

Printing date 03.02.2023 Version number 2 (replaces version 1) Revision: 03.02.2023

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

1.1 Product identifier

Trade name: MEDABUR

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:

Ready-to-use disinfectant for burs and rotary instruments.

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:

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.

Hazard pictograms: Void

Signal word: Void

Hazard statements:

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.

P273 Avoid release to the environment.

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

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.



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SECTION 3: Composition/information on ingredients 3.2 Mixtures Description: Mixture: consisting of the following components.					
CAS: 67-63-0 EINECS: 200-661-7 Index number: 603-117-00-0 Reg.nr.: 01-2119457558-25- XXXX	propan-2-ol Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	≥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. 1C, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1,	≥0.25-<1%			

Additional information: For the wording of the listed hazard phrases refer to section 16.

H410 (M=1)

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 discomfort call a doctor.

After inhalation:

If breathing is difficult, remove to fresh air. Restore breathing. Keep warm and quiet.

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.

Remove contaminated clothing.

If skin irritation continues, consult a doctor.

After eve 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 15 minutes.

Get medical attention if irritation occurs.

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.



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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 contact with skin and eyes.

Ensure adequate ventilation.

6.1.1 For non-emergency personnel

Avoid contact with dripping or leaking material

Use personal protective equipment.

6.1.2 For emergency responders

First-aid responders must wear protectice clothing, gloves, goggles and respiratory device with filter type A.

6.2 Environmental precautions: No special measures required.

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.

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 and eyes.

Wash contaminated clothing before reuse.

Wash your hands thoroughly after handling.

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

Avoid splashes or spray in enclosed areas.

Information about fire - and explosion protection:

Keep away from heat, sparks, open flames and hot surfaces.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in cool, dry conditions in well sealed receptacles.

Requirements to be met by storerooms and receptacles: Store in a cool location.

Information about storage in one common storage facility: Store away from oxidising agents.

Further information about storage conditions: 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:

CAS: 67-63-0 propan-2-ol

WEL (Great Britain) Short-term value: 1250 mg/m³, 500 ppm

Long-term value: 999 mg/m³, 400 ppm

DNELs

(CAS: 67-63-0) Propan-2-ol, Isopropanol

Workers

Long-term systemic effects, dermal: 888 mg/kg Long-term systemic effects, inhalation: 500 mg/m³

Consumers

Long-term systemic effects, dermal: 319 mg/kg Long-term systemic effects, inhalation: 89 mg/m³ Long-term systemic effects, oral: 26 mg/kg

8.2 Exposure controls

8.2.1. Appropriate engineering controls Provide adequate ventilation.

Individual protection measures, such as personal protective equipment General protective and hygienic measures:

Avoid contact with skin and eyes.

Remove contaminated clothes and wash before reusing them.

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

Be sure to clean skin thoroughly after work and before breaks.

Respiratory protection:



Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection



Wear suitable gloves (EN 374)

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

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

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

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.

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Penetration time of glove material

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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
Colour:
Transparent
Odour:
Characteristic
Odour threshold:
Melting point/freezing point:
Not determined
Not determined

Boiling point or initial boiling point and

boiling rangeNot determinedFlammabilityNot applicable

Lower and upper explosion limit

Lower:
Upper:
Not determined
Flash point:
Not Flammable
Auto-ignition temperature:
Not determined
Not determined
Not determined
Not determined

pH 9.3-11

Viscosity:

Kinematic viscosity Dynamic:Not determined
Not determined

Solubility

water: Not determined

Partition coefficient n-octanol/water (log

Value)Not determined **Vapour pressure:**Not determined

Density and/or relative density

Density:Not determinedRelative densityNot determinedVapour densityNot determined

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9.2 Other information

Appearance:

Form: Liquid

Important information on protection of health

and environment, and on safety.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Cloud point / clarification point:

Oxidising properties Not classified as an oxidant according to CLP

Regulation 1272/2008/EC.

Evaporation rateNot determined

Information with regard to physical hazard

classes

Explosives Void Flammable gases Void **Aerosols** Void Oxidising gases Void Gases under pressure Void Flammable liquids Void 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

SECTION 10: Stability and reactivity

- 10.1 Reactivity Stable under normal conditions
- 10.2 Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

Stable at environment temperature.

- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- 10.4 Conditions to avoid Avoid heat, flames, sparks, other sources of ignition.
- 10.5 Incompatible materials Oxidizing agents
- 10.6 Hazardous decomposition products No dangerous decomposition products known.



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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 v	alues	relevant 1	for c	lassification:
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ATE (Acute Toxicity Estimates)

Oral LD50 43,500 mg/kg

CAS: 67-63-0 propan-2-ol

 Oral
 LD50
 5,840 mg/kg (rat)

 Dermal
 LD50
 13,900 mg/kg (rabbit)

 Inhalative
 LC50(6h)
 > 10,000 ppm (rat)

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

Oral LD50 261 mg/kg (rat)
Dermal LD50 >600 mg/kg (rat)

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

Serious eye damage/irritation 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:

CAS: 67-63-0 propan-2-ol

EC50 (72h) 1,800 mg/l (algae)

LC50 (96h) 9,640-10,000 mg/l (Pimephales promelas) (Fish, Acute Toxicity Test) EC50(24h) 9,714 mg/l (Daphnia magna) (Daphnia sp. Acute Immobilisation Test)

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

LC50 (96h) 0.431 mg/l (fis)

EC10 0.0095 mg/L (algae)

NOEC(10d) | 127.14 mg/kg (Corophium volutator)

NOEC (28d) 320 mg/kg (Chironomus riparius)

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12.2 Persistence and degradability

(CAS: 67-63-0) propan-2-ol

BOD 5: 53 % ThOD: 72 %

12.3 Bioaccumulative potential

(CAS: 67-63-0) Propan-2-ol

Partition coefficient n-octanol/water: 0,05 No bioaccumulation expected (log Pow < 1).

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes:

Toxic for aquatic organisms

Not known to be hazardous to water.

SECTION 13: Disposal considerations

13.1 Waste treatment methods Recommendation



Dispose according to National Regulations.

Contact manufacturer for recycling information.

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 numberNot classified as dangerous for transport.

ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class Void

14.4 Packing group

ADR, IMDG, IATA Void

14.5 Environmental hazards: Not applicable.

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14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to

IMO instruments

Not applicable.

Transport/Additional information: If IATA criteria a

If IATA criteria are met, product is classified as:

ID Number:8000

Class: 9

Proper Shipping name: Consumer Commodity

UN "Model Regulation": Void

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.

Council Directive 94/33/EC on the protection of young people at work, as ammended.

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 ammended

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

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).

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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.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H319 Causes serious eve 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.

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.

Classification according to Regulation (EC) No 1272/2008

Hazardous to the aquatic environment - longterm (chronic) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

Department issuing SDS:



SUST SUSTCHEM S.A.

REACH & Chemical Services Department

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Version number of previous version: 1

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) 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 Acute Tox. 3: Acute toxicity - Category 3

Skin Corr. 1C: Skin corrosion/irritation - Category 1C Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) - Category 2

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Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

* Data compared to the previous version altered.

ΕN