HETERO LABS LIMITED
"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http//www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Product Name	Metoprolol Succinate Extended Release Tablets, USP 25mg,50 mg, 100 mg, 200 mg.
Recommended use	Antihypertensive; antianginal; antiarrhythmic (class II)
Manufacturer	**Hetero Labs Limited Unit III** 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Hazard statements :

H315	Causes skin irritation.
H360	May damage the unborn child.
H362	May cause harm to breast-fed children.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements :

P201	Obtain special instructions before use.
P260	Do not breathe dust or mist.
P273	Avoid release to the environment.
P280	Wear protective gloves.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P501	Dispose of contents/ container to an approved incineration plant.

Other hazards: May cause eye irritation. May form explosible dust-air mixture if dispersed.

Section 3: Composition/Information on Ingredients

Ingredient	Metoprolol Succinate
CAS	98418-47-4

Section 4: First-Aid Measures

Description of first aid measures

Ingestion Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.

Inhalation	Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact	Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention
Eye Contact	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects occur.
Most important symptoms and effects, both acute and delayed	Refer to sections 2 and 11
Indication of any immediate medical attention and special treatment needed	Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

Section 5: Fire-Fighting Measures

Extinguishing Media(suitable)	water spray, foam, dry powder or CO2
Extinguishing Media(suitable)	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Special hazards arising from the substance or mixture	If involved in a fire, it may burn and emit noxious and toxic fumes.
Special protective actions for fire-fighters:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire-extinguishing water from contaminating surface water or the ground water system.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.
Environmental precautions	Prevent entry into drains, sewers or watercourses. Collect spillage.
Method for cleaning up	Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
Storage	Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Control parameters

Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Respiratory protection

Use an air fed hood if the risk assessment does not support the selection of other protection

Skin protection

Use impervious clothing to protect against direct contact with the product or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use

	impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid. **Eye protection** Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
Section 9: Physical and Chemical Properties	
Physical Form	Coated Tablet White to off white, oval, biconvex film coated tablets score line on both sides debossed with 'J' on one side and 75 on the other side separating 7 & 5 with score line. Bottle of 30 Tablets (NDC 31722-589-30) Bottle of 100Tablets (NDC 31722-589-01) Bottle of 500Tablets (NDC 31722-589-05) Bottle of 1000Tablets (NDC 31722-589-10) Metoprolol Succinate ER tablets USP , 50 mg White to off white, round, biconvex film coated tablets debossed with 'J' on one side and '76' on the other side separating 7&6 with score line. Bottle of 30 Tablets (NDC 31722-590-30) Bottle of 100 Tablets (NDC 31722-590-01) Bottle of 500 Tablets (NDC 31722-590-05) Bottle of 1000 Tablets (NDC 31722-590-10) Metoprolol Succinate ER tablets USP , 100 mg White to off white, round, biconvex film coated tablets debossed with 'J' on one side and '77' on the other side separating 7&7 with score line. Bottle of 30 Tablets (NDC 31722-591-30) Bottle of 100 Tablets (NDC 31722-591-01) Bottle of 500 Tablets (NDC 31722-591-05) Bottle of 1000 Tablets (NDC 31722-591-10) Metoprolol Succinate ER tablets USP,200 mg White to off white, oval, biconvex film coated tablets debossed with 'J' on one side and '78'

	on the other side separating 7&8 with score line. Bottle of 30 Tablets (NDC 31722-592-30) Bottle of 100 Tablets (NDC 31722-592-01) Bottle of 500 Tablets (NDC 31722-592-05) Bottle of 1000 Tablets (NDC 31722-592-10)

Section 10: Stability and Reactivity

Reactivity	No known reactivity hazard under normal conditions.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None known.
Conditions to avoid	No conditions producing hazardous situations known.
Incompatible materials	None known.
Hazardous decomposition products	No hazardous decomposition products are known.

Section 11: Toxicological Information

Inhalation	May cause effects as described under single exposure.(STOT)
Skin Contact	Causes skin irritation.
Eye Contact	May cause eye irritation. May cause excessive watering of the eye (lachrymation).
Ingestion	May cause effects as described under single exposure.(STOT)
Specific Target Organ Toxicity (STOT)	**Single exposure** Exposure routes: Inhalation, Oral May cause lowering of blood pressure (resulting in dizziness, fatigue and headache), change in heart rhythm and gastrointestinal disorders **Repeated exposure** May cause effects as described under single exposure. (STOT).
Sensitisation	Rare cases of skin sensitisation have been reported**.**
Carcinogenicity	No evidence of carcinogencity in animal

	studies.
Mutagenicity	There is no evidence of genotoxic potential in in vitro and in vivo tests.
Reproductive toxicity	Studies in animals have shown that repeated doses produce embryo/foetotoxic effects. By analogy with other beta-blockers: May damage the unborn child. Foetal and neonatal toxicity in babies born to women receiving treatment during pregnancy has been reported. May cause harm to breast-fed children.

Section 12: Ecological Information

Harmful to aquatic life with long lasting effects. No information on this formulation. The following information refers to Metoprolol succinate

Toxicity	EC50 green algae 72 H biomass 22,8 mg/l ErC50 green algae 72 H 58,3 mg/l (OECD 201) NOEC green algae 72 H growth rate 7,5 mg/l (OECD 201) EC50 Daphnia magna 48 H 120 mg/l (OECD 202) NOEC Daphnia magna 48 H 30 mg/l (OECD 202) LC50 Rainbow trout 96 H 130 mg/l (OECD 203) NOEC Rainbow trout 96 H 32 mg/l (OECD 203).
Effect on Effluent Treatment	There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l
Persistence and degradability	Not readily biodegradable.
Bioaccumulative potential	The substance has low potential for bioaccumulation.
Mobility in soil	Water solubility >= 1 mg/l.
Other adverse effects	No information available.

Section 13: Disposal Considerations

Waste treatment methods	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal disposal is via incineration operated by an accredited disposal contractor.
Contaminated Packaging	Empty container will retain product residue. Observe all hazard precautions.

Section 14: Transport Information

Not Restricted For Transport.

Section 15: Regulatory Information

In order to comply with legal duties it is necessary to consult local and national legislation.

Section 16: Other Information

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Version: 00

Revision note: New

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.