

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

HYDRALAZINI HYDROCHLORIDUM

EN

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Hydralazine hydrochloride
Hydralazini hydrochloridum
Hydralazinehydrochloride
Hydralazine (chlorhydrate d')

N° CAS: 304-20-1

N° EC: 206-151-0

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 3	H301
Eye Irrit. 2B	H320
Acute Tox. 4	H322
STOT SE 2	H371

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H320	Causes eye irritation.

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H322	Harmful if inhaled.
H371	May cause damage to organs.
Precautionary statements:	
P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P330	Rinse mouth.
P304+P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P308+P313	If eye irritation persists: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container to in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hydralazine hydrochloride
IUPAC name:	Phthalazin-1-ylhydrazine;hydrochloride
Synonyms:	Apresoline Hydralazine hydrochloride
N° CAS:	304-20-1
N° EC:	206-151-0
Molecular Formula:	C ₈ H ₉ ClN ₄
Content:	98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	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 exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Patients
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	developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
After inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a POISON CENTER or doctor/physician if you feel unwell.
After skin contact:	Remove contaminated clothing. Flush area with large amount of water. USE SOAP. Seek medical attention.
After eye contact:	Flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention immediately.
After ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. If vomiting occurs, keep head low so stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Seek medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Irritation of eyes and mucous membranes. Cardiovascular effects.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment of overdose should be symptomatic and supportive and may include the following:

1. To decrease absorption, perform gastric lavage and administer an activated charcoal slurry.
2. Monitor and support cardiovascular and renal function.
3. For tachycardia, use beta-blocking agents. Digitalization may be needed.
4. Treat shock with plasma expanders; if a vasopressor is required, care should be taken not to precipitate or aggravate cardiac arrhythmia.
5. Monitor fluid and electrolyte levels, as well as renal function.
6. For peripheral neuropathies, administer pyridoxine. [USP DI 2008; Meditext 2008]

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water, foam, dry chemical, CO₂.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

No unusual fire or explosion hazard noted.

5.3 Advice for firefighters

Surrounding fires:	Fight fire from a safe distance. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. As with all fires, evacuate personnel to a safe area.
Protection against fire:	Wear full protective clothing. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.
Hazardous combustion products:	Not available.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

For emergency responders

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

6.2 Environmental precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

6.3 Methods and material for containment and cleaning up

For containment: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.

Methods for cleaning up: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

Other information: Wash clothing and equipment after handling.

6.4 Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Wear gloves. Keep away from heat and sources of ignition. Never add water to this product in case of insufficient ventilation.

Personal protection:

Wear suitable reparatory equipment. Do not ingest. Do not breathe dust. Avoid contact with skin and eyes.

Technical protective measures:

Not available.

Handling:

Handling temperature: 25 °C.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Preserve in tight dry containers. Store locked up.

Conditions for safe storage, including any incompatibilities:

Store at 25°C, excursions permitted between 15°C and 30°C.

Storage – away from:

Store protected from light. Keep away from heat. Keep away from sources of ignition.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

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Not available.

8.2 Exposure controls

Appropriate engineering control

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures. Handle in accordance with good industrial hygiene and safety practice.

Individual protection measures

Eye/face protection:	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection:	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Hand protection:	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Respiratory protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134)
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder
Odour:	Odourless
Odour threshold:	Not available.
pH:	3.5 to 4.2
Melting/freezing point:	Decomposes at 273 °C.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.

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Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96%), very slightly soluble in methylene chloride.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Decomposes at 273 °C.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Toxic if swallowed. Harmful if inhaled. Oral LD50 (mouse): 210 mg/kg Oral LD50 (rat): 173 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Causes eye irritation.

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Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause damage to organs (cardiovascular system).
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes eye irritation. Symptoms: Watery eyes.
Skin contact:	Symptoms: Skin rash or blisters.
Inhalation:	Harmful if inhaled. May cause damage to organs (cardiovascular system). Symptoms: Chest pain, headache, nausea. Vapours may cause drowsiness and dizziness.
Ingestion:	Toxic if swallowed. May cause damage to organs (cardiovascular system). Symptoms: Diarrhoea, nausea, vomiting.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology - general: Soluble in water, slightly soluble in alcohol.
Ecology - air: Not dangerous for the ozone layer (1999/45/EC).

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

The substance has low potential for bioaccumulation.

12.4 Mobility in soil

Ecology – soil: The substance has moderate mobility in groundwater/soil.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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Disposal instructions: Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Waste from residues/unused products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Toxic solid, organic, n.o.s. (Hydralazine Hydrochloride)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

R20 Harmful by inhalation.

R25 Toxic if swallowed.

R36 Irritating to eyes.

R67 Vapours may cause drowsiness and dizziness.

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Safety phrases:

S1 Keep locked up.
S23 Do not breathe dust/fume/gas/mist/vapours/spray.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35 This material and its container must be disposed of in a safe way.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S46 If swallowed, seek medical advice immediately and show this container or label.
S51 Use only in well-ventilated areas.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

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The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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