



Safety Data Sheet

Hydralazine HCL Injection, USP

Section 1: Chemical Product and Company Identification

Product Name: Hydralazine Hydrochloride Injection, USP

Chemical Name(s): 1-hydrazinophthalazine monohydrochloride

Synonym: Not available

CAS Number: 304-20-1

RTECS #: TH9000000

Trade Name: Hydralazine Hydrochloride Injection

Chemical Formula: $C_8H_8N_4 \cdot HCL$

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen.us

Emergency phone number:

National Poison Control

1-800-222-1222



Health	3
Fire	1
Reactivity	0
Personal Protection	E

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



Potential Acute Health Effects: Not Available

Potential Chronic Health Effects: Prolonged or repeated exposure may lead to damage to the liver, lungs, kidneys, cardiovascular, hemopoietic and central nervous system. Chronic exposure may lead to an autoimmune response.

Personnel with impaired cardiovascular and hemopoietic systems should minimize their exposure to this product. Pregnant workers should avoid exposure to this product.

Carcinogenic Effects: Two animal studies illustrated that Hydralazine is considered carcinogenic. No adequate and well controlled studies in humans have been conducted.

Mutagenic Effects: Hydralazine was found to be mutagenic in bacteria. No adequate and well controlled studies in humans have been conducted.

Teratogenic Effects: Not available

Developmental Toxicity: Based on animal test data, Hydralazine is considered a teratogen. No adequate and well controlled studies in humans have been conducted.

Adverse effects: Not available

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Hydralazine HCL USP	304-20-1	2.0%
Propylene Glycol USP	57-55-6	10.36%
Hydrochloric Acid NF	7647-01-0	As needed to adjust to pH 3.6
Sodium Hydroxide NF	1310-73-2	As needed to adjust to pH 3.6
Water for Injection USP	7732-18-5	QS to 1 ml

Section 4: First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Inhalation: This product is not likely to be hazardous by inhalation. May cause irritation of the upper and lower respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention immediately.

Skin contact: In case of contact, immediately wash skin with plenty of water. Gently and thoroughly wash the contaminated skin with cold running water and non-abrasive soap. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

Eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes, keep eyelids open. May use cold water. Seek medical attention immediately.

Ingestion: Ingestion of product may cause irritation, nausea and diarrhea. May cause irritation of the gastrointestinal tract. DO NOT induce vomiting. Rinse mouth out with water. If large quantities of this material are swallowed, call physician immediately. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

Notes to physician: Exposure to this product may result in headache, nausea, vomiting, diarrhea, palpitations, tachycardia, hypotension and flushing of the skin. Seek product package insert for complete information.

Overdose Treatment: Treat overdose symptomatically.

Section 5: Fire Fighting Measures

Flammability of the product: Not established.

Combustion Products: When heated, Hydralazine solution thermally decomposes to form toxic vapors.

Unusual Fire and Explosion Hazards: This product may decompose and produce irritating fumes and toxic gases. Thermal decomposition may result in the emission of hazardous combustion products such as: carbon dioxide, carbon monoxide, nitrogen oxides and halogenated compounds.

Extinguishing Media and Instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam, dry chemical or Carbon Dioxide (CO₂). Caution: CO₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus (SCBA) and full urn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small spill: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions. Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large spill: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: Not available

Release to water: This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Refer to local water authority; drain disposal is not recommended.

Protective equipment: Keep unnecessary personnel away. Wear approved respiratory protection, chemical safety goggles, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

Section 7: Handling and Storage

Handling: As a general rule, when handling Hydralazine HCL Injection, avoid all contact and inhalation of mists and/or vapors associated with the material. Avoid contact with skin, eyes, or clothing. Do not mix with other drugs. Use in a well ventilated area. Wash thoroughly after handling.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. DO NOT ingest. Avoid contact with skin. Wear suitable protective clothing in case of insufficient ventilation. If you feel unwell, seek medical attention and show label when possible. Use only in accordance with directions.

Storage: Keep container dry and tightly closed. Keep container in a cool, dry, well ventilated area. Controlled room temperature should be 20 - 25°C (68 - 77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Reactive with oxidizers.

Section 8: Exposure Controls / Personal Protection

Engineering controls: No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protection: Splash goggles. Lab coat. Nitrile or latex gloves. Respirator. Be sure to use an approved/ certified respirator or equivalent. **In case of large spill:** Wear ANSI approved splash goggles. Full suit. Respirator. Boots. Nitrile or latex gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory protection: Under normal use, respirators are not required. When required, use NIOSH approved air purifying respirator with combination P-100/organic vapor/acid gas cartridges. Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure Guidelines	OSHA PEL	ACGIH TLV
Hydralazine HCL USP	Not Listed	Not Listed
Propylene Glycol USP	Not Listed	Not Listed
Hydrochloric Acid NF	5 parts per million - Ceiling	2 parts per million - Ceiling
Sodium Hydroxide NF	2 milligrams/cubic meter – 8hr TWA	2 milligrams/cubic meter – Ceiling
Water for Injection USP	Not Listed	Not Listed

Section 9: Physical and Chemical Properties

Physical appearance: Liquid

Color: Clear, colorless to slightly yellow solution

Molecular Weight: 196.64 g/mole

Taste: Not available

Odor: Characteristic odor (i.e. parabens)

Odor Threshold: Not available

pH: 3.4 to 4.4

Melting Point: Not available

Freezing Point: Below 32 °F

Boiling Point: ~ 230°F

Flash Point: Not available

Evaporation rate: Not available

Flammability: Not available

Upper Flammable Limit: Not available

Lower Flammable Limit: Not available

Vapor Pressure: Not available

Vapor Density: Not available

Relative density: Not available

Partition Coefficient: Not available

Auto-Ignition Temperature: Not available

Decomposition Temperature: Not available

Viscosity: Not available

Dispersion Properties: Not available

Solubility: Soluble in water

Specific Gravity: ~ 1.0

Section 10: Stability and Reactivity

Reactivity: Not available

Chemical stability: The product is stable.

Conditions to avoid: Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.

Incompatible materials: Reactive with oxidizers.

Possibility of hazardous reaction: Hazardous polymerization will not occur.

Hazardous decomposition products: Carbon Monoxide, Carbon Dioxide, Halogenated Compounds and Nitrogen Oxides may be released by thermal decomposition.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of exposure: Eye contact, skin contact, inhalation and ingestion.

Symptoms:

Short term: Slightly hazardous in case of skin contact (irritant). Product is considered a skin sensitizer.

Long term: Very hazardous in case of skin contact (permeator), ingestion or inhalation. This substance is toxic to lungs and the nervous system.

Reproductive toxicity: No adequate and well controlled studies in humans or animals regarding the reproductive effects of Hydralazine have been conducted.

FDA Pregnancy Category: C

Acute Effects:

Oral Rat: LD₅₀: 280 mg/kg

IV Rat: LD₅₀: 34 mg/kg

Intraperitoneal Mouse: LD₅₀: 83 mg/kg

Oral Mouse: LD₅₀: 188 mg/kg

IV Mouse: LD₅₀: 71 mg/kg

Dermal: LD₅₀: No data available

Measures of toxicity: Not available

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The products of degradation are more toxic.

Section 13: Disposal Information

Waste classification: Hazardous

Waste from residues/unused products: Do not mix with other substances. Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not considered a DOT regulated material – non-hazardous for shipment.

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

ICAO / IATA:

IATA Proper shipping name:	NA
IATA UN NUMBER	NA
IATA Primary Hazard	3
IATA Packing group:	NA
ICAO ERG Code:	NA

Section 15: Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Hydralazine

Other Regulations: Not available

Other Classifications:

WHMIS (Canada): CLASS D-1B: Causes immediate and serious toxic effects.
CLASS D-2A: Causes other toxic effects.

DSCL (EEC): Not available

HMIS (U.S.A.):

Health Hazard: 3

Fire Hazard: 1

Reactivity: 0

Personal Protection: Not available

National Fire Protection Association (U.S.A.):

Health: 3

Flammability: 1

Reactivity: 0

Protective Equipment: Nitrile or latex gloves, lab coat, safety glasses and respirator. Tyvek SL or equivalent coveralls and PVC booties for clean-up.

Section 16: Other Information

References: Not available

Created: 6/30/2015

Last Updated: 8/19/2015

Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.