

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

Printing date 05.10.2022

Version number 1

Revision: 05.10.2022

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

1.1 Product identifier

Trade name: CITRALKAN

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 neutralizing agent for surgical instrument reprocessing.

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:



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

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:



GHS07

Signal word: Warning

Hazard-determining components of labelling:

citric acid

Hazard statements:

H319 Causes serious eye irritation.

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H335 May cause respiratory irritation.

Precautionary statements

P261 Avoid breathing mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P280 Wear eye protection / face protection
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.
P312 Call a POISON CENTER/doctor if you feel unwell.
P337+P313 If eye irritation persists: Get medical advice/attention.
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture: consisting of the following components.

Ingredients according Regulation (EU) 2020/878:

CAS: 77-92-9 EINECS: 201-069-1 Index number: 607-750-00-3 Reg.nr.: 01-2119457026-42-XXXX	citric acid ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	≥40-<60%
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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Take affected persons out into the fresh air.

Seek immediate medical advice.

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:

Wash the skin immediately with soap and water.

In case of skin irritation, consult a physician.

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 15 minutes.

Get medical attention if irritation occurs.

Avoid strong water jet-risk of cornea damage, consult a doctor.

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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.

Foam

Sand or soil

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.

Wear eye protection.

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.

Avoid inhalation of vapors or spray.

For information on protective measures, see sections 7 and 8.

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 protective clothing, gloves, goggles and respiratory device with filter type A.

6.2 Environmental precautions:

Prevent the product from being discharged into rivers or the aquatic environment.

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.

Ensure adequate ventilation.

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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with eyes, skin and clothing.
Do not eat, drink or smoke during the usage of the product.
Avoid inhaling vapors.
Wash hands before each break and after finishing work.
Open and handle receptacle with care.
Observe the general safety regulations when handling chemicals.

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.

Further information about storage conditions: Keep container tightly sealed.

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:

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

PNECs

(CAS: 77-92-9) Citric acid
PNEC (fresh water) 0.44 mg/l
PNEC (marine water) 0.044 mg/l
PNEC (fresh water) precipitate 34.6 mg/kg dwt
Sludge PNEC (marine water) 3.46 mg/kg dwt
PNEC soil 33.1 mg/kg dwt
Sewage treatment plant PNEC > 1000 mg/l

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:

Keep away from foodstuffs, beverages and feed.
Avoid contact with skin and eyes.
Do not eat, drink or smoke while using the product.
Do not breathe vapours or mists.
Wash hands before breaks and at the end of work.

Respiratory protection:



In conditions of inadequate ventilation, use an appropriate respirator.

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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.

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:

Colourless

Odour:

Odourless

Odour threshold:

Not determined

Flammability

Not applicable

Lower and upper explosion limit

Lower:

Not determined

Upper:

Not determined

Flash point:

>93 °C (CAS: 77-92-9 citric acid)

Auto-ignition temperature:

Not Flammable

Decomposition temperature:

Not determined

pH at 20 °C

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Viscosity:

Kinematic viscosity Not determined

Dynamic: Not determined

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: 1.15 g/cm³

Relative density Not determined

Vapour density Not 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 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.

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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 Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

CAS: 77-92-9 citric acid

Oral	LD50	5,040 mg/kg (mouse)
		11,700 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

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

Serious eye damage/irritation Causes serious eye irritation.

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

The product is classified as Specific Target Organ Toxicity after single exposure Category 3
 May cause respiratory irritation.

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: 77-92-9 citric acid

EC50 (72h)	120 mg/l (daphnia magna)
LC50 (96h)	440-706 mg/l (Leuciscus Idus)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential

(CAS: 77-92-9) Citric acid

BCF: 0,01

Partition coefficient n-octanol/water: -1,72 at 20 °C

12.4 Mobility in soil No further relevant information available.

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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 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.

European waste catalogue

HP4 Irritant - skin irritation and eye damage

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA Void

14.2 UN proper shipping name

ADR, 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

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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

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.

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

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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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:

 SUSTCHEM S.A.
REACH & Chemical Services Department
A: 144, 3rd Septemvriou, GR 112 51 | Athens, Greece
T: +30 210 8252510 | F: +30 210 8252575
W: www.sustchem.gr | E: info@suschem.gr

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)
PNEC: Predicted No-Effect Concentration (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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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