

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937561

N/A

Safety Data Sheet for Drug product

Date of issue: 22-APR-2016

Replaces version of:

CEFTRIAXONE 1G 1PSOIJ 44020288 (KUNDL)

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

Product name CEFTRIAXONE 1G 1PSOIJ
Generic Name CEFTRIAXONE SODIUM
Pharmacological Action Antibiotic
Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name Sandoz GmbH
Biochemiestrasse 10
6250 Kundl, Tirol, Austria
+43 5338 200 0, E-Mail: sds.support@novartis.com
Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
CEFTRIAXONE SODIUM	1 GRAM	74578-69-1

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

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).
Skin Contact Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation Remove the victim from danger zone, avoid further exposure.
Ingestion If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media No restrictions
Dangerous Combustion Products carbon monoxide, Carbon dioxide, sulfur dioxide, nitrogen oxides
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.

Safety Data Sheet for Drug product

Date of issue: 22-APR-2016

Replaces version of:

CEFTRIAZONE 1G 1PSOIJ 44020288 (KUNDL)

Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

CEFTRIAZONE SODIUM

no data available

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Flash Point not applicable
no data available

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity Data of CEFTRIAZONE SODIUM
LD50: > 10000 mg/kg
Route: oral
Species: rat
Data of CEFTRIAZONE SODIUM
LD50: > 10000 mg/kg
Route: oral
Species: rabbit
Data of CEFTRIAZONE SODIUM
LD50: > 10000 mg/kg
Route: oral
Species: mouse

Irritation, Corrosion no data available

Sensitisation Data of CEFTRIAZONE SODIUM
Respiratory system (Species: human) sensitizing
Data of CEFTRIAZONE SODIUM
Skin (Species: human) sensitizing

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

Mutagenicity no data available

Safety Data Sheet for Drug product

Date of issue: 22-APR-2016

Replaces version of:

CEFTRIAZONE 1G 1PSOIJ 44020288 (KUNDL)

12. Ecological information

Biological Elimination	no data available
Fish acute toxicity	no data available
Aquatic invertebrate acute toxicity	no data available
Algae Toxicity	no data available
Bacterial Respiration Inhibition	no data available
Ecotoxicity Summary	Data of CEFTRIAZONE SODIUM No quantifiable data available. Data of CEFTRIAZONE SODIUM Avoid release to the environment.

13. Disposal considerations


Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
CEFTRIAZONE SODIUM	1 GRAM	74578-69-1		D	H334, H317

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H317: May cause an allergic skin reaction.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Recipient Assotiate Director Operations Koula Christides
Sandoz Inc.
SCM
College Road West
NJ 08540
Princeton
USA

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.