency responders

Use chemicals resistant gloves.

Use safety goggles, in case of contact with the eyes.

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

Do not allow to penetrate the ground/soil.

6.3 Methods and material for containment and cleaning up:

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

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Send for recovery or disposal in suitable receptacles.

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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.
 Keep receptacles tightly sealed.
 Prevent formation of aerosols.
 Avoid splashes or spray in enclosed areas.
 Store in cool, dry place in tightly closed receptacles.
 Avoid contact with skin, eyes and clothing.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:**

Store in a cool location.
 Prevent any seepage into the ground.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Keep container tightly sealed.
 Store under lock and key and with access restricted to technical experts or their assistants only.
 Store under lock and key and out of the reach of children.

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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57-55-6 propane-1,2-diol

WEL (Great Britain)	Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates
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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.
 Immediately remove all soiled and contaminated clothing.
 Wash hands before breaks and at the end of work.
 Do not inhale gases / fumes / aerosols.

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Avoid contact with the eyes.
 Do not eat or drink while working.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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 to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

PVC gloves

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: blue

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Odour:	Aromatic
Odour threshold:	Not determined
pH value:	12.0-12.8
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
Flash point:	Not determined
Flammability (solid, gaseous):	Not applicable
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined
Upper:	Not determined
Vapour pressure:	Not determined
Density:	Not determined
Relative density	Not determined
Vapour density	Not determined
Evaporation rate	Not determined
Solubility in / Miscibility with water:	Fully miscible
Partition coefficient (n-octanol/water):	Not determined
Viscosity:	
Dynamic:	Not determined
Kinematic:	Not determined
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided Stable at environment temperature.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous decomposition products No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Harmful if swallowed.

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LD/LC50 values relevant for classification:

Oral	LD50	597 mg/kg
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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)

7173-51-5 didecyldimethylammonium chloride

Oral	LD50	84 mg/kg (rat)
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Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/irritation

Causes serious eye damage.

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.**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.**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.**Ecotoxicological effects:****Remark:** Toxic for fish**Additional ecological information:****General notes:**

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Also poisonous for fish and plankton in water bodies.

The product contains materials that are harmful to the environment.

12.5 Results of PBT and vPvB assessment**PBT:** Not applicable.**vPvB:** Not applicable.**12.6 Other adverse effects** No further relevant information available.

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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

UN1760

14.2 UN proper shipping name ADR

1760 CORROSIVE LIQUID, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine), ENVIRONMENTALLY HAZARDOUS

IMDG CORROSIVE LIQUID, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1.3-diamine, SODIUM NITRITE), MARINE POLLUTANT

IATA CORROSIVE LIQUID, N.O.S. (N-(3-aminopropyl)-N-dodecylpropane-1.3-diamine)

14.3 Transport hazard class(es)

ADR, IMDG



Class
Label

8 Corrosive substances.
8

IATA



Class
Label

8 Corrosive substances.
8

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14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards:	Product contains environmentally hazardous substances: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
Marine pollutant:	Yes
Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user Danger code (Kemler): EMS Number: Segregation groups	Warning: Corrosive substances. 80 F-A,S-B Nitrites and their mixtures
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	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	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 1760 CORROSIVE LIQUID, N.O.S. (N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE), 8, II, ENVIRONMENTALLY HAZARDOUS

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 E1 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t

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Qualifying quantity (tonnes) for the application of upper-tier requirements 200 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.

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

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

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Department issuing MSDS:



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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

Flam. Liq. 3: Flammable liquids, Hazard Category 3

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

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Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
Asp. Tox. 1: Aspiration hazard, Hazard Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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