



MSN Laboratories Private Limited  
R&D Center, Formulation Division.

## SAFETY DATA SHEET

Page No.1 of 5

**Product Name** Dapagliflozin Tablets 5 mg and 10 mg

### 1. Product Information

**Product Name :** Dapagliflozin Tablets 5 mg and 10 mg

**Chemical Family:** Mixture

**Intended use:** Anti diabetic

**Details of the manufacturer:**

MSN Laboratories Private Limited. Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324, Nandigama Village & Mandal,

Ranga Reddy Dist, Telangana State, India. PIN 509228

**Phone: +918548699000**

### 2. Hazards Identification

#### 2.1 Classification in accordance with 29 CFR 1910.1200

Classification of the finished drug product is not required according to OSHA 29 CFR 1910.1200.

The following information is provided for the drug substance:

Classification:

Reproductive toxicity, Category 1B

Effects on or via lactation

Specific target organ toxicity - repeated exposure, Category 2

#### 2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance:

**Signal Word: Warning**

**Hazard Statement(s):** Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. May cause damage to kidneys through prolonged or repeated exposure if swallowed.

**Symbol(s): Health hazard**

**Precautionary Statement(s):**

Prevention: Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Do not handle until all safety precautions have been read and understood. Wear protective gloves. Do not breathe dust. Wash hands thoroughly after handling. Do not eat, drink or smoke while using this product.

Response: If exposed or concerned: Get medical attention.

Storage: Store locked up.

Disposal: Dispose of in accordance with applicable regional, national and local laws and regulations.

#### 2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

## SAFETY DATA SHEET

Page No.2 of 5

<b>Product Name</b>	<b>Dapagliflozin Tablets 5 mg and 10 mg</b>
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**3. Composition/Information on Ingredients**

C.A.S. No : 461432-26-8  
Molecular Formula :  $C_{21}H_{25}ClO_6$   
Molecular Weight : 408.87  
Chemical Name : (1S)-1,5-anhydro-1-C-{4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl}-D-glucitol.

**4. First Aid Measures**

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention.

**Ingestion:** Give moderate amount (200 -300 mL) of water and seek medical attention.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

**5. Fire Fighting Measures**

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**6. Accidental Release Measures**

**Measures for Personal Safety:** Take proper precautions to minimize exposure by using appropriate personal protective equipment

**Measures for Environmental :** Not to released into environment. Care should be taken to avoid environment release. If the product has escaped into water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

**7. Handling and Storage**

**General Handling:** Avoid generating airborne dust. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling.

**Storage Conditions:** Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

**8. Exposure Controls/Personal Protection**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

**Personal Protective Equipment: Hands:** Rubber gloves

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. If the applicable Occupational Exposure Limit

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<b>SAFETY DATA SHEET</b>		Page No.3 of 5
<b>Product Name</b>	<b>Dapagliflozin Tablets 5 mg and 10 mg</b>	

**Hygiene measures:** Wash skin thoroughly with soap and water.

### 9. Physical Properties

**5 mg :** Yellow coloured, round , biconvex, film coated tablets debossed with "D1" on one side and "M" on other side

**10 mg :** Yellow coloured, diamond , biconvex, film coated tablets debossed with "D2" on one side and "M" on other side.

### 10. Stability and Reactivity

**Conditions to Avoid** : Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:** Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide and halogen containing gases.

**Polymerization:** Will not occur

### 11. Toxicological Information

- **Acute toxicity:**
- Lethal Dose  $Ld_{50}$  Rat {Oral} : 2000 mg/kg.
- **Skin corrosion/irritation:**
- No data available.
- **Serious eye damage/eye irritation:**
- No data available.
- **Respiratory or skin sensitization:**
- No data available.
- **Carcinogenicity:** Dapagliflozin was non-carcinogenic.
- **Mutagenicity:** Dapagliflozin is considered not to be genotoxic.
- **Reproductive toxicology & Teratology:** In rats, no effects on male and female fertility were seen with Dapagliflozin
- **Specific target organ toxicity - single exposure:** Not available
- **Specific target organ toxicity - repeated exposure:** No data available
- **Aspiration hazard:** No data available
- **Potential health effects:**
- **Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.
- **Ingestion:** May be harmful if swallowed
- **Skin:** May be harmful if absorbed through skin. May cause skin irritation.

## SAFETY DATA SHEET

Page No.4 of 5

<b>Product Name</b>	<b>Dapagliflozin Tablets 5 mg and 10 mg</b>
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- **Eyes:** May cause eye irritation.
- **Additional Information**

RTECS: Not available

**12. Ecological Information****Persistence and degradability:** no data available**Toxicity:** no data available**Bio accumulative potential:** no data available**Mobility in soil:** no data available**PBT and vPvB assessment:** no data available**Other adverse effects:** no data available**13. Disposal Considerations**

Dispose of in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging: Dispose of as unused product.

"LATEX and PRESERVATIVE FREE"

**14. Transport Information****U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS:** This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.**TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:** This product is not classified as Dangerous Goods, per regulations of Transport Canada.**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):** This product is not classified as Dangerous Goods, by rules of IATA.**INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:** This product is not classified as Dangerous Goods by the International Maritime Organization.**EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BYROAD (ADR):** This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.**TRANSPORT IN BULK ACCORDING TO THE IBC CODE:** Not applicable.**ENVIRONMENTAL HAZARDS:** This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and not component is specifically listed in Annex III under MARPOL 73/78.**Environmental hazard:** None.**Transport in bulk:** Not available.**Special precautions needed with transport:** Always transport in closed containers that are upright and secure. Ensure that persons transporting the product known what to do in the event of an accident or spillage.**15. Regulatory Information****OSHA Hazards:** Harmful by ingestion, Teratogen

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MSN Laboratories Private Limited  
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<b>SAFETY DATA SHEET</b>		Page No.5 of 5
<b>Product Name</b>	<b>Dapagliflozin Tablets 5 mg and 10 mg</b>	

**SARA 302 Components:** SARA 302: No chemical in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components:** SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.

**SARA 311/312 Hazards:** No SARA Hazards

**Massachusetts Right To Know Components:** No components are subject to the Massachusetts Right to Know Act.

**California Prop. 65 Components:** This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

#### 16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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