



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

SAFETY DATA SHEET

Product Name	Dapagliflozin and Metformin Hydrochloride ER Tablets 5mg/500mg, 10mg/500mg, 5mg/1000mg and 10mg/1000mg	Page No: Page 1 of 7
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1. Identification

Product Name: Dapagliflozin and Metformin Hydrochloride ER Tablets 5mg/500mg, 10mg/500mg, 5mg/1000mg and 10mg/1000mg

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. Hazard (s) Identification

Hazard statement(s): H302 Harmful if swallowed.
H315+H320 Causes skin and eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.

Precautionary statement(s): P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P301+312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

HMIS Classification

Health hazard: 1

Flammability: 0

Physical hazards: 0

NFPA Rating

Health Hazard: 1

Fire: 0

Reactivity Hazard: 0

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause irritation

Eyes: May cause eye irritation

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3. Composition/Information on Ingredients

Dapagliflozin:

C.A.S. No : 461432-26-8
Molecular Formula : C₂₁H₂₅ClO₆
Molecular Weight : 408.9
Chemical Name : (2S,3R,4R,5S,6R)-2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6
(hydroxymethyl)oxane-3,4,5-triol.

Metformin Hydrochloride

C.A.S. No : 1115-70-4
Molecular Formula : C₄H₁₁N₅.HCl
Molecular Weight : 165.62
Chemical Name : 1,1-dimethylbiguanide hydrochloride

4. First Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Condition of flammability: Not flammable or combustible.

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

Hazardous combustion products: Hazardous decomposition products formed under fire conditions—carbon oxides, nitrogen oxides.

5. Fire Fighting Measures

- Suitable extinguishing media** - Water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid)** - Not applicable
- Specific hazards** - Very high probability of ignition of dust whirled up
- Formation of toxic and corrosive combustion gases (hydrogen

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fluoride, nitrogen oxides) possible

Protection of fire-fighters

- Consider danger for the environment: dike spilled liquid
- Precipitate gases/vapours/mists with water spray
- Use self-contained breathing apparatus
- Avoid skin contact

6. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

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

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1(EN 143) dust masks. Use respirators and components tested and

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approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

9. Physical and Chemical Properties

Appearance:

5mg/500mg: Capsule shaped, film coated tablets bilayered, White to off white color, debossed with "MD32" on one side and light pink with red color spots, plain on other side, free from physical defects.

10mg/500mg: Capsule shaped, film coated tablets bilayered, White to off white color, debossed with "MD30" on one side and pink with red color spots, plain on other side, free from physical defects.

5mg/1000mg: Oval shaped, film coated tablets bilayered, White to off white color, debossed with "MD29" on one side and light pink with red color spots, plain on other side, free from physical defects.

10mg/1000mg: Oval shaped, film coated tablets bilayered, White to off white color, debossed with "MD28" on one side and pink with red color spots, plain on other side, free from physical defects.

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

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: None known

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11. Toxicological Information

Skin corrosion/irritation: Not irritating to skin

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: no data available

Teratogenicity: May be harmful to fetus.

Specific target organ toxicity – single exposure (GHS): no data available

Specific target organ toxicity – repeated exposure (GHS): no data available

Aspiration hazard: no data available

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: Harmful if swallowed.

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic Effects: no data available

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

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13. Disposal Considerations

Product: Observe all federal, state, and local environmental 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 know what to do in the event of an accident or spillage.

15. Regulatory Information

OSHA Hazards: Harmful by ingestion, Teratogen

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.

Pennsylvania Right To Know Components: Dapagliflozin and Metformin Hydrochloride

New Jersey Right To Know Components: Dapagliflozin and Metformin Hydrochloride

California Prop. 65 Components: This product does not contain any chemicals known to State of

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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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