

MSDS: HydrALAZINE HCl Injection 2.0% (20mg/mL)

Manufacturer: Akorn Incorporated
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Section 1- IDENTIFICATION

TRADE NAME: Hydralazine Hydrochloride Injection
Description: Antihypertensive
Presentation:
NDC: 17478-934-01 1mL/2-mL tubing vial, type 1 glass, clear

Composition	CAS#	TLV (mg/m³)	PEL (mg/m³)	%Content
Hydralazine Hydrochloride	304-20-1	NE	NE	2.0%
Propylene Glycol	57-55-6	NE	NE	10.36%
Methylparaben	99-76-3	NE	NE	0.065%
Propylparaben	94-13-3	NE	NE	0.035%
Water for Injection	7732-18-5	NE	NE	QS to 1 mL
Hydrochloric acid, NF/Sodium Hydroxide, NF to adjust pH				

Common name of active ingredient: Hydralazine Hydrochloride
Chemical Formula (s): C₈H₈N₄HCl (MW=196.64)
Legal Category: Prescription Only
Therapeutic Category: Antihypertensive

For use only by technically qualified individuals.
All general safety regulations should be observed when handling.

Section 2- HAZARDOUS INGREDIENTS

Principal Hazardous Ingredient: Hydralazine Hydrochloride
Carcinogenicity: No classification data on carcinogenic properties of this product is available from the EPA< IARC< NTP<OSHA or ACGIH.

Section 3- PHYSICAL AND CHEMICAL CHARACTERISTICS

Description:	Hydralazine HCl Injection is a sterile, nonpyrogenic solution intended for intravenous and intramuscular administration.
Appearance & Odor:	Clear colorless to slightly yellow solution with a characteristic odor of parabens.
Boiling Point (C°):	NE
Vapor Pressure (mm Hg at 20°C):	NE
Vapor Density (g/m³):	NE
Viscosity:	NE
pH:	Between 3.4 and 4.4
Specific Gravity:	~1.014 @25°C
Solubility in Water:	Soluble
Latex Free:	Yes

Section 4- FIRE AND EXPLOSION HAZARD DATA

Flash Point:	N/A
Extinguisher Media:	Water spray or Carbon dioxide, foam or dry chemical powder, as appropriate for surrounding fire and materials
Flammable Limits:	N/A
Hazardous Decomposition Products:	Hydralazine HCl emits toxic fumes when heated to decomposition.
Special Fire Fighting Procedures:	As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Unusual Fire and Explosion Hazards:	Emits toxic fumes

Section 5- REACTIVITY DATA

Stability:	Stable
Conditions to avoid:	Do not mix with other drugs
Hazardous Polymerization:	Will not occur

Section 6- HEALTH HAZARDS

Primary Routes of Exposure: Inhalation, Ingestion, Eyes and Skin Absorption

Chemical Listing as Carcinogen:

National Toxicology Program: No

IARC Monographs: Animal - Limited Evidence

OSHA: No

Signs and Symptoms of Overexposure

Possible allergic reaction if inhaled, ingested or in contact with skin

Possible hypersensitization

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic doses include: Headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia and angina pectoris. No deaths due to acute poisoning have been reported. Highest known dose survived: adults, 10 gm orally. Occupational exposure has not been fully investigated.

Emergency and First Aid Procedures:

Inhalation: Remove persons to fresh air. Remove contaminated clothing. Seek medical attention.

Eye Contact: Flush with copious amount of water. Seek medical attention.

Skin: Flush area with copious quantities of water. Remove contaminated clothing. Seek medical attention.

Ingestion: Flush mouth with water. Seek medical attention.

Section 7- PROTECTION INFORMATION

Respiratory Protection: NIOSH approved respirator

Ventilation: Adequate local and mechanical exhaust recommended

Mechanical/ Engineering Controls: Available safety shower and eye bath

Eye Protection: Safety goggles

Gloves: Rubber

Section 8- SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES**Precautions to be taken in handling and storage:**

Usual precautionary measures for handling pharmaceutical products should be followed. Keep away from foodstuffs and beverages. Remove any soiled and contaminated clothing immediately. Wash hands frequently. Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.

Storage: Store at controlled room temperature 15° to 25°C (59° to 77°F)

Steps to be taken in case material is released or spilled:

May be harmful by inhalation, ingestion or skin absorption.

Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Place spillage in appropriate container for waste disposal.

Section 9- DISPOSAL CONSIDERATIONS**Appropriate Method of Disposal of Product, Preparation, Packaging:**

Disposal must be made according to official regulations. Consult state, local and national governmental requirements.

Section 10- TOXICOLOGY INFORMATION**Route of Exposure**

Skin Contact:	May cause skin irritation
Skin Absorption:	May be harmful if absorbed by the skin
Eye Contact:	May cause eye irritation
Inhalation:	May be harmful if inhaled
Ingestion:	May be harmful if swallowed

Target Organ or System: Blood, Heart

Toxicity Data (for active ingredient Hydralazine HCl)

<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
LD ₅₀	Oral	Rat	280mg/kg
LD ₅₀	IV	Rat	34mg/kg
LD ₅₀	Oral	Mouse	188mg/kg
LD ₅₀	IP	Mouse	83mg/kg
LD ₅₀	SC	Mouse	73mg/kg
LD ₅₀	IV	Mouse	71mg/kg

Additional reproductive health data may be available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section 11- REGULATORY AND ECOLOGICAL INFORMATION

Chemical fate information:	Not a hazardous material for transportation
DOT Hazard Class:	None
IMDG Maritime Transport Class:	None
ICAO / IATA Air Transport Class:	None
TSCA:	NE

Section 12- OTHER**ABBREVIATIONS:**

ACGIH:	American Conference of Governmental Industrial Hygienists
IARC:	International Agency for Research on Cancer
EPA:	Environmental Protection Agency
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
DOT:	Department of Transportation
NE:	Not Established
NDC:	National Drug Code
IMDG:	International Maritime Dangerous Goods
ICAO:	International Civil Aviation Organization
IATA:	International Air Transport Association
TSCA:	Toxic Substance Control Act
N/A:	Not Applicable

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