

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

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

#### 1.1 Product identifier

Product name: Erythromycin  
Erythromycinum  
Erythromycine  
Érythromycine  
Erythromycin

N° CAS: 114-07-8

N° EC: 204-040-1

#### 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

Acute Tox. 4	H302
Acute Tox. 4	H312
Skin Sens. 1	H317
Eye Irrit. 2	H319
Acute Tox. 4	H332
Resp. Sens. 1	H334
Repr. 2	H361
Lact.	H362

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger  
Warning

Hazard statements:

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

H302	Harmful if swallowed.
H312	Harmful if contact with skin.
H317	May cause an allergic skin reaction.
H319	Cause serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H362	May cause harm to breast-fed children.
Precautionary statements:	
P201	Obtain special instructions before use.
P202	Don't handle until all safety precautions have been read and understood.
P260	Don't breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash face, hands and any exposed skin thoroughly after handling.
P270	Don't eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P284	In case of inadequate ventilation, wear respiratory protection.
P330	Rinse mouth.
P301+P312	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	If exposed or concerned: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician.
P362+P364	Take off contaminated clothing and wash it before reuse.
P302+P352+P313	IF ON SKIN: Wash with plenty of water/cleaning agents. Immediately call a POISON CENTER/doctor/physician if you feel unwell.
P305+P351+P338	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container to an approved waste disposal plant.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Erythromycin
IUPAC name:	(3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-6-[(2S,3R,4S,6R)-4-(dimethylamino)-3-hydroxy-6-methyloxan-2-yl]oxy-14-ethyl-7,12,13-trihydroxy-4-[(2R,4R,5S,6S)-5-

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

Synonyms:	hydroxy-4-methoxy-4,6-dimethyloxan-2-yl]oxy-3,5,7,9,11,13-hexamethyl-oxacyclotetradecane-2,10-dione
N° CAS:	None
N° EC:	114-07-8
Molecular Formula:	204-040-1
Content:	$C_{37}H_{67}NO_{13}$
	Sum of erythromycins A, B and C: 93.0% to 102.0% (anhydrous substance). Contains max. 5.0% of Erythromycin B (anhydrous substance). Contains max. 5.0% of Erythromycin C (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Person developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
After inhalation:	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
After skin contact:	Remove affected clothing and rinse all exposed skin area with water/shower. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. Get medical attention if irritation develops and persists.
After eye contact:	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not use an eye ointment.
After ingestion:	Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison centre immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

Irritation of eyes and mucous membranes. Gastrointestinal disturbances.

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

Treatment of overdose should be symptomatic and supportive. Perform gastric lavage. Administer activated charcoal as a slurry. Monitor vital signs. Monitor ECG. Monitor fluid and electrolyte status. Monitor liver enzymes. Monitor pancreatic enzyme levels. For allergic or anaphylactoid reactions, open airway and administer antihistamines, corticosteroids, and/or epinephrine.

For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

Hemodialysis is unlikely to be of benefit.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry chemical powder or CO <sub>2</sub> .
Unsuitable extinguishing media:	Do not use heavy water stream or water jet.

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

Explosion hazard: avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

#### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Hazardous combustion products:	Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Keep unnecessary personnel away. Don't touch damaged containers or spilled materials unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

##### For emergency responders

Not available.

#### 6.2 Environmental precautions

Keeping away from drains, surface and ground water.

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

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the MSDS. Clean surface thoroughly to remove residual contamination.

#### 6.4 Reference to other sections

Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Clean equipment and work surfaces with suitable detergent or solvent after use. Empty containers pose a fire risk; evaporate the residue under a fume hood.
Personal protection:	Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. After removing gloves, wash hands and other exposed skin thoroughly.
Technical protective measures:	Ground all equipment containing material.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

Handling:

Clean equipment and work surfaces with suitable detergent or solvent after use.

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

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Protected from light and store at not more than 30°C. Keep container dry and in a cool space. Keep container tightly closed and in a well-ventilated space.

Storage – away from:

Keep away from heat. Keep away from sources of ignition. Store away from combustible materials and strong oxidizing agents.

### 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

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contamination at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

#### Individual protection measures

Eye/face protection:

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.

Skin protection:

Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including use of apron, face shield, boots or full body protection. A safety shower should be located in the work area. Recommended protective materials include: Butyl rubber and for limited contact Teflon.

Hand protection:

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powder latex gloves should be avoided due to the risk of latex allergy.

Respiratory protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards:

Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

Appearance:	White and slightly yellow crystals.
Odour:	Odourless, bitter in taste
Odour threshold:	Not available.
pH:	8.0 – 10.5
Melting/freezing point:	135-140°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 alcohol, soluble in methanol.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	3.06
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: 733.94 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No reactivity hazards known.

### 10.2 Chemical stability

Stable at normal conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known under conditions of normal use.

### 10.4 Conditions to avoid

Heat, flames, and sparks.

### 10.5 Incompatible materials

Strong oxidizing agents.

### 10.6 Hazardous decomposition products

NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire condition.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat) : 4600 mg/kg Oral LD50 (mouse) : 2580 mg/kg Oral LD50 (hamster) : 3018 mg/kg Dermal LD50 (rabbit) : Not available Inhalation LC50 (rat) : Not available
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
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:	Symptoms related to the physical, chemical and the toxicological characteristics: macrolide antibiotics : Nausea. Vomiting. Abdominal pain. Diarrhoea. Taste perversion. Yellow eyes or skin. Hearing loss. Ringing in ears. Fever.

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

Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation. May be harmful if absorbed through skin.
Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

LC50 (Fathead Minnows): 349 mg/l
EC50 (Daphnia): 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.

# Material Safety Data Sheet

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

## ERYTHROMYCINUM

EN

FORM-06-14-01 (V00)

Page 8/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Disposal procedure: Dispose of waste in a safe manner in accordance with all applicable Federal, State and local laws.

Waste from residues/ unused products: Dispose of waste in a safe manner in accordance with local regulations. Empty container or lines may retain some product residues. This material and its container must be disposed of in a safe manner. (See: Disposal instructions)

Contaminated packaging: Empty container should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warning even after container is emptied.

### 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) : UN3077

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Environmentally hazardous substance, solid, n.o.s.

##### 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) : Not classified.

##### 14.5 Environmental hazards

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

##### 14.6 Special precautions for user

Transport and intermediate store at not more than 30°C is recommended. Not more than 40+/-2°C & 75%+-5%RH for short-term excursions (within 6 months) outside the recommended conditions.

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

Not available.

##### 14.8 Additional transport information

Not available.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant



Toxic

Risk phrases:

R42/43 May cause sensitization by inhalation and skin contact.  
R63 Possible risk of harm to the unborn child.

Safety phrases:

S22 Do not breathe dust.



# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



## ERYTHROMYCINUM

S24 Avoid contact with skin.  
S36/37 Wear suitable protective clothing and gloves.  
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).  
S51 Use only in well-ventilated areas.  
S53 Avoid exposure – Obtain special instructions before use.

### 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 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.

# Material Safety Data Sheet

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

## ERYTHROMYCINUM

EN

FORM-06-14-01 (V00)

Page 10/10

Publication: 19/02/2022

Revision: XX/XX/XXXX

Version: 00



This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### 16.8 Department issuing MSDS

Quality Department  
FAC SECUNDUM ARTEM NV  
info@magis-pharma.be