

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: MEDAZYM

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: Cleaning product 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:

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

Labelling according to Regulation EC No 1272/2008 CLP: Void

Hazard pictograms: Void

Signal word: Void

Hazard statements: Void

Precautionary statements

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

P102 Keep out of reach of children.

Additional information:

EUH208 Contains Subtilisin. May produce an allergic reaction.

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

non-ionic surfactants	< 5%
preservation agents ("2-BROMO-2-NITROPROPANE-1,3-DIOL"), enzymes	

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 Chemical characterisation: Mixtures

Description: Cleansing agent

Dangerous Ingredients: Void

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Take affected persons out into the fresh air.
 Never give anything by mouth to an unconscious person.

After inhalation:

In case of unconsciousness place patient stably in side position for transportation.
 Seek medical treatment in case of complaints.

After skin contact: Generally the product does not irritate the skin.

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.
 Use fire extinguishing methods suitable to surrounding conditions.

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.

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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:**

Ensure adequate ventilation.

Avoid contact with spilled material.

Avoid contact with skin and eyes.

Avoid inhalation of vapors.

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

6.1.1 For non-emergency personnel Ensure sufficient ventilation.**6.1.2 For emergency responders** Use safety goggles, in case of contact with the 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).

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**

Keep receptacles tightly sealed.

Avoid prolonged exposure with skin

Avoid contact with skin, eyes and clothing.

Keep away from heat and direct sunlight.

Ensure good ventilation/exhaustion at the workplace.

Store in cool, dry place in tightly closed receptacles.

Use in well ventilated areas.

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:**

Keep container tightly closed when not in use

Store in a cool location.

Information about storage in one common storage facility: Not required.**Further information about storage conditions:** None.**7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

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:

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Do not inhale dust / smoke / mist.

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

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

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.

Eye protection:



Safety glasses

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

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Colour:	transparent - yellowish
Odour:	Odourless
Odour threshold:	Not determined
pH value:	6-6,5
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:	Not determined
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.

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

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Serious eye damage/irritation Potentially irritant**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.**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, 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.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
UN "Model Regulation":	Void

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 from their suppliers.

Directive 2012/18/EU**Named dangerous substances - ANNEX I** 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).

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.

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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)
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative

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