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

1.1 Product identifier
Product name: CEFTRIAXON NATRIUM
Chemical Name: CEFTRIAXONE SODIUM
CAS Number: 74578-69-1

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

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.

2.3 Other hazards
Specific hazards: no data available

Section 3: Composition / information on ingredients

Chemical characterisation of the substance / preparation:
Chemical Name: CEFTRIAXONE SODIUM
CAS Number: 74578-69-1
EINECS: 2779300
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). 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

Acute/Chronic Effects
Allergy.

4.3 Indication of any immediate medical attention and special treatment needed

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
High volume water jet

5.2 Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up
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.

6.4 Reference to other sections
For personal protection see Section 8, for disposal considerations see Section 13

Section 7: Handling and storage

7.1. Precautions for safe handling
Storage and Handling  Keep dry.
Precautions  For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

7.2 Conditions for safe storage, including any incompatibilities
Conditions of storage  Protect against light
Preventive Precautions  Take precautionary measures against static discharges. Avoid formation of dust.
(fire/explosion)

7.3 Specific end use(s)
See Subsection 1.2

Section 8: Exposure controls / Personal protection

8.1 Control parameters
no data available

8.2 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) worn over disposable gloves
Additional protection : Disposable dust-proof suit (EN465, type 4) worn over long underwear
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.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Formulation  powder
Physical state  solid
Particle Size  > 10 µm (Concentration: > 50 %)
Colour  white to faint beige
Odour  odourless
Odour threshold  no data available
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

Section 11: Toxicological information

11.1 Information on toxicological effects
Acute Toxicity
LD50 oral: > 10000 mg/kg Species: rat
LD50 oral: > 10000 mg/kg Species: rabbit
LD50 oral: > 10000 mg/kg Species: mouse

Irritation, Corrosion unknown

Sensitisation Respiratory system (Species: human) sensitizing
Skin (Species: human) sensitizing

Additional advice Did not show teratogenic effects in animal experiments.
The product showed negative results in mutagenicity studies.

Mutagenicity unknown

Section 12: Ecological information

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

12.1 Toxicity
Fish acute toxicity unknown
Aquatic invertebrate acute toxicity unknown
Algae Toxicity unknown
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
Section 13: Disposal considerations

13.1. Waste treatment methods

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

Section 14: Transport information

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<th>Class</th>
<th>UN No.</th>
<th>PG</th>
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</tbody>
</table>

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

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

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.