

Trade name: Chlorhexidini digluconatis sol 20%

Substance number: 072770 Version: 10 / CH Date revised: 12.04.2022

Replaces Version: 9 / CH Print date: 12.04.22

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

1.1. Product identifier

Chlorhexidini digluconatis sol 20% Item No. 07277000

Registration no.

EC No.: 242-354-0 CAS No. 18472-51-0

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Active pharmacutical substance

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG Industriestrasse 35 9100 Herisau

Telephone no. 0041 (0)71 353 58 58 E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland: 145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification ***

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Eye Dam. 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 2 H411

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008 For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms





Signal word

Danger

Hazard statements ***

H318 Causes serious eye damage. H400 Very toxic to aquatic life.



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H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/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 or doctor.

P391 Collect spillage.

P501.3 Disposal in compliance with local and national regulations.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-

tetraazatetradecanediamidine (2:1)

SECTION 3: Composition/information on ingredients ***

Hazardous ingredients

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

CAS No. 18472-51-0 EINECS no. 242-354-0

Concentration >= 10 < 25 %

Classification (Regulation (EC) No. 1272/2008)

Eye Dam. 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Concentration limits (Regulation (EC) No. 1272/2008)

Aquatic Acute 1 M = 10 M = 10 Aquatic Chronic M = 10 M = 1

Further ingredients ***

water

CAS No. 7732-18-5 EINECS no. 231-791-2

Concentration >= 50 %

Advice: [4]

Note

[4] Voluntary information

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated, soaked clothing immediately and dispose of safely. Remove affected person from danger area, lay him down. Keep warm, calm and covered up. Do not leave casualty unattended. If the patient is likely to become unconscious, place and transport in stable sideways position. Adhere to personal protective measures when giving first aid

After inhalation

Remove the casualty into fresh air and keep him calm. In case of respiratory arrest induce breathing with a respiratory device. Seek medical advice. Summon a doctor immediately. In case of respiratory arrest induce breathing with a respiratory device. Seek medical advice.



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After skin contact

Wash skin thoroughly with water (15 min.). Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately.

After ingestion

Rinse out mouth and give plenty of water to drink. Summon a doctor immediately.

4.2. Most important symptoms and effects, both acute and delayed

In the foreground the local effect stays at first, characterized by a quickly in the depth moving damage of the tissue. Irritating to respiratory system. Danger of blindness. Causes very strong irritations of the eyes, skin and mucous membranes. Chemical burn

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray jet, Foam, Carbon dioxide, Dry powder, Water mist

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In the event of fire the following can be released: Hydrogen chloride (HCI); Carbon monoxide (CO); Carbon dioxide (CO2); In case of combustion, evolution of health hazardous partially burned gases. Nitrogen oxides (NOx)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Wear full protective suit.

Other information

Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep away unprotected persons.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil. Advise water authority if spillage has entered water course or drainage system.

6.3. Methods and material for containment and cleaning up

Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder, sawdust). When picked up, treat material as prescribed under Section 13 "Disposal". Send in suitable containers for recovery or disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special measures necessary if used correctly. Product should be handled only by trained personnel. Wear protective equipment. Do not return rest to the storage containers.

Advice on protection against fire and explosion



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The product is not combustible.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value 1 - 25 °C

Storage stability

Store at room temperature. Storage time: 24 months

Requirements for storage rooms and vessels

Keep tightly closed in a dry and cool place. Keep only in original packaging. Protect from frost.

Storage classes

Storage class according to TRGS 510 12 Non-combustible liquids

Storage category (Switzerland) 8 Caustic and corrosive substances

Further information on storage conditions

Protect from light. Protect from sun.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

At work do not eat, drink, smoke or take drugs. Wash hands before breaks and after work. Take off immediately all contaminated clothing. Observe the usual precautions for handling chemicals.

Respiratory protection

Breathing apparatus in the event of aerosol or mist formation. Short term: filter apparatus; Multi-purpose filter ABEK; At intensive and longer exposition use self-contained breathing apparatus.

Hand protection

Gloves

Appropriate Material nitrile

Material thickness 0.11 mm

Gloves

Appropriate Material Polychloroprene

Material thickness 0.65 mm

Eye protection

Safety glasses with side protection shield; Safety goggles

Body protection

Protective clothing; Wear disposal (one-way) overall

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form liquid

Colour colourless to yellowish

Odour characteristic

Odour threshold

Remarks Not applicable

pH value

Value 5.5 to 7.0

Concentration/H2O 50 g/l Temperature 20 °C



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Freezing point

Remarks No data available

Initial boiling point and boiling range

Value appr. 100 °C

Remarks No data available

Flash point

Value °C Remarks Not applicable

Upper/lower flammability or explosive limits

Remarks Not applicable

Vapour pressure

Value 23 hPa

Temperature 20 °C

Density

Value 1.06 to 1.07 g/cm³

Temperature 20 °C Method 92/69/EEC, A.3

Solubility in water

Temperature 20 °C

Method OECD 105

Remarks Completely miscible

Solubility(ies)

Ethanol

Value appr. 21 g/l

Isopropanol

Value appr. 35 g/l

Acetone

Value appr. 44 g/l

9.2. Other information

Solvent content

Value 79 to 81 %

SECTION 10: Stability and reactivity

10.1. Reactivity

None known

10.2. Chemical stability

No hazardous reactions known.

10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Protect from light. Protect from direct sunlight. Protect from frost.

10.5. Incompatible materials

Alkalies, Avoid contact with oxidizing substances. No hazardous reactions when stored and handled according to prescribed instructions. Strong oxidising agents

10.6. Hazardous decomposition products

Chlorine, Carbon monoxide and carbon dioxide



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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-

tetraazatetradecanediamidine (2:1)

Remarks No data available.

Acute dermal toxicity (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-

tetraazatetradecanediamidine (2:1)
Species rabbit

LD50 > 5000

Source US EPA Proposed Guideline for Toxicology - Section 162.81-2

h

Acute inhalative toxicity (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-

tetraazatetradecanediamidine (2:1)

Remarks No data available.

Skin corrosion/irritation (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

Species rabbit

Duration of exposure 4

evaluation slightly irritant Method OECD 404

Serious eye damage/irritation (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-

tetraazatetradecanediamidine (2:1)
Species rabbit

evaluation irritant - risk of serious damage to eyes

Method OECD 405 Source 5% Solution

Sensitization (Components)

D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

Species guinea pig evaluation non-sensitizing Method OECD 406

Mutagenicity

Species Salmonella typhimurium

evaluation No mutagenicity in the Ames-test.

Method OECD 471

Reproductive toxicity

Species rat

Remarks No indications of toxic effects were observed in reproduction studies in

animals.

Carcinogenicity

Route of exposure oral

Species Rats (male/female)
Duration of exposure 735 d



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evaluation No indications of carcinogenic effects are available from long-term trials.

Remarks No evidence available on carcinogenicity.

Source Literature value

Route of exposure oral Species mouse

Duration of exposure 546 d

Remarks None

SECTION 12: Ecological information

12.1. Toxicity

Fish toxicity

Species zebra fish (Brachydanio rerio)

LC50 2.08 mg/l

Duration of exposure 96 h

Method OECD 203

Daphnia toxicity

Species Daphnia magna

NOEC 0.1 mg/l

Duration of exposure 21 d

Method OECD 211
Species Daphnia magna

EC50 0.174 mg/l

Duration of exposure 21 d

Method OECD 211

Species Daphnia magna

NOEC 0.0206 mg/l

Duration of exposure 21 d

Method OECD 211 Species Daphnia magna

EC50 0.0358 mg/l

Duration of exposure 21 d

Method OECD 211
Species Daphnia magna

EC50 0.087 mg/l

Duration of exposure 48 h

Method OECD 202

Algae toxicity

Species Desmodesmus subspicatus

EC50 0.081 mg/l

Duration of exposure 72 h

Method OECD 201

Bacteria toxicity

Species activated sludge

EC50 25 mg/l

Duration of exposure 3 h

Method OECD 209

12.2. Persistence and degradability

Biodegradability

evaluation not readily degradable

12.5. Results of PBT and vPvB assessment

General information



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There are no data available on the mixture itself.

12.6. Other adverse effects

General information / ecology

Do not allow it to reach soil, ground water, water bodies or sewage system.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

Disposal in compliance with local and national regulations.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
Tunnel restriction code	-		
14.1. UN number	3082	3082	3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es)	9	9	9
Label	Ap.		*
14.4. Packing group	III	III	III
Limited Quantity	51		
Transport category	3		

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water Hazard Class (Germany)

Water Hazard Class

WGK 3

(Germany)

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information



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Hazard statements listed in Chapter 3

H318 Causes serious eye damage. H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

CLP categories listed in Chapter 3

Aquatic Acute 1 Hazardous to the aquatic environment, acute, Category 1 Aquatic Chronic 1 Hazardous to the aquatic environment, chronic, Category 1

Eye Dam. 1 Serious eye damage, Category 1

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: *** This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.