

Section 1: IDENTIFICATION OF SUBSTANCE AND SOCIETY

1.1. Identification of the substance

Product form: Powder for solution

Product name: Cefotaxime Sodium Sterile.

Chemical name: Sodium [6R-[6 α ,7 β (Z)]]-3-(acetoxymethyl)-7-[(2-aminothiazol-4-yl)(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.

Synonym:

National Drug Code (NDC): 1g/vial : 21586-011-2; 2g/vial : 21586-012-2.

Molecular formula: C₁₆H₁₆N₅NaO₇S₂.

CAS No.: 64485-93-4.

REACH No.: Substance/mixture is not subject to registration under REACH for their use.

1.2. Uses

Antibiotic. Intramuscular or Intravenous Use.

1.3. Information about the security data sheet provider

| Company | Distributor |
|---|--|
| Provepharm SAS 22 Rue Marc Donadille 13013 Marseille, France Phones: 04 91 08 69 30 Website: www.provepharm.com Email: hse@provepharm.com | Provepharm Inc. 100 Springhouse drive, Suite 105, Collegeville, PA 19426, USA Phone: +1 610 601 8600 |

1.4. Emergency telephone number:

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or the mixture

Classification (GHS-US)

Skin sensitisation (Category 1), H317

Respiratory sensitisation (Category 1), H334

2.2. Label elements

Warning mention: 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/vapors/spray.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P362 - Take off contaminated clothing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.

P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container to an approved waste disposal plant.

2.3. Other hazards

Health Effects: Ingestion: may cause heartburn and abdominal pain.
 Inhalation exposure: may cause upper respiratory tract irritation.
 Contact with skin: may cause irritation.
 Contact with eyes: may cause irritation.
 Sensitization: may cause sensitization by inhalation and skin contact. People who are allergic to beta – lactam (penicillin, cephalosporin, griseofulvin, penicillamine) should avoid exposure to this substance/mixture. Adverse drug reactions such as anaphylactic shock, asthma, rash or other phenomena may occur.

Physico-chemical Effects: The substance/mixture can form explosive mixtures, under certain conditions. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture, and any source of ignition, i.e. flame or spark, may cause fire or explosion. In case of fire, the substance/mixture emits toxic fumes.

2.4. Unknown acute toxicity

Not applicable.

Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE
3.1. Substances

| Name | Product identifier | % | Classification |
|-------------------|---|---------|---|
| Cefotaxime Sodium | CAS-No.: 64485-93-4 Molecular weight: 477.45 g/mol EC number: 264-915-9 | <= 100% | Resp. Sens. 1,H334 Skin Sens. 1,H317 |

Full text of hazard classes and H-statements: see section 16.

3.2. Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES
4.1. Description of first aid measures

General: In case of serious allergic reactions, get immediately medical attention.

After inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

After skin contact: In case of contact, immediately wash skin with plenty of water and soap or mild detergent for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

After eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water or normal saline solution for at least 15 minutes. Seek medical attention immediately.

After ingestion: Wash out mouth with water and administer fresh water if the person is conscious. Do not induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

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

Acute symptoms and effects inhalation exposure: may cause upper respiratory tract irritation.

Acute symptoms and effects contact with skin: May cause irritation.

Acute symptoms and effects contact with eyes: May cause irritation.

Acute symptoms and effects ingestion: may cause heartburn and abdominal pain

Symptoms and delayed effects: Exposure to the substance/mixture may cause sensitization.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Small fire: Use water spray, dry chemical, carbon dioxide or foam, as appropriate for surrounding fire and materials. Large fire: Use water spray, fog or foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: Not know.

5.2. Special hazards arising from the substance or mixture

Combustion Products: In case of combustion, can produce toxic fumes of NO_x, CO_x, SO_x.

Other special hazards: The substance/mixture can form explosive mixtures, under certain conditions. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture, and any source of ignition, i.e. flame or spark, may cause fire or explosion. In case of fire, the substance/mixture emits toxic fumes.

5.3. Advice for firefighters

Protective equipment & precautions for firefighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General Measures: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE) as identified in section 8.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. Refer to section 8: Exposure controls/personal protection.

Emergency Procedures: Isolate the hazard area. Ventilate area.

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. A high efficiency vacuum may be used to collect spillage. Avoid breathing dust. Finish cleaning by spreading water and soap on the contaminated spill site.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. AVOID breathing dust. Finish cleaning by spreading water and soap on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container labelled appropriately for disposal.

For proper waste disposal, see section 13 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Recommendations for handling: Avoid exposure to light, air, moisture and excessive heat.

Keep away from oxidizing agents.

Handle in a well-ventilated place.

Avoid contact with incompatible materials.

Wear suitable Personal Protection Equipment (see section 8).

Keep the substance/mixture away from drains, surface or ground waters.

Recommendations for personal hygiene: Do not eat, drink and smoke in the working areas.
Wash hands after handling the substance/mixture.
Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Do not expose to heat sources.
Keep container tightly closed. Keep container in a cool. Store between 15° to 30°C (59° to 86°F) and dry place. Do not expose to high temperature.
Do not store in a damp place. Hygroscopic substance/mixture.
Do not expose to sunlight. Store in containers photoresist.
Incompatibilities: Strong oxidizing agents. It is recommended not to mix the substance with a solution of sodium bicarbonate.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limit: Not available.

8.2. Exposure controls

Appropriate engineering controls: Use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operation generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Hand protection: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations (in accordance with EN374, ASTM F1001 or international equivalent).

Eye protection: Wear safety glasses or goggles if eye contact is possible (in accordance with EN166, ANSI Z87.1 or international equivalent).

Skin and body protection: Wear suitable working clothes.

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter) (in accordance with EN140, EN143, ASTM F2704-10 or international equivalent).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Physical state: | Solid powder |
| Appearance: | crystalline |
| Color: | creamy white |
| Odor: | No data available |
| Odor threshold: | No data available |
| pH: | No data available |
| Melting point: | No data available |
| Freezing point: | No data available |
| Boiling point: | No data available |
| Flash point: | No data available |
| Relative evaporation rate (butyl acetate=1): | No data available |
| Flammability (solid, gas): | No data available |
| Vapor pressure: | No data available |
| Relative vapor density at 20 °C: | No data available |
| Relative density: | No data available |
| Solubility: | Soluble in water; poorly soluble in common organic solvents including ethanol |
| Partition coefficient n-octanol/water (Log Pow): | No data available |
| Auto-ignition temperature: | No data available |
| Decomposition temperature: | No data available |
| Viscosity, kinematic: | No data available |

| | |
|------------------------------|-------------------|
| Viscosity, dynamic: | No data available |
| Explosion limits: | No data available |
| Explosive properties: | No data available |
| Oxidizing properties: | No data available |

9.2. Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

The product is stable under normal conditions.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

Avoid exposure to light, air, moisture and heat.

10.5. Incompatible materials

Strong oxidising agents. It is recommended not to mix the substance with a solution of sodium bicarbonate.

10.6. Hazardous decomposition products

If heated at high temperatures, the substance/mixture decomposes releasing toxic gases of CO_x, NO_x, SO_x.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects****Acute toxicity:**

LD50 (oral), rat: 20 g/kg

Skin Corrosion/Irritation: Skin irritation is possible.

Serious Eye Damage/Irritation: eye irritation is possible.

Respiratory or Skin Sensitization: may cause sensitization by inhalation and skin contact.

Ingestion: may cause heartburn and abdominal pain.

Inhalation: may cause upper respiratory tract irritation.

Other information: Potential adverse effect: gastrointestinal disorders

Potential Chronic Toxicity

Germ Cell Mutagenicity: No data

Carcinogenicity: No data

Reproductive Toxicity: No data.

Developmental: No data

Specific Target Organ Toxicity (Single Exposure): No data

Specific Target Organ Toxicity (Repeated Exposure): No data

Aspiration Hazard: No data

11.2. Additionnal information

Because of the similarity in structure of the penicillins and cephalosporins, those who are allergic to one class of agents may manifest cross-allergenicity when a member of the other class is encountered.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Advice on disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste disposal number of waste from residues/unused products : Dispose of waste in accordance with federal, state and local environment control regulations.

Contaminated packaging: Empty containers should be taken for local waste disposal. Contaminated packaging should be emptied as far as possible. Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: TRANSPORT INFORMATION

14.1 In Accordance with DOT Not considered a DOT regulated material - Non-hazardous for shipment.

14.2 In Accordance with IMDG Not regulated for transport

14.3 In Accordance with IATA Not considered a DOT regulated material - Non-hazardous for shipment.

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

U.S. Regulations:

TSCA - No CERCLA - Not listed

SARA 302 – Not listed

SARA 311/312 Hazard categories - See section 2 for more information

SARA 313 – Not listed

OSHA Substance Specific – Not listed

SECTION 16: OTHER INFORMATION

Full text of H-phrases:

| | |
|---------------|---|
| Resp. Sens. 1 | Respiratory sensitisation (Category 1) |
| Skin Sens. 1 | Skin sensitisation (Category 1) |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H317 | May cause an allergic skin reaction. |