

## SAFETY DATA SHEET (SDS)

### Hydralazine Hydrochloride Tablets, USP 25 mg, 50 mg, 100 mg

Revision Date: 03-March-2023

Version 1.0

#### 1. IDENTIFICATION

**Product Name:** Hydralazine Hydrochloride Tablets, USP 25 mg, 50 mg, 100 mg

**Product Information:** Hydralazine Hydrochloride

**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:

**GHS-US Classification** H301 Acute toxicity, Oral (Category 3)  
H315 Skin irritation (Category 2) H319 Eye irritation (Category 2A)  
H335 Specific target organ toxicity - single exposure (Category 3),  
Respiratory system

**GHS-US Labeling** Acute toxicity, oral Category 4 Skin corrosion/irritation Category 1  
Serious eye damage/eye irritation Category 1

**OSHA hazard(s)** Not classified.

**Signal word** Danger  
Flammable. Irritant.

**Hazard statements** This product, as supplied, is not an explosive. However, undiluted isosorbide dinitrate is explosive by percussion or excessive heat. Any separation of it from the diluent in this mixture, even in small amounts, is extremely hazardous.

OSHA regulatory status: This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).

Hazard statement(s) H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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**Precautionary  
statements  
Prevention  
Response**

Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

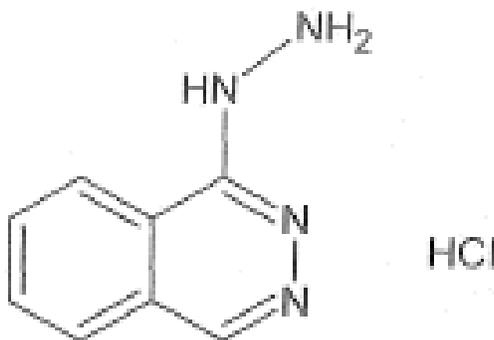
If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/medical professional.

**Disposal**

Dispose of contents/container to an approved disposal site.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Name:** Phthalazine, 1-hydrazino-, monohydrochloride. 1-hydrazinophthalazine monohydrochloride



**Hydralazine Hydrochloride**

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**Product Code:** Not applicable

**Hazardous Ingredients / Components:** Not Applicable

**CAS No.:** 304201

**Other Components:**

<i>Component</i>	<i>CAS No.</i>
Mannitol SD 200	69658
Microcrystalline Cellulose (Avicel PH 112)	9004346
Sodium Starch Glycolate (Glycolys LV)	9063381
Stearic Acid (SPEZIOL L2SM GF PHARM)	57114
FD& C Yellow # 6	2783940

#### 4. FIRST – AID MEASURES

<b>Eye contact</b>	Eye irritation. Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get immediate medical attention.
<b>Skin contact</b>	Immediately flush the skin with plenty of water while removing contaminated clothing and shoes. Get immediate medical attention. Wash contaminated clothing before reuse.
<b>Inhalation</b>	Remove exposed person from source of exposure to fresh air. If not breathing, clear airway and start cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.
<b>Ingestion</b>	Get immediate medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth with water.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

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#### 5. FIRE-FIGHTING MEASURES

<b>Suitable extinguishing media</b>	Use dry chemical, alcohol-resistant foam, or carbon dioxide.
<b>Fire Fighting Procedures:</b>	Do not flush down sewers or other drainage systems. Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full protective clothing.
<b>Conditions of flammability</b>	Not flammable or combustible.
<b>Combustion Products:</b>	Irritating or toxic substances may be emitted upon thermal decomposition. Thermal decomposition products may include Carbon Oxides (CO, CO <sub>2</sub> ) and Nitrogen Oxides (NO <sub>x</sub> ), Hydrogen Chloride Gas.
<b>Flash Point</b>	Not found.
<b>Auto-Ignition Temperature</b>	Not found.
<b>Minimum explosive concentration for dust</b>	Not found

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal precautions</b>	Avoid dust formation. Avoid breathing vapours, mist or gas.
<b>Environmental precautions</b>	Do not let product enter drains. REFER TO SECTION 15 FOR SPILL/RELEASE REPORTING INFORMATION.
<b>Spill/Clean-up</b>	Isolate area to restrict unnecessary personnel. Put on suitable protective clothing and equipment. Collect spilled material with paper toweling or other absorbent material. For larger spills of material, use a scoop or shovel to collect spilled material into a labeled container for recovery or disposal. Clean area thoroughly using several washes with detergent and water. Treat product, and contaminated materials (including wash/rinse liquid) as hazardous waste and place in a suitable container for disposal.

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#### 7. HANDLING AND STORAGE

<b>Precautions for safe handling</b>	Use with adequate ventilation. Avoid crushing tablets. If tablets are crushed, avoid contact with eye, skin and clothing. Minimize aerosol generation and avoid inhalation of material. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use gloves and protective clothing as recommended in Section 8.
<b>Container Requirements</b>	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.
<b>Storage Conditions</b>	Store at 25°C (77°F), excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.] Keep bottles tightly closed.
<b>Specific use(s)</b>	Pharmaceutical product

#### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

<b>Engineering Controls</b>	Local exhaust ventilation may be necessary to control air contaminants to their exposure limits. General room ventilation is adequate unless the process generates aerosol. If aerosol generation is probable, use appropriate ventilation such as a fume hood.
<b>Respiratory Protection</b>	Respiratory protection is not required under normal conditions. If exposure limits are exceeded, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
<b>Eye protection</b>	Wear chemical safety goggles and face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Have eye-wash stations available where eye contact can occur.
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is Protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is corrosive. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and clean-up of the material, and remove the inner gloves only after removing other personal protective equipment.

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<b>Skin and body Protection</b>	Avoid skin contact. Wear gloves impervious to conditions of 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.
<b>Environmental exposure controls</b>	Prevent release to drains and waterways.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Thermal hazards</b>	Not available
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where Significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### General Information

#### *Appearance*

<b>Physical State</b>	solid
<b>Color</b>	orange
<b>Form</b>	tablets
<b><i>Odour</i></b>	
<b>Odour</b>	Not available
<b>Odor Threshold</b>	Not available
<b>pH</b>	Not available
<b><i>Other information</i></b>	
<b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Molecular formula</b>	Not applicable
<b>Hydrolysis/Photolysis</b>	Not available
<b>Hygroscopicity</b>	Not available
<b>Molecular Weight</b>	Not applicable
<b>Log Octanol/Water Partition</b>	
<b>Coeff [log Kow]</b>	Not available
<b>Surface Tension</b>	Not available
<b>pKa</b>	Not available
<b>Particle Size</b>	Not available
<b>Solubility, Water</b>	very slightly soluble
<b>Specific Gravity/ Relative Density</b>	Not available
<b>Viscosity, dynamic</b>	Not available
<b>Viscosity, kinematic</b>	Not available

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<b>% Volatile</b>	Not available
<i>Thermal/Stability properties</i>	
<b>Autoignition temperature</b>	Not available
<b>Boiling Point</b>	Not available
<b>Thermal decomposition</b>	Not available
<b>Explosive Limits, LEL</b>	Not available
<b>Explosive limits, UEL</b>	Not available
<b>Explosiveness</b>	Not available
<b>Flammability</b>	Not available
<b>Flash point</b>	Not available
<b>Melting Point</b>	Not available
<b>Oxidizing Potential</b>	Not available
<i>Vapor Properties</i>	
<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Saturated Vapor Concentration</b>	Not available

#### 10. STABILITY AND REACTIVITY

**stability**

<b>Chemical Stability</b>	Stable under normal conditions
Incompatibilities	Water, acids, alkalis, and strong oxidizers
Conditions of Reactivity	Heat, flames and sparks
<b>Hazardous Decomposition products</b>	Carbon oxides, nitrogen oxides, hydrogen chloride gas
Hazardous Polymerization	Not expected to polymerize.

#### 11. TOXICOLOGY INFORMATION

<b>General</b>	Handling of formulated product is not expected to cause any toxicological effects.
<b>Target organ</b>	Eye contact, skin contact and inhalation is not great risk as this product is tablet.
<b>Other information</b>	Limited evidence of a carcinogenic effect. Studies in animals have shown that repeated doses produce cancer in rats and mice. The substance is not considered to be genotoxic. May impair fertility.

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May cause harm to the unborn child. In male rats reproductive performance was reduced but was reversible after cessation of dosing. Evidence of suppressed sexual development was observed in the Male offspring of female rats. None of these effects are likely to occur in humans, provided exposure is maintained at or below the occupational exposure limit. Oral

Toxicology : ORAL (LD50): Acute: 188 mg/kg [Mice].

#### 12. ECOLOGICAL INFORMATION

No information is currently available on the environmental impact of this product.

#### 13. DISPOSAL CONSIDERATIONS

Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

#### 14. TRANSPORT INFORMATION

The product is not hazardous when shipped via air (IATA), grounds (DOT), sea (IMDC) or (TDG).

#### 15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on September 18, 2024 and the ANDA Number is 203845.

#### 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.