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

SAFETY DATA SHEET

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Product Name Prucalopride Tablets 1 mg and 2 mg/Prucalopride 1 mg and 2 mg Film Coated Tablets

1. Product Information

Product Name : Prucalopride Tablets 1 mg and 2 mg/Prucalopride 1 mg and 2 mg Film Coated Tablets

Chemical Family: Mixture

Intended use: Indicated for the treatment of chronic idiopathic constipation (CIC) in adults

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: +91 40 3044 9200

2. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients

C.A.S. No : : 179474-85-2

Molecular Formula : $C_{18}H_{26}ClN_3O_3 \cdot C_4H_6O_4$

Formula Weight : 485.96

Chemical Name : 4-amino-5-chloro-N-[1-(3-methoxypropyl)piperidin-4-yl]-2,3-dihydro benzofuran-7-carboxamide succinate

4. First Aid Measures

Eye Contact: Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

Skin Contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

Ingestion: If swallowed, wash out mouth with copious amounts of water; call a physician.

Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

5. Fire Fighting Measures

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

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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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 or capsules 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:

US : Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (between 59°F to 86°F) [see USP Controlled Room Temperature]. Store in the original container to protect from moisture.

Canada : Store between 15-30°C.

ROW : Store below 30°C.

Europe : Store in the original blister in order to protect from moisture

8. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. Physical and Chemical Properties

Appearance :

1 mg : White to off white, round, biconvex, film coated tablets debossed with "P" on one side and "1" on other side, free from physical defects.

2 mg: Light pink to pink, round, biconvex, film coated tablets debossed with "P" on one side and "2" 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

11. Toxicological Information

Acute inhalation toxicity: No data available.

Acute dermal toxicity : No data available.

Skin irritation : Non-irritant (rabbit)

Eye irritation : No data available.

Reproductive toxicity : No data available.

Teratogenicity : No data available.

Aspiration hazard : No data available.

Carcinogenicity : NTP?No IARC Monographs ?No OSHA Regulated?No

12. Ecological Information

[Aquatic Toxicity]

No information is available about the potential of this product to produce adverse environmental affects.

13. Disposal Considerations

Product : Dispose of in accordance with local authority regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

14. Transport Information

DOT (US): Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

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15. Regulatory Information

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

Special precautions for users: N/D

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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