MATERIAL SAFETY DATA SHEET

SECTION 1- CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metoprolol Succinate Extended-Release Tablets

Therapeutic Use: Hypertension and Angina Pectoris and Heart Failure

Manufacturer's Name: Visum Pharmaceutical Co., Ltd.

Address: 273-D, Nanhai Blvd, Haikou, China, 570311

Emergency Telephone: +86-898-3663 6555

SECTION 2- HAZARDS IDENTIFICATION

Adverse Effects: Adverse effects of beta-adrenergic blockers may include dizziness, difficulty breathing, headache, depression, insomnia, drowsiness, weakness, slow heartbeat, cold hands and feet, sexual dysfunction, nausea, and vomiting. This material may also cause diarrhea and shin rash. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose effects of beta-adrenergic agonists may include nausea, vomiting, seizures, slow or irregular heartbeat, heart failure, low blood pressure, severe dizziness, respiratory depression or arrest, and coma.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart disorders (e,g., congestive heart failure and angina), low blood pressure, peripheral vascular disease (e.g., Raynauds syndrome), respiratory disorders (e.g., asthma, emphysema, chronic bronchitis), psoriasis, history of allergies, type-1 diabetes, hyperthyroidism, depression, pheochromocytoma, impaired kidney or liver function.

Cross Sensitivity: Persons sensitive to one beta-adrenergic blocker may be sensitive to this material also.

Target Organs: Cardiovascular system.

For additional information on toxicity, see Section 11.

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SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Substance/ Mixture: Mixture

Ingredient Name	%	CAS number
Metoprolol Succinate	23.1	98418-47-4
Hypromellose	1.1	9004-65-3
Talc	1.9	14807-96-6
Magnesium stearat	0.5	91031-63-9
Microcrystalline Cellulose	64.6	9004-34-6
Ethylcellulose	5.6	9004-57-3
Polyethylene Glycol 4000	0.3	25322-68-3
Opadry	2.9	None (Mixture)

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 – FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Contact with Eyes: May cause irritation. Flush with copious quantities of water.

Contact with Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is rapidly and completely absorbed from the gastrointestinal tract.

Instructions for the doctor: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

Note to Physicians

Overdose Treatment: Treatment for overdose of a beta-adrenergic blocker should be symptomatic and supportive and may include the following:

1. Do not induce vomiting.
2. Maintain an open airway and assist ventilation if necessary.
3. Administer activated charcoal as a slurry and perform gastric lavage to decrease

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absorption. Gastric lavage may increase vagal tone.

4. Perform an early echocardiographic evaluation to expedite diagnosis and treatment of cardiac toxicity.
5. For hypotension: If mild, administer IV fluids. If severe, administer IV glucagon, calcium, or catecholamines (dopamine, norepinephrine, epinephrine). Concurrent high-dose insulin euglycemia therapy may allow for a decrease in the dose of catecholamine.
6. For bradycardia: Administer IV atropine, glucagon, and isproterenol. Cardiac pacing may also be needed.
7. For bronchospasm: Administer nebulized bronchodilators, Systemic corticosteroids may also be beneficial.
8. For seizures: Administer a benzodiazepine (diazepam or lorazepam) intravenously. Muscle relaxants and artificial ventilation may also be required.
9. Sodium bicarbonate may be helpful for dysrhythmias and conduction defects.
10. For hypoglycemia: Administer glucose or glucagon.
11. Metoprolol is not removed by hemodialysis. [Poisoning and Drug Overdose, 4th ed; USP DI 2005; Poisindex 2011].

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media: Water spray, dry chemicals, carbon dioxide of foam as appropriate for surrounding fire and materials.

Special fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautionary measures: Keep unnecessary personnel away. Avoid contact with eyes, skin or clothing. Provide adequate ventilation. Wear approved respiratory protection, chemically compatible gloves, and protective clothing.

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Environment protection measure: Do not allow entrance in sewage water, water suppliers or stretches of groundwater.

Cleaning measures: Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and sash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handing USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Storage: Store as directed by product packaging.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Metoprolol Succinate: Exposure limits: Industry: 1mg/m^3 .

Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be use with highly potent materials should be assessed be use of nontoxic surrogate materials.

Respiratory Protection: where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in materials.

Eye Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection(e. g., bearing the ANSI Z87 or CSA stamp) is preferred.

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Maintain eyewash facilities in the work area.

Clothing Protection: For handing of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Hand Protection: Chemically compatible. For handling solution, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoid due to the risk of latex allergy.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid

Color: White

Odor: Not found

Odor Threshold: Not found

Molecular Formula: Not found

Molecular Weight: Not found

Solvent Solubility: Not found

Water Solubility: Not found

pH: Not found

Melting/ Freezing Point: Not found

Boiling Point: Not found

Flash Point: Not found

Autoignition Temperature: Not found

Evaporation Rate: Not found

Upper Flammability Limit: Not found

Lower Flammability Limit: Not found

Vapor Pressure: Not found

Vapor Density: Not found

Partition Coefficient: Not found

Percent Volatile: Not found

Reactivity in Water: Not found

Explosive Properties: Not found

Oxidizing Properties: Not found

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SECTION 10 - STABILITY AND REACTIVITY

Reactivity: Not found

Conditions to Avoid: Not found

Incompatibilities: Not found

Dangerous products of decompostion: When heated to decomposition, material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stability: Stable under recommended storage conditions.

Hazardous Polymerization: Not found

SECTION 11 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: ＞2000mg/ Kg

Oral Mouse: Not found

Other Toxicity Data: Not found

Irritancy Data: Not found

Corrosivity: Not found

Sensitization Date: Not found

Listed as a Carcinogen by: NTP: No, **IARC:** No, **OSHA:** No

Other Carcinogenicity Data: In two-year studies in rats at oral dosage levels of up to 800mg/kg/day, there was no increase in the development of spontaneously occurring benign or malignant neoplasms of any type. In a 21-month study in Swiss albino mice receiving the highest dose than in untreated control animals. There was no increase in malignant or total lung tumors, nor in the overall incidence of tumors or malignant tumors. This 21-month study in CD-1 mice, and no statistically or biologically significant differences were observed between treated and control mice of either sex for any type of tumor.

Mutagenicity Data: Metoprolol succinate was not mutagenic in a Salmonella/ mammalian-microsome test. Metoprolol tartrate was not mutagenic in a dominat lethal study in mice, chromosome studies in somatic cells, a Salmonella/ mammalian-microsome test, and a nucleus anomaly test in somatic interphase nuclei.

Reproductive and Developmental Effects: Some beta-adrenergic blocking agents have been reported to cause fetal and neonatal bradycardia, hypotension, and hypoglycemia when

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administered during pregnancy, and may also be associated with fetal growth retardation. A placebo-controlled trial of metoprolol as a treatment of hypertension during pregnancy showed no evidence of beta-blockade in newborns or decreased birth weights at maternal doses of 50 to 100 mg. metoprolol tartrate given to rats and rabbits at doses of 500 mg/kg and 64mg/kg, respectively, resulted in inhibited implantation and slight growth retardation in the rat, and increased embryo lethality in the rabbit.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: Not readily biodegradable.

Green algae: EC50: 47 mg/L (72 hr)

Daphnia magna: EC50: 90 mg/L(48 hr)

Fish:LC50: 170 mg/L

SECTION 13 - DISPOSAL

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 - TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

International Regulatory Information: Not found

SECTION 16 - OTHER INFORMATION

Disclaimer: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. It shall be used only as a guide. Users should make their own

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