



MATERIAL SAFETY DATA SHEET

HYDRALAZINE HYDROCHLORIDE TABLETS, USP 25 mg, 50 mg and 100 mg

STRIDES ARCOLAB LIMITED

Opp. IIM, Bilekahalli,
Bannerghatta Road.
Bangalore- 76, India

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Hydralazine Hydrochloride Tablets, USP

Chemical Name: 1-hydrazinophthalazine monohydrochloride.

Molecular formula: $C_8H_8N_4 \cdot HCl$

Molecular weight: 196.64

Indications: Essential hypertension, alone or as an adjunct.

Synonyms: None

2. COMPOSITION/INFORMATION ON INGREDIENTS

ACTIVE INGREDIENT / CAS NUMBER: Hydralazine Hydrochloride / 304-20-1

3. HAZARDS IDENTIFICATION

Emergency Overview:

Physical State: Tablets

25 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed "25" on one side and plain on other side.

50 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed "50" on one side and plain on other side

100 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed "100" on one side and plain on other side.

Odor: No data available

Primary route(s) of Entry: Ingestion.

POTENTIAL HEALTH EFFECTS:

Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.

Eye Contact: Not expected to be a hazard to the eye in final pharmaceutical form.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.

Effects of Overdose: Sign & symptom of overdose include hypertension, tachycardia, headache, & generalized skin flushing.

4. FIRST AID MEASURES

Eye Exposure: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

Skin Exposure: Wash with soap and water. Get medical attention if symptoms occur.

Ingestion : Call a physician or poison control center immediately.

Inhalation: Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.

5. FIRE AND EXPLOSION HAZARDS

Flammability: Flammable, Keep away from heat.

Extinguishing Media Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area.

Special Fire Fighting Procedures : Wear full protective clothing and self-contained breathing apparatus.

Unusual Fire/Explosion Hazards : Not Applicable

Hazardous Combustion Products: Not Applicable.

6. ACCIDENTAL RELEASE INFORMATION

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:

Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions Handling Significant Quantities of Product: Observe good industrial hygiene practices.

Storage: Store at 20° to 25 °C (68° to 77°F). [See USP controlled room temperature].

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Limits: None

Engineering Controls :Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Personal Protection: Not required when handling tablets. If containers are compromised or exposure is likely wear Goggles, Lab Coat, Gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Tablet.

Appearance: 25 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed “25” on one side and plain on other side.

50 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed “50” on one side and plain on other side

100 mg Tablets: Orange colored circular, flat bevel edged tablets, debossed “100” on one side and plain on other side

Chemical Properties:

Odor: No applicable information found

Boiling Point: No applicable information found

Melting Point: No applicable information found

Solubility: No applicable information found

Density: No applicable information found

Vapor Pressure: No applicable information found

10. STABILITY AND REACTIVITY DATA.

Stability : Stable

Incompatibility: Not known

Hazardous Decomposition : Not applicable

Conditions to Avoid : Excessive heat, light, moisture

Hazardous Polymerization : Will not occur.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity:

Active Ingredient:

LD50 Oral (rat): 173 and 187 mg/kg.

Carcinogenicity: Not carcinogenic.

12. ENVIRONMENTAL IMPACT INFORMATION:

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

13. DISPOSAL INFORMATION:

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

At home: Discard away from children's reach.

14. TRANSPORT INFORMATION:

This product is not subject to the regulations for the safe transport of hazardous chemicals.

DOT: Not regulated

TDG: Not regulated

IATA: Not regulated

IMDG: Not regulated

15. REGULATORY INFORMATION:

DEA: Hydralazine Hydrochloride is not a controlled substance.

FDA: Hydralazine Hydrochloride is an approved prescription medication.