



Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.10.2024

Version number 1.00

Revision: 10.10.2024

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

- **Product identifier**
- **Trade name:** Chlorhexidine digluconate solution (aqueous, ca. 20%), API
- **Article number:** 4178
- **CAS Number:**
18472-51-0
- **EC number:**
242-354-0
- **Registration number** The substance is exempt from REACH-registration.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- **Uses advised against** No relevant information available.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY
- **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
- **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Eye Dam. 1 H318 Causes serious eye damage.
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.

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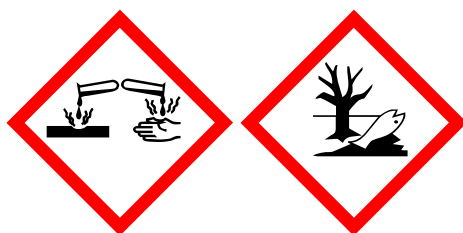
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Hazard pictograms

GHS05

GHS09

Signal word Danger**Hazard statements**

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P391 Collect spillage.

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

Other hazards**Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**Determination of endocrine-disrupting properties** Not applicable.

3 Composition/information on ingredients

Substances**CAS No. Description**

CAS: 18472-51-0 Chlorhexidine digluconate

Identification number(s)**EC number:** 242-354-0

4 First aid measures

Description of first aid measures**After inhalation:** Supply fresh air; consult doctor in case of complaints.**After skin contact:** Generally the product does not irritate the skin.**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.**After swallowing:** If symptoms persist consult doctor.**Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.
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5 Firefighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
 - **Special hazards arising from the substance or mixture** No further relevant information available.
 - **Advice for firefighters**
 - **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
 - **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.
-

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
 - **Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
 - **Methods and material for containment and cleaning up:**
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
 - **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.
-

7 Handling and storage

- **Precautions for safe handling** No special precautions are necessary if used correctly.
 - **Information about fire - and explosion protection:** No special measures required.
 - **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:**
No special requirements.
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Keep container tightly sealed.
 - **Storage class:** TRHS 510: 8 B Non-combustible corrosive substances
 - **Specific end use(s)** No further relevant information available.
-

8 Exposure controls/personal protection

- **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.

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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes.
 - Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Hand protection** Protective gloves
- **Material of gloves**
 - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 - 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.
 - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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.
- **Eye/face protection** Tightly sealed goggles

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** Clear
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 169 °C
- **Boiling point or initial boiling point and boiling range** 288 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** 5.5–7
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Soluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.

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· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.32 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Other information	
· Appearance:	
· Form:	Not determined.
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· 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

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

· Information on hazard classes as defined in Regulation (EC) No 1272/2008

- **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.
- **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.

· Information on other hazards

· Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

· Toxicity

· Aquatic toxicity:

EC50 397 mg/L (algae)

980 mg/L (invertebrates)

- **Persistence and degradability** No further relevant information available.

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

· Results of PBT and vPvB assessment

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

· Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

The product does not contain substances with endocrine disrupting properties.

· Other adverse effects

- **Remark:** Very toxic for fish

· Additional ecological information:

· General notes:

Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

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Very toxic for aquatic organisms

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
 - **European waste catalogue**
HP4 Irritant - skin irritation and eye damage
HP14 Ecotoxic
 - **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to local regulations.
-

14 Transport information

- **UN number or ID number**
- **ADR, IMDG, IATA** UN3082
- **UN proper shipping name**
- **ADR** 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Chlorhexidine digluconate)
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Chlorhexidine digluconate)
- **IATA** Environmentally hazardous substance, liquid, n.o.s. (Chlorhexidine digluconate)
- **Transport hazard class(es)**
- **ADR, IMDG, IATA**
- **Class** 9 Miscellaneous dangerous substances and articles.
- **Label** 9
- **Packing group**
- **ADR, IMDG, IATA** III
- **Environmental hazards:**
- **Marine pollutant:** Symbol (fish and tree)
- **Special marking (ADR):** Symbol (fish and tree)
- **Special marking (IATA):** Symbol (fish and tree)
- **Special precautions for user** Warning: Miscellaneous dangerous substances and articles.
- **Hazard identification number (Kemler code):** 90
- **EMS Number:** F-A,S-F
- **Maritime transport in bulk according to IMO instruments** Not applicable.
- **Transport/Additional information:**
- **ADR**
- **Limited quantities (LQ)** 5L
- **Transport category** 3
- **Tunnel restriction code** (-)

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- **IMDG**
 - **Limited quantities (LQ)** 5L
 - **UN "Model Regulation":** UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (CHLORHEXIDINE DIGLUCONATE), 9, III
-

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **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**
Substance is not listed.
 - **National regulations:**
 - **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 8 B Non-combustible corrosive substances
 - **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.
-

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- **Reasons for alterations** This version replaces all old versions.
 - **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
 - CAS: Chemical Abstracts Service (division of the American Chemical Society)
 - MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 - 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
-