

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 08.03.2023

Version number 3.00 (replaces version 2.00)

Revision: 08.03.2023

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

- **Product identifier**
- **Trade name:** Chlorhexidindigluconat-Lösung (wässrig, ca. 20%), API
- **Article number:** 4178
- **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 product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05



GHS09

- **Signal word** Danger
- **Hazard statements**  
H318 Causes serious eye damage.

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H410 Very toxic to aquatic life with long lasting effects.

**· Precautionary statements**

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read carefully and follow all instructions.
- 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

**· Mixtures****· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 18472-51-0 Chlorhexidine digluconate 20.0%  
EINECS: 242-354-0 Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

**· Non-hazardous components** CAS: 7732-18-5 Water**· Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

**· Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### 5 Firefighting measures

**· Extinguishing media****· Suitable extinguishing agents:**

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

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- **Special hazards arising from the substance or mixture**  
not combustible  
During heating or in case of fire poisonous gases are produced.
  - **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.  
Avoid contact with the substance.
  - **Environmental precautions:**  
Do not allow to enter sewers/ surface or ground water.  
Inform respective authorities in case of seepage into water course or sewage system.
  - **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 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** Thorough dedusting.
  - **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:**  
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.
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### 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.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.

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- **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:** Dust protection mask.
- **Hand protection** Protective gloves
- **Material of gloves**
  - 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
  - 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.
- **Eye/face protection** Tightly sealed goggles

## \* 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **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 (CAS: 18472-51-0 Chlorhexidine digluconate)
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Soluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.
- **Density and/or relative density**
- **Density at 20 °C:** 1.32 g/cm<sup>3</sup>
- **Relative density** Not determined.
- **Vapour density** Not applicable.

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· Particle characteristics	Not determined
· Other information	
· Appearance:	
· Form:	Fluid
· 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.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
	Void
· Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
· Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
· Self-reactive substances and mixtures	Void
	Void
· Pyrophoric liquids	Void
	Void
· Pyrophoric solids	Void
	Void
· Self-heating substances and mixtures	Void
	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void
· Oxidising solids	Void
	Void
· Organic peroxides	Void
	Void
· Corrosive to metals	Void
	Void

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- **Desensitised explosives** Void  
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:** organic chlorine compounds
- 

### \* 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.
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### \* 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity:**  
**CAS: 18472-51-0 Chlorhexidine digluconate**  
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.
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**· 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.

**· Other adverse effects****· Remark:** Very toxic for fish**· Additional ecological information:****· General notes:**

Water hazard class 3 (German Regulation) (Self-assessment): 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.

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.

**· Uncleaned packaging:****· Recommendation:** Disposal must be made according to local regulations.**· Recommended cleansing agents:** Water, if necessary together with cleansing agents.**14 Transport information****· UN number or ID number**

UN3077

**· ADR, IMDG, IATA****· UN proper shipping name****· ADR**

3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1))

**· IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1), MARINE POLLUTANT

**· IATA**

Environmentally hazardous substance, solid, n.o.s. D-Gluconic acid,

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	compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1))
· <b>Transport hazard class(es)</b>	
· <b>ADR, IMDG, IATA</b>	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles.
· <b>Label</b>	9
· <b>Packing group</b>	
· <b>ADR, IMDG, IATA</b>	III
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	Symbol (fish and tree)
· <b>Special marking (ADR):</b>	Symbol (fish and tree)
· <b>Special marking (IATA):</b>	Symbol (fish and tree)
· <b>Special precautions for user</b>	Warning: Miscellaneous dangerous substances and articles.
· <b>Hazard identification number (Kemler code):</b>	90
· <b>EMS Number:</b>	F-A,S-F
· <b>Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	-
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>UN "Model Regulation":</b>	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. 9, III

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
- **REGULATION (EC) No 1907/2006 ANNEX XVII** 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.
- **National regulations:**
- **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**  
TRHS 510: 8 B Non-combustible corrosive substances

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- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.
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### 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.

- **Relevant phrases**

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **Date of previous version:** 06.03.2023

- **Version number of previous version:** 2.00

- **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)

MAL-Code: Måleteknisk Arbejdshygjensk 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

- **\* Data compared to the previous version altered.**
-