

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078935351

N/A



## GLENMARK PHARMACEUTICALS LIMITED

### SAFETY DATA SHEET

**PRODUCT: POTASSIUM CHLORIDE  
EXTENDED-RELEASE CAPSULES, 10 mEq**

**SDS NO. : SDSGHS.040.00**

**EFFECTIVE DATE :20/01/2016**

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#### **Section 1. Identification**

**1.1 Substance Name:** Potassium Chloride Extended-Release Capsules, 10 mEq

**1.2 Chemical Name:** Potassium Chloride

**1.3 Relevant identified uses of the substance or mixture and uses advised against:**  
Pharmaceutical use.

**1.4 Company Identification:** Glenmark Pharmaceuticals Inc., USA  
750 Corporate Drive  
Mahwah, NJ 07430

**1.6 Emergency Contact details:** (201) 684-8000

#### **Section 2. Hazard Identification**

**2.1 Classification of the substance or mixture**

**Classification according to Regulation GHS**

Skin contact with powder may cause irritation. Eye contact with powder may cause irritation.

**2.2 Label elements:** Not Known

**2.3 Risk Hazard:** R36/38 – Irritating to eyes and skin.

**2.4 Safety Advice:** Not Known

**2.5 Other hazards:** Not Known



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### Section 3- Composition/Information on Ingredients

#### 3.1 Substances

| COMPONENTS                                       | CAS       | CONCENTRATION<br>(WT %) | EXPOSURE |
|--|-----------|-------------------------|----------|
| Potassium Chloride                               | 7447-40-7 | Proprietary             | N/E      |
| ingredients determined not to be hazardous [Mfr] | -         | Proprietary             | N/E      |

### Section 4. First aid Measures

**4.1 Inhalation:** Remove to fresh air. If breathing is difficult, administer oxygen (by qualified medical personnel only). If breathing has stopped, give artificial respiration. Seek immediate medical attention.

**4.2 Skin:** Remove by wiping and wash skin thoroughly with soap and water. If irritation persists, seek medical attention.

**4.3 Eyes:** Flush eyes with large amounts of lukewarm water for 15 minutes. If irritation persists, seek medical attention.

**4.4 Ingestion:** Not a primary route of overexposure. Do not induce vomiting. Drink copious amounts of water. Get medical attention immediately.

#### **4.5 Most important symptoms and effects, both acute and delayed**

Treat Symptomatically



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#### **Section 5. Fire-fighting Measures**

**5.1 General Information:** Use firefighting measures which suit the environment and take into account other materials which may be involved. Wear self-contained breathing apparatus and protective clothing. If fire is in areas where large amounts of product are stored, evacuate to a safe distance in all directions.

**5.2 Extinguishing Media:** Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.

**5.3 Fire/Explosion Hazard:** Toxic gases may be evolved in a fire situation. Remain upwind and notify those downwind of hazard.

**5.4 NFPA Rating:** Health=2, Flammability=1 and Reactivity=0

#### **Section 6. Accidental Release Measures**

**6.1 General Information:** Use appropriate personal protective equipment (safety glasses, protective clothing and gloves) to minimize exposure.

**6.2 Major/Minor Spills:** Use appropriate tools to put the caplets in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. Use a shovel for large spills. If the caplets have broken open, use a HEPA vacuum to collect the powder. Do not dry sweep.

#### **Section 7. Handling and Storage**

**7.1 Handling:** Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

**7.2 Storage:** Store in cool, dry area away from heat sources. Keep containers tightly closed when not in use. Store upright and prevent containers from being knocked over.



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**7.3 Storage Incompatibility:** Not Known

## Section 8. Exposure Controls/Personal Protection

### 8.1 Occupational Exposure Limits (OEL):

| Components                         | Type     | Value     |
|------------------------------------|----------|-----------|
| Potassium Chloride (CAS 7447-40-7) | 8 HR TWA | Not Known |

### 8.2 Exposure controls:

#### Appropriate engineering controls

General ventilation used in combination with local exhaust as necessary to control air contaminants at or below irritant levels.

**General Information:** Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection:** Avoid eye contact. Safety glasses are acceptable for ordinary product usage.

**Skin protection:** Avoid prolonged or repeated contact with skin. Wash thoroughly after exposure. Gloves may be worn to reduce contact.

**Hand protection:** Acid –alkali gloves is to be used while handling.

**Hygiene measures:** An eye wash station should be available. Wear appropriate clothing to avoid skin contact. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.



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**Section 9. Physical and Chemical Properties**

**9.1 Information on basic physical and chemical properties**

|                                    |   |                        |
|------------------------------------|---|------------------------|
| Physical State                     | : | Solid                  |
| Appearance                         | : | white, granular powder |
| Colour                             | : | White                  |
| pH Value                           | : | 5.5 to 8.5 (50 g/L)    |
| Vapour Pressure                    | : | Not Known              |
| Vapour Density                     | : | Not Known              |
| Evaporation Rate                   | : | Not Known              |
| <i>Other information</i>           |   |                        |
| Flash point                        | : | Not Known              |
| Molecular Weight                   | : | Not Known              |
| Melting point/range                | : | 790°C                  |
| Boiling point/boiling range        | : | 1413°C                 |
| Density                            | : | Not Known              |
| Viscosity                          | : | Not Known              |
| Water solubility                   | : | Soluble                |
| Solubility in other solvents       | : | Insoluble              |
| Minimum ignition energy (MIE)      | : | Not Known              |
| Minimum ignition temperature (MIT) | : | Not Known              |
| Layer ignition temperature (LIT)   | : | Not Known              |
| Flammability/explosivity           | : | Not Known              |
| Reactivity/exotherms               | : | Not Known              |
| Electrostatic nature               | : | Not Known              |



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|  |   |           |
|--|---|-----------|
| Highly dusty material  | : | Not Known |
| Any other properties which cause handling or processing difficulties | : | Not Known |
| Average PSD (particle size distribution (micron))                    | : | Not Known |

**9.2 Other Information:** Not Known

### Section 10. Stability and Reactivity

**10.1 Reactivity:** Stable under recommended storage conditions.

**10.2 Chemical stability:** Stable at recommended storage conditions.

**10.3 Conditions to Avoid:** Avoid heat, sparks, open flames and other ignition sources.

**10.4 Incompatibilities with Other Materials:** Incompatible (potentially explosive) with oxidising agents (eg. hypochlorites).

**10.5 Hazardous Decomposition Products:** May evolve toxic gases (potassium oxides, chlorides) when heated to decomposition.

**10.6 Hazardous Polymerization:** Will not occur

### Section 11. Toxicological Information

#### 11.1 Information on toxicological effects

##### Active Ingredient (Acyclovir)

##### Acute Toxicity:

Potassium Chloride (7447-40-7)

LD50 (ingestion): 2600 mg/kg (rats)

LD50 (intraperitoneal): 620 mg/kg (mouse)



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LD50 (intravenous): 117 mg/kg (mouse)  
LDLo (ingestion): 20 mg/kg (man)  
LDLo (intraperitoneal): 900 mg/kg (guinea pig)  
LDLo (intravenous): 77 mg/kg (guinea pig)  
LDLo (subcutaneous): 2120 mg/kg (frog)  
TDLo (ingestion): 60 mg/kg/days (woman)

**Health Hazard Summary:** Low toxicity. Use safe work practices to avoid eye or skin contact and inhalation. Acute potassium poisoning via ingestion is rare as a large single dose usually induces vomiting, and potassium is rapidly excreted by the body, however this product does have the potential to cause cardiovascular disorders.

**Eye:** Low to moderate irritant. Contact may result in irritation, lacrimation, pain and redness.

**Inhalation:** Low irritant. Over exposure may result in irritation of the nose and throat, with coughing.

**Skin:** Low irritant. Prolonged or repeated contact may result in mild irritation, rash and dermatitis.

**Ingestion:** Low toxicity. Ingestion may result in gastrointestinal irritation, nausea, vomiting, abdominal pain and diarrhoea. Ingestion of large quantities may result in blood clotting changes, cardiac arrhythmias, increased respiration, muscle weakness, convulsions and coma. Potassium poisoning disturbs the rhythm of the heart. Large single doses have been shown to cause death in humans. However, when the same amounts have been taken in divided doses over a 24 hour period, no adverse health effects have occurred. Potassium chloride, used to coat enteric tablets has been associated with ulceration, lesions and haemorrhage of the small intestine. Obstruction and perforation of the small intestine and bowel have also been reported.





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#### **Section 12. Ecological Information**

**12.1 Toxicity:** Limited ecotoxicity data was available for this product at the time this report was prepared. Ensure appropriate measures are taken to prevent this product from entering the environment.

**12.2 Persistence and degradability:** Not Known.

**12.3 Bioaccumulative potential:** Not Known.

**12.4 Mobility in soil:** Not Known.

**12.5 Other:** Not Known.

#### **Section 13. Disposal Considerations**

##### **13.1 Waste treatment methods**

Waste Disposal Collect and place in sealable containers and dispose of to an approved landfill site. Contact the manufacturer for additional information. Legislation Dispose of in accordance with relevant local legislation.

#### **Section 14. Transport Information**

##### **14. 1 Special precautions for user:**

DOT PROPER SHIPPING NAME: Not regulated by DOT

DOT HAZARD CLASS: Not applicable

UN IDENTIFICATION NUMBER: Not applicable



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**Section 15. Regulatory Information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

WHMIS CLASSIFICATION: This product has not been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

TSCA INVENTORY: Potassium chloride is listed on the TSCA inventory.

SARA TITLE III – SECTION 313 SUPPLIER NOTIFICATION: This product does not contain ingredients subject to the reporting requirements of section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986 and 40 CFR 372.

CALIFORNIA PROPOSITION 65: This product does not contain ingredients known to the State of California to cause cancer or reproductive toxicity.

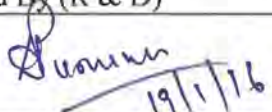
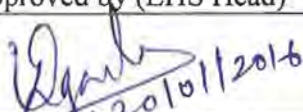
Canadian Domestic Controlled Substances List – Yes (potassium chloride)

R36/38 – Irritating to eyes and skin.

**Section 16. Additional Information**

**Disclaimer:**

The information provided in this 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 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.

| Compiled By (R & D)   | Approved by (EHS Head)   |
|---|--|
|  |  |
| Signature /Date<br>19/1/16  | Signature /Date<br>20/01/2016  |