

SAFETY DATA SHEET



* 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	CEFTIN TABLETS
Synonym(s)	CEFTIN TABLETS 125 MG * CEFTIN TABLETS 250 MG * CEFTIN TABLETS 500 MG * CEFTUM TABLETS * CEFUROX TABLETS * CUROCEF TABLETS * ELOBACT TABLETS * ORACEF TABLETS * ZINADOL TABLETS * ZINAT TABLETS * ZINNAT TABLETS * ZIPOS TABLETS * ZOREF TABLETS * NDC NO 0173-0387-00 * NDC NO 0173-0394-00 * CEFUROXIME AXETIL, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
CEFUROXIME AXETIL	64544-07-6	51.6 to 54.9	
NON-HAZARDOUS INGREDIENTS	Unassigned	45.1 to 48.4	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Exposure might occur via skin; eyes; ingestion. May produce allergic skin reactions. Respiratory allergen. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); nausea; vomiting; diarrhoea. Health effects information is based on hazards of components.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of a cephalosporin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma. This material may cause or aggravate allergy to cephalosporin antibiotics.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

HANDLING

General Requirements Avoid breaking or crushing tablets.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	CEFUROXIME AXETIL
GSK Occupational Hazard Category	3
GSK Occupational Exposure Limit	100 mcg/m3 (15 MIN STEL) RESPIRATORY SENSITISER, SKIN SENSITISER
Occupational Hygiene Air Monitoring Methods	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
ENGINEERING CONTROLS	
Exposure 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Respirators	If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects	This material is an antibiotic; a cephalosporin. It is an agent intended for the treatment of bacterial infections.
Target Organ Effects	No specific target organ effects have been identified.
Routes of Exposure	
Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	Can produce respiratory irritation. Adverse effects might occur following inhalation.
Skin Effects	Irritation might occur following direct contact.
Eye Effects	Irritation might occur following direct contact with eyes.
Sensitisation	Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions. No adverse effects have been reported following extensive use or exposure in humans.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary

This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY**Aquatic****Activated Sludge Respiration**

This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 100 mg/l, 3 Hours, Activated sludge

Microbial Growth Inhibition

This material contains an active pharmaceutical ingredient that is toxic to these microorganisms.

Minimum Inhibition Concentration:

0.2 mg/l, , Azotobacter beijerinckii
0.2 mg/l, , Nostoc commune
> 1 mg/l, , Pseudomonas aeruginosa
> 1 mg/l, , Trichoderma harzianum
> 1 mg/l, , Aspergillus niger

Algal

This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 91 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test

NOEC: 91 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test

Daphnid

This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

NOEC: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

Fish

This material contains an active pharmaceutical ingredient that is not toxic to fish.

Adult Oncorhynchus mykiss, rainbow trout

EC50: > 120 mg/l, 96 Hours, Static test

Adult Oncorhynchus mykiss, rainbow trout

NOEC: 120 mg/l, 96 Hours, Static test

MOBILITY**Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant Estimated at 25 C

Adsorption

This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Soil Sediment Sorption 1.09 to 1.19
(log K_{oc}):

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION**Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Material CEFTIN TABLETS

Half-Life, Neutral: 30.2 Hours
 Half-Life, Acidic: 299 Hours
 Half-Life, Basic: 1.05 Hours

Photolysis

This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation.

UV/Visible Spectrum: 290 nm

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: 42 %, 64 days, Modified Sturm test.

Aerobic - Ready

Percent Degradation: 28 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 74 %, < 1 day, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Aerobic - Soil

Percent Degradation: 42.8 to 80 %, 64 days

Bioaccumulation

This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

US OSHA Standard (29 CFR Part 1910.1200)**Classification**

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations**TSCA Status**

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

10

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY**Subsections**

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.