

# Safety Data Sheet (GHS)

according to Regulation (EC) No.1907/2006

Date of issue: 31-JUL-2012

Replaces version of: 29-MAR-2011

AMOXICILLIN 3HDR N AT12 GR C1 EU 40003683 (KUNDL)



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

### 1.1 Product Identifier

Product name AMOXICILLIN 3HDR N AT12 GR C1 EU  
Chemical Name AMOXICILLIN TRIHYDRATE  
CAS Number 61336-70-7

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

Usage 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

Skin sensitizer: Cat.1;

Respiratory sensitizer: Cat.1;

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

H317: May cause an allergic skin reaction.  
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### Precautionary statements

P302/352: IF ON SKIN: Wash with plenty of soap and water.  
P342/311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P333/313: If skin irritation or rash occurs: Get medical advice/attention.  
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

### 2.3 Other hazards

Specific hazards no data available

## Section 3: Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Chemical Name AMOXICILLIN TRIHYDRATE  
CAS Number 61336-70-7  
EINECS 2480038

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Content: > 99 %

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	Remove from danger zone. Obtain immediate medical assistance.
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

**Dangerous Combustion Products** Carbon dioxide  
carbon monoxide  
sulfur dioxide  
nitrogen oxides

### 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.

### 6.4 Reference to other sections

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

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## Section 7: Handling and storage

### 7.1. Precautions for safe handling

**Storage and Handling** Keep container tightly closed. Keep dry. Store in a dark place  
**Precautions**

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

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

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

### 7.3 Specific end use(s)

See Subsection 1.2

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## Section 8: Exposure controls / Personal protection

### 8.1 Control parameters

no data available

### 8.2 Exposure controls

<b>Industrial Hygiene</b>	Avoid exposure. Change contaminated clothes immediately. Minimize open handling. Ensure sufficient exhaust ventilation. Wear suitable protective clothing.
<b>Open Handling</b>	Respiration : Disposable fine dust protection mask (EN149) 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.

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## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Formulation</b>	powder
<b>Physical state</b>	solid
<b>Particle Size</b>	2 µm 4 µm (Concentration: 50 %)
<b>Colour</b>	white
<b>Odour</b>	odourless
<b>Occupational Exposure Limit (OEL)</b>	no data available
<b>pH</b>	3.5 - 5.5 (Concentration: 2 g/l, Temperature: 20 °C)
<b>Melting point/range</b>	> 194 °C (decomposing)
<b>Boiling Point</b>	unknown
<b>Flash Point</b>	not available
<b>Solubility (Aqueous Solvents)</b>	Water: 4 g/l (Temperature: 20 °C)
<b>Solubility (Solvents)</b>	Methanol: 7.5 g/l (Temperature: 20 °C)

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Partition Coefficient	unknown
Autoignition	Temperature: 450 °C Method: BAM (fluidized dust)
Dynamic Decomposition	Exothermy: 140 °C Method: Grewer test method, air stream, as is (temp.progr. 1,2°C/min, examined up to 350°C) Exothermy: > 350 °C Method: Lütolf, open cup, as is (isoperibole)
Isoperibolic Decomposition (>8h)	Stable up to: 150 °C Method: long duration test open cup (8h)
Flammable Gases over Explosivity/Reactivity	Temperature: 350 °C (Gas volume: 40 l/kg) Deflagration: No suspect of deflagration based on thermal data Drop-Weight Test: Negative Method: Drop-Weight Test

## 9.2 Other Information

Bulk Density	500 - 750 kg/m <sup>3</sup>
Dust Explosion	Positive Minimum Ignition Energy: 30 - 100 mJ
Specific Resistivity	1.8 - 2 * 10E12 Ohm m
pKa	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

Hazardous Decomposition Products no data available

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## Section 11: Toxicological information

### 11.1 Information on toxicological effects

Acute Toxicity	LD50 oral: > 15000 mg/kg Species: rat LD50 oral: > 12500 mg/kg Species: rabbit
Irritation, Corrosion	unknown
Sensitisation	Skin (Species: human) sensitizing

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**Additional advice** Respiratory system (Species: human) sensitizing  
Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments.  
**Mutagenicity** unknown  
**Reproduction Toxicity** Negative  
Species: mouse, Sex: female

## Section 12: Ecological information

**Ecotoxicity Summary** Avoid release to the environment.

### 12.1 Toxicity

**Fish acute toxicity** LC50: > 1000 mg/l

**Aquatic invertebrate acute toxicity** EC50: > 1000 mg/l

**Algae Toxicity** NOEC: 250 mg/l

**Bacterial Respiration Inhibition** unknown

### 12.2 Persistence and degradability

**Biological Elimination** unknown

### 12.3 Bioaccumulative potential

**Partition Coefficient** unknown

**Biological accumulation** 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.

## 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:** -

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 **SANDOZ**  
a Novartis company

## 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

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.

S36: Wear suitable protective clothing.

### 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

Section 1: Identification of the substance/preparation and of the company  
Section 16: Other information

Pharmacological Action Antibiotic

Abbreviations used

Recipient

Deborah Overcash  
Sandoz Inc.  
QM Pharmacovigilance 01  
2555 West Midway Boulevard  
Broomfield, CO 80020  
US

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.