

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Substance name : Fortaz (Ceftazidime for Injection)
Other means of identification : FORTAZ 500MG * FORTAZ 1G * FORTAZ 2G * FORTAZ 6G * CEFTAZIDIME
PENTAHYDRATE, FORMULATED PRODUCT

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

Use of the substance/preparation : Pharmaceutical Agent

1.3. Details of the supplier of the safety data sheet

Covis Pharma S.à.r.l.
Luxembourg, Zug Branch
Bahnhofstrasse 11
CH-6300 Zug, Switzerland

CH General Information:

Office : 0041 (0) 41 748 04 04 / Fax : 0041 (0) 41 748 04 09

Note : Zug Area code is 041. In Switzerland this area code must be used before the 7 digit tel. number

Medical Emergency : see U.S. information below

Information and Advice: US number, available 24 hours

Multi-language response

1.4. Emergency telephone number

Covis Pharmaceuticals, Inc

1513 Walnut Street

Suite 270

Cary, NC 27511

P : 919-535-3049 / Fax : 866-869-9215

e : info@covispharma.com

Transport Emergency: For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency +1-866-488-4423

US number, available 24 hours

Multi-language response

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****GHS-US classification**

Skin Sens. 1B H317

STOT SE 3 H335

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2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Warning

Hazard statements (GHS-US)

: H317 - May cause an allergic skin reaction
H335 - May cause respiratory irritation

Precautionary statements (GHS-US)

: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P271 - Use only outdoors or in a well-ventilated area
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 water/...
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P312 - Call a POISON CENTER/doctor/.../if you feel unwell
P321 - Specific treatment (see ... on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P403+P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
P501 - Dispose of contents/container to ...

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	GHS-US classification
Fortaz (Ceftazidime for Injection) (Main constituent)	(CAS No.) 78439-06-2	90.9	Skin Sens. 1B, H317 STOT SE 3, H335

Full text of H-phrases: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after 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.

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- First-aid measures after 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.
- First-aid measures after eye contact : Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
- First-aid measures after 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.

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

No additional information available

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

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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

None.

6.3. Methods and material for containment and cleaning up

For containment : Recover the product by vacuuming, shovelling or sweeping.

Methods for cleaning up : Recycle product or dispose properly.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : 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.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use neoprene or rubber gloves.

Eye protection : In case of dust production: protective goggles.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour : White/off-white.

Odour : No data available

Odour threshold : No data available

pH : No data available

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Self ignition temperature : No data available

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Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT / ADR / RID / ADN / IMDG / ICAO / IATA

14.1. UN number

UN 3077

14.2. UN proper shipping name

DOT Proper Shipping Name : Environmentally hazardous substances, solid, n.o.s. (FORTAZ (CEFTAZIDIME FOR INJECTION))

Department of Transportation (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140

Hazard Classes

Hazard labels (DOT) : 9 - Miscellaneous dangerous compounds



DOT Symbols : G - Identifies PSN requiring a technical name

Packing group (DOT) : III - Minor Danger

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DOT Special Provisions (49 CFR 172.102)

: 8 - A hazardous substance that is not a hazardous waste may be shipped under the shipping description "Other regulated substances, liquid or solid, n.o.s.", as appropriate. In addition, for solid materials, special provision B54 applies.

146 - This description may be used for a material that poses a hazard to the environment but does not meet the definition for a hazardous waste or a hazardous substance, as defined in 171.8 of this subchapter, or any hazard class as defined in Part 173 of this subchapter, if it is designated as environmentally hazardous by the Competent Authority of the country of origin, transit or destination.

335 - Mixtures of solids that are not subject to this subchapter and environmentally hazardous liquids or solids may be classified as "Environmentally hazardous substances, solid, n.o.s," UN3077 and may be transported under this entry, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Each transport unit must be leakproof when used as bulk packaging. B54 - Open-top, sift-proof rail cars are also authorized.

IB8 - Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1, 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2).

IP3 - Flexible IBCs must be sift-proof and water-resistant or must be fitted with a sift-proof and water-resistant liner.

N20 - A 5M1 multi-wall paper bag is authorized if transported in a closed transport vehicle.

T1 - 1.5 178.274(d)(2) Normal..... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 155

DOT Packaging Non Bulk (49 CFR 173.xxx) : 213

DOT Packaging Bulk (49 CFR 173.xxx) : 240

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

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15.2. US State regulations

No additional information available

SECTION 16: Other information

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.