

SAFETY DATA SHEETS

This SDS packet was issued with item:

078379220

N/A



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name

HYDRALAZINE HYDROCHLORIDE

Alternative Names

Alphapress,

1(2H)-phthalazinone hydrazone Hydrochloride.

Address / Phone Number : **Hetero House,**
H.No.8-3-166/7/1,
Erragadda,
Hyderabad – 500018,
A.P,
INDIA.
Tel: 23704923/24/25
Fax: 91-40-23704926, 23714250

2. PRODUCT COMPOSITION

HYDRALAZINE HYDROCHLORIDE

CAS No. : [304-20-1]

Therapeutic category : Antihypertensive.



3. IDENTIFICATION OF POTENTIAL HAZARDS

May impair fertility. May cause harm to the unborn child. Limited evidence of a carcinogenic effect.

4. FIRST AID MEASURES

- Inhalation : Move to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
- Skin Contact : Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention.
- Eye Contact : Immediately flush eyes with copious amounts of Water for at least 15 minutes. Seek medical advice.
- Ingestion : If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice.

5. FIRE FIGHTING MEASURES

- Flammable Powder Class : N/A
- Minimum Ignition : Not Available (NA)

The material can form flammable dust clouds in air. Strong dust explosion indicated in test (ST2). Thermal decomposition will evolve flammable vapors.

Extinguishing Media (suitable): Water spray, foam, dry chemical powder or Carbon dioxide.

6. ACCIDENTAL RELEASE MEASURES

Moisten spillages with water. Ensure suitable personal protection (including respiratory protection) during removal of spillages.



Hetero (R&D)

7. HANDLING AND STORAGE

7.1 HANDLING

Do not breathe dust. Avoid contact with skin and eyes. Atmospheric levels should be controlled in compliance with the occupational exposure limit.

7.2 STORAGE

Store at 25°C (86°F), excursions permitted to 15-30°C (59-86°F).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls : No ACGIH TLV or OSHA PEL assigned.

Occupational Exposure Limits

CONTROL PARAMETERS	TWA	STEL/CEILING(C)
Hydralazine Hydrochloride	0.01 mg/m ³	COM

This is an in-house
Standard for the active
Ingredient during
Manufacture

Personal Protective Equipment	:	Wear suitable respiratory protective Equipment. If exposure to levels above the occupational exposure limit is likely. Wear suitable protective clothing, gloves and eye/face protection.
Respirators	:	Use a NIOSH approved respirator for toxic particulates with a TLV less than 0.05mg/m ³ (i.e approved for radionuclides). Fit testing with a fit test agent is recommended. Use positive pressure air supplied respirator if exposures are high.
Protective Clothing	:	Impervious gloves and apron.
Eye Protection	:	Safety glasses with side shields.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Form	:	A white to off-white crystalline powder
Color	:	White
Molecular Weight	:	196.94
Molecular Formula	:	$C_8H_8N_4.HCl$
p ^H	:	3.5-4.2
Melting Point	:	273-277 ⁰ C
Vapor Pressure	:	No data
Solubility (Water)	:	In soluble in water
Solubility (Other)	:	Slightly soluble in alcohol
Partition Coefficient	:	No data
Specific Gravity	:	No data
Vapor Density	:	No data
Dissociation constant	:	No data

10. PRODUCT STABILITY AND REACTIVITY

HYDRALAZINE HYDROCHLORIDE is stable at specified storage conditions

Hazardous Reactions	:	N/A
Hazardous Decomposition	:	N/A
Product(s)		

11. TOXICOLOGICAL INFORMATION

Skin Contact	:	Non-irritant following repeated applications to Rabbit skin. Unlikely to cause skin irritation in man. It is not a skin sensitizer in animal tests. Unlikely to Cause skin sensitization.
Eye Contact	:	Non-irritant to rabbit eyes causing practically no Initial pain. Unlikely to cause eye irritation in man.
Long Term Exposure	:	Limited evidence of a carcinogenic effect. Studies in animals have shown that repeated doses produce

cancer in rats and mice. The substance is not considered to be genotoxic. May impair fertility. May cause harm to the unborn child. In male rats Reproductive performance was reduced but was Reversible after cessation of dosing. Evidence of Suppressed sexual development was observed in the Male offspring of female rats. None of these effects are likely to occur in humans, provided exposure is maintained at or below the occupational exposure limit.

Oral Toxicology : ORAL (LD50): Acute: 188 mg/kg [Mice].

12. ECOLOGICAL INFORMATION

Environmental Fate and Distribution

The substance is sparingly soluble in water. It should be noted that this solubility is different from that quoted in Section 9. The substance has low potential for bioaccumulation. The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

Persistence and Degradation

The substance shows no evidence for biodegradability in water. There is no evidence of hydrolysis in water.

Toxicity

ORAL (LD50): Acute: 188 mg/kg [Mice].

Effect on Effluent Treatment

There is no evidence of inhibition to the aerobic treatment process at a concentration (mg/l) of 100 mg/l

Effect on Atmospheric Ozone

No information available.



13. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with local, state or national legislation.

Disposal Method : Discarded product is not a hazardous waste
Under RCRA, 40 CFR 261. However
Hetero recommends disposal of waste
Material via high-temperature incineration.

Container Disposal : Empty container retains product residue.
Observe all hazard precautions.

14. TRANSPORT INFORMATION

ICAO/IATA :

UN No. : -

Proper Shipping Name: ENVIRONMENTALLY NON-HAZARDOUS
SUBSTANCE, SOLID, N.O.S.(HYDRALAZINE
HYDROCHLORIDE)

IMO/IMDG :

UN No. : -

Proper Shipping Name: ENVIRONMENTALLY NON-HAZARDOUS
SUBSTANCE, SOILD, N.O.S.(HYDRALAZINE
HYDROCHLORIDE)

Class : -

Marine pollutant : Not classified as a Marine Pollutant

Packing Group : It is not dangerous goods.

NOT RESTRICTED AS PER IATA

DOT (Department of Transport)

UN No. : -

Proper Shipping Name: ENVIRONMENTALLY NON-HAZARDOUS
SUBSTANCES, SOILD, N.O.S (HYDRALAZINE
HYDROCHLORIDE)



15. REGULATORY INFORMATION

TSCA (toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation. CERCLA and SARA Regulations (40 CFR 302, 355, 370 and 372): This product does not contain any chemicals subject to the reporting requirements of SARA Section 313.

16. OTHER INFORMATION

The following sections contain revisions or new statements:

12, 15

This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, and modified 1998.

GLOSSARY

COM	:	The company aims to control exposure in its workplace to This limit. This is an in-house standard for the active Ingredient handled during manufacture
TLV	:	The company aims to control exposure in its workplace to The ACGIH limit
SK	:	Can be absorbed through skin
Sen	:	Capable of causing respiratory sensitisation

The information herein is given in good faith but no warranty, expressed or implied, is made.