

## SAFETY DATA SHEET (SDS)

Sildenafil Tablets, USP 25 mg, 50 mg and 100 mg

Revision Date: 27-April-2024

Version 1.0

### 1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY UNDERTAKING

**Product Name:** Sildenafil Tablets, USP 25 mg, 50 mg and 100 mg

**Product Information:** Sildenafil Tablets, USP

**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:

**Identification Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Information:**

**Classification of the Substance or Mixture**

**GHS - Classification** Serious eye damage/eye irritation Category 2B

**Label elements**

**Signal word** Warning

**Hazard statement** H320 - Causes eye irritation

**Precautionary statements** P264 - Wash hands thoroughly after handling

P305 + P351 +P338: IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical advice/attention

**Other Hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Name:**

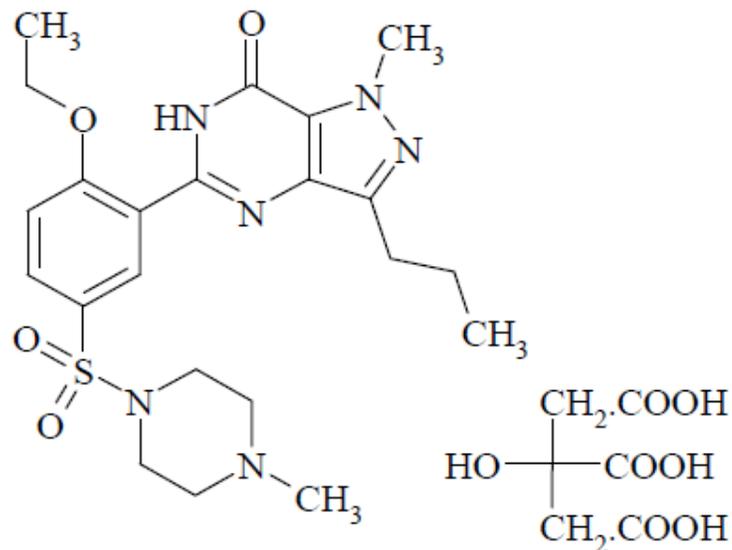
5-[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-propyl-6,7-dihydro-1H-pyrazolo[4,3-d]pyrimidin-7-one dihydrogen 2-hydroxypropane -1,2,3-tricarboxylate.

or

Piperazine, 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

or

1-[[3-(6,7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate.



**Sildenafil Citrate USP**

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**Product Code:** Not applicable

**Hazardous Ingredients / Components:** Not Applicable

**CAS No.:** 171599-83-0

**Other Components:**

Inactive Ingredients	Exposure Limit	CAS No.
Microcrystalline Cellulose (Emcocel XLM 90)	Not Found	9004-34-6
Anhydrous dibasic calcium phosphate (A-TAB)	Not Found	7757-93-9
Croscarmellose Sodium (Ac-Di-Sol SD-711)	Not Found	74811-65-7
HPMC 5 CPS (Methocel E5 LV)	Not Found	9004-65-3
Magnesium Stearate (Veg Grade)	Not Found	557-04-0
HPMC 2910/ Hypromellose	Not Found	9004-65-3
Lactose Monohydrate	Not Found	64044-51-5
Titanium Dioxide	Not Found	13463-67-7
Triacetin	Not Found	102-76-1
FD&C blue #2/indigo carmine aluminum lake	Not Found	16521-38-3

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### 4. FIRST – AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known.

**Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician:** None.

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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### **Special Hazards Arising from the Substance or Mixture Hazardous Combustion Products:**

Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### **Advice for Fire-Fighters:**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Additional Information:** Not applicable.

### 6. ACCIDENTAL RELEASE MEASURES

#### **Personal Precautions, Protective Equipment and Emergency Procedures:**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### **Environmental Precautions:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### **Methods and Material for Containment and Cleaning Up Measures for Cleaning / Collecting:**

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

#### **Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling:

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

#### Conditions for Safe Storage, Including any Incompatibilities Storage Conditions:

Store as directed by product packaging.

#### Specific end use(s):

Pharmaceutical drug product

#### Storage:

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

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### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

#### Control Parameters:

Refer to available public information for specific member state Occupational Exposure Limits.

#### Sildenafil citrate

**Sildenafil OEL TWA-8 Hr:** 350µg/m<sup>3</sup>

#### Titanium dioxide

<b>ACGIH Threshold Limit Value (TWA)</b>	10 mg/m <sup>3</sup>
<b>Australia TWA</b>	10 mg/m <sup>3</sup>
<b>Austria OEL – MAKs</b>	5 mg/m <sup>3</sup>
<b>Belgium OEL – TWA</b>	10 mg/m <sup>3</sup>
<b>Bulgaria OEL – TWA</b>	10.0 mg/m <sup>3</sup>
<b>Denmark OEL – TWA</b>	6 mg/m <sup>3</sup>
<b>Estonia OEL – TWA</b>	5 mg/m <sup>3</sup>
<b>France OEL - TWA</b>	10 mg/m <sup>3</sup>
<b>Greece OEL – TWA</b>	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	10 mg/m <sup>3</sup>
<b>Lithuania OEL – TWA</b>	5 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	15 mg/m <sup>3</sup>
<b>Poland OEL - TWA</b>	10.0 mg/m <sup>3</sup>
<b>Portugal OEL – TWA</b>	10 mg/m <sup>3</sup>
<b>Romania OEL - TWA</b>	10 mg/m <sup>3</sup>

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Russia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

#### Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA	10 mg/m <sup>3</sup>
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#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

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#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Exposure Controls Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

#### Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

#### Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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#### **Skin:**

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

#### **Respiratory protection:**

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### **Appearance:**

##### **Sildenafil Tablets, USP 25 mg**

Blue, film-coated, rounded-diamond shaped tablets debossed with 'S25' on one side and plain on other side.

##### **Sildenafil Tablets, USP 50 mg**

Blue, film-coated, rounded-diamond shaped tablets debossed with 'S50' on one side and plain on other side.

##### **Sildenafil Tablets, USP 100 mg**

Blue, film-coated, rounded-diamond shaped tablets debossed with 'S100' on one side and plain on other side.

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<b>Physical State</b>	Tablet
<b>Color</b>	Blue
<b>Odour</b>	No data available
<b>Molecular Formula</b>	Mixture
<b>Molecular Weight</b>	Mixture
<b>Solvent Solubility</b>	No data available
<b>Water Solub</b>	No data available
<b>pH</b>	No data available
<b>Melting/Freezing Point (°C)</b>	No data available
<b>Boiling Point (°C)</b>	No data available
<b>Partition Coefficient (Method, pH, Endpoint, Value)</b>	
<b>Sildenafil citrate</b>	Predicted 7.4 Log D 2.26
<b>Hydroxypropyl methylcellulose</b>	No data available
<b>Titanium dioxide</b>	No data available
<b>Lactose Monohydrate</b>	No data available
<b>Triacetin</b>	No data available
<b>FD &amp; C Blue No. 2, Aluminum lake</b>	No data available
<b>Decomposition Temperature (°C)</b>	No data available
<b>Evaporation Rate (Gram/s)</b>	No data available
<b>Vapor Pressure (kPa)</b>	No data available
<b>Vapor Density (g/ml)</b>	No data available
<b>Relative Density</b>	No data available
<b>Viscosity</b>	No data available
<b>Flammability:</b>	
<b>Autoignition Temperature (Solid) (°C)</b>	No data available
<b>Flammability (Solids)</b>	No data available
<b>Flash Point (Liquid) (°C)</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.)</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.)</b>	No data available

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### 10. STABILITY AND REACTIVITY

**Reactivity:** Not Applicable

**Chemical Stability:** Stable under normal conditions of use.

#### Possibility of Hazardous Reactions

**Oxidizing Properties:** No data available

**Conditions to Avoid:** None known

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGY INFORMATION

#### Information on Toxicological Effects General Information:

The information included in this section describes the potential hazards of the individual ingredients.

#### Short Term:

Active ingredient may be harmful if swallowed. May cause eye irritation (based on components).

#### Long Term:

Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

#### Known Clinical Effects:

Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

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**Acute Toxicity: (Species, Route, End Point, Dose)**

**Sildenafil citrate:**

Rat	Oral	LDmin.	300-500 mg/kg
Mouse	Oral	LDmin.	500-1000 mg/kg
Rat	Dermal	LD50	> 2000 mg/kg

**Microcrystalline cellulose:**

Rat	Oral	LD50 >	5000 mg/kg
Rabbit	Dermal	LD50 >	2000 mg/kg

**Magnesium stearate:**

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m <sup>3</sup>

**Hydroxypropyl methylcellulose:**

Rat	Oral	LD50	> 10,000 mg/kg
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**Titanium dioxide:**

Rat	Oral	LD50	> 7500 mg/kg
Rat	Subcutaneous	LD50	50 mg/kg

**Lactose Monohydrate:**

Rat	Oral	LD 50	29700 mg/kg
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**Triacetin:**

Rat	Oral	LD 50	3000 mg/kg
Mouse	Oral	LD 50	1100mg/kg

**Acute Toxicity Comments: \_**

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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**Irritation / Sensitization: (Study Type, Species, Severity)**

**Sildenafil citrate:**

Eye	Irritation	Rabbit	Moderate
Skin	Irritation	Rabbit	Non-irritating
Skin	Sensitization	Guinea Pig	Negative

**Microcrystalline cellulose:**

Skin Irritation	Rabbit	Non-irritating
Eye Irritation	Rabbit	Non-irritating

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Sildenafil citrate:**

6 Month(s)	Rat	Oral	3 mg/kg/day	NOAEL	Adrenal gland, Liver, Thyroid
6 Month(s)	Dog	Oral	15 mg/kg/day	NOAEL	Cardiovascular system

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Sildenafil citrate:**

Reproductive & Fertility	Rat	Oral	60 mg/kg/day	NOEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	NOEL	Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg/day	NOEL	Maternal Toxicity, Not Teratogenic

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Sildenafil citrate:**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Salmonella	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus Chromosome Aberration	Mouse Bone Marrow	Negative

**Lactose Monohydrate:**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Salmonella , E. coli	Negative
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**Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Sildenafil citrate**

24 Month(s)	Mouse	Oral	5 mg/kg/day	NOAEL	Not carcinogenic
24 Month(s)	Rat	Oral	60 mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:**

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

**Titanium dioxide:**

**IARC:** Group 2B (Possibly Carcinogenic to Humans)

**12. ECOLOGICAL INFORMATION**

**Environmental Overview:**

In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater .

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Sildenafil citrate**

<i>Daphnia magna</i> (Water Flea)	TAD EC50	48 Hours	14 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD LC50	96 Hours	> 9.5 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD EC50	72 Hours	20 mg/L

**Aquatic Toxicity Comments:**

A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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### **Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

#### **Sildenafil citrate**

Activated sludge      OECD      EC50      > 1000 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**

### **Partition Coefficient: (Method, pH, Endpoint, Value)**

#### **Sildenafil citrate**

Predicted      7.4      Log D      2.26

**Mobility in Soil:**              No data available

## 13. DISPOSAL CONSIDERATIONS

### **Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture.

#### **Sildenafil citrate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### **FD & C Blue No. 2, Aluminum lake**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	240-589-3

#### **Lactose Monohydrate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### **Triacetin**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9

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#### **Hydroxypropyl methylcellulose**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

#### **Croscarmellose sodium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### **Titanium dioxide**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

#### **Calcium phosphate dibasic, anhydrous**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-826-1

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#### **Microcrystalline cellulose**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

#### **Magnesium stearate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

## 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

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 MSDS.