

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

Printing date 04.12.2019

Version number 2

Revision: 04.12.2019

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

1.1 Product identifier

Trade name: **MEDASPIR**

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 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.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:



GHS05 corrosion

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

Eye Dam. 1 H318 Causes serious eye damage.

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:



GHS05

Signal word: Danger

Hazard-determining components of labelling:

dimethyldioctylammonium chloride

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides

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Hazard statements:

H314 Causes severe skin burns and eye damage.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P260 Do not breathe dusts or mists.
P264 Wash thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P280 Wear eye protection / face protection.
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 [or shower].
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

| | |
|------------------------------------|-----------|
| cationic surfactants | ≥5 - <15% |
| non-ionic surfactants, phosphates | <5% |
| disinfectants, perfumes (Limonene) | |

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.

Ingredients according Regulation (EU) 830/2015:

| | | |
|--------------------------------------|--|----------|
| CAS: 5538-94-3 | dimethyldioctylammonium chloride ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302 | 2.5-<10% |
| 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) | 1-≤2.5% |
| CAS: 85409-22-9 EINECS: 287-089-1 | Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312 | 1-≤2.5% |

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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.

If skin irritation continues, consult a doctor.

Remove contaminated clothing.

Wash contaminated clothing before use.

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.

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, powder or water spray. Fight larger fires with 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.

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Avoid contact with spilled material.

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

Avoid contact with skin and eyes.

6.1.1 For non-emergency personnel

Ensure sufficient ventilation.

Use personal protective equipment.

Avoid contact with skin and eyes.

6.1.2 For emergency responders

Ventilate area of leak or spill.

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

Use chemicals resistant gloves.

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).

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

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.

Keep receptacles tightly sealed.

Prevent formation of aerosols.

Avoid contact with skin, eyes and clothing.

Do not breathe dust. Do not ingest.

Information about fire - and explosion protection:

Protect against electrostatic charges.

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: 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.

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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:

CAS: 57-55-6 Propylene glycol

| | |
|---------------------|--|
| WEL (Great Britain) | Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates |
|---------------------|--|

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 eat, drink or smoke while using the product.

Respiratory protection:



Use suitable respiratory protective device in case of insufficient ventilation.

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.

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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 (EN 166).

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: | Characteristic |
| Odour threshold: | Not determined |

pH value: 12.3-12.8
Not determined

Melting point/freezing point: Not determined

Initial boiling point and boiling range: Not determined

Flash point: >60 °C

Flammability (solid, gas): Not applicable

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: 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

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Density: Not determined
Relative density at 20 °C 1.031 g/cm³
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 Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

| | | |
|--------|------|-------------|
| Oral | LD50 | 3326 mg/kg |
| Dermal | LD50 | 73333 mg/kg |

CAS: 5538-94-3 dimethyldioctylammonium chloride

| | | |
|------|------|------------------|
| Oral | LD50 | 1025 mg/kg (rat) |
|------|------|------------------|

CAS: 85409-22-9 Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides

| | | |
|------|------|-----------------|
| Oral | LD50 | 400 mg/kg (rat) |
|------|------|-----------------|

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.

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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 No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

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

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values.

A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

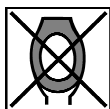
SECTION 13: Disposal considerations

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.

Contact manufacturer for recycling information.

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

Packaging may be reused or recycled after cleaning.

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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.
IMDG, IATA CORROSIVE LIQUID, N.O.S.

14.3 Transport hazard class(es)
ADR, IMDG, IATA



Class 8 Corrosive substances.
Label 8

14.4 Packing group
ADR, IMDG, IATA II

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user Warning: Corrosive substances.

Danger code (Kemler): 80
EMS Number: F-A,S-B
Stowage Category B
Stowage Code SW2 Clear of living quarters.

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., 8, II

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SECTION 15: Regulatory information

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

Detergent Regulation No. 648/2004/EC

CLP Regulation No. 1272/2008/EC

Regulation (EU) 2015/830

Regulation REACH (EC) 1907/2006

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

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.

Relevant phrases

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

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

H400 Very toxic to aquatic life.

Department issuing SDS:



SUSTCHEM S.A.

REACH & Chemical Services Department

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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)

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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

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

*** Data compared to the previous version altered.**

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