

# Material Safety Data Sheet

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

## CHLORAMPHENICOLUM

EN

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

#### 1.1 Product identifier

Product name: Chloramphenicol  
Chloramphenicolum  
Chlooramfenicol  
Chloramphénicol  
Chloramphenicol

N° CAS: 56-75-7

N° EC: 200-287-4

#### 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: 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 Dam. 1	H318
Carc. 1B	H350
Carc. 2	H351
Repr. 2	H361

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Corrosive, Harmful, Irritant

Hazard statements:

H317 May cause an allergic skin reaction.

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H318	Causes serious eye damage.
H350	May cause cancer.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.
Precautionary statements:	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P234	Keep only in original packaging.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and 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.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	

### 2.3 Other hazards

None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Chloramphenicol
IUPAC name:	2,2-Dichloro-N-[(1R,2R)-1,3-dihydroxy-1-(4-nitrophenyl)propan-2-yl]acetamide
Synonyms:	Chloromycetin Chlornitromycin Levomycetin
N° CAS:	56-75-7
N° EC:	200-287-4
Molecular Formula:	C <sub>11</sub> H <sub>12</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>5</sub>
Content:	97.5 per cent to 102.0 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.

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After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give 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. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including 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

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

In case of fire, fumes harmful to health may be produced.

### 5.3 Advice for firefighters

Surrounding fires:	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, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas.

Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

#### For emergency responders

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas.

Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

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### 6.2 Environmental precautions

Prevent further leakage or spillage if this can be done safely.

Do not allow product to enter sewage system.

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

Collect and prepare disposal without creating dust.

Clean and shovel.

Store 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 formation of dust and aerosols.

Avoid exposure - obtain special instructions before use.

Personal protection:

Not available.

Technical protective measures:

Adequate extraction should be provided where dust is formed.

Normal fire precautionary measures.

Handling:

Not available.

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

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in a dry and well-ventilated place.

Store in a cool place.

If the substance is sterile, the container is also sterile, airtight and tamper-evident.

Storage – away from:

Store protected from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Does not contain substances with occupational exposure limit values.

### 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.

Hygiene measures: Handle with proper 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.

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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:	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, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	149 °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:	Freely soluble in ethanol (96 per cent) and in propylene glycol.
Solubility in water:	Slightly soluble in water.
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: 323.13 g/mol

Density (25 °C): 0.569 g/mL

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### 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 established.

#### 10.4 Conditions to avoid

Avoid any improper handling: high pressures and/or high temperatures. Direct sunlight.

#### 10.5 Incompatible materials

Strong acids, oxidizing agents, acid chlorides and acid anhydrides.

#### 10.6 Hazardous decomposition products

Decomposition by heat may produce toxic fumes of CO, CO<sub>2</sub>, NO<sub>x</sub> and HCl.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD <sub>50</sub> , rat): 2500 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Mutagenic effects have been observed in laboratory experiments. Genotoxicity in vitro (rat): Liver. DNA damage. Genotoxicity in vivo (mouse): Intraperitoneal. Cytogenetic analysis.
Carcinogenicity:	This product is or contains a component that is probably carcinogenic to humans. IARC, Group 2A: Probably carcinogenic to humans.
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:	Signs and Symptoms of Exposure: Nausea, headache and vomiting. N° RTECS: AB6825000

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

Eye contact:	May cause eye irritation. Causes serious eye damage.
Skin contact:	Harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

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### 12.1 Toxicity

Invertebrate toxicity (EC<sub>50</sub>): 345 mg/L/48 hours (*Daphnia magna*)

### 12.2 Persistence and degradability

May cause long-term negative environmental effects.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

### 12.6 Other adverse effects

Avoid release into the environment.

## 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.

## 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) : It is not dangerous in transport.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

#### 14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

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### 14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

Corrosive Harmful, Irritant

R41 Risk of serious damage to eyes.

R43 May cause sensitisation by skin contact.

R45 May cause cancer.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 After contact with skin, wash immediately with plenty of soap and water.

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

S49 Keep only in the original container.

S53 Avoid exposure – obtain special instructions before use.

### 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 Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

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<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  
FAC SECUNDUM ARTEM NV  
[info@magis-pharma.be](mailto:info@magis-pharma.be)