SAFETY DATA SHEET

GlaxoSmithKline

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

Material **FORTAZ (CEFTAZIDIME FOR INJECTION)**

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 0173-0380-32 * NDC NO 0173-0378-35 * NDC NO 0173-0381-32 * NDC NO 0173-0379-34 * NDC NO 0173-0377-31 * NDC NO 0173-0382-37 * NDC NO 0173-0434-00 * NDC NO 0173-0435-00 * CEFTAZIDIME PENTAHYDRATE, FORMULATED PRODUCT

Company Name

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US General Information:	+1-888-825-5249
Transport Emergency (non EU)	+1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
CEFTAZIDIME PENTAHYDRATE	78439-06-2	90.9
NON-HAZARDOUS INGREDIENTS	Unassigned	9.1

3. HAZARDS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

Health	Exposure might occur via skin; eyes; ingestion; inhalation. 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.
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	Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
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	The combustibility of the product is not known, however the packaging is combustible.
Extinguishing Media	Water or foam extinguishers are recommended. Carbon dioxide or dry powder 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	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	CEFTAZIDIME PENTAHYDRATE	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	100 mcg/m3 (15 MIN STEL)	SKIN SENSITISER, RESPIRATORY SENSITISER

Occupational Hygiene Air Monitoring Methods	For advice on suitable monitoring methods, consult your local occupational or industrial hygiene specialist, health and safety department, or the health and safety group identified in section 1.

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	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	White/off-white.
Physical Form	Powder.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

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 Minor irritation might occur following direct contact with eyes.

Target Organ Effects No specific target organ effects have been identified.

Sensitisation Allergic skin reactions might occur following dermal exposure. Respiratory sensitisation (allergic) reactions might occur following 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 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.

Pharmacological Effects This material is an antibiotic; a cephalosporin. It is an agent intended for the treatment of bacterial infections.

12. ECOLOGICAL INFORMATION

Summary No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

PERSISTENCE/DEGRADATION

Biodegradation Cephalosporins are generally susceptible to degradation by a number of micro-organisms found in wastewater treatment plants and the general environment.

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

Date Approved/Revised 08-Mar-2004 **SDS Version Number** 11

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
REGULATORY INFORMATION	European Union Classification and Labelling
	Other Regulations
	Other US Regulations - California Proposition 65
	Other US Regulations - TSCA Status
	State Regulations
	Summary
	US Environmental (EPA) Requirements
	US OSHA Standard (29 CFR Part 1910.1200) -
	US OSHA Standard (29 CFR Part 1910.1200) -

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.