



Srini Pharmaceuticals Pvt. Limited  
Survey No.247, Choutuppal,  
Yadadri Bhuvanagiri (Dist),  
T.S., INDIA.

## SAFETY DATA SHEET

(Form No: 564 / Rev. 3)

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**Material Name:** Tadalafil

Effective date:  
**January,2021**

### SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifiers

Product name : Tadalafil (TAD)

CAS-No. : 171596-29-5

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer/Supplier:

Srini Pharmaceuticals Pvt Limited,  
Sy. No: 247, Choutuppal, Yadadri Bhuvanagiri.

#### 1.4. Further information obtainable from:

Emergency response telephone number:

+91-994 999 7583

##### Emergency telephone number:

Emergency response telephone number:

+91 994 999 7567

### SECTION 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

GHS Signal word: NONE. Not hazardous.

#### 2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

#### 2.3 Other hazards - none

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Formula : C<sub>22</sub>H<sub>19</sub>N<sub>3</sub>O<sub>4</sub>

Molecular weight : 389.41 g/mol

CAS-No. : 171596-29-5

#### Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Tadalafil	CAS-No. : 171596-29-5	<= 100 %

**Composition comments:** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

### SECTION 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

##### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

##### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

##### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

##### In case of eye contact

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Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

### **If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### **4.2 Most important symptoms and effects, both acute and delayed**

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

### **4.3 Indication of any immediate medical attention and special treatment needed**

No data available

## **SECTION 5. FIRE FIGHTING MEASURES**

### **5.1 Extinguishing media**

#### **Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

### **5.2 Special hazards arising from the substance or mixture**

Carbon oxides, Nitrogen oxides (NOx)

### **5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

### **6.2 Environmental precautions**

Do not let product enter drains.

### **6.3 Methods and materials for containment and cleaning up**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### **6.4 Reference to other sections**

For disposal see section 13

## **SECTION 7. HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

### **7.2 Conditions for safe storage, including any incompatibilities**

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): Non Combustible Solids

### **7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1 Control parameters**

### **8.2 Exposure controls**

#### **Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### **Personal protective equipment**

#### **Eye/face protection**

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Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

### **Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

### **Body Protection**

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### **Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls. If the full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### **Control of environmental exposure**

Do not let product enter drains.

## **SECTION- 09 PHYSICAL/ CHEMICAL PROPERTIES**

### **9.1 Information on basic physical and chemical properties**

- a) Appearance Form: solid
- b) Odour No data available
- c) Odour Threshold No data available
- d) pH No data available
- e) Melting point/freezing point No data available
- f) Initial boiling point and boiling range No data available
- g) Flash point No data available
- h) Evaporation rate No data available
- i) Flammability (solid, gas) No data available
- j) Upper/lower flammability or explosive limits No data available
- k) Vapour pressure No data available
- l) Vapour density No data available
- m) Relative density No data available
- n) Water solubility No data available
- o) Partition coefficient: octanol/ water No data available
- p) Auto-ignition temperature No data available
- q) Decomposition temperature No data available
- r) Viscosity No data available
- s) Explosive properties No data available
- t) Oxidizing properties No data available

### **9.2 Other safety information**

No data available

## **SECTION 10. STABILITY AND REACTIVITY**

### **10.1 Reactivity**

No data available

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## 10.2 Chemical stability

Stable under recommended storage conditions.

## 10.3 Possibility of hazardous reactions

No data available

## 10.4 Conditions to avoid

No data available

## 10.5 Incompatible materials

Strong oxidizing agents

## 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

In the event of fire: see section 5

## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available Tadalafil

#### Skin corrosion/irritation

No data available (Tadalafil)

#### Serious eye damage/eye irritation

No data available (Tadalafil)

#### Respiratory or skin sensitisation

No data available (Tadalafil)

#### Germ cell mutagenicity

No data available (Tadalafil)

#### Carcinogenicity

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.

#### Reproductive toxicity

No data available (Tadalafil)

#### Specific target organ toxicity - single exposure

May cause respiratory irritation. (Tadalafil)

**Specific target organ toxicity - repeated exposure** No data available

**Aspiration hazard** No data available (Tadalafil)

#### Additional Information

RTECS: Not available

Headache, Back pain, dyspepsia, myalgia (Tadalafil)

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

## SECTION 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

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No data available(Tadalafil)

## 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical scrubber.

#### Contaminated packaging

Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### 14.1 UN number

ADR/RID: - IMDG: - IATA: -

### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

### 14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

### 14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

### 14.6 Special precautions for user

No data available

## SECTION 15 REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

### 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

## SECTION 16 OTHER INFORMATION

### Further information

The above information is Hazard Communication and should be used to assist the risk assessment. Many factors determine whether the reported Hazards are Risk in the work place or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered and shall be used only as a guide.