

Safety Data Sheet

ROCEPHIN(R) Vials (1 g)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	ROCEPHIN(R) Vials (1 g)	
Product code	SAP-10083676	
Roche number	Ro0139904-015	
CAS number	104376-79-6	with water of crystallization
	74578-69-1	anhydrous
Synonyms	- ROCEPHIN Powder Vials 1000 mg	

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance (broad-band spectrum antibiotic)

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries:	Local representation:
	Genentech, Inc.	
	1 DNA Way	
	South San Francisco	
	USA-CA 94080	
	United States of America	
	Phone	001-(650) 225-1000
	E-Mail	info.sds@roche.com
	US Chemtrec phone:	
		(800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

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SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.4Respiratory or skin sensitization (Category 1)

H317 May cause an allergic skin reaction.

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

Signalword: Danger

Label:



Precautionary statements:

- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

Other hazards

Note

- HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.
- may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Characterization

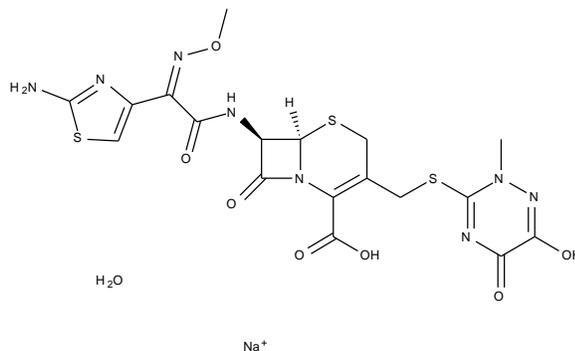
pharmaceutical active substance in the class of cephalosporines without excipients

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

100 %



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SECTION 4: First aid measures

4.1. Description of 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
- in the event of symptoms get medical treatment |

4.2. Most important symptoms and effects, both acute and delayed

- | | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

4.3. Indication of any immediate medical attention and special treatment needed

- | | |
|-------------------|--|
| 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 |
|-------------------|--|

SECTION 5: Firefighting measures

5.1. Extinguishing media

- | | |
|------------------------------|--|
| Suitable extinguishing media | - adapt extinguishing media to surrounding fire conditions |
| Flash point (liquid) | not applicable |

5.2. Special hazards arising from the substance or mixture

- | | |
|------------------|---|
| 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 |
|------------------|---|

5.3. Advice for firefighters

- | | |
|-----------------------------|--|
| Protection of fire-fighters | - precipitate gases/vapours/mists with water spray |
|-----------------------------|--|

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Personal precautions
- avoid exposure
 - ensure adequate ventilation

6.2. Environmental precautions

- Environmental protection
- do not allow to enter drains or waterways
 - if the substance reaches waters or the sewer system, inform the competent authority

6.3. Methods and material for containment and cleaning up

- 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
 - dust may be removed from floors and surfaces with vacuum cleaners equipped with absolute filters (H13) or other adequate measures avoiding dust generation and distribution

SECTION 7: Handling and storage

7.1. Precautions for safe 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

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions
- below 30 °C
 - protected from light and humidity
- Validity
- ≤ 30 °C, see "best use before" date stated on the label
- Packaging materials
- in sealed containers
 - tightly closing; material: stainless steel, aluminium, enamel
 - glass vials, colourless
 - keep it in the outer carton in order to protect from light
- Note
- highly active substance: risk of cross contamination
 - avoid open handling

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air

- STEL: 0.06 mg/m³ (4 x 15 min) (sensitiser)
- IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³ (sensitiser)

8.2. Exposure controls

General protective and hygiene measures

- instruction of employees mandatory
- shower after work recommended

Hand protection

- protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection

- safety glasses

Analytics

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

Remarks

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color

white to yellowish

Form

crystalline powder

Odor

none to faint

Molecular mass

661.59 g/mol

Empirical formula

$C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5H_2O$

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)

9.2. Other information

Note

- hygroscopic

SECTION 10: Stability and reactivity

10.1. Reactivity

Note

- no information available

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10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - humidity
- warming
- light

10.5. Incompatible materials

Materials to avoid - oxidizing agents, heavy metals

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD₅₀ > 10'000 mg/kg (oral, mouse)
- LD₅₀ > 10'000 mg/kg (oral, rat)
- LD₅₀ > 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)

Reproductive 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 hematological alterations

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: not listed by NTP, IARC or OSHA

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SECTION 12: Ecological information

12.1. Toxicity

- Ecotoxicity
- barely toxic for algae (*Selenastrum capricornutum*)
EbC₅₀ (72 h) > 100 mg/l
ErC₅₀ (72 h) > 100 mg/l
NOEC (72 h) 100 mg/l
(OECD No. 201)
 - barely toxic for planktonic crustaceans (*Daphnia magna*)
EC₅₀ (48 h) > 100 mg/l
NOEC (48 h) 86 mg/l
(OECD No. 202)
 - barely toxic for fish (rainbow trout)
LC₀ > 1000 mg/l
 - strongly toxic for microorganisms (activated sludge)
LC₀ 10 mg/l

12.2. Persistence and degradability

- Ready biodegradability
- not readily biodegradable
3 %, 28 d
(Closed Bottle Test, OECD No. 301 D)
- Inherent biodegradability
- 0 %, 28 d
(MITI Test II, OECD No. 302 C)

12.3. Bioaccumulative potential

- Note
- no information available

12.4. Mobility in soil

- Note
- no information available

12.5. Results of PBT and vPvB assessment

- Note
- no information available

12.6. Other adverse effects

- Note
- highly active substance
 - avoid any contamination of the environment!

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

- 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

SECTION 14: Transport information

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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- 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.

SECTION 16: Other information

- Safety-lab number
- BS-4961
- Edition documentation
- changes from previous version in sections 2

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.