



SAFETY DATA SHEET

Revision Date 05-Feb-2019

Version 10.01

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

Product identifier

Chemical Name Ceftaroline Fosamil

Other means of identification

Product Code 400827-46-5

Synonyms Teflaro

Recommended use of the chemical and restrictions on use

Recommended Use Cephalosporin antibiotics Should be used to treat any ABSSSI or CABP that are proven or strongly suspected to be caused by susceptible bacteria.

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.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address

SDS@Allergan.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization	Category 1B
Skin sensitization	Category 1A

Label elements

Emergency Overview

Danger

Hazard statements

H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H410 - Very toxic to aquatic life with long lasting effects
H400 - Very toxic to aquatic life

**Appearance** powder**Physical state** Solid**Odor** No information available**Chemical Name**
Ceftaroline Fosamil**Symptoms**

Adverse effects include diarrhea, nausea, rash, vomiting, pyrexia, anaphylaxis, anemia, abdominal pain, eosinophilia, neutropenia, thrombocytopenia, bradycardia, palpitations, hepatitis, hypersensitivity, clostridium difficile colitis, hyperglycemia, hyperkalemia, dizziness, convulsion, renal failure, and urticaria.

Chemical Name
Ceftaroline Fosamil**Medical Conditions Aggravated by Exposure**

Known serious hypersensitivity to cephalosporins or other beta lactams.

Precautionary statements

P285 - In case of inadequate ventilation wear respiratory protection

P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P321 - Specific treatment (see supplemental first aid instructions on this label)

P363 - Wash contaminated clothing before reuse

P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	EINECS	Weight-%
Ceftaroline Fosamil	400827-46-5	N/A	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES**First aid measures****General advice**

Call 911 or emergency medical service. Remove and isolate contaminated clothing and shoes.

Eye contact

In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.

Skin Contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation

Move victim to fresh air. If breathing is irregular or stopped, administer artificial respiration. Administer oxygen if breathing is difficult.

Ingestion Consult a physician if necessary.

Chemical Name
Ceftaroline Fosamil

Note to physicians

In the event of overdose, Teflaro should be discontinued and general supportive treatment given. Ceftaroline can be removed by hemodialysis. In subjects with ESRD administered 400 mg of Teflaro, the mean total recovery of ceftaroline in the dialysate following a 4-hour hemodialysis session started 4 hours after dosing was 76.5 mg (21.6% of the dose). However, no information is available on the use of hemodialysis to treat overdosage.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Dry chemical, CO₂, water spray or regular foam. Water spray, fog or regular foam. Move containers from fire area if you can do it without risk. Dike fire-control water for later disposal.

Unsuitable extinguishing media

Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the chemical

Some may burn but none ignite readily. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Some may be transported hot.

Explosion data

Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

Not impact sensitive.

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Do not touch or walk through spilled material. Stop leak if you can do it without risk.

Environmental precautions

Prevent entry into waterways, sewers, basements or confined areas. See Section 12 for additional ecological information.

Methods for containment

Prevent dust cloud.

Methods for cleaning up

Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling

Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials

Strong acids. Strong bases. Incompatible with oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Individual protection measures, such as personal protective equipment

PPE The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	powder
Color	pale, yellowish-white to light yellow	Odor	No information available
Odor threshold	No information available		

Property

pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	Soluble in water
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Values

Other Information

Molecular weight	762.75
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

Strong acids. Strong bases. Incompatible with oxidizing agents.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ceftaroline Fosamil	>2,000 (Oral Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Ceftaroline Fosamil	Did not show evidence of mutagenic activity in in vitro tests that included a bacterial reverse mutation assay and the mouse lymphoma assay. Not mutagenic in an in vitro mammalian cell assay. In vivo did not induce unscheduled DNA synthesis in rat hepatocytes and did not induce the formation of micro nucleated erythrocytes in rat or mouse bone marrow.	Long-term studies in animals to determine the carcinogenicity potential of this medication have not been conducted.	Developmental toxicity studies on rats demonstrated no maternal toxicity and no effects on the fetus. Ceftaroline did not affect the postnatal development of reproductive performance of the offspring of rats given IV doses up to 40 mg/kg/day.	No information available

Chronic toxicity

May cause adverse effects on the bone marrow and blood-forming system. May cause adverse liver effects.

Target Organ Effects

Skin, Central nervous system, Cardiovascular system, Immune system, Gastrointestinal tract (GI), blood, kidney, liver.

Numerical measures of toxicity - Product Information**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Ceftaroline Fosamil 400827-46-5	EC 50 - 111 mg/l green algae(72H)	5 mg/l 32 day Fat head minnow	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Ceftaroline Fosamil 400827-46-5	NOT READILY BIODEGRADABLE	Low	N/A	N/A

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION**DOT**

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Special Provisions	146, 335, A112, B54, B120, IB8, IP3, N20, N91, T1, TP33, 8
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
Emergency Response Guide Number	171

TDG

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III

ICAO (air)

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Special Provisions	A158, A97, A179, A197
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III

IATA

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
ERG Code	9L
Special Provisions	A158, A179, A97, A197
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III

IMDG

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
EmS-No.	F-A, S-F
Special Provisions	274, 335, 966, 967, 969
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III

ADR

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III

Classification code	M7
Tunnel restriction code	(E)
Special Provisions	274, 335, 601, 375
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III, (E)
Labels	9

ADN

UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Classification code	M7
Special Provisions	274, 335, 601
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
Hazard label(s)	9
Limited quantity (LQ)	5 kg

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date 05-Feb-2019
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet