

# Material Safety Data Sheet

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

## CLINDAMYCINI HYDROCHLORIDUM

EN

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

#### 1.1 Product identifier

Product name:	Clindamycin hydrochloride Clindamycini hydrochloridum Clindamycine hydrochloride Clindamycine (chlorhydrate de) Clindamycinhydrochlorid
N° CAS:	21462-39-5
N° EC:	244-398-6

#### 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

Skin Sens. 1	H317
Eye Irrit. 2	H319

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Precautionary statements:

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

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P261	Avoid breathing combustion products, vapours, gases or air condensation.
P333+P313	If skin irritation or a rash occurs: Get medical advice/attention.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Additional applicable label elements:	

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Clindamycin hydrochloride
IUPAC name:	(2S,4R)-N-[(1S,2S)-2-chloro-1-[(2R,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(methylsulfanyl)oxan-2-yl]propyl]-1-methyl-4-propylpyrrolidine-2-carboxamide hydrochloride
Synonyms:	Cleocin Clinsol
N° CAS:	21462-39-5
N° EC:	244-398-6
Molecular Formula:	C <sub>18</sub> H <sub>34</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>5</sub> S
Content:	92.0 per cent to 102.0 per cent (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## 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 in attendance.
After inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off immediately all contaminated clothing. Get medical attention if irritation occurs and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	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

Not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

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Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water spray.  
Neighbouring fires: Use water spray or water mist to cool fire-exposed containers.

Unsuitable extinguishing media: Do not use direct stream of water.

### 5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion products (carbon oxides, toxic pyrolysis products, etc.). The product is combustible and, when the dust is dispersed in the air in sufficient concentrations and in the presence of an ignition agent, it can give explosive mixtures with air. The fire may grow or be further driven by the solid, possibly leaking from the container when it reaches high temperatures or by contact with sources of ignition.

### 5.3 Advice for firefighters

Surrounding fires: Extinguishing media: Atomized or nebulized water. Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist), gloves (fireproof and dielectric), a mask with face mask covering the whole face of the operator or the car (self shield) in case of large amounts of smoke.

Hazardous combustion products: In case of fire, fumes harmful to health may be produced.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Equip clean-up personnel with appropriate protective equipment. Avoid both the formation and inhalation of dust. Avoid breathing vapours, gases or air condensation. Ventilate area and evacuate unnecessary personnel. For further information on exposure control and personal protective measures, see section 8.

#### For emergency responders

Equip clean-up personnel with appropriate protective equipment. Avoid both the formation and inhalation of dust. Avoid breathing vapours, gases or air condensation. Ventilate area and evacuate unnecessary personnel. For further information on exposure control and personal protective measures, see section 8.

### 6.2 Environmental precautions

Prevent product from entering sewers, surface water, groundwater and/or neighbouring areas.

### 6.3 Methods and material for containment and cleaning up

Sweep up, limiting the formation of dust, and place the spilled substance in containers.  
Ensure that waste is collected and stored safely in appropriate, closed containers for disposal.

### 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.

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Personal protection:	The usual measures on clothing for protection against fire must be observed.
Technical protective measures:	Avoid formation of dust and aerosols. Provide adequate ventilation where dust may be generated.
Handling:	Wash thoroughly after handling. Wash contaminated clothing before reuse. Contaminated work clothes should not be taken out of the workplace.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container.
Conditions for safe storage, including any incompatibilities:	Store at room temperature in the original container in a cool, well-ventilated place.
Storage – away from:	Store away from strong bases, sources of heat and ignition and direct sunlight.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Since the use of appropriate technical measures must 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. Handle with appropriate industrial hygiene precautions and observe safety practices. Wash hands before breaks and after finishing work.

#### 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 standard EN 374 derived from it.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
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:	White or almost white, crystalline powder, slightly hygroscopic.
Odour:	Characteristic.
Odour threshold:	Not available.

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pH:	3.5 – 5.5 (10% in water, 20 °C)
Melting/freezing point:	~ 134 °C
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:	Slightly soluble in ethanol (96%).
Solubility in water:	Very soluble in water.
Partition coefficient (n-octanol/water):	1.015 (20 °C)
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No special conditions.

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

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Direct sunlight, humidity and extremely high temperatures.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Toxic fumes of carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), hydrogen chloride (HCl) and sulphur oxides (SO<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 2193 mg/kg
	Intraperitoneal LD50 (rat): 745 mg/kg

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Skin corrosion/irritation:	May cause irritation with erythema, oedema, dryness and cracking.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Causes irritation of upper and lower respiratory tract.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	Based on animal tests, overexposure may cause reproductive disturbances.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Target organs: gastrointestinal system, nerves and liver.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	May cause an allergic skin reaction. Harmful if absorbed through skin. May cause skin irritation with erythema, oedema, dryness and cracking.
Inhalation:	May cause respiratory tract irritation. May cause pulmonary oedema in high concentrations.
Ingestion:	Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting.
Aspiration:	Not available.

## 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

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 packaging: Dispose of as unused product.

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### SECTION 14: TRANSPORT INFORMATION

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

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 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

It is not dangerous in transport.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R36 Irritating to eyes.  
R43 May cause sensitisation by skin contact.

Safety phrases:

S23 Do not breathe combustion products, vapours, gases or air condensation.  
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S28 Avoid contact with skin, wash immediately with plenty of soap and water.  
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

#### 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

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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

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

Quality Department

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