

Safety Data Sheet (GHS)

according to Regulation (EC) No. 1907/2006

Date of issue: 29-MAR-2011

Replaces version of: 16-FEB-2011

AMOXICILLIN TRIHYDRAT KOMPAKTIERT (BCSA) 472188 (KUNDL)



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

Product name AMOXICILLIN TRIHYDRAT KOMPAKTIERT (BCSA)
Usage Antibiotic, Pharmaceutical active ingredient
Company name Sandoz GmbH
Biochemiestrasse 10
6250 Kundl / Tirol
Austria
Emergency phone number +43 5338 200 0, E-Mail: sds.support@novartis.com

2. Hazards identification

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.

GHS hazard category

Skin sensitizer: Cat.1;

Respiratory sensitizer: Cat.1;

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

3. Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Chemical Name AMOXICILLIN TRIHYDRATE
CAS Number 61338-70-7
EINECS 2480038
Content: > 99 %

For TLV values of declared components, see chapter 8

Full text of H-Phrases see under chapter 16

4. 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.

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5. Fire fighting measures

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

Unsuitable Extinguishing Media No restrictions

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.

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

For personal protection see chapter 8; for disposal considerations see chapter 13

7. Handling and storage

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

For industrial hygiene measures see chapter 8

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

8. Exposure controls / Personal protection

Occupational Exposure Controls

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

Open Handling

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.

9. Physical and chemical properties

Appearance

Formulation powder

Physical state solid

Colour white

Odour odourless

Safety relevant basic data

Melting point/range > 194 °C (decomposing)

Boiling Point unknown

Bulk Density 500 - 750 kg/m³

Particle Size 2 µm

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	4 µm (Concentration: 50 %)
Solubility (Aqueous Solvents)	Water: 4 g/l (Temperature: 20 °C)
Solubility (Solvents)	Methanol: 7.5 g/l (Temperature: 20 °C)
pH	3.5 - 5.5 (Concentration: 2 g/l, Temperature: 20 °C)
pKa	Not available
Specific Resistivity	1.8 - 2 * 10E12 Ohm m
Safety Tests	
Autoignition	Temperature: 450 °C Method: BAM (fluidized dust)
Dynamic Decomposition	Exothermy: 140 °C Method: Grever 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)
Dust Explosion	Positive Minimum Ignition Energy: 30 - 100 mJ
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 suspicion, due to decomposition test Drop-Weight Test: Negative Method: Drop-Weight Test

10. Stability and reactivity

Dangerous Combustion Products	Carbon dioxide carbon monoxide sulfur dioxide nitrogen oxides
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11. Toxicological information

Acute Toxicity	LD50 oral: > 15000 mg/kg Species: rat LD50 oral: > 12500 mg/kg Species: rabbit
Irritation, Corrosion	unknown
Sensitisation	Skin (Species: human) sensitizing Respiratory system (Species: human) sensitizing
Additional advice	Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments.
Mutagenicity	unknown
Reproduction Toxicity	Negative Species: mouse, Sex: female

12. Ecological Information

Ecotoxicity Summary Avoid release to the environment.

Environmental Toxicity

Fish acute toxicity	LC50: > 1000 mg/l
Aquatic Invertebrate acute toxicity	EC50: > 1000 mg/l
Algae Toxicity	NOEC: 250 mg/l

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Bacterial Respiration unknown
Inhibition

Persistence and degradability

Biological Elimination unknown

13. Disposal considerations

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

14. Transport information

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

ICAO/IATA-DGR: no dangerous good

15. Regulatory information

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.

Chemical Safety Assessment not required.

16. Other information

Abbreviations used

Recipient To whom it may concern

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.

Transport/Regulatory information



Date of issue: 29-Mar-2011

AMOXICILLIN TRIHYDRAT KOMPAKTIERT (BCSA) 472188 (KUNDL)

1. Product Identification

Product name AMOXICILLIN TRIHYDRAT KOMPAKTIERT (BCSA)
Product Number 472188 (KUNDL)
Chemical Name AMOXICILLIN TRIHYDRATE MICROFINE, ORAL
AMOXICILLIN TRIHYDRATE
CAS Number 61336-70-7

2. Transport Classification

Regulation	Class
RID/ADR:	not restricted
IMDG-Code:	not restricted
ICAO/IATA-DGR:	not restricted
DOT-Code:	not restricted

RID/ADR: no dangerous good

IMDG-Code: no dangerous good

Solubility (Aqueous Solvents) Water: 4 g/l (Temperature: 20 °C)

ICAO/IATA-DGR: no dangerous good

DOT-Code: no dangerous good

3. Regulations

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.

EC Label assessment: Labelling according to EC Directives:



Xn harmful

Risk Phrases R42/43: May cause sensitization by inhalation and skin contact.

Occupational Hazard Category 3 Highly hazardous substance
assessment: by NPOHC

Storage Category 20.2 Combustible solids
Novartis (NSC)