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

1.1 Product identifier

Trade name: NOSOCLEAN

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:

Alkaline detergent for the reprocessing of surgical instruments & equipment.

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:

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

P102 Keep out of reach of children.

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

non-ionic surfactants <5% enzymes

2.3 Other hazards

Results of PBT and vPvB assessment

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

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3.2 Mixtures

Description: Mixture: consisting of the following components.

| Ingredients according Regulation (EU) 2020/878: | | | | |
|---|--|-------|--|--|
| CAS: 160875-66-1 | 1-Heptanol, 2-propyl-, 7EO | <1% | | |
| EC number: 605-233-7 | 🥎 Eye Dam. 1, H318; 🗘 Acute Tox. 4, H302 | | | |
| CAS: 9014-01-1 | Subtilisin | <0.1% | | |
| EINECS: 232-752-2 | 🕸 Resp. Sens. 1, H334; 📀 Eye Dam. 1, H318; 🕦 Skin Irrit. | | | |
| Index number: 647-012-00-8 | 2, H315; STOT SE 3, H335 | | | |

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Take affected persons out into the fresh air.

In all cases call a doctor.

After inhalation:

Keep patient calm, remove to fresh air.

Keep person warm and at rest.

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.

After eye contact:

Rinse opened eye for several minutes under running water.

Remove contact lenses and continue rinsing for several minutes

If symptoms persist, consult a doctor.

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.

Never give anything by mouth to an unconscious person.

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.

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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 the skin, eyes and clothing.

6.1.1 For non-emergency personnel Avoid contact with dripping or leaking material

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: 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 ael).

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

Do not eat, drink or smoke at the workplace.

Avoid contact with skin, eyes and clothing.

Wash hands before each break and after finishing work.

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

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.

Keep containers closed.

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

Further information about storage conditions:

Protect from heat and direct sunlight.

Store under lock and key and out of the reach of children.

Recommended storage temperature: 5°C - 35°C

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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Take appropriate protective measures with regard to the handling of chemicals and mixtures.

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

Wash hands before breaks and at the end of work.

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

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

Respiratory protection: Not required.

Hand protection



Protective gloves resistant to chemicals (standard EN 374-1)

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

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

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 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



Gogales recommended during refilling

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Safety data sheet

complying with Regulation 1907/2006/EC (REACH Regulation), EU 2020/878 and Regulation No 1272/2008/EC (CLP)

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Body protection:

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Wear appropriate protective clothing.

Environmental exposure controls

Prevent enter of the product into drains, surface and groundwater and soil.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state Liquid

Colour:Not determinedOdour:CharacteristicOdour threshold:Not 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
Phat 20 °C
9.5-10.5

Viscosity:

Kinematic viscosity Dynamic at 20 °C:Not determined
<50 mPas</p>

Solubility

water: Fully miscible

Partition coefficient n-octanol/water (log

value)Not determinedVapour pressure:Not determined

Density and/or relative density

Density at 20 °C:1.05 g/cm³Relative densityNot determinedVapour densityNot determined

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.

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| Evaporation rate | Not determined | (Contd. of page 5) |
|--|----------------|--------------------|
| | | |
| 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 Material is stable under normal conditions.

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** Avoid heat, sparkles, naked flame or other sources of ignition.
- 10.5 Incompatible materials

Do not use in combination with other detergents, soaps or disinfectants.

10.6 Hazardous decomposition products No dangerous decomposition products known.

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 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 12,319 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.

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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: 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 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes: Not known to be hazardous to water.

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.

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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 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 Maritime transport in bulk according to

IMO instruments Not applicable.

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.648/2004 on detergents, as amended.

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed.

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.

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Safety data sheet complying with Regulation 1907/2006/EC (REACH

Regulation), EU 2020/878 and Regulation No 1272/2008/EC (CLP)

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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).

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

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eve damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

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 SDS:

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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

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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 Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Resp. Sens. 1: Respiratory sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

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