

SAFETY DATA SHEETS

This SDS packet was issued with item:

078906572

N/A

MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product name	Metoprolol Succinate Extended Release Tablets USP 25/50/100/200mg
Synonyms	Metoprolol Succinate Extended Release Tablets USP 25/50/100/200mg
Chemical family	(±)1-(isopropylamino)-3-[p-(2-methoxyethyl) phenoxy]-2-propanol succinate (2:1) (salt).
Therapeutic use	Anti-hypertensive and Anti-anginal
Description	<p>25mg: White, film coated, biconvex, oval shaped tablets, scored on both sides and debossed with 'W' and '34' on either side of the score on one side</p> <p>50mg: White, circular, biconvex, beveled edge film coated tablets debossed with W on one side and score on the other side.</p> <p style="text-align: center;">735</p> <p>100mg: White, film coated circular tablets with beveled edge debossed with W on one side and scored on other side.</p> <p style="text-align: center;">736</p> <p>200mg: White, film coated, oval shaped tablets with beveled edge, debossed with 'W737' on one side and score on the other side.</p>

* For 25mg: Each tablet contains 23.75mg Metoprolol Succinate equivalent to 25mg Metoprolol Tartrate USP

For 50mg: Each tablet contains 47.5mg Metoprolol Succinate equivalent to 50mg Metoprolol Tartrate USP

For 100mg: Each tablet contains 95mg Metoprolol Succinate equivalent to 100mg Metoprolol Tartrate USP

For 200mg: Each tablet contains 190mg Metoprolol Succinate equivalent to 200mg Metoprolol Tartrate USP

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient	Amount
Metoprolol Succinate,	Trade Secret
Microcrystalline cellulose,	Trade Secret
Opadry Clear YS-1R-7006,	Trade Secret
Triethyl citrate,	Trade Secret
Ethylcellulose,	Trade Secret
Talc,	Trade Secret
Eudragit L30D 55,	Trade Secret
Polyethylene glycol	Trade Secret
Prosolv SMCC 90	Trade Secret

Croscarmellose sodium	Trade Secret
Sodium stearyl fumarate	Trade Secret
Opadry 03F28415 White	Trade Secret

SECTION 3 - HAZARDS IDENTIFICATION

Form : Tablets

Color : White to off- white

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.

SECTION 4 - FIRST AID MEASURES

Eyes	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention.
Skin	Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
Inhalation	Remove patient from exposure. Obtain medical attention if ill effects occur.
Ingestion	Wash out mouth with water and give 200-300ml of water to drink. Do not induce vomiting. Obtain medical attention if ill effects occur.

Note to Physicians

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

SECTION 5 - FIRE FIGHTING MEASURES

Flammable Properties

The product may form flammable dust clouds in air, if dust from tablets is allowed to accumulate and if it is dispersed. Thermal decomposition will evolve toxic and corrosive vapours.

Extinguishing Media: water spray, foam, dry chemical or CO₂.

Fire Fighting Protective Equipment: A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Small spillages: Absorb with a wet disposable towel and collect in a plastic bag designed for pharmaceutical waste. Large spillages: Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. In case of accident, avoid breathing dust from crushed tablets. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.

SECTION 7 - HANDLING AND STORAGE

7.1 HANDLING

No special precautions are necessary when handling packed product. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes.

Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible dusts. (or explosive dusts)

7.2 STORAGE

Store at controlled room temperature 20° - 25°C (68° – 77°F)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls	No ACGIH TLV or OSHA PEL assigned.
Respiratory Protection	Use NIOSH respirator approved for dusts with a TLV greater than 0.05 mg/m ³ .
Eyes	Chemical tight goggles and full faceshield.
Gloves	Impervious gloves.
Other PPE Data	Eyewash station and safety shower in work area.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Form : Tablets

Color : White to off-white

Solubility (Water): freely soluble

SECTION 10 - STABILITY AND REACTIVITY

Chemical Stability	Stable under normal conditions
Hazardous decomposition products	None known
Hazardous reactions	None known

SECTION 11 - TOXICOLOGY INFORMATION

The following information refers to active ingredient

Inhalation	Atmospheric concentrations in excess of the occupational exposure limit may lead to headache, dizziness, nausea, vomiting and diarrhoea. A lowering of blood pressure and change in heart rhythm may also occur.
Skin contact	By analogy with a similar substance this material is unlikely to be irritant.
Eye contact	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).
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

Environmental Fate and Distribution	The substance is soluble in water. The substance has low potential for bioaccumulation.
Persistence and Degradation	May cause long-term adverse effects in the aquatic environment. Not readily biodegradable.
Toxicity	Harmful to aquatic organisms. EC50 (green algae) (72 hour) 47mg/l. EC50 (Daphnia magna) (48 hour) 90mg/l. LC50 (fish) 170mg/l.
Effect on Effluent Treatment	No information available.
Effect on Atmospheric Ozone	No information available.

SECTION 13 - DISPOSAL INFORMATION

Disposal should be in accordance with local, state or national legislation.

Container Disposal: Empty container retains product residue. Observe all hazard precautions.

SECTION 14 - TRANSPORTATION INFORMATION

Not Classified as Dangerous for Transport.

SECTION 15 - REGULATORY INFORMATION

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 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

Summary	Not applicable
Disclaimer	Wockhardt 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