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

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

1.1 Product identifier

Trade name: NEUTRALKAN

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:
Acidic neutralizer for automated reprocessing of surgical instruments and 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:

GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

GHS07

Acute Tox. 4 H302 Harmful if swallowed.

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 GHS07

Signal word: Danger

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Hazard-determining components of labelling:
orthophosphoric acid.

Hazard statements:
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.

Precautionary statements

P102	Keep out of reach of children.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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	
phosphates	≥30%

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures
Description: Mixture: consisting of the following components.

Ingredients according Regulation (EU) 2020/878:		
CAS: 7664-38-2 EINECS: 231-633-2 Index number: 015-011-00-6	orthophosphoric acid. Met. Corr.1, H290; Skin Corr. 1B, H314; Acute Tox. 4, H302 Specific concentration limits: Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	30-<60%
CAS: 5949-29-1 EINECS: 201-069-1	Citric Acid Eye Irrit. 2, H319	≥2.5-<10%

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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.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
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 the product causes burning or chilling, do not remove the clothing as this may aggravate the injury if the garment sticks to the skin. If blisters are formed on the skin, they should never drop because the risk of contamination will increase.
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.
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.
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.

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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.
Ensure adequate ventilation.
Wear protective clothing.
6.1.1 For non-emergency personnel Avoid contact with dripping or leaking material
6.1.2 For emergency responders
Wear protective equipment. Keep unprotected persons away.
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 gel).
Use neutralising agent.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
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.
Ensure good ventilation.
Do not eat, drink or smoke at the workplace.
Keep away from heat and direct sunlight.
Wash hands before each break and after finishing work.
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: 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: Not required.
Further information about storage conditions:
Keep container tightly sealed.
Store under lock and key and out of the reach of children.
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:	
CAS: 7664-38-2 orthophosphoric acid.	
IOELV (EU)	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³
WEL (Great Britain)	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

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:
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with skin and eyes.
Contaminated clothes must be washed before reuse.
Ensure adequate ventilation during use.
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.

Hand protection

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

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.

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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 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

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	
Physical state	Liquid
Colour:	Not determined
Odour:	Characteristic
Odour threshold:	Not determined
Flammability	Not applicable
Lower and upper explosion limit	
Lower:	Not determined
Upper:	Not determined
Flash point:	Not Flammable
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
pH at 20 °C	<2
Viscosity:	
Kinematic viscosity	Not determined
Dynamic at 20 °C:	<50 mPas
Solubility	
water:	Fully miscible
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure:	Not determined
Density and/or relative density	
Density at 20 °C:	1.45 g/cm³
Relative density	Not determined
Vapour density	Not 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 oxidising
Evaporation rate	Not 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 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 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 hazard classes as defined in Regulation (EC) No 1272/2008
Acute toxicity
Harmful if swallowed.

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LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	840 mg/kg

CAS: 5949-29-1 Citric Acid		
Oral	LD50	11,700 mg/kg (gnp)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h (vapour)	5,800 mg/l

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.
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: 5949-29-1 Citric Acid	
EC50 (72h)	425 mg/l (algae)
EC50 (48h)	440 mg/l (fis)

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.

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12.7 Other adverse effects
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 decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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.

*

SECTION 14: Transport information

14.1 UN number or ID number
ADR, IMDG, IATA UN1805
14.2 UN proper shipping name
ADR 1805 PHOSPHORIC ACID, SOLUTION
IMDG, IATA PHOSPHORIC ACID, SOLUTION
14.3 Transport hazard class(es)

ADR, IMDG, IATA

Class 8 Corrosive substances.
Label 8
14.4 Packing group
ADR, IMDG, IATA III
14.5 Environmental hazards: Not applicable.
14.6 Special precautions for user Warning: Corrosive substances.
Hazard identification number (Kemler code): 80
EMS Number: F-A,S-B
Segregation groups (SGG1) Acids

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Stowage Category	A
Segregation Code	SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	

ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
Transport category	3
Tunnel restriction code	E

IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III

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.
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.

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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

H290 May be corrosive to metals.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H319 Causes serious eye 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.

Classification according to Regulation (EC) No 1272/2008

Acute toxicity - oral Skin corrosion/irritation Serious eye damage/irritation	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:

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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)

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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
Met. Corr.1: Corrosive to metals – Category 1
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
*** Data compared to the previous version altered.**