SAFETY DATA SHEET

Section 1. Identification

Manufacturer Name:	Rubicon Research Pvt. Ltd.
Address:	Plot No K 30/4 &K 30/5, Additional M.I.D.C., Ambernath District: Thane, Maharashtra, INDIA.
Phone Number:	0251-6619500 / 6619520
Emergency Phone Number:	0251 262 592 (Govind Hiwrale - Director Quality Assurance)
Product Name:	Metoprolol Tartrate Tablets USP 25/50/100 mg
Chemical Name:	Mixture
Recommended Use:	Cardio-selective Beta-Blocker, Anti-anginal; anti-hypertensive, anti-arrhythmic

Section 2. Hazard(s) Identification

Appearance:

25 mg: Pink color coated tablet with R25 on one surface and score-line on other surface.

50 mg: Pink color coated tablet with R50 on one surface and score-line on other surface.

100 mg: Pink color coated tablet with R100 on one surface and score-line on other surface.

Additional Hazard Information:

Form:	Tablets
Known Clinical Effects:	Adverse effects most commonly reported in clinical use include irregular heartbeat (cardiac arrhythmia), symptoms of asthma, decreased blood sugar (hypoglycemia), troubled breathing, swelling, nausea, stomach discomfort, and lack of appetite. Due to intended use, dangerous lowering of blood pressure can occur.
Short Term:	Antihypertensive drug: Has blood pressure-lowering properties may have harmful effects on the aquatic environment.
Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus. May have long term toxic effects on the aquatic environment.

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Section 3. Composition / Information on Ingredients

Sr. No.	Ingredient	CAS Number
1.	Microcrystalline cellulose	9004-34-6
2.	Lactose anhydrous	63-42-3
3.	Sodium starch glycolate	9063-38-1
4.	Aerosil	7631-86-9
5.	Magnesium stearate	557-04-0
6.	Metoprolol Tartrate	56392-17-7
7.	Opadry Pink 03F84419 IH	--

Section 4. First -Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Notes to physician Treat patient symptomatically.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Section 5. Fire- Fighting Measures

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

Hazardous combustion product Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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Section 6. Accidental Release Measures

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
Environmental Precautions:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up	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.
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.

Section 7. Handling And Storage

General Handling:	No special precautions are necessary when handling packed product. 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. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.
Storage Conditions:	Store as directed by product packaging.

Section 8. Exposure Controls / Personal Protection

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use-of personal protective equipment (PPE).
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.

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Skin:	Impervious protective clothing is recommended
Respiratory protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

Section 9. Physical and Chemical Properties

Physical State:	Tablet
Color:	Pink
Solubility (Water):	Freely soluble
Molecular Weight:	Mixture
Molecular Formula:	Mixture
Partition Coefficient (Calculated; pH 7.4 - Log D):	-0.33 (Metoprolol)
Partition Coefficient (Measured - Log Pow/Log Kow):	2.15 (Metoprolol)

Section 10. Stability and Reactivity

Chemical 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

Section 11. Toxicological Information

The following information refers to active ingredient

Inhalation:	Atmospheric conditions in excess of the occupational exposure limit may lead to headache dizziness nausea, vomiting, diarrhea. A lowering of blood pressure and change in heart rhythm may occur.
Skin irritation:	By analogy with a similar substance this material is unlikely to be an irritant.
Eye irritation:	May cause eye irritation. May cause excessive watering of the eye. (Lacrimation).
Ingestion:	Adverse effects similar to inhalation may occur. Oral Median Lethal Dose >2000 mg/kg (rat).
Genotoxicity in vitro:	Not mutagenic

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Carcinogenicity:	Non Carcinogenic
Long term exposure:	The following data relates to an analogous substance: Studies in animals have shown that repeated doses produce no significant effects.

Section 12. Ecological Information

The following information refers to active ingredient

Mobility, Persistence and Degradability:	May cause long-term adverse effects in the aquatic environment. Not readily biodegradable.
Environmental Overview:	The substance is soluble in water. The substance has low potential for bioaccumulation.
Toxicity:	Harmful to aquatic organisms. EC50 (green algae) (72 hour) 47mg/l.EC50 (Daphnia magna) (48 hour) 90mg/l. LC50 (fish) 170mg/l.
Ingestion:	Adverse effects similar to inhalation may occur. Oral Median Lethal Dose >2000 mg/kg (rat).
Effect on Effluent Treatment:	No information available.
Effect on Atmospheric Ozone:	No information available.

Section 13. Disposal Considerations

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release.
Contaminated packaging	Empty container retains product residue. Observe all hazard precautions.

Section 14. Transport Information

The following refers to all modes of transportation unless specified below.

Not Classified as Dangerous for Transport.

Section 15. Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation. CERCLA and SARA Regulations (40 CFR 355, 370 and 372): This product does not

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contain any chemicals subject to the reporting requirements of SARA Section 313. Other Determined Regulations: California Proposition 65: No warnings are necessary.

Section 16. Other Information

Summary:	Not applicable
Data Sources:	Publicly available toxicity information.
Disclaimer:	Rubicon research Pvt. Ltd. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time
Date of Preparation:	21 Jun 2018
Edition No:	01

End of Safety Data Sheet

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Date: 21 June 2018

To
TruPharma, LLC,
Tampa, FL 33609

Re: OSHA Hazard Communication Standard (HCS) SDS Exemption

Dear Sir / Madam,
Rubicon Research Private Limited certifies that, the drug product Metoprolol Tartrate Tablets USP 25 mg, 50 mg and 100 mg meets the exemption requirements according to section (b)(6)(vii) of the OSHA Hazard Communication Standards (HCS), Subpart Z, Toxic and Hazardous Substances, 29 CFR 1910.1200 (b)(6)(vii), because it is a drug, as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.),* in solid, final form for direct administration to the patient. *(e.g.,* tablets or pills).

21 Jun 2018

Sincerely,
Govind Hiwrale
Director Quality Assurance
Rubicon Research Private Limited
K-30/4 & K-30/5, Anand Nagar, Additional
M.LD.C., Ambemath (E) .
Dist.: Thane 421 506 Maharashtra, India.