Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CHLORHEXIDINI DIGLUCONATIS SOLUTIO

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Version: 01

MAGIS PHARMA

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Chlorhexidine digluconate solution 20 % Chlorhexidini digluconatis solutio 20 % Chloorhexidine digluconaat 20 % oplossing Solution de digluconate de chlorhexidine 20 % Chlorhexidindigluconat Lösung 20 %
N° CAS:	18472-51-0
N° EC:	242-354-0

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Eye Dam. 1	H318
Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): 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 protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with local regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Chlorhexidine digluconate solution 20%
IUPAC name:	N^1,$N^{1'}$-(Hexane-1,6-diyl)bis[N^3-(4-chlorophenyl)imidodicar-bonimidic diamide] di-D-gluconate.
Synonyms:	Chlorhexamed Hexidine
N° CAS:	18372-51-0
N° EC:	242-354-0
Molecular Formula:	$C_{34}H_{54}Cl_2N_{10}O_{14}$
Content:	190 g/L to 210 g/L

3.2 Mixtures

Product name : Water
IUPAC name : Oxidane
Synonyms : distilled water, dihydrogen oxide, purified water
N° CAS : 7732-18-5
N° EC : 231-791-2
Molecular Formula : H_2O
Content : 80 %

Product name : Chlorhexidine digluconate
IUPAC name : (1E)-2-[6-[[amino-[(E)-[amino-(4-chloroanilino)methylidene]amino]methylidene]amino]hexyl]-1-[amino-(4-chloroanilino)methylidene]guanidine;(2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanoic acid
Synonyms : Chlorhexidine D-digluconate, Unisept
N° CAS : 18472-51-0
N° EC : 242-354-0
Molecular Formula : $C_{34}H_{54}Cl_2N_{10}O_{14}$
Content : ≥ 20% - < 25%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Pay attention to self-protection. Remove victims from hazardous area. Immediately remove soiled or soaked clothing and remove it to a safe distance. Keep victim warm, in a stabilized position and covered. Do not leave victims unattended. If the casualty is unconscious: Place the victim in the recovery position.
After inhalation:	Potential for exposure by inhalation if aerosols or mists are generated. After inhalation move subject to fresh air. With labored breathing: Provide with oxygen. Consult a doctor. If the casualty is not breathing: Perform mouth-to-mouth resuscitation, notify emergency physician immediately.
After skin contact:	Wash off affected area immediately with plenty of water for at least 15 minutes. If symptoms persist, consult a physician for treatment.
After eye contact:	With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes. Inform emergency physician immediately. (key term: caustic eye burn)
After ingestion:	Rinse mouth. Immediately give large quantities of water to drink. Inform emergency physician immediately.
Self-protection of the first aider:	Wear a self contained respiratory apparatus, full protective suit.

4.2 Most important symptoms and effects, both acute and delayed

Causes eye burns. Causes severe eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

The initial focus is only on the local action, characterized by quickly progressing deep tissue damage. Coughing is a symptom of a respiratory tract irritation after inhalation of aerosols or mists from caustic liquids. In the eye, caustic liquids cause, depending on the intensity of exposure, severe irritation, destruction, and ablation of the epithelium of the conjunctiva and cornea, corneal clouding, edema and ulcerations. Danger! Possible loss of eyesight! Superficial irritations and damage up to ulcerations and scarring develop on the skin.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, foam, CO_2, dry powder, mist
Unsuitable extinguishing media:	Do not use a solid water stream as it may scatter and spread fire

5.2 Special hazards arising from the substance/mixture

May be released in case of fire: hydrogen chloride, carbon monoxide, carbon dioxide, organic products of decomposition, flammable smoldering gases, Nitrogen Oxides.

5.3 Advice for firefighters

Surrounding fires:	Contaminated extinguishing water must be treated at a suitable disposal plant in accordance with waste management laws. In case of fire, remove the endangered containers and bring to a safe place, if this can be done safely. Water used to extinguish fire should not enter drainage systems, soil or stretches of water. Use water spray to cool unopened containers. Fire residues should be disposed of in accordance with the regulations. Keep out unprotected persons.
Protection against fire:	Wear a self contained respiratory apparatus full protective suit.
Hazardous combustion products:	The product itself does not burn.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unauthorized personnel away.

For emergency responders

Keep unauthorized personnel away.

6.2 Environmental precautions

Observe regulations on prevention of water pollution (check, dam up, cover up). Do not allow entrance in sewage water, soil, stretches of water, drainage systems, surface water. If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material e.g. inert absorbent Pack and label wastes like the pure substance. Do not detach label from the delivery containers prior to disposal. Transfer into suitable containers. Disposal according to local authority regulations. Clean contaminated surface thoroughly.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use personal protective equipment. The product should only be handled by trained personnel. No special measures are necessary if properly handled. Avoid residues of the product on the containers.
Personal protection:	Use personal protective equipment.
Technical protective measures:	Normal measures for preventive fire protection. Ensure there are sufficient retaining facilities for water used to extinguish fire.
Handling:	The product itself does not burn.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in the original receptacle, keeping this tightly sealed, under cool and dry conditions. The product should not be stored at under 1°C or above 25°C.
Conditions for safe storage, including any incompatibilities:	Store in the original receptacle, keeping this tightly sealed, under cool and dry conditions.
Storage – away from:	Avoid exposure to light /sunlight. Protect from frost.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits: Observe national threshold limit values.

Biological limit values: No biological exposure limits noted for the ingredients.

8.2 Exposure controls

Appropriate engineering control

Ensure suitable suction/aeration at the work place and with operational machinery. Provide for installation of emergency shower and eye bath.

Individual protection measures

Eye/face protection:	Safety glasses with side-shields conforming to EN166 or when handling larger quantities: basket-shaped glasses.
Skin protection:	Wear appropriate protective clothing to prevent skin exposure.
Hand protection:	Wear appropriate protective gloves to prevent skin exposure.
Respiratory protection:	Use suitable respiratory protection where aerosols/vapours are generated. When handling for a short time: Respirator with ABEK combination filter in the event of prolonged exposure during handling: wear a self contained respiratory apparatus Note time limit for wearing respiratory protective equipment.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Almost colourless or pale-yellowish liquid.
Odour:	Odourless
Odour threshold:	Not applicable.
pH:	5,5 – 7,0 (10g/L, 20 °C)
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	100°C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Density: 1,065 g/cm3 (20 °C) (OECD Test Guideline 109)
Solubility:	Ethanol.: approx. 21 g/L Chlorhexidine di(gluconate) Isopropanol: approx. 35 g/L Chlorhexidine di(gluconate) Acetone: approx. 44 g/L Chlorhexidine di(gluconate)
Solubility in water:	(20 °C, OECD Test Guideline 105) completely miscible tested substance: Chlorhexidine di(gluconate)
Partition coefficient (n-octanol/water):	-1,81 (OECD TG 107, measured) tested substance: Chlorhexidine di(gluconate)
Auto-ignition temperature:	Not available.

Decomposition temperature:	157 °C initial temperature of decomposition
Viscosity:	Kinematic viscosity: 2,51 mm2/s (20 °C, OECD 114) | 1,46 mm2/s (40 °C, OECD 114) Dynamic viscosity: 2,51 mPa·s (20 °C) | 1,46 mPa·s (40 °C)
Explosive properties:	Not to be expected in view of the structure.
Oxidising properties:	Not to be expected in view of the structure.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Under proper storage conditions, the specification parameters as per the European Pharmacopoeia are maintained over a period of 24 months. (stability conditions 25°C+- 2 K and 60%+-5%)

10.3 Possibility of hazardous reactions

No hazardous reactions are known if properly handled and stored.

10.4 Conditions to avoid

Light effect exposure to sunlight. Freezing.

10.5 Incompatible materials

Avoid contact with oxidizing agents. Alkalis

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral: Acute toxicity estimate: > 5.000 mg/kg Dermal: LD 50 (Rabbit): > 5.000 mg/kg [Chlorhexidine di(gluconate)]
Skin corrosion/irritation:	Slightly irritating. OECD Test Guideline 404 (Rabbit, 4 h): Slightly irritating.
Serious eye damage/irritation:	Risk of serious damage to eyes. Rabbit: Risk of serious damage to eyes.
Respiratory/skin sensitisation:	Maximization test, OECD Test Guideline 406 (Guinea Pig): Not a skin sensitizer. literature
Germ cell mutagenicity:	In vitro: Ames test (OECD 471): negative Gene mutation (HGPRT-Test) (OECD 476): negative Cytogenetic test (OECD TG 473): negative Solution, 5% In vivo: Not available.
Carcinogenicity:	Did not show carcinogenic effects in animal experiments.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.

STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Relevant route of exposure. Symptoms not available.
Skin contact:	Relevant route of exposure. Symptoms not available.
Inhalation:	Relevant route of exposure. Symptoms not available.
Ingestion:	If handled correctly, not a relevant route of exposure. Symptoms not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute hazards to the aquatic environment:
Fish: LC 50 (Brachydanio rerio, 96 h): 2,08 mg/L
Aquatic Invertebrates: EC50 (Daphnia magna (Water flea), 48 h): 0,087 mg/L

Chronic hazards to the aquatic environment:
Fish: Not available.
Aquatic Invertebrates: NOEC (Daphnia magna (Water flea), 21 d): 0,1 mg/L
EC 50 (Daphnia magna (Water flea), 21 d): 0,174 mg/L
NOEC (Daphnia magna (Water flea), 21 d): 0,0206 mg/L
EC50 (Daphnia magna (Water flea), 21 d): 0,0358 mg/L
Toxicity to Aquatic Plants: ErC10 (Desmodesmus subspicatus (green algae), 72 h): 0,03 mg/L growth rate
EC 50 (Desmodesmus subspicatus (green algae), 72 h): 0,081 mg/L growth rate

12.2 Persistence and degradability

Biodegradation: Not readily biodegradable. A number of studies in sewage treatment plants were located in the scientific literature. These studies resulted either in no degradation or only slight degradation.
BOD/COD Ratio: Not available.

12.3 Bioaccumulative potential

Bioconcentration Factor (BCF): Leuciscus idus (Golden orfe), Bioconcentration Factor (BCF): 42 (Measured) low literature
Leuciscus idus (Golden orfe), Bioconcentration Factor (BCF): 40 (Measured) low literature

12.4 Mobility in soil

Log Koc: > 3,9 (OECD Test Guideline 121)

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

The substance can damage sediment organisms (NOEC Chironomus riparius (OECD 218): 21 mg/kg dry weight)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Contaminated packaging: Do not reuse empty containers and dispose of in accordance with the regulations issued by the appropriate local authorities.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	3082

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	IATA-DGR: Environmentally hazardous substance, liquid, n.o.s. (chlorhexidine digluconate) IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (chlorhexidine digluconate)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	9

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	IATA-DGR: Environmentally hazardous IMDG: Marine pollutant

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

In order to ensure due transportation, make certain that stacks are of the correct height, containers are securely fastened so as not to fall off, and labelled according to the regulations. In the event of internal transportation, already-opened containers are to be kept closed in order to avoid spillage.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Corrosive

Dangerous for the environment

Risk phrases:

R41: Risk of serious damage to eyes

R42/43 May cause sensitization by inhalation and skin contact.

R50/53: Very toxic to aquatic organisms, may cause long-term

	adverse effects in the aquatic environment.
Safety phrases:	S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection. S61: Avoid release to the environment. Refer to special instructions/Safety Data Sheets.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.
https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation

(EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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