

Roche

P55
157229
157230
157231
157232

Material Safety Data Sheet

Ceftriaxone sodium

1. Product and Company Identification

Product name Ceftriaxone sodium

Product code 04 0597 3

Company information Enquiries: Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Local representation:

Phone 001-973/235 50 00

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

Roche Nutley Inventory Code 20140

Roche number Ro 13-9904/015

CAS number 104376-79-6 with water of crystallization
74578-69-1 anhydrous

Synonyms

- ROCEPHIN(R)
- Ceftriaxone disodium salt
- ROCEPHIN substance sterile
- Ceftriaxone sodium crude (code no. 04 0595 7)

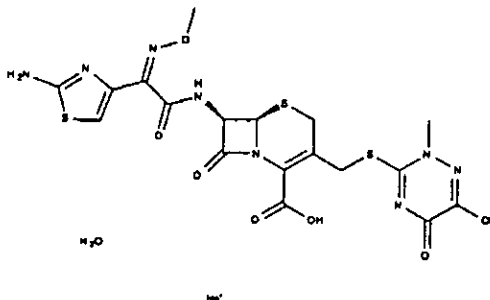
Characterization pharmaceutical active substance in the class of cephalosporines

2. Composition/Information on ingredients

Chemical name

- (6R,7R)-7-[(Z)-2-(2-Amino-4-thiazolyl)-2-(methoxyimino)acetamido]-3-[[[(2,5-dihydro-6-hydroxy-2-methyl-5-oxo-as-triazin-3-yl)thio]methyl]-8-oxo-5-thia-1-aza-bicyclo-[4.2.0]oct-2-ene-2-carboxylic acid disodium salt hydrate

Percentage 95 %



Ceftriaxone sodium

3. Hazards identification

Emergency Overview

Form crystalline powder

Color white to yellowish

Odor none to faint

Hazard Overview

- May cause allergic reactions.
- Dust explosion hazard
- Violent decomposition can occur when heated or in a fire

Potential Health Effects

- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: skin, kidneys, liver, gastrointestinal system, Central nervous system, Hematopoietic/blood system
- Acute Effects: May cause allergic reactions., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause headache., May cause hepatic (liver) system effects., Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes)., May cause renal (kidney) system effects., Signs and symptoms may include urine retention, increase or decrease in urine production, painful urination and presence of blood in urine., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite., May cause blood system changes.
- Chronic Effects: No adverse effects known
- Carcinogenicity: not listed by NTP, IARC or OSHA

Additional Health Information

- Conditions Aggravated: Hypersensitivity to penicillin and other antibiotics.
- Additional Health Hazard Information: Since this material has been shown to be excreted in breast milk, nursing mothers should exercise caution regarding exposure.

Ceftriaxone sodium

4. First-aid measures

Eye contact	- rinse with tap water for 10 minutes - open eyelids forcibly
Skin contact	- remove contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - consult physician
Note to physician	- treat symptomatically - in case of strong sensitization against Cephalosporines anaphylaxis and asthma are possible: weak cases: - Antihistaminica i.v. - in case of asthma topical steroids and inhalative β -Mimetica severe cases: - Adrenalin 0.3 - 0.5 mg i.v. - Antihistaminica i.v. - high dosage of steroids i.v. - In case of asthma additional inhalation with topical steroids and β -Mimetica

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- formation of toxic and corrosive combustion gases (nitrogen oxides, sulfur oxides) possible - consider dust explosion hazard - substance is hazardous for water: contain fire-fighting wastewater
Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

6. Accidental release measures

Environmental protection	- do not allow to enter drains or waterways
Methods for cleaning up	- collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers - clean contaminated area/containers with a alkaline cleaner

Ceftriaxone sodium

7. Handling and storage

Handling

- Technical measures
- processing only in closed rooms with reduced pressure and high efficiency particulate air filter (HEPA filter; GMP)
 - avoid dust formation; high dust explosion hazard
 - local exhaust ventilation necessary
 - take precautionary measures against electrostatic charging

- Suitable materials
- glass, stainless steel

Storage

- Validity
- 24 months, $\leq 25^{\circ}\text{C}$,

- Packaging materials
- in sealed containers
 - tightly closing; material: stainless steel, aluminium, enamel

- Note
- highly active substance: risk of cross contamination
 - avoid open handling

8. Exposure controls/Personal protection

- Engineering Measures
- see 7.

Monitoring

- Threshold value (Roche) air
- STEL: 0.06 mg/m^3 (4 x 30 min)
 - IOEL: 0.02 mg/m^3 (sensitiser)

- Analytics
- air: sampling on paper filter and microbiological antibiotic test
 - surfaces: wipe test with paper filter and microbiological antibiotic test

Personal protective equipment

- Respiratory protection
- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
 - in case of open handling or accidental release: particle mask or respirator with independent air supply

- Hand protection
- protective gloves

- Eye protection
- safety glasses

- Body protection
- disposable protective clothing including gloves, cap and overshoes

- General protective and hygiene measures
- instruction of employees mandatory
 - shower after work mandatory

- Remarks
- allergic persons should possibly be excluded from any occupational to Ceftriaxone (evaluation of aptitude by physician)

Ceftriaxone sodium

9. Physical and chemical properties

Color	white to yellowish
Form	crystalline powder
Odor	none to faint
Molecular mass	661.59 g/mol
Empirical formula	$C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5H_2O$
Bulk density	0.3 kg/l
Solubility	470'000 mg/l, water (22 °C) 32'000 mg/l, methanol (22 °C) 200 mg/l, acetone (22 °C)
Partition coefficient	$\log P_{ow} = 0.025$ (octanol/water) pH 2.0
pH value	6.0 to 7.5 (10 % aqueous solution)
Melting temperature	> 155 °C (with decomposition)
Note	- hygroscopic

10. Stability and reactivity

Conditions to avoid	- humidity - warming - light
Materials to avoid	- oxidizing agents, heavy metals

11. Toxicological information

Acute toxicity	- LD ₅₀ > 10'000 mg/kg (oral, mouse) - LD ₅₀ > 10'000 mg/kg (oral, rat) - LD ₅₀ > 2'000 mg/kg (i.v., several species)
Sensitization	- may sensitize (allergy)
Chronic toxicity	- good tolerance during several weeks application (rat, dog, baboon)
Mutagenicity	- not mutagenic (OECD No. 474 (Micronucleus Test)) - not mutagenic (Ames test)
Reproduction toxicity	- not teratogenic - not embryotoxic
Note	- dosage: daily clinical dose 1 - 2 g (human) - half-life of elimination: approx. 8 hours - persons sensitized to cephalosporin or penicillin may show allergic symptoms like skin reactions (exanthema), urticaria, asthma, rhino-conjunctivitis and hermatological alterations

Ceftriaxone sodium

12. Ecological information

- | | |
|---------------------------|---|
| Inherent biodegradability | - not inherently biodegradable
0 %, 28 days
(MITI Test II, OECD No. 302 C) |
| Ecotoxicity | - strongly toxic for microorganisms (activated sludge)
LC ₅₀ 10 mg/l
- barely toxic for fish (rainbow trout)
LC ₅₀ > 1000 mg/l
- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>)
EC ₅₀ (48 h) > 100 mg/l
NOEC (48 h) 86 mg/l
(OECD No. 202)
- barely toxic for algae (<i>Selenastrum capricornutum</i>)
EbC ₅₀ (72 h) > 100 mg/l
ErC ₅₀ (72 h) > 100 mg/l
NOEC (72 h) 100 mg/l
(OECD No. 201) |
| Air pollution | - observe local/national regulations |
| Note | - highly active substance
- avoid any contamination of the environment! |

13. Disposal considerations

- | | |
|---------------------|---|
| Waste from residues | - small amounts (up to approx. 100 grams): dissolve in water and decompose with sodium hydroxide or prolonged boiling, afterwards the solution can be drained
- large amounts: incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal |
| RCRA waste | - not regulated under RCRA |

14. Transport information

- | | |
|------|---|
| Note | - not classified by transport regulations, proper shipping name non-regulated |
|------|---|

15. Regulatory information

- | | |
|------------------------|--|
| TSCA Status | - FDA Exemption - not on inventory |
| Reporting Requirements | - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements. |

Ceftriaxone sodium

16. Other information

- | | |
|-----------------------|---|
| Use | - pharmaceutical active substance (broad-band spectrum antibiotic) |
| Safety-lab number | - BS-4961 |
| Note | - with the exception of sterility requirements the present safety data sheet also covers Ceftriaxone sodium crude, Product Code 04 0595 7 |
| Edition documentation | - changes from previous version in sections 7 |

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.