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

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 person responsible for this SDS sdb@haenseler.ch

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.

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	H400	M = 10
Aquatic Chronic 1	H410	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.

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 (HCl); 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

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 slightly yellow
Odour	odourless

Odour threshold

Remarks	Not applicable

pH value

Value	5.5	to	7.0
Concentration/H2O	10	g/l	
Temperature	20	°C	
Source	Safety Data Sheet Supplier		

Freezing point

Remarks No data available

Initial boiling point and boiling range

Remarks No data available

Flash point

Value °C

Remarks Not applicable

Upper/lower flammability or explosive limits

Remarks Not applicable

Vapour pressure ***

Remarks No data available

Density

Value	1.065		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

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.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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 h
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
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

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			
14.4. Packing group	III	III	III
Limited Quantity	5 l		
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 (Germany)	WGK 3
Remarks	Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information

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.