

## MATERIAL SAFETY DATA SHEET

**Cipla**

<b>Product</b>	: <b>Fosfomycin Tromethamine For Oral Solution</b>		
<b>Date of Issue</b>	: <b>22.08.2018</b>	<b>Revision No.</b>	: <b>01</b>

### 1 IDENTIFICATION OF SUBSTANCE

**Trade Name** : Fosfomycin Tromethamine For Oral Solution

**Company** : Cipla Limited

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### 2 HAZARD IDENTIFICATION

#### **Classification as per EC-**

**Physical:** This material is assumed to be combustible. May emit toxic fumes under fire conditions.

**Health:** Not expected to occur during normal handling of this product.

**Environmental:** No information is available about the potential of this material to produce adverse environmental effects.

**Label in accordance with EC -** information not available.

**Single word – Not classified**

**Contains –API:** Fosfomycin Tromethamine

**Hazard Statement - ----**

#### **Precautionary statements -**

- P102: Keep out of reach of children
- P103: Read label before use

**Supplementary Precautionary Statement – ----**

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

Fosfomycin Tromethamine –active Ingredient

**Chemical name** : (1R,2S)-(1,2-Epoxypropyl)-phosphonic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

**Molecular Formula** : C<sub>3</sub>H<sub>7</sub>O<sub>4</sub>P.C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>

**Molecular Weight** : 259.19

**CAS No** : 78964-85-9 **UN No.** : Data not available **EC No.** : Data not available

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#### 4 **FIRST-AID MEASURES**

##### **General advice**

- Inhalation** : Does not cause a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.
- Skin Contact** : Remove contaminated clothing. Flush with copious quantity of water. Receive immediate medical attention.
- Eye Contact** : Flush eyes with copious quantity of water for at least 15 minutes Receive immediate medical attention.
- 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. Received immediate medical attention.

##### **Notes to Health Professionals**

- Medical Treatment** : In cases of overdose of the product patient should be treated according to locally approved protocols.
- Medical conditions Caused or Aggravated by exposure** : No specific data available
- Antidote** : No specific data available

#### 5 **FIRE FIGHTING MEASURES**

- Fire & Explosion hazard** : This material is assumed to be combustible. May emit toxic fumes under fire conditions.
- Extinguishing media** : Water spray, Foam, Carbon dioxide, Dry Chemical Powder as appropriate for surrounding fire and material.
- Special fire fighting procedure and protective measures** : As with all fires, evacuate persons to safe area. Fire fighter should use self-contained breathing apparatus and protective clothing. If possible, contain and collect firefighting water for later disposal.
- Hazardous Combustion Products** : Under fire conditions - May emit toxic fumes, carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides.

#### 6 **ACCIDENTAL RELEASE MEASURES**

- Personal Precautions** : Avoid unwanted exposure. Wear protective and equipment Consistent and compatible with the degree of hazard.
- Environmental Precaution** : Sweep up the material, place in a bag / container and hold for waste disposal. Take precautions to prevent entry into waterways, sewers or surface drain systems.
- Clean - up Procedure** : Place material in appropriate and labeled container / bag for

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waste disposal. Wash contaminated clothing before reuse. Dispose off waste in accordance with applicable federal, state and local laws.

**Decontamination Procedure** : No specific decontamination procedure has been identified.

## 7 HANDLING AND STORAGE

**Handling** : Handle material with care. Avoid exposure to moisture, humid conditions and direct Sunlight. This material should be handled as per instructions to ensure product integrity. Handle product with wearing proper personal protective equipment mentioned in section 8. Do not permit eating, drinking or smoking near the material. Handle material in accordance with applicable good industrial hygiene and safety procedures.

**Storage** :

- 1. Bulk Storage** - Store in well – closed container at the demarcated place i.e. well ventilated places. Store material in dry place protected from light. Avoid exposure to moisture, humid conditions and direct sunlight. Keep away from all heat sources, ignition sources including sparks and incompatible material. This material should be handled and stored as per instructions to ensure product integrity.

- 2. Department Storage** - As mentioned above

**Pictograms -**



Keep Away From  
Water



Keep Away From Sunlight,  
cold, radioactive and Heat



Store between  
20°C to 25 °C

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hazard category and Exposure Limits**

Refer section 9, 10, 11 and 12

**Personal protective equipment**



**Ensure before use** - Personal Protective Equipment selected are consistent and compatible with degree of hazard. Ensure that Personal protective equipment which are to be use are tested and approved under appropriate government standards such as NIOSH ( US ) or CEN ( EU ) etc.

**Respiratory protection** : Not required when handling capsule or containers. Approved respirator for protection should be used if respirators are found to be necessary.

**Hand protection** : Not required when handling capsule or containers, if containers are compromised or exposure is likely wear hand gloves.

**Eye protection** : Not required when handling capsule or containers, if containers are compromised or exposure is likely wear goggles.

**Skin protection** : Not required when handling tablets or containers, if containers are compromised or exposure is likely wear protective clothing including apron

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/ suit.

**Exposure control Ventilation :** Adequate ventilation is required. Provide local exhaust and mechanical ventilation.

**Hygiene Measure :** Do not expose any body part to material. In case of exposed clean body part with plenty of water.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

**Appearance and odor :** oral suspension

**Vapour pressure :** Data not available

**Vapour density :** Not applicable

**Flash point :** Data not available

**Viscosity :** Not applicable

**Melting range :** Data not available

**Boiling point :** Data not available

**Specific gravity :** Not applicable

**Auto-ignition :** Not applicable

**Relative density :** Data not available

**Flammability :** Data not available.

**Solubility :** Data not available

## 10 STABILITY AND REACTIVITY

**Stability :** Stable (From safety point of view)

**Incompatibilities / Conditions to avoid :** Data not available

**Hazardous decomposition products :** When heated to decomposition, may emit toxic fumes.

**Hazardous reactions :** None under normal condition

**Hazardous polymerization :** Will not occur

## 11 TOXICOLOGICAL INFORMATION

**Oral Toxicity :** Not expected for oral suspension

**Skin Effects :** Not expected for oral suspension

**Inhalation Toxicity :** Not expected for oral suspension

**Eye Effects :** May cause irritation

**Toxicity data** Fosfomycin Tromethamine –active Ingredient  
**ORL - RAT LD 50 :** >5000 mg/kg

## 12 ENVIRONMENTAL / ECOLOGICAL INFORMATION

**Summary:** This product may be harmful if releases directly to the environment. Appropriate precautions should be taken to limit release of this material in the environment. Local regulations and procedures should be consulted prior to environmental release.

## 13 DISPOSAL CONSIDERATION

**Disposal Recommendations :** Dispose material as Hazardous Waste and as per local, state and federal regulatory procedures and laws.

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### 14 **TRANSPORT INFORMATION** (UN Classification & Labeling)

Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release.

This material is not a dangerous good for the purpose of transportation.

### 15 **REGULATORY INFORMATION**

**Labeling according to EEC directives** : As mentioned in section 14 of this document

**National legislation / regulations** : ----

**Any other regulatory information** : ----

### 16 **OTHER INFORMATION**

**Therapeutic category of material** : Urinary Anti-infectives

**Reference** 1. MSDS of Fosfomycin Tromethamine

*The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendations given are best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. Recipients of material must take responsibility for observing existing laws, regulations and suitability of material for handling, transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with the handling, storage, use and disposal of the product. Information mention in this document relates only to the specific material designated and may not valid for such material used in combination with other material or any process.*