# Safety Data Sheet for Drug Products (EU)

Date of issue: 15-JUN-2018 Replaces version of: 10-NOV-2016

**AMPICILLIN 500MG 10PSOIJ** 960568 (AT14)



# 1. Identification of the substance/preparation and of the company

AMPICILLIN 500MG 10PSOIJ **Product name** 

**Chemical Class** antibiotics

**Generic Name** AMPICILLIN SODIUM

Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical

intermediate)

Novartis Pharma AG Company name

> 4002 Basel Switzerland

Tel: +41 61 324 11 11, email: sds.support@novartis.com

**Emergency phone** 

number

CHEMTEL (International) +1 813 676 1670 (365/24/7)

#### 2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

## 3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
AMPICILLIN SODIUM	500 mg	69-52-3

#### Remaining components are inert ingredients.

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

#### 4. First aid measures

**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).

**Skin Contact** Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and

soap and seek medical advice.

Inhalation Remove the victim from danger zone, avoid further exposure.

Ingestion If swallowed, seek medical advice immediately and show this container or label.

**Notes to Physician** General measures to eliminate the substance and to reduce absorption.

### 5. Fire fighting measures

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

Media

Unsuitable No restrictions

**Extinguishing Media** 

Dangerous Combustion Carbon dioxide, carbon monoxide, sulfur dioxide, nitrogen oxides

**Products** 

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

for firefighters

#### 6. Accidental release measures

Personal precautions Avoid contact with skin, eyes and clothing.

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

precautions

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discharge properly.

## 7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

# 8. Exposure controls / Personal protection

**Occupational Exposure Limit (OEL)** 

no data available

TLV values of declared components

Contains:

**AMPICILLIN SODIUM** 

List type	Value Unit		
Internal exposure limit	110 μg/m3	HHA Database	

#### Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

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## 9. Physical and chemical properties

Flash Point not applicable

no data available

## 10. Stability and reactivity

Under the normal conditions of use, the product is stable.

## 11. Toxicological information

Acute Toxicity Data of AMPICILLIN SODIUM

LD50: > 5314 mg/kg

Route: oral Species: rat

Irritation, Corrosion

no data available

Sensitisation

Data of AMPICILLIN SODIUM

Respiratory system (Species: human) sensitizing

Data of AMPICILLIN SODIUM Skin (Species: human) sensitizing

Additional advice Data of AMPICILLIN SODIUM

It was concluded that this substance is devoid of genotoxic and oncogenic potential.

Mutagenicity no data available

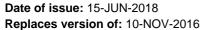
## 12. Ecological information

**Biological Elimination** no data available **Fish acute toxicity** no data available **Aquatic invertebrate** no data available

acute toxicity

Algae Toxicity no data available

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**Bacterial Respiration** 

Inhibition

no data available

**Ecotoxicity Summary** Data of AMPICILLIN SODIUM

No quantifiable data available. Data of AMPICILLIN SODIUM Avoid release to the environment.

## 13. Disposal considerations

**Disposal Requirements** Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved,

controlled furnace with combustion gas scrubbing and emission gas control. Local regulations

should be adhered to.

## 14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.

# 15. Regulatory information

#### Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
AMPICILLIN SODIUM	500 mg	69-52-3	<b>&amp;</b>	D	H334, H317

Remaining components are inert ingredients.

### 16. Other information

#### Abbreviations used

H317: May cause an allergic skin reaction.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Recipient

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.

