

Hydralazine Hydrochloride Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Hydralazine Hydrochloride Injection; 20 mg per mL; 1 mL Single-Dose Vials Package of 25;
NDC 55150-400-25

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315
Eye Irrit. 2 H319

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS07

Signal word (GHS US) :

Warning

Hazard statements (GHS US) :

H315 - Causes skin irritation
H319 - Causes serious eye irritation

Precautionary statements (GHS US) :

P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Hydralazine Hydrochloride Injection

Safety Data Sheet

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	< 99	Not classified
1,2-Propanediol	(CAS-No.) 57-55-6	10 – 12	Not classified
Hydralazine hydrochloride	(CAS-No.) 304-20-1	2	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Sodium hydroxide	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0	≤ 1	Skin Corr. 1, H314 Eye Dam. 1, H318
Propyl 4-hydroxybenzoate	(CAS-No.) 94-13-3	≤ 1	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Benzoic acid, 4-hydroxy-, methyl ester	(CAS-No.) 99-76-3	≤ 1	Aquatic Chronic 3, H412

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If not breathing, give artificial respiration.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water. Seek immediate medical attention.
- First-aid measures after ingestion : Wash mouth with water. Do not induce vomiting unless directed by medical personnel. Seek immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : None anticipated under normal product handling conditions.
- Symptoms/effects after skin contact : Causes skin irritation.
- Symptoms/effects after eye contact : Causes serious eye irritation.
- Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Recycle product or dispose safely.

Hydralazine Hydrochloride Injection

Safety Data Sheet

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store between 20°C and 25°C (68°F and 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)		
Not applicable		
1,2-Propanediol (57-55-6)		
AIHA	WEEL TWA	10 mg/m ³
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m ³
OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
IDLH	IDLH	10 mg/m ³
NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
NIOSH	NIOSH REL C [ppm]	5 ppm
Propyl 4-hydroxybenzoate (94-13-3)		
Not applicable		
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)		
Not applicable		
Hydralazine hydrochloride (304-20-1)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use suitable protective gloves to minimize skin contact.

Eye protection : Wear safety glasses or goggles.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : Wear NIOSH approved respirator if workplace exposure limits may be exceeded.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless
Odor	: odorless
Odor threshold	: No data available

Hydralazine Hydrochloride Injection

Safety Data Sheet

pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: No data available
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Do not freeze.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
1,2-Propanediol (57-55-6)	
LD50 oral rat	20 g/kg
LD50 dermal rabbit	20800 mg/kg
ATE US (oral)	20000 mg/kg body weight
ATE US (dermal)	20800 mg/kg body weight
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Hydralazine Hydrochloride Injection

Safety Data Sheet

Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
ATE US (oral)	2100 mg/kg

Hydralazine hydrochloride (304-20-1)	
ATE US (oral)	100 mg/kg body weight

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

1,2-Propanediol (57-55-6)	
LC50 - Fish [1]	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 - Fish [2]	41 – 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

1,2-Propanediol (57-55-6)	
BCF - Fish [1]	< 1

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

Hydralazine Hydrochloride Injection

Safety Data Sheet

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT) International Air Transport Association (IATA)

In accordance with DOT In accordance with IATA

Not applicable Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

1,2-Propanediol (57-55-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
-----------	---------

Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
-----------	---------

SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
--	-------------------

SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
---------------------------------------	--

Propyl 4-hydroxybenzoate (94-13-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

1,2-Propanediol (57-55-6)

U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Hydralazine Hydrochloride Injection

Safety Data Sheet

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.