

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

Product name	AMPICILLIN 500MG 10PSOIJ
Chemical Class	antibiotics
Generic Name	AMPICILLIN SODIUM
Usage	Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name	Novartis Pharma AG 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 Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Dangerous Combustion Products	Carbon dioxide, carbon monoxide, sulfur dioxide, nitrogen oxides
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental precautions	Must not be released into sewers, drains or wells.

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Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and 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/m ³	HHA Database

Personal protection for open handling

Health care personnel



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

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 acute toxicity no data available

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		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.