acc. to OSHA HCS

Printing date 12/22/2023 Reviewed on 12/22/2023

1 Identification

· Product identifier

· Trade name: <u>Hydralazine hydrochloride</u> Hydralazini hydrochloridum

· Article number: 104062

• **CAS Number:** 304-20-1

• **EC number:** 206-151-0

- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations
- · Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Fagron Inc 2400 Pilot Knob Road St. Paul, MN 55120 www.fagron.us QA@fagron.us

· Information department:

Tel.: 800-423-6967 Fax: 800-339-1596

· Emergency telephone number:

Emergency Telephone: US: 1-800-535-5053

International: 1-352-323-3500

2 Hazard(s) identification

· Classification of the substance or mixture

Acute Toxicity - Oral 3 H301 Toxic if swallowed.
Skin Irritation 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

Specific Target Organ Toxicity - Single Exposure 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS06 GHS07

- · Signal word Danger
- · Hazard statements

Toxic if swallowed.

Causes skin irritation.

Causes serious eye irritation.

May cause respiratory irritation.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

(Contd. on page 2)

Fagron
personalizing
medicine

Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 1)

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Wear eye protection / face protection.

If swallowed: Immediately call a poison center/doctor.

Specific treatment (see on this label).

Rinse mouth.

If on skin: Wash with plenty of water.

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.

Call a poison center/doctor if you feel unwell.

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Store in a well-ventilated place. Keep container tightly closed.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 2 Fire = 0 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



· Other hazards

Health = 2 Fire = 0 Reactivity = 0

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description

CAS: 304-20-1 Hydralazine hydrochloride

Hydralazini hydrochloridum

- · Identification number(s)
- EC number: 206-151-0

4 First-aid measures

- · Description of first aid measures
- General information:

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

(Contd. on page 3)



acc. to OSHA HCS

Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 2)

- · After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: Do not induce vomiting; immediately call for medical help.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Water spray

Foam

Fire-extinguishing powder

Carbon dioxide

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon monoxide (CO)

Nitrogen oxides (NOx)

Hydrogen chloride (HCI)

Phosgene gas

- Advice for firefighters
- · Protective equipment:

Wear fully protective suit.

Wear self-contained respiratory protective device.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

- Protective Action Criteria for Chemicals
- · PAC-1: Substance is not listed.
- · PAC-2: Substance is not listed.
- · PAC-3: Substance is not listed.

USA

(Contd. on page 4)



Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 3)

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Keep receptacles tightly sealed.

Thorough dedusting.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep receptacle tightly sealed.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

Rubber gloves

Nitrile rubber, NBR

PVC gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

(Contd. on page 5)

- USA



Safety Data Sheet acc. to OSHA HCS

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

· Penetration time of glove material

(Contd. of page 4)

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties · General Information · Appearance: Form: Crystalline powder Color: Whitish · Odor: Odorless · Odor threshold: Not determined. · pH-value: Not applicable. · Change in condition Melting point/Melting range: 273°C (523.4°F) Boiling point/Boiling range: Undetermined. · Flash point: Not applicable. · Flammability (solid, gaseous): Product is not flammable. Decomposition temperature: Not determined. · Ignition temperature: Not determined. · Danger of explosion: Product does not present an explosion hazard. · Explosion limits: Lower: Not determined. Not determined. Upper: · Vapor pressure: Not applicable. · Density: Not determined. · Relative density Not determined. · Vapor density Not applicable. Evaporation rate Not applicable. · Solubility in / Miscibility with Water: Soluble. · Partition coefficient (n-octanol/water): Not determined. · Viscosity: **Dynamic:** Not applicable.

(Contd. on page 6)





acc. to OSHA HCS

Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 5)

		(Conta. or page 5
Kinematic:	Not applicable.	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products:

Carbon monoxide and carbon dioxide

Hydrogen chloride (HCI)

Phosgene

Nitrogen oxides (NOx)

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

Oral LD50 280 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.
- · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

(Contd. on page 7)



acc. to OSHA HCS

Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 6)

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must be specially treated adhering to official regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

14 Transport information	
· UN-Number · DOT, IMDG, IATA	UN3249
· UN proper shipping name· DOT, IATA· IMDG	Medicine, solid, toxic, n.o.s. MEDICINE, SOLID, TOXIC, N.O.S.
· Transport hazard class(es)	
· DOT	
TOXIC	
· Class	6.1 Toxic substances
· Label	6.1
· IMDG, IATA	
· Class	6.1 Toxic substances
· Label	6.1
· Packing group · DOT, IMDG, IATA	III
· Environmental hazards:	Not applicable.
 Special precautions for user Hazard identification number (Kemler code) EMS Number: 	Warning: Toxic substances : 60 F-A,S-A



(Contd. on page 8)

acc. to OSHA HCS

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

	(Contd. of page
Stowage Category	E
Stowage Code	SW2 Clear of living quarters.
Transport in bulk according to Annex II of	
MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
DOT	
· Quantity limitations	On passenger aircraft/rail: 100 kg
•	On cargo aircraft only: 200 kg
·IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1
,	Maximum net quantity per inner packaging: 30 g
	Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3249 MEDICINE, SOLID, TOXIC, N.O.S. 6.1, II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara
- · Section 355 (extremely hazardous substances): Substance is not listed.
- · Section 313 (Specific toxic chemical listings): Substance is not listed.
- · TSCA (Toxic Substances Control Act): ACTIVE
- · Hazardous Air Pollutants Substance is not listed.
- · Proposition 65
- · Chemicals known to cause cancer: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- · Chemicals known to cause developmental toxicity: Substance is not listed.
- · Carcinogenic categories
- · EPA (Environmental Protection Agency) Substance is not listed.
- · TLV (Threshold Limit Value) Substance is not listed.
- · NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS:

Fagron US

Quality Assurance

- · Contact: QA@fagron.us
- · Date of preparation / last revision 12/22/2023

(Contd. on page 9)





acc. to OSHA HCS

Printing date 12/22/2023 Reviewed on 12/22/2023

Trade name: Hydralazine hydrochloride Hydralazini hydrochloridum

(Contd. of page 8)

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health TLV: Threshold Limit Value

PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

Acute Toxicity - Oral 3: Acute toxicity - Category 3 Skin Irritation 2: Skin corrosion/irritation - Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.

USA

