

Safety Data Sheet (GHS)

according to Regulation (EC) No.1907/2006

Date of issue: 17-NOV-2011

Replaces version of: 09-NOV-2011

CEFPODOXIME PROXETIL 40000826 (KUNDL)



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

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

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 (R,S)-1-(Isopropoxycarbonyloxy) ethyl (+) - (6R, 7R) -7- (2-(2-amino-4-thiazolyl) - 2-((Z)-methoxyimino)-acetoamido)-3-methoxymethyl-8-oxo-5-thia-1-azabi-cyclo (4.2.0) oct-2-en-2-carboxylate
Cefpodoxim Proxetil

CAS Number 87239-81-4

Content: >= 90 %

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. Avoid formation of dust. 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) or reusable halfmask (EN140)
Eye	:	Safety glasses (EN166)
Hand	:	Disposable gloves or chemical-resistant gloves, normal length (EN374/EN388)
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 brownish

Odour odourless

Safety relevant basic data

Melting point/range unknown

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Boiling Point	unknown
Particle Size	> 63 µm (Concentration: 21 %) 12 µm (Concentration: 50 %)
Solubility (Aqueous Solvents)	Water: insoluble (Temperature: 20 °C)
Solubility (Solvents)	Acetone: soluble Methanol: soluble
pH	not available
pKa	not available
Specific Resistivity	3 - 4.6 * 10E13 Ohm m

Safety Tests

Dynamic Decomposition	Exothermy: 140 °C Method: Lütolf, open cup, as is (Temp.progr. 2.5°C/min, examined up to 350°C) Exothermy: 150 °C Method: Grewer test method, air stream, as is (temp.progr. 1,2°C/min, examined up to 350°C)
Combustibility Test	Standard conditions: 2 = after ignition the fire dies out rapidly (Temperature: 20 °C) Method: Combustibility test safety lab Clariant
Dust Explosion	Positive: Positive Minimum Ignition Energy: 1 - 3 mJ Method: modified Hartmann tube
Isoperibolic Decomposition (>8h)	Stable up to: 110 °C Method: Radex isoperibolic (long duration decomposition test open cup 8h)
Flammable Gases over	Temperature: 230 °C (Gas volume: 170 l/kg)

10. Stability and reactivity

Conditions to avoid	Stable at normal conditions
Materials to avoid	none known
Dangerous Combustion Products	carbon monoxide Carbon dioxide sulfur dioxide nitrogen oxides
Hazardous Decomposition Products	nitrogen oxides carbon oxides

11. Toxicological information

Acute Toxicity	LD50 oral: > 4000 mg/kg Species: rat
Irritation, Corrosion	unknown
Sensitisation	Respiratory system (Species: human) Suspicion Skin (Species: human) Suspicion
Additional advice	The product showed negative results in mutagenicity studies. Animal studies showed no reproductive toxicity potential relevant to man.
Mutagenicity	unknown

12. Ecological information

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

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Fish acute toxicity unknown

Aquatic invertebrate acute toxicity unknown

Algae Toxicity unknown

Bacterial Respiration Inhibition unknown

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			N.A.
IMDG-Code:	not restricted	0			
ICAO/IATA-DGR:	not restricted	0			

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

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

Changes since the previous version in chapter 10. Stability and reactivity

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.