Material Safety Data Sheet

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

CHLORHEXIDINI DIACETAS

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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 diacetate Chlorhexidini diacetas Chloorhexidine diacetaat Chlorhexidine (diacétate de) Chlorhexidindiacetat
N° CAS:	56-95-1
N° EC:	200-302-4

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

Flam. Sol. 1	H228
Eye Dam. 1	H318
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Danger

Harmful to the environment
Corrosive

	Flammable
Hazard statements:	
H228	Flammable solid.
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.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Chlorhexidine diacetate
IUPAC name:	N1,N1'-(Hexane-1,6-diyl)bis-[N3-(4-chlorophenyl)imido-dicarbonimidic diamide]diacetate
Synonyms:	Nolvasan Bactigras Chlorhexidine acetate Hibitane diacetate Chlorohexidine diacetate
N° CAS:	56-95-1
N° EC:	200-302-4
Molecular Formula:	$C_{26}H_{38}Cl_2N_{10}O_4$
Content:	98.0 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	

After skin contact:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After eye contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After ingestion:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention. If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Serious eye damage (eye contact) and gastric/intestinal mucosal irritation (ingestion).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

The vapours emitted during combustion are heavier than air.

5.3 Advice for firefighters

Surrounding fires:	Cool tanks, cisterns or containers near the source of heat or fire with water. Take wind direction into account. Prevent products used in fire fighting from entering drains, sewers or watercourses.
Protection against fire:	Depending on the size of the fire, heat protection suits, self-contained breathing apparatus, gloves, goggles or face masks and boots may be required.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid formation of dust. Avoid contact with the substance. Proceed with ventilation in enclosed areas.

Wear suitable protective equipment (including personal protective equipment detailed under heading 8) to avoid contamination of skin, eyes and persons.

For emergency responders

Avoid formation of dust. Avoid contact with the substance. Proceed with ventilation in enclosed areas.

Wear suitable protective equipment (including personal protective equipment detailed under heading 8) to avoid contamination of skin, eyes and persons.

6.2 Environmental precautions

Avoid release to the environment. Eliminate sources of ignition. Clean and remove dust from the blade and dispose of as ordinary cabbage. Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Renew mechanically. Then remove emergency containers to an area for later recycling or disposal.

Evacuate personnel to a safe area. Ensure that all national/local regulations are complied with.

Dispose of materials or solid waste at an authorised site.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin and eyes. Wear personal protective equipment. Avoid breathing dust, mist or aerosols. Do not eat, drink or smoke during use. Wash hands thoroughly after handling.
Personal protection:	Not available.
Technical protective measures:	Ensure good ventilation of the workplace. Avoid dust formation.
Handling:	Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep containers closed. Store in a well-ventilated place. Keep container tightly closed.
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

No Occupational Exposure Limit assigned.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	We recommend the use of a P-type filter mask (EN 149) or equivalent device, whose class (1, 2 or 3) and actual need will be determined by the outcome of the risk assessment.
Thermal hazards:	Not determined.

Environmental exposure control

Emissions from production processes, including those from ventilation equipment, should be monitored for compliance with environmental protection standards. Product residues should not be discharged uncontrolled into drains or waterways. For information on environmental exposure control, refer to the exposure scenarios attached to this Safety Data Sheet.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, microcrystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
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:	Not available.
Solubility:	Soluble in ethanol (96 per cent), slightly soluble in glycerol and in propylene glycol.
Solubility in water:	Sparingly soluble in water. 1.9 g/100 mL (20 °C)
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.

Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 625.57 g/mol

As with all dry powders, it is recommended to ground the mechanical device in contact with dry material to disperse potential static electricity.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Due to the cationic nature of chlorhexidine salts, they are chemically incompatible with anionic compounds. Keep away from sulphates, borates, bicarbonates, chlorides...

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

No dangerous reactions are known under normal conditions of use.

10.4 Conditions to avoid

Avoid ignition sources. Protect from heat and direct sunlight.

10.5 Incompatible materials

No contact with: strong acids, strong bases and strong oxidizing agents. Incompatible with: anionic compounds.

10.6 Hazardous decomposition products

Under fire or decomposition conditions, this material emits small amounts of p-chloroaniline and related toxic fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Skin. (rabbit) Slightly irritating.
Serious eye damage/irritation:	Causes serious eye damage. Very irritating.
Respiratory/skin sensitisation:	May be toxic if inhaled.
Germ cell mutagenicity:	No evidence of mutagenic potential.
Carcinogenicity:	Not available.
Reproductive toxicity:	Unlikely.
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:	Causes serious eye damage.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

LC_{50} (fish):	1.9 mg/L hours (*Oncorhynchus mykiss*)
EC_{50} (crustaceans):	0.06 mg/L (*Daphnia magna*)
EC_{50} (algae):	0.6 mg/L minutes (*Lepomis macrochirus*)

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

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

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) :	3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR/RID: SOLID SUBSTANCE DANGEROUS FOR THE ENVIRONMENT, N.O.S. (CHLORHEXIDINE DIACETATE) IMDG: SOLID SUBSTANCE DANGEROUS FOR THE ENVIRONMENT, N.O.S. (CHLORHEXIDINE DIACETATE) IATA: SOLID SUBSTANCE DANGEROUS FOR THE ENVIRONMENT, N.O.S. (CHLORHEXIDINE DIACETATE)

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) :	ADR/RID: Dangerous for the Environment IMDG: Marine Pollutant IATA: Dangerous for the environment

14.6 Special precautions for user

Not available.

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

Not available.

14.8 Additional transport information

The product is classified according to the hazardous materials conventions.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Harmful to the environment
Corrosive
Flammable

Risk phrases:

R10 Flammable.

R41 Risk of serious damage to eyes.

R50 Very toxic to aquatic organisms.

R51/53 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.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

15.2 Chemical safety assessment

A chemical safety assessment of the product 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 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

Not applicable.

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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