

Material Safety Data Sheet

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

CHLORHEXIDINI DIGLUCONAS 0.5%

EN

FORM-06-14-01 (V00)

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

1.1 Product identifier

Product name:	Chlorhexidine digluconate 0.5% in ethanol 70% Chlorhexidini digluconas 0.5% in ethanol 70% Chloorhexidine digluconaat 0.5% in ethanol 70% Digluconate de chlorhexidine 0.5% dans l'éthanol 70% Chlorhexidindigluconat 0.5% in ethanol 70%
N° CAS:	64-17-5
N° EC:	200-578-6

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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 Irrit. 2	H319
Flam. Liq. 2	H225

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long-lasting effect.

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Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof electrical equipment.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305+ P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name :	Ethyl Alcohol 70%
IUPAC name :	Ethanol
Synonyms :	Methylcarbinol, Ethanol
N° CAS :	64-17-5
N° EC :	200-578-6
Molecular Formula :	C ₂ H ₆ O
Content :	99,5%
Product name :	Chlorhexidine Digluconate 20%
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 Gluconate
N° CAS :	18472-51-0
N° EC :	242-354-0
Molecular Formula :	C ₃₄ H ₅₄ Cl ₂ N ₁₀ O ₁₄
Content :	0,5%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	In case of unconsciousness, position and transport in recovery position.
After skin contact:	Immediately wash with water and soap and rinse thoroughly.

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After eye contact:	Rinse eyes under running water for several minutes while keeping the eye slit open. Consult a doctor in case of persistent complaints.
After ingestion:	Rinse mouth and drink plenty of water

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	CO ₂ , extinguishing powder or water jet. Fight larger fires with water jet or alcohol resistant foam.
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Unsuitable extinguishing media:	Not available.
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5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	No special measures required.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Put on protective clothing. Keep unprotected persons away.

For emergency responders

Put on protective clothing. Keep unprotected persons away.

6.2 Environmental precautions

Dilute with plenty of water. Do not allow to enter sewers/surface water/ground water.

6.3 Methods and material for containment and cleaning up

Take up with liquid-binding material (sand, mountain meal, acid binder, universal binder, sawdust). Provide adequate ventilation.

6.4 Reference to other sections

No dangerous substances are released.
Information on safe use - see chapter 7.
Information regarding personal protective equipment - see chapter 8.
Disposal information - see chapter 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	No special measures are required when used properly. Keep ignition sources away - no smoking.
Personal protection:	Not available.
Technical protective measures:	Take precautions against static electricity discharge.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store cool and dry in tightly closed containers.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: 64-17-5 Ethyl Alcohol.
PEL: Long-term value: 1900 mg/m³, 1000 ppm
REL: Long-term value: 1900 mg/m³, 1000 ppm
TLV: Short-term value: 1880 mg/m³, 1000 ppm

8.2 Exposure controls

Appropriate engineering control

Keep away from food and drink. Take off immediately all contaminated clothing. Avoid contact with eyes and skin.

Individual protection measures

Eye/face protection:	Tightly sealed goggles.
Skin protection:	Not determined.
Hand protection:	The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Respiratory protection:	Fresh air mask.
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:	Clear liquid
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Odour:	Odourless
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	100 °C
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	2,5 – 13,5 Vol %
Vapour pressure:	57,3 hPa (20 °C)
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Product is not selfigniting. Ignition temperature: 363 °C
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Product does not present an explosion hazard.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used as directed.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

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10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Irritates the skin and mucous membranes .
Serious eye damage/irritation:	Causes serious eye irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
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:	Irritating.
Skin contact:	Irritating.
Inhalation:	Irritating.
Ingestion:	Irritating.
Aspiration:	Irritating.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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12.6 Other adverse effects

General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

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

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

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of together with household waste or end up in the sewage system.

Contaminated packaging:

Recommendation: Dispose of according to government regulations.

Recommended cleaning agent: Water, possibly with the addition of cleaning agents.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 1170
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), ADR: 1170 ETHANOL (ETHYLALCOHOL)
IATA/ICAO (Air) : IMDG: ETHANOL (ETHYL ALCOHOL)
IATA: ETHANOL

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 3
IATA/ICAO (Air) :

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine pollutant: No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Warning: Flammable liquids

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

Not applicable.

14.8 Additional transport information

ADR: Limited quantities (LQ): 1L

SECTION 15: REGULATORY INFORMATION

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

Not applicable.

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15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

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 Bioaccumulative

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

Classification based on the main ingredient.

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

Quality Department

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