

SAFETY DATA SHEET



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

Product identifier

ZINFORO POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Zinforo (ceftaroline fosamil), iv, 600 mg
Ceftaroline fosamil powder for concentrate for solution for infusion

CAS No. : Not applicable
Use : cephalosporin (beta-lactam) antibiotic

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS		
Hazard class	Category	Hazard statements
Skin sensitisation	1	H317
Respiratory sensitisation	1	H334
Acute aquatic toxicity	1	H400
Chronic aquatic toxicity	1	H410
		# Refer to Section 16 'Other Information'

Label elements	
Signal word 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.

Precautionary statements

P261	Avoid breathing dust.
P285	In case of inadequate ventilation wear respiratory protection.
P302 + P352	: IF ON SKIN: Wash with plenty of soap and water.
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.
P501	: Dispose of contents/ container to an approved incineration plant.

Other hazards

May form explosible dust-air mixture if dispersed. See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS**Mixture:**

Component	%	CAS No.		
Ceftaroline Fosamil	63	400827-55-6		
		Hazard class #	Category	Hazard statements #
		Skin sensitisation	1	H317
		Respiratory sensitisation	1	H334
		Acute aquatic toxicity	1	H400
Chronic aquatic toxicity	1	H410		

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES**Description of first aid measures**

Inhalation	:	Remove patient from exposure, keep warm and at rest. Obtain medical attention for symptoms of difficulty in breathing and wheeziness, however minor.
Skin Contact	:	Take off immediately all contaminated clothing. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
Eye Contact	:	Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Ingestion	:	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable)	:	water spray, foam, dry powder or CO ₂ .
Extinguishing Media (unsuitable)	:	Avoid high pressure media which could cause the formation of

a potentially explosible dust-air mixture.

Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.

Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.

Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.

Methods and material for containment and cleaning up : Avoid dust generation. Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

7. HANDLING AND STORAGE

Precautions for safe handling : Do not breathe dust. Avoid contact with skin and eyes. Minimize dust generation and accumulation. Wear protective gloves. See Section 8. The material may form explosible dust-air mixture if dispersed. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Protect from light.

Specific end use(s) : Storage temperature : < 25 °C
Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Ceftaroline Fosamil	0,1 mg/m ³	LTEL 8hr TWA	This value is not a health based OEL. The exposure should be kept as low as possible below this level to protect against respiratory sensitisation.

Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains. See Section 6 for environmental precautions.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Respiratory protection

Use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

Skin protection

Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Eye protection

Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : powder
Colour : yellowish-white, to, light yellow

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	Oxidizing agents Strong acids Bases
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation	:	No information available on acute toxicity. May cause effects as described under single exposure.(STOT)
Skin Contact	:	No information available.
Eye Contact	:	No information available.
Ingestion	:	The following information refers to active ingredient: Oral Median Lethal Dose (rat) > 2 000 mg/kg
Specific Target Organ Toxicity (STOT)	:	Single exposure May cause seizures., May cause effects as described under repeated exposure.(STOT) Repeated exposure May cause headache, nausea, vomiting, diarrhoea and skin rash., Studies in animals have shown that repeated doses produce adverse effects on kidneys and urinary tract.
Sensitisation	:	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Symptoms may include wheeziness, difficulty in breathing and skin rashes.
Carcinogenicity	:	No information available.
Mutagenicity	:	High doses have shown evidence of genotoxicity in vitro. No evidence of genotoxicity in in vivo tests.
Reproductive toxicity	:	Studies in animals have shown that exposures produce no teratogenic effects.

12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to active ingredient:

Toxicity	:	EC50 blue-green algae 72 H 0,018 mg/l (OECD 201) NOEC blue-green algae 72 H 0,0061 mg/l (OECD 201) EC50 green algae 72 H 111 mg/l (OECD 201) NOEC green algae 72 H 56 mg/l (OECD 201) EC50 Daphnia magna 48 H > 100 mg/l (OECD 202) NOEC Daphnia magna 21 d 7,9 mg/l (OECD 202) NOEC Daphnia 48 H 100 mg/l NOEC fathead minnow 32 d 5 mg/l
Effect on Effluent Treatment	:	There is no evidence of inhibition to the aerobic treatment process at a concentration of up to 100 mg/l
Persistence and degradability	:	Not rapidly degradable. There is evidence of hydrolysis in water.
Bioaccumulative potential	:	The substance has low potential for bioaccumulation.
Mobility in soil	:	Water solubility \geq 1 mg/l.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	Disposal should be in accordance with local, state or national legislation. This material and/or its container must be disposed of as hazardous waste. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal disposal is via incineration operated by an accredited disposal contractor.
Contaminated Packaging	:	Empty container will retain residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

ICAO/IATA	
UN No.	3077
Proper Shipping Name	: Environmentally hazardous substance, solid, n.o.s. (CEFTAROLINE FOSAMIL)
Class	: 9
Packing Group	: III
Environmental hazards	: Environmentally hazardous

IMO/MDG

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(CEFTAROLINE FOSAMIL)
Class : 9
Packing Group : III
Marine pollutant : Marine pollutant

ADR

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(CEFTAROLINE FOSAMIL)
Class : 9
Label(s) : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

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

The following sections contain revisions or new statements :

Minor changes: 2, 5, 6, 7, 8, 16

GLOSSARY

COM : In-house occupational exposure limit
LTEL : Long-term exposure limit (8 hour TWA (time-weighted average))
STEL : Short-term exposure limit (15-minute TWA (time-weighted average))
TLV : Threshold Limit Value (ACGIH)
TLV-C : Threshold Limit Value - Ceiling limit (ACGIH)
HYG : An in-house analytical method for occupational exposure monitoring is available
Sk : Can be absorbed through skin, thus contributing to systemic effects
Sen : Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.