

# Safety Data Sheet (GHS)

according to Regulation (EC) No 1907/2006

Date of issue: 27-JAN-2015

Replaces version of: 28-OCT-2013

CLARITHROMYCIN, POWDER 472952 (KUNDL)



## Section 1: Identification of the substance/preparation and of the company

### 1.1 Product identifier

Product name CLARITHROMYCIN, POWDER  
Chemical Name Clarithromycin, powder  
CAS Number 81103-11-9

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Usage Antibiotic, Pharmaceutical active ingredient

### 1.3 Details of the supplier of the Safety Data Sheet

Company name Sandoz GmbH  
Biochemiestrasse 10  
6250 Kundl / Tirol  
Austria

### 1.4 Emergency telephone number

Emergency phone number +43 5338 200 0, E-Mail: sds.support@novartis.com

## Section 2: Hazards identification

### 2.1 Classification of the substance or mixture

GHS hazard category

Acute Toxicity (oral): Cat.4;

Skin sensitizer: Cat.1;

Respiratory sensitizer Cat.1;

Reproductive toxicity: Cat.2;

Classification according EU Directive 67/548/EEC or 1999/45/EC see Section 15

### 2.2 Label elements

Pictogram, Signal Word Self assessment according REGULATION (EC) No 1272/2008



Danger

### Hazard statements

H302: Harmful if swallowed.  
H317: May cause an allergic skin reaction.  
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361: Suspected of damaging fertility or the unborn child.

### Precautionary statements

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.  
P270: Do not eat, drink or smoke when using this product.  
P281: Use personal protective equipment as required.  
P330: Rinse mouth.  
P302/352: IF ON SKIN: Wash with plenty of water/...  
P308/313: IF exposed or concerned: Get medical advice/attention.

### 2.3 Other hazards

Specific hazards no data available

## Section 3: Composition / information on ingredients

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## Chemical characterisation of the substance / preparation:

**Chemical Class** antibiotics  
**Chemical Name** Clarithromycin, powder  
**CAS Number** 81103-11-9

### EINECS

For TLV values of declared components, see Section 8, Exposure controls / Personal

Full text of H-Phrases see under Section 16

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## Section 4: First aid measures

### 4.1 Description of first aid measures

**Inhalation** Take patient immediately to factory medical centre or call for an ambulance.  
**Skin Contact** Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and seek medical advice.  
**Eye Contact** Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).  
**Ingestion** If feeling sick, immediately call for a physician or take patient to factory medical centre (if necessary, call for an ambulance). If swallowed, seek medical advice immediately and show this container or label.

Self-protection of the first aider

For personal protection see Section 8

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

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

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## Section 5: Fire fighting measures

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Water spray or fog, foam, dry chemical powder, CO2, dry sand

**Unsuitable Extinguishing Media** No restrictions

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

### 5.3. Advice for firefighters

**Protective equipment for firefighters** Wear self-contained breathing apparatus and fire protective suite.

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## Section 6: Accidental release measures

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

**Personal precautions** Avoid contact with skin, eyes and clothing.

### 6.2 Environmental precautions

**Environmental precautions** Must not be released into sewers, drains or wells.

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

**Methods for cleaning** Transfer large quantities into a container, rinse the rest with plenty of water.

**Accidental Release** Wastes must be properly contained and labelled for disposal.

### 6.4 Reference to other sections

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For personal protection see Section 8, for disposal considerations see Section 13

## Section 7: Handling and storage

### 7.1. Precautions for safe handling

**Storage and Handling** Open handling without suitable personal protective equipment must be avoided. Handle product only in closed system or provide appropriate exhaust ventilation at machinery. Keep container tightly closed. Keep dry. Store in a dark place

For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

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

**Technical measures/** Preferably handle in closed system.  
**Precautions**

**Preventive Precautions** Take precautionary measures against static discharges. Avoid formation of dust. Keep away (fire/explosion) from sources of ignition.

### 7.3 Specific end use(s)

See Subsection 1.2

## Section 8: Exposure controls / Personal protection

### 8.1 Control parameters

List type	µg/m3	
Internal exposure limit	3000	/

### 8.2 Exposure controls

**Industrial Hygiene** Avoid exposure.  
Change contaminated clothes immediately.  
Minimize open handling.  
Ensure sufficient exhaust ventilation.  
Wear suitable protective clothing.

**Open Handling** Respiration : Full face mask (EN136)  
Eye : Safety glasses (EN166)  
Hand : Butyl rubber gloves (EN374)  
Additional protection : Disposable dust-proof suit (EN465, type 4) worn over long underwear

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Formulation	powder
Physical state	solid
Colour	off-white
Odour	odourless
Odour threshold	no data available
pH	7.5 - 10 (Concentration: 2 g/l)
Melting point/range	220 °C (decomposing)
Boiling Point	not applicable
Flash Point	not available

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<b>Combustibility Test</b>	Standard conditions: 2 = after ignition the fire dies out rapidly (Temperature: 20 °C) Method: Combustibility test safety lab Clariant Standard conditions: 2 = after ignition the fire dies out rapidly (Temperature: 100 °C) Method: Combustibility test safety lab Clariant
<b>Solubility (Aqueous Solvents)</b>	Water: practically insoluble
<b>Solubility (Solvents)</b>	organic solvents: soluble
<b>Partition Coefficient</b>	unknown
<b>Autoignition/MIT</b>	Temperature: 310 °C Method: BAM (fluidized dust)
<b>Dynamic Decomposition</b>	Exotherm: > 350 °C Method: Lütolf, open cup, as is (Temp.progr. 2.5°C/min, examined up to 350°C) Exotherm: > 200 °C Method: Grewer test method, air stream, as is (temp.progr. 1,2°C/min, examined up to 350°C)
<b>Isoperibolic Decomposition (&gt;8h)</b>	Stable up to: > 170 °C (Air open cup) Method: Radex isoperibolic (long duration decomposition test open cup 8h)
<b>Flammable Gases over Explosivity/Reactivity</b>	Temperature: 350 °C (Gas volume: 20 l/kg) Drop-Weight Test: Negative Method: Lütolf test method

## 9.2 Other information

<b>Bulk Density</b>	400 - 600 kg/m <sup>3</sup>
<b>Dust Explosion</b>	Positive Minimum Ignition Energy: 1 - 3 mJ Method: modified Hartmann tube
<b>Specific Resistivity pKa</b>	1.5 - 1.9 * 10E13 Ohm m no data available

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## Section 10: Stability and reactivity

### 10.1 Reactivity

Reaction products with water no data available

### 10.2 Chemical stability

Stability in solvents no data available  
Hydrolysis no data available

### 10.3 Possibility of hazardous reactions

Materials to avoid no data available

### 10.4 Conditions to avoid

Conditions to avoid no data available

### 10.5 Incompatible materials

For incompatible materials see Subsection 7.2 Conditions for safe storage, including any incompatibilities

### 10.6 Hazardous decomposition products

<b>Hazardous Decomposition Products</b>	nitrogen oxides Carbon dioxide carbon monoxide
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## Section 11: Toxicological information

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## 11.1 Information on toxicological effects

<b>Acute Toxicity</b>	LD50 oral: 1270 mg/kg Species: rat LD50 subcutaneous: > 5000 mg/kg Species: rat LD50 intraperitoneal: 669 mg/kg Species: rat
<b>Irritation, Corrosion</b>	unknown
<b>Sensitisation</b>	Skin (Species: human) sensitizing Respiratory system (Species: human) sensitizing
<b>Additional advice</b>	Reproductive toxic effects have been observed in studies with animals.
<b>Mutagenicity</b>	The product showed negative results in in vitro mutagenicity studies. Negative (AMES-Test (reverse mutation assay)) Cell: Strains of salmonella typhimurium.

## Section 12: Ecological information

**Ecotoxicity Summary** No quantifiable data available.  
Avoid release to the environment.

### 12.1 Toxicity

<b>Fish acute toxicity</b>	unknown
<b>Aquatic invertebrate acute toxicity</b>	unknown
<b>Algae Toxicity</b>	unknown
<b>Bacterial Respiration Inhibition</b>	unknown

### 12.2 Persistence and degradability

**Biological Elimination** unknown

### 12.3 Bioaccumulative potential

<b>Partition Coefficient</b>	unknown
<b>Biological accumulation</b>	unknown

### 12.4 Mobility in soil

**Soil and Sludge Sorption/Desorption** unknown

### 12.5 Results of PBT and vPvB assessment

**PBT assessment** unknown

### 12.6 Other adverse effects

**Other adverse effects** unknown

### 12.7 Additional Information

no data available

## Section 13: Disposal considerations

### 13.1. Waste treatment methods

**Disposal Requirements** May be incinerated if local official regulations are observed.

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 **SANDOZ**  
a Novartis company

## Section 14: Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	not restricted	0			N.A.
IMDG-Code:	not restricted	0			
ICAO/IATA-DGR:	not restricted	0			

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

## Section 15: Regulatory information

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

EC Label assessment: Labelling according to EC Directives:



Xn harmful

#### Risk Phrases

R22: Harmful if swallowed.  
R63: Possible risk of harm to the unborn child.  
R62: Possible risk of impaired fertility.  
R42/43: May cause sensitization by inhalation and skin contact.

#### Safety Phrases

S22: Do not breathe dust.  
S24/25: Avoid contact with skin and eyes.  
S37: Wear suitable gloves.

### Other national and international regulations

#### 15.2 Chemical Safety Assessment

Chemical Safety Assessment not required.

## Section 16: Other information

Changes since the previous version in Section 9: Physical and chemical properties

#### Abbreviations used

Recipient To whom it may concern .  
EMA

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.