

# Safety Data Sheet (GHS)

according to Regulation (EC) No.1907/2006

Date of issue: 16-DEC-2010

Replaces version of: 19-OCT-2010

CEFTRIAXON NATRIUM 471001 (KUNDL)



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

**Product name** CEFTRIAXON NATRIUM  
**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, signalword** 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** CEFTRIAXONE SODIUM

**CAS Number** 74578-69-1

**EINECS** 2779300

**Content:** > 96 %

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.  
**Acute/Chronic Effects** Allergy.

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## and Symptoms

## 5. Fire fighting measures

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

**Unsuitable Extinguishing Media** High volume water jet

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

## 6. Accidental release measures

**Personal precautions** Wear chemical resistant protective suite. Minimize number of personnel in risk area. Keep away unprotected persons. Wear chemical-proof clothes and masks while undressing contaminated persons or cleaning contaminated equipment.

**Environmental precautions** Firefighting water may not spill into open rivers and ponds. Collect spilled material by all available means. Do not release into the environment.

**Methods for cleaning** Moisten spilled material with water (in order to avoid dust formation), cover with wet sand or wetted binder, then take up. Wash away remains with plenty of water. Put into lead-sealable and labelled drums.

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

## 7. Handling and storage

**Storage and Handling Precautions** Keep dry.

For industrial hygiene measures see chapter 8

**Conditions of storage** Protect against light

**Preventive Precautions (fire/explosion)** Take precautionary measures against static discharges. Avoid formation of dust.

## 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           | : Full face mask (EN136)  |
| Filter                | : P3 (EN143)  |
| Eye                   | : Yes, by face mask   |
| Hand                  | : Normal length chemical-mechanical-resistant gloves (EN374/EN388)<br>worn over disposable gloves           |
| Additional protection | : Disposable dust-proof suit (EN465, type 4) worn over long underwear<br>Disposable boot covers, conductive |

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

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|                |                   |
|----------------|-------------------|
| Physical state | solid             |
| Colour         | white light beige |
| Odour          | odourless         |

## **Safety relevant basic data**

|                               |  |
|-------------------------------|--|
| Melting point/range           | > 155 °C (decomposing)                             |
| Boiling Point                 | unknown  |
| Bulk Density                  | approx. 300 kg/m <sup>3</sup>                      |
| Solubility (Aqueous Solvents) | Water: approx. 400 g/l (Temperature: 25 °C)        |
| Solubility (Solvents)         | Not available                                      |
| pH                            | 6 - 8 (Concentration: 100 g/l, Temperature: 25 °C) |
| pKa                           | Not available                                      |

## **Safety Tests**

|                        |                        |
|------------------------|------------------------|
| Dust Explosion         | Negative               |
| Explosivity/Reactivity | Deflagration: Negative |

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## **10. Stability and reactivity**

|                               |  |
|-------------------------------|--|
| Dangerous Combustion Products | carbon monoxide<br>Carbon dioxide<br>sulfur dioxide<br>nitrogen oxides |
|-------------------------------|--|

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## **11. Toxicological information**

|                       |   |
|-----------------------|---|
| Acute Toxicity        | LD50 oral: > 10000 mg/kg<br>Species: rat<br>LD50 oral: > 10000 mg/kg<br>Species: rabbit<br>LD50 oral: > 10000 mg/kg<br>Species: mouse |
| Irritation, Corrosion | unknown   |
| Sensitisation         | respiratory system (Species: human) sensitizing<br>Skin (Species: human) sensitizing  |
| Additional advice     | Did not show teratogenic effects in animal experiments.<br>The product showed negative results in mutagenicity studies.               |
| Mutagenicity          | unknown   |

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## **12. Ecological information**

|                     |  |
|---------------------|--|
| Ecotoxicity Summary | No quantifiable data available.<br>Avoid release into the environment. |
|---------------------|--|

### **Environmental Toxicity**

|                                     |         |
|-------------------------------------|---------|
| Fish acute toxicity                 | unknown |
| Aquatic invertebrate acute toxicity | unknown |
| Algae Toxicity                      | unknown |
| Bacterial Respiration Inhibition    | unknown |

### **Persistence and degradability**

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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

Changes since the previous version in chapter 7. Handling and storage

Pharmacological Action Antibiotic

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.