



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>ZINACEF (CEFUROXIME FOR INJECTION)</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	ZINACEF 750MG VIAL * ZINACEF 1.5G VIAL * ZINACEF INJECTION 250MG * ZINACEF INJECTION 750MG * ZINACEF INJECTION 1G * ZINACEF 750MG IV INFUSION PACK * ZINACEF 1.5G IV INFUSION PACK * ZINACEF 7.5G PHARMACY BULK PACKAGE * ZINACEF 750MG ADD-VANTAGE VIAL * ZINACEF 1.5G ADD-VANTAGE VIAL * NDC NO 0173-0352-10 * NDC NO 0173-0354-10 * NDC NO 0173-0400-00 * NDC NO 0173-0436-00 * NDC NO 0173-0437-00 * CEFUROXIME SODIUM, FORMULATED PRODUCT
<b>Recommended use</b>	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  
Website: 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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
CEFUROXIME SODIUM	OM SPECTRAZOL CEPHALOSPORIN 640/359 SODIUM CCI13296E CCI13372 UOMC UOMF OMIT 115 (GW ACN)	56238-63-2	100

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

## 4. First-aid measures

### Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

<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>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<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.
<b>Most important symptoms/effects, acute and delayed</b>	May cause allergic skin reaction. May cause allergic respiratory reaction. The following adverse effects have been noted with therapeutic use of this material: diarrhoea; nausea; abdominal pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).
<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 centre.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<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>	In the event of fire, cool tanks with water spray.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 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. Wear appropriate protective equipment and clothing during clean-up. Do not touch or walk through spilled material. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
<b>Environmental precautions</b>	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the MSDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

GSK Components	Type	Value	Note
CEFUROXIME SODIUM (CAS 56238-63-2)	15 MIN STEL	100 mcg/m <sup>3</sup>	
	OHC	3 3	SKIN SENSITISER RESPIRATORY SENSITISER

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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<b>Appropriate engineering controls</b>	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. No special engineering controls are required. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
<b>Other</b>	Not normally needed.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Contaminated work clothing should not be allowed out of the workplace. Wash hands after handling.

## 9. Physical and chemical properties

<b>Appearance</b>	
<b>Physical state</b>	Solid.
<b>Form</b>	Vial.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.
<b>Inhalation</b>	Health injuries are not known or expected under normal use. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Skin contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin. May cause an allergic skin reaction.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

**Symptoms related to the physical, chemical and toxicological characteristics** May cause allergic skin reaction. May cause allergic respiratory reaction. The following adverse effects have been noted with therapeutic use of this material: diarrhoea; nausea; abdominal pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). No specific target organ effects have been identified.

### Information on toxicological effects

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

Components	Species	Test Results
CEFUROXIME SODIUM (CAS 56238-63-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 g/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. May be irritating to the skin.

<b>Corrosivity</b>	
CEFUROXIME SODIUM	Read across Result: Mild irritant Species: Human

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

<b>Eye</b>	
CEFUROXIME SODIUM	Read across Result: Mild irritant Species: Human

**Respiratory sensitization** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

CEFUROXIME SODIUM	Read Across Result: Positive Species: Human
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**Skin sensitization** Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

<b>Sensitization</b>	
CEFUROXIME SODIUM	Read Across Result: Positive Species: Human

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

CEFUROXIME SODIUM	Ames Result: Negative BlueScreen Assay Result: Negative Chromosomal Aberration Assay In Vitro Result: Positive GreenScreen mammalian cell mutation assay Result: Negative Mouse Lymphoma Cell Assay Result: Negative
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CEFUROXIME SODIUM

SOS/umu Assay  
 Result: Positive  
 in vitro micronucleus assay  
 Result: Negative  
 Species: Rat

**Carcinogenicity** Health injuries are not known or expected under normal use. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

CEFUROXIME SODIUM

Embryofetal Development  
 Result: No known effects  
 Species: Human

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** None known.

**Aspiration hazard** Not available.

## 12. Ecological information

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

Components		Species	Test Results
CEFUROXIME SODIUM (CAS 56238-63-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 87.6 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	> 91 mg/l, 72 hours, Static test, OECD 201
	NOEC	Algae	91 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	> 876 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	> 876 mg/l, 48 hours, Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 105 mg/l, 96 hours, Static, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	105 mg/l
Microtox	MIC	Azotobacter beijerinckii	0.18 mg/l
Other	MIC	Aspergillus niger	> 0.88 mg/l
		Nostoc commune	0.18 mg/l
		Pseudomonas aeruginosa	> 0.88 mg/l
		Trichoderma harzianum	> 0.88 mg/l

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

### Persistence and degradability

#### Photolysis

##### UV/visible spectrum wavelength

CEFUROXIME SODIUM 290 nm

#### Hydrolysis

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

CEFUROXIME SODIUM 299 Hours

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

CEFUROXIME SODIUM 1.05 Hours

##### Half-life (Hydrolysis-neutral)

CEFUROXIME SODIUM 30.2 Hours

#### Biodegradability

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

CEFUROXIME SODIUM 42.8 - 80 %, 64 days

### Bioaccumulative potential

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

CEFUROXIME SODIUM 0.429 (Calculated).

## Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

CEFUROXIME SODIUM

1.09 - 1.19

**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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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).
<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

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as a dangerous good.
<b>IMDG</b>	Not regulated as a dangerous good.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	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

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.

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

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	No
<b>SARA 311/312 Hazardous chemical</b>	No
<b>NFPA ratings</b>	Health: 2 Flammability: 0 Instability: 0
<b>HMIS® ratings</b>	Health: 2 Flammability: 0 Physical hazard: 0

### 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.**Food and Drug Administration (FDA)** Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

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

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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	Yes
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****Issue date** 12-09-2013**Revision date** 12-09-2013**Version #** 08**Further information** HMIS® is a registered trade and service mark of the NPCA.**HMIS® ratings** Health: 2  
Flammability: 0  
Physical hazard: 0**NFPA ratings** Health: 2  
Flammability: 0  
Instability: 0**References** GSK Hazard Determination**Disclaimer** 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.**Revision Information** Product and Company Identification: Business Units  
Composition / Information on Ingredients: Disclosure Overrides  
Exposure Controls / Personal Protection:  
Physical & Chemical Properties:  
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection  
Regulatory Information: United States  
GHS: Classification