

## SAFETY DATA SHEET (SDS)

Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

Revision date: 21-jan-2022

Version 2.0

### 1. IDENTIFICATION

**Product Name:** Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

**Product Information:** Nebivolol Tablets, USP

**Company Name:** Cadila Pharmaceuticals Limited

**Address:** 1389, Trasad Road, Dholka - 382225, District: Ahmedabad, Gujarat, India.

**Phone No.:** +91 2714 221481/83

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### 2. HAZARD(S) IDENTIFICATION

➤ **Classification of the substance or mixture**

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Chronic aquatic toxicity (Category 4), H413

➤ **GHS Label elements, including precautionary statements**

Pictogram None

Signal word: None

Hazard statement(s)

H413: May cause long lasting harmful effects to aquatic life.

Precautionary statement(s)

P273: Avoid release to the environment.

P501: Dispose of contents/ container to an approved waste disposal plant.

➤ **Hazards not otherwise classified (HNOC) or not covered by GHS**

None

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Name:**  $\alpha,\alpha'$ -[Iminobis(methylene)]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] hydrochloride salt

**SAFETY DATA SHEET (SDS)****Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg**

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**Product Code:** Not applicable**Hazardous Ingredients / Components:** Not Applicable**CAS No.:** 99200-09-6**Other Components:**

<b>Inactive Ingredients</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
Lactose Monohydrate	Not Found	10039-26-6
Pre-gelatinized starch	Not Found	9005-25-8
Croscarmellose Sodium	Not Found	74811-65-7
Hydroxypropylmethyl Cellulose	Not Found	9004-65-3
Sodium lauryl sulphate	Not Found	151-21-3
Polysorbate-80	Not Found	9005-65-6
Microcrystalline Cellulose	Not Found	9004-34-6
Colloidal Silicon dioxide	Not Found	7631-86-9
Magnesium Stearate	Not Found	557-04-0

**4. FIRST – AID MEASURES**

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

**Skin contact:** Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

**Eye contact:** Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

**Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

## SAFETY DATA SHEET (SDS)

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Version 2.0

### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing media:** None known.

**Specific hazards arising from the chemical:** Fire may produce irritating, corrosive and/or toxic gases.

#### **Explosion data:**

Sensitivity to Mechanical Impact - Not impact sensitive.

Sensitivity to Static Discharge - Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Fire Fighting Protective Equipment:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

### 6. ACCIDENTAL RELEASE MEASURES

**Protective Precautions, Protective Equipment and Emergency Procedures:** Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

**Environmental precautions:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

**Method and Material Containment and cleaning up:** Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

## SAFETY DATA SHEET (SDS)

### Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

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#### 7. HANDLING AND STORAGE

**Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

**Storage:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

**Incompatible materials:** Strong oxidizing agents.

#### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering measures:** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

**Respiratory Protection:** Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**Eye Protection:** No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Personal protective equipment:** The type of protective equipment must be selected based on the amount and concentration of the dangerous material being used in the workplace.

**Skin and body protection:** During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:**

**Nebivolol Tablets, USP 2.5 mg**

White to off-white, round, biconvex, unscored tablets, debossed with “C50” on one side and plain on other side.

## SAFETY DATA SHEET (SDS)

Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

Revision date: 21-jan-2022

Version 2.0

### Nebivolol Tablets, USP 5 mg

White to off-white, round, biconvex, unscored tablets, debossed with “C51” on one side and plain on other side.

### Nebivolol Tablets, USP 10 mg

White to off-white, round, biconvex, unscored tablets, debossed with “C52” on one side and plain on other side.

### Nebivolol Tablets, USP 20 mg

White to off-white, round, biconvex, unscored tablets, debossed with “C53” on one side and plain on other side.

<b>Odour:</b>	No information available
<b>pH (Value):</b>	No information available
<b>Boiling Point:</b>	No information available
<b>Melting Point:</b>	220-222°C
<b>Solubility :</b>	Sparingly soluble in methanol
<b>Partition Coefficient:</b>	3.914±0.546
<b>Molecular Formula:</b>	C <sub>22</sub> H <sub>26</sub> O <sub>4</sub> NCIF <sub>2</sub>
<b>Molecular Weight:</b>	441.90

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not defined As Reactive substance

**Chemical stability:** Stable under normal conditions.

**Possibility of Hazardous Reactions:** None under normal processing.

**Conditions to avoid:** Aerosol formation.

## SAFETY DATA SHEET (SDS)

Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

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Version 2.0

**Incompatible materials:** None known based on information supplied.

**Hazardous Decomposition Product(s):** None known based on information supplied.

### 11. TOXICOLOGY INFORMATION

#### Information on toxicological effects

<b>Acute toxicity:</b>	No data available
Inhalation:	No data available
Dermal:	No data available
<b>Skin corrosion/irritation</b>	No data available
<b>Serious eye damage/eye irritation</b>	No data available
<b>Respiratory or skin sensitisation</b>	No data available
<b>Germ cell mutagenicity</b>	No data available
<b>Carcinogenicity</b>	No data available
IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a Carcinogen or potential carcinogen by OSHA.
<b>Reproductive toxicity</b>	No data available
<b>Specific target organ toxicity - single exposure</b>	No data available
<b>Specific target organ toxicity - repeated exposure</b>	No data available
<b>Aspiration hazard</b>	
<b>Additional Information</b>	RTECS: Not available

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To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

### 12. ECOLOGICAL INFORMATION

**Products Biodegradation:** No data available

**Persistence and degradability:** No data available

**Bioaccumulative potential:** No data available

**Mobility in soil:** No data available

**Results of PBT and vPvB assessment:** PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

**Toxicity:** No data available

**Other adverse effects:** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

### 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**

**Product:** Offer surplus and non-recyclable solutions to a licensed disposal company.

**Contaminated packaging:** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

### 14. TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ICAO (air): Not regulated

IATA: Not regulated

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IMDG: Not regulated

ADR: Not regulated

ADN: Not regulated

### 15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on December 17, 2021 & the ANDA Number is 208717.

### 16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this SDS.

**End of Safety Data Sheet**