



# SAFETY DATA SHEET

## 1. Identification

**Product identifier**

**FORTAZ (CEFTAZIDIME FOR INJECTION)**

**Other means of identification**

**Synonyms**

FORTAZ 500MG VIAL \* FORTAZ 1G VIAL \* FORTAZ 2G VIAL \* FORTAZ 1G IV INFUSION PACK \* FORTAZ 2G IV INFUSION PACK \* FORTAZ 6G PHARMACY BULK PACK \* FORTAZ 1G ADD-VANTAGE VIALS \* FORTAZ 2G ADD-VANTAGE VIALS \* FORTUM INJECTION 250MG VIAL \* FORTUM INJECTION 500MG VIAL \* FORTUM INJECTION 1G VIAL \* FORTUM INJECTION 2G VIAL \* FORTUM INJECTION 3G VIAL \* FORTUM INFUSION 2G VIAL \* FORTUM MONOVIAL 2G VIAL \* NDC NO 0173-0377-10 \* NDC NO 0173-0378-10 \* NDC NO 0173-0379-34 \* NDC NO 0173-0382-37 \* NDC NO 0173-0434-00 \* NDC NO 0173-0435-00 \* CEFTAZIDIME PENTAHYDRATE, FORMULATED PRODUCT

**Recommended use**

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Label elements**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Hazard(s) not otherwise classified (HNOC)**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
CEFTAZIDIME PENTAHYDRATE	CEFTAZIDIME * UCRH * UCRL * UCRZ * UCR * UCRM * UCRB * 2/CR * 3/CR * 2/2CR * 1/CR * CRR * CR/NR * CRZ/NR * CRH/NR * CRZ * 6 (GW ACN) * PYRIDINIUM, 1-((7-(((2-AMINO-4-THIAZOLYL)((1-CARBOXY-1-METHYLETHOXY) IMINO)ACETYL)AMINO)-2-CARBOXY-8-OXO-5-THIA-1-AZABICYCLO(4.2.0)OCT-2-EN-3-YL )METHYL)-, HYDROXIDE, INNER SALT,(6R-(6-ALPHA,7-BETA(Z))), PENTAHYDRATE * (Z)-(7R)-7-[2-(2-AMINOTHIAZOL-4-YL)-2-(1-CARBOXY-1-METHYLETHOXYIMINO)ACETAMIDO]-3-(1-PYRIDINIOMETHYL)-3-CEPHEM-4-CARBOXYLATE PENTAHYDRATE * CCI20263BQ	78439-06-2	90.9
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT * BISODIUM CARBONATE * DISODIUM CARBONATE * SODA ASH	497-19-8	9.1

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); diarrhoea; nausea; vomiting; gastrointestinal distress.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

**7. Handling and storage****Precautions for safe handling**

Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection****Occupational exposure limits****GSK****Components****Type****Value****Note**

CEFTAZIDIME  
PENTAHYDRATE (CAS  
78439-06-2)

15 MIN STEL

100 mcg/m3

OHC

3

SKIN SENSITISER  
RESPIRATORY  
SENSITISER

3

SODIUM CARBONATE  
(CAS 497-19-8)

8 HR TWA

5000 mcg/m3

OHC

1

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines****Appropriate engineering controls**

General ventilation normally adequate.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Skin protection****Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Other**

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**9. Physical and chemical properties****Appearance****Physical state**

Solid.

**Form**

Powder.

**Color**

White/off-white.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
<b>Upper/lower flammability or explosive limits</b>	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
<b>Solubility(ies)</b>	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

## 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); diarrhoea; nausea; vomiting; gastrointestinal distress.
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### Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
CEFTAZIDIME PENTAHYDRATE (CAS 78439-06-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

\* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
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#### Corrosivity

CEFTAZIDIME PENTAHYDRATE	Acute dermal irritation Result: Non-irritant Species: Rabbit
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**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use.

**Eye**

CEFTAZIDIME PENTAHYDRATE

Acute ocular irritation

Result: Mild irritant

Species: Rabbit

SODIUM CARBONATE

Acute ocular irritation; OECD 405

Result: Moderate Irritant

Species: Rabbit

**Respiratory or skin sensitization**

**Respiratory sensitization** Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

CEFTAZIDIME PENTAHYDRATE

Read Across

Result: Positive

**Skin sensitization** May cause an allergic skin reaction.

**Sensitization**

CEFTAZIDIME PENTAHYDRATE

Read across

Result: Positive

**Germ cell mutagenicity** Health injuries are not known or expected under normal use.

**Mutagenicity**

CEFTAZIDIME PENTAHYDRATE

Ames Assay (GLP)

Result: Negative

In vivo Micronucleus

Result: Negative

Species: Mouse

in vitro UDS assay

Result: Positive

**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure.

CEFTAZIDIME PENTAHYDRATE

SAR

Result: No structural alerts identified.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Health injuries are not known or expected under normal use.

**Specific target organ toxicity - single exposure** Not assigned.

**Specific target organ toxicity - repeated exposure** Not assigned.

**Aspiration hazard** Not an aspiration hazard.

**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information**

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
CEFTAZIDIME PENTAHYDRATE (CAS 78439-06-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 103 mg/l, 3 hours Nominal
	NOEC	Residential sludge	103 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	> 106 mg/l, 48 hours Measured
	NOEC	Water flea (Daphnia magna)	106 mg/l
Fish	EC50	Rainbow trout (Juvenile Oncorhynchus mykiss)	> 106 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Juvenile Oncorhynchus mykiss)	106 mg/l
Microtox	MIC	Pseudomonas	<= 2 mg/l Measured

Components		Species	Test Results
Other	EC50	Anabena flos-aquae	0.025 mg/l, 72 hours Measured
	NOEC	Anabena flos-aquae	0.013 mg/l
<b>SODIUM CARBONATE (CAS 497-19-8)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 800 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	265 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	300 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	< 850 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	740 mg/l, 96 hours Static test

\* Estimates for product may be based on additional component data not shown.

### Persistence and degradability

#### Hydrolysis

##### Half-life (Hydrolysis-acidic)

CEFTAZIDIME PENTAHYDRATE < 100 Hours Measured

##### Half-life (Hydrolysis-basic)

CEFTAZIDIME PENTAHYDRATE < 1 Hours Measured

#### Biodegradability

##### Percent degradation (Aerobic biodegradation-inherent)

CEFTAZIDIME PENTAHYDRATE 34 %, 14 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

### Bioaccumulative potential

#### Partition coefficient n-octanol / water (log Kow)

CEFTAZIDIME PENTAHYDRATE -6.182 (Calculated).

### Mobility in soil

#### Adsorption

##### Soil/sediment sorption - log Koc

CEFTAZIDIME PENTAHYDRATE 0.78 Measured, pH 7

### Mobility in general

#### Distribution

##### Octanol/water distribution coefficient log DOW

CEFTAZIDIME PENTAHYDRATE -3.07, pH 7.4

**Other adverse effects** Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

#### **IATA**

Not regulated as dangerous goods.

#### **IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## **15. Regulatory information**

### **US federal regulations**

#### **TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

#### **CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

#### **SARA 304 Emergency release notification**

Not regulated.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

### **Superfund Amendments and Reauthorization Act of 1986 (SARA)**

#### **Hazard categories**

Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### **SARA 302 Extremely hazardous substance**

Not listed.

#### **SARA 311/312 Hazardous chemical**

No

#### **SARA 313 (TRI reporting)**

Not regulated.

### **Other federal regulations**

#### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

#### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

#### **Safe Drinking Water Act (SDWA)**

Not regulated.

### **US state regulations**

#### **US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

#### **US. Massachusetts RTK - Substance List**

Not regulated.

#### **US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

#### **US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

#### **US. Rhode Island RTK**

Not regulated.

#### **US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	01-19-2015
<b>Revision date</b>	01-19-2015
<b>Version #</b>	17
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2* Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Exposure Controls / Personal Protection: Physical & Chemical Properties: Transport Information: