SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	ZINACEF (CEFUROXIME FOR INJECTION)
Registration number	-
Synonyms	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
Issue date	09-December-2013
Version number	08
Revision date	09-December-2013

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

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CEFUROXIME SODIUM	100	56238-63-2 260-073-1	-	-	

Classification: **DSD:** R42/43

CLP: Skin Sens. 1;H317, Resp. Sens. 1;H334

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information 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.

4.1. Description of 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.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.

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

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

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions 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.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling 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.

7.2. Conditions for safe storage, including any incompatibilities 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).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
CEFUROXIME SODIUM (CAS 56238-63-2)	15 MIN STEL	100 mcg/m3	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls 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.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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.

Environmental exposure controls

Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Vial.
Colour	Not available.
Odour	Not available.
Odour 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.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

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

Eye contact Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Symptoms 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.

11.1. 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)		
Acute		
Oral		
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.

Corrosivity
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.

Eye
CEFUROXIME SODIUM
Read across
Result: Mild irritant
Species: Human

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.
CEFUROXIME SODIUM
Read Across
Result: positive
Species: Human

Skin sensitisation Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

Sensitisation
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.

Germ cell mutagenicity

Mutagenicity
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
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.

Reproductive toxicity

Reproductivity
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.
Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
CEFUROXIME SODIUM (CAS 56238-63-2)			
Aquatic			
Acute			
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.

12.2. Persistence and degradability

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-inherent)

CEFUROXIME SODIUM 74 %, < 1 day Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

CEFUROXIME SODIUM 28 %, 28 days Modified Sturm test.
42 %, 64 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

CEFUROXIME SODIUM 42.8 - 80 %, 64 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

CEFUROXIME SODIUM 0.429 (Calculated).

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CEFUROXIME SODIUM	1.09 - 1.19

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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).

Contaminated packaging 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information 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.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R42/43 May cause sensitization by inhalation and skin contact. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 and Packaging Type/Transport Mode Selection Regulatory Information: United States GHS: Classification
Training information	Follow training instructions when handling this material.
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.