

**SAFETY DATA SHEET (SDS)****Rivastigmine Tartrate Capsules USP 1.5 mg, 3 mg, 4.5 mg and 6 mg**

Revision date: 22-Feb-2022

Version 2.0

**1. IDENTIFICATION****Product Name:** Rivastigmine Tartrate Capsules, USP 1.5 mg, 3 mg, 4.5 mg and 6 mg**Product Information:** Rivastigmine Tartrate Capsules**Company Name:** Cadila Pharmaceuticals Limited**Address:** 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.**Phone No.:** 02714/221481**Fax No.:** 02714/220315**2. HAZARD(S) IDENTIFICATION:****Emergency overview:** Harmful if swallowed.**Potential Health Effects:** The toxicological properties of this material have not been investigated. Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation. Compound is Non-hazardous. Compound is Non-hazardous, Non-Toxic/Non-Flammable.**3. COMPOSITION / INFORMATION ON INGREDIENTS****Chemical Name:** Ethyl methyl carbamic acid, 3-[(S)-1-(dimethylamino)ethyl]phenyl ester, (2R,3R)-2,3-dihydroxybutanedioate;**Product Code:** Not applicable**Hazardous Ingredients / Components:** Not Applicable**CAS No.:** 129101-54-8**Other Components:**

Inactive Ingredients	Exposure Limit	CAS No.
Hydroxypropyl Methylcellulose	Not Found	9004-65-3
Magnesium Stearate	Not Found	557-04-0

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Microcrystalline Cellulose	Not Found	9004-34-6
Colloidal Silicon Dioxide	Not Found	7631-86-9

#### 4. FIRST – AID MEASURES

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

**In case of 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.

**In case of 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.

**In case of 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.

#### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

**Unsuitable Extinguishing Media:** A solid water stream may be inefficient.

**Fire Fighting instructions:** 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

**Personal Precautions:** 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).

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**Environmental precautions:** Take steps to avoid release into the environment, if safe to do so.

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

#### 7. HANDLING AND STORAGE

**Precautions To be Taken in Handling:** Avoid breathing dust/fume/ gas/ mist/ vapours/ spray.

Avoid prolonged or repeated exposure.

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

#### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels.

##### Personal Protective Equipment

- **Eyes:** Wear safety glasses and chemical goggles if splashing is possible.
- **Skin:** Wear appropriate protective gloves and clothing to prevent skin exposure.
- **Clothing:** Wear appropriate protective clothing to minimize contact with skin.
- **Respirators:** Wear a NIOSH/MSHA or European Standard EN 149 approved full-facepiece airline respirator in the positive pressure mode with emergency escape provisions.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:**

**Rivastigmine Tartrate Capsules, USP 1.5 mg**

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White to off white powder filled in size “2” hard gelatin capsules with yellow opaque colour cap and yellow opaque colour body imprinted “C 91”

#### **Rivastigmine Tartrate Capsules, USP 3 mg**

White to off white powder filled in size “2” hard gelatin capsules with orange opaque colour cap and Orange opaque colour body imprinted “C 92”

#### **Rivastigmine Tartrate Capsules, USP 4.5 mg**

White to off white powder filled in size “2” hard gelatin capsules with Red opaque colour cap and Red opaque colour body imprinted “C 93”

#### **Rivastigmine Tartrate Capsules, USP 6 mg**

White to off white powder filled in size “2” hard gelatin capsules with Red opaque colour cap and Orange opaque colour body imprinted “C 94”.

<b>Odour</b>	Not Applicable
<b>pH</b>	Not Applicable
<b>Melting Point</b>	Not Applicable
<b>Boiling Point</b>	Not Applicable
<b>Flash Point</b>	Not Applicable
<b>Evaporation Rate</b>	Not Applicable
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Explosive Limits</b>	Not Applicable
<b>Vapor Density (vs. Air = 1)</b>	Not Applicable
<b>Pressure (vs. Air or mm Hg)</b>	Not Applicable
<b>Specific Gravity (Water = 1)</b>	Not Applicable
<b>Solubility in Water</b>	Very soluble
<b>Solubility Notes</b>	Not Applicable
<b>Octanol/Water Partition Coefficient</b>	Not Applicable
<b>Autoignition Point</b>	Not Applicable
<b>Decomposition Temperature</b>	Not Applicable
<b>Viscosity</b>	Not Applicable
<b>Other Information:</b>	Very soluble in water, sparingly soluble in methanol, practically insoluble in ethyl acetate.

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**Molecular formula:**  $C_{14}H_{22}N_2O_2 \cdot C_4H_6O_6$   
**Molecular weight:** 400.42 g/mol

#### 10. STABILITY AND REACTIVITY

**Reactivity:** No further relevant information available.

##### Chemical stability

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** strong oxidizing agents.
- **Hazardous decomposition products:** carbon dioxide, carbon monoxide, nitrogen oxides

#### 11. TOXICOLOGY INFORMATION

**Toxicological Effects:** The toxicological effects of this product have not been thoroughly studied. Rivastigmine (tartrate) - Toxicity Data: Oral TDLO (rat): 400.43  $\mu$ g/kg; Oral TDLO (mouse): 2 mg/kg; Intraperitoneal TDLO (rat): 400.43  $\mu$ g/kg; Intraperitoneal TDLO (mouse): 1  $\mu$ g/kg; Intraperitoneal TDLO (mouse): 6  $\mu$ g/kg/6D (intermittent); Intraperitoneal TDLO (mouse): 2 mg/kg /4D (intermittent);

**Chronic Toxicological:** Only select Registry of Toxic Effects of Chemical substance (RTECS) data is Presented Rivastigmine (tartrate) RTECS Number: FA9550000

#### 12. ECOLOGICAL INFORMATION

**Toxicity:** Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

#### 13. DISPOSAL CONSIDERATIONS

##### Waste treatment methods

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**Recommendation:** Must not be disposed of together with household garbage. Do not allow product to reach sewage

**Uncleaned packagings:**

**Recommendation:** Disposal must be made according to official regulations.

#### 14. TRANSPORT INFORMATION

Classified according to the criteria of the UN Model Regulations as reflected in the IMDG Code, ADR, RID and IATA.

- **UN-Number:**

Does not meet the criteria for classification as hazardous for transport.

- **UN proper shipping name:**

Does not meet the criteria for classification as hazardous for transport.

- **Transport hazard class(es)**

Does not meet the criteria for classification as hazardous for transport.

- **Packaging group**

Does not meet the criteria for classification as hazardous for transport.

- **Environmental hazards**

This product is not classified as environmentally hazardous according to the UN Model Regulations, nor a marine pollutant according to the IMDG Code.

- **Special precautions for users**

No data available.

#### 15. REGULATORY INFORMATION

Generic Medicine: Approved by USFDA on Feb 13, 2017 and the ANDA Number is 203844.

#### 16. OTHER INFORMATION

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

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implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incident, consequential or exemplary damage, howsoever arising, even if the company has been advised of the possibility of such damages.

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**